

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

•

Table of Contents

- Policy: Commercial
- Policy: Medicare
- <u>Authorization Information</u>
- <u>Coding Information</u>
 - **Description**
- Policy History

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 <u>MEDICALLY NECESSARY</u> 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 <u>MEDICALLY NECESSARY</u> 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 **<u>INVESTIGATIONAL</u>** 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 <u>MEDICALLY NECESSARY</u> as part of the treatment of acute ischemic stroke for individuals who meet all of the following criteria:

- Information Pertaining to All Policies
- <u>References</u>

- 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 <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

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

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .

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 <u>medical necessity criteria MUST</u> 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
	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
61635	angioplasty, if performed
	Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological
61645	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 (ie, stents), and angioplasty with or without stenting have been investigated for the treatment of cerebrovascular diseases.

Acute Stroke

Acute stroke is the fifth leading cause of death in the United States; further, it is a leading cause of adult disability.¹The 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 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 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.

Policy History

Date	Action
6/2023	Annual policy review. Minor editorial refinements to policy statements; intent unchanged.
6/2022	Annual policy review. Description, summary, and references updated. Policy
= /2.2.2.4	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
1/2021	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

<u>Clinical Exception Process</u> Medical Technology Assessment Guidelines

References

- 1. U.S. Centers for Disease Control and Prevention. Stroke facts. October 14, 2022. https://www.cdc.gov/stroke/facts.htm. Accessed February 21, 2023.
- 2. Rha JH, Saver JL. The impact of recanalization on ischemic stroke outcome: a meta-analysis. Stroke. Mar 2007; 38(3): 967-73. PMID 17272772
- 3. Sheriff F, Xu H, Maud A, et al. Temporal Trends in Racial and Ethnic Disparities in Endovascular Therapy in Acute Ischemic Stroke. J Am Heart Assoc. Mar 15 2022; 11(6): e023212. PMID 35229659
- de Havenon A, Sheth K, Johnston KC, et al. Acute Ischemic Stroke Interventions in the United States and Racial, Socioeconomic, and Geographic Disparities. Neurology. Dec 07 2021; 97(23): e2292e2303. PMID 34649872
- Kim Y, Sharrief A, Kwak MJ, et al. Underutilization of Endovascular Therapy in Black Patients With Ischemic Stroke: An Analysis of State and Nationwide Cohorts. Stroke. Mar 2022; 53(3): 855-863. PMID 35067099
