Percutaneous Intracranial Angioplasty and Stenting

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DESCRIPTION

Intracranial arterial disease includes thromboembolic events, vascular stenosis, and aneurysms. Endovascular techniques have been investigated for the treatment of intracranial arterial disease. Endovascular therapy is used as an alternative or adjunct to intravenous tissue plasminogen activator (tPA) and supportive care for acute stenosis and as an adjunct to risk factor modification for chronic stenosis. For cerebral aneurysms, stent-assisted coiling and the use of flow-diverting stents have been evaluated as an alternative to endovascular coiling in patients whose anatomy is not amendable to simple coiling.

Acute stroke is the fifth leading cause of death in the United States; further, it is a leading cause of adult disability. Eighty-seven percent of strokes are ischemic and 13% hemorrhagic. Differentiation between the 2 types of strokes is necessary to determine the appropriate treatment. Ischemic stroke occurs when an artery to the brain is blocked by a

blood clot, which forms in the artery (thrombotic), or when another substance (i.e., plaque, fatty material) travels to an artery in the brain causing a blockage (embolism). Recanalization of the artery, particularly in the first few hours after occlusion, reduces rates of disability and death.

It is estimated that intracranial atherosclerotic lesions (stenosis) cause 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 (i.e., aspirin).

Two devices were approved by the FDA through humanitarian device exemption process for atherosclerotic disease. This form of the FDA approval is available for devices used to treat conditions with an incident rate of 4000 or fewer cases per year; the FDA only requires data showing "probable safety and effectiveness." Devices with their labeled indications are as follows.

- **Neurolink System**: The 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 ≥ 50% stenosis and that are accessible to the stent system.
- **Wingspan Stent System:** The Wingspan Stent System [Boston Scientific] with Gateway PTA [percutaneous transluminal angioplasty] Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system.

Compared with acute ischemic stroke, cerebral aneurysms (intracranial aneurysms) have a much lower incidence in the United States, with prevalence between 0.5% and 6% of the population. However, they are associated with significant morbidity and mortality due to subarachnoid hemorrhage resulting from aneurysm rupture.

Endovascular Interventions for Symptomatic Intracranial Atherosclerotic Disease

Clinical Context and Therapy Purpose

The purpose of endovascular interventions in patients with intracranial atherosclerotic disease is to prevent stroke or recurrent stroke.

Populations

Individuals with severe stenosis (70 to 99% of the diameter of a major intracranial artery).

Interventions
Devices for treatment of intracranial stenosis have received the FDA approval through the humanitarian device exemption process. The Neurolink System was approved based on the Stenting of Symptomatic Atherosclerosis Lesions in the Vertebral or Intracranial Arteries (SSYLVIA) trial, a prospective, nonrandomized, multicenter, international study of 61 patients. The Wingspan Stent System was evaluated in a prospective study of 45 patients enrolled at 12 international centers. The SSYLVIA study reported an all-stroke rate of 13.1% over a mean follow-up of 216 days; the Wingspan study reported an all-stroke rate of 9.5% over a mean follow-up of 174 days.

The FDA summary of safety and effectiveness for the Wingspan device offered the following conclusions and the FDA appears to have based its approval of Wingspan in part on the favorable comparison with the Neurolink device: "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."

Comparators
Medical treatment typically includes either anticoagulant therapy (i.e., warfarin) or antiplatelet therapy (eg, aspirin). The Warfarin-Aspirin Symptomatic Intracranial Disease trial assessed the incidence of stroke brain hemorrhage or death among individuals randomized to 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. Also, if symptoms could be attributed to low-flow ischemia, agents to increase mean arterial blood pressure and avoid orthostatic hypotension may be recommended. However, medical therapy has been considered less than optimal. For example, in individuals with persistent symptoms despite antithrombotic therapy, the subsequent rate of stroke or death has been extremely high, estimated in 1 study at 45%, with recurrent events within 1 month of the initial event. Surgical approaches have met with limited success. The widely cited extracranial-intracranial bypass study randomized 1377 individuals with symptomatic atherosclerosis of the internal carotid or middle cerebral arteries to medical care or extracranial-intracranial bypass. Outcomes in both groups were similar, suggesting that the extracranial-intracranial 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 intracranial circulation, due to technical difficulties in the 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 percutaneous transluminal angioplasty as a minimally invasive treatment of this difficult-to treat population. Most published studies

of intracranial percutaneous transluminal angioplasty have focused on vertebrobasilar circulation.

