

# MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)
Policy Number	7.01.82
Category	Technology Assessment
Effective Date	12/18/08
Revised Date	11/19/09, 11/18/10, 10/20/11, 09/20/12, 10/17/13, 09/18/14, 09/17/15, 08/18/16, 08/17/17, 07/19/18, 08/15/19
Product Disclaimer	<ul style="list-style-type: none"> <li>• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</li> <li>• If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</li> </ul>

## POLICY STATEMENT

Based upon our criteria and review of the peer-reviewed literature;

I. Endovascular treatment of acute ischemic stroke (e.g., mechanical embolectomy, microcatheter/ microwire clot maceration, percutaneous angioplasty [PTA], or stent deployment) may be considered a **medically appropriate** treatment option only for selected patients with angiographically documented occlusion and profound neurological deficits and only when performed in an institution with a multidisciplinary stroke team (*See Policy Guideline II below*).

II. Endovascular treatment of acute ischemic stroke for all other patients is considered **investigational**.

*Refer to Corporate Medical Policy # 7.01.60 regarding Extracranial Carotid and Vertebral Artery Angioplasty and Stents.*

*Refer to Corporate Medical Policy # 7.01.70 regarding Angioplasty of Intracranial Atherosclerotic Stenoses with or without Stenting*

*Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services.*

*Refer to Corporate Medical Policy #11.01.10 regarding Clinical Trials.*

## POLICY GUIDELINES

I. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

II. Covered procedures must be performed at a facility:

A. Recognized by the New York State Department of Health or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as a designated stroke center, and

B. Have 24 hour/day 7 days/week availability of a multidisciplinary stroke team that includes a neuroendovascular interventionalist.

## DESCRIPTION

Approximately 750,000 strokes occur in the US annually. Some strokes are caused by emboli and frequently present as acute neurologic emergencies. Intravenous tissue plasminogen activator (tPA) given within 3 hours of symptom onset is currently the only FDA approved treatment for acute ischemic stroke. However, many patients fail or are not candidates for tPA due to time of presentation for treatment or contraindications to thrombolytic therapy. Several endovascular

## **Medical Policy: ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)**

**Policy Number: 7.01.82**

**Page: 2 of 12**

treatments, including mechanical clot disruption via microcatheter/ microwire clot maceration, percutaneous angioplasty (PTA), stent deployment, or use of a snare device have been proposed as treatments for this population. The most studied of these procedures is mechanical embolectomy using the Merci Retriever.

### **RATIONALE**

The Merci Retriever was cleared by the FDA in August 2004 through the 510(k) process. The FDA clearance indicated that the MERCI Clinical Study established that no new issues of safety and effectiveness exist when the Merci Retriever is used for thrombus removal versus foreign body removal from the neurovasculature. A modified Merci Retriever, also manufactured by Concentric Medical, Inc., received 510(k) clearance from the FDA in May 2006. The clearance notes that the Modified Merci Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. Patients who are ineligible for treatment with IV t-PA therapy or who fail IV t-PA therapy are candidates for treatment. The Merci Retriever has clearance for retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.

Support for use of the Merci Retrieval System comes from the MERCI (Mechanical Embolus Removal in Cerebral Ischemia) trial. This was a prospective, nonrandomized, multicenter trial for patients with symptoms of acute stroke for less than 8 hours who were not candidates for thrombolytic therapy, either because of contraindications (approximately 25%) or because symptoms were present for more than 3 hours. Of the 151 patients enrolled in the trial, 141 had the device deployed. Recanalization was achieved in 46% (69/151) of patients on intention to treat analysis, and in 48% (68/141) of patients in whom the device was deployed. Clinically significant procedural complications occurred in 10 of 141 (7.1%) patients and symptomatic intracranial hemorrhages were observed in 11 (7.8%). Good neurological outcomes were more frequent at 90 days in those with successful recanalization compared to those with unsuccessful recanalization (46% vs. 10%,  $p$  less than 0.0001) and mortality was less (32% vs. 54%,  $p$  equal to 0.01). This rate is significantly higher than that expected using a historical control (PROACT II trial) of 18% ( $P$  less than 0.0001). Of note, in the study up to 6 passes could be made to remove the clot, and at least 2 devices were used in each patient in the MERCI trial. Overall mortality in the MERCI trial was 44%. The study fails to confirm that the flow restoration is due to thrombus removal (embolectomy), as opposed to clot disruption with proximal revascularization and distal embolization.

Two randomized controlled trials (RCTs) evaluating the efficacy of endovascular treatment for acute ischemic stroke were published in 2013. The IMS III trial was an open-label RCT with a planned enrollment of 900 patients (Broderick, et al.). This trial enrolled patients with acute ischemic stroke who presented within 3 hours of symptom onset and had a moderate to severe neurologic deficit on presentation. Patients were randomized to intravenous tissue plasminogen activator (tPA) alone or intravenous tPA plus endovascular intervention. Patients randomized to the endovascular group underwent immediate angiography followed by endovascular intervention if a treatable vascular occlusion was present. Endovascular intervention consisted of either endovascular delivery of tPA at the site of occlusion or mechanical thrombectomy, at the discretion of the treating physician. The primary outcome was a modified Rankin score of 2 or less at 90 days. The trial was stopped prematurely due to futility after enrollment of 656 patients. At this point, the primary outcome had been reached by 40.8% of patients in the endovascular group compared with 38.7% of patients in the intravenous tPA group. The adjusted difference in the primary outcome was 1.5%, with a 95% confidence interval (CI) for the difference of -6.1 to 9.1. Subarachnoid hemorrhage was more frequent in the endovascular group compared to the tPA group (11.5% vs. 5.8%,  $p=0.02$ ), as was asymptomatic intracerebral hemorrhage (27.4% vs. 18.9%,  $p=0.01$ ). There were no significant differences between groups in other adverse events, including death and symptomatic intracerebral hemorrhage.