- Meyers PM, Schumacher HC, Higashida RT, et al. Indications for the performance of intracranial endovascular neurointerventional procedures: a scientific statement from the American Heart Association Council on Cardiovascular Radiology and Intervention, Stroke Council, Council on Cardiovascular Surgery and Anesthesia, Interdisciplinary Council on Peripheral Vascular Disease, and Interdisciplinary Council on Quality of Care and Outcomes Research. Circulation. Apr 28 2009; 119(16): 2235-49. PMID 19349327
- 7. Food and Drug Administration (FDA). Summary of Safety and Effectiveness: PipelineTM Embolization Device. 2011; https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100018b.pdf. Accessed February 17, 2023.
- 8. Becske T, Kallmes DF, Saatci I, et al. Pipeline for uncoilable or failed aneurysms: results from a multicenter clinical trial. Radiology. Jun 2013; 267(3): 858-68. PMID 23418004
- Kahles T, Garcia-Esperon C, Zeller S, et al. Mechanical Thrombectomy Using the New ERIC Retrieval Device Is Feasible, Efficient, and Safe in Acute Ischemic Stroke: A Swiss Stroke Center Experience. AJNR Am J Neuroradiol. Jan 2016; 37(1): 114-9. PMID 26294644
- 10. Vizient. Vascular technologies. Coronary, peripheral, and neurovascular devices. Technology watch. 2019. https://www.vizientinc.com/our-solutions/supply-chain-solutions/tech-watch. Accessed February 21, 2023.
- Abruzzo T, Moran C, Blackham KA, et al. Invasive interventional management of post-hemorrhagic cerebral vasospasm in patients with aneurysmal subarachnoid hemorrhage. J Neurointerv Surg. May 2012; 4(3): 169-77. PMID 22374130
- 12. Diringer MN, Bleck TP, Claude Hemphill J, et al. Critical care management of patients following aneurysmal subarachnoid hemorrhage: recommendations from the Neurocritical Care Society's Multidisciplinary Consensus Conference. Neurocrit Care. Sep 2011; 15(2): 211-40. PMID 21773873
- 13. Schwamm LH, Ali SF, Reeves MJ, et al. Temporal trends in patient characteristics and treatment with intravenous thrombolysis among acute ischemic stroke patients at Get With The Guidelines-Stroke hospitals. Circ Cardiovasc Qual Outcomes. Sep 01 2013; 6(5): 543-9. PMID 24046398
- 14. Bhatia R, Hill MD, Shobha N, et al. Low rates of acute recanalization with intravenous recombinant tissue plasminogen activator in ischemic stroke: real-world experience and a call for action. Stroke. Oct 2010; 41(10): 2254-8. PMID 20829513
- 15. Badhiwala JH, Nassiri F, Alhazzani W, et al. Endovascular Thrombectomy for Acute Ischemic Stroke: A Meta-analysis. JAMA. Nov 03 2015; 314(17): 1832-43. PMID 26529161
- 16. Ciccone A, Valvassori L, Nichelatti M, et al. Endovascular treatment for acute ischemic stroke. N Engl J Med. Mar 07 2013; 368(10): 904-13. PMID 23387822
- 17. Kidwell CS, Jahan R, Gornbein J, et al. A trial of imaging selection and endovascular treatment for ischemic stroke. N Engl J Med. Mar 07 2013; 368(10): 914-23. PMID 23394476
- 18. Broderick JP, Palesch YY, Demchuk AM, et al. Endovascular therapy after intravenous t-PA versus t-PA alone for stroke. N Engl J Med. Mar 07 2013; 368(10): 893-903. PMID 23390923
- 19. Berkhemer OA, Fransen PS, Beumer D, et al. A randomized trial of intraarterial treatment for acute ischemic stroke. N Engl J Med. Jan 01 2015; 372(1): 11-20. PMID 25517348