Outcomes
The outcomes of interest are stroke, death, function, and quality of life (QOL). Treatment-related adverse effects, including vessel perforation, hemorrhage, or thrombus formation in a new site, are important safety outcomes. Evidence for both short-term (30 day) and long-term (out to 2-years) outcomes are needed.

Systematic Reviews
In 2020, Wang et. al. completed a Cochrane review that compared the safety and efficacy of endovascular therapy (ET) plus conventional medical treatment (CMT) with CMT alone for the management of intracranial atherosclerotic stenosis (ICAS). Intracranial atherosclerotic stenosis (ICAS) is an arterial narrowing in the brain that can cause stroke. Endovascular therapy and medical management may be used to prevent recurrent ischemic stroke caused by ICAS. However, there is no consensus on the best treatment for people with ICAS. The selection criteria included the following: Randomized controlled trials (RCTs) comparing ET plus CMT with CMT alone for the treatment of symptomatic ICAS. ET modalities included angioplasty alone, balloon-mounted stent, and angioplasty followed by placement of a self-expanding stent. CMT included antiplatelet therapy in addition to control of risk factors such as hypertension, hyperlipidemia, and diabetes. Two review authors independently screened trials to select potentially eligible RCTs and extracted data. Any disagreements were resolved by discussing and reaching consensus decisions with the full team. The risk of bias was assessed and applied the GRADE approach to assess the quality of the evidence. The primary outcome was death of any cause or non-fatal stroke of any type within three months of randomization. Secondary outcomes included any-cause death or non-fatal stroke of any type more than three months of randomization, ipsilateral stroke, type of recurrent event, death, restenosis, dependency, and health-related quality of life. Three RCTs were included with 632 participants who had symptomatic ICAS with an age range of 18 to 85 years. The included trials had high risks of performance bias and other potential sources of bias due to the impossibility of blinding of the endovascular intervention and early termination of the trials. Moreover, one trial had a high risk of attrition bias because of the high rate of loss of one-year follow-up and the high proportion of participants transferred from endovascular therapy to medical management. The quality of evidence ranged from low to moderate, downgraded for imprecision. Compared to CMT, ET probably results in a higher rate of 30-day death or stroke (risk ratio (RR) 3.07, 95% confidence interval (CI) 1.80 to 5.24; 3 RCTs, 632 participants, moderate-quality evidence), 30-day ipsilateral stroke (RR 3.54, 95% CI 1.98 to 6.33; 3 RCTs, 632 participants, moderate-quality evidence), 30-day ischemic stroke (RR 2.52, 95% CI 1.37 to 4.62; 3 RCTs, 632 participants, moderate-quality evidence), and 30-day hemorrhagic stroke (RR 15.53, 95% CI 2.10 to 115.16; 3 RCTs, 632 participants, low-quality evidence). ET was also likely associated with a worse outcome in one-year death or stroke (RR 1.69, 95% CI 1.21 to 2.36; 3 RCTs, 632 participants, moderate-quality evidence), one-year ipsilateral stroke (RR 2.28, 95% CI 1.52 to 3.42; 3 RCTs, 632

participants, moderate-quality evidence), one-year ischemic stroke (RR 2.07, 95% CI 1.37 to 3.13; 3 RCTs, 632 participants, moderate-quality evidence), and one-year hemorrhagic stroke (RR 10.13, 95% CI 1.31 to 78.51; 2 RCTs, 521 participants, low-quality evidence). There were no significant differences between ET and CMT in 30-day transient ischemic attacks (TIA) (RR 0.52, 95% CI 0.11 to 2.35, P = 0.39; 2 RCTs, 181 participants, moderate-quality evidence), 30-day death (RR 5.53, 95% CI 0.98 to 31.17, P = 0.05; 3 RCTs, 632 participants, low-quality evidence), one-year TIA (RR 0.82, 95% CI 0.32 to 2.12; 2 RCTs, 181 participants, moderate-quality evidence), one-year death (RR 1.20, 95% CI 0.50 to 2.86, P = 0.68; 3 RCTs, 632 participants, moderate-quality evidence), and one-year dependency (RR 1.90, 95% CI 0.91 to 3.97, P = 0.09; 3 RCTs, 613 participants, moderate-quality evidence). No data on restenosis and health-related quality of life for meta-analysis were available from the included trials. Two RCTs are ongoing. The authors concluded this systematic review provides moderate-quality evidence showing that ET, compared with CMT, in people with recent symptomatic severe intracranial atherosclerotic stenosis probably does not prevent recurrent stroke and appears to carry an increased hazard. The impact of delayed ET intervention (more than three weeks after a qualifying event) is unclear and may warrant further study.

