Protocol

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

(20154)

Medical Benefit		**Effective Date**: 10/01/18	**Next Review Date**: 07/19
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	

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.

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 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, eight RCTs were published comparing endovascular therapies with noninterventional care for acute stroke in patients with anterior circulation occlusions. Several trials that were ongoing at the time of publication of these eight RCTs were stopped early and results with the limited enrollment have been published. Trials published from 2014 to 2015 demonstrated a significant benefit regarding reduced disability at 90 days posttreatment. The trials that demonstrated a benefit 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. Two trials published in 2018 demonstrated that it was possible to extend the window for mechanical thrombectomy up to about 24 hours for select patients. To achieve results in real-world settings similar to those in the clinical trials, treatment times, clinical protocols, and patient selection criteria should be similar to those in the RCTs. The evidence is sufficient to determine that the technology results in a meaningful 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 a nonrandomized comparative study and several case series. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. These studies have indicated that high rates of recanalization can be achieved with mechanical thrombectomy. However, additional comparative studies are needed to demonstrate that mechanical thrombectomy is superior to standard therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have symptomatic intracranial arterial stenosis who receive intracranial percutaneous transluminal angioplasty with or without stenting, the evidence includes two RCTs and a number of nonrandomized comparative studies and case series. 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 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 two RCTs does not suggest that intracranial percutaneous transluminal angioplasty with or without stenting improves outcomes for individuals with symptomatic intracranial stenosis. The evidence is sufficient to determine that the technology is unlikely to improve 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 an RCT, several nonran-

domized 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 three 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 the effects of the technology on health outcomes.

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 (four 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 (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 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)	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 eight 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 eight 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 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)	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 (≥ 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.

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 trial. The REVASCAT and

ESCAPE 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 specified an NIHSS score of eight or more and less than 30 at the time of randomization.

The DAWN and DEFUSE 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)	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)	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.

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 four 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 **investigational**, 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 third leading cause of death in the United States, Canada, Europe, and Japan; further, it is the leading cause of adult disability in the United States.[1] Eighty-seven percent of strokes are ischemic and 13% hemorrhagic. Differentiation between the two types of stroke is necessary to determine the appropriate treatment. Ischemic stroke occurs when an artery to the brain is blocked by a blood clot, which forms in the artery (thrombotic), or when another substance (i.e., plaque, fatty material) 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.[2]

Treatment

The prompt use of intravenous (IV) thrombolytic therapy with recombinant tissue plasminogen activator (tPA) to recanalize occluded blood vessels has been associated with improved outcomes in multiple RCTs and meta-analyses.[3] Therefore, use of IV tPA in ischemic stroke patients presenting within three hours (up to 4.5 hours in some cases) of stroke onset in expert centers is recommended.

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

- Requirement for treatment within 4.5 hours of stroke onset. Relatively few patients present for care within the time window in which tPA has shown benefit. In addition, determining the time of onset of symptoms is challenging in patients awakening with symptoms of acute stroke; patients with symptoms on awakening are considered to have symptom onset when they went to sleep. In 2010 and 2011, fewer than 10% of all ischemic stroke patients arrived at the hospital and received IV tPA within the three-hour window.[4]
- Risks associated with IV tPA therapy. tPA is associated with increased risk of intracranial bleeding. It is contraindicated in hemorrhagic stroke and in some ischemic stroke patients for whom the risk of bleeding outweighs the potential benefit, such as those with mild or resolving symptoms, hypocoagulable state, or advanced age.
- Variable recanalization rates. For patients receiving tPA, recanalization rates are around 21% and range from 4% in the distal internal carotid artery and basilar artery to 32% in the middle cerebral artery.[5] The treatment of large vessel strokes with IV tPA may be less successful.

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

Several types of endovascular treatments for ischemic strokes have been used:

- Intra-arterial fibrinolytic therapy (i.e., intra-arterial tPA). Although tPA-only has approval from the U.S. Food and Drug Administration (FDA) for its IV route of delivery, intra-arterial tPA has been considered for patients who fail to present within the window of treatment for IV tPA or who have failed to show benefit from IV tPA. It is also frequently used in conjunction with other endovascular devices.
- Acute angioplasty and/or stent deployment. Balloon angioplasty and balloon-expandable stents have been investigated for acute stroke. Given the concern for higher risks of complications in the cerebral vasculature with the use of balloon-expandable stents, self-expanding stents have gained more attention. At present, no balloon- or self-expandable stent has FDA approval for treatment of acute stroke.
- Endovascular mechanical embolectomy. Endovascular embolectomy devices remove or disrupt clots by a number of mechanisms. Four devices have FDA approval for treatment of acute stroke (see Regulatory Status section): Merci Retriever, Penumbra System, Solitaire Flow Restoration Device, and the Trevo