- 20. Goyal M, Demchuk AM, Menon BK, et al. Randomized assessment of rapid endovascular treatment of ischemic stroke. N Engl J Med. Mar 12 2015; 372(11): 1019-30. PMID 25671798
- 21. Campbell BC, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusionimaging selection. N Engl J Med. Mar 12 2015; 372(11): 1009-18. PMID 25671797
- 22. Saver JL, Goyal M, Bonafe A, et al. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. N Engl J Med. Jun 11 2015; 372(24): 2285-95. PMID 25882376
- 23. Jovin TG, Chamorro A, Cobo E, et al. Thrombectomy within 8 hours after symptom onset in ischemic stroke. N Engl J Med. Jun 11 2015; 372(24): 2296-306. PMID 25882510
- 24. Chen CJ, Ding D, Starke RM, et al. Endovascular vs medical management of acute ischemic stroke. Neurology. Dec 01 2015; 85(22): 1980-90. PMID 26537058
- Roaldsen MB, Jusufovic M, Berge E, et al. Endovascular thrombectomy and intra-arterial interventions for acute ischaemic stroke. Cochrane Database Syst Rev. Jun 14 2021; 6(6): CD007574. PMID 34125952
- Bush CK, Kurimella D, Cross LJ, et al. Endovascular Treatment with Stent-Retriever Devices for Acute Ischemic Stroke: A Meta-Analysis of Randomized Controlled Trials. PLoS One. 2016; 11(1): e0147287. PMID 26807742
- Hong KS, Ko SB, Lee JS, et al. Endovascular Recanalization Therapy in Acute Ischemic Stroke: Updated Meta-analysis of Randomized Controlled Trials. J Stroke. Sep 2015; 17(3): 268-81. PMID 26437993
- 28. Kennedy SA, Baerlocher MO, Baerlocher F, et al. Meta-Analysis of Local Endovascular Therapy for Acute Ischemic Stroke. J Vasc Interv Radiol. Mar 2016; 27(3): 307-21.e2. PMID 26803573
- Grech R, Schembri M, Thornton J. Stent-based thrombectomy versus intravenous tissue plasminogen activator in acute ischaemic stroke: A systematic review and meta-analysis. Interv Neuroradiol. Dec 2015; 21(6): 684-90. PMID 26490828
- Marmagkiolis K, Hakeem A, Cilingiroglu M, et al. Safety and Efficacy of Stent Retrievers for the Management of Acute Ischemic Stroke: Comprehensive Review and Meta-Analysis. JACC Cardiovasc Interv. Nov 2015; 8(13): 1758-65. PMID 26476611
- Touma L, Filion KB, Sterling LH, et al. Stent Retrievers for the Treatment of Acute Ischemic Stroke: A Systematic Review and Meta-analysis of Randomized Clinical Trials. JAMA Neurol. Mar 2016; 73(3): 275-81. PMID 26810499
- 32. Martins SO, Mont'Alverne F, Rebello LC, et al. Thrombectomy for Stroke in the Public Health Care System of Brazil. N Engl J Med. Jun 11 2020; 382(24): 2316-2326. PMID 32521133
- 33. Albers GW, Marks MP, Kemp S, et al. Thrombectomy for Stroke at 6 to 16 Hours with Selection by Perfusion Imaging. N Engl J Med. Feb 22 2018; 378(8): 708-718. PMID 29364767
- 34. Nogueira RG, Jadhav AP, Haussen DC, et al. Thrombectomy 6 to 24 Hours after Stroke with a Mismatch between Deficit and Infarct. N Engl J Med. Jan 04 2018; 378(1): 11-21. PMID 29129157
- Khoury NN, Darsaut TE, Ghostine J, et al. Endovascular thrombectomy and medical therapy versus medical therapy alone in acute stroke: A randomized care trial. J Neuroradiol. Jun 2017; 44(3): 198-202. PMID 28238522
- Muir KW, Ford GA, Messow CM, et al. Endovascular therapy for acute ischaemic stroke: the Pragmatic Ischaemic Stroke Thrombectomy Evaluation (PISTE) randomised, controlled trial. J Neurol Neurosurg Psychiatry. Jan 2017; 88(1): 38-44. PMID 27756804
- 37. Mocco J, Zaidat OO, von Kummer R, et al. Aspiration Thrombectomy After Intravenous Alteplase Versus Intravenous Alteplase Alone. Stroke. Sep 2016; 47(9): 2331-8. PMID 27486173
- Bracard S, Ducrocq X, Mas JL, et al. Mechanical thrombectomy after intravenous alteplase versus alteplase alone after stroke (THRACE): a randomised controlled trial. Lancet Neurol. Oct 2016; 15(11): 1138-47. PMID 27567239
- 39. Tomsick TA, Yeatts SD, Liebeskind DS, et al. Endovascular revascularization results in IMS III: intracranial ICA and M1 occlusions. J Neurointerv Surg. Nov 2015; 7(11): 795-802. PMID 25342652
- Demchuk AM, Goyal M, Yeatts SD, et al. Recanalization and clinical outcome of occlusion sites at baseline CT angiography in the Interventional Management of Stroke III trial. Radiology. Oct 2014; 273(1): 202-10. PMID 24895878
- Tekle WG, Hassan AE, Jadhav AP, et al. Impact of Periprocedural and Technical Factors and Patient Characteristics on Revascularization and Outcome in the DAWN Trial. Stroke. Jan 2020; 51(1): 247-253. PMID 31744425