Randomized Controlled Trials

The Vitesse Intracranial Stent Study for Ischemic Stroke Therapy (VISSIT) trial, a randomized controlled trial (RCT) comparing a balloon-expandable stent plus medical management with medical management alone among patients who had symptomatic intracranial stenosis of 70% or greater. Eligible patients had stenosis of 70% to 99% of the internal carotid, middle cerebral, intracranial vertebral, or basilar arteries with a 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 Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) trial were published. A total of 112 patients were enrolled from 2009 to 2012 and randomized to the 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 3 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 trial used a primary composite endpoint that included any stroke in the same territory as the presenting event within 1 year of randomization and “hard TIA ” in the same territory as the presenting event from 2 days to 1 year after randomization. Among 29 patients who met 1 of the primary endpoints within 1 year of randomization, 8 (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 SAMMPRIS trial was a randomized controlled trial (RCT) comparing aggressive medical management alone with aggressive medical management plus stenting in patients who had symptomatic cerebrovascular disease and intracranial stenosis between 70% and 99%. This trial used the Wingspan stent system implanted by experienced neurointerventionalists credentialed to participate in the trial. The authors planned to enroll 750 patients based on power calculations. However, the trial was stopped early for futility after 451 patients had been randomized, 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 with 5.8% (95% CI, 3.4% to 9.7%; p=0.002) in the medical management group. At the time of trial termination, mean follow-up was 11.9 months. Kaplan-Meier estimates of the primary outcome (stroke or death at 1 year) was 20.5% (95% CI, 15.2% to 26.0%) in the stenting group and 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 with expected values.

The SAMMPRIS investigators, also published results from long-term subject follow-up. Primary endpoints (in addition to stroke or death within 30 days of enrollment) included ischemic stroke in 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 (15%) of 227 patients in the best medical management group and 52 (23%) of 224 patients in the stenting group had a primary endpoint event, with a significantly higher cumulative probability of a primary endpoint 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 the benefits of aggressive medical management over percutaneous angioplasty and stenting among patients with intracranial stenosis persist over long-term follow-up.

Post-Market Surveillance

In 2019, Alexander et. al. reported results from the Wingspan Stent System Post Market Surveillance (WEAVE) post-marketing surveillance study. WEAVE was an FDA-mandated, prospective, single-arm study evaluating the rate of stroke and death within 72 hours post-stenting in patients who met the FDA on-label usage criteria. One hundred fifty-two consecutive patients were enrolled at 24 hospitals. The study was designed to enroll 389 patients but was stopped early when the second, predetermined interim data analysis indicated that the safety benchmarks were met. The primary outcome included 2 nonfatal strokes and 2 deaths from strokes for a total of 4 patients (2.6%) with an event of stroke, bleed, or death.

Summary of Evidence
The strongest evidence on the efficacy of endovascular treatment for symptomatic intracranial stenosis is from the SAMMPRIS and VISSIT RCTs. The SAMMPRIS trial was stopped early due to harms because the rate of stroke or death at 30 days following treatment was higher in the endovascular arm, which received percutaneous angioplasty with stenting. Follow-up of the SAMMPRIS subjects has demonstrated no long-term benefit from endovascular therapy. The VISSIT RCT similarly found no benefit with endovascular treatment. These studies support the conclusion that outcomes of endovascular treatment are worse than medical therapy in individuals with symptomatic intracranial stenosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Stent-Assisted Endovascular Treatment of Intracranial Aneurysms

Clinical Content and Therapy Purpose
The purpose of endovascular interventions in individuals with intracranial aneurysm is to remove the aneurysm from the circulation and prevent possible rupture (or if the aneurysm had already ruptured, to stop bleeding and prevent re-rupture) or to divert blood flow away from an aneurysm.

Populations
The population of interest is individuals with intracranial aneurysms. Treatment decisions depend on the individual and aneurysm characteristics. Small (<7 mm) asymptomatic aneurysms can generally be observed. Larger and asymptomatic aneurysms may be considered for treatment according to anatomical location and morphological characteristics of the aneurysm and relative risks for specific treatments.