The second RCT, by Ciccone and colleagues randomized 362 patients with acute ischemic stroke presenting within 4.5 hours of symptom onset to intravenous tPA or endovascular treatment. Endovascular treatment consisted of either endovascular delivery of tPA at the site of thrombosis, mechanical thrombectomy, or both. The choice of endovascular intervention was at the discretion of the treating physician, based on results of angiography. The trial was unblinded to treatment assignment, but did include blinded endpoint assessment. The primary outcome was disability-free survival at 90 days, defined as a survival with a modified Rankin score of 0 or 1. At 90 days of follow-up, the proportion of patients with disability-free survival was 30.4% in the endovascular group and 34.8% in the intravenous tPA group. On multivariate analysis, the odds ratio for disability-free survival with endovascular treatment was 0.71 (95% CI: 0.44-1.14,  $p=0.16$ ). There were no significant differences in adverse events at 7 days, including intracerebral hemorrhage and

## **Medical Policy: ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)**

**Policy Number: 7.01.82**

**Page: 3 of 12**

neurologic deterioration. Subgroup analysis did not reveal any patient subgroups in which endovascular treatment was superior to tPA.

The primary results of the MR RESCUE trial (Randomized Trial of Neuroimaging Selection for mechanical embolectomy versus standard care for acute ischemic stroke) was presented at the February 2013 International Stroke Conference by CS Kidwell. In this phase 2b, multicenter, controlled, blinded outcome study, the researchers randomly assigned 118 eligible patients within 8 hours of the onset of large-vessel, anterior circulation strokes to undergo mechanical embolectomy with the Merci Retriever or the Penumbra System or to receive standard care. All patients underwent multimodal CT or MRI before treatment, and randomization was stratified by whether they had a favorable penumbral pattern or a nonpenumbral pattern (a large infarct core with a small or no penumbra). Patients who had received intravenous thrombolysis were allowed into the trial if vessel imaging after treatment showed a persistent target occlusion. Clinical outcomes were assessed by using the modified Rankin Scale (mRS). The mean age of patients was 65.5 years, mean time to enrollment was 5.5 hours, and 58% of patients had a favorable penumbral pattern. Revascularization in the embolectomy group was achieved in 67% of patients. At 90 days, mortality was 21% in the overall group, the rate of symptomatic intracranial hemorrhage was 4%, and neither outcome differed between groups. "For the primary hypothesis, there was no significant interaction between treatment assignment and penumbral pattern by shift analysis of the day 90 modified Rankin score. As such, MR RESCUE failed to demonstrate that penumbral imaging identifies patients who will differentially benefit from endovascular therapy for acute ischemic stroke."

Because intravenous (IV) recombinant tissue plasminogen activator (rtPA) does not always lead to a good outcome in a considerable proportion of patients, combined IV rtPA and rescue endovascular therapy (ET) have been performed in several recent studies. Other studies have evaluated mechanical endovascular treatments for patients who are not candidates for rtPA. Based on the acute nature of these neurologic emergencies most studies reported are relatively small, retrospective case series. Some have compared outcomes to matched historical controls.

A review by Lutsep (2008) compares recent trials using mechanical endovascular therapies to treat acute stroke. The Multi Mechanical Embolus Removal in Cerebral Ischemia trial showed that good revascularization success could be obtained using the Merci retrievers within 8 h of symptom onset. In patients with persistent vascular occlusions despite intravenous tissue plasminogen activator, mechanical embolectomy appeared to be safe.

In September 2007, the FDA granted 510(k) marketing clearance to the Penumbra System™. Penumbra System (Penumbra Inc., San Leandro, California, USA) first aspirates clot and then employs clot extraction if needed. A feasibility study and a single-arm trial were recently completed. In the feasibility study, the first 20 patients treated with the device had occlusions located in the MCA, internal carotid and basilar arteries. The primary occlusion was recanalized in 100% of cases. Intra-arterial tPA or urokinase was used to treat occlusions distal to the primary occlusion in 35% of (7/20) cases. Good outcomes (4-point improvement on the NIHSS) were observed in 42% of patients and 45% died. A single-arm study of 125 patients at 35 centers in Europe and the USA included patients aged between 18 and 79 years with an NIHSS score of 8 or more presenting within 8 hours of symptom onset. Patients refractory to intravenous tPA were eligible. Success criteria included a 48% or more revascularization rate and device related serious adverse event rate of 15% or less. R Tarr and colleagues (2009) assessed the post-market experience of the Penumbra System in a retrospective case review of 139 patients at seven international centers. After use of the Penumbra System, 84% of the treated vessels to TIMI 2 or 3. At discharge, 34% of patients had a NIHSS score of 0-1 or an improvement of at least 10 points. Eight procedural serious adverse events were reported in 139 patients; there were a total of 10 symptomatic intracerebral hemorrhage reported at 24 hours. To date, all-cause mortality is 23%. Of the 110 patients who have died or reached 90-day follow-up, 40% had a modified Rankin Scale score less than 2. Patients who were successfully revascularized by the Penumbra System had significantly better outcomes than those who were not.