- 42. Jovin TG, Nogueira RG, Lansberg MG, et al. Thrombectomy for anterior circulation stroke beyond 6 h from time last known well (AURORA): a systematic review and individual patient data meta-analysis. Lancet. Jan 15 2022; 399(10321): 249-258. PMID 34774198
- 43. Saver JL, Jahan R, Levy EI, et al. Solitaire flow restoration device versus the Merci Retriever in patients with acute ischaemic stroke (SWIFT): a randomised, parallel-group, non-inferiority trial. Lancet. Oct 06 2012; 380(9849): 1241-9. PMID 22932715
- Akins PT, Amar AP, Pakbaz RS, et al. Complications of endovascular treatment for acute stroke in the SWIFT trial with solitaire and Merci devices. AJNR Am J Neuroradiol. Mar 2014; 35(3): 524-8. PMID 24029392
- 45. Nogueira RG, Lutsep HL, Gupta R, et al. Trevo versus Merci retrievers for thrombectomy revascularisation of large vessel occlusions in acute ischaemic stroke (TREVO 2): a randomised trial. Lancet. Oct 06 2012; 380(9849): 1231-40. PMID 22932714
- 46. Saposnik G, Lebovic G, Demchuk A, et al. Added Benefit of Stent Retriever Technology for Acute Ischemic Stroke: A Pooled Analysis of the NINDS tPA, SWIFT, and STAR Trials. Neurosurgery. Sep 2015; 77(3): 454-61. PMID 26280825
- Pereira VM, Gralla J, Davalos A, et al. Prospective, multicenter, single-arm study of mechanical thrombectomy using Solitaire Flow Restoration in acute ischemic stroke. Stroke. Oct 2013; 44(10): 2802-7. PMID 23908066
- Nogueira RG, Frei D, Kirmani JF, et al. Safety and Efficacy of a 3-Dimensional Stent Retriever With Aspiration-Based Thrombectomy vs Aspiration-Based Thrombectomy Alone in Acute Ischemic Stroke Intervention: A Randomized Clinical Trial. JAMA Neurol. Mar 01 2018; 75(3): 304-311. PMID 29296999
- Cao J, Lin H, Lin M, et al. RECO Flow Restoration Device Versus Solitaire FR With the Intention for Thrombectomy Study (REDIRECT): a prospective randomized controlled trial. J Neurosurg. Jun 05 2020; 134(5): 1569-1577. PMID 32502991
- 50. Mattle HP, Arnold M, Lindsberg PJ, et al. Basilar artery occlusion. Lancet Neurol. Nov 2011; 10(11): 1002-14. PMID 22014435
- Schonewille WJ, Wijman CA, Michel P, et al. Treatment and outcomes of acute basilar artery occlusion in the Basilar Artery International Cooperation Study (BASICS): a prospective registry study. Lancet Neurol. Aug 2009; 8(8): 724-30. PMID 19577962
- Liu X, Dai Q, Ye R, et al. Endovascular treatment versus standard medical treatment for vertebrobasilar artery occlusion (BEST): an open-label, randomised controlled trial. Lancet Neurol. Feb 2020; 19(2): 115-122. PMID 31831388
- Bose A, Hartmann M, Henkes H, et al. A novel, self-expanding, nitinol stent in medically refractory intracranial atherosclerotic stenoses: the Wingspan study. Stroke. May 2007; 38(5): 1531-7. PMID 17395864
- 54. Chimowitz MI, Lynn MJ, Howlett-Smith H, et al. Comparison of warfarin and aspirin for symptomatic intracranial arterial stenosis. N Engl J Med. Mar 31 2005; 352(13): 1305-16. PMID 15800226
- EC/IC Bypass Study Group. Failure of extracranial-intracranial arterial bypass to reduce the risk of ischemic stroke. Results of an international randomized trial. N Engl J Med. Nov 07 1985; 313(19): 1191-200. PMID 2865674
- Luo J, Wang T, Yang K, et al. Endovascular therapy versus medical treatment for symptomatic intracranial artery stenosis. Cochrane Database Syst Rev. Feb 03 2023; 2(2): CD013267. PMID 36738471
- 57. Zaidat OO, Fitzsimmons BF, Woodward BK, et al. Effect of a balloon-expandable intracranial stent vs medical therapy on risk of stroke in patients with symptomatic intracranial stenosis: the VISSIT randomized clinical trial. JAMA. Mar 2015; 313(12): 1240-8. PMID 25803346
- 58. Chimowitz MI, Lynn MJ, Derdeyn CP, et al. Stenting versus aggressive medical therapy for intracranial arterial stenosis. N Engl J Med. Sep 15 2011; 365(11): 993-1003. PMID 21899409
- 59. Derdeyn CP, Chimowitz MI, Lynn MJ, et al. Aggressive medical treatment with or without stenting in high-risk patients with intracranial artery stenosis (SAMMPRIS): the final results of a randomised trial. Lancet. Jan 25 2014; 383(9914): 333-41. PMID 24168957
- 60. Lutsep HL, Barnwell SL, Larsen DT, et al. Outcome in patients previously on antithrombotic therapy in the SAMMPRIS trial: subgroup analysis. Stroke. Mar 2015; 46(3): 775-9. PMID 25593135

