

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Extracranial Carotid Angioplasty Stenting is addressed separately in medical policy 00155.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider percutaneous intracranial artery stent placement with or without angioplasty as part of the treatment of individuals with an intracranial aneurysm when ALL of the following criteria are met to be **eligible for coverage**:**

- Surgical treatment is not appropriate or attempted surgery was unsuccessful; **and**
- Standard endovascular techniques (coiling) are inadequate to achieve complete isolation of the aneurysm because of anatomic considerations which include, but are not limited to:
 - wide-neck aneurysm (4 mm or more); **or**
 - sack-to-neck ratio less than 2:1.

Based on review of available data, the Company may consider the use of endovascular mechanical embolectomy using a device with U.S. Food and Drug Administration (FDA) approval for the treatment of acute ischemic stroke to be **eligible for coverage**** as part of the treatment of acute ischemic stroke for individuals that meet the patient selection criteria.

Patient Selection Criteria

Coverage eligibility for the use of endovascular mechanical embolectomy using a device with FDA approval for the treatment of acute ischemic stroke will be considered when ALL of the criteria below is met:

- 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**

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

- Have evidence of substantial and clinically significant neurologic deficits (see Policy Guidelines section); AND
- Have evidence of salvageable brain tissue in the affected vascular territory (see Policy Guidelines section); AND
- Have no evidence of intracranial hemorrhage or arterial dissection on computed tomography (CT) or magnetic resonance imaging (MRI).

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers intracranial stent placement in the treatment of intracranial aneurysms, except as noted above, to be **investigational**.*

Based on review of available data, the Company considers intracranial percutaneous transluminal angioplasty with or without stenting in the treatment of atherosclerotic cerebrovascular disease to be **investigational**.*

Based on review of available data, the Company considers endovascular interventions for the treatment of acute ischemic stroke when the above criteria are not met to be **investigational**.*

Policy Guidelines

Selection of Individuals for Endovascular Mechanical Embolectomy for Acute Ischemic Stroke

The major randomized controlled trials (RCTs) demonstrating a benefit with endovascular mechanical embolectomy vary in criteria for selecting individuals based on the presence or absence of salvageable brain tissue. Several RCTs use the Alberta Stroke Program Early Computed Tomography Score, which is a 10-point quantitative computed tomography (CT) score to assess the presence of early ischemic changes. MR CLEAN (Endovascular treatment for acute ischemic stroke in the Netherlands) (Berkhemer et al 2015) did not specify imaging criteria to demonstrate salvageable brain tissue. Table PG1 lists the criteria used by other trials.

Table PG1. Trial Selection Criteria for Salvageable Brain Tissue

Trial	Inclusion or Exclusion	Criteria
REVASCAT (Jovin et al 2015)	Exclusion	Hypodensity on CT or restricted diffusion demonstrated by:

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

		- An ASPECTS <7 on CT, CT perfusion CBV, CTA source imaging; OR - An ASPECTS <6 on DWI MRI
ESCAPE (Goyal et al 2015)	Exclusion	Baseline non-contrast CT with extensive early ischemic changes of ASPECTS of 0-5 in the territory of symptomatic intracranial occlusion; OR other confirmation of a moderate-to-large core defined 1 of 3 ways: - On a single-phase, multiphase, or dynamic CTA: no or minimal collaterals in a region greater than 50% of the MCA territory when compared with pial filling on the contralateral side (multiphase/dynamic CTA preferred); OR - On CT perfusion (>8 cm coverage): a low CBV and very low CBF, ASPECTS <6 AND in the symptomatic MCA territory; OR - On CT perfusion (<8 cm coverage): a region of low CBV and very low CBF greater than one-third of the CT perfusion-imaged symptomatic MCA territory
EXTEND-IA (Campbell et al 2015)	Inclusion	Based on CT perfusion imaging using CT or MRI with a Tmax more than 6-s delay perfusion volume and either CT regional CBF or DWI infarct core volume as follows: Mismatch ratio >1.2; AND Absolute mismatch volume >10 mL; AND Infarct core lesion volume <70 mL
SWIFT-PRIME (Saver et al 2015)	Exclusion	Related to imaging-demonstrated core infarct and hypoperfusion: MRI-assessed core infarct lesion greater than: 50 cm³ for subjects age 18-79 y; 20 cm³ for subjects age 80-85 y CT-assessed core infarct lesion greater than: 40 cm³ for subjects age 18-79 y; 15 cm³ for subjects age 80-85 y For all subjects, severe hypoperfusion lesion (³10-s Tmax lesion >100 cm³) For all subjects, ischemic penumbra of ≥15 cm³ and mismatch ratio >1.8

ASPECTS: Alberta Stroke Program Early Computed Tomography Score; CBF: cerebral blood flow; CBV: cerebral blood volume; CT: computed tomography; CTA: computed tomography

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

angiography; DWI: diffusion-weighted imaging; ESCAPE: Endovascular Treatment for Small Core and Proximal Occlusion Ischemic Stroke; EXTEND-IA: Extending the Time for Thrombolysis in Emergency Neurological Deficits - Intra-Arterial; MCA: middle cerebral artery; MRI: magnetic resonance imaging; REVASCAT: Endovascular Revascularization With Solitaire Device Versus Best Medical Therapy in Anterior Circulation Stroke Within 8 Hours; SWIFT-PRIME: Solitaire With the Intention For Thrombectomy as PRIMary Endovascular Treatment; Tmax: time to maximum.

The RCTs demonstrating a benefit to endovascular mechanical embolectomy in acute stroke generally had some inclusion criteria to reflect stroke severity with the exception of the EXTEND-IA (Extending the Time for Thrombolysis in Emergency Neurological Deficits - Intra-Arterial) trial. The REVASCAT (Endovascular Revascularization With Solitaire Device Versus Best Medical Therapy in Anterior Circulation Stroke Within 8 Hours) and ESCAPE (Endovascular Treatment for Small Core and Proximal Occlusion Ischemic Stroke) trials both required a baseline (poststroke) National Institutes of Health Stroke Scale score of 6 or higher. MR CLEAN specified a clinical diagnosis of acute stroke with a deficit on the National Institutes of Health Stroke Scale score of 2 points or more; SWIFT-PRIME (Solitaire With the Intention For Thrombectomy as PRIMary Endovascular Treatment) specified a National Institutes of Health Stroke Scale score of 8 or more and less than 30 at the time of randomization.

The DAWN (Clinical Mismatch in the Triage of Wake Up and Late Presenting Strokes Undergoing Neurointervention With Trevo) and DEFUSE 3 (Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3) studies enrolled individuals from 6 up to 24 hours of the time last time 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) (see Table PG2).

Table PG2. Trial Selection Criteria for Individuals 6 to 25 Hours Post Infarct

Trial	Inclusion or Exclusion	Criteria
DAWN Trial (Nogueira et al 2018)	Inclusion	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
DEFUSE 3 Trial	Inclusion	6 to 16 hours related to mismatch between severity of clinical deficit and infarct volume: Infarct size of < 70 mL; AND ratio of ischemic

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

(Albers et al 2018)	tissue volume to infarct volume of ≥ 1.8 ; AND ischemic penumbra of $\geq 15 \text{ cm}^3$
---------------------	---

DAWN: Clinical Mismatch in the Triage of Wake Up and Late Presenting Strokes Undergoing Neurointervention With Trevo; DEFUSE 3: Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3; NIHSS: National Institutes of Health Stroke Scale.

Other Policy Guidelines

Flow-diverting stents are indicated for the treatment of 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.

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 delayed cerebral ischemia after aneurysmal subarachnoid hemorrhage.

Background/Overview

Cerebrovascular Diseases

Cerebrovascular diseases include a range of processes affecting the cerebral vascular system, including arterial thromboembolism, arterial stenosis, and arterial aneurysms, all of which can restrict 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 the 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. The risk of stroke among Black patients is nearly double the risk among White patients, and Black patients have a higher risk of death due to stroke than other racial groups. Eighty-seven percent of strokes are ischemic and 13% are hemorrhagic. Differentiation between the 2 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 (ie, 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.

