



MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Endovascular Repair (Coil Embolization) of Intracranial Aneurysms
Policy Number	7.01.81
Category	Technology Assessment
Effective Date	12/18/08
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Edited Date	09/28/05, 11/16/06, 12/20/07
Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • 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.

POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature:

- I. Endovascular repair of intracranial aneurysms using coil embolization has been medically proven to be effective and, therefore, is considered **medically appropriate** as an alternative to aneurysm clipping in the treatment of intracranial aneurysms.
- II. Endovascular repair of wide-necked intracranial aneurysms using stent-assisted embolic coiling or flow-diverting stents with U.S. Food and Drug Administration (FDA) approval for the treatment of intracranial aneurysms are considered **medically appropriate** treatment for otherwise inoperable aneurysms only when performed in an institution with a multidisciplinary neurosurgical team. (See Policy Guideline I.)
- III. Endovascular repair of intracranial aneurysms using an intrasaccular flow-disrupter device, i.e., Woven EndoBridge (WEB) device, has not been medically proven to be effective and is considered **investigational**.

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

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

POLICY GUIDELINES

- I. Stent assisted embolic coiling and flow-diverting stent deployment must be performed at a facility having 24 hours/day, seven days/week availability of a multidisciplinary team that includes a neuroendovascular interventionalist.
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the 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.

DESCRIPTION

Surgical ligation/clipping has long been the standard treatment of intracranial aneurysms. Microsurgical techniques have evolved over the years, and a variety of surgical approaches and metal aneurysm clips have been developed. Surgical

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treatment has proven to be highly effective, with reported rates of complete occlusion of unruptured aneurysms of approximately 90–95%, with an extremely low rate of subsequent subarachnoid hemorrhage. Surgical repair of aneurysms in the posterior intracranial circulation, however, is extremely difficult due to technical access issues.

Endovascular repair of intracranial aneurysms, also called coil embolization, was originally performed only to treat aneurysms unsuitable for surgery. As clinical experience with this technique has grown, and coil design has been refined, endovascular treatment has been used with increasing frequency even for patients who could be treated by conventional surgical clipping. Reported complications of endovascular coiling include bleeding, cerebral embolus, cerebral vasospasm, coil stretching, herniation, or migration, dissection, errant coil placement, and thrombosis. Incomplete obliteration and aneurysm recurrence may also occur.

Stent-assisted embolic coiling has been investigated in the treatment of wide-necked aneurysms where coils alone cannot be safely contained within the aneurysm fundus. The stent-assisted coil delivery procedure consists of the placement of the stent in the parent artery across the aneurysm neck. A microcatheter is then navigated through the stent interstices into the aneurysm sac, and coil embolization is performed. In a modified stent delivery procedure, the microcatheter is inserted into the aneurysm sac first, and then the stent is placed across the wide neck of the lesion. This locks the microcatheter in the aneurysm, helping to stabilize the device during delivery of the coils. The disadvantage with this method is that there is the potential to move or even damage the stent when removing the microcatheter. The stent serves as a mechanical scaffold for placement of the coils into the aneurysm. Stent placement can allow safe packing of the lesion, preventing herniation of the coils into the parent vessels and allowing for a denser coil mesh. A disadvantage is that these devices are very thrombogenic. An intravascular stent stimulates platelet aggregation as soon as it is exposed to the patient's blood. It is currently recommended that patients receive dual antiplatelet therapy three days before stent placement. Consequently, an unruptured aneurysm is ideal for stent-assisted coil placement.

The Pipeline Embolization Device (PED) is a flow-diverting stent-like device that is utilized in anatomical situations where stent-assisted coiling becomes difficult, such as in giant or fusiform aneurysms. The primary goal of the device is to divert blood flow away from the aneurysm by placing a mesh structure, similar to a stent, on the aneurysm neck along the parent artery. The device provides a scaffold for endothelial growth and the achievement of a biological seal. While blood flow through the parent vessel is maintained, flow within the aneurysm sac is disrupted, leading to blood stasis and thrombus formation inside the aneurysm.

