MEDICAL POLICY

POLICY TITLE	ENDOVASCULAR PROCEDURES FOR INTRACRANIAL ARTERIAL DISEASE (ATHEROSCLEROSIS AND ANEURYSMS)
POLICY NUMBER	MP-2.032

Effective Date:	9/1/2023

I. POLICY

Intracranial stent placement may be considered **medically necessary** as part of the endovascular treatment of intracranial aneurysms for patients when surgical treatment is not appropriate and standard endovascular techniques do not allow for complete isolation of the aneurysm, e.g., wide-neck aneurysm (≥4mm) or a sack-to-neck ratio less than 2:1.

Intracranial flow diverting stents with U. S. Food and Drug Administration (FDA) approval for the treatment of intracranial aneurysms may be considered **medically necessary** as part of the endovascular treatment of intracranial aneurysms that meet anatomic criteria (see "Policy Guidelines") and are not amenable to surgical treatment or standard endovascular therapy.

Intracranial stent placement is considered **investigational** in the treatment of intracranial aneurysms except as noted above. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

Intracranial percutaneous transluminal angioplasty with or without stenting is considered **investigational**, in the treatment of atherosclerotic cerebrovascular diseases. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures. (For Humanitarian Device Exceptions, please see MP 2.383 Orphan Drugs and Humanitarian Use Device).

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

- Have a demonstrated occlusion within the proximal intracranial anterior circulation (intracranial internal carotid artery, or M1 or M2 segments of the middle cerebral artery, or A1 or A2 segments of the anterior cerebral artery); **AND**
- Can receive endovascular mechanical embolectomy within 12 hours of symptom onset OR within 24 hours of symptom onset if there is evidence of a mismatch between specific clinical imaging criteria (see Policy Guidelines); **AND**
- Have evidence of substantial and clinically significant neurological deficits (see "Policy Guidelines"); **AND**

- Have evidence of salvageable brain tissue in the affected vascular territory (see "Policy Guidelines"); **AND**
- Have no evidence of intracranial hemorrhage or arterial dissection on computed tomography (CT) or magnetic resonance imaging (MRI) imaging.

Endovascular interventions are considered **investigational** for the treatment of acute ischemic stroke when the above criteria are not met. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

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: • 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: o 50 cm^3 for subjects age 18-79 y; o 20 cm^3 for subjects age 80-85 y; • CT-assessed core infarct lesion greater than: o 40 cm^3 for subjects age 18-79 y; o 15 cm^3 for subjects age 80-85 y; • For all subjects, severe hypoperfusion lesion (³10-s Tmax lesion >100 cm^3); • For all subjects, ischemic penumbra of ≥15 cm^3 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 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.

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 (NIHSS) score of 6 or higher. MR CLEAN specified a clinical diagnosis of acute stroke with a deficit on the NIHSS score of 2 points or more; SWIFT-PRIME (Solitaire With the Intention For Thrombectomy as PRIMary Endovascular Treatment) specified an NIHSS 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 Patients 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 (Albers et al, 2018)	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 tissue volume to infarct volume of ≥1.8; AND • Ischemic penumbra of ≥15 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.

Cross-references:

MP 2.383 Orphan Drugs and Humanitarian Use Device

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO- Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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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 patients whose anatomy is not amenable to simple coiling.

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 treatment of cerebrovascular diseases.

Acute Stroke

Acute stroke is the fifth leading cause of death in the United States; further it is the 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% 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 (i.e., plaque, fatty material) travels to an artery in the brain causing a blockage (embolism). Recanalization of the artery, particularly in the first few hours after occlusion, reduces rates of disability and death.

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 (adjusted odds ratio [aOR], 0.83; 95% confidence interval [CI], 0.76 to 0.90).10, 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.

REGULATORY STATUS

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 (HDE) 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.

Table 1. FDA-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 8h of symptom onset
Stent retrievers			
Solitaire™ 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 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 incidents per year; FDA only requires data showing "probable safety and effectiveness." Devices with their labeled indications are as follows.

Neurolink System®
"The Neurolink system [Guidant] is indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with ≥50% stenosis and that are accessible to the stent system."

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

Intracranial Aneurysms
In 2011, the Pipeline® Embolization Device (Covidien/eV3 Neurovascular), an intracranial aneurysm flow diverter, was approved by 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 for Failed Aneurysms Study, a single-arm, open-label feasibility study, reported by Becske et al (2013) that included 108 patients, ages 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 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 or equal to 18 years of age with saccular wide-necked (neck width greater or equal to 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of greater or equal to 2.0 mm and less than or equal to 4.5 mm." Product Code: QCA.

Enterprise™ 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 July 2014, the Low-Profile Visualized Intraluminal Support Device (LVIS™ and LVIS™ Jr.; MicroVention) was approved by the FDA through the humanitarian device exemption process 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 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.

IV. RATIONALE

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Summary of Evidence

For individuals who have acute ischemic stroke due to occlusion of an anterior circulation vessel who receive endovascular mechanical embolectomy, the evidence includes randomized clinical trials (RCTs) comparing endovascular therapy with standard care and systematic reviews of these RCTs. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. From 2013 to 2015, 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 acute ischemic stroke due to basilar artery occlusion who receive endovascular mechanical embolectomy, the evidence includes an RCT. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. The RCT was terminated early due to high crossovers and poor recruitment. There was not a statistically significant difference in the proportion of participants with modified Rankin Scale 0 to 3 at 90 days or in 90-day mortality rates in the endovascular and standard therapy groups. Additional RCTs are ongoing. 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 who receive intracranial percutaneous transluminal angioplasty with or without stenting, the evidence includes a systematic review and 2 major RCTs. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, and treatment-related mortality and morbidity. Both 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 2 RCTs does not suggest that intracranial percutaneous transluminal angioplasty with or without stenting improves outcomes for individuals with symptomatic intracranial stenosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have intracranial aneurysm(s) who receive endovascular coiling with intracranial stent placement or intracranial placement of a flow-diverting stent, the evidence includes RCTs, several nonrandomized comparative studies, and multiple single-arm studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. The available nonrandomized comparative studies 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 Suprass flow diverter device. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

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ANASTOMOSIS refers to a natural communication between two vessels; may be direct or by means of connecting channels.

ANGIOPLASTY refers to any endovascular procedure that reopens narrowed blood vessels and restores forward blood flow.

ATHERECTOMY is a technique using high-speed drills to remove atheromatous (fatty) plaques from arteries**.**

PERCUTANEOUS refers to that which is passed or effected through the skin.

STENOSIS is a constriction or narrowing of a passage or orifice.

STENT is any material or device used to hold tissue in place, to maintain open blood vessels, or to provide support for a graft or anastomoses while healing is taking place.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and

providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Intracranial percutaneous transluminal angioplasty with or without stenting is considered investigational in the treatment of atherosclerotic cerebrovascular diseases; therefore, not covered:

Procedure Codes							
61630							

Covered when medically necessary endovascular mechanical embolectomy:

Procedure Codes							
61645							

ICD-10-CM Diagnosis Codes	Description
I63.031	Cerebral infarction due to thrombosis of right carotid artery
I63.032	Cerebral infarction due to thrombosis of left carotid artery
I63.112	Cerebral infarction due to embolism of left vertebral artery
I63.113	Cerebral infarction due to embolism of bilateral vertebral arteries
I63.119	Cerebral infarction due to embolism of unspecified vertebral artery
I63.12	Cerebral infarction due to embolism of basilar artery

ICD-10-CM Diagnosis Codes	Description
I63.131	Cerebral infarction due to embolism of right carotid artery
I63.132	Cerebral infarction due to embolism of left carotid artery
I63.133	Cerebral infarction due to embolism of bilateral carotid arteries
I63.139	Cerebral infarction due to embolism of unspecified carotid artery
I63.19	Cerebral infarction due to embolism of other precerebral artery
I63.20	Cerebral infarction due to unspecified occlusion or stenosis of unspecified precerebral arteries
I63.211	Cerebral infarction due to unspecified occlusion or stenosis of right vertebral artery
I63.212	Cerebral infarction due to unspecified occlusion or stenosis of left vertebral artery
I63.213	Cerebral infarction due to unspecified occlusion or stenosis of bilateral vertebral arteries
I63.219	Cerebral infarction due to unspecified occlusion or stenosis of unspecified vertebral artery
I63.22	Cerebral infarction due to unspecified occlusion or stenosis of basilar artery
I63.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
I63.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
I63.233	Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries
I63.239	Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid artery
I63.29	Cerebral infarction due to unspecified occlusion or stenosis of other precerebral arteries
I63.30	Cerebral infarction due to thrombosis of unspecified cerebral artery
I63.311	Cerebral infarction due to thrombosis of right middle cerebral artery
I63.312	Cerebral infarction due to thrombosis of left middle cerebral artery
I63.313	Cerebral infarction due to thrombosis of bilateral middle cerebral arteries
I63.319	Cerebral infarction due to thrombosis of unspecified middle cerebral artery
I63.321	Cerebral infarction due to thrombosis of right anterior cerebral artery
I63.322	Cerebral infarction due to thrombosis of left anterior cerebral artery
I63.323	Cerebral infarction due to thrombosis of bilateral anterior cerebral arteries
I63.329	Cerebral infarction due to thrombosis of unspecified anterior cerebral artery
I63.331	Cerebral infarction due to thrombosis of right posterior cerebral artery
I63.332	Cerebral infarction due to thrombosis of left posterior cerebral artery
I63.333	Cerebral infarction due to thrombosis of bilateral posterior cerebral arteries
I63.339	Cerebral infarction due to thrombosis of unspecified posterior cerebral artery
I63.341	Cerebral infarction due to thrombosis of right cerebellar artery