Racial differences in the utilization of endovascular therapy for acute stroke have been reported. Sheriff et al (2022) analyzed the Get With The Guidelines-Stroke database; between 2015 and 2019, Black patients had lower odds of receiving endovascular therapy compared to non-Hispanic Whites

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

(adjusted odds ratio [aOR], 0.83; 95% confidence interval [CI], 0.76 to 0.90). At 3 months, functional independence as assessed by the modified Rankin Scale was less common among Black (aOR, 0.84; 95% CI, 0.75 to 0.95) and Asian (aOR, 0.79; 95% CI, 0.65 to 0.98) individuals compared to non-Hispanic Whites. de Havenon et al (2021) found that Black patients were less likely to receive endovascular therapy compared to White patients (odds ratio [OR], 0.75; 95% CI, 0.70 to 0.81) according to National Inpatient Sample data from 2016 to 2018. Kim et al (2022) conducted a retrospective study of 40,814 acute ischemic strokes that occurred in Texas during 2019 which found that Black patients received endovascular therapy less frequently than White patients (4.1% vs. 5.3%, respectively; adjusted relative risk [aRR], 0.76; 95% CI, 0.66 to 0.88; $p < .001$) despite similar rates of hospital admission. The rate of receipt of endovascular therapy was similar between White and Hispanic patients.

Intracranial Arterial Stenosis

It is estimated that intracranial atherosclerosis causes about 8% of all ischemic strokes. Intracranial stenosis may contribute to stroke in 2 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.

Intracranial Aneurysms

Compared with acute ischemic stroke, cerebral 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several devices for endovascular treatment of intracranial arterial disease were cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process or the humanitarian device exemption process. By indication, approved devices are as follows.

Acute Stroke

Table 1 summarizes the first generation devices with FDA clearance for the endovascular treatment of acute stroke and subsequent approval of stent retrievers.

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

Table 1. Food and Drug Administration-Cleared Mechanical Embolectomy Devices for Acute Stroke

Device	510(k) No. for Original Device	Approval Date for Original Device	Indications
Penumbra System ^{®†} (Reperfusion Catheter RED ^{™†} 43)	K222808	Dec 2022	Patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease within 8 h of symptom onset who are ineligible for or who fail IV tPA
Esperance ^{™†} Aspiration Catheter System (Wallaby Medical)	K211697	Nov 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA
Embotrap ^{®†} III Revascularization Device (Neuravi Ltd)	K211338	July 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA
ZOOM ^{™†} 71 Reperfusion Catheter (Imperative Care, Inc)	K211476	June 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA
ZOOM Reperfusion Catheter (Imperative Care, Inc)	K210996	April 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA
Tigertriever ^{™†} and Tigertriever 17 Resvascularization Devices (Rapid Medical, Ltd)	K203592	Mar 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA
Merci ^{®†} Retriever (Concentric Medical; acquired by Stryker Neurovascular in 2011)	K033736	Aug 2004 (modified device approved May 2006)	Patients with acute ischemic stroke and who are ineligible for or who fail IV tPA therapy
Penumbra System ^{®†} (Penumbra)	K072718	Dec 2007	Patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease within 8 h of symptom onset
Stent retrievers			

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

Solitaire ^{TM†} FR Revascularization Device (Covidien/ev3 Neurovascular)	K113455	Mar 2012	Patients with acute ischemic stroke due to large intracranial vessel occlusion who are ineligible for or who fail IV tPA
Trevo ^{®†} NXT ProVue Retriever (Stryker Neurovascular)	K210502	Aug 2021	Patients with acute ischemic stroke within 6 h of symptom onset who fail IV tPA; patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV tPA; patients with smaller core infarcts may start therapy as late as 24 h after last seen well
Trevo ^{®†} Retriever device (Stryker Neurovascular)	K122478	Aug 2012	Patients with acute ischemic stroke due to large intracranial vessel occlusion who are ineligible for or who fail IV tPA
EmboTrap ^{®†} II Revascularization Device	K173452	May 2018	Patients with ischemic stroke within 8 hours of symptom onset who are ineligible for or who fail IV tPA

IV: intravenous; tPA: tissue plasminogen activator.

Intracranial Arterial Stenosis

Two devices were approved by the FDA through the humanitarian device exemption process for atherosclerotic disease. This form of 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 $\geq 50\%$ stenosis and that are accessible to the stent system.”

Wingspan^{TM†} 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

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

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, 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. Approval was based on the Pipeline for Uncoilable or Failed Aneurysms Study, a single-arm, open-label feasibility study, reported by Becske et al (2013) 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 (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.

The following stents have been approved by the FDA through the humanitarian device exemption process for treatment of intracranial aneurysms.

Neuroform[™]† Microdelivery Stent System

In 2002, based on a series of approximately 30 patients with 6-month follow-up, the Neuroform Microdelivery Stent System (Stryker) was approved by the FDA through the humanitarian device exemption process (H020002) for use with embolic coils for the treatment of wide-neck intracranial aneurysms that cannot be treated by surgical clipping.

Neuroform[™]† Atlas Stent System

In 2019, the Neuroform Atlas Stent System (Stryker) was approved by the FDA through the premarket approval 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." Product Code: QCA.

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

Enterprise^{TM†} Vascular Reconstruction Device and Delivery System

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.

The Low-Profile Visualized Intraluminal Support Device

In 2014, the Low-Profile Visualized Intraluminal Support Device (LVIS^{TM†} and LVIS^{TM†} 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 premarket approval process (P170013).

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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Intracranial arterial disease includes thromboembolic events, vascular stenoses, 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 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.

Summary of Evidence

For individuals who have an acute ischemic stroke due to occlusion of an anterior circulation vessel who receive endovascular mechanical embolectomy, the evidence includes randomized controlled 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-

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

related mortality and morbidity. From 2013 to 2015, 8 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 8 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 for 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 for 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 clinical trials, treatment times, clinical protocols, and patient selection criteria should be similar to those in RCTs. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have an acute ischemic stroke due to basilar artery occlusion who receive endovascular mechanical embolectomy, the evidence includes 4 RCTs and systematic reviews of 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 3 major RCTs. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, and treatment-related mortality and morbidity. All available RCTs have 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 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 3 RCTs does not suggest that intracranial

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

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 have reported occlusion rates for stent-assisted coiling that are similar to or higher than coiling alone and recurrence rates that may be lower than those for coiling alone. For stent-assisted coiling with self-expanding stents, some evidence has also shown that adverse event rates are relatively high, and a nonrandomized comparative trial has 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 3 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 has 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.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests, input was received from 4 physician specialty societies and 2 academic medical centers while this policy was under review in 2014. Input focused on the use of flow-diverting stents such as the Pipeline Embolization Device for the treatment of intracranial aneurysms. There was general support for the use of intracranial stent placement for intracranial

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

aneurysms meeting the criteria outlined in the policy statements. There was also general support for the use of flow-diverting stents for the treatment of intracranial aneurysms and general support for the statement that flow-diverting stents are preferable to other stents for certain aneurysm characteristics.

There was general support for the use of endovascular interventions for the treatment of acute stroke, particularly for: (1) patients who have failed to respond to intravenous (IV) tissue plasminogen activator (tPA); and (2) patients who present outside the range of time for which tPA would be considered (≤ 8 hours of last known normal state or symptom onset).

2011 Input

In response to requests, input was received from 3 physician specialty societies and 3 academic medical centers while this policy was under review in 2011. For treatment of intracranial stenosis, most providing input would consider the use of this technology in selected patients who remained symptomatic from intracranial atherosclerotic disease, despite maximum medical therapy. There was unanimous support for the use of this technology in select 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.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association and American Stroke Association

In 2018, the American Heart Association (AHA) and the American Stroke Association (ASA) (update 2019) published joint guidelines on the early management of patients with acute ischemic stroke (Table 2). These guidelines included several recommendations relevant to the use of endovascular therapies for acute stroke.

