



MASSACHUSETTS

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## Medical Policy

# Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

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### Policy Number: 323

BCBSA Reference Number: 2.01.54

NCD/LCD: National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7)

### Related Policies

Carotid, Vertebral and Intracranial Artery Stent Placement with or without Angioplasty, [#219](#)

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

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, eg, wide-neck aneurysms ( $\geq 4$  mm) or a sack-to-neck ratio less than 2:1.

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

\*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.

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; AND
- Have evidence of substantial and clinically significant neurological deficits; AND
- Have evidence of salvageable brain tissue in the affected vascular territory; 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.

This policy only addresses endovascular therapies used on intracranial vessels.

## **Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members**

### **Indications and Limitations of Coverage**

#### **Nationally Covered Indications**

The PTA is covered when used under the following conditions:

#### **Concurrent with Intracranial Stent Placement in FDA-Approved Category B IDE Clinical Trials**

Effective November 6, 2006, Medicare covers PTA and stenting of intracranial arteries for the treatment of cerebral artery stenosis  $\geq 50\%$  in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. CMS determines that coverage of intracranial PTA and stenting is reasonable and necessary under these circumstances.

#### **Nationally Non- Covered Indications**

All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain noncovered. The safety and efficacy of these procedures are not established. All other indications for PTA without stenting for which CMS has not specifically indicated coverage remain noncovered.

[National Coverage Determination \(NCD\) for Percutaneous Transluminal Angioplasty \(PTA\) \(20.7\)](#)

### **Prior Authorization Information**

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required.

Yes indicates that prior authorization is required.

No indicates that prior authorization is not required.

N/A indicates that this service is primarily performed in an inpatient setting.

	<b>Outpatient</b>
<b>Commercial Managed Care (HMO and POS)</b>	N/A
<b>Commercial PPO and Indemnity</b>	N/A
<b>Medicare HMO Blue<sup>SM</sup></b>	N/A
<b>Medicare PPO Blue<sup>SM</sup></b>	N/A

## CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), Indemnity, Medicare HMO Blue and Medicare PPO Blue:

### CPT Codes

CPT codes:	Code Description
61630	Balloon angioplasty, intracranial (e.g., atherosclerotic stenosis), percutaneous
61635	Transcatheter placement of intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed
61645	Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s)

## Description

### 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 devices types of devices (ie, 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.<sup>1</sup> 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 (ie, plaque, fatty material) travels to an artery in the brain causing a blockage (embolism). Recanalization of the artery, particularly in the first few hours after occlusion, reduces rates of disability and death.<sup>2</sup>

#### 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 randomized controlled trials and meta-analyses.<sup>3</sup> Therefore, use of IV tPA in ischemic stroke patients presenting within 3 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 3-hour window.<sup>4</sup>
- **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.<sup>5</sup> 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 (ie, 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 evidence review 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).<sup>6</sup>

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 3 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 (eg, calcium channel blockers) and transluminal balloon angioplasty may be used.<sup>7,8</sup> 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 evidence review.

## **Intracranial Arterial Stenosis**

It is estimated that intracranial atherosclerosis causes about 8% of all ischemic strokes. Intracranial stenosis may contribute to stroke in 2 ways: either due to embolism or low-flow ischemia in the absence of collateral circulation. Recurrent annual stroke rates are estimated at 4% to 12% per year with atherosclerosis of the intracranial anterior circulation and 2.5% to 15% per year with lesions of the posterior (vertebrobasilar) circulation.

### ***Treatment***

Medical treatment typically includes either anticoagulant therapy (ie, warfarin) or antiplatelet therapy (eg, 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.<sup>9</sup> 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 1 study at 45%, with recurrent events within 1 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.<sup>10</sup> 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.<sup>11</sup> 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.

## **Summary**

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.

For individuals who have acute ischemic stroke due to occlusion of an anterior circulation vessel who receive endovascular mechanical embolectomy, the evidence includes randomized clinical trials (RCTs) comparing endovascular therapy with standard care and systematic reviews of these RCTs. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. From 2013 to 2015, 8 RCTs were published comparing endovascular therapies with noninterventional care for acute stroke in patients with anterior circulation occlusions. Several trials that were ongoing at the time of publication of these 8 RCTs were stopped early and results with the limited enrollment have been published. Trials published from 2014 to 2015 demonstrated a significant benefit regarding reduced disability at 90 days posttreatment. The trials that demonstrated a benefit for endovascular therapy either exclusively used stent retriever devices or allowed the treating physician to select a device, mostly a stent retriever device, and had high rates of mechanical embolectomy device use in patients randomized to endovascular therapy. Studies that demonstrated a benefit for endovascular therapy required demonstration of a large vessel, anterior circulation occlusion for enrollment. Also, they were characterized by fast time-to-treatment. 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 2 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 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 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 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 the effects of the technology on health outcomes.

Clinical input obtained in 2011 indicated strong support for the use of stent-assisted coiling for the treatment of aneurysms that are not amenable to surgery or simple coiling. Clinical input obtained in 2014 indicated general support for the use of flow-diverting stents for certain types of aneurysms when surgical treatment is not appropriate.

## Policy History

Date	Action
9/2018	BCBSA National medical policy review. Policy criteria revised to reflect extension of the time window for mechanical thrombectomy up to 24 hours after symptom onset for select patients. Clarified coding information. Effective 9/1/2018.
10/2017	New references added from BCBSA National medical policy.
7/2016	Clarified coding language.
5/2016	New references added from BCBSA National medical policy.
2/2016	BCBSA National medical policy review. Policy statement revised to indicate that mechanical embolectomy for acute stroke may be considered medically necessary with criteria. Effective 2/1/2016.
11/2014	BCBSA National medical policy review. New medically necessary indications described. Clarified coding information. Effective 11/1/2014.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
4/2014	New references added from BCBSA National medical policy.
3/2014	BCBSA National medical policy review. Investigational statement from medical policy 184, Mechanical Embolectomy for Treatment of Acute Stroke added. Effective 3/1/2014. Coding information clarified
1/2014	Coding information clarified
6/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
11/1/2011	New policy, effective 11/1/2011, describing covered and non-covered indication.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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