Retriever. With the Merci device, a microcatheter is passed through the thrombus from a larger, percutaneous catheter positioned proximal to the occlusion. A helical snare is deployed, and the catheter and clot are withdrawn together. With the Penumbra device, an opening at the tip of the percutaneous catheter uses suction to extract the clot. Both the Solitaire Flow Restoration Device and the Trevo Retriever are retrievable stents, which are positioned to integrate the clot with the stent for removal with the stent's struts.

This protocol focuses on the devices listed above with an indication for endovascular embolectomy for acute stroke. Additional retrievable stent devices are under investigation, such as the Embolus Retriever with Interlinked Cages (ERIC; MicroVention).[6]

An additional clinical situation in which endovascular therapies may be used in the treatment of acute ischemic stroke is in the setting of cerebral vasospasm following intracranial (subarachnoid) hemorrhage. Delayed cerebral ischemia occurs about three to 14 days after the acute bleed in about 30% of patients experiencing subarachnoid hemorrhage and is a significant contributor to morbidity and mortality in patients who survive the initial bleed. In cases refractory to medical measures, rescue invasive therapies including intra-arterial vasodilator infusion therapy (e.g., calcium channel blockers) and transluminal balloon angioplasty may be used.[7, 8] The mechanism of disease, patient population, and time course of therapy differ for delayed cerebral ischemia occurring after subarachnoid hemorrhage compared with ischemic stroke due to atheroembolic disease. Therefore, this indication for endovascular intervention is not addressed in this protocol.

Intracranial Arterial Stenosis

It is estimated that intracranial atherosclerosis causes about 8% of all ischemic strokes. Intracranial stenosis may contribute to stroke in two ways: either due to embolism or low-flow ischemia in the absence of collateral circulation. Recurrent annual stroke rates are estimated at 4% 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.

Treatment

Medical treatment typically includes either anticoagulant therapy (i.e., warfarin) or antiplatelet therapy (e.g., aspirin). The Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) trial assessed the incidence of stroke brain hemorrhage or death among patients randomized to aspirin or warfarin.[9] The trial found that over a mean 1.8 years of follow-up, warfarin provided no benefit over aspirin and was associated with a significantly higher rate of complications. Also, if symptoms could be attributed to low-flow ischemia, agents to increase mean arterial blood pressure and avoid orthostatic hypotension may be recommended. However, medical therapy has been considered less than optimal. For example, in patients with persistent symptoms despite antithrombotic therapy, the subsequent rate of stroke or death has been extremely high, estimated in one study at 45%, with recurrent events within one month of the initial event. Surgical approaches have met with limited success. The widely cited extracranial-intracranial bypass study randomized 1377 patients with symptomatic atherosclerosis of the internal carotid or middle cerebral arteries to medical care or extracranial-intracranial bypass.[10] Outcomes in both groups were similar, suggesting that the extracranial-intracranial bypass is ineffective in preventing cerebral ischemia. Due to inaccessibility, surgical options for the posterior circulation are even more limited.

Percutaneous transluminal angioplasty (PTA) has been approached cautiously for use in intracranial circulation, due to technical difficulties in the catheter and stent design and the risk of embolism, which may result in devastating complications if occurring in the posterior fossa or brain stem. However, improvement in the ability to track catheterization, allowing catheterization of tortuous vessels, and the increased use of stents have created ongoing interest in PTA as a minimally invasive treatment of this difficult-to-treat population. Most published studies of intracranial PTA have focused on vertebrobasilar circulation. Two endovascular devices have FDA approval for treatment of symptomatic intracranial stenosis and are considered here (see Regulatory Status section).

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.[11] However, they are associated with significant morbidity and mortality due to subarachnoid hemorrhage resulting from aneurysm rupture.