Interventions
Self-expanding stents have FDA approval through the humanitarian device exemption program for the endovascular treatment of intracranial aneurysms.

Intracranial stents are being used to treat 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 has grown, stenting has also been used in smaller berry aneurysms as an approach to decrease the rate of retreatment needed in individuals who receive coiling.

Comparators
Small asymptomatic aneurysms can generally be observed without surgery. Surgical clipping of intracranial aneurysms has been used since the 1960s, but the feasibility of clipping for aneurysms depends on the aneurysm location.

Outcomes
The Executive Summary of an FDA meeting of the Neurological Devices Advisory Panel in 2018 states the primary safety outcomes for regulatory review have traditionally been

focused on neurological deaths and major ipsilateral strokes (defined as an increase of ≥ 4 points in the National Institutes of Health Stroke Scale score during the stroke event) and the percentage of patients who had a disabling stroke (defined as a modified Rankin Scale score ≥ 3 assessed at a minimum of 90 days post-stroke event) within 6 months to 1 year of treatment. The FDA is considering an additional outcome to assess functional independence defined as the change in the modified Rankin Scale score at 1- year post-treatment compared to pre-procedure. The FDA has traditionally used a composite efficacy outcome defined as the percentage of patients demonstrating a Raymond I classification for complete occlusion (i.e., 100% aneurysmal occlusion) without retreatment of the target aneurysm or significant parent artery stenosis (≥ 50%) evaluated within 1- year post-procedure.

Self-Expanding Stent-Assisted Coiling and Flow Diverting Stents for Intracranial Aneurysms

For individuals who have intracranial aneurysm(s) who received endovascular coiling with intracranial stent placement or intracranial placement of a flow-diverting stent, the evidence includes randomized controlled trials (RCTs), nonrandomized comparative studies and single-arm studies. The available nonrandomized comparative studies report occlusion rates for stent-assisted coiling that are similar to or higher than coiling alone and recurrence rates that may be lower than coiling alone. For stent-assisted coiling with self-expanding stents, there is also some evidence that adverse event rates are relatively high, and one nonrandomized comparative trial reported that mortality is higher with stent-assisted coiling than with coiling alone. For placement of flow-diverting stents, a RCT and registry study have compared flow diversion with standard management (observation, coil embolization or parent vessel occlusion) in individuals for whom flow diversion was considered a promising treatment. The RCT was stopped early after crossing a predefined safety boundary with 16% of individuals treated with flow diversion were dead or dependent at three months or later. Flow diversion was also not as effective as the investigators had hypothesized. A nonrandomized study comparing the flow-diverting stents with endovascular coiling for intracranial aneurysms demonstrated higher rates of aneurysm obliteration in those treatment with the Pipeline endovascular device than those treatment with coiling, with similar rates of good clinical outcomes. The evidence does not provide high certainty whether stent-assisted coiling or placement of a flow-diverting stent improves outcomes for individuals with intracranial aneurysms because the risk-benefit ration cannot be adequately defined. However, clinical input indicated strong support of the use of stent-assisted coiling for treatment of aneurysms that are not amendable to surgery or simple coiling. Similarly, clinical input indicated general support for the use of flow-diverting stents for certain types of aneurysms when surgical treatment is not appropriate.

Angioplasty and Stenting of Intra-Cranial Arteries for the Treatment of Cerebral Vasospasms after Aneurysmal Subarachnoid Hemorrhage

Aneurysmal subarachnoid hemorrhage (SAH) is a common form of stroke. Frequently, a significant number of individuals with this condition develop angiographical or clinical vasospasm with devastating consequences. The pathogenesis of cerebral vasospasm

following SAH remains unclear despite extensive research. Due to the lack of a clear etiology, medical treatment is still largely limited to hypertensive-hypervolemic-hemodilution (triple-H) therapy, and calcium channel blockers (e.g., nimodipine). Cerebral vasospasm that has become refractory to maximal medical therapy can be treated with intra-arterial infusion of vasodilators (e.g., papaverine). Moreover, recent advent in the field of interventional neurology and the development of minimally invasive techniques has resulted in expansion of potential therapeutic approaches for cerebral vasospasm secondary to aneurysmal SAH. Balloon angioplasty and stenting is being investigated as a treatment option in individuals with vasospasm following aneurysmal SAH; however, its effectiveness for this indication has yet to be established and additional prospective randomized controlled trials are needed. The evidence is insufficient to determine that the technology results in an improvement in net health outcomes.

