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 (For Plans internal use only)

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 individuals when surgical treatment is not appropriate and standard endovascular techniques do not allow for complete isolation of the aneurysm, eg, wide-neck aneurysms (≥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 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; **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.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This procedure is performed in the inpatient setting.
Commercial PPO and Indemnity	This procedure is performed in the inpatient setting.

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 performedTranscatheter 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 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 a leading cause of death in the United States; further, it is a leading cause of adult disability.[1] The risk of stroke among Black patients is nearly double the risk among White patients, and Black patients have a higher risk of death due to stroke than other racial groups. Eighty-seven percent of strokes are ischemic and 13% are 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.[2]

Racial differences in the utilization of endovascular therapy for acute stroke have been reported. Sheriff et al (2022) analyzed the Get With The Guidelines-Stroke database; between 2015 and 2019, Black patients had lower odds of receiving endovascular therapy compared to non-Hispanic Whites (adjusted odds ratio [aOR], 0.83; 95% confidence interval [CI], 0.76 to 0.90).[3] At 3 months, functional independence as assessed by the modified Rankin Scale was less common among Black (aOR, 0.84; 95% CI, 0.75 to 0.95) and Asian (aOR, 0.79; 95% CI, 0.65 to 0.98) individuals compared to non-Hispanic Whites. de Havenon et al (2021) found that Black patients were less likely to receive endovascular therapy compared to White patients (odds ratio [OR], 0.75; 95% CI, 0.70 to 0.81) according to National Inpatient Sample data from 2016 to 2018.[4] Kim et al (2022) conducted a retrospective study of 40,814 acute ischemic strokes that occurred in Texas during 2019 which found that Black patients received endovascular therapy less frequently than White patients (4.1% vs. 5.3%, respectively; adjusted relative risk [aRR], 0.76; 95% CI, 0.66 to 0.88; p<.001) despite similar rates of hospital admission.[5] The rate of receipt of endovascular therapy was similar between White and Hispanic patients.

Intracranial Arterial Stenosis

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

Intracranial Aneurysms

Compared with acute ischemic stroke, cerebral aneurysms have a much lower incidence in the United States, with prevalence between 0.5% and 6% of the population.[6] However, they are associated with significant morbidity and mortality due to subarachnoid hemorrhage resulting from aneurysm rupture.

Summary

Description

Intracranial arterial disease includes thromboembolic events, vascular stenoses, and aneurysms. Endovascular techniques have been investigated for the treatment of intracranial arterial disease. Endovascular therapy is used as an alternative or adjunct to intravenous tissue plasminogen activator and supportive care for acute stenosis and as an adjunct to risk-factor modification for chronic stenosis. For cerebral aneurysms, stent-assisted coiling and the use of flow-diverting stents have been evaluated as an alternative to endovascular coiling in patients whose anatomy is not amenable to simple coiling.

Summary of Evidence

For individuals who have an acute ischemic stroke due to occlusion of an anterior circulation vessel who receive endovascular mechanical embolectomy, the evidence includes randomized 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 4 RCTs and systematic reviews of these RCTs and observational studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. Results among these studies are inconsistent for functional outcomes and 90-day mortality. Systematic reviews of both RCTs and observational studies support the efficacy of endovascular therapy for improving functional outcomes and reducing mortality, but rates of symptomatic intracranial hemorrhage are higher with endovascular intervention than with medical therapy. The generalizability of the RCT results may be limited due to lack of inclusion of any U.S. populations. 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 due to atherosclerosis who receive intracranial percutaneous transluminal angioplasty with or without stenting, the evidence includes systematic reviews and 3 major RCTs. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, and treatment-related mortality and morbidity. All 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 3 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 Surpass flow diverter device. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
1/2025	Clarified prior authorization table.
6/2024	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2023	Annual policy review. Minor editorial refinements to policy statements; intent unchanged.
6/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
6/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2018	Annual 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 Annual policy review.
7/2016	Clarified coding language.
5/2016	New references added from Annual policy review.
2/2016	Annual 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	Annual 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 Annual policy review.
3/2014	Annual 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 Annual policy review.
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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