Public Statement:

Percutaneous angioplasty and stenting (enlarging a restricted artery with a catheter) for vertebral artery stenosis is a covered service for certain patients with recurrent stroke or transient ischemic attacks.

Medical Policy Statement:

Percutaneous transluminal angioplasty and stenting of intracranial and extracranial vertebral artery stenosis is considered medically necessary in patients meeting the following criteria:

- Symptomatic patients (recurrent stroke or TIA) with stenosis refractory to medical therapy; AND
- Atherosclerosis with greater than or equal to 50% stenosis in an intracranial or extracranial vertebral artery that is accessible to the angioplasty/stent system approved for marketing by the FDA for this specific indication.

Percutaneous transluminal intracerebral angioplasty/endovascular balloon dilatation of cerebral arteries is considered medically necessary for the treatment of vasospasm.

Percutaneous transluminal angioplasty and stenting for intracranial artery stenosis other than vertebral artery is not considered medically necessary, because there is a lack of
adequate scientific evidence of effectiveness. This treatment is currently being studied in a clinical trial.

Limits:

Percutaneous transluminal angioplasty and stenting for intracranial artery stenosis is not covered for vessels other than vertebral artery.

Background:

It is estimated that intracranial atherosclerosis causes about 8% of all ischemic strokes. Intracranial stenosis may contribute to stroke in two ways: either due to embolism or low flow ischemia in the absence of collateral circulation. Recurrent annual stroke rates are estimated at 4%–12% per year with atherosclerosis of the intracranial anterior circulation, and 2.5%–15% per year with lesions of the posterior (vertebrobasilar) circulation. Medical treatment typically includes either anticoagulant therapy (i.e., warfarin) or antiplatelet therapy (i.e., aspirin). The WASID trial (Warfarin-Aspirin Symptomatic Intracranial Disease) was a randomized trial that compared the incidence of stroke brain hemorrhage or death among patients randomized to receive either aspirin or warfarin. The report indicated that, with a mean 1.8 years of follow-up, warfarin provided no benefit over aspirin and was associated with a significantly higher rate of complications. In addition, if symptoms could be attributed to low flow ischemia, agents to increase mean arterial blood pressure and avoidance of orthostatic hypotension may be recommended. However, medical therapy has been considered less than optimal. For example, in patients with persistent symptoms despite antithrombotic therapy, the subsequent rate of stroke or death has been extremely high, estimated in 1 study at 45%, with recurrent events occurring within a month of the initial recurrence. Surgical approaches have met with limited success. The widely quoted Extracranial-Intracranial (EC/IC) Bypass study randomized 1,377 patients with symptomatic atherosclerosis of the internal carotid or middle cerebral arteries to medical care or EC/IC bypass. The outcomes in the 2 groups were similar, suggesting that the EC/IC bypass is ineffective in preventing cerebral ischemia. More recently, another EC/IC bypass trial has been initiated. Due to inaccessibility, surgical options for the posterior circulation are even more limited.

Percutaneous transluminal angioplasty (PTA) has been approached cautiously for use in the intracranial circulation, due to technical difficulties in catheter and stent design and the risk of embolism, which may result in devastating complications if occurring in the posterior fossa or brain stem. However, improvement in the ability to track catheterization, allowing catheterization of tortuous veins, and the increased use of stents have created ongoing interest in exploring PTA as a minimally invasive treatment of this difficult-to-treat population. The majority of published studies of intracranial PTA has focused on the vertebrobasilar circulation.

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Currently two devices have received approval from the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption (HDE) process. This form of FDA approval is available for devices used to treat conditions with an incidence of 4,000 or less per year and the FDA only requires data showing “probable safety and effectiveness.” Devices with their labeled indications are as follows:

**Neurolink System® (Guidant, Santa Clara, CA)**
“The Neurolink system is indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with >= 50% stenosis and that are accessible to the stent system.”

**Wingspan™ Stent System (Boston Scientific, Fremont, CA)**
“The Wingspan Stent System with Gateway PTA Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with >= 50% stenosis that are accessible to the system.”

References:


Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

Last modified by:   Date: