

Corporate Medical Policy

Endovascular Procedures for Intracranial Arterial Disease

File Name: endovascular_procedures_for_intracranial_arterial_disease
Origination: 2/1996
Last Review: 5/2024

Description of Procedure or Service

Intracranial arterial disease includes thromboembolic events, vascular stenoses, and aneurysms. Endovascular techniques have been investigated for 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 individuals whose anatomy is not amenable to simple coiling.

Cerebrovascular diseases include a range of processes affecting the cerebral vascular system, including arterial thromboembolism, arterial stenosis, and arterial aneurysms, all of which can lead to restrictions in cerebral blood flow due to ischemia or hemorrhage. Endovascular techniques, including endovascular mechanical embolectomy with various types of devices (i.e., stents), and angioplasty with or without stenting, have been investigated for treatment of cerebrovascular diseases.

Acute Stroke

Acute stroke is a 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% are hemorrhagic. Differentiation between the two types of stroke 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) or a blood clot 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.

The prompt use of intravenous (IV) thrombolytic therapy with recombinant tissue plasminogen activator (tPA) to recanalize occluded blood vessels has been associated with improved outcomes in multiple randomized controlled trials (RCTs) and meta-analyses. Therefore, use of IV tPA in ischemic stroke individuals presenting within three hours (up to 4.5 hours in some cases) of stroke onset in expert centers is recommended.

Despite the potential benefits of IV tPA in eligible individuals who present within the appropriate time window, limitations to reperfusion therapy with IV tPA have prompted investigations of alternative acute stroke therapies. These limitations include:

- **Requirement for treatment within 4.5 hours of stroke onset.** Relatively few individuals present for care within the time window in which tPA has shown benefit. In addition, determining the time of onset of symptoms is challenging in individuals awakening with symptoms of acute stroke; individuals with symptoms on awakening are considered to have symptom onset when they went to sleep. In 2010 to 2011, fewer than 10% of all individuals presenting with ischemic stroke arrived at the hospital and received IV tPA within the 3-hour window.

Endovascular Procedures for Intracranial Arterial Disease

- **Risks associated with IV tPA therapy.** Intravenous tPA is associated with increased risk of intracranial bleeding. It is contraindicated in hemorrhagic stroke and in some individuals with ischemic stroke for whom the risk of bleeding outweighs the potential benefit, such as those with mild or resolving symptoms, hypocoagulable state, or advanced age.
- **Variable recanalization rates.** For individuals receiving tPA, recanalization rates are around 21% and range from about 4% in the distal internal carotid artery and basilar artery to about 32% in the middle cerebral artery. The treatment of large-vessel strokes with IV tPA may be less successful.

Researchers have studied intra-arterial tPA, transcranial ultrasound energy, and mechanical clot destruction or clot removal as alternatives or second lines, to the established intravenous tPA therapy.

Endovascular mechanical embolectomy. Endovascular embolectomy devices remove or disrupt clots by a number of mechanisms. Several devices have FDA approval for treatment of acute stroke (see “Regulatory Status”): The first generation devices were the Merci® Retriever and Penumbra System®. The second generation devices included stent retrievers: the Solitaire™ Flow Restoration Device and the Trevo® Retriever. With the Merci® device, a microcatheter is passed through the thrombus from a larger, percutaneous catheter positioned proximal to the occlusion. A helical snare is deployed, and the catheter and clot are withdrawn together. With the Penumbra® device, an opening at the tip of the percutaneous catheter utilizes suction to extract the clot. Both the Solitaire Flow Restoration Device and the Trevo Retriever are retrievable stents, which are positioned to integrate the clot with the stent for removal with the stent’s struts. Recently the EmboTrap Revascularization Device (Neuravi Ltd.) was cleared with the Solitaire and Trevo as predicate devices.

This policy focuses on the devices listed above with an indication for endovascular embolectomy for acute stroke. Additional retrievable stent devices are under investigation, such as the Embolus Retriever with Interlinked Cages (MicroVention, Tustin, CA).

An additional clinical situation in which endovascular therapies may be used in the treatment of acute ischemic stroke is in the setting of cerebral vasospasm following intracranial (subarachnoid) hemorrhage. Delayed cerebral ischemia (DCI) occurs about 3 to 14 days following the acute bleed in about 30% of individuals experiencing subarachnoid hemorrhage and is a significant contributor to morbidity and mortality in individuals who survive the initial bleed. In cases refractory to medical measures, rescue invasive therapies including intra-arterial vasodilator infusion therapy (e.g., calcium channel blockers) and transluminal balloon angioplasty may be used. The mechanism of disease, patient population, and time course of therapy differ for DCI occurring post-subarachnoid hemorrhage compared with ischemic stroke due to atheroembolic disease. Therefore, this indication for endovascular intervention will not be addressed in this policy.

Intracranial Arterial Stenosis

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 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

Endovascular Procedures for Intracranial Arterial Disease

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 event. Surgical approaches have met with limited success. The widely cited 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. Two endovascular devices have FDA approval for treatment of symptomatic intracranial stenosis and are considered here (see “Regulatory Status”).

Intracranial Aneurysms

Compared with acute ischemic stroke, cerebral aneurysms have a much lower incidence among the U.S. population, 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. 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 grew, stenting was also used in smaller berry aneurysms as an approach to decrease the rate of retreatment needed in patients who receive coiling. In 2011, the Pipeline® Embolization Device, which falls into a new device category called “intracranial aneurysm flow diverters,” or flow-diverting stents, received FDA premarket approval for endovascular treatment of large or giant wide-necked intracranial aneurysms in the internal carotid artery. 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. According to the FDA documentation, the Surpass Streamline Flow Diverter has the same mechanism of action as the approved Pipeline Embolization Device.

Regulatory Status:

Several devices for endovascular treatment of intracranial arterial disease have received clearance by FDA through either the 510(k) process or through the humanitarian device exemption (HDE) process. By indication, approved devices are as follows:

Acute Stroke

1. The Merci® Retriever (Concentric Medical, Mountain View, CA). In August 2004, the Merci® Retriever was cleared by FDA through the 510(k) process. This device was judged equivalent to a predicate device, the Concentric Retriever, which was indicated for endovascular foreign body removal. The FDA clearance indicated that the Mechanical Embolus Removal in Cerebral Ischemia (MERCi) Clinical Study established that no new issues of safety and effectiveness exist when the Merci Retriever is used for thrombus removal versus foreign body removal from the neurovasculature. A modified Merci Retriever, also manufactured by Concentric Medical Inc., received 510(k) clearance from FDA in May 2006. The clearance notes that the Modified Merci Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in individuals experiencing ischemic stroke. Individuals who are ineligible for intravenous tPA or who fail intravenous tPA therapy are candidates for treatment. The device also has clearance

Endovascular Procedures for Intracranial Arterial Disease

for retrieval of foreign bodies misplaced during interventional radiologic procedures in the neuro, peripheral, and coronary vasculature.