Table 2. Recommendations on Use of Endovascular Therapies to Manage Acute Stroke

Recommendation	COR	LOE
“Mechanical thrombectomy requires the patient to be at an experienced stroke center with rapid access to cerebral angiography, qualified neurointerventionalists, and a comprehensive periprocedural care team. Systems should be designed, executed, and monitored to emphasize expeditious assessment and treatment. Outcomes for all patients should be tracked. Facilities are encouraged to define	I	C

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

Recommendation	COR	LOE
criteria that can be used to credential individuals who can perform safe and timely intra-arterial revascularization procedures.“		
"Patients should receive mechanical thrombectomy with a stent retriever if they meet all the following criteria: • "Prestroke mRS score 0 to 1, • Causative occlusion of the internal carotid artery or MCA (M1), • Age ≥ 18 years, • NIHSS score of ≥ 6, • ASPECTS of ≥ 6, and • "Treatment can be initiated (groin puncture) within 6 hours of symptom onset."	I	A
In selected patients with acute ischemic stroke within 6 to 16 hours of last known normal who have LVO in the anterior circulation and meet other DAWN or DEFUSE 3 eligibility criteria, mechanical thrombectomy is recommended.	I	A
“The technical goal of the thrombectomy procedure should be a reperfusion to a modified TIC1 2b/3 angiographic result to maximize the probability of a good functional clinical outcome.”	I	A
As with intravenous alteplase, reduced time from symptom onset to reperfusion with endovascular therapies is highly associated with better clinical outcomes. To ensure benefit, reperfusion to TIC1 grade 2b/3 should be achieved as early as possible and within the therapeutic window."	I	B-R
"Use of stent retrievers is indicated in preference to the MERCI device. The use of mechanical thrombectomy devices other than stent retrievers may be reasonable in some circumstances."	IIIb	AB-NR
“The use of proximal balloon guide catheter or a large bore distal access catheter rather than a cervical guide catheter alone in conjunction with stent retrievers may be beneficial. Future studies should examine which systems provide the highest recanalization rates with the lowest risk for nontarget embolization.”	Ila	C-LD

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

Recommendation	COR	LOE
In selected patients with acute ischemic stroke within 16 to 24 hours of last known normal who have LVO in the anterior circulation and meet other DAWN eligibility criteria, mechanical thrombectomy is reasonable.	IIa	B-R
“In carefully selected patients with anterior circulation occlusion who have contraindications to intravenous r-tPA, endovascular therapy with stent retrievers completed within 6 hours of stroke onset is reasonable. There are inadequate data available at this time to determine the clinical efficacy of endovascular therapy with stent retrievers for those patients whose contraindications are time-based or nontime-based (eg, prior stroke, serious head trauma, hemorrhagic coagulopathy, or receiving anticoagulant medications).”	IIa	C
“Although the benefits are uncertain, use of mechanical thrombectomy with stent retrievers may be reasonable for carefully selected patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have causative occlusion of the M2 or M3 portion of the MCAs.”	IIb	B-R
“Although the benefits are uncertain, use of mechanical thrombectomy with stent retrievers may be reasonable for carefully selected patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have causative occlusion of the anterior cerebral arteries, vertebral arteries, basilar artery, or posterior cerebral arteries.”	IIb	C
“Although the benefits are uncertain, use of mechanical thrombectomy with stent retrievers may be reasonable for patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have prestroke mRS score of >1, ASPECTS <6, or NIHSS score <6 and causative occlusion of the internal carotid artery or proximal MCA (M1). Additional randomized trial data are needed.”	IIb	B-R
In patients under consideration for mechanical thrombectomy, observation after IV alteplase to assess for clinical response should not be performed.	III	B-R
“Use of salvage technical adjuncts including intra-arterial fibrinolysis may be reasonable to achieve these angiographic results”	IIb	C-LD
“Intra-arterial fibrinolysis initiated within 6 hours of stroke onset in carefully selected patients who have contraindications to the use of intravenous alteplase might be considered, but the consequences are unknown.”	IIb	C-EO

ASPECTS: Alberta Stroke Program Early Computed Tomography Score; COR: class of recommendation; DAWN: Clinical Mismatch in the Triage of Wake Up and Late Presenting Strokes

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

Undergoing Neurointervention With Trevo; DEFUSE 3: Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3; IV: intravenous; LOE: level of recommendation; LVO: large vessel occlusion; MCA: middle cerebral artery; mRS: modified Rankin Scale; NIHSS: National Institutes of Health Stroke Scale; r-tPA: recombinant tissue plasminogen activator; TICI: Thrombolysis in Cerebral Infarction.

The AHA and ASA also published joint guidelines on the management of patients with unruptured intracranial aneurysms in 2015. These guidelines included the following recommendations relevant to the use of endovascular therapies for aneurysms (Table 3).

Table 3. Recommendations on Management of Unruptured Intracranial Aneurysms

Recommendation	COR	LOE
“...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”	IIb	B
“Endovascular treatment of unruptured intracranial aneurysms is recommended to be performed at high-volume centers.”	I	B

COR: class of recommendation; LOE: level of recommendation.

In 2022, the AHA and ASA released a scientific statement on endovascular treatment and thrombolysis for acute ischemic stroke in patients with premorbid disability or dementia. The statement reports that several observational studies have evaluated the safety of endovascular therapy (including mechanical thrombectomy) in this patient population which suggests the potential of these patients to retain their pre-stroke level of disability; however, results also show a generally worse prognosis overall and more higher-quality registries and clinical trials are needed to validate results.

Society of NeuroInterventional Surgery

The Society of NeuroInterventional Surgery (SNIS) has published various reports from their standards and guidelines committee over the years, including on indications for thrombectomy in acute ischemic stroke from emergent large vessel occlusion (LVO; Jayaraman et al 2015; Mokin et al 2019) and endovascular strategies for posterior circulation LVO stroke (Kayan et al 2019). Most recently, in 2024, SNIS published a focused update to their guidelines for endovascular therapy for emergent LVO, specifically in individuals with basilar artery occlusion (Heit et al 2024). A summary of their most updated recommendations relevant to this evidence review are provided in Table 4.

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

Table 4. SNIS Recommendations on Endovascular Procedures Across Relevant Guidelines

Recommendation	COR	LOE
<i>2019: Indications for thrombectomy in acute ischemic stroke from ELVO</i>		
"For anterior circulation AIS, thrombectomy is indicated in select patients up to 16 hours from symptom onset or time last known well for unwitnessed strokes, including wake-up strokes [class I, level A], and is indicated in select patients up to 24 hours from last known normal [class IIa, level B]."	I, IIa	A, B
"Thrombectomy may be reasonable within the first 6 hours of symptom onset in patients with a large core infarct volume such as CT ASPECTS of <6, MRI DWI or CTP-estimated core volume >70 mL."	IIa	A
"In patients with anterior circulation AIS due to intracranial ICA and/or M1 occlusion within 6–24 hours of symptom onset who meet the advanced MRI DWI-PWI or CTP imaging criteria for DAWN or DEFUSE 3, thrombectomy is indicated."	I	B
"Thrombectomy may be indicated in carefully selected patients with anterior circulation AIS within 6–24 hours of symptom onset who do not meet imaging criteria for DAWN and DEFUSE 3 but otherwise have a 'favorable' imaging profile such as CT ASPECTS of 6–10, MRI DWI ASPECTS of 6–10, moderate-to-good collateral status on mCTA, or small (<70 mL) core infarct on advanced MRI DWI-PWI or CTP imaging."	IIb	B-NR
"Thrombectomy is indicated in patients with occlusions of the ICA (including intracranial, cervical segments or tandem occlusion) and M1/M2 MCA."	I	A
"The benefit of thrombectomy in more distal segments, such as MCA M3 or anterior cerebral artery is unclear. Thrombectomy of such patients may be reasonable in some cases and should be considered on a case-by-case basis."	IIb	B-NR
"Thrombectomy is indicated in patients with anterior circulation ELVO with NIHSS score ≥6."	I	A
"Thrombectomy may be considered in patients with anterior circulation AIS and NIHSS score <6 when associated with disabling symptoms. However, care should be taken when treating these patients to keep complication and hemorrhagic rates below those reported in RCTs."	IIa	B-NR
"Age >80 years should not be used as a contraindication for thrombectomy."	IIa	A
<i>2024: Focused update to guidelines for endovascular therapy for ELVO: basilar artery occlusion patients</i>		