Treatment

Surgical clipping of intracranial aneurysms has been used since the 1960s, but the feasibility of clipping for aneurysms depends on the aneurysm location. Intracranial stents are also being used to treat cerebral aneurysms. Stent-assisted coiling began as an approach to treat fusiform or wide-neck aneurysms in which other surgical or endovascular treatment strategies may not be feasible. As experience has grown, stenting has also been used in smaller berry aneurysms as an approach to decrease the rate of retreatment needed in patients who receive coiling. A randomized trial has demonstrated that treatment of ruptured intracranial aneurysms with coiling leads to improved short-term outcome compared with surgical clipping; however, patients who receive coiling need more repeat or follow-up procedures. In 2011, the Pipeline Embolization Device, which falls into a new device category called "intracranial aneurysm flow diverters," or flow-diverting stents, received FDA premarket approval for endovascular treatment of large or giant wide-necked intracranial aneurysms in the internal carotid artery. The Pipeline device is a braided, wire mesh device that is placed within the parent artery of an aneurysm to redirect blood flow away from the aneurysm, with the goal of preventing aneurysm rupture and possibly decreasing aneurysm size.

REGULATORY STATUS

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

Acute Stroke

Merci® Retriever

In 2004, the Merci® Retriever (Concentric Medical) was cleared for marketing by the FDA through the 510(k) process. This device was judged equivalent to a predicate device, the Concentric Retriever, which was indicated for endovascular foreign body removal. FDA clearance indicated that the Mechanical Embolus Removal in Cerebral Ischemia (MERCI) Clinical Study established that no new issues of safety or effectiveness exist when the Merci® Retriever is used for thrombus removal vs. foreign body removal from the neurovasculature. In 2006, a modified Merci® Retriever, also manufactured by Concentric Medical, was cleared for marketing by FDA through the 510(k) process. The clearance notes that the Modified Merci® Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing an ischemic stroke. Patients who are ineligible for tPA or who fail IV tPA therapy are candidates for treatment. The device also has clearance for retrieval of foreign bodies misplaced during interventional radiologic procedures in the neuro-, peripheral, and coronary vasculature. FDA product code: NRY.

The Penumbra System®

In 2007, the Penumbra System® (Penumbra) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral [Ml and M2] segments, basilar, and vertebral arteries) within eight hours of symptom onset. FDA product code: NRY.

Solitaire™ FR

In 2012, the Solitaire™ FR device (Covidien/ev3 Neurovascular) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to the Merci® Retriever device, based on a randomized controlled trial, of 113 patients, submitted to the FDA comparing the Merci® and Solitaire™ devices. Indications for the device are patients with ischemic stroke due to large intracranial vessel occlusion who are ineligible for IV tPA, or who fail IV tPA. FDA product code: NRY.

Trevo Pro Retriever™

In 2012, the Trevo Pro Retriever™ device (Stryker Neurovascular) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to the Merci® Retriever device, based on a RCT of 178 patients from 27 centers in the United States and Europe that compared the Trevo® device with the Merci® device. Indications for the device are patients with acute ischemic stroke due to large intracranial vessel occlusion who are ineligible for or fail intravenous tPA. Later versions of the Trevo® Retriever are called the Modified Trevo® Retriever, the Trevo® ProVue Retriever, and the Modified Trevo® ProVue Retriever; the name Trevo® Retriever is used throughout this protocol. In February 2018, the FDA expanded the indication for the Trevo® Retriever to include patients experiencing acute ischemic stroke up to 24 hours from symptom onset. FDA product code: NRY.

Table 1 FDA-Cleared Mechanical Embolectomy Devices for Acute Stroke

Device	510(k) No. for Original Device	Approval Date for Original Device	Indications
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

FDA: Food and Drug Administration; IV: intravenous; tPA: tissue plasminogen activator.

Intracranial Arterial Stenosis

Two devices were approved by the FDA through the HDE 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; 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 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.[12] Approval was based on the Pipeline for Uncoil-able 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.[13]

Three stents have been approved by the FDA through the HDE process for treatment of intracranial aneurysms.

Neuroform™ Microdelivery Stent System

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

Enterprise™ Vascular Reconstruction Device and Delivery System

In 2007, based on a series of approximately 30 patients with six-month follow-up, the Enterprise™ Vascular Reconstruction Device and Delivery (Cordis Neurovascular) was approved by the FDA through the HDE process (H060001) for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneu-rysms.

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 HDE process (H130005) for use with embolic coils for the treatment of unruptured, wide-neck (neck, ≥ four mm or dome-to-neck ratio, < two), intracranial, saccular aneurysms arising from a parent vessel with a diameter of 2.5 mm or greater and 4.5 mm or smaller.

RELATED PROTOCOL

Extracranial Carotid Artery Stenting

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