- Lutsep HL, Lynn MJ, Cotsonis GA, et al. Does the Stenting Versus Aggressive Medical Therapy Trial Support Stenting for Subgroups With Intracranial Stenosis?. Stroke. Nov 2015; 46(11): 3282-4. PMID 26382173
- Coward LJ, McCabe DJ, Ederle J, et al. Long-term outcome after angioplasty and stenting for symptomatic vertebral artery stenosis compared with medical treatment in the Carotid And Vertebral Artery Transluminal Angioplasty Study (CAVATAS): a randomized trial. Stroke. May 2007; 38(5): 1526-30. PMID 17395869
- Qureshi AI, Chaudhry SA, Siddiq F, et al. A randomized trial comparing primary angioplasty versus stent placement for symptomatic intracranial stenosis. J Vasc Interv Neurol. Dec 2013; 6(2): 34-41. PMID 24358415
- 64. Alexander MJ, Zauner A, Chaloupka JC, et al. WEAVE Trial: Final Results in 152 On-Label Patients. Stroke. Apr 2019; 50(4): 889-894. PMID 31125298
- 65. Food and Drug Administration. FDA Executive Summary General Issues: Meeting to Discuss the Evaluation of Safety and Effectiveness of Endovascular Medical Devices Intended to Treat Intracranial Aneurysms. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesPanel/UCM598459.pdf. Accessed February
- 20, 2023. 66. Hong Y, Wang YJ, Deng Z, et al. Stent-assisted coiling versus coiling in treatment of intracranial
- 66. Hong Y, Wang YJ, Deng Z, et al. Stent-assisted colling versus colling in treatment of intracranial aneurysm: a systematic review and meta-analysis. PLoS One. 2014; 9(1): e82311. PMID 24454690
 67. Dwy CIM, Dark S, Ship HS, et al. Complications in Start Assisted Colling in Treatment of Intracranial aneurysm: a systematic review and meta-analysis. PLoS One. 2014; 9(1): e82311. PMID 24454690
- Ryu CW, Park S, Shin HS, et al. Complications in Stent-Assisted Endovascular Therapy of Ruptured Intracranial Aneurysms and Relevance to Antiplatelet Administration: A Systematic Review. AJNR Am J Neuroradiol. Sep 2015; 36(9): 1682-8. PMID 26138136
- Piotin M, Blanc R, Spelle L, et al. Stent-assisted coiling of intracranial aneurysms: clinical and angiographic results in 216 consecutive aneurysms. Stroke. Jan 2010; 41(1): 110-5. PMID 19959540
- 69. Hetts SW, Turk A, English JD, et al. Stent-assisted coiling versus coiling alone in unruptured intracranial aneurysms in the matrix and platinum science trial: safety, efficacy, and mid-term outcomes. AJNR Am J Neuroradiol. Apr 2014; 35(4): 698-705. PMID 24184523
- 70. Consoli A, Vignoli C, Renieri L, et al. Assisted coiling of saccular wide-necked unruptured intracranial aneurysms: stent versus balloon. J Neurointerv Surg. Jan 2016; 8(1): 52-7. PMID 25428449
- 71. Liu YQ, Wang QJ, Zheng T, et al. Single-centre comparison of procedural complications, clinical outcome, and angiographic follow-up between coiling and stent-assisted coiling for posterior communicating artery aneurysms. J Clin Neurosci. Dec 2014; 21(12): 2140-4. PMID 25037315
- King B, Vaziri S, Singla A, et al. Clinical and angiographic outcomes after stent-assisted coiling of cerebral aneurysms with Enterprise and Neuroform stents: a comparative analysis of the literature. J Neurointerv Surg. Dec 2015; 7(12): 905-9. PMID 25352581
- Geyik S, Yavuz K, Yurttutan N, et al. Stent-assisted coiling in endovascular treatment of 500 consecutive cerebral aneurysms with long-term follow-up. AJNR Am J Neuroradiol. 2013; 34(11): 2157-62. PMID 23886748
- Lee KM, Jo KI, Jeon P, et al. Predictor and Prognosis of Procedural Rupture during Coil Embolization for Unruptured Intracranial Aneurysm. J Korean Neurosurg Soc. Jan 2016; 59(1): 6-10. PMID 26885280
- 75. Jankowitz BT, Hanel R, Jadhav AP, et al. Neuroform Atlas Stent System for the treatment of intracranial aneurysm: primary results of the Atlas Humanitarian Device Exemption cohort. J Neurointerv Surg. Aug 2019; 11(8): 801-806. PMID 30670625
- Food and Drug Administration (FDA). SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED): Neuroform Atlas Stent System (P180031). 2019. https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180031B.pdf Accessed February 16, 2023.
- 77. Fiorella D, Boulos A, Turk AS, et al. The safety and effectiveness of the LVIS stent system for the treatment of wide-necked cerebral aneurysms: final results of the pivotal US LVIS trial. J Neurointerv Surg. Apr 2019; 11(4): 357-361. PMID 30297543
- 78. Food and Drug Administration (FDA). SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED): Low-Profile Visualized Intraluminal Support (LVIS) and LVIS Jr (P170013). 2018. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170013B.pdf. Accessed February 15, 2023.