A systematic review and meta-analysis by Stead, et al. (2008) of mechanical thrombectomy in the treatment of ischemic stroke and assessed factors for technical and clinical success and survival. The pooled cohort was compared with a historical cohort matched for sex, age, and National Institutes of Health Stroke Survey score. The search yielded 114 publications. Mean preprocedure National Institutes of Health Stroke Survey (NIHSS) score was 20.4. The middle cerebral artery (36%) and the posterior circulation (38%) were the most frequently occluded areas. The clot was accessible in 85% of the patients. Hemorrhage occurred in 22% of the patients. Of 81 patients with concurrent thrombolysis, 18.5%

## **Medical Policy: ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)**

**Policy Number: 7.01.82**

**Page: 4 of 12**

had hemorrhage compared with 27.3% of 66 patients without thrombolysis ( $P = .21$ ). Of the 126 patients with accessible clots, 36% had a good modified Rankin score (less than or equal to 2) and 29% died; in patients with inaccessible clots, 24% had a good modified Rankin score and 38% died. Factors associated with clinical success were younger age ( $P = .001$ ) and lower NIHSS score at admission to the hospital ( $P = .001$ ). Compared with a matched cohort, patients who received mechanical intervention were 14.8 times more likely to have a good modified Rankin score (95% confidence interval, 4.4-50.0;  $p$  less than .001).

Mokin et al. published a systematic review in 2012 that evaluated clinical outcomes from endovascular therapy compared to thrombolysis. The authors selected studies that used either thrombolysis or endovascular therapy for patients with acute ischemic stroke due to internal carotid artery occlusion. Included studies reported on functional outcomes past 30 days, mortality rates beyond 30 days, and rates of symptomatic intracerebral hemorrhage. A total of 28 studies were reviewed, including 385 patients treated with thrombolysis and 584 patients treated with endovascular therapy. There were no differences in mortality between the thrombolysis and endovascular groups (27.3% vs. 32.0%,  $p=0.12$ ). A favorable clinical outcome, defined as a Rankin scale of less than 2 or a Barthel index of 90-100, was attained by a greater percentage of patients in the endovascular group compared to the thrombolysis group (33.6% vs. 24.9%,  $p=0.004$ ). Symptomatic intracranial hemorrhage was also more common in the endovascular group compared to thrombolysis (11.1% vs. 4.9%,  $p=0.001$ ).

Almekhlafi et al. published a systematic review of observational studies of endovascular treatment in 2012. The authors identified 16 eligible studies and classified them according to the type of device used. There were 4 studies ( $n=357$ ) that used the Merci device, 8 studies ( $n=455$ ) that used the Penumbra system, and 4 studies ( $n=113$ ) that used a retrievable stent. Mean procedural time was 120 minutes for the Merci device, compared to 65 and 55 minutes for the Penumbra and retrievable stents. The successful recanalization rate was 59.1% for the Merci group, 86.6% for the Penumbra system, and 92.9% for the retrievable stent group.

The Solitaire™ FR Revascularization Device (Covidien plc) received FDA 510(k) clearance in February 2012. It is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV-t-PA or have failed IB t-PA therapy are candidates for treatment. The device is intended for use in the neurovasculature such as the internal carotid artery, middle cerebral artery, vertebral and basilar arteries. It is a nitinol self-expanding, fully retrievable stent based design that allows for clot retrieval when deployed in occluded target vessels after acute ischemic stroke. The FDA approval was based on results from the SWIFT trial, an active-comparator, non-inferiority study ( $n=144$ ) where patients with acute ischemic stroke (NIHSS greater than 8 and less than 30) were randomized to receive treatment with either the Merci retriever or the Solitaire device. The primary and secondary efficacy endpoints included successful recanalization with no symptomatic intracerebral hemorrhage (ICH), and neurological assessments at 90-day (+ 15 days) follow-up. Analysis of the primary efficacy endpoint showed statistically significant evidence that Solitaire FR was non inferior to the Merci device in the arterial recanalization of the occluded target vessels without any presence of symptomatic intracranial hemorrhage. The Solitaire FR group success rate was 60.7% (34/56) compared to 24.1% (13/54) for the merci group. The criterion for non-inferiority was met with an associated  $p$  less than 0.0001. At 30 days, the good neurological outcome (GNO) for the Solitaire FR was 50.9% compared to 33.3% for Merci; 90-day GNO was 58.2% and 33.3% respectively. Mortality rates for subjects randomized to the Merci group was 38.2% compared to 17.2 for the Solitaire FR group. The rate of symptomatic intracranial hemorrhage was 10.9% in the Merci group and 1.7% in the Solitaire FR group; and the rate of all intracranial hemorrhage was 38.2% and 17.2% respectively. The nominal overall device and/or procedure-related serious adverse event rate for the Solitaire was observed to be lower also (22.4% vs 40.0%).

FDA 510(k) approval was received for the Mindframe Capture™ LP Revascularization Device (Micro Therapeutics, Inc.) in 2015. The FDA determined that the device is substantially equivalent to legally marketed predicate devices [Solitaire™]. The Capture™ LP Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV-tPA) or have failed IV t-PA are candidates for treatment. An urgent Class I recall was initiated by Micro Therapeutics Inc. on February 26, 2018 due to a risk of the delivery wire breaking or separating during use.

