The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

### Description

The majority of strokes are caused by thrombotic or embolic occlusion, and these frequently present as acute neurologic emergencies. Tissue plasminogen activator (tPA), given intravenously within three hours of symptom onset, is approved by the U.S. Food and Drug Administration (FDA) for treatment of acute ischemic strokes. Mechanical embolectomy is being studied as another method of stroke treatment.

### Background

The acute brain injury of stroke has two major types: ischemic and hemorrhagic. Of patients with stroke presenting to the emergency department, approximately 80% will be diagnosed with ischemic brain injury. Distinguishing between these types of stroke is important because the established treatments for each are significantly different. The focus of treatment in ischemic stroke is reperfusion of hypoxic brain tissue, while the focus in hemorrhagic stroke is correction of the condition which led to bleeding. If the underlying cause of ischemia is systemic hypotension, this must be corrected. Far more commonly, however, a clot occluding an intracranial vessel is the cause of ischemic stroke. Recanalization of the vessel, particularly in the first few hours after occlusion, has been shown to reduce rates of disability and death.

While spontaneous thrombolysis does occur, treatment of ischemic stroke has focused on the use of intravenous tissue plasminogen activator (tPA) to promote dissolution of the clot and subsequent restoration of blood flow to the ischemic area of the brain. Reperfusion benefits decrease over time; infarcted brain tissue will not recover. Because tPA is associated with an increased risk of intracranial bleeding, it is contraindicated in hemorrhagic stroke and in some ischemic stroke patients in which the risk of bleeding outweighs potential benefit, such as those with mild or resolving symptoms, hypocoagulable state, or advanced age.

Intravenous tPA has improved outcomes for many, but not all, ischemic stroke patients. Researchers have studied intra-arterial tPA, transcranial ultrasound energy, and mechanical clot destruction or clot removal as an alternative, or second line, to the established intravenous tPA therapy. Clots can be defined as located in large or small vessels. Large intracranial arteries include the internal carotid, Circle of Willis and the first two branches of the anterior (A1 and A2), middle (M1 and M2), and posterior (P1 and P2) cerebral arteries. These can be accessed with a catheter; further branches of the cerebral circulation are defined as small vessels and are too tortuous to be mechanically accessed with available technology. Two devices are considered here (see “Regulatory Status”), the Merci® Retriever and Penumbra System®. With the Merci® device, a microcatheter is passed through the thrombus from a larger, percutaneous catheter positioned proximal to the occlusion. A helical snare is deployed, and the catheter and clot are withdrawn together. With the Penumbra® device, an opening at the tip of the percutaneous catheter utilizes suction to extract the clot.
**Regulatory Status**

In August 2004, “The Merci® Retriever” (Concentric Medical, Mountainview, CA) was cleared by the FDA through the 510(k) process. This device was judged equivalent to a predicate device, the Concentric Retriever which was indicated for endovascular foreign body removal. 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 intravenous tPA or who fail intravenous tPA therapy are candidates for treatment. The device also has clearance for retrieval of foreign bodies misplaced during interventional radiologic procedures in the neuro, peripheral, and coronary vasculature.

In December 2007, “The Penumbra System®” (Penumbra Inc., Alameda, CA) was cleared through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within eight hours of symptom onset.

**Related Protocol:**

Endovascular Procedures (Angioplasty and/or Stenting) for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

**Corporate Medical Guideline**

Mechanical embolectomy is considered **investigational** in the treatment of acute stroke.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

**References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


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. Circulation 2007; 115(20):e478-534.