- 79. Feng Z, Fang Y, Xu Y, et al. The safety and efficacy of low profile visualized intraluminal support (LVIS) stents in assisting coil embolization of intracranial saccular aneurysms: a single center experience. J Neurointerv Surg. Nov 2016; 8(11): 1192-1196. PMID 26747876
- Aydin K, Arat A, Sencer S, et al. Stent-Assisted Coiling of Wide-Neck Intracranial Aneurysms Using Low-Profile LEO Baby Stents: Initial and Midterm Results. AJNR Am J Neuroradiol. Oct 2015; 36(10): 1934-41. PMID 26021624
- 81. Chalouhi N, Jabbour P, Starke RM, et al. Endovascular treatment of proximal and distal posterior inferior cerebellar artery aneurysms. J Neurosurg. May 2013; 118(5): 991-9. PMID 23350778
- 82. Chen Z, Yang Y, Miao H, et al. Endovascular treatment for large and giant fusiform aneurysms of the vertebrobasilar arteries. Clin Imaging. 2013; 37(2): 227-31. PMID 23465972
- Gentric JC, Biondi A, Piotin M, et al. Safety and efficacy of neuroform for treatment of intracranial aneurysms: a prospective, consecutive, French multicentric study. AJNR Am J Neuroradiol. 2013; 34(6): 1203-8. PMID 23348764
- 84. Johnson AK, Heiferman DM, Lopes DK. Stent-assisted embolization of 100 middle cerebral artery aneurysms. J Neurosurg. May 2013; 118(5): 950-5. PMID 23394339
- Kulcsár Z, Göricke SL, Gizewski ER, et al. Neuroform stent-assisted treatment of intracranial aneurysms: long-term follow-up study of aneurysm recurrence and in-stent stenosis rates. Neuroradiology. Mar 2013; 55(4): 459-65. PMID 23358878
- 86. Food and Drug Administration. PMA P170024: Summary of Safety and Effectiveness (SSED). Intracranial Aneurysm Flow Diverter. 2018.