## **Medical Policy: ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)**

**Policy Number: 7.01.82**

**Page: 5 of 12**

The FDA issued 510(k) marketing approval for the Trevo<sup>®</sup> Pro Retrieval System by device maker Stryker in August 2012. TREVO 2 trial results presented in May at the 2012 European Stroke Conference. The trial randomized 178 individuals for treatment with either the Trevo Pro or the Merci Retriever following acute ischemic stroke. Results demonstrated significantly greater revascularization rates for the Trevo Pro compared to the Merci (86.4% vs. 60%). Functional outcomes were also improved with Trevo Pro, with 40% of patients having a modified Rankin score of two or less in the Trevo Pro arm of the study, compared to 21.8% in the Merci arm. Other measures that favored the Trevo Pro included National Institutes of Health Stroke Scale scores and hospital length of stay.

In 2015, an updated draft Blue Cross and Blue Shield Association TEC Assessment assessed endovascular therapy for acute ischemic stroke in adults to reflect several RCTs published after an earlier TEC Assessment (2014). The draft Assessment focused on 4 RCTs published from 2014 to 2015 comparing endovascular mechanical embolectomy with medical therapy (Berkhemer et al [2015], Goyal et al [2015], Campbell et al [2015], Saver et al [2015]). The Assessment made the following observations and conclusions:

“Four recent well-designed and well-conducted RCTs have demonstrated reduced disability among adults with acute ischemic stroke treated with mechanical embolectomy compared with standard medical care, usually IV tPA. These 4 RCTs address some of the limitations in 3 RCTs published in 2013, which showed no significant benefit to endovascular therapy. In particular, trials demonstrating a benefit to 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.”

The draft Assessment also concluded that the use of endovascular treatment with mechanical embolectomy in adults with radiologically confirmed large vessel, anterior circulation acute ischemic stroke met TEC criteria.

Based on review of published literature, endovascular treatment of angiographically documented intracranial arterial occlusions has demonstrated sufficient safety and efficacy to consider the procedures appropriate for a select group of acute ischemic stroke patients with profound neurological deficits who have failed or are not candidates for thrombolysis. Patients with vessels revascularized by devices have consistently exhibited better outcomes than those without revascularization. When performed in an institution with a multidisciplinary stroke team, recanalization rates have approached 75% and the greater than 50% favorable outcomes achieved are clearly different from the natural history of the disease in this narrowly defined subgroup.

The American Heart Association and the American Stroke Association (2018) published joint guidelines on the early management of patients with acute ischemic stroke. These guidelines included several recommendations relevant to the use to endovascular therapies for acute stroke.

- I. Mechanical thrombectomy requires the patient to be at an experienced stroke center with rapid access to cerebral angiography, qualified neurointerventionalists, and a comprehensive periprocedural care team. Systems should be designed, executed, and monitored to emphasize expeditious assessment and treatment. Outcomes for all patients should be tracked. Facilities are encouraged to define criteria that can be used to credential individuals who can perform safe and timely intra-arterial revascularization procedures. (Class I, Level of Evidence C-EO)
- II. Patients should receive mechanical thrombectomy with a stent retriever if they meet all the following criteria: (1) prestroke mRS score of 0 to 1; (2) causative occlusion of the internal carotid artery or MCA segment 1 (M1); (3) age  $\geq$  18 years; (4) NIHSS score of  $\geq$  6; (5) ASPECTS of  $\geq$  6; and (6) treatment can be initiated (groin puncture) within 6 hours of symptom onset. (Class I, Level of Evidence A)
- III. As with IV alteplase, reduced time from symptom onset to reperfusion with endovascular therapies is highly associated with better clinical outcomes. To ensure benefit, reperfusion to TICI grade 2b/3 should be achieved as early as possible within the therapeutic window. (Class I, Level of Evidence B-R)
- IV. The use of mechanical thrombectomy devices other than stent retrievers as first-line devices for mechanical thrombectomy may be reasonable in some circumstances, but stent retrievers remain the first choice. (Class IIIb, Level of Evidence B-R)

**Medical Policy: ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)**

**Policy Number: 7.01.82**

**Page: 6 of 12**

**CODES**

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

**CPT Codes**

<b>Code</b>	<b>Description</b>
There are no specific CPT codes for these procedures. Components of the procedure would include the following:	
36215-36218	Selective catheter placement, arterial system, thoracic or brachiocephalic family (code range)
36221	Non-selective catheter placement, thoracic aorta, with angiography of the external carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed
36223	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed
36224	Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the external carotid and cervicocerebral arch, when performed
36228	Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selective vessel circulation and all associated radiological supervision and interpretation (e.g., middle cerebral artery, posterior inferior cerebellar artery)
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)

*Copyright © 2019 American Medical Association, Chicago, IL*

**HCPCS Codes**

<b>Code</b>	<b>Description</b>
No specific intracranial codes	

**ICD10 Codes**

<b>Code</b>	<b>Description</b>
I63.011-I63.119	Cerebral infarction due to thrombus/embolism of vertebral artery (code range)
I63.211-I63.219	Cerebral infarction due to unspecified occlusion or stenosis vertebral artery (code range)
I63.30-I63.49	Cerebral infarction due to thrombosis/embolism of cerebral artery (code range)

**Medical Policy: ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)**

**Policy Number: 7.01.82**

**Page: 7 of 12**

<b>Code</b>	<b>Description</b>
I63.50-I63.9	Cerebral infarction due to unspecified occlusion or stenosis of cerebral artery (code range)
I65.01-I65.09	Occlusion and stenosis of vertebral artery (code range)
I66.01-I66.9	Occlusion and stenosis of cerebral artery (code range)
I67.1	Cerebral aneurysm
I67.2	Cerebral atherosclerosis
I67.4-I67.9	Cerebrovascular diseases (code range)

**REFERENCES**

\*Abou-Chebl A, et al. Endovascular treatment of acute ischemic stroke may be safely performed with no time limit in appropriately selected patients. Stroke 2010 Sep;41(9):1996-2000.