RATIONALE

The Guglielmi Detachable Coil (GDC) (Boston Scientific/Target, Fremont, CA) received FDA approval in 1995 as a Class III device through the 510(k) process. The Guglielmi coil is a bare platinum coil. Numerous additional coils fabricated of various components, including coils with biologically active materials, have subsequently received FDA 510(k) approval as Class II devices.

Published literature assessing randomized, controlled trials comparing endovascular coil occlusion with traditional surgical treatment supports that endovascular treatment is a safe and effective alternative to surgical clipping.

In 2005, the National Institute for Clinical Excellence stated that then-current evidence suggests that the coil embolization of unruptured intracranial aneurysms is efficacious in obliterating unruptured intracranial aneurysms and that its safety is similar to that of surgical treatments. Guidance regarding coil embolization of ruptured intracranial aneurysms issued in 2005 was similar, stating that current evidence on the safety and efficacy appears adequate to support use of the procedure.

A Cochrane Systematic Review (2006) compared the effects of endovascular coiling versus neurosurgical clipping in patients with aneurysmal subarachnoid hemorrhage. The review was based primarily on the ISAT and Vanninen/Koivisto randomized trials, as well as an unpublished, controlled trial of a series of 20 patients randomly assigned to surgical or endovascular treatment. The Cochrane review concluded that, for patients in good clinical condition with ruptured aneurysms of either the anterior or the posterior circulation, there is firm evidence that endovascular treatment is associated with a better outcome in cases in which the aneurysm is considered suitable for either treatment.

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Currently self-expanding intracranial microstents (SEIMs) for use with embolic coils are available for use in the U.S. In 2003, the Neuroform Microdelivery Stent System (Boston Scientific) was released for use in treating wide-necked aneurysms under the Humanitarian Device Exemption (HDE). In 2007, the FDA also granted HDE approval for the Codman & Shurtleff Enterprise Vascular Reconstruction Device and Delivery System for use with embolic coils in the treatment of wide-necked intracranial aneurysms. MicroVention, Inc.'s, Low-profile Visualized Intraluminal Support Device ("LVIS" and "LVIS Jr.") received HDE approval from the FDA in July 2014 and Premarket Approval (PMA) in May 2018. The LVIS is a stent-assisted coiling device that is intended for use with bare platinum coils for the treatment of unruptured, wide-necked (neck greater or equal to 4.0 mm or dome to neck ratio less than two), intracranial, saccular aneurysms arising from a parent vessel with a diameter of equal to or greater than 2.0 mm and less than or equal to 4.5 mm. In June 2017, the PulseRider Aneurysm Neck Reconstruction Device (Pulsar Vascular, Inc.) received HDE approval for use with neurovascular embolic coils in adult patients for the treatment of unruptured, wide-necked, intracranial aneurysms originating on or near a vessel bifurcation of the basilar tip or carotid terminus, with at least a portion of the aneurysm neck overlapping the lumen of the parent artery.

Published literature regarding use of stent-assisted embolic coiling in wide-necked aneurysm therapy consists mostly of retrospective case series. Early data suggest improved durability of repair, but with the risk of delayed stenosis. Evidence is sufficient to indicate that, when performed in an institution with a multidisciplinary team, successful stent deployment rates above 90% can be achieved, and outcomes are improved, compared to the natural history of these aneurysms for this otherwise inoperable, high-risk population.

The Pipeline Embolization Device (Chestnut Medical Technologies) received FDA PMA approval in April 2011. This flow-diverter stent device is approved for the endovascular treatment of wide-necked or giant aneurysms in the internal carotid artery from the petrous to superior hypophyseal segments. The Pipeline Flex Embolization Device (Micro Therapeutics, Inc., d/b/a ev3 Neurovascular) received FDA PMA approval in December 2018, which expanded the indications to include small and medium wide-necked intracranial aneurysms. The device is indicated for use in the internal carotid artery up to the terminus and includes saccular or fusiform intracranial aneurysms (IAs) arising from a parent vessel with a diameter between 2.0 mm and 5.0 mm.

