

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: 6/2010
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Last Review: 6/2010

Description of Procedure or Service

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 Once lodged in the clot, the device and clot are withdrawn from the vessel.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

Mechanical embolectomy may not be appropriate in the treatment of acute stroke. Use of this procedure is considered investigational 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

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

Support for use of the Merci Retrieval System comes from the mechanical embolus removal in cerebral ischemia (MERCİ) trial. The MERCİ investigators compared their patients to the placebo arm of the PROACT II (Pro-lyse in Acute Cerebral Thromboembolism II) study to determine safety and efficacy of mechanical embolectomy. Concerns have been raised about using the patients from the PROACT II study as historic controls. These concerns include the fact that the MERCİ trial included patients with different types of occlusions. Questions have also been raised about the outcome measure of recanalization since the MERCİ study did not look for distal emboli. There are also concerns about the reliability of the TIMI perfusion scores as reported in this trial, and thus questions about whether the recanalization rates can be compared among studies.

Overall, there exists considerable controversy regarding the clinical implications of the MERCİ study. Many commentators feel that recanalization does not necessarily equate to improved health outcomes for stroke patients. The current data are not convincing for improved clinical outcomes, and large, randomized, controlled trials will be required to demonstrate the clinical safety and efficacy of mechanical embolectomy. A number of additional trials of the device are ongoing including the Mechanical Retrieval and Recanalization of Stroke Clots Using Embolectomy (MR RESCUE) trial.

Benefits Application

This medical policy 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 medical policy.

Billing/Coding/Physician Documentation Information

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.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: Not Applicable

There is no specific CPT code for this procedure. The manufacturer is recommending the 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

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 MERCİ trial. *Stroke* 2005; 36(7):1432-8. Retrieved 1/27/09 from <http://stroke.ahajournals.org/cgi/reprint/36/7/1432>

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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

Policy Implementation/Update Information

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)

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