

UPMC Health Plan POLICY AND PROCEDURE MANUAL

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SUBJECT: Intracranial Stenting
INDEX TITLE: Medical Management
ORIGINAL DATE: May 2007

This policy applies to the following lines of business: (Check those that apply.)

Commercial:				
HMO ()	POS ()	PPO ()	OOA ()	
Fully Insured ()	Self-funded/ASO ()	HSA ()	All (X)	
Medicare Select ