Protocol

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

(20154)

Medical Benefit		**Effective Date**: 10/01/20	**Next Review Date**: 07/23
Preauthorization	No	**Review Dates**: 01/08, 09/08, 09/09, 09/10, 09/11, 07/12, 07/13, 05/14, 11/14, 11/15, 11/16, 11/17, 07/18, 07/19, 07/20, 07/21, 07/22	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

RELATED PROTOCOL

Extracranial Carotid Artery Stenting

Populations	Interventions	Comparators	Outcomes
Individuals: • With acute ischemic stroke due to occlusion of an anterior circulation vessel	Interventions of interest are: • Endovascular mechanical embolectomy	Comparators of interest are: • Standard care without endovascular therapy	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related mortality • Treatment-related morbidity
Individuals: • With acute ischemic stroke due to basilar artery occlusion	Interventions of interest are: • Endovascular mechanical embolectomy	Comparators of interest are: • Standard care without endovascular therapy	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related mortality • Treatment-related morbidity
Individuals: • With symptomatic intracranial arterial stenosis	Interventions of interest are: • Intracranial percutaneous transluminal angioplasty with or without stenting	Comparators of interest are: • Standard care without endovascular therapy	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Functional outcomes • Treatment-related mortality • Treatment-related morbidity
Individuals: • With intracranial aneurysm(s)	Interventions of interest are: • Endovascular coiling with intracranial stent placement • Intracranial placement of a flow-diverting stent	Comparators of interest are: • Endovascular coiling without stent placement • Surgical therapy • Observation or medical therapy	Relevant outcomes include: • Overall survival • Morbid events • Functional outcomes • Treatment-related mortality • Treatment-related morbidity

DESCRIPTION

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.

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 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 an acute ischemic stroke due to basilar artery occlusion who receive endovascular mechanical embolectomy, the evidence includes 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 a modified Rankin Scale of 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 out-

comes 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 nonrandomized study 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 (4 mm or more) or sack-to-neck ratio less than 2:1.

Intracranial flow diverting stents with the 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.

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

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 and 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 or magnetic resonance imaging.

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

POLICY GUIDELINES

PATIENT SELECTION FOR ENDOVASCULAR MECHANICAL EMBOLECTOMY FOR ACUTE ISCHEMIC STROKE

The major RCTs demonstrating a benefit with endovascular mechanical embolectomy vary in criteria for selecting patients based on the presence or absence of salvageable brain tissue. Several RCTs use the Alberta Stroke Program Early Computed Tomography Score (ASPECTs) 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)[1]	Exclusion	Hypodensity on CT or restricted diffusion demonstrated by: • An ASPECTS less than seven on CT, CT perfusion CBV, CTA source imaging; OR • An ASPECTS less than six on DWI MRI
ESCAPE (Goyal et al, 2015)[2]	Exclusion	• Baseline non–contrast CT with extensive early ischemic changes of ASPECTS of zero to five in the territory of symptomatic intracranial occlusion; OR • Other confirmation of a moderate-to-large core defined one of three ways: o 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 o On CT perfusion (larger than 8 cm coverage): a low CBV and very low CBF, ASPECTS less than six AND in the symptomatic MCA territory; OR o On CT perfusion (less than 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)[3]	Inclusion	Based on CT perfusion imaging using CT or MRI with a Tmax more than six-second 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)[4]	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

Trial	Inclusion or Exclusion	Criteria
		• For all subjects, severe hypoperfusion lesion (≥10-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; MCA: middle cerebral artery; MRI: magnetic resonance 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;
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

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 six or higher. MR CLEAN specified a clinical diagnosis of acute stroke with a deficit on the NIHSS of two points or more. SWIFT PRIME (Solitaire™ With the Intention For Thrombectomy as PRIMary Endovascular Treatment) specified an NIHSS score of eight 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 Neuro-intervention With Trevo) and DEFUSE 3 (Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3) studies enrolled patients from six 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 six to 25 Hours Post Infarct

Trial	Inclusion or Exclusion	Criteria
DAWN Trial (Nogueira et al, 2018)[5]	Inclusion	Six 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)[6]	Inclusion	Six 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

NIHSS: National Institutes of Health Stroke Scale; 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.

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 protocol 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.

MEDICARE ADVANTAGE

For Medicare Advantage, all indications for percutaneous transluminal angioplasty (PTA) with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries are **not medically necessary**, unless they are provided for the treatment of cerebral artery stenosis of 50% or more in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing FDA-approved Category B IDE clinical trials.

BACKGROUND

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 the fifth leading cause of death in the United States; further, it is a leading cause of adult disability.[8] 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.[9]

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.[11] 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.[12] 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 circula-

tion. 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.[13] 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 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. Food and Drug Administration-Cleared Mechanical Embolectomy Devices for Acute Stroke

Device	510(k) No. for Original Device	Approval Date for Original Device	Indications
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 t-PA
Embotrap® III Revascularization Device (Neuravi Ltd)	K211338	Jul 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV t-PA
ZOOM™ 71 Reperfusion Catheter (Imperative Care, Inc)	K211476	Jun 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV t-PA
ZOOM Reperfusion Catheter (Imperative Care, Inc)	K210996	Apr 2021	Patients with acute ischemic stroke within 8 h of symptom onset who are ineligible for or who fail IV t-PA
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 t-PA
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 eight hours 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® 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 eight hours of symptom onset who are ineligible for

Device	510(k) No. for Original Device	Approval Date for Original Device	Indications
			or who fail IV t-PA

IV: intravenous; tPA: tissue plasminogen activator.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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