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

"In patients with acute BAO who meet criteria from the BAOCHE or ATTENTION trials (NIHSS score ≥ 6 , PC- ASPECTS ≥ 6 , CTA with BAO, age 18–89 years), thrombectomy is indicated within 12 hours of last known well."	I	B-R
"In patients with acute BAO who present between 12 and 24 hours from the last known well, NIHSS score ≥ 6 , or PC- ASPECTS ≥ 6 , thrombectomy is reasonable."	IIa	B-R
"In patients with acute BAO who present beyond 24 hours from last known well, with NIHSS score ≥ 6 or PC- ASPECTS ≥ 6 , it may be reasonable to consider thrombectomy on a case by case basis."	IIb	C-EO
"In aged <18 years or >89 years presenting with acute BAO, it is reasonable to consider thrombectomy on a case by case basis."	IIb	C-EO

AIS: acute ischemic stroke; ASPECTS: Alberta Stroke Program Early CT Score; ATTENTION: Endovascular Treatment for Acute Basilar Artery Occlusion; BAO: basilar artery occlusion; BAOCHE: Basilar Artery Occlusion Chinese Endovascular Trial; COR: class of recommendation; CT: computed tomography; CTA: CT angiography; CTP: CT perfusion; DAWN: Clinical Mismatch in the Triage of Wake-up and Late Presenting Strokes Undergoing Neurointervention with Trevo Trial; DEFUSE 3: Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3 Trial; DWI: diffusion weighted imaging; ELVO: emergent large vessel occlusion; ICA: internal carotid artery; LOE: level of recommendation; MCA: middle cerebral artery; mCTA: multiphase CTA; MRI: magnetic resonance imaging; NIHSS: National Institutes of Health Stroke Scale; PC: posterior circulation; PWI: perfusion weighted imaging; RCT: randomized controlled trial; SNIS: Society of NeuroInterventional Surgery.

Society of Vascular and Interventional Neurology

In 2016, the Society of Vascular and Interventional Neurology (SVIN) published recommendations on comprehensive stroke center requirements and endovascular stroke systems of care. The recommendations were based on 5 multicenter, prospective, randomized, open-label, blinded endpoint clinical trials that demonstrated the benefits of endovascular therapy with mechanical thrombectomy in acute ischemic strokes with LVOs. Their recommendation pertinent to this evidence review is:

“Endovascular mechanical thrombectomy, in addition to treatment with IV tPA in eligible patients, is recommended for anterior circulation large vessel occlusion ischemic strokes in patients presenting within 6 h of symptom onset.”

In 2024, SVIN published guidelines on endovascular therapy with mechanical thrombectomy in late presentation of anterior circulation LVO stroke. The recommendations pertained to individuals with acute ischemic stroke with LVO presenting in the 6 to 24 hour time window, and were based on 3

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

high quality randomized controlled trials and several observational studies. Their recommendation pertinent to this evidence review is:

"In patients presenting within 6 to 24 hours from last known well with proximal anterior circulation LVO, and with clinical imaging mismatch as defined in the DAWN or DEFUSE 3 trials, endovascular therapy (ET) is recommended; COR [class of recommendation]-1; LOE [level of evidence] A)"

U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force (USPSTF) recommendations for treatment of intracranial arterial disease were identified. The USPSTF has recommended against screening for asymptomatic carotid artery stenosis in the general population.

Medicare National Coverage

A Medicare national coverage determination on intracranial angioplasty and stenting was released by the Centers for Medicare & Medicaid Services (CMS) in 2008 and updated in 2023 to a decision. This updated decision was based on a review of available studies at that time, which consisted of several randomized controlled trials. The Centers for Medicare & Medicaid Services review indicated that "coverage of percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting is reasonable and necessary with the placement of a Food and Drug Administration (FDA) approved carotid stent with an FDA-approved or cleared embolic protection device...under the following conditions:

1. Patients with symptomatic carotid artery stenosis $\geq 50\%$; and
2. Patients with asymptomatic carotid artery stenosis $\geq 70\%$."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Endovascular interventions for acute ischemic stroke			
<i>Ongoing</i>			
NCT05983757	A Phase III, Randomized, Multicenter, Investigational, Open Label Clinical Trial That Will Examine Whether Treatment With Endovascular Thrombectomy is Superior to Standard Medical Therapy Alone in Patients Who	564	Dec 2026

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

	Suffer a Distal Medium Vessel Occlusion Ischemic Strokes		
NCT06143488	Endovascular Therapy Versus Best Medical Treatment for Acute Large Vessel Occlusion Stroke With Low NIHSS	264	Sept 2025
NCT06101667	Efficacy and Safety of Endovascular Recanalization for Acute Basilar Artery Occlusion With Extended Time Window -- A Multicenter, Prospective, Open-label, Blind Endpoint, Randomized Controlled Trial (ANGEL-BAO)	224	Dec 2025
NCT06155032	Study of Rescue Endovascular Therapy for Progressive Acute Mild Ischemic Stroke With Large Vascular Occlusion--- A Multi-centered, Prospective, Open-label, Blind Endpoint, Randomized Controlled Trial (RESCUE END-LOW)	272	Mar 2026
NCT06146790	Evaluation of Endovascular Treatment in Acute Intracranial Distal Medium Vessel Occlusion Stroke - a Multicenter, Randomized Controlled, Clinical Trial	564	Mar 2026
NCT05827042	Endovascular Thrombectomy Alone Versus Intravenous Thrombolysis Plus Endovascular Thrombectomy on Acute Basilar Artery Occlusion - a Multicenter, Randomized Controlled, Clinical Trial	338	Mar 2026
NCT05911568	Treatment With Endovascular Intervention for STroke Patients With Existing Disability	1060	Apr 2028
NCT06289985	STEP: StrokeNet Thrombectomy Endovascular Platform	2000	Jan 2030
NCT04167527	Endovascular Therapy for Low NIHSS Ischemic Strokes	200	Dec 2024
Endovascular interventions for symptomatic intracranial atherosclerotic disease			
<i>Unpublished</i>			

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

NCT05757505	The Efficacy and Safety of the Intracranial Stent (Tonbridge) in Endovascular Treatment of Symptomatic Intracranial Atherosclerotic Stenosis: A Prospective, Multicenter, Randomized Controlled, Non-inferiority Trial	200	Dec 2025
NCT04631055 ^a	A Prospective, Multicenter, Randomized Controlled Clinical Trial to Evaluate the Efficacy and Safety of Intracranial Drug-coated Balloon Catheters in the Treatment of Symptomatic Intracranial Atherosclerotic de Novo Stenosis	180	Apr 2023
Stent-assisted endovascular treatment of intracranial aneurysms			
<i>Ongoing</i>			
NCT05755516 ^a	Efficacy and Safety of the Self-expanding Intracranial Stent (Tonbridge) for Endovascular Treatment of Intracranial Aneurysms: A Prospective, Multi-center, Randomized, Open, Parallel Positive Controlled, Non-inferiority Trial	204	Apr 2025
NCT06158087 ^a	Prospective, Multicenter, Single-arm Clinical Trial to Evaluate the Safety and Efficacy of pEGASUS Stent System for Assisted Endovascular Treatment of Intracranial Aneurysms	130	Jun 2026
NCT02998229 ^a	ARTISSE Intrasaccular Device IDE	220	Feb 2032
NCT04548856	Microsurgical Clipping and Endovascular Embolization Comparative Prospective Randomized Trial	4	May 2025
<i>Unpublished</i>			
NCT03993340	Rescue Stenting for Failed Endovascular Thrombectomy in Acute Ischemic Stroke (ReSET)	78	July 2021

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

References

1. U.S. Centers for Disease Control and Prevention. Stroke facts. October 24, 2024. https://www.cdc.gov/stroke/data-research/facts-stats/?CDC_AAref_Val=https://www.cdc.gov/stroke/facts.htm.

