



## MASSACHUSETTS

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### Medical Policy

## Carotid, Vertebral and Intracranial Artery Stent Placement with or without Angioplasty

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### Policy Number: 219

BCBSA Reference Number: N/A

NCD/LCD: National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7)

### Related Policies

None

### Policy<sup>1</sup>

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

#### Extracranial Stent Placement with or without Angioplasty

Extracranial carotid artery stent placement with or without angioplasty is considered **MEDICALLY NECESSARY** for individuals who meet EITHER A or B of the following criteria **and** can be safely treated by this approach **and** who have no angiographically visible intraluminal thrombus:

- A. Symptomatic stenosis equal to or greater than 50%, **or** asymptomatic stenosis equal to or greater than 80%; **and One or more** of the following conditions which put the individual at a high risk for surgery:
  1. Congestive heart failure (NYHA Class III/IV) or left ventricular ejection fraction less than 30%; **or**
  2. Open heart surgery needed within the next 6 weeks; **or**
  3. Recent myocardial infarction (greater than 24 hours and less than 4 weeks); **or**
  4. Severe chronic obstructive pulmonary disease; **or**
  5. Unstable angina (CCS class III/IV)
  6. Inability to move the neck to a suitable position for surgery; **or**
  7. Tracheostomy.**or**
- B. Symptomatic stenosis equal to or greater than 50%, **or** asymptomatic stenosis equal to or greater than 80%; **and**  
**One or more** of the following conditions:
  1. Contralateral laryngeal nerve palsy; **or**

2. Existence of lesions distal or proximal to the carotid bulb and bifurcation of the common carotid; **or**
3. Pseudoaneurysm; **or**
4. Radiation-induced stenosis following previous radiation therapy to the neck or radical neck dissection; **or**
5. Restenosis after carotid endarterectomy (CEA); **or**
6. Severe tandem lesions that may require endovascular therapy; **or**
7. Stenosis secondary to arterial dissection; **or**
8. Stenosis secondary to fibromuscular dysplasia; **or**
9. Stenosis secondary to Takayasu arteritis; **or**
10. Stenosis that is surgically difficult to access (for example, high bifurcation requiring mandibular dislocation); **or**
11. Stenosis associated with contralateral carotid artery occlusion; **or**
12. Inability to move the neck to a suitable position for surgery; **or**
13. Tracheostomy.

*Note:* If, in exceptional circumstances, extracranial carotid artery angioplasty is performed without stent placement, the above medically necessary criteria must still be met.

### **Intracranial Stent with or without Angioplasty**

Percutaneous intracranial artery stent placement with or without angioplasty is considered **MEDICALLY NECESSARY** as part of the treatment of individuals with an intracranial aneurysm when **ALL** of the following criteria are met:

- A. Surgical treatment is not appropriate or attempted surgery was unsuccessful; **and**
- B. Standard endovascular techniques (coiling) are inadequate to achieve complete isolation of the aneurysm because of anatomic considerations which include, but are not limited to:
  1. wide-neck aneurysm (4 mm or more); **or**
  2. sack-to-neck ratio less than 2:1.

Carotid artery angioplasty and stent placement (CAS) is considered **NOT MEDICALLY NECESSARY** in individuals with **one or both** of the following conditions:

- A. Carotid stenosis with angiographically visible intraluminal thrombus; **or**
- B. A stenosis that cannot be safely reached or crossed by endovascular approach.

Carotid artery angioplasty and stent placement (CAS) is considered **INVESTIGATIONAL and NOT MEDICALLY NECESSARY** when the above criteria are not met, including but not limited to, the following conditions:

- A. Complete occlusion (100% stenosis) of the relevant carotid artery; **or**
- B. Severe symptomatic carotid stenosis in individuals not meeting the criteria above; **or**
- C. Symptomatic stenosis less than 50% of the relevant carotid artery; **or**
- D. Asymptomatic stenosis less than 80% of the relevant carotid artery.

Percutaneous stent placement with or without associated percutaneous angioplasty is considered **INVESTIGATIONAL and NOT MEDICALLY NECESSARY** when used in the treatment of stenosis or aneurysm of:

- A. Vertebral arteries; **or**
- B. Intracranial arteries, except when the criteria above are met.

Percutaneous angioplasty of the intracranial arteries when performed without associated stent placement is considered **INVESTIGATIONAL and NOT MEDICALLY NECESSARY**.

## Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Medical necessity criteria and coding guidance can be found through the link below.

[National Coverage Determination \(NCD\) for Percutaneous Transluminal Angioplasty \(PTA\) \(20.7\)](#)

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

#### Outpatient

- For services described in this policy, see below for situations where prior authorization might be required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>not required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>not required</b> .
Medicare HMO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .
Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:**

#### CPT Codes

CPT codes:	Code Description
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection
37216	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; without distal embolic protection
61635	Transcatheter placement of intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed

**The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

#### CPT Codes

CPT codes:	Code Description
0075T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel
0076T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; each additional vessel (List separately in addition to code for primary procedure)

## Description

### Description of Disease

Approximately 700,000 people in the U.S. will have a stroke this year, and close to 30% will be under the age of 65. Stroke is the third leading cause of death in the U.S. and stenosis of one or both of the carotid arteries is a leading risk factor for stroke. Treatment of carotid artery stenosis includes risk factor modification, that is, smoking cessation, weight reduction, lower cholesterol levels, exercise, reduction of elevated blood pressure, glycemic control, medication (for example, antiplatelet therapy), and in some cases surgical intervention (CEA, CAS). The NASCET (North American Symptomatic Carotid Endarterectomy Trial), a major trial that confirmed the efficacy of CEA, defined "severe" stenosis to be 70%-99%. At this level of stenosis, affected individuals are typically referred for CEA if there are no safety issues (for example, due to comorbidities or characteristics of the lesions).

Fibromuscular dysplasia is a nonatherosclerotic, noninflammatory disease of the blood vessels that most commonly affects the internal carotid and renal arteries. The condition is rare and the cause is unknown, although cigarette smoking and a history of hypertension may increase the risk. The severity of symptoms varies widely and may result in arterial stenosis, aneurysms, and dissection (separation of the layers of the vessel wall) that result in significant morbidity. Therapy may include drug therapy (to treat hypertension that results from renal artery involvement), surgical revascularization, and angioplasty. Vertebral artery and intracranial artery stenosis have a poor prognosis and generally lead to neurological deterioration or death. Medical management is the treatment option most used. Surgical risks and complications are significant.

### Description of Technology

Traditionally, surgical treatment has been with open CEA. The carotid artery is exposed through an incision, and the atherosclerotic plaque causing the narrowing is removed surgically. Recently, CAS emerged as an alternative to open surgery. While carotid angioplasty has been performed alone, currently this procedure typically includes the placement of a stent, in order to prevent restenosis. However, in certain conditions of fibromuscular dysplasia and in situations where stent placement is technically not feasible, angioplasty alone may be performed.

Stent implantation is a supplement to angioplasty, in which a balloon introduced via a catheter is inserted through a blockage and expanded to enlarge the vessel, allowing restoration of blood flow. This procedure involves the permanent placement of a mechanical device within blocked arteries or veins, in order to compress the obstructive material and to support the vessel wall, preventing both constriction and further blockage. Insertion of an embolic protection device may accompany stent placement. This device consists of a small wire mesh or basket that is used to capture any embolic debris that may dislodge from the lesion, in order to prevent the debris from reaching the brain or other intracranial areas. Such devices are purported to further decrease the neurologic event risk from CAS.

In 2007, a consensus document on carotid stenting was released by the American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions/Society for Vascular Medicine and Biology/Society of Interventional Radiology/American Society of Interventional & Therapeutic Neuroradiology (ACCF/SCAI/SVMB/SIR/ASITN). This document states that:

CAS is viewed as a reasonable alternative to CEA, particularly in subjects at high risk for CEA, and use of EPDs (embolic protection devices) seems to be important in reducing risk of stroke... At the present time, the evidence is insufficient to support CAS in asymptomatic high-risk subjects who have less than 80% stenosis or in those who are not at high-risk for surgery (Bates, 2007).

In 2003, a collaborative panel of the Joint Standards of Practice Committee of the American Society of Interventional and Therapeutic Neuroradiology, the American Society of Neuroradiology, and the Society of Interventional Radiology developed quality improvement guidelines for the performance of cervical CAS. The document includes standards for qualifications and responsibilities of personnel, specifications of the procedure, equipment quality and control, documentation, thresholds, success and complication rates, quality control and improvement, safety, infection control, and candidate education concerns.

Furthermore, the document outlines suggested inclusion criteria and relative and absolute contraindications for CAS (Barr, 2003).

Human Device Exemptions (HDEs) differ from the standard FDA approval process and are designed to allow the use of qualified devices without requiring the rigorous safety and efficacy testing required for standard device approvals. A humanitarian device is one that is intended to benefit individuals in the treatment and diagnosis of rare diseases or conditions that affect or are manifested in fewer than 4000 individuals in the United States per year. The goal of the HDE process is to allow the use of specific devices for indications where other alternatives are unavailable. A healthcare provider is responsible for obtaining Institutional Review Board approval before a humanitarian device with an exemption may be administered or implanted. For the NEUROLINK System, the Center for Devices and Radiological Health (CDRH) of the FDA determined that, based on the data submitted in the HDE, the NEUROLINK System will not expose recipients to an unreasonable or significant risk of illness or injury. The probable benefit to health from using the device outweighs the risks of illness or injury as follows:

For the treatment of individuals with recurrent stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with greater than or equal to 50% stenosis that are accessible to the stent system.

The FDA issued an approval order on August 9, 2002.

### **Proposed Benefits**

CAS is purported to decrease stenosis in carotid arteries with varying degrees of blockage. Theoretically, with blood flowing more freely through the artery, symptoms, such as TIA, are diminished or relieved completely, and the risk of stroke and associated neurological impairment is also greatly diminished. Although CEA provides the same advantages, CAS is a less invasive procedure and is promoted as an alternative to CEA particularly where an invasive procedure would lead to a high risk of complications. Studies show that the technical success of CAS ranges from about 96% to 100% and residual stenosis after CAS ranges from 2% to 15%. Percutaneous intracranial artery stent placement with or without angioplasty is also used in the treatment of intracranial aneurysms where certain clinical factors contribute to high risk for life threatening events and established surgical and medical management strategies are either contraindicated or ineffective.

### **Possible Risks**

Risks from CAS include restenosis after implantation of the stent (generally uncommon). Non-neurologic complications (for example, slow heart rate, transient loss of consciousness) may occur during the procedure. Neurologic complications are generally due to embolic debris that dislodged from the site of the lesion either during or after the procedure and may lead to stroke and/or death. In recent studies, the overall postoperative neurologic complication rates for CAS of the extracranial carotids for the treatment of stenosis have ranged from about 0% to 10%.

## **Summary**

### **Extracranial Carotid Artery Angioplasty with Stent Placement (CAS) for Treatment of Atherosclerotic Stenosis of the Extracranial Carotid Arteries:**

Currently, carotid endarterectomy (CEA) is considered the established "gold standard" procedure for individuals with symptomatic and significant carotid artery stenosis. However, this is an invasive procedure associated with well-defined, (albeit acceptable) complications including the possibility of nerve injuries. A percutaneous endovascular approach to carotid artery lesions has been attractive, particularly since this technique has been applied successfully in other areas of the vascular tree including the coronary and lower limb circulation. However, unlike coronary or iliac angioplasty, occlusion of the carotid artery may not be amenable to emergency surgical correction. Serious embolic complications including stroke and death remain an issue.

The majority of published data represent prospective uncontrolled studies with a number of variables including candidate selection criteria, type of stent used, and use or non-use of an embolic protection

device. Initial studies reported higher complication rates for stroke and/or death than with CEA (10-12% for CAS versus 5.8% for CEA). More recent studies, however, including two randomized studies, suggest similar major complication rates for the two procedures, together with similar restenosis rates. However, the two randomized studies were performed at a single institution by a particularly experienced operator and consisted of relatively small sample sizes. Also, in other studies, issues related to candidate selection, inconsistent use of stents and protection devices and short follow-up indicate the need for further larger scale, longer term, randomized, controlled studies comparing CAS with CEA to determine the relative efficacy and complication rates of these procedures. The multi-center Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS) randomized 504 mostly symptomatic subjects with 70% carotid artery stenosis to receive endovascular treatment or CEA. There was no difference in the rates of death or stroke at 30 days, and 3 year follow-up showed no difference in the rate of stroke. This trial has been criticized, however, because the rate of stroke or death was higher than that reported in other randomized trials of CEA. Also, residual restenosis was more frequent with the endovascular approach than CEA (14% versus 4% respectively). However, it should be noted that only 22% of participants in this trial received stents. Two earlier randomized trials of carotid stenting were stopped early because of inferior outcomes, which were thought to be related to earlier stent designs and inexperience with the technique.

Brown, the principal investigator of CAVATAS and CAVATAS-2 (an ongoing international study), in an editorial in the American Journal of Medicine (2004) wrote, "There is, therefore, a need for further randomized trials of CAS with protection devices compared with CEA to establish convincingly the value of CAS." Brown further stated:

Although the early results of CAS with protection devices appear encouraging, there are no long term data to rival that available from the carotid surgical trials. Hence, caution argues that stenting should continue to be seen as an experimental procedure and carried out only in the context of randomized clinical trials.

Currently, there are multi-center, randomized, controlled studies in progress in Europe and the United States. Results of two trials, the SPACE trial (Stent Supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy) and the EVA-3S trial (Endarterectomy versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis) are now available. The SPACE trial was a randomized non-inferiority trial that provided outcomes data at 30 days which failed to prove the non-inferiority of CAS, compared to conventional CEA. However, the authors state that the results do not justify widespread use in the short term of CAS, and outcomes at 6-24 months are awaited (Ringleb, 2006). Published results of the EVA-3S trial reported finding that, for symptomatic subjects with carotid stenosis of 60% or more, the rates of death and stroke at 30 days and 6 months following surgery were lower for CEA, compared with CAS (Mas, 2006).

Four year follow-up results of the EVA-3S trial found that the safety of stenting needs to be improved for individuals with symptomatic carotid stenosis. This multicenter, randomized trial compared the safety of CAS with CEA. Participants were eligible for the EVA-3S study if they were 18 years or older, had a transient ischemic attack (TIA) or a nondisabling stroke (or retinal infarct) within 120 days before enrollment, and had an atherosclerotic stenosis of 60% to 99% of the symptomatic carotid artery. The study enrolled 527 subjects who were randomly assigned to undergo CEA (n=262) or CAS (n=265). The primary endpoint was the rate of any periprocedural stroke or death within 30 days postprocedure; the EVA-3S trial was terminated early because of a higher 30-day risk of stroke or death in the CAS group. The main secondary endpoint was a composite of any periprocedural stroke or death and any nonprocedural ipsilateral stroke during 4 years of follow-up.

Results of the 4 years of follow-up of the EVA-3S data found the cumulative probability of periprocedural stroke or death and nonprocedural ipsilateral stroke was higher with CAS than with CEA (11.1% versus 6.2%; hazard ratio [HR], 1.97; 95% confidence interval [CI], 1.06 to 3.67; p=0.03). The HR for any periprocedural disabling stroke or death or any nonprocedural fatal or disabling ipsilateral stroke was 2.00 (CI, 0.75 to 5.33; p=0.17). A hazard function analysis showed the 4-year differences in the cumulative probabilities of outcomes between stenting and CEA were largely accounted for by the higher

periprocedural (within 30 days of the procedure) risk of stenting compared with CEA. After the periprocedural period, the risk of ipsilateral stroke was low and similar in both treatment groups. The authors concluded that for individuals with symptomatic carotid stenosis, CAS is not as safe an alternative as CEA, although CAS is as effective as CEA for prevention of middle-term ipsilateral stroke (Mas, 2008).

Yadav and colleagues reported on results of the SAPPHERE trial (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy) in October 2004. This trial included 334 participants classified as "high risk," based on the presence of neurological symptoms and a greater than 50% stenosis of the common or internal carotid artery or who were asymptomatic with greater than 80% stenosis, who were randomized to CEA or CAS. Of the 167 subjects randomly assigned to stenting, 159 received the assigned treatment. Of the 167 assigned to surgery, 151 received the assigned treatment. All participants also had one or more medical or surgical comorbid conditions that placed them at high risk for CEA. Exclusion criteria for the trial included history of a bleeding disorder, along with other criteria. The technique employed the Cordis Corporation's PRECISE™ Nitinol Stent System with the ANGIOGUARD™ Embolic Capture Guide-wire System. At 1 year, superior results were reported for the CAS group, measured by a composite endpoint of major adverse events including all-cause death, stroke, and myocardial infarction (12% for CAS vs. 20% for CEA). The authors concluded that among individuals with severe carotid-artery stenosis and coexisting conditions, CAS with the use of an embolic-protection device is not inferior to CEA. Additional information on results of the SAPPHERE trial were subsequently reported which indicated that, among subjects at high surgical risk, CAS was associated with less health status impairment during the initial 2 week post-surgical recovery period than CEA-treated subjects. However, these differences in quality of life measures resolved by 1 month post-procedures, and no other differences between the 2 treatment groups in health-related quality of life were noted (Stolker, 2010).