FDA approval was based on data from the Pipeline for Uncoilable or Failed Aneurysms (PUFS) study. PUFS was a prospective, multi-center, single-arm, open label clinical study conducted at eight sites in the U.S. and two sites outside of the U.S. PUFS subjects were adults with a single-target aneurysm on the internal carotid artery that was at least 10 mm in size and a neck of at least 4.0 mm. The primary effectiveness endpoint of the study was complete occlusion of the target aneurysm on 180-day cerebral angiography, in the absence of use of other treatments and in the absence of major (>50%) stenosis of the parent artery. The primary safety endpoint was the occurrence of major ipsilateral stroke or neurologic death by 180 days. The primary safety endpoint was judged by a clinical events committee. PED was placed successfully in 107 of 108 attempted (99.0%) subjects. In one subject, the parent artery distal to the IA could not be catheterized, and the PED procedure was abandoned. A mean of 3.1 PEDs were placed per subject. Complete IA occlusion was seen in 81.8% of subjects at 180 days and 85.7% at one year. The study's primary safety endpoint, ipsilateral major stroke or neurologic death by 180 days after treatment, occurred in six subjects. The posterior probability that the major safety endpoint rate was less than 20%, the predetermined safety success threshold, was 0.999979. Both the effectiveness and safety endpoint posterior probability values exceeded the pre-study probability threshold of 0.975, indicating that both results were statistically significant. The study met the pre-specified primary effectiveness and safety endpoints at 180 days and remained statistically significant at one year.

The Surpass Streamline Flow Diverter (Stryker Neurovascular) received FDA PMA approval on July 7, 2018. This device is reported to have the same mechanism of action as the Pipeline Embolization Device and is indicated for use in adult patients with unruptured, large or giant, saccular, wide-necked or fusiform intracranial aneurysms in the internal carotid artery.

The Flow Re-Direction Endoluminal Device (FRED) System (MicroVention, Inc., Aliso Viejo, CA) received FDA PMA approval on December 16, 2019. The FRED System is indicated for the treatment of brain aneurysms in patients 22 years of age and older, when the aneurysm is bulging on one side (saccular) or both sides of the vessel wall (fusiform). The device can be used when there is a wide entry point to the aneurysm area (a "neck" width 4.0 mm or wider or dome-to-

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neck ratio less than 2.0 mm) in certain regions of the internal carotid artery when the diameter is between 2 mm and 5 mm.

In December 2018, the Woven EndoBridge aneurysm embolization system or WEB device (Sequent Medical, Aliso Viejo, CA) received FDA approval. It is an intrasaccular flow disrupter designed to alter the flow inside the aneurysm, inducing intrasaccular thrombosis. It is a self-expanding mesh ball implant for use at the middle cerebral artery (MCA) bifurcation, internal carotid artery (ICA) terminus, anterior communicating artery (AComm) complex, or basilar artery apex for the endovascular treatment of adult patients with saccular, wide-necked, bifurcation intracranial aneurysms. Some evidence shows the WEB intrasaccular flow disruptor device to be a promising treatment; however, two studies (Da Ros, 2019 and Tau, 2018) have shown that procedure-related complications may be not negligible in the treatment of ruptured and unruptured intracranial aneurysms. Larger studies demonstrating long-term results and comparative studies with other surgical procedures are needed to confirm the safety and efficacy of flow disrupting devices.

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

Code	Description
61624	Transcatheter permanent occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord).
61635	Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed.
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation

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HCPCS Codes

Code	Description
No codes	

ICD10 Codes

Code	Description
I60.00-I60.9	Nontraumatic subarachnoid hemorrhage (code range)
I61.0-I61.9	Nontraumatic intracerebral hemorrhage (code range)
I62.00-I62.9	Other and unspecified nontraumatic intracranial hemorrhage (code range)
I67.0-167.1	Cerebral aneurysm, nonruptured (code range)
Q27.30	Arteriovenous malformation, site unspecified
Q27.4	Congenital phlebectasia
Q28.2-Q28.3	Arteriovenous malformation or other malformation of cerebral vessels (code range)

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*Key Article

KEY WORDS

Enterprise stent, Guglielmi coil, intracranial aneurysm, Neuroform stent, Pipeline Embolization Device (PED), transcatheter intracranial embolization.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, endovascular repair using coil embolization, as a method of treating intracranial aneurysms is not addressed in National or Regional Medicare coverage determinations or policies.