2. The Penumbra System® (Penumbra Inc., Alameda, CA). In December 2007, the Penumbra System® was cleared through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use in the revascularization of individuals with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.
3. The Solitaire™ FR device (Covidien/ ev3 Neurovascular, Irvine, CA). In March 2012, the Solitaire™ FR device was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to the Merci Retriever device, based on a randomized controlled trial (RCT) of 113 patients submitted to FDA comparing the Merci and Solitaire devices. Indications for the device are individuals with ischemic stroke due to large intracranial vessel occlusion who are ineligible for intravenous tPA, or who fail intravenous tPA.
4. The Trevo Pro Retriever™ device (Stryker Neurovascular, Kalamazoo, MI). In August 2012, the Trevo Pro Retriever™ device was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to the Merci Retriever device, based on an RCT of 178 patients from 27 centers in the U.S. and Europe that compared the Trevo device with the Merci device. Indications for the device are individuals with acute ischemic stroke due to large intracranial vessel occlusion who are ineligible for or fail intravenous tPA. Later versions of the Trevo® Retriever are called the Modified Trevo® Retriever, the Trevo® ProVue Retriever, and the Modified Trevo® ProVue Retriever; the name Trevo Retriever is used throughout this review. In February 2018, FDA expanded the indication for the Trevo® Retriever to include individuals experiencing acute ischemic stroke up to 24 hours from symptom onset.
5. The EmboTrap® II Revascularization Device was cleared for marketing by FDA through the 510(k) process in May 2018. The device is indicated for individuals with ischemic stroke within eight hours of symptom onset who are ineligible for or who fail IV tPA.

Since March 2021, the following devices have been approved by FDA for “Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA”:

1. Penumbra System® (Reperfusion Catheter RED™ 43) approved in December 2022.
2. Esperance™ Aspiration Catheter System (Wallaby Medical) approved in November 2021.
3. Embotrap® III Revascularization Device (Neuravi Ltd) approved in July 2021.
4. ZOOM™ 71 Reperfusion Catheter (Imperative Care, Inc) approved in June 2021.
5. ZOOM Reperfusion Catheter (Imperative Care, Inc) approved in April 2021.
6. Tigertriever™ and Tigertriever 17 Resvascularization Devices (Rapid Medical, Ltd) approved in March 2021.

Intracranial Arterial Stenosis

Currently 2 devices have received approval for atherosclerotic disease from FDA through HDE process. This form of FDA approval is available for devices used to treat conditions with an incidence of 4,000 or less per year; FDA only requires data showing “probable safety and effectiveness.” Devices with their labeled indications are as follows:

1. NeuroLink System® (Guidant, Santa Clara, CA). “The NeuroLink system 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.”
2. Wingspan™ Stent System (Boston Scientific, Fremont, CA). “The Wingspan Stent System with Gateway PTA Balloon Catheter is indicated for use in improving cerebral artery lumen diameter

Endovascular Procedures for Intracranial Arterial Disease

in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with $\geq 50\%$ stenosis that are accessible to the system.”

Intracranial Aneurysms

In 2011, FDA granted premarket approval to the Pipeline® Embolization Device (Covidien/eV3 Neurovascular, Irvine, CA), an intracranial aneurysm flow diverter, for the endovascular treatment of adults (≥ 22 years of age) with large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments (P100018). Approval was based on the Pipeline for Uncoilable or Failed Aneurysms Study, a single-arm, open-label feasibility study that included 108 patients aged 30 to 75 years with unruptured large and giant wide-necked aneurysms.

In 2018, Surpass Streamline™ Flow Diverter (Stryker Neurovascular) was approved by the FDA through the premarket approval process for use in the endovascular treatment of individuals (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 one 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 five years post-procedure as a post-approval study.

The following stents have received FDA approval through the HDE program for treatment of intracranial aneurysms:

1. Neuroform™ Microdelivery Stent System (Stryker, Kalamazoo, MI). In 2002, based on a series of approximately 30 patients with 6-month follow-up, the Neuroform Microdelivery Stent System was approved (HDE) for use with embolic coils for treatment of wide-neck intracranial aneurysms that cannot be treated by surgical clipping (H020002).
2. 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 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 or equal to 2.0 mm and less than or equal to 4.5 mm."
3. Enterprise™ Vascular Reconstruction Device and Delivery System (Cordis Neurovascular Inc., Miami Lakes, FL) In 2007, based on a series of approximately 30 patients with 6-month follow-up, the Enterprise Vascular Reconstruction Device and Delivery System was approved (HDE) for use with embolic coils for treatment of wide-neck, intracranial, saccular or fusiform aneurysms (H060001).
4. The Low-Profile Visualized Intraluminal Support Device (LVIS™ and LVIS™ Jr.) (MicroVention Inc., Tustin, CA) received HDE approval in July 2014 (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 ≥ 2.5 mm and ≤ 4.5 mm. In 2018, the LVIS and LVIS Jr. were approved through the PMA process (P170013).
5. PulseRider Aneurysm Neck Reconstruction Device (Pulsar Vascular). In 2017, the PulseRider Aneurysm Neck Reconstruction Device received HDE approval (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 less than 2.