Most authors currently writing in the literature are of the opinion that CEA, a proven effective long-term surgical approach, remains the gold standard of interventional care, and they do not advocate the widespread practice of CAS with stenting as an alternative, at this time, particularly in those who are not at high risk for CEA. This includes the short-term results of a multicenter, open, randomized, controlled trial, the International Carotid Stenting Study (ICSS), which enrolled only symptomatic subjects within 1 year and carotid artery stenosis of 50% or greater; 853 participants were randomized to CAS and 857 to CEA. Randomization procedures effectively concealed allocation to investigators; study subjects were unblinded, and embolic protection devices were recommended, but not required. The investigators acknowledged that the follow-up data was insufficient to examine the primary endpoint, that is, 3-year rates of fatal or disabling stroke; only the 30-day morbidity, as reflected by stroke, death, or myocardial infarction (a secondary endpoint) was reported. In per-protocol analyses, the 30-day stroke and death rate was 3.4% and 7.4% following CEA and CAS, respectively. While 30-day stroke and death rates were not specifically reported in an intention-to-treat analysis, the corresponding estimated rates were 3.4% and 6.8%. There were few periprocedural myocardial infarctions (MIs)—3 in the stenting arm (0.4%) and 5 following CEA (0.6%). These preliminary ICSS results are noted to be consistent with two previously reported large randomized controlled trials enrolling similar symptomatic subjects (SPACE, EVA-3S). The authors also noted that within the ICSS results, CAS was not performed with periprocedural (30-day) stroke and death rates sufficiently low (that is, less than 6%) to achieve a net clinical benefit and CAS was inferior to CEA (Ederle, 2010).

Preliminary results were published for the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST), which is a large, ongoing, randomized, controlled trial with blinded endpoint adjudication, sponsored by the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institutes of Health (NIH). The primary aim is to compare the outcomes of CAS with those of CEA among subjects with symptomatic or asymptomatic extracranial carotid stenosis. Trial participants were considered to be symptomatic if they had had a TIA, amaurosis fugax, or minor nondisabling stroke involving the study carotid artery within 180 days before randomization. Eligibility criteria were stenosis of 50% or more on angiography, 70% or more on ultrasonography, or 70% or more on computed tomographic angiography (CTA) or magnetic resonance angiography (MRA) if the stenosis on ultrasonography was 50 to 69%. Eligibility was extended in 2005 to include asymptomatic subjects, for whom the criteria were stenosis of 60% or more on angiography, 70% or more on ultrasonography, or

80% or more on CTA or MRA if the stenosis on ultrasonography was 50 to 69%. Subjects were excluded if they had had a previous stroke that was sufficiently severe to confound the assessment of endpoints. Trial participants from 108 centers in the U.S. and Canada included 2502 subjects over a median follow-up period of 2.5 years. Total numbers were 1262 received CAS, and 1240 underwent CEA. Participants were not randomly assigned to a treatment group until the operators performing both the CAS and CEA procedures had been certified, which included 224 interventionalists who were certified after satisfactory evaluation of their endovascular experience, CAS results, and participation in both hands-on training and a lead-in phase of training.

Preliminary results among subjects with symptomatic or asymptomatic carotid stenosis indicated that the risk of the composite primary outcome of stroke, MI, or death did not differ significantly in the two treatment groups. However, it was noted that there was a higher risk of stroke in the CAS group and a higher risk of MI in the CEA group during the periprocedural period. These countervailing effects during the periprocedural period resulted in similar rates of the primary outcomes, because the rates of events after the periprocedural period were similar in the two groups. The authors acknowledge that the differential results for MI and stroke offer opportunities for improvement in the training of surgeons and interventionalists performing CAS procedures, expanded knowledge and experience with stent designs and embolic protection devices, as well as better informed candidate selection, especially amongst those over 70 years of age. The authors note that candidate selection may require attention to age for either procedure, due to the association between older age and increased risk for adverse events. This interaction between age and treatment efficacy was detected at approximately 70 years of age. The effects of advanced age on the differences between CAS- and CEA-treated groups were seen in the SPACE trial results, as well as in these early CREST results where younger participants had slightly better outcomes with CAS and older persons had a better outcome with CEA. The trial investigators speculated that mechanisms underlying the increased risk with CAS in the very elderly (age over 70) probably include vascular tortuosity and severe vascular calcification. It is generally considered that these preliminary results (mean follow-up of 2.5 years) lack sufficient detail for firm conclusions and are viewed as consistent with the growing body of evidence examining outcomes of CAS, in comparison to CEA, that indicate the need for further robust study. The absence of comparison with current best medical therapy is another significant limitation of CREST (Brott, 2010). Silver published final results of the CREST in 2011 which reflected that, although the participating interventionalists performing CAS were highly selected, periprocedural death/stroke rates following CAS exceeded those for CEA: in symptomatic subjects 5.6% versus 2.4%, respectively (the lowest rate for CAS reported in any trial); in asymptomatic subjects 2.6% versus 1.4%, respectively. The relative risk (RR) for periprocedural death/stroke in the symptomatic group was 1.89 (95% CI, 1.11 to 3.21) and in the asymptomatic group was 1.85 (95% CI, 0.79 to 4.34). The trial had limited power to detect a difference between procedures in the asymptomatic group (Silver, 2011). Additional meta-analyses have generally found that restenosis is more common following CAS than CEA (Bangalore, 2011; Economopoulos, 2011; Murad, 2011).

In August 2004, the U.S. Food and Drug Administration (FDA) granted Premarket Approval (PMA) to Guidant Corporation's two stent systems (the ACCULINK™ Carotid Stent System and the RX ACCULINK™ Carotid Stent System), which are used in conjunction with two carotid embolic protection systems (the ACCUNET™ and the RX ACCUNET™ Embolic Protection Systems, Guidant Corp., Santa Clara, CA) for the treatment of individuals considered to be at high risk for adverse events from CEA who require carotid revascularization and meet the following criteria:

1. Persons with neurological symptoms and equal to or greater than 50% stenosis of the common or internal carotid artery by ultrasound or angiogram OR persons without neurological symptoms and equal to or greater than 80% stenosis of the common or internal carotid artery by ultrasound or angiogram; AND
2. Individuals must have a reference vessel diameter within the range of 4.0 mm and 9.0 mm at the target lesion.

