



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Endovascular Repair of Intracranial Aneurysms

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Endovascular Repair of Abdominal Aortic Aneurysms
Endovascular Repair of Thoracic Aortic Aneurysms

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Coverage Policy

CIGNA covers endovascular repair of intracranial aneurysms as medically necessary for EITHER of the following:

- ruptured intracranial aneurysm or pseudoaneurysm
- unruptured intracranial aneurysm or pseudoaneurysm, when aneurysm size, location and characteristics make surgical repair technically difficult, not feasible or contraindicated

General Background

An intracranial aneurysm is a weakness in the wall of an artery that is thought to be caused by congenital defects in the vascular wall combined with degenerative changes that cause bulging and may eventually lead to rupture. The majority of intracranial aneurysms occur in the anterior circulation. A pseudoaneurysm is a bulging or dissected segment in the cerebral circulation and is usually caused by accidental or surgical trauma. Most intracranial aneurysms are asymptomatic but may be discovered incidentally during neuroimaging studies. Unruptured aneurysms are also detected when symptoms appear due to the compression of nerves or adjacent brain tissue. Bulging of an aneurysm can cause headache, vomiting, and altered level of consciousness. In some cases, an intracranial aneurysm is not detected until it has ruptured. Rupture of an intracranial aneurysm beneath the arachnoid membrane causes bleeding into the brain (i.e., subarachnoid hemorrhage), causing ischemia and brain damage, decreased cerebral perfusion, brain shift and herniation, hydrocephalus, severe motor and sensory loss, and may lead to coma and death.

Surgical ligation and clipping is the definitive treatment for intracranial aneurysms. Microsurgical techniques have evolved using a variety of surgical approaches and metal aneurysm clips. Surgical treatment has proven to be highly effective, with 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, also referred to as coil embolization, is a less invasive approach introduced in the early 1990s. In this procedure, one or more electrolytic detachable platinum coils are introduced 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. An electrical current is delivered to the guide wire, and thrombosis occurs 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. With wide-necked aneurysms, a stent may also be deployed across the aneurysm neck to prevent the coil from herniating into the parent vessel (Chen, et al., 2003; Johnson, et al., 2002; Mayer et al., 2010).

Endovascular intracranial aneurysm repair 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. A disadvantage of endovascular treatment is the requirement for periodic evaluation to ensure durable aneurysm occlusion. (Chen, et al., 2003; Johnson, et al., 2002, Mayer et al., 2010)

U.S. Food and Drug Administration (FDA)

The Guglielmi Detachable Coil (GDC[®]) (Boston Scientific/Target, Fremont, CA) was approved by the U.S. Food and Drug Administration (FDA) as a Class III device through the 510(k) process in 1995. 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. Numerous stents have also received FDA approval for use in conjunction with endovascular aneurysm repair.

Literature Review

Gerlach et al. (2006) conducted a prospective single-center case series to evaluate clinical outcomes of patients with unruptured intracranial aneurysms, in terms of complications and successful obliteration by surgical clipping or endovascular coiling. A total of 206 unruptured aneurysms were identified in 173 patients. Treatment was performed in 118 (68.2%) patients. In 55 patients (73 aneurysms) conservative management was provided. A total of 91 aneurysms were initially assigned to surgical treatment and 42 to endovascular treatment. Endovascular treatment was not feasible in three aneurysms and was abandoned. Definitive treatment was provided by surgery in 94 aneurysms (81 patients) and by endovascular treatment in 39 aneurysms (37 patients). Immediately after treatment, 6.4% of the surgical patients and 7.7% of the endovascular patients demonstrated new neurological deficits, primarily related to cerebral ischemia. After six months, two surgical patients and one endovascular patient had treatment-related unfavorable outcome. Following surgical clipping, complete occlusion was achieved in 88 (93.6%) aneurysms, and near complete occlusion (i.e., small residual neck) was achieved in four (4.3%) of 94 aneurysms. After endovascular treatment, obliteration was complete in 26 (6.6%) aneurysms, and small residual neck was seen in 23 (33.3%) aneurysms. Five patients in the endovascular group underwent repeated endovascular treatment after aneurysm recanalization. The authors concluded that if patients are carefully selected and assigned to their optimum treatment modality, unruptured intracranial aneurysms can be obliterated by surgery or endovascular treatment in the majority of patients, and in this case series the outcomes were not dependent on treatment. The rate of recanalization was higher after endovascular obliteration, however.

The International Subarachnoid Aneurysm Trial (ISAT) (ISAT Collaborative Group, 2002) was a large multicenter randomized trial in which endovascular coiling was compared to neurosurgical clipping in 2143 patients with ruptured intracranial aneurysms. Patients were randomly assigned to neurosurgical clipping (n=1070) or endovascular treatment by detachable platinum coils (n=1073). Clinical outcomes were evaluated at two months and at one year, with interim assessment of rebleeds and death. The primary outcome measure was the proportion of patients at one year with a modified Rankin scale score of 3–6 (indicating dependency or death). At one year, 23.7% of patients in the endovascular group were either dependent or had died, compared to 30.6% in the neurosurgical group. The risk of rebleeding was slightly higher in the endovascular group at two per 1276 patient years vs. zero per 1081 patient years for the surgical group. The authors concluded that in patients with a ruptured intracranial aneurysm for which endovascular coiling and neurosurgical clipping are

options, the outcome in terms of disability-free survival at one year is significantly better with endovascular coiling, and that the long-term risk of further bleeding is low with either therapy, although slightly higher with endovascular treatment.