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ICD-10-CM Diagnosis Codes	Description
I63.342	Cerebral infarction due to thrombosis of left cerebellar artery
I63.343	Cerebral infarction due to thrombosis of bilateral cerebellar arteries
I63.349	Cerebral infarction due to thrombosis of unspecified cerebellar artery
I63.39	Cerebral infarction due to thrombosis of other cerebral artery
I63.411	Cerebral infarction due to embolism of right middle cerebral artery
I63.412	Cerebral infarction due to embolism of left middle cerebral artery
I63.421	Cerebral infarction due to embolism of right anterior cerebral artery
I63.422	Cerebral infarction due to embolism of left anterior cerebral artery
I63.49	Cerebral infarction due to embolism of other cerebral artery
I67.89	Other cerebrovascular disease

Covered when medically necessary intracranial stenting:

Procedure Codes							
61624	62635						

ICD-10-CM Diagnosis Codes	Description
I67.0	Dissection of cerebral arteries, nonrupture
I67.1	Cerebral aneurysm, nonruptured
I67.2	Cerebral atherosclerosis
I67.3	Progressive vascular leukoencephalopathy
I67.4	Hypertensive encephalopathy
I67.5	Moyamoya disease
I67.6	Nonpyogenic thrombosis of intracranial venous system
I67.7	Cerebral arteritis, not elsewhere classified
I67.81	Acute cerebrovascular insufficiency
I67.82	Cerebral ischemia
I67.83	Posterior reversible encephalopathy syndrome
I67.841	Reversible cerebrovascular vasoconstriction syndrome
I67.848	Other cerebrovascular vasospasm and vasoconstriction
I67.850	Cerebral autosomal dominant arteriopathy with subcortical infarcts and leukoencephalopathy
I67.858	Other hereditary cerebrovascular disease
I67.89	Other cerebrovascular disease
I67.9	Cerebrovascular disease, unspecified
Q28.3	Other malformations of cerebral vessels

IX. References

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X. POLICY HISTORY

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MP-2.032	**CAC 11/30/04**
	CAC 5/31/05
	CAC 9/27/05
	CAC 1/31/06
	CAC 1/30/07
	CAC 11/27/07
	CAC 11/25/08
	CAC 9/29/09 Consensus – Policy statement unchanged. References updated.
	CAC 11/30/10 Consensus Review
	CAC 7/26/11 Minor revision. Intracranial stent placement now considered medically necessary for selected patients with intracranial aneurysms who meet specific criteria, use for all other indications remains investigational. An FEP variation was added.
	CAC 10/30/12 Consensus. No change to policy statements. References updated. FEP variation added to reference MP-2.01.54 Endovascular Procedures for Intracranial Arterial Disease. Standard FEP variation remains in

	place for the other procedures addressed in the policy. Codes reviewed and updated 10/22/12
	2013 Codes added-12/20/2013
	04/08/13 Codes reviewed
	CAC 11/26/13 Consensus review. No changes to the policy statements. References updated. 2014 New codes added to policy.
	01/2015- New 2015 CPT codes added to policy.
	CAC 3/24/15 Minor. Criteria for the following removed from the policy: • Non-coronary Percutaneous Transluminal Angioplasty/Atherectomy • Non-Coronary Laser Angioplasty • Coronary Artery Percutaneous Transluminal Angioplasty/Atherectomy • Pulmonary Artery Percutaneous Transluminal Balloon Angioplasty Added the following statements • Intracranial flow diverting stents with FDA approval for the treatment of intracranial aneurysms may be considered **medically necessary** as part of the endovascular treatment of intracranial aneurysms that meet anatomic criteria. • Endovascular interventions (mechanical embolectomy, angioplasty, stenting) are considered **investigational** in the treatment of acute stroke. BCBSA adopted for all policy statements. Added policy guidelines. Coding reviewed.
	CAC 11/24/15 Minor revision. Policy title revised from Intravascular Therapeutic Procedures to "Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms). BCBSA policy adopted. Policy statement revised to indicate that mechanical embolectomy for acute stroke may be considered medically necessary with criteria. Background, rationale, and references updated. Medicare variation revised to refer to the CMS decision memo. Coding reviewed/updated
	CAC 11/29/16 Consensus review. No changes to the policy statements. Background, references and rationale updated**.** Variations reformatted**.** Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies
	CAC 1/30/18 Minor revision. Added a statement that endovascular interventions are considered investigational for the treatment of acute ischemic stroke when the policy criteria are not met. References and rationale updated. Coding reviewed.
	2/27/19 Minor revision. Policy statement revised to reflect extension for time window for mechanical thrombectomy up to 24 hours after symptom onset in select patients. Background and references updated. Rationale revised.
	2/24/2020 Consensus review. Policy statement unchanged. References updated. Coding updated.

POLICY TITLE	ENDOVASCULAR PROCEDURES FOR INTRACRANIAL ARTERIAL DISEASE (ATHEROSCLEROSIS AND ANEURYSMS)
POLICY NUMBER	MP-2.032

	1/12/2021: Consensus Review. Policy statement unchanged. Background and references updated.
	05/31/2022 Consensus Review. No change to policy statements. FEP language revised. Background, Rationale and References updated.
	05/31/2023 Consensus Review. No change to policy statement. Removed referenced policy 2.003 as it is retired. Added referenced policy 2.383. Policy Guidelines, Background, Rationale and References updated.

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