As part of this approval, Guidant agreed to conduct long-term follow-up of subjects in the studies it submitted to the FDA and conduct another post approval study including 1,000 newly enrolled participants. The data submitted to the FDA, on which its approval was based, were from 3 prospective,

non-randomized, multicenter, single arm trials known as ARCHeR 1, 2 and 3 (ACCULINK for Revascularization of Carotids in High Risk Patients) enrolling a total of 581 subjects who were considered either high-risk for CEA or not surgical candidates for current surgical options (CEA) and who were symptomatic with a 50% or greater carotid artery stenosis, or asymptomatic with an 80% or greater stenosis. The ARCHeR results were published in 2006 (Gray, 2006). The primary composite endpoint of 30-day combined incidence of death, stroke and MI plus 1 year incidence of ipsilateral stroke was 9.6%. This was compared to 14.4% for historical surgical controls involving similar high surgical risk populations. Target lesion revascularization at 1 and 2 years was 2.2% and 2.9% respectively. These studies suggested that CAS may be safe and effective in a subset of individuals who are not candidates for CEA. In 2006, Guidant Corporation's vascular intervention and endovascular business was acquired by Abbott Vascular Solutions, Inc. (Temecula, CA).

On September 6, 2005, the FDA granted PMA approval to the Xact™ Carotid Stent System (Abbott Vascular Solutions, Inc.) for use in conjunction with the Abbott Emboshield® Embolic Protection System for very similar indications to the ACCULINK and RX ACCULINK devices.

Several additional carotid stent and embolic protection systems have been granted PMA approvals by the FDA as substantially equivalent to the RX ACCULINK and Xact device systems including, but not limited to: the Protégé® GPS™ and Protégé® RX Carotid Stent Systems used with the SpiderRX™ Embolic Protection Device (ev3 Inc., Plymouth, MN), which received FDA approval in January 2007. This CAS system was evaluated via the Carotid Revascularization with ev3 Inc. Arterial Technology Evolution (CREATE) Trial. The NexStent® Carotid Stent and Monorail® Delivery System (Endotex Interventional Systems, Inc., Cupertino, CA) received FDA clearance in October 2006. It is also compatible with the FilterWire EZ™ Embolic Protection System (Boston Scientific Corporation, San Jose, CA). FDA clearance for the FilterWire EZ Embolic Protection System, as well as for the two associated CAS systems, was based on a prospective, nonrandomized multicenter clinical trial (Carotid Artery Revascularization using the Boston Scientific EPI FilterWire EX and the EndoTex NExStent [CABERNET]). These devices received FDA clearance for similar indications to the prior approved devices.

CAS appears to be a reasonable option for select individuals who are poor surgical candidates, for reasons of either anatomy or comorbidities, and who otherwise meet the criteria for revascularization. However, CEA remains the gold standard procedure for those who are not at high risk for this procedure. A report from the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology (Chaturvedi, 2005) commented that there are several important areas for further investigation pertaining to CAS, including the role of cerebral hemodynamics in risk stratification for individuals with carotid stenosis.

In 2012, the Blue Cross Blue Shield Association published a Technology Evaluation Center (TEC) Assessment update on Angioplasty and Stenting of the Cervical Carotid Artery with Embolic Protection of the Cerebral Circulation. This report concluded that amongst individuals selected because of medical comorbidities and/or unfavorable anatomy, there is generalizable and applicable evidence that CAS is performed with periprocedural death/stroke rates exceeding 3% for asymptomatic and 6% for symptomatic subjects and, therefore, not accompanied by net clinical benefit. At present, the use of CAS with embolic protection of the cerebral circulation for individuals with carotid artery stenosis does not meet the TEC criteria (2012).

In 2011, the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery issued Guidelines on the Management of Patients with Extracranial Carotid and Vertebral Artery Disease. The following recommendations are excerpted:

#### Class I:

CAS is indicated as an alternative to CEA for symptomatic patients at average or low risk of complications associated with endovascular intervention when the diameter of the lumen of the internal carotid artery is reduced by more than 70% as documented by noninvasive imaging or more than 50% as documented by catheter angiography and the anticipated rate of periprocedural stroke or mortality is less than 6% (Evidence Level: B).

#### Class IIa:

It is reasonable to choose CEA over CAS when revascularization is indicated in older patients, particularly when arterial patho-anatomy is unfavorable for endovascular intervention (Evidence Level: B). It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery (Evidence Level: B) (Brott, 2011).

Although there are few studies dealing with the effect of CAS on symptomatic carotid stenosis due to fibromuscular dysplasia, there are few treatment options for this population. In addition, the rarity of the condition also makes it unlikely that studies with moderate to large sample sizes will be conducted in the near future. Consequently, angioplasty with or without stenting remains an important treatment option for these individuals and has been successfully carried out in the practice community. Regarding use of CAS in asymptomatic disease, the American Heart Association/American Stroke Association (AHA/ASA) issued Guidelines for the Primary Prevention of Stroke in 2011, in which it was noted that advances in optimal medical therapy have resulted in uncertainty about the need for, and benefit of, CEA or CAS in the asymptomatic subgroup with carotid artery stenosis. The findings in this document conclude that more data are needed to compare long-term outcomes following CEA and CAS in asymptomatic individuals with carotid artery stenosis (Goldstein, 2011). Another updated guideline, the Society for Vascular Surgery Guidelines for Management of Extracranial Carotid Disease, concurs with the AHA/ASA guidance regarding asymptomatic disease (Ricotta, 2011).

There is limited evidence concerning the net benefit of angioplasty and stenting for vertebral arteries, and large well designed trial results are not available at this time.

