MEDICAL POLICY

SUBJECT: ENDOVASCULAR REPAIR (COIL EMBOLIZATION) OF INTRACRANIAL ANEURYSMS

POLICY NUMBER: 7.01.81
CATEGORY: Technology Assessment

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 is considered medically appropriate as an alternative to aneurysm clipping in the treatment of intra-cranial aneurysms.

II. Endovascular repair of wide-necked intracranial aneurysms using stent assisted embolic coiling is considered a medically appropriate treatment for otherwise inoperable aneurysms only when performed in an institution with a multidisciplinary neurosurgical team. (See policy guidelines II and III.)

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

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. Stent assisted embolic coiling must be performed at a facility having 24 hour/day 7 days/week availability of a multidisciplinary team that includes a neuroendovascular interventionalist.

III. Flow-diverting stents are indicated for the treatment of large or giant wide-necked intracranial aneurysms, with a size of 10 mm or more and a neck diameter of 4 mm or more, in the internal carotid artery from the petrous to the superior hypophyseal segments.

DESCRIPTION:
Surgical ligation and 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 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.

In 1991, Guido Guglielmi described a technique of occluding aneurysms with an endovascular approach using an electrolytic detachable platinum coil. In this procedure, one or more coils are introduced under radiologic guidance directly into the aneurysm via a microcatheter. The first coil is introduced into the aneurysm dome to form a basket, with subsequent coils of decreasing size placed within the aneurysm. The coils fill the aneurysm, blocking blood flow. A low positive direct electrical current is then delivered to the guide wire. Thrombosis occurs within the aneurysm due to the attraction of negatively charged white blood cells, red blood cells, platelets and fibrinogen to the positively charged platinum coil within the aneurysm. Electrical current detaches the platinum coil within a few minutes due to electrolysis of the stainless steel wire closest to the thrombus-covered coil.
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 3 days before stent placement. Consequently, the ideal aneurysm for stent-assisted coil placement is an unruptured one.

The Pipeline Embolization Device (PED) is 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, Freemont, 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, including randomized controlled trials, comparing endovascular coil occlusion with traditional surgical treatment have demonstrated that endovascular treatment is a safe and effective alternative to surgical clipping.

The National Institute for Clinical Excellence (2005) states that current evidence suggests that the coil embolization of unruptured intracranial aneurysms issued 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 and 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.

Currently three self-expanding intracranial microstents (SEIMs) for use with embolic coils are available for use in the US. 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 Cordis Enterprise (TM) Vascular Reconstruction Device and Delivery System for use with embolic coils in the treatment of wide-neck intracranial aneurysms. MicroVention Inc’s, Low-profile Visualized Intraluminal Support Device (LVIS and LVIS Jr) received HDE approval from the FDA in July 2014. The LVIS is a stent assisted coiling device that is intended for use with bare platinum coils for the treatment of unruptured, wide neck (neck greater or equal to 44 mm or dome to neck ration < 2), intracranial, saccular aneurysms arising from a parent vessel with a diameter of equal to or greater than > 2.5 mm and less than or equal to 4.5 mm.

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-neck or giant aneurysms in the internal carotid artery from the petrous to superior hypophyseal segments.

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 8 sites in the US and 2 sites outside of the US. PUFS subjects were adults with a single target aneurysm on the internal carotid artery with size of at least 10 mm and neck of at least 4 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 was placed per subject. Complete IA occlusion was seen in 81.8% of subjects at 180 days and 85.7% at 1 year. The study's primary safety endpoint, ipsilateral major stroke or neurologic death by 180 days after treatment, occurred in 6 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 which remained statistically significant at one year.

Examples of other flow diverting devices that are currently being investigated (no known FDA approval) include the Flow Redirection Endoluminal Device System (FRED), the Surpass Flow Diverter, the Luna Aneurysm Embolization System, and the Barrel Vascular Reconstruction Device.

CODES:  

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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.

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HCPCS:
No codes

ICD10:
747.89 Other aneurysm, congenital, specified site not elsewhere classified

160.00-160.9 Nontraumatic subarachnoid hemorrhage (code range)
161.0-161.9 Nontraumatic intracerebral hemorrhage (code range)
167.0-167.1 Cerebral aneurysm, nonruptured (code range)
Q27.30 Arteriovenous malformation, site unspecified
Q27.4 Congenital phlebectasis
Q28.0-Q28.3 Arteriovenous malformation or other malformation of precerebral/cerebral vessels (code range)
Q28.8 Other specified congenital malformations of circulatory system

REFERENCES:


*Proprietary Information of Excellus Health Plan, Inc.


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**Key Words:**

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

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**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.