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

2. Rha JH, Saver JL. The impact of recanalization on ischemic stroke outcome: a meta-analysis. *Stroke*. Mar 2007; 38(3): 967-73. PMID 17272772
3. Sheriff F, Xu H, Maud A, et al. Temporal Trends in Racial and Ethnic Disparities in Endovascular Therapy in Acute Ischemic Stroke. *J Am Heart Assoc*. Mar 15 2022; 11(6): e023212. PMID 35229659
4. de Havenon A, Sheth K, Johnston KC, et al. Acute Ischemic Stroke Interventions in the United States and Racial, Socioeconomic, and Geographic Disparities. *Neurology*. Dec 07 2021; 97(23): e2292-e2303. PMID 34649872
5. Kim Y, Sharrief A, Kwak MJ, et al. Underutilization of Endovascular Therapy in Black Patients With Ischemic Stroke: An Analysis of State and Nationwide Cohorts. *Stroke*. Mar 2022; 53(3): 855-863. PMID 35067099
6. 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
7. Food and Drug Administration (FDA). Summary of Safety and Effectiveness: Pipeline™ Embolization Device. 2011; https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100018b.pdf.
8. Becks 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
9. Kahles T, Garcia-Esperon C, Zeller S, et al. Mechanical Thrombectomy Using the New ERIC Retrieval Device Is Feasible, Efficient, and Safe in Acute Ischemic Stroke: A Swiss Stroke Center Experience. *AJNR Am J Neuroradiol*. Jan 2016; 37(1): 114-9. PMID 26294644
10. Vizient. Vascular technologies. Coronary, peripheral, and neurovascular devices. Technology watch. 2019. <https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/ea03a0d943970fa27ffaa45543a78a444292d1aa>.
11. Abruzzo T, Moran C, Blackham KA, et al. Invasive interventional management of post-hemorrhagic cerebral vasospasm in patients with aneurysmal subarachnoid hemorrhage. *J Neurointerv Surg*. May 2012; 4(3): 169-77. PMID 22374130
12. Diringer MN, Bleck TP, Claude Hemphill J, et al. Critical care management of patients following aneurysmal subarachnoid hemorrhage: recommendations from the Neurocritical Care Society's Multidisciplinary Consensus Conference. *Neurocrit Care*. Sep 2011; 15(2): 211-40. PMID 21773873
13. Schwamm LH, Ali SF, Reeves MJ, et al. Temporal trends in patient characteristics and treatment with intravenous thrombolysis among acute ischemic stroke patients at Get With The Guidelines-Stroke hospitals. *Circ Cardiovasc Qual Outcomes*. Sep 01 2013; 6(5): 543-9. PMID 24046398
14. Bhatia R, Hill MD, Shobha N, et al. Low rates of acute recanalization with intravenous recombinant tissue plasminogen activator in ischemic stroke: real-world experience and a call for action. *Stroke*. Oct 2010; 41(10): 2254-8. PMID 20829513

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

15. Badhiwala JH, Nassiri F, Alhazzani W, et al. Endovascular Thrombectomy for Acute Ischemic Stroke: A Meta-analysis. *JAMA*. Nov 03 2015; 314(17): 1832-43. PMID 26529161
16. Ciccone A, Valvassori L, Nichelatti M, et al. Endovascular treatment for acute ischemic stroke. *N Engl J Med*. Mar 07 2013; 368(10): 904-13. PMID 23387822
17. Kidwell CS, Jahan R, Gornbein J, et al. A trial of imaging selection and endovascular treatment for ischemic stroke. *N Engl J Med*. Mar 07 2013; 368(10): 914-23. PMID 23394476
18. Broderick JP, Palesch YY, Demchuk AM, et al. Endovascular therapy after intravenous t-PA versus t-PA alone for stroke. *N Engl J Med*. Mar 07 2013; 368(10): 893-903. PMID 23390923
19. Berkhemer OA, Fransen PS, Beumer D, et al. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med*. Jan 01 2015; 372(1): 11-20. PMID 25517348
20. Goyal M, Demchuk AM, Menon BK, et al. Randomized assessment of rapid endovascular treatment of ischemic stroke. *N Engl J Med*. Mar 12 2015; 372(11): 1019-30. PMID 25671798
21. Campbell BC, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med*. Mar 12 2015; 372(11): 1009-18. PMID 25671797
22. Saver JL, Goyal M, Bonafe A, et al. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. *N Engl J Med*. Jun 11 2015; 372(24): 2285-95. PMID 25882376
23. Jovin TG, Chamorro A, Cobo E, et al. Thrombectomy within 8 hours after symptom onset in ischemic stroke. *N Engl J Med*. Jun 11 2015; 372(24): 2296-306. PMID 25882510
24. Chen CJ, Ding D, Starke RM, et al. Endovascular vs medical management of acute ischemic stroke. *Neurology*. Dec 01 2015; 85(22): 1980-90. PMID 26537058
25. Roaldsen MB, Jusufovic M, Berge E, et al. Endovascular thrombectomy and intra-arterial interventions for acute ischaemic stroke. *Cochrane Database Syst Rev*. Jun 14 2021; 6(6): CD007574. PMID 34125952
26. Bush CK, Kurimella D, Cross LJ, et al. Endovascular Treatment with Stent-Retriever Devices for Acute Ischemic Stroke: A Meta-Analysis of Randomized Controlled Trials. *PLoS One*. 2016; 11(1): e0147287. PMID 26807742
27. Hong KS, Ko SB, Lee JS, et al. Endovascular Recanalization Therapy in Acute Ischemic Stroke: Updated Meta-analysis of Randomized Controlled Trials. *J Stroke*. Sep 2015; 17(3): 268-81. PMID 26437993
28. Kennedy SA, Baerlocher MO, Baerlocher F, et al. Meta-Analysis of Local Endovascular Therapy for Acute Ischemic Stroke. *J Vasc Interv Radiol*. Mar 2016; 27(3): 307-21.e2. PMID 26803573
29. Grech R, Schembri M, Thornton J. Stent-based thrombectomy versus intravenous tissue plasminogen activator in acute ischaemic stroke: A systematic review and meta-analysis. *Interv Neuroradiol*. Dec 2015; 21(6): 684-90. PMID 26490828
30. Marmagkiolis K, Hakeem A, Cilingiroglu M, et al. Safety and Efficacy of Stent Retrievers for the Management of Acute Ischemic Stroke: Comprehensive Review and Meta-Analysis. *JACC Cardiovasc Interv*. Nov 2015; 8(13): 1758-65. PMID 26476611
31. Touma L, Filion KB, Sterling LH, et al. Stent Retrievers for the Treatment of Acute Ischemic Stroke: A Systematic Review and Meta-analysis of Randomized Clinical Trials. *JAMA Neurol*. Mar 2016; 73(3): 275-81. PMID 26810499

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

32. Bai X, Zhang X, Gong H, et al. Different types of percutaneous endovascular interventions for acute ischemic stroke. *Cochrane Database Syst Rev*. May 30 2023; 5(5): CD014676. PMID 37249304
33. Zaidat OO, Ikeme S, Sheth SA, et al. MASTRO I: Meta-Analysis and Systematic Review of thrombectomy stent retriever outcomes: comparing functional, safety and recanalization outcomes between EmboTrap, Solitaire and Trevo in acute ischemic stroke. *J Comp Eff Res*. May 2023; 12(5): e230001. PMID 37039285
34. Martins SO, Mont'Alverne F, Rebello LC, et al. Thrombectomy for Stroke in the Public Health Care System of Brazil. *N Engl J Med*. Jun 11 2020; 382(24): 2316-2326. PMID 32521133
35. Albers GW, Marks MP, Kemp S, et al. Thrombectomy for Stroke at 6 to 16 Hours with Selection by Perfusion Imaging. *N Engl J Med*. Feb 22 2018; 378(8): 708-718. PMID 29364767
36. Nogueira RG, Jadhav AP, Haussen DC, et al. Thrombectomy 6 to 24 Hours after Stroke with a Mismatch between Deficit and Infarct. *N Engl J Med*. Jan 04 2018; 378(1): 11-21. PMID 29129157
37. Khoury NN, Darsaut TE, Ghostine J, et al. Endovascular thrombectomy and medical therapy versus medical therapy alone in acute stroke: A randomized care trial. *J Neuroradiol*. Jun 2017; 44(3): 198-202. PMID 28238522
38. Muir KW, Ford GA, Messow CM, et al. Endovascular therapy for acute ischaemic stroke: the Pragmatic Ischaemic Stroke Thrombectomy Evaluation (PISTE) randomised, controlled trial. *J Neurol Neurosurg Psychiatry*. Jan 2017; 88(1): 38-44. PMID 27756804
39. Mocco J, Zaidat OO, von Kummer R, et al. Aspiration Thrombectomy After Intravenous Alteplase Versus Intravenous Alteplase Alone. *Stroke*. Sep 2016; 47(9): 2331-8. PMID 27486173
40. Bracard S, Ducrocq X, Mas JL, et al. Mechanical thrombectomy after intravenous alteplase versus alteplase alone after stroke (THRACE): a randomised controlled trial. *Lancet Neurol*. Oct 2016; 15(11): 1138-47. PMID 27567239
41. Tomsick TA, Yeatts SD, Liebeskind DS, et al. Endovascular revascularization results in IMS III: intracranial ICA and M1 occlusions. *J Neurointerv Surg*. Nov 2015; 7(11): 795-802. PMID 25342652
42. Demchuk AM, Goyal M, Yeatts SD, et al. Recanalization and clinical outcome of occlusion sites at baseline CT angiography in the Interventional Management of Stroke III trial. *Radiology*. Oct 2014; 273(1): 202-10. PMID 24895878
43. Tekle WG, Hassan AE, Jadhav AP, et al. Impact of Periprocedural and Technical Factors and Patient Characteristics on Revascularization and Outcome in the DAWN Trial. *Stroke*. Jan 2020; 51(1): 247-253. PMID 31744425
44. Jovin TG, Nogueira RG, Lansberg MG, et al. Thrombectomy for anterior circulation stroke beyond 6 h from time last known well (AURORA): a systematic review and individual patient data meta-analysis. *Lancet*. Jan 15 2022; 399(10321): 249-258. PMID 34774198
45. Sarraj A, Hassan AE, Abraham MG, et al. Trial of Endovascular Thrombectomy for Large Ischemic Strokes. *N Engl J Med*. Apr 06 2023; 388(14): 1259-1271. PMID 36762865