\*Adams HP, et al. Guidelines for the early management of adults with ischemic stroke: a guideline from the American Heart Association/American Stroke Association Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology and Intervention Council, and the Atherosclerotic Peripheral Vascular Disease and Quality of Care Outcomes in Research Interdisciplinary Working Groups: the American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists. Stroke 2007 May;38(5):1655-711.

Akins PT, et al. Complications of endovascular treatment for acute stroke in the SWIFT trial with Solitaire and Merci devices. AJNR Am J Neuroradiol 2014 Mar;35(3):524-8.

Albers GW, et al. Thrombectomy for stroke at 6 to 16 hours with selection by perfusion imaging. NEJM 2018; 378:708-718.

\*Almekhlafi MA, et al. A meta-analysis of observational intra-arterial stroke therapy studies using the merci device, penumbra system, and retrievable stents. AJNR Am J Neuroradiol 2013 Jan;34(1):140-145.

Badhiwala JH, et al. Endovascular thrombectomy for acute ischemic stroke: a meta-analysis. JAMA 2015 Nov 3;314(17):1832-43.

Baek JM, et al. Acute basilar artery occlusion: outcome of mechanical thrombectomy with Solitaire stent within 8 hours of stroke onset. AJNR Am J Neuroradiol 2014 May;35(5):989-93.

Barral M, et al. Stent retriever thrombectomy for acute ischemic stroke: a systematic review and meta-analysis of randomized controlled trials, including THRACE. Rev Neurol (Paris) 2018 May;174(5):319-326.

Beheme D, et al. Multicenter clinical experience in over 125 patients with the Penumbra Separator 3D for mechanical thrombectomy in acute ischemic stroke. J Neurointerv Surg 2016 Jan;8(1):8-12..

Berkemer OA, et al. A randomized trial of intraarterial treatment for acute ischemic stroke. N Engl J Med 2015 Jan 1;372(1):11-20.

Bigi S, et al. Feasibility, safety, and outcome of recanalization treatment in childhood stroke. Ann Neurol 2018 Jun;83(6):1125-1132.

Binning MJ, et al. Early postmarket experience after UD Food and Drug Administration approval with the Trevo device for thrombectomy for acute ischemic stroke. Neurosurgery 2014 Nov;75(5):584-9.

BlueCross BlueShield Association. Technology Evaluation Center (TEC). Endovascular Treatments for Acute Ischemic Stroke in Adults. Jan 2015;29(11).

BlueCross BlueShield Association. Mechanical embolectomy for treatment of acute stroke. Medical Policy Reference Manual Policy #2.01.76. 2013 Sep 12. Archived 2014 Jan 9.

**Medical Policy: ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)**

**Policy Number: 7.01.82**

**Page: 8 of 12**

BlueCross BlueShield Association Endovascular procedures for intracranial arterial disease (atherosclerosis and aneurysms). Medical Policy Reference Manual #2.01.54. 2018 April 12.

Bracard S, et al. Mechanical thrombectomy after intravenous alteplase versus alteplase alone after stroke (THRACE): a randomized controlled trial. Lancet Neurol 2016 Oct;15(11):1138-1147.

\*Broderick JP, et al. Endovascular therapy after intravenous t-PA versus t-PA alone for stroke. N Engl J Med 2013 Mar 7;368(10):893-903.

Broussalis E, et al. Thrombectomy in patients with large cerebral artery occlusion: a single-center experience with a new stent retriever. Vasc Endovascular Surg 2014 Feb;48(2):144-52.

Bush CK, et al. Endovascular treatment with stent-retriever devices for acute ischemic stroke: a meta-analysis of randomized controlled trials. PLoS One 2016 Jan 25;11(1):e0147287.

Campbell BC, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. N Engl J Med 2015 Mar 12;372(11):1009-18.

Campbell BC, et al. Safety and efficacy of Solitaire Stent Thrombectomy: individual patient data meta-analysis of randomized trials. Stroke 2016 March;47(3):798-806.

Caranfa JT, et al. Mechanical endovascular therapy for acute ischemic stroke: an indirect treatment comparison between Solitaire and Penumbra thrombectomy devices. PLoS One 2018 Mar 7;13(3):e0191657.

\*Castano C, et al. Mechanical thrombectomy with the solitaire AB device in large artery occlusions of the anterior circulation. A pilot study. Stroke 2010 Aug;41(8):1836-40.

Cheang MY, et al. Recanalization success is associated with good clinical outcome despite advanced age and stroke severity in patients treated with the Solitaire stent retriever. J Clin Neurosci 2014 Mar;21(3):401-5.