Related Policies:

Carotid Artery Angioplasty/Stenting (CAS)

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Endovascular Procedures for Intracranial Arterial Disease

Policy

BCBSNC will provide coverage for Endovascular Procedures for Intracranial Arterial Disease when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Endovascular Procedures for Intracranial Arterial Disease are covered

Intracranial stent placement may be considered **medically necessary** as part of the endovascular treatment of intracranial aneurysms for individuals when:

- 1) surgical treatment is not appropriate; and
- 2) 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.

Intracranial flow diverting stents with USFDA approval for the treatment of intracranial aneurysms may be considered **medically necessary** as part of the endovascular treatment of intracranial aneurysms when:

- 1) used to treat large or giant wide-necked intracranial aneurysms, with a size of 10 mm or more and a neck diameter of 4 mm or more, in the internal carotid artery from the petrous to the superior hypophyseal segments; and
- 2) intracranial aneurysm is not amenable to surgical treatment or standard endovascular therapy.

The use of endovascular mechanical embolectomy with a device with FDA approval for the treatment of acute ischemic stroke may be considered **medically necessary** as part of the treatment of acute ischemic stroke for individuals who meet all of the following criteria:

- Have a demonstrated occlusion within the proximal intracranial anterior circulation (intracranial internal carotid artery, or M1 or M2 segments of the middle cerebral artery, or A1 or A2 segments of the anterior cerebral artery); AND
- Can receive endovascular mechanical embolectomy within 12 hours of symptom onset OR within 24 hours of symptom onset if there is evidence of a mismatch between specific clinical and imaging criteria (see Policy Guidelines); AND
- Have evidence of substantial and clinically significant neurological deficits; AND
- Have evidence of salvageable brain tissue in the affected vascular territory); AND
- Have no evidence of intracranial hemorrhage or arterial dissection on computed tomography (CT) or magnetic resonance imaging.

When Endovascular Procedures for Intracranial Arterial Disease are not covered

Intracranial stent placement is considered **investigational** in the treatment of intracranial aneurysms except as noted above.

Intracranial percutaneous transluminal angioplasty with or without stenting is considered **investigational** in the treatment of atherosclerotic cerebrovascular disease

Endovascular interventions are considered **investigational** for the treatment of acute ischemic stroke when the above criteria are not met.

Endovascular Procedures for Intracranial Arterial Disease

Policy Guidelines

The DAWN and DEFUSE 3 studies enrolled patients from 6 up to 24 hours of the time last known to be well if there was evidence of a mismatch between specific clinical and imaging criteria (infarct size and volume was assessed with the use of diffusion-weighted magnetic resonance imaging or perfusion CT).

Inclusion criteria for the DAWN trial were:

6 to 24 hours related to mismatch between severity of clinical deficit and infarct volume:

- ≥ 80 years of age, score ≥ 10 on the NIHSS, and had an infarct volume < 21 mL; OR
- ≤ 80 years age, score of ≥ 10 on the NIHSS, and had an infarct volume < 31 mL; OR
- ≤ 80 years of age, had a score ≥ 20 on the NIHSS, and had an infarct volume of 31 to < 51 mL.

Inclusion criteria for the DEFUSE 3 trial were:

6 to 16 hours related to mismatch between severity of clinical deficit and infarct volume:

- Infarct size of < 70 mL; AND
- Ratio of ischemic tissue volume to infarct volume of ≥ 1.8 ; AND
- Ischemic penumbra of ≥ 15 cm³.

NIHSS: National Institutes of Health Stroke Scale

This policy only addresses endovascular therapies used on intracranial vessels.

These policy statements are not intended to address the use of rescue endovascular therapies, including intra-arterial vasodilator infusion and intracranial percutaneous transluminal angiography, in the setting of delayed cerebral ischemia after aneurysmal subarachnoid hemorrhage.

For individuals who have acute ischemic stroke due to occlusion of an anterior circulation vessel who receive endovascular mechanical embolectomy, the evidence includes randomized clinical trials (RCTs) comparing endovascular therapy with standard care and systematic reviews of these RCTs. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. From 2013 to 2015, eight RCTs were published comparing endovascular therapies with noninterventional care for acute stroke in patients with anterior circulation occlusions. Several trials that were ongoing at the time of publication of these eight RCTs were stopped early and results with the limited enrollment have been published. Trials published from 2014 to 2015 demonstrated a significant benefit regarding reduced disability at 90 days posttreatment. The trials that demonstrated a benefit to endovascular therapy either exclusively used stent retriever devices or allowed the treating physician to select a device, mostly a stent retriever device, and had high rates of mechanical embolectomy device use in patients randomized to endovascular therapy. Studies that demonstrated a benefit to endovascular therapy required demonstration of a large-vessel, anterior circulation occlusion for enrollment. Also, they were characterized by fast time-to-treatment. Not all studies published after 2015 have shown a benefit of endovascular therapy in major clinical outcomes, possibly due to small sample sizes and lack of power to detect differences, but systematic reviews have found significant effects. Two trials published in 2018 demonstrated that it was possible to extend the window for mechanical thrombectomy up to about 24 hours for select patients. To achieve results in real-world settings similar to those in the clinical trials, treatment times, clinical protocols, and patient selection criteria should be similar to those in the RCTs. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have acute ischemic stroke due to basilar artery occlusion who receive endovascular mechanical embolectomy, the evidence includes four RCTs and systematic review of

Endovascular Procedures for Intracranial Arterial Disease

these RCTs and observational studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. Results among these studies are inconsistent for functional outcomes and 90-day mortality. Systematic reviews of both RCTs and observational studies support the efficacy of endovascular therapy for improving functional outcomes and reducing mortality, but rates of symptomatic intracranial hemorrhage are higher with endovascular intervention than with medical therapy. The generalizability of the RCT results may be limited due to lack of inclusion of any U.S. populations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic intracranial arterial stenosis due to atherosclerosis who receive intracranial percutaneous transluminal angioplasty with or without stenting, the evidence includes systematic reviews and three major RCTs. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, and treatment-related mortality and morbidity. All available RCTs demonstrated no significant benefit with endovascular therapy. In particular, the Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) trial was stopped early due to harms, because the rate of stroke or death at 30 days posttreatment 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. Although some nonrandomized studies have suggested a benefit from endovascular therapy, the available evidence from three RCTs does not suggest that intracranial percutaneous transluminal angioplasty with or without stenting improves outcomes for individuals with symptomatic intracranial stenosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome..

For individuals who have intracranial aneurysm(s) who receive endovascular coiling with intracranial stent placement or intracranial placement of a flow-diverting stent, the evidence includes RCTs, several nonrandomized comparative studies and multiple single-arm studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. 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 for 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 pragmatic RCT and registry study have compared flow diversion with standard management (observation, coil embolization, or parent vessel occlusion) in patients for whom flow diversion was considered a promising treatment. The pragmatic study was stopped early after crossing a predefined safety boundary when 16% of patients 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 systematic review comparing the flow-diverting stents with endovascular coiling for intracranial aneurysms demonstrated higher rates of aneurysm obliteration in those treated with the Pipeline endovascular device than those treated 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 patients with intracranial aneurysms because the risk-benefit ratio cannot be adequately defined. One randomized study demonstrated adequate aneurysm occlusion with the Surpass flow diverter device. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Endovascular Procedures for Intracranial Arterial Disease