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

46. Sarraj A, Abraham MG, Hassan AE, et al. Endovascular thrombectomy plus medical care versus medical care alone for large ischaemic stroke: 1-year outcomes of the SELECT2 trial. *Lancet*. Feb 24 2024; 403(10428): 731-740. PMID 38346442
47. Saver JL, Jahan R, Levy EI, et al. Solitaire flow restoration device versus the Merci Retriever in patients with acute ischaemic stroke (SWIFT): a randomised, parallel-group, non-inferiority trial. *Lancet*. Oct 06 2012; 380(9849): 1241-9. PMID 22932715
48. Akins PT, Amar AP, Pakbaz RS, et al. Complications of endovascular treatment for acute stroke in the SWIFT trial with solitaire and Merci devices. *AJNR Am J Neuroradiol*. Mar 2014; 35(3): 524-8. PMID 24029392
49. Nogueira RG, Lutsep HL, Gupta R, et al. Trevo versus Merci retrievers for thrombectomy revascularisation of large vessel occlusions in acute ischaemic stroke (TREVO 2): a randomised trial. *Lancet*. Oct 06 2012; 380(9849): 1231-40. PMID 22932714
50. Saposnik G, Lebovic G, Demchuk A, et al. Added Benefit of Stent Retriever Technology for Acute Ischemic Stroke: A Pooled Analysis of the NINDS tPA, SWIFT, and STAR Trials. *Neurosurgery*. Sep 2015; 77(3): 454-61. PMID 26280825
51. Pereira VM, Gralla J, Davalos A, et al. Prospective, multicenter, single-arm study of mechanical thrombectomy using Solitaire Flow Restoration in acute ischemic stroke. *Stroke*. Oct 2013; 44(10): 2802-7. PMID 23908066
52. Nogueira RG, Frei D, Kirmani JF, et al. Safety and Efficacy of a 3-Dimensional Stent Retriever With Aspiration-Based Thrombectomy vs Aspiration-Based Thrombectomy Alone in Acute Ischemic Stroke Intervention: A Randomized Clinical Trial. *JAMA Neurol*. Mar 01 2018; 75(3): 304-311. PMID 29296999
53. Cao J, Lin H, Lin M, et al. RECO Flow Restoration Device Versus Solitaire FR With the Intention for Thrombectomy Study (REDIRECT): a prospective randomized controlled trial. *J Neurosurg*. May 01 2021; 134(5): 1569-1577. PMID 32502991
54. Nogueira RG, Lobsien D, Klisch J, et al. Thrombectomy With the pRESET vs Solitaire Stent Retrievers as First-Line Large Vessel Occlusion Stroke Treatment: A Randomized Clinical Trial. *JAMA Neurol*. Feb 01 2024; 81(2): 170-178. PMID 38165690
55. Mattle HP, Arnold M, Lindsberg PJ, et al. Basilar artery occlusion. *Lancet Neurol*. Nov 2011; 10(11): 1002-14. PMID 22014435
56. Schonewille WJ, Wijman CA, Michel P, et al. Treatment and outcomes of acute basilar artery occlusion in the Basilar Artery International Cooperation Study (BASICS): a prospective registry study. *Lancet Neurol*. Aug 2009; 8(8): 724-30. PMID 19577962
57. Adusumilli G, Kobeissi H, Ghozy S, et al. Endovascular thrombectomy after acute ischemic stroke of the basilar artery: a meta-analysis of four randomized controlled trials. *J Neurointerv Surg*. Dec 21 2023; 15(e3): e446-e451. PMID 36597942
58. Yu Y, Lou Y, Cui R, et al. Endovascular treatment versus standard medical treatment for basilar artery occlusion: a meta-analysis of randomized controlled trials. *J Neurosurg*. Sep 01 2023; 139(3): 732-740. PMID 36738467
59. Jovin TG, Li C, Wu L, et al. Trial of Thrombectomy 6 to 24 Hours after Stroke Due to Basilar-Artery Occlusion. *N Engl J Med*. Oct 13 2022; 387(15): 1373-1384. PMID 36239645

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

60. Tao C, Nogueira RG, Zhu Y, et al. Trial of Endovascular Treatment of Acute Basilar-Artery Occlusion. *N Engl J Med*. Oct 13 2022; 387(15): 1361-1372. PMID 36239644
61. Langezaal LCM, van der Hoeven EJ, Mont'Alverne FJA, et al. Endovascular Therapy for Stroke Due to Basilar-Artery Occlusion. *N Engl J Med*. May 20 2021; 384(20): 1910-1920. PMID 34010530
62. Liu X, Dai Q, Ye R, et al. Endovascular treatment versus standard medical treatment for vertebrobasilar artery occlusion (BEST): an open-label, randomised controlled trial. *Lancet Neurol*. Feb 2020; 19(2): 115-122. PMID 31831388
63. Bose A, Hartmann M, Henkes H, et al. A novel, self-expanding, nitinol stent in medically refractory intracranial atherosclerotic stenoses: the Wingspan study. *Stroke*. May 2007; 38(5): 1531-7. PMID 17395864
64. Chimowitz MI, Lynn MJ, Howlett-Smith H, et al. Comparison of warfarin and aspirin for symptomatic intracranial arterial stenosis. *N Engl J Med*. Mar 31 2005; 352(13): 1305-16. PMID 15800226
65. EC/IC Bypass Study Group. Failure of extracranial-intracranial arterial bypass to reduce the risk of ischemic stroke. Results of an international randomized trial. *N Engl J Med*. Nov 07 1985; 313(19): 1191-200. PMID 2865674
66. 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
67. Yeo JYP, Yau CE, Ong NY, et al. Comparing the Impact of Stenting vs. Medical Therapy for Intracranial Arterial Stenosis : A Systematic Review and One-stage and Two-stage Meta-Analysis of Randomized Clinical Trials. *Clin Neuroradiol*. Jun 2024; 34(2): 379-390. PMID 38172262
68. Shi T, Chen S, Long Y, et al. Safety and efficacy of stenting for symptomatic intracranial artery stenosis: a systematic review and meta-analysis. *Front Pharmacol*. 2023; 14: 1122842. PMID 37361212
69. Gao P, Wang T, Wang D, et al. Effect of Stenting Plus Medical Therapy vs Medical Therapy Alone on Risk of Stroke and Death in Patients With Symptomatic Intracranial Stenosis: The CASSISS Randomized Clinical Trial. *JAMA*. Aug 09 2022; 328(6): 534-542. PMID 35943472
70. Zaidat OO, Fitzsimmons BF, Woodward BK, et al. Effect of a balloon-expandable intracranial stent vs medical therapy on risk of stroke in patients with symptomatic intracranial stenosis: the VISSIT randomized clinical trial. *JAMA*. Mar 2015; 313(12): 1240-8. PMID 25803346
71. Chimowitz MI, Lynn MJ, Derdeyn CP, et al. Stenting versus aggressive medical therapy for intracranial arterial stenosis. *N Engl J Med*. Sep 15 2011; 365(11): 993-1003. PMID 21899409
72. Derdeyn CP, Chimowitz MI, Lynn MJ, et al. Aggressive medical treatment with or without stenting in high-risk patients with intracranial artery stenosis (SAMMPRIS): the final results of a randomised trial. *Lancet*. Jan 25 2014; 383(9914): 333-41. PMID 24168957
73. Lutsep HL, Barnwell SL, Larsen DT, et al. Outcome in patients previously on antithrombotic therapy in the SAMMPRIS trial: subgroup analysis. *Stroke*. Mar 2015; 46(3): 775-9. PMID 25593135

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

74. Lutsep HL, Lynn MJ, Cotsonis GA, et al. Does the Stenting Versus Aggressive Medical Therapy Trial Support Stenting for Subgroups With Intracranial Stenosis?. *Stroke*. Nov 2015; 46(11): 3282-4. PMID 26382173
75. Coward LJ, McCabe DJ, Ederle J, et al. Long-term outcome after angioplasty and stenting for symptomatic vertebral artery stenosis compared with medical treatment in the Carotid And Vertebral Artery Transluminal Angioplasty Study (CAVATAS): a randomized trial. *Stroke*. May 2007; 38(5): 1526-30. PMID 17395869
76. Qureshi AI, Chaudhry SA, Siddiq F, et al. A randomized trial comparing primary angioplasty versus stent placement for symptomatic intracranial stenosis. *J Vasc Interv Neurol*. Dec 2013; 6(2): 34-41. PMID 24358415
77. Alexander MJ, Zauner A, Chaloupka JC, et al. WEAVE Trial: Final Results in 152 On-Label Patients. *Stroke*. Apr 2019; 50(4): 889-894. PMID 31125298
78. 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/UCM598459.pdf>.
79. Darsaut TE, Findlay JM, Bojanowski MW, et al. A Pragmatic Randomized Trial Comparing Surgical Clipping and Endovascular Treatment of Unruptured Intracranial Aneurysms. *AJNR Am J Neuroradiol*. Jun 2023; 44(6): 634-640. PMID 37169541
80. Hong Y, Wang YJ, Deng Z, et al. Stent-assisted coiling versus coiling in treatment of intracranial aneurysm: a systematic review and meta-analysis. *PLoS One*. 2014; 9(1): e82311. PMID 24454690
81. Ryu CW, Park S, Shin HS, et al. Complications in Stent-Assisted Endovascular Therapy of Ruptured Intracranial Aneurysms and Relevance to Antiplatelet Administration: A Systematic Review. *AJNR Am J Neuroradiol*. Sep 2015; 36(9): 1682-8. PMID 26138136
82. Boisseau W, Darsaut TE, Fahed R, et al. Stent-Assisted Coiling in the Treatment of Unruptured Intracranial Aneurysms: A Randomized Clinical Trial. *AJNR Am J Neuroradiol*. Apr 2023; 44(4): 381-389. PMID 36927759
83. Pötin M, Blanc R, Spelle L, et al. Stent-assisted coiling of intracranial aneurysms: clinical and angiographic results in 216 consecutive aneurysms. *Stroke*. Jan 2010; 41(1): 110-5. PMID 19959540
84. Hetts SW, Turk A, English JD, et al. Stent-assisted coiling versus coiling alone in unruptured intracranial aneurysms in the matrix and platinum science trial: safety, efficacy, and mid-term outcomes. *AJNR Am J Neuroradiol*. Apr 2014; 35(4): 698-705. PMID 24184523
85. Consoli A, Vignoli C, Renieri L, et al. Assisted coiling of saccular wide-necked unruptured intracranial aneurysms: stent versus balloon. *J Neurointerv Surg*. Jan 2016; 8(1): 52-7. PMID 25428449
86. Liu YQ, Wang QJ, Zheng T, et al. Single-centre comparison of procedural complications, clinical outcome, and angiographic follow-up between coiling and stent-assisted coiling for

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

- posterior communicating artery aneurysms. *J Clin Neurosci*. Dec 2014; 21(12): 2140-4. PMID 25037315
87. King B, Vaziri S, Singla A, et al. Clinical and angiographic outcomes after stent-assisted coiling of cerebral aneurysms with Enterprise and Neuroform stents: a comparative analysis of the literature. *J Neurointerv Surg*. Dec 2015; 7(12): 905-9. PMID 25352581
88. Geyik S, Yavuz K, Yurttutan N, et al. Stent-assisted coiling in endovascular treatment of 500 consecutive cerebral aneurysms with long-term follow-up. *AJNR Am J Neuroradiol*. 2013; 34(11): 2157-62. PMID 23886748
89. Lee KM, Jo KI, Jeon P, et al. Predictor and Prognosis of Procedural Rupture during Coil Embolization for Unruptured Intracranial Aneurysm. *J Korean Neurosurg Soc*. Jan 2016; 59(1): 6-10. PMID 26885280
90. Jankowitz BT, Hanel R, Jadhav AP, et al. Neuroform Atlas Stent System for the treatment of intracranial aneurysm: primary results of the Atlas Humanitarian Device Exemption cohort. *J Neurointerv Surg*. Aug 2019; 11(8): 801-806. PMID 30670625
91. Food and Drug Administration (FDA). SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED): Neuroform Atlas Stent System (P180031). 2019. https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180031B.pdf
92. Fiorella D, Boulos A, Turk AS, et al. The safety and effectiveness of the LVIS stent system for the treatment of wide-necked cerebral aneurysms: final results of the pivotal US LVIS trial. *J Neurointerv Surg*. Apr 2019; 11(4): 357-361. PMID 30297543
93. Food and Drug Administration (FDA). SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED): Low-Profile Visualized Intraluminal Support (LVIS) and LVIS Jr (P170013). 2018. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170013B.pdf.
94. Feng Z, Fang Y, Xu Y, et al. The safety and efficacy of low profile visualized intraluminal support (LVIS) stents in assisting coil embolization of intracranial saccular aneurysms: a single center experience. *J Neurointerv Surg*. Nov 2016; 8(11): 1192-1196. PMID 26747876
95. Aydin K, Arat A, Sencer S, et al. Stent-Assisted Coiling of Wide-Neck Intracranial Aneurysms Using Low-Profile LEO Baby Stents: Initial and Midterm Results. *AJNR Am J Neuroradiol*. Oct 2015; 36(10): 1934-41. PMID 26021624
96. Chalouhi N, Jabbour P, Starke RM, et al. Endovascular treatment of proximal and distal posterior inferior cerebellar artery aneurysms. *J Neurosurg*. May 2013; 118(5): 991-9. PMID 23350778
97. Chen Z, Yang Y, Miao H, et al. Endovascular treatment for large and giant fusiform aneurysms of the vertebrobasilar arteries. *Clin Imaging*. 2013; 37(2): 227-31. PMID 23465972
98. Gentric JC, Biondi A, Piotin M, et al. Safety and efficacy of neuroform for treatment of intracranial aneurysms: a prospective, consecutive, French multicentric study. *AJNR Am J Neuroradiol*. 2013; 34(6): 1203-8. PMID 23348764
99. Johnson AK, Heiferman DM, Lopes DK. Stent-assisted embolization of 100 middle cerebral artery aneurysms. *J Neurosurg*. May 2013; 118(5): 950-5. PMID 23394339
100. Kulcsár Z, Göricke SL, Gizewski ER, et al. Neuroform stent-assisted treatment of intracranial aneurysms: long-term follow-up study of aneurysm recurrence and in-stent stenosis rates. *Neuroradiology*. Mar 2013; 55(4): 459-65. PMID 23358878

