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FEP Medical Policy Manual

FEP 2.01.54 Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

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Related Policies:

7.01.68 - Extracranial Carotid Artery Stenting

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Description

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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.

OBJECTIVE

The objective of this evidence review is to determine whether endovascular therapies improve the net health outcome in patients with acute ischemic stroke, intracranial arterial stenosis, or intracranial aneurysm.

POLICY STATEMENT

Intracranial stent placement may be considered **medically necessary** as part of the endovascular treatment of intracranial aneurysms for individuals when surgical treatment is not appropriate and standard endovascular techniques do not allow for complete isolation of the aneurysm, eg, wide-neck aneurysm (≥4 mm) 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 section) 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 individuals who meet all of the following criteria:

Have a demonstrated occlusion within the proximal intracranial anterior circulation (intracranial internal carotid artery, or M1 or M2 segments of the middle cerebral artery, or A1 or A2 segments of the anterior cerebral artery); AND

- Can receive endovascular mechanical embolectomy within 12 hours of symptom onset OR within 24 hours of symptom onset if there is evidence of a mismatch between specific clinical and imaging criteria (see Policy Guidelines); AND
- Have evidence of substantial and clinically significant 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 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

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: 50 cm^3 for subjects age 18-79 y; 20 cm^3 for subjects age 80-85 y CT-assessed core infarct lesion greater than: 40 cm^3 for subjects age 18-79 y; 15 cm^3 for subjects age 80-85 y 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; 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.

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 (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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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
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			
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 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 ≥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 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.[7,] 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, aged 30 to 75 years, with unruptured large and giant wide-necked aneurysms.[8,]

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.

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 2014, the Low-Profile Visualized Intraluminal Support Device (LVIS™ and LVIS™ Jr.; MicroVention) was approved by the FDA through the humanitarian device exemption process (H130005) for use with embolic coils for the treatment of unruptured, wide-neck (neck, ≥4 mm or dome-to-neck

ratio, <2), intracranial, saccular aneurysms arising from a parent vessel with a diameter of 2.5 mm or greater and 4.5 mm or smaller. In 2018, the LVIS and LVIS Jr. were approved through the 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

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-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 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 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 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.

SUPPLEMENTAL INFORMATION

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.

Society of Vascular and Interventional Neurology

In 2016, the Society of Vascular and Interventional Neurology published recommendations on comprehensive stroke center requirements and endovascular stroke systems of care.[93,] 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 large vessel occlusions. 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."

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).[94,95,] 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 criteria that can be used to credential individuals who can perform safe and timely intra-arterial revascularization procedures."	I	C
"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 TICI 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 TICI 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."	IIa	C-LD
In selected patients with AIS 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

AIS: acute ischemic stroke; 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 Undergoing Neurointervention With Trevo; DEFUSE 3: Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3;**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.**[96,]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.[97,]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.

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 in 2008.[98,] This decision was based on a review of available studies at that time, which consisted of several uncontrolled case series. The Centers for Medicare & Medicaid Services review indicated that this evidence was promising and that, while further well-designed randomized controlled trials were needed to confirm whether outcomes were improved, coverage should be allowed. The national coverage determination contained the following coverage determinations:

1. "Medicare coverage for angioplasty and or stenting for symptomatic patients with greater than 70 percent intracranial arterial stenosis; and
2. Medicare coverage for intracranial angioplasty and stenting for other patients within the context of Category B investigational device exemption trials under coverage with evidence development within a registry."

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
December 2012	Replace policy	Rationale and references updated with literature review. No change to policy.
September 2013	Replace policy	Policy updated with literature review, References 4-7 added. Editorial revisions made to rationale. No change to policy statements.
March 2014	Replace policy	Policy Background and Rationale sections extensively revised and reorganized to incorporate indications and devices previously included in policy 2.01.76 Mechanical Embolectomy for Treatment of Acute Stroke (Archived). Policy updated with literature review through adding reference numbers 1, 3-5, 11, 13-16, 43-51, 56, 60, 67, 70-84 and 86-88. Policy statement from 2.01.76 added; no other change to policy statements.
September 2014	Replace policy	Policy statement added to provide clarity for medically necessary intent for FDA approved devices and their intended uses. No new references
March 2015	Replace policy	Policy updated with literature review through December 12, 2014. References 3-5, 9, 13-14, 19-20, 30-31, 38-39, 54-61, 69, 75-78, 82, 86, 90, 95-96, 106, and 109-111 added. Language added to policy guidelines to specify that policy statements do not apply to endovascular interventions to treat cerebral ischemia resulting from vasospasm after aneurysmal subarachnoid hemorrhage. Policy statements otherwise unchanged.
December 2016	Replace policy	Policy updated with literature review. References 6, 12, 21-27, 32, 39, 44-45, 84, 98, 109, 112, 116, 120-123, 128, 130, 135- 136, and 138-141 added. Policy statements unchanged.
December 2017	Replace policy	Policy updated with literature review through July 21, 2017; reference 148 added. Policy statements unchanged except "not medically necessary, corrected to "investigational.
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; references 9-10, 40-44, 53, 113, and 135-136 added. Policy statements changed to reflect extension of the time window for mechanical thrombectomy up to 24 hours after symptom onset for select patients.
June 2019	Replace policy	Policy updated with literature review through February 7, 2019; multiple references removed; references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through February 18, 2020; references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through March 11, 2021; references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through March 2, 2022; references added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through February 20, 2023; references added. Minor editorial refinements to policy statements; intent unchanged.