

## Evidence Based Guideline

### Mechanical Embolectomy for Treatment of Acute Stroke

**File Name:** mechanical\_embolectomy\_for\_treatment\_of\_acute\_stroke  
**Origination:** 1/2009  
**Last CAP Review:** 6/2011  
**Next CAP Review:** 6/2012  
**Last Review:** 6/2011

#### Description of Procedure or Service

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Approximately 750,000 strokes occur in the U.S. annually, of which 85% are ischemic. Ischemic stroke may be caused by occlusion of large intracranial arteries, and large-vessel occlusions carry a particularly high mortality (estimated between 53% and 92%). Reopening large cerebral vessels would be expected to reduce neurological morbidity and mortality if performed before ischemic brain injury is maximal. Tissue plasminogen activator (tPA) given intravenously within 3 hours of symptom onset has demonstrated improved neurological outcome. However, pharmaceutical thrombolytics may take as long as 2 hours to dissolve a thrombus and many patients are ineligible for thrombolytic therapy.

Mechanical embolectomy is being studied as a method of stroke treatment. A number of mechanical thrombolysis devices have entered clinical trials. These devices use a variety of techniques to physically remove the clot.

The Merci® Retriever was cleared by the FDA in August 2004 through the 510(k) process. This device was judged equivalent to a predicate device, the Concentric Retriever. A modified Merci Retriever received 510(k) clearance from the FDA in May 2006. The device consists of a flexible wire with corkscrew shaped loops at the distal end. A radiopaque coil covers the tip allowing visualization under fluoroscopy. The corkscrew itself resides in the catheter tip, which shields it from the wall of the vessel until it is ready to be burrowed into the clot. The catheter tip is placed distal to the thrombus or foreign body and then retracted to deploy the loops. Once lodged in the clot, the device and clot are withdrawn from the vessel.

The Modified Merci® Retriever is intended to restore blood flow in the neurovasculature by removing thrombi in patients experiencing ischemic stroke. Patients who are ineligible for intravenous tissue plasminogen activator (IV tPA) or who fail IV tPA therapy are candidates for treatment. It is also indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.

In September 2007, the FDA granted 510(k) marketing clearance to the Penumbra System™ which is another mechanical device designed to reduce clot burden in acute stroke due to large-vessel occlusive disease. This system removes clots through the use of a small suction device.

**\*\*\*Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Evidence Based Guideline for Mechanical Embolectomy for Treatment of Acute Stroke

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Mechanical embolectomy may not be appropriate in the treatment of acute stroke. Use of this procedure is not recommended because the data are not sufficient to determine if it improves health outcomes.

# Mechanical Embolectomy for Treatment of Acute Stroke

## Medical Evidence regarding Mechanical Embolectomy for Treatment of Acute Stroke indicates it is not recommended in the following situations

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Mechanical embolectomy is not recommended for the treatment of acute stroke.

The scientific evidence does not permit conclusions concerning the effect of mechanical embolectomy on patient outcomes. The existing observational data are not sufficient to determine whether this approach improves net health outcomes. Single-arm studies report a high rate of recanalization of the infarcted vessel, however only a subset of patients with successful recanalization achieves good functional outcomes. Comparison with historical controls receiving thrombolysis suggests higher rates of recanalization with embolectomy, but lower rates of good functional outcomes. Given the lack of controlled studies to assess the impact of this treatment compared with alternatives, the use of embolectomy devices for acute stroke is not recommended.

## Benefits Application

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This evidence based guideline relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this guideline.

## Billing/Coding/Physician Documentation Information

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This guideline may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcsnc.com](http://www.bcsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: There is no specific CPT code for this procedure. The manufacturer is recommending that physicians code the components of the procedure separately, so they would submit codes for the catheterization (36215-36218), intervention (37184-37185), and radiological supervision and interpretation (75660-75680).*

## Scientific Background and Reference Sources

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U.S. Food and Drug Administration. 510(k) Summary. <http://www.fda.gov/cdrh/pdf6/K061059.pdf>

Smith WS, Sung G, Starkman S, et al. Safety and efficacy of mechanical embolectomy in acute ischemic stroke: Results of the MERCI trial. *Stroke* 2005; 36(7):1432-8. Retrieved 1/27/09 from <http://stroke.ahajournals.org/cgi/reprint/36/7/1432>

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.76, 12/13/07

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Bose A, Henkes H, Alfke K, et al. The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism. *AJNR Am J Neuroradiol* 2008; 29(7):1409-13

Nogueira RG, Yoo AJ, Buonanno FS, Hirsch JA, Endovascular Approaches to Acute Stroke Part 2: A Comprehensive Review of Studies and Trials. *American Journal of AJNR Am J Neuroradiol* 2009, 30(5):859-875

Specialty Matched Consultant Advisory Panel review 6/2010

# Mechanical Embolectomy for Treatment of Acute Stroke

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.76, 9/16/10

Specialty Matched Consultant Advisory Panel review 6/2011.

Agency for Healthcare Research and Quality (AHRQ) Technical Brief: Neurothrombectomy Devices for Treatment of Acute Ischemic Stroke. January 18, 2011. Retrieved on October 7, 2011 from [http://www.effectivehealthcare.ahrq.gov/ehc/products/161/400/Neurothrombectomy%20Protocol%20\(2-17-2010\)%20FINAL.pdf](http://www.effectivehealthcare.ahrq.gov/ehc/products/161/400/Neurothrombectomy%20Protocol%20(2-17-2010)%20FINAL.pdf)

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.76, 9/1/11

## Policy Implementation/Update Information

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3/2/09 New Evidence Based Guideline issued. Mechanical embolectomy may not be appropriate for treatment of acute stroke. Use of this procedure is considered investigational because the data are not sufficient to determine if it improves health outcomes.

12/7/09 Specialty Matched Consultant Advisory Panel review meeting 10/30/09. Guidelines accepted as written. (adn)

8/3/2010 Specialty Matched Consultant Advisory Panel review 6/2010. Policy Guideline number removed. References updated. (mco)

7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. References updated. The “Not Recommended” section updated. Replaced the term “investigational” with the term “not recommended.”(mco)

11/8/11 “Not Recommended” section updated. References updated. No changes to guideline statements. (mco)

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