Practice Guidelines and Position Statements

American Heart Association and American Stroke Association

In 2018, The American Heart Association and the American Stroke Association published joint guidelines on the early management of patients with acute ischemic stroke (updated in 2019). These guidelines included several recommendations relevant to the use of endovascular therapies for acute stroke which included the following:

- Coil embolization may be superior to surgical clipping with respect to procedural morbidity and mortality, length of stay, and hospital costs, so it may be reasonable to choose endovascular therapy over surgical clipping in the treatment of select unruptured intracranial aneurysms, particularly in cases for which surgical morbidity is high, such as at the basilar apex and in the elderly.
- Endovascular treatment of unruptured intracranial aneurysms is recommended to be performed at high-volume centers.

Regulatory Status

Device	Description
Enterprise™ Vascular Reconstruction Device and Delivery	In 2007, based on a series of approximately 30 patients with 6-month follow-up, the Enterprise™ Vascular Reconstruction Device and Delivery (Cordis Neurovascular) was approved by the FDA through the humanitarian device exemption process (H060001) for use with embolic coils for the treatment of wide-neck, intracranial, saccular, or fusiform aneurysms.

Low-Profile Visualized Intraluminal Support Device	In 2014, the Low-Profile Visualized Intraluminal Support Device (LVIS™ and LVIS™ Jr.; MicroVention) was approved by the FDA through the humanitarian device exemption process (H130005) for use with embolic coils for the treatment of unruptured, wide-neck (neck, ≥4 mm or dome-to-neck ratio, <2), intracranial, saccular aneurysms arising from a parent vessel with a diameter of 2.5 mm or greater and 4.5 mm or smaller. In 2018, the LVIS™ and LVIS™ Jr. were approved through the PMA process (P170013).
Neuroform™ Atlas Stent System	In 2019, the Neuroform™ Atlas Stent System (Stryker) was approved by the FDA through the PMA process (P190031) based on the pivotal ATLAS study including 201 patients with up to 12 months of follow-up. The approved indication is "for use with neurovascular embolization coils in the anterior circulation of the neurovasculature for the endovascular treatment of patients greater than or equal to 18 years of age with saccular wide-necked (neck width greater or equal to 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of greater than or equal to 2.0 mm and less than or equal to 4.5 mm."
Neuroform™ Microdelivery Stent System	In 2002, the Neuroform™ Microdelivery Stent System received HDE approval from the FDA for use with embolic coils for treatment of wide-neck intracranial aneurysms that cannot be treated by surgical clipping. Similarly, in 2007, the Enterprise Vascular Reconstruction Device and Delivery System received HDE approval from the FDA for use with embolic coils for treatment of wide-neck, intracranial, saccular, or fusiform aneurysms.

Neurolink® System	The Neurolink® system, marketed by the Guidant Corporation, is indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with a stenosis greater than or equal to 50% and that are accessible to the stent system.
Pipeline® Embolization Device	In 2011, the Pipeline® Embolization Device (Covidien/eV3 Neurovascular), an intracranial aneurysm flow-diverter, was approved by the FDA through the premarket approval process (P100018) for the endovascular treatment of adults (≥22 years) with large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments.
PulseRider® Aneurysm Neck Reconstruction Device	In 2017, the PulseRider® Aneurysm Neck Reconstruction Device (Pulsar Vascular, Inc.) was approved by the FDA through the humanitarian device exemption process (H160002) for use with neurovascular embolic coils for treatment of unruptured wide-necked intracranial aneurysms with neck width at least 4 mm or dome to neck ratio greater than 2.
Surpass Streamline Flow Diverter	In 2018, Surpass Streamline Flow Diverter (Stryker Neurovascular) was approved by the FDA through the premarket approval process (P170024) for use in the endovascular treatment of patients (18 years of age and older) with unruptured large or giant saccular wide-neck (neck width ≥ 4 mm or dome-to-neck ratio < 2) or fusiform intracranial aneurysms in the internal carotid artery from the petrous segment to the terminus arising from a parent vessel with a