#### **Intracranial Artery Stent Placement with or without Angioplasty for the Treatment of Intracranial Arterial Stenosis:**

Through Humanitarian Device Exemptions (HDEs), the FDA has cleared the following intracranial stent systems: the NEUROLINK® Intracranial Stent System (Guidant Corp., Menlo Park, CA) in August 2002 and the Wingspan Stent System™ with Gateway™ PTA Balloon Catheter (Stryker Neurovascular, Fremont, CA) in August 2005. The NEUROLINK System is indicated for the treatment of individuals with recurrent intracranial stroke caused by atherosclerotic disease refractory to pharmacotherapies, in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with greater than or equal to 50% stenosis that are accessible to the stent system. The Wingspan Stent System is indicated for improving cerebral artery lumen diameter in individuals with intracranial atherosclerotic disease, refractory to pharmacotherapies, in intracranial vessels with greater than or equal to 50% stenosis that are accessible to the system. On August 8, 2012 the FDA announced the indications for use and labeling for the Wingspan System *have changed to limit the use of Wingspan to:*

A narrow, select group of patients and conditions. These changes are based on analysis of the original HDE clinical study, data from studies performed after the HDE approval was granted, and data from a clinical trial called the Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) study. After reviewing the available safety information, the FDA believes that a very specific group of patients with severe intracranial stenosis and recurrent stroke, despite continued medical management, who have not had any new symptoms of stroke within the 7 days prior to planned treatment with Wingspan, may benefit from the use of the device. The agency's assessment of benefits and risks for this device considered that these patients are at serious risk of life-threatening stroke and have limited alternative treatment options (FDA, 2012).

The SSYLVA trial (Stenting of Symptomatic Atherosclerotic Lesions in the Vertebral or Intracranial Arteries) was a multicenter, non-randomized prospective feasibility study using the NEUROLINK Intracranial Stent System. It included 61 symptomatic subjects who had suffered a TIA or stroke attributable to a single arterial stenosis of at least 50%. Following stent placement, the stroke rate within 30 days was 6.6%, and 30-day to 12 month stroke rate was 7.3%. At 6 months, the restenosis rate (of greater than 50% stenosis) was 32.4% for intracranial stents and 42.9% for extracranial vertebral stents. The investigators acknowledged, "Currently there is no proven benefit of this procedure relative to medical therapy" (SSYLVA, 2004).

The Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) trial was intended to compare percutaneous transluminal angioplasty and stenting (PTAS) to intensive medical therapy among subjects with 70-99% stenosis. This large trial was sponsored by the Medical University of South Carolina, in collaboration with the National Institutes of Health (NIH) and the National Institute of Neurological Disorders and Stroke (NINDS). The primary outcome measure was to determine whether intracranial stenting (with the Wingspan stent) with intensive medical therapy is superior to medical therapy alone for preventing secondary stroke in high-risk subjects with symptomatic stenosis of a major intracranial artery. Recruitment took place at 50 sites in the U.S. with a target enrollment of 764 participants. However, this study was halted early in 2011, due to a higher rate of adverse events in the angioplasty/stenting group (NCT00576693).

Subsequent further analysis of the SAMMPRIS data have concurred with the preliminary findings noting that the 30-day rate of stroke or death was 14.7% in the PTAS group (nonfatal stroke, 12.5%; fatal stroke, 2.2%) and 5.8% in the medical management group (nonfatal stroke, 5.3%; non-stroke-related death, 0.4%) ( $p=0.002$ ). Beyond 30 days, stroke in the same intracerebral territory occurred in 13 subjects in each group. The probability of the occurrence of a primary endpoint event over time differed significantly between the 2 treatment groups ( $p=0.009$ ), with 1-year rates of the primary endpoint of 20.0% in the PTAS group and 12.2% in the medical management group. The investigators concluded that, in individuals with intracranial arterial stenosis, aggressive medical management was superior to PTAS with the use of the Wingspan stent system, both because the risk of early stroke after PTAS was high and because the risk of stroke with aggressive medical therapy alone was lower than expected (Chaudhry, 2011; Chimowitz, 2011; Derdeyn, 2014; Siddiq, 2012).

In 2009, the American Heart Association Council on Cardiovascular Radiology and Intervention, Stroke Council, Council on Cardiovascular Surgery and Anesthesia, Interdisciplinary Council on Peripheral Vascular Disease, and Interdisciplinary Council on Quality of Care and Outcomes Research issued a scientific statement on Indications for Intracranial Endovascular Neuro-interventional Procedures. The recommendation related to endovascular treatment of symptomatic intracranial stenosis was noted as Class IIb with Level of Evidence C (usefulness/effectiveness is unknown/unclear). The level of evidence was the same for use of angioplasty and stenting in the treatment of acute ischemic stroke (Meyers, 2009). These findings align with results of a pilot study, the Stent-Assisted Recanalization in Acute Ischemic Stroke Trial (SARIS) which was a prospective, single-arm trial that investigated the safety and efficacy of primary stent deployment (with the Wingspan System) for revascularization in 20 individuals with acute stroke. The 1-month mortality rate was 25% which, according to the authors, suggested the possibility of benefit of intracranial stenting in acute stroke treatment. However, no robust conclusions could be drawn from this small ( $n=20$ ), non-randomized, single center study and additional larger trials are needed (Levy, 2009).