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

101. Food and Drug Administration. PMA P170024: Summary of Safety and Effectiveness (SSED). Intracranial Aneurysm Flow Diverter. 2018. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170024B.pdf.
102. Zhou G, Zhu YQ, Su M, et al. Flow-Diverting Devices versus Coil Embolization for Intracranial Aneurysms: A Systematic Literature Review and Meta-analysis. *World Neurosurg.* Apr 2016; 88: 640-645. PMID 26585732
103. Xin WQ, Xin QQ, Yuan Y, et al. Comparison of Flow Diversion and Coiling for the Treatment of Unruptured Intracranial Aneurysms. *World Neurosurg.* Aug 2019; 128: 464-472. PMID 31132489
104. Raymond J, Gentric JC, Darsaut TE, et al. Flow diversion in the treatment of aneurysms: a randomized care trial and registry. *J Neurosurg.* Sep 2017; 127(3): 454-462. PMID 27813466
105. Kiselev R, Orlov K, Dubovoy A, et al. Flow diversion versus parent artery occlusion with bypass in the treatment of complex intracranial aneurysms: Immediate and short-term outcomes of the randomized trial. *Clin Neurol Neurosurg.* Sep 2018; 172: 183-189. PMID 30053620
106. Kan P, Mohanty A, Meyers PM, et al. Treatment of large and giant posterior communicating artery aneurysms with the Surpass streamline flow diverter: results from the SCENT trial. *J Neurointerv Surg.* Jul 2023; 15(7): 679-683. PMID 35551072
107. Hanel RA, Cortez GM, Coon AL, et al. Surpass Intracranial Aneurysm Embolization System Pivotal Trial to Treat Large or Giant Wide-Neck Aneurysms - SCENT: 3-year outcomes. *J Neurointerv Surg.* Nov 2023; 15(11): 1084-1089. PMID 36375835
108. Powers WJ, Rabinstein AA, Ackerson T, et al. 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* Mar 2018; 49(3): e46-e110. PMID 29367334
109. Powers WJ, Rabinstein AA, Ackerson T, et al. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* Dec 2019; 50(12): e344-e418. PMID 31662037
110. Thompson BG, Brown RD, Amin-Hanjani S, et al. Guidelines for the Management of Patients With Unruptured Intracranial Aneurysms: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* Aug 2015; 46(8): 2368-400. PMID 26089327
111. Ganesh A, Fraser JF, Gordon Perue GL, et al. Endovascular Treatment and Thrombolysis for Acute Ischemic Stroke in Patients With Premorbid Disability or Dementia: A Scientific Statement From the American Heart Association/American Stroke Association. *Stroke.* May 2022; 53(5): e204-e217. PMID 35343235
112. Jayaraman MV, Hussain MS, Abruzzo T, et al. Embolectomy for stroke with emergent large vessel occlusion (ELVO): report of the Standards and Guidelines Committee of the Society of NeuroInterventional Surgery. *J Neurointerv Surg.* May 2015; 7(5): 316-21. PMID 25765949

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

113. Mokin M, Ansari SA, McTaggart RA, et al. Indications for thrombectomy in acute ischemic stroke from emergent large vessel occlusion (ELVO): report of the SNIS Standards and Guidelines Committee. J Neurointerv Surg. Mar 2019; 11(3): 215-220. PMID 30610069
114. Kayan Y, Meyers PM, Prestigiacomo CJ, et al. Current endovascular strategies for posterior circulation large vessel occlusion stroke: report of the Society of NeuroInterventional Surgery Standards and Guidelines Committee. J Neurointerv Surg. Oct 2019; 11(10): 1055-1062. PMID 31103994
115. Heit JJ, Chaudhary N, Mascitelli JR, et al. Focused update to guidelines for endovascular therapy for emergent large vessel occlusion: basilar artery occlusion patients. J Neurointerv Surg. Jul 16 2024; 16(8): 752-755. PMID 38670791
116. English JD, Yavagal DR, Gupta R, et al. Mechanical Thrombectomy-Ready Comprehensive Stroke Center Requirements and Endovascular Stroke Systems of Care: Recommendations from the Endovascular Stroke Standards Committee of the Society of Vascular and Interventional Neurology (SVIN). Interv Neurol. Mar 2016; 4(3-4): 138-50. PMID 27051410
117. Nguyen TN, Castonguay AC, Siegler JE, et al. Mechanical Thrombectomy in the Late Presentation of Anterior Circulation Large Vessel Occlusion Stroke: A Guideline From the Society of Vascular and Interventional Neurology Guidelines and Practice Standards Committee. Stroke Vasc Interv Neurol. Jan 2023; 3(1). PMID 39380893
118. Center for Medicare & Medicaid Services. Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG- 00085R8). 2023; <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=3111&fromdb=true>.

Policy History

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

02/01/2006	Medical Director review
02/15/2006	Medical Policy Committee review
02/23/2006	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
04/02/2008	Medical Director review
04/16/2008	Medical Policy Committee approval. No change in policy statement. Rationale totally rewritten with focus on FDA approved devices.
04/02/2009	Medical Director review
04/15/2009	Medical Policy Committee approval. No change to coverage eligibility.
04/08/2010	Medical Policy Committee approval
04/21/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2011	Medical Policy Committee review

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

04/13/2011	Medical Policy Implementation Committee approval. Changed title from “Percutaneous Transluminal Angioplasty of Intracranial Atherosclerotic Stenoses With or Without Stenting” to “Endovascular Procedures (Angioplasty and/or Stenting) for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)”. Added that intracranial stent placement is eligible for coverage 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 (4mm or more) or sack-to-neck ratio less than 2:1. Added that intracranial stent placement in the treatment of intracranial aneurysms, except as noted above, is investigational.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/04/2013	Medical Policy Committee review
04/24/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2014	Medical Policy Committee review
04/23/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Policy 00366 (Mechanical Embolectomy for Treatment of Acute Stroke) retired and combined with this policy.
04/02/2015	Medical Policy Committee review
04/20/2015	Medical Policy Implementation Committee approval. Added new coverage statement for Intracranial flow diverting stents with FDA approval and patient selection criterion. Updated rationale and references.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. Policy statement revised to indicate that mechanical embolectomy for acute stroke may be considered medically necessary with criteria.
10/01/2016	Coding update
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update.
05/04/2017	Medical Policy Committee review
05/17/2017	Medical Policy Implementation Committee approval. No change to coverage.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Policy statements changed to reflect extension of the time window for mechanical thrombectomy up to 24 hours after symptom onset for select patients. Added Policy Guidelines section.
01/01/2019	Coding update
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Reformatted the coverage section for clarity.
06/04/2020	Medical Policy Committee review

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

06/10/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2023	Medical Policy Committee review
06/14/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Removed “Based on review of available data, the Company may consider intracranial flow-diverting stents with U.S. Food and Drug Administration (FDA) approval for the treatment of intracranial aneurysms to be eligible for coverage as part of the endovascular treatment of intracranial aneurysms for individuals that meet the patient selection criterion and are not amenable to surgical treatment or standard endovascular therapy. Patient Selection Criterion Coverage eligibility for intracranial flow-diverting stents with FDA approval for the treatment of intracranial aneurysms will be considered when the criterion below is met: Flow-diverting stents are indicated for the treatment of 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.” Added “Based on review of available data, the Company may consider percutaneous intracranial artery stent placement with or without angioplasty as part of the treatment of individuals with an intracranial aneurysm when ALL of the following criteria are met to be eligible for coverage: • Surgical treatment is not appropriate or attempted surgery was unsuccessful; and • Standard endovascular techniques (coiling) are inadequate to achieve complete isolation of the aneurysm because of anatomic considerations which include, but are not limited to: ○ wide-neck aneurysm (4 mm or more); or ○ sack-to-neck ratio less than 2:1.”
11/07/2024	Medical Policy Committee review

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

11/13/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

11/06/2025 Medical Policy Committee review

11/12/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 11/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)[‡], copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	61624, 61630, 61635, 61645
HCPCS	No codes
ICD-10 Diagnosis	I67.1, Q28.2, Q28.3

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Policy # 00198

Original Effective Date: 02/23/2006

Current Effective Date: 12/01/2025

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.