Applicable service codes: 37246, 37247, 61624, 61630, 61635, 61645

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Cerebral Angioplasty

Food and Drug Administration

Medical Policy Advisory Group Review - 3/99

Specialty Matched Consultant Advisory Panel - 10/2000

Consultant Review - 11/2000

Polin RS, Coenen VA, Hansen CA, et al. Efficacy of transluminal angioplasty for the management of symptomatic cerebral vasospasm following aneurysmal subarachnoid hemorrhage. *J Neurosurg.* 2000 Feb;92(2):284-90.

Mori T, Fukuoka M, Kazita K, Mori K. Follow-up study after percutaneous transluminal cerebral angioplasty. *Eur Radiol.* 1998;8(3):403-8.

Albers GW. Management of acute ischemic stroke. An update for primary care physicians. *West J Med.* 1997 Apr;166(4):253-62.

Specialty Matched Consultant Advisory Panel - 7/2002

BCBSA Medical Policy Reference Manual, 2.01.54; 12/18/02

Specialty Matched Consultant Advisory Panel - 7/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 3/15/2005

Specialty Matched Consultant Advisory Panel - 6/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 4/25/2006

Specialty Matched Consultant Advisory Panel - 5/2007

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 7/10/2008

Specialty Matched Consultant Advisory Panel - 5/2009

Title Change – Endovascular Procedures for Intracranial Arterial Disease

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 2/10/11

Specialty Matched Consultant Advisory Panel - 5/2011

Specialty Matched Consultant Advisory Panel – 5/2012

Endovascular Procedures for Intracranial Arterial Disease

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 5/10/2012

Medical Director – 6/2012

Specialty Matched Consultant Advisory Panel – 5/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 5/9/2013

Senior Medical Director – 7/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 1/9/2014

Senior Medical Director – 4/2014

Specialty Matched Consultant Advisory Panel – 5/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 6/12/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 1/15/2015

Specialty Matched Consultant Advisory Panel – 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 9/10/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 4/14/2016

Specialty Matched Consultant Advisory Panel – 5/2016

Specialty Matched Consultant Advisory Panel – 5/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 9/14/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 4/12/2018

Specialty Matched Consultant Advisory Panel – 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 4/8/2019

Specialty Matched Consultant Advisory Panel – 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 4/16/2020

Specialty Matched Consultant Advisory Panel – 5/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 4/8/2021

Specialty Matched Consultant Advisory Panel – 5/2021

Specialty Matched Consultant Advisory Panel – 5/2022

U.S. Centers for Disease Control and Prevention. Stroke facts. October 14, 2022.
<https://www.cdc.gov/stroke/facts.htm>.

Endovascular Procedures for Intracranial Arterial Disease

Vizient. Vascular technologies. Coronary, peripheral, and neurovascular devices. Technology watch. 2019. <https://www.vizientinc.com/our-solutions/supply-chain-solutions/tech-watch>.

Luo J, Wang T, Yang K, et al. Endovascular therapy versus medical treatment for symptomatic intracranial artery stenosis. *Cochrane Database Syst Rev*. Feb 03 2023;2(2): CD013267. PMID 36738471

Food and Drug Administration. FDA Executive Summary General Issues: Meeting to Discuss the Evaluation of Safety and Effectiveness of Endovascular Medical Devices Intended to Treat Intracranial Aneurysms. <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/UCM59845>

Specialty Matched Consultant Advisory Panel – 5/2023

Rha JH, Saver JL. The impact of recanalization on ischemic stroke outcome: a meta-analysis. *Stroke*. Mar 2007; 38(3): 967-73. PMID 17272772