Chen CJ, et al. Endovascular vs medical management of acute ischemic stroke. Neurology 2015 Dec 1;85(22):1980-90.

\*Ciccone A, et al. Endovascular treatment for acute ischemic stroke. N Engl J Med 2013 Mar 7;368(10):904-13.

Coutinho JM, et al. Combined intravenous thrombolysis and thrombectomy vs thrombectomy alone for acute ischemic stroke: a pooled analysis of the SWIFT and STAR studies. JAMA Neurol 2017 March 1;74(3):268-274.

Davalos A, et al. Safety and efficacy of thrombectomy in acute ischemic stroke (REVASCAT): 1-year follow-up of a randomized open-label trial. Lancet Neurol 2017 May;16(5):369-376.

Demchuk AM, et al. Recanalization and clinical outcome of occlusion sites at baseline CT angiography in the Interventional Management of Stroke III trial. Radiology 2014 Oct;273(1):202-10.

Emprechtlinger R, et al. Thrombectomy for ischemic stroke: meta-analyses of recurrent strokes, vasospasms, and subarachnoid hemorrhages. J Neurol 2017 March;264(3):432-436.

Eskey CJ, et al. Indications for the performance of intracranial endovascular neurointerventional procedures: a scientific statement from the American Heart Association. Circulation 2018 May 22;137(21):e661-e689.

Eugene F, et al. One-year MT angiographic and clinical follow-up after intracranial mechanical thrombectomy using a stent retriever device. AJNR Am J Neuroradiol 2015 Jan;36(1):126-32.

\*Fields JD, et al. Higher degrees of recanalization after mechanical thrombectomy for acute stroke are associated with improved outcome and decreased mortality: pooled analysis of the MERCI and Multi MERCI trials. AJNR Am J Neuroradiol 2011 Dec;32:2170-95.

\*Gandhi CD, et al. Neuroendovascular management of emergent large vessel occlusion: update on the technical aspects and standards of practice by the Standards and Guidelines Committee of the Society of NeuroInterventional Surgery. J Neurointerv Surg 2018 Mar;10(3):315-320.

**Medical Policy: ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)**

**Policy Number: 7.01.82**

**Page: 9 of 12**

- Gascou G, et al. Stent retrievers in acute ischemic stroke: complications and failures during the perioperative period. AJNR Am J Neuroradiol 2014 Apr;35(4):734-40.
- Goyal M, et al. Randomized assessment of rapid endovascular treatment of ischemic stroke. N Engl J Med 2015 Mar 12;372(11):1019-30.
- Goyal M, et al. Endovascular thrombectomy after large vessel ischemic stroke: a meta-analysis of individual patient data from five randomized trials. Lancet 2016 Apr 23;387(10029):1723-31.
- Gratz PP, et al. Outcome of standard and high-risk patients with acute anterior circulation stroke after stent retriever thrombectomy. Stroke 2014 Jan;45(1):152-8.
- Grech R, et al. Stent-based thrombectomy versus intravenous tissue plasminogen activator in acute ischaemic stroke: a systematic review and meta-analysis. Interv Neuroradiol 2015 Dec;21(6):684-90.
- Griessenauer CJ, et al. Endovascular mechanical thrombectomy in large-vessel occlusion ischemic stroke presenting with low National Institutes of Health Stroke Scale: systematic review and meta-analysis. World Neurosurg 2018 Feb;110:263-269.
- Hong KS, et al. Endovascular recanalization therapy in acute ischemic stroke: updated meta-analysis of randomized controlled trials. J Stroke 2015 Sep;17(3):268-81.
- Huo X, et al. Endovascular mechanical thrombectomy with the Solitaire Device for the treatment of acute basilar artery occlusion. World Neurosurg 2016 May;89:301-308.
- \*Hussein HM, et al. occurrence and predictors of futile recanalization following endovascular treatment among Patients with acute ischemic stroke: a multicenter study. AJNR Am J Neuroradiol 2010 Mar;31(3):454-8.
- Jovin TG, et al. Thrombectomy within 8 hours after symptom onset in ischemic stroke. N Engl J Med 2015 Jun 11;372(24):2296-306.
- Kahles T, 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 2016 Jan;37(1):114-19.
- Kappelhof M, et al. Intra-arterial treatment of patients with acute ischemic stroke and internal carotid artery occlusion: a literature review. J Neurointerv Surg Jan 2015;7(1):8-15.
- Kennedy SA, et al. Meta-analysis of local endovascular therapy for acute ischemic stroke. J Vasc Interv Radiol 2016 Mar;27(3):307-21.
- Khoury NN, et al. Endovascular thrombectomy and medical therapy versus medical therapy alone in acute stroke: a randomized care trial. J Neuroradiol 2017 June;44(3):198-202.
- \*Linfante I, et al. Self-expandable stents in the treatment of acute ischemic stroke refractory to current thrombectomy devices. Stroke 2011 Sep;42(9):2636-8.
- Lopez-Cancio E. et al. Endovascular treatment improves cognition after stroke: a secondary analysis of REVASCAT trial. Neurology 2017 Jan 17;88(3):245-251.
- \*Lutsep HL. Mechanical endovascular recanalization therapies. Curr Opin Neurol 2008 Feb;21(1):70-5.
- Marmagkiolis K, et al. Safety and efficacy of stent retrievers for the management of acute ischemic stroke: comprehensive review and meta-analysis. JACC Cardiovasc Interv 2015 Nov;8(13):1758-65.
- Mendonca N, et al. Trevo versus Solitaire a head-to-head comparison between two heavy weights of clot retrieval. J Neuroimaging 2014 Mar-Apr;24(2):167-70.
- Meurer WJ, et al. Rapid systematic review: intra-arterial thrombectomy (“clot retrieval”) for selected patients with acute ischemic stroke. J Emerg Med 2017 Feb;52(2):255-261.