In 2012, standards of practice recommendations were published on behalf of the Society of NeuroInterventional Surgery, which were based on assessment of available evidence from an updated literature review which extracted published literature from 2000 to 2011 regarding the treatment of symptomatic intracranial atherosclerotic disease (ICAD). Evidence was evaluated and classified according to American Heart Association (AHA)/American Stroke Association standards with recommendations developed which were based on guidelines for evidence based medicine proposed by the American Academy of Neurology (AAN), the Stroke Council of the AHA and the University of Oxford, Centre for Evidence Based Medicine (CEBM). This evidence-based assessment identified 59 publications and noted that the SAMMPRIS study is the only prospective, randomized, controlled trial

currently available (which was given an AHA level B designation, AAN class II and CEBM level 1b). The Stenting of Symptomatic Atherosclerotic Lesions in the Vertebral or Intracranial arteries (SSYLIVIA) trial was a prospective, non-randomized study with the outcome assessment made by a non-operator study neurologist, (which allowed an AHA level B, AAN class III and CEBM level 2 rating). The remaining studies were uncontrolled or did not have objective outcome measurement, (and were classified as AHA level C, AAN class IV and CEBM level 4 rating). These investigators concluded that medical management with combination aspirin and clopidogrel for 3 months and aggressive risk factor modification should be first line therapy for individuals with symptomatic ICAD. Endovascular angioplasty, with or without stenting, is a possible therapeutic option for selected subjects with symptomatic ICAD and may be considered in subjects with symptomatic 70-99% intracranial stenosis when aggressive maximal medical therapy has failed. However, further studies are necessary to define appropriate selection criteria and the best therapeutic approach for various subsets of affected individuals (Hussain, 2012).

In 2013, the American Heart Association Stroke Council, Council on Cardiovascular Nursing, Council on Peripheral Vascular Disease, and Council on Clinical Cardiology issued Guidelines for the Early Management of Patients with Acute Ischemic Stroke which contain two new recommendations that concur with the other specialty medical society guidance regarding extracranial and intracranial artery angioplasty and stenting as a treatment of acute ischemic stroke as follows:

The usefulness of emergent intracranial angioplasty and/or stenting is not well established. These procedures should be used in the setting of clinical trials (Class IIb; Level of Evidence C);

The usefulness of emergent angioplasty and/or stenting of the extracranial carotid or vertebral arteries in unselected patients is not well established (Class IIb; Level of Evidence C). Use of these techniques may be considered in certain circumstances, such as in the treatment of acute ischemic stroke resulting from cervical atherosclerosis or dissection (Class IIb; Level of Evidence C). Additional randomized trial data are needed (Jauch, 2013).

### **Intracranial Artery Stent Placement with or without Angioplasty for the Treatment of Intracranial Arterial Aneurysms:**

The International Study of Unruptured Intracranial Aneurysms (ISUIA) trial assessed 4060 subjects with unruptured aneurysms, recording the natural history of those who had no surgery and evaluating morbidity and mortality associated with repair of unruptured aneurysms by surgical clipping or endovascular repair. Over a 5-year period, 18% of the 1692 trial participants who did not receive endovascular or surgical treatment died due to intracranial hemorrhage. Outcomes were much better for the 451 subjects who received endovascular therapy and the 1917 individuals who received surgical clipping with death rates of 1.8% and 1.5%, respectively (Wiebers, 2003).

The largest clinical series describing use of stents in treating intracranial aneurysms was published in 2010 reporting on a series of 1137 subjects (1325 aneurysms) treated between 2002 and 2009. In this series, 1109 individuals with aneurysms (83.5%) were treated without stents (coiling) and 216 (16.5%) were treated with stents (15 balloon-expandable and 201 self-expandable stents). Stents were delivered after coiling in 55% (119/216) and before coiling in 45% (97/216) of the cases. Permanent neurological procedure-related complications occurred in 7.4% (16 of 216) of the procedures with stents versus 3.8% (42 of 1109) in the procedures without stents (logistic regression  $p=0.644$ ; odds ratio [OR], 1.289; 95% CI, 0.439-3.779). Procedure-induced mortality occurred in 4.6% (10 of 216) of the procedures with stents versus 1.2% (13 of 1109) in the procedures without stents (logistic regression  $p=0.006$ ; OR, 0.116; 95% CI, 0.025-0.531). Thus far, the authors have followed 53% (114 of 216) of individuals with aneurysms treated with stents and 70% (774 of 1109) of individuals with aneurysms treated without stents, with angiographic recurrence in 14.9% (17 of 114) of stent-treated subjects versus 33.5% (259 of 774), of subjects treated with coiling without stenting ( $p<0.0001$ ; OR, 0.3485; 95% CI, 0.2038-0.5960). Based on this series, the authors concluded that use of stents was associated with a significant decrease of angiographic recurrences, but with more lethal complications compared with coiling without stents (Piotin, 2010). Additional small studies note the need for additional data to further define the technical challenges

in stent deployment, the durability of endovascular stent grafting for intracranial aneurysms and the exact role of this treatment (Biondi, 2007; Mocco, 2009; Wajnberg, 2009).

A prospective, multicenter trial which used observational registry data with consecutive intent-to-treat to obtain safety and efficacy data on another stent system, the Neuroform3™ (Boston Scientific Corp., Natick, MA), which is used in conjunction with occlusive devices, such as coils, for the treatment of wide neck aneurysms, was completed in 2011. The Safety and Efficacy of Neuroform3 for Intracranial Aneurysm Treatment (SENAT) trial objectives of this industry-sponsored study were:

- To describe and quantify morbidity-mortality at 1 month and 12-18 months following the treatment of the intracranial aneurysm with the Neuroform3 stent;
- To describe and quantify the adverse events rate;
- To get an angiographic assessment performed at 12-18 months compared to the initial post-treatment assessment consisting of residual aneurysm, modified Rankin scale, and a same/better/worse scale; and
- To get a neurologic assessment: Modified Rankin Scale at 12-18 months, evaluated as a categorical change compared to baseline (Stryker, NCT00928265; 2011).