Meyers PM, Schumacher HC, Higashida RT, et al. Indications for the performance of intracranial endovascular neurointerventional procedures: a scientific statement from the American Heart Association Council on Cardiovascular Radiology and Intervention, Stroke Council, Council on Cardiovascular Surgery and Anesthesia, Interdisciplinary Council on Peripheral Vascular Disease, and Interdisciplinary Council on Quality of Care and Outcomes Research. *Circulation*. Apr 28 2009; 119(16): 2235-49. PMID 19349327

Becske T, Kallmes DF, Saatci I, et al. Pipeline for uncoilable or failed aneurysms: results from a multicenter clinical trial. *Radiology*. Jun 2013; 267(3): 858-68. PMID 23418004

Specialty Matched Consultant Advisory Panel- 5/2024

Medical Director Review- 5/2024

Policy Implementation/Update Information

2/96	Original policy issued.
2/97	Reaffirmed
3/99	Reaffirmed
8/99	Reformatted, Medical Term Definitions added.
10/00	System coding changes.
11/00	Specialty Matched Consultant Advisory Panel review. Consultant review. Literature search through 11/2000 in MEDLINE and MD Consult. No change in criteria. Reaffirm.
11/01	Coding format change.
8/02	Specialty Matched Consultant Advisory Panel review 7/12/2002. No changes.
7/03	Specialty Matched Consultant Advisory Panel review 7/15/03. No changes to criteria. Benefits Application section revised. Codes 36100, 36215-36218, 35475 added to Billing/Coding section.

Endovascular Procedures for Intracranial Arterial Disease

- 1/04 Billing/Coding section updated for consistency.
- 7/7/05 Specialty Matched Consultant Advisory Panel review 6/24/2005. No changes to criteria. Rationale added to “Policy Guidelines” section. Policy number added to “Policy Key Words” section. References added.
- 7/10/06 Added new 2006 CPT codes 61640, 61641, and 61642 to the Billing/Coding section. Added “with or without stenting” to “Policy” section. “Neurolink System” and “Wingspan Stent System with Gateway PTA Balloon Catheter” added to “Policy Key Words” section.
- 12/11/06 Added CPT codes 61630 and 61635 to the “Billing/Coding” section.
- 8/13/07 Specialty Matched Consultant Advisory Panel review 5/23/07. Updated “Description” section. Added statement; “***Please note that this policy does not pertain to Carotid Artery Angioplasty/Stenting (CAS), policy number SUR6115.” References added.
- 7/6/09 Specialty Matched Consultant Advisory Panel review 5/28/09. Revised “Description” section. No change to policy statement. References added. (btw)
- 6/22/10 Policy Number(s) removed (amw)
- 6/21/11 Policy title changed from “Cerebral Angioplasty” to “Endovascular Procedures for Intracranial Arterial Disease”. Specialty Matched Consultant Advisory Panel review 5/25/2011. Revised “Description” section to include information regarding endovascular procedures for aneurysm. Changed the “Policy” statement; “BCBSNC will provide coverage for Endovascular Procedures (Angioplasty and/or Stenting) for Intracranial Arterial Disease (Atherosclerosis and Aneurysms) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.” Added the following statement to the “When Covered” section; “Intracranial stent placement may be considered medically necessary as part of the endovascular treatment of intracranial aneurysms for patients when surgical treatment is not appropriate and 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.” Revised the “When Not Covered” section to; “Intracranial stent placement is considered investigational in the treatment of intracranial aneurysms except as noted above. Intracranial percutaneous transluminal angioplasty with or without stenting is considered investigational in the treatment of atherosclerotic cerebrovascular disease.” Updated “Policy Guidelines” section. References added. (btw)
- 5/29/12 Specialty Matched Consultant Advisory Panel review 5/16/2012. No change to policy intent. Removed CPT 61640, 61641, and 61642 from Billing/Coding section as they do not apply to this policy. (btw)
- 6/29/12 Description section revised. Policy Guidelines section updated. Medical Director review 6/14/2012. Reference added. (btw)
- 7/1/13 Specialty Matched Consultant Advisory Panel review 5/15/2013. No change to policy. (btw)
- 8/13/13 Policy Guidelines updated. Reference added. Senior Medical Director review 7/26/2013. (btw)
- 4/15/14 Description and Policy Guidelines sections updated. Added the following statements to the When Not Covered section; “Intracranial percutaneous transluminal angioplasty with or without stenting is considered investigational in the treatment of cerebral vasospasm after aneurysmal subarachnoid hemorrhage.” “Use of intracranial aneurysm flow diverter systems