**Medical Policy: ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)**

**Policy Number: 7.01.82**

**Page: 10 of 12**

\*Meyers PM, 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 2009 Apr 28;119(16):2235-49.

Mocco J, et al. Aspiration thrombectomy after intravenous alteplase versus intravenous alteplase alone. Stroke 2016 Sept;47(9):2331-1338.

Mohlenbruch M, et al. Mechanical thrombectomy with stent retrievers in acute basilar artery occlusion. AJNR Am J Neuroradiol 2014 May;35(5):959-64.

\*Mokin M, et al. Intravenous thrombolysis and endovascular therapy for acute ischemic stroke with internal carotid artery occlusion: a systematic review of clinical outcomes. Stroke 2012 Sep;43(9):2362-8.

Mourand I, et al. Mechanical thrombectomy with Solitaire device in acute basilar artery occlusion. J Neurointerv Surg 2014 Apr 1;6(3):200-4.

Nikoubashman O, et al. Postinterventional subarachnoid haemorrhage after endovascular stroke treatment with stent retrievers. Neuroradiology 2014 Dec;56(12):1087-96.

Nogueira RG, et al. Thrombectomy 6 to 24 hours after stroke with a mismatch between deficit and infarct. N Engl J Med. Jan 4 2018;378(1):11-21.

Pan X, et al. Comparative efficacy and safety of bridging strategies with direct mechanical thrombectomy in large vessel occlusion: a systematic review and meta-analysis. Medicine (Baltimore) 2019 Apr;98(14):e14956.

Parrilla G, et al. Recanalization and mortality rates of thrombectomy with stent-retrievers in octogenarian patients with acute ischemic stroke. Cardiovasc Interv Radiol 2015 Apr;38(2):288-94.

Phan K, et al. Endovascular therapy including thrombectomy for acute ischemic stroke: a systematic review and meta-analysis with trial sequential analysis. J Clin Neurosci 2016 July;29:38-45.

\*Powers WJ, 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.

Primiani CT, et al. Direct aspiration versus stent retriever thrombectomy for acute stroke: a systematic review and meta-analysis in 9127 patients. J Stroke Cerebrovasc Dis 2019 May;28(5):1329-1337.

Qin C, et al. Efficacy and safety of direct aspiration versus stent-retriever for recanalization in acute cerebral infarction: A PRISMA compliant systematic review and meta-analysis. Medicine (Baltimore) 2018 Oct;97(41):e12770.

\*Qureshi AI, et al. Mechanical disruption of thrombus following intravenous tissue plasminogen activator for ischemic stroke. J Neuroimaging 2007 Apr;17(2):124-30.

Rodrigues FB, et al. Endovascular treatment versus medical care alone for ischemic stroke: systematic review and meta-analysis. BMJ 2016 April;353:i1754.

\*Sacco RL, et al. Guidelines for prevention of stroke in patients with ischemic stroke or transient ischemic attack: a statement for healthcare professionals from the American Heart Association/American Stroke Association Council on Stroke: co-sponsored by the Council on Cardiovascular Radiology and Intervention. Stroke 2006;37:577– 617.

Saposnik G, et al. Added benefit of stent retriever technology for acute ischemic stroke: a pooled analysis of the NINDS tPA, SWIFT, and STAR trials. Neurosurgery 2015 Sep;77(3):454-61.

Sardar P, et al. Endovascular therapy for acute ischemic stroke: a systematic review and meta-analysis of randomized trials. Eur Heart J 2015 Sep 14;36(35):2373-80.

Sarraj A, et al. Endovascular therapy for acute ischemic stroke with occlusion of the middle cerebral artery M2 segment. JAMA Neurol 2016 Nov 1;73(11):1291-1296.

**Medical Policy: ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)**

**Policy Number: 7.01.82**

**Page: 11 of 12**

Saver JL, et al. Solitaire™ with the intention for thrombectomy (SWIFT) trial: design of a randomized, controlled, multicenter study comparing the SOLITAIRE™ Flow Restoration device and the MERCI retriever in acute ischaemic stroke. Int J Stroke 2014 Jul;9(5):658-68.

Saver JL, et al. Stent-retriever thrombectomy after intravenous t-PA vs t-PA alone in stroke. N Engl J Med 2015 Jun 11;372(24):2285-95.

Saver JL, et al. Time to treatment with endovascular thrombectomy and outcomes from ischemic stroke: a meta-analysis. JAMA 2016 Sept;316(12):1279-1288.

Sharma M, et al. Acute Stroke: Evaluation and Treatment. Summary, Evidence Report/Technology Assessment No.127. Agency for Healthcare Research and Quality.

[<https://archive.ahrq.gov/downloads/pub/evidence/pdf/acutestroke/acstroke.pdf>] accessed 4/30/19.

