Medical Coverage Policies

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Percutaneous Transluminal Angioplasty (PTA) of Intracranial Atherosclerotic Stenosis With or Without Stenting

EFFECTIVE DATE	03/01/2009	LAST UPDATED	11/16/2010

Description:
Intracranial atherosclerotic disease is the narrowing or obstruction of arteries within the skull that supply the brain. It is caused by atheromatous plaques in the innermost layer of the arterial wall, called the endothelium. Intracranial atherosclerotic disease can lead to transient ischemic attack (TIA), stroke or death, and is usually diagnosed in patients who have presented with a TIA or stroke. Intracranial atherosclerotic disease is usually treated with anticoagulant therapy (i.e., warfarin) or antiplatelet therapy (e.g., aspirin), together with medication to control risk factors for atherosclerosis.

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.

Currently 2 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.”

The U. S. National Institutes of Health (NIH) are currently recruiting for clinical trials on the Wingspan Stenting for Symptomatic Severe Stenosis of Intracranial Atherosclerosis. The U.S. NIH clinical trials website can be found at http://www.clinicaltrials.gov/.

Medical Criteria:
Percutaneous transluminal angioplasty of intracranial atherosclerotic stenoses with or without stenting is considered not medically necessary as there is insufficient evidence to support its use for all product lines except for BlueCHiP for Medicare members enrolled in a clinical trial (see below) as the safety and efficacy of the procedure has not been established.

BlueCHiP for Medicare:
Effective November 6, 2006, BlueCHiP for Medicare covers PTA concurrent with stenting of intracranial arteries for the treatment of cerebral artery stenosis >50% in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. To access the specific clinical trial site on the web click on http://www.clinicaltrials.gov/ct2/show/NCT00685308?cond=%22Intracranial+Arterial+Diseases%22&rank=12

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be

offered, at least, the same services as Medicare offers.

Policy:
Percutaneous transluminal angioplasty of intracranial atherosclerotic stenoses with or without stenting is considered not medically necessary for all product lines except for BlueCHiP for Medicare members enrolled in a clinical trial as the safety and efficacy of the procedure has not been established.

BlueCHiP for Medicare non-covered:
All other indications not mentioned above for PTA with or without stenting to treat obstructive lesions of the intracranial arteries are non-covered.

Coverage:
Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, subscriber agreement or RIte Care contract for the applicable "Services Not Medically Necessary" coverage/benefits.

Coding:
The following codes are considered not medically necessary for all product lines:
61630
61635

Related topics:
NA

Also know as:
Cerebral stenoses
Wingspan™
Neurolink System®
Atherosclerotic

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