Molyneux et al., for the ISAT collaboration (2009), assessed the long-term risks of disability and rebleeding in patients assigned to clipping of endovascular coiling in the ISAT trial, described above. Annual follow-up was performed for a minimum of six years and a maximum of 14 years (mean 9 years), with all deaths and rebleeding events recorded. A total of 24 rebleeds occurred more than a year after treatment. Of these rebleeds, 13 were from the treated aneurysm (10 in the coiling group and 3 in the clipping group; $p=0.06$). At five years, 11% (112 of 1046) of the patients in the endovascular group had died, compared to 14% (144 of 1041) of patients in the surgical clipping group. The risk of death at five years was significantly lower in the endovascular group than in the surgical clipping group ($p=0.03$), but there was no difference in the proportion of surviving patients who were independent at five years. The mortality rate, conditional on survival at one year, was increased for patients treated for ruptured aneurysms compared to the general population ($p<0.0001$).

Vanninen et al. (1999) conducted a relatively small prospective randomized study ($n=109$) to compare coil occlusion ($n=52$) with surgical ligation ($n=57$) for the management of acutely ruptured intracranial aneurysms. Outcome measures included angiographically-confirmed obliteration of the aneurysm, technique-related mortality and clinical outcome as measured by the Glasgow Outcome Scale (GOS). Primary angiographic results were better after surgery in patients with anterior cerebral artery aneurysms ($n=55$) and after endovascular treatment in patients with posterior circulation aneurysm ($n=11$). No significant difference in angiographic results was seen in patients with middle cerebral artery or internal carotid artery aneurysms. The technique-related mortality rate was 4% in the surgical group and 2% in the endovascular group. There was no significant difference between the groups in clinical outcome as measured by GOS score at three months.

One-year outcomes of this study were subsequently published by Koivisto et al. (2000). Of the 57 patients assigned to surgical treatment, 43 had good or moderate recovery, five had severe disability or were in a vegetative state, and nine had died. Of the 52 patients who received endovascular treatment, 41 had good or moderate recovery, four had severe disability or were in a vegetative state, and seven had died. Patients with good clinical outcome did not differ in their neuropsychological test scores. The authors concluded that endovascular treatment of acutely ruptured intracranial aneurysms results in early clinical and neuropsychological outcome equal to the outcome of acute surgical clipping, and that MRI-detectable brain injury is significantly less frequent with endovascular treatment. The authors stated that endovascular treatment is suitable for a selected group of patients, but its long-term efficacy in preventing rebleeding remains unknown.

The Vanninen/Koivisto and ISAT studies are the only two published randomized studies comparing endovascular coil occlusion with traditional surgical treatment. Both studies evaluated patients with ruptured intracranial aneurysms. No prospective randomized trials have been conducted to compare surgical and endovascular treatment for unruptured cerebral aneurysms. The International Study of Unruptured Intracranial Aneurysms (ISUIA) (Wiebers, et al., 2003) assessed 4060 patients with unruptured aneurysms, recording the natural history of patients who had no surgery and evaluating morbidity and mortality associated with repair of unruptured aneurysms by surgical clipping or endovascular repair. Over a five-year period, 18% of the 1692 patients who did not receive endovascular or surgical treatment died due to intracranial hemorrhage. Outcomes were much better for the 451 patients who received endovascular therapy and the 1917 who received surgical clipping, with death rates of 1.8% and 1.5%, respectively.

A Cochrane systematic review (van der Schaaf, et al., 2006) compared the effects of endovascular coiling vs. neurosurgical clipping in patients with aneurysmal subarachnoid hemorrhage. The review was based primarily on the ISAT and Vanninen/Koivisto randomized trials described above, 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 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.

National Institute for Clinical Excellence (NICE) (United Kingdom)

Guidance on coil embolization of unruptured intracranial aneurysms issued by the in 2005 states that current evidence suggests that the procedure 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, provided that normal arrangements are in place for consent, audit and clinical governance.

Professional Societies/Organizations

The American Association of Neurological Surgeons (AANS) does not have a published position on the use of endovascular therapy in the treatment of intracranial aneurysms. The AANS issued a position statement regarding the ISAT Trial in 2002, stating that the study results demonstrated that a particular subset of patients with ruptured aneurysms treated with coiling at designated study centers fared better than patients treated with clipping. According to the AANS statement, while the ISAT report is an important step in defining the roles of endovascular and microsurgical treatment of patients with ruptured intracranial aneurysms, more study is needed to develop definitive evidence on this issue. The statement cautions that extrapolating the early results of the ISAT study to all patients with intracranial aneurysms (ruptured or not) would be a misinterpretation of the ISAT data.

Summary

Endovascular repair of intracranial aneurysms, also called coil embolization, was originally performed only to treat aneurysms unsuitable for surgery but has been used with increasing frequency for patients who could be treated by conventional surgical clipping. Evidence from a number of prospective studies, case series and retrospective studies (Murayama, et al., 2003; Proust, et al., 2003; Raymond, et al., 2003), in addition to evidence from the trials described above, has demonstrated that endovascular treatment is a safe and effective alternative to traditional craniotomy and surgical clipping in patients with ruptured intracranial aneurysms or pseudoaneurysms suitable for this technique.

Based on the available evidence, endovascular repair is a feasible alternative to surgical clipping for unruptured aneurysms only when the aneurysm size, location, and characteristics make surgical repair technically difficult or unfeasible.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®*	Description
61623	Endovascular temporary balloon arterial occlusion, head or neck (extracranial/intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascular injuring post occlusion
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)

ICD-9-CM Diagnosis Codes	Description
430	Subarachnoid hemorrhage
437.3	Cerebral aneurysm, nonruptured
747.81	Anomalies of cerebrovascular system
747.89	Other aneurysm, congenital, specified site not elsewhere classified

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	3/15/2008	0295	Endovascular Repair of Intracranial Aneurysms

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