\*Shi ZS, et al. Clinical outcomes in middle cerebral artery trunk occlusions versus secondary division occlusions after mechanical thrombectomy: pooled analysis of the Mechanical Embolus Removal in Cerebral Ischemia (MERCI) and Multi MERCI trials. Stroke 2010 May;41(5):953-60.

Shireman TI, et al. Cost-effectiveness of solitaire stent retriever thrombectomy for acute ischemic stroke: results from the SWIFT-PRIME Trial (Solitaire with the intention for thrombectomy as primary endovascular treatment for acute ischemic stroke). Stroke 2017 Feb;48(2):379-387.

\*Smith WS, et al. Safety and efficacy of mechanical embolectomy in acute ischemic stroke: results of the MERCI trial. Stroke 2005 Jul;36(7):1432-8.

\*Smith WS. Safety of mechanical thrombectomy and intravenous tissue plasminogen activator in acute ischemic stroke. Results of the multi Mechanical Embolus Removal in Cerebral Ischemia (MERCI) trial, part I. AJNR Am J Neuroradiol 2006 Jun-Jul;27(6):1177-82.

Song D, et al. Comparison of stent retriever and intra-arterial fibrinolysis in patients with acute ischaemic stroke. Eur J Neurol 2014 May;21(5):779-84.

\*Stead LG, et al. Percutaneous clot removal devices in acute ischemic stroke: a systematic review and meta-analysis. Arch Neurol 2008 Aug;65(8):1024-30.

\*Tarr R, et al. SNIS Annual meeting. Abstract #028 Revascularization of large vessel occlusion by the Penumbra System in acute ischemic stroke contributes to good functional outcome. J Neurointerv Surg 2009;1:84.

\*Taschner CA, et al. mechanical thrombectomy with the Penumbra recanalization device in acute ischemic stroke. J Neuroradiol 2011 Mar;38(1):47-52.

\*Tenser MS, et al. Mechanical thrombectomy for acute ischemic stroke using the MERCI retriever and penumbra aspiration systems. World Neurosurg 2011 Dec;76(6Suppl):S16-23.

Tomsick TA, et al. Endovascular revascularization results in IMS III: intracranial ICA and M1 occlusions. J Neurointerv Surg 2015 Nov;7(11):795-802.

Touma L, et al. Stent retrievers for the treatment of acute ischemic stroke: a systematic review and meta-analysis of randomized clinical trials. JAMA Neurol 2016 Mar 1;73(3):275-81.

Turc G, et al. European Stroke Organisation (ESO) - European Society for Minimally Invasive Neurological Therapy (ESMINT) Guidelines. J Neurointerv Surg 2019 Feb 26. [Epub ahead of print]

Turk AS, et al. Comparison of endovascular treatment approaches for acute ischemic stroke: cost-effectiveness, technical success, and clinical outcomes. J Neurointerv Surg 2015 Sep;7(9):666-70.

Turk AS 3<sup>rd</sup>, et al. Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomised, open label, blinded outcome, non-inferiority trial. Lancet 2019 Mar 9;393(10175):998-1008.

**Medical Policy: ENDOVASCULAR TREATMENT OF ACUTE ISCHEMIC STROKE (e.g. MECHANICAL EMBOLECTOMY)**

**Policy Number: 7.01.82**

**Page: 12 of 12**

Urra X, et al. Medical and endovascular treatment of patients with large vessel occlusion presenting with mild symptoms: an observational multicenter study. Cerebrovasc Dis 2014;38(6):418-24.

Wilson JL, et al. Endovascular therapy in pediatric stroke: utilization, patient characteristics, and outcomes. Pediatric Neuro 2017 April;69:87-92.

Zaidat OO, et al. North American Solitaire stent retriever acute stroke registry: post-marketing revascularization and clinical outcome results. J Neurointerv Surg 2014 Oct;6(8):584-588.

Zheng F and Xie W. Imaging-based patient selection and endovascular therapy for ischemic stroke: a stratified meta-analysis. Medicine 2015 Sep;94(38):e1539.

\*Key Article

**KEY WORDS**

Angioplasty, Intracranial Circulation, Percutaneous Transluminal Angioplasty, Merci Retriever, Mechanical Embolectomy, Penumbra, Solitaire™, Trevo®.

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based on our review, mechanical retrieval of clots following an ischemic stroke is not addressed in National or Regional Medicare coverage determinations or policies.

There is currently a National Coverage Determination (NCD) for percutaneous transluminal angioplasty (PTA) and a CMS decision memo related to percutaneous transluminal angioplasty (PTA) with intracranial stent placement. Please refer to the following NCD website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCID=201&ncdver=10&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAAAA%3d%3d&>

**Decision memo:**

[http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=214&NcaName=Intracranial+Stenting+and+Angioplasty&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNCD%7CMEDCAC%7CTA%7CMCD&ArticleType=SAD%7CEd&PolicyType=Final&s=---%7C5%7C6%7C66%7C67%7C44&KeyWord=percutaneous+transluminal+angioplasty+\(PTA\)+with+intracranial+stent+placement&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAABAACAAAAA%3D%3D&](http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=214&NcaName=Intracranial+Stenting+and+Angioplasty&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNCD%7CMEDCAC%7CTA%7CMCD&ArticleType=SAD%7CEd&PolicyType=Final&s=---%7C5%7C6%7C66%7C67%7C44&KeyWord=percutaneous+transluminal+angioplasty+(PTA)+with+intracranial+stent+placement&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAABAACAAAAA%3D%3D&)