https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170024B.pdf. Accessed February 21, 2023.

- Zhou G, Zhu YQ, Su M, et al. Flow-Diverting Devices versus Coil Embolization for Intracranial Aneurysms: A Systematic Literature Review and Meta-analysis. World Neurosurg. Apr 2016; 88: 640-645. PMID 26585732
- 88. Xin WQ, Xin QQ, Yuan Y, et al. Comparison of Flow Diversion and Coiling for the Treatment of Unruptured Intracranial Aneurysms. World Neurosurg. Aug 2019; 128: 464-472. PMID 31132489
- 89. Raymond J, Gentric JC, Darsaut TE, et al. Flow diversion in the treatment of aneurysms: a randomized care trial and registry. J Neurosurg. Sep 2017; 127(3): 454-462. PMID 27813466
- 90. Kiselev R, Orlov K, Dubovoy A, et al. Flow diversion versus parent artery occlusion with bypass in the treatment of complex intracranial aneurysms: Immediate and short-term outcomes of the randomized trial. Clin Neurol Neurosurg. Sep 2018; 172: 183-189. PMID 30053620
- 91. Kan P, Mohanty A, Meyers PM, et al. Treatment of large and giant posterior communicating artery aneurysms with the Surpass streamline flow diverter: results from the SCENT trial. J Neurointerv Surg. May 12 2022. PMID 35551072
- Hanel RA, Cortez GM, Coon AL, et al. Surpass Intracranial Aneurysm Embolization System Pivotal Trial to Treat Large or Giant Wide-Neck Aneurysms - SCENT: 3-year outcomes. J Neurointerv Surg. Nov 14 2022. PMID 36375835
- 93. English JD, Yavagal DR, Gupta R, et al. Mechanical Thrombectomy-Ready Comprehensive Stroke Center Requirements and Endovascular Stroke Systems of Care: Recommendations from the Endovascular Stroke Standards Committee of the Society of Vascular and Interventional Neurology (SVIN). Interv Neurol. Mar 2016; 4(3-4): 138-50. PMID 27051410
- 94. Powers WJ, Rabinstein AA, Ackerson T, et al. 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. Stroke. Mar 2018; 49(3): e46-e110. PMID 29367334
- 95. Powers WJ, Rabinstein AA, Ackerson T, et al. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. Stroke. Dec 2019; 50(12): e344-e418. PMID 31662037
- 96. Thompson BG, Brown RD, Amin-Hanjani S, et al. Guidelines for the Management of Patients With Unruptured Intracranial Aneurysms: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. Stroke. Aug 2015; 46(8): 2368-400. PMID 26089327
- 97. Ganesh A, Fraser JF, Gordon Perue GL, et al. Endovascular Treatment and Thrombolysis for Acute Ischemic Stroke in Patients With Premorbid Disability or Dementia: A Scientific Statement From the American Heart Association/American Stroke Association. Stroke. May 2022; 53(5): e204-e217. PMID 35343235

98. Center for Medicare & Medicaid Services. Decision Memo for Intracranial Stenting and Angioplasty (CAG- 00085R5). 2008; https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=214&fromdb=true. Accessed February 21, 2023.