Endovascular Procedures for Intracranial Arterial Disease

(i.e., Pipeline® Embolization Device) for the endovascular treatment of adults (22 years of age or older) with large or giant wide-necked intracranial aneurysms is considered investigational.” “Endovascular interventions (mechanical embolectomy, angioplasty, stenting) are considered investigational in the treatment of acute stroke.” This information was previously located in the medical policy titled, Mechanical Embolectomy for Treatment of Acute Stroke which is being archived. Senior Medical Director review 4/27/2014. Reference added. Specialty Matched Consultant Advisory Panel review 5/27/14. Notification given 4/15/2014. Policy effective 7/1/2014. (btw)

- 12/9/14 Reference added. Policy statements updated to include statement that intracranial flow diverting stents may be medically necessary for aneurysms meeting criteria. Statement added to “Policy Guidelines” that this policy addresses only intracranial endovascular interventions. (sk)
- 5/26/15 Reference added. Paragraph added to Description section that endovascular therapies used in the treatment of acute ischemic stroke in the setting of cerebral vasospasm following intracranial (subarachnoid) hemorrhage will not be addressed in this policy. Low-Profile Visualized Intraluminal Support Device added to the list of FDA approved stents for intracranial aneurysms. Removed cerebral vasospasm after aneurysmal subarachnoid hemorrhage from Not Covered section. Policy Guidelines updated. (sk)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/27/15. (sk)
- 11/24/15 Reference added. Policy statement revised to indicate that mechanical embolectomy for acute stroke may be considered medically necessary when criteria are met. Description section updated. Policy Guidelines updated. Added codes 37184, 37185, and 37186 to Billing/Coding section. Removed codes 61640, 61641, and 61642 from Billing/Coding section. (sk)
- 12/30/15 Code 61645 added to Billing/Coding section. (sk)
- 7/1/16 Reference added. Description section updated. Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)
- 12/30/16 Codes 37246 and 37247 added to Billing/Coding section. (sk)
- 6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)
- 10/27/17 Reference added. (sk)
- 6/29/18 Reference added. Policy statement changed to reflect extension of the time window for mechanical thrombectomy up to 24 hours after symptom onset for select patients. Codes 37184, 37185, and 37186 removed from Billing/Coding section. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)
- 7/1/19 Reference added. Specialty Matched Consultant Advisory Panel review 5/15/2019. (sk)
- 6/9/20 Reference added. Regulatory Status updated. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/20/2020. (sk)
- 6/1/21 Reference added. Specialty Matched Consultant Advisory Panel review 5/19/2021. (sk)
- 6/14/22 Specialty Matched Consultant Advisory Panel review 5/18/2022. (sk)

Endovascular Procedures for Intracranial Arterial Disease

- 6/30/23 References added. Specialty Matched Consultant Advisory Panel review 5/17/2023. Additional FDA approved devices for treatment of acute stroke added to Regulatory Status. (sk)

- 5/29/24 When Covered section revised specific to intracranial flow diverting stents; moved anatomic criteria for intracranial flow diverting stents from the Policy Guidelines section. Policy Guidelines also updated. No change to policy intent. References updated. Specialty Matched Consultant Advisory Panel review 5/2024. Medical Director review 5/2024. (ldh)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.