Santillan published results of the SENAT trial which included 79 subjects harboring wide-necked intracranial aneurysms who were treated using the Neuroform3 stent. The stenting procedure failed in 2 subjects. Therefore, 77 individuals harboring 79 intracranial aneurysms were included for analysis. Subject and aneurysm characteristics, progression of aneurysm occlusion, and occurrence of complications were analyzed with follow-up imaging that included digital subtraction angiography (DSA) or MRA. Overall, complete aneurysm occlusion was observed in 42.4% of the cases immediately after treatment and progressed to 96.5% at 7-year follow-up. The mean angiographic follow-up time was 25.8 months (range, 0-84 months). Eleven aneurysms (14%) were retreated. Sixty-eight subjects (88.3%) had a favorable clinical outcome with a modified Rankin Scale (mRS)  $\leq 1$ ; 3 subjects (3.9%) had an mRS of 2 and 5 (6.5%) did not have a clinical follow-up. The mean clinical follow-up time was 45.4 months (range, 3-92 months). One subject (1.3%) died from a procedure-related hemorrhage. The authors concluded that the Neuroform3 stent-assisted coil embolization of wide-necked intracranial aneurysms prevents hemorrhage and provides a high rate of aneurysm occlusion at long-term follow-up (Santillan, 2011).

In 2007, the ENTERPRISE™ Vascular Reconstruction Device and Delivery System (Cordis Neurovascular, Inc., Miami Lakes, FL) also received HDE designation clearance from the FDA for:

Use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of  $\geq 3$  mm and  $\leq 4$  mm. Wide-neck is defined as having a neck width  $\geq 4$ mm or a dome-to-neck ratio  $< 2$ .

Although cleared by the FDA, the clinical effectiveness of these intracranial stent systems has not been clearly established. Preliminary findings, on which the FDA clearances were based, need further validation in large randomized controlled trials. On April 6, 2011 the FDA announced its clearance of another device for repair of wide neck aneurysms, the Pipeline Embolization Device™ (ev3, Inc. Menlo Park, CA) which includes a flow-diverting stent and is for use in the endovascular treatment of large wide-necked intracranial aneurysms in the cavernous and paraclinoid regions of the internal carotid artery (FDA, 2011).

Additional recent research reports on studies using angioplasty/stenting devices and endovascular coils to repair intracranial aneurysms. There is some evidence demonstrating improved short-term outcomes when compared to medical therapy alone (Fiorella, 2007; Lylyk, 2005; Molyneux, 2009; Murayama, 2003; Pierot, 2010; Raja, 2008; Timaran, 2009), however, this evidence is mostly in the form of case reports. There is much interest in the use of stents, in addition to endovascular coils, when presented with aneurysms with challenging anatomy where conventional surgical options are not effective, for example wide-necked aneurysms. Clinical feedback has been consistent regarding the selective use of stents, as part of endovascular treatment of intracranial aneurysms in these rare situations. Based on the results from these case series, use of stent devices to supplement coil therapy of an aneurysm is

appropriate with wide-neck aneurysms (4 mm or more) or when the sack-to-neck ratio is less than 2:1. However, the current evidence does not demonstrate the safety or efficacy of percutaneous angioplasty procedures without stent placement for the treatment of intracranial aneurysms (Piotin, 2010).

### **Intracranial Artery Stent Placement with or without Angioplasty for the Treatment of Intracerebral Vasospasm associated with Subarachnoid Hemorrhage (SAH):**

In March 2005, the FDA granted an HDE clearance to the CoAxia NeuroFlo™ catheter for, "The treatment of cerebral ischemia caused by symptomatic vasospasm following aneurysmal subarachnoid hemorrhage (SAH). The device can be secured by either surgical or endovascular intervention for those who have failed maximal medical management." The CoAxia NeuroFlo catheter (CoAxia, Inc., Maple Grove, MN) is a multi-lumen device with two balloons mounted near the tip. The balloons can be inflated or deflated independently for controlled partial obstruction of aortic blood flow. It is assumed that the obstruction created by the inflated balloons will reduce blood flow to the lower part of the body while increasing blood volume to the upper part of the body, including the brain, without significant increase in pressure. The increase in cerebral blood volume presumably drives blood flow into the penumbra, restoring circulation and improving chances of recovery. This procedure has not exhibited significant cardiac, cerebral, or renal complications in clinical trials. The CoAxia NeuroFlo catheter is inserted through an introducer sheath through the femoral artery, and balloons are placed on either side of the renal arteries. The infra-renal (IR) balloon is inflated first to 70% occlusion. It is recommended that the supra-renal (SR) balloon be inflated to 70% occlusion about 5 minutes later. Inflation of both balloons should be maintained for 40 minutes. Balloon inflation may be modified over this period, based on blood pressure. The balloons should then be sequentially deflated, SR then IR, and removed. Treatment with the CoAxia NeuroFlo catheter is recommended only after subjects have failed or are ineligible for medical therapy (FDA, 2005).

Additional small studies of intracranial endovascular angioplasty continue to reflect some benefit for individuals with vasospasm associated with SAH. However, the outcomes data is limited and shows significant complication rates. Further investigation is warranted (Abruzzo, 2012; Jestaedt, 2008; Jun, 2010; Khatri, 2011; Murai, 2005; Turowski, 2005; Velat, 2011; Zwienenberg-Lee, 2008).

### **Policy History**

<b>Date</b>	<b>Action</b>
5/2018	Policy criteria clarified. Effective 5/1/2018.
3/2017	New medically necessary indications described. Title changed. Clarified coding information. Effective 3/1/2017.
7/2016	New references added from BCBSA National medical policy.
12/2015	Added coding language.
9/2015	Clarified coding information.
5/2015	NCD language updated.
1/2015	Clarified coding information.
5/2014	New references from BCBSA National medical policy. Added transcervical approach to background.
1/2014	Updated to add new CPT codes 37217, 37238 and 37239.
5/2013	New references from BCBSA National medical policy.
2/2013	BCBSA National medical policy review. Changes to policy statement. Effective 2/4/2013.
1/2013	Updated to add new CPT codes 36221-36228.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
12/2011	BCBSA National medical policy review. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.

8/1/2010	New policy, effective 8/1/2010, describing covered and non-covered indications.
8/2008	BCBSA National medical policy review. No changes to policy statements.
3/2008	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
7/2007	BCBSA National medical policy review. No changes to policy statements.

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## Endnotes

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<sup>1</sup> Based on expert opinion