	diameter ≥ 2.5 mm and ≤ 5.3 mm. The approval was based on 1- year results of the Surpass Intracranial Aneurysm Embolization System Pivotal Trial to Treat Large or Giant Wide Neck Aneurysms (SCENT) study. The SCENT study is continuing follow-up to 5 years post-procedure as a post-approval study.
Wingspan Stent System with Gateway™ PTA Balloon Catheter	The Wingspan™ Stent System with Gateway™ PTA Balloon Catheter, marketed by Boston Scientific, received HDE approval from the FDA in 2005 to treat refractory intracranial atherosclerotic disease resulting in 50 percent or greater narrowing in the intracranial arteries. Following analysis of data from the SAMMPRIS study, the original HDE clinical study and other clinical studies performed after the stent's HDE approval, the FDA revised the use and labeling for the Wingspan™ stent in August 2012. The new labeling approves the use of Wingspan™ stent for a very select group of patients who are between 22 and 80 years of age and meet all the following criteria: • Have had two or more strokes despite aggressive medical management. • Their most recent stroke occurred more than seven days prior to Wingspan™ placement and • Have 70-99% stenosis due to atherosclerosis of the intracranial artery related to the recurrent strokes; and • Have made good recovery from previous stroke with a modified Rankin score of 3 or less prior to Wingspan™ treatment. The Wingspan™ Stent System should not be used for the treatment of TIAs or

	treatment of stroke with onset of symptoms within seven days or less of treatment.
Woven Endobridge (WEB®)	In 2018, the Woven Endobridge (WEB®) Aneurysm Embolization System (Sequent Medical™ Inc. [MicroVention, Inc.] Aliso Viejo, CA) received FDA premarket approval for use at the middle cerebral artery (MCA) bifurcation, internal carotid artery (ICA) terminus, anterior communicating artery (AComm) complex, or basilar artery apex for the endovascular treatment of adults with saccular, wide neck, bifurcating intracranial aneurysms with dome diameter from 3 mm to 10 mm and either neck size of 4 mm or greater or a dome-to-neck ratio greater than 1 and less than 2.

PRIOR APPROVAL

Not applicable

POLICY

See Related Medical Policy

- 10.01.14 Humanitarian Use Devices

Intracranial Stent Placement

Intracranial stent placement may be considered **medically necessary** as part of the endovascular treatment of an intracranial aneurysm for individuals when **ALL** the following criteria are met:

- When surgical treatment is not appropriate; **and**
- Standard endovascular techniques do not allow for complete isolation of the aneurysm due to its anatomy, e.g., wide-neck aneurysm ($\geq$ 4 mm) or sack-to-neck ratio less than 2:1.

Intracranial Flow-Diverting Stents

Intracranial flow-diverting stents with U.S. Food and Drug Administration (FDA) approval (*see Regulatory Status information above*) for the treatment of intracranial aneurysms may be considered **medically necessary** as part of the endovascular treatment of intracranial aneurysms for individuals meeting **ALL** the following criteria:

- Not amendable to surgical treatment or standard endovascular therapy; **and**
- The treatment is for large or giant wide-necked aneurysm with a size of ≥10 mm and has a neck diameter ≥ 4 mm in the internal carotid artery from the petrous to the superior hypophyseal segments.

Intracranial stent placement and intracranial flow-diverting stents is considered **investigational** in the treatment of intracranial aneurysms except as indicated above and for all other indications because the evidence is insufficient in the available published peer-reviewed literature to support a conclusion concerning the safety and/or effectiveness that this technology results in an improvement in the net health outcomes.

Percutaneous Intracranial Transluminal Angioplasty
Percutaneous intracranial transluminal angioplasty with or without stenting is considered **investigational** for the treatment of atherosclerotic cerebrovascular disease because the evidence is insufficient in the available published peer-reviewed literature to support a conclusion concerning the safety and/or effectiveness that this technology results in an improvement in the net health outcomes.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 61630 Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous
- 61635 Transcatheter placement of intravascular stent(s), intracranial (eg, 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
- 61642 Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in different vascular family

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POLICY HISTORY		
Date	**Reason**	**Action**

June 2022	Annual Review	Policy Revised
June 2021	Annual Review	Policy Revised
June 2020	Annual Review	Policy Revised
June 2019	Annual Review	Policy Revised
June 2018	Annual Review	Policy Renewed
June 2017	Annual Review	Policy Revised
June 2016	Annual Review	Policy Renewed
June 2015	Annual Review	Policy Renewed
July 2014	Annual Review	Policy Revised
September 2013	Annual Review	Policy Revised
October 2012	Annual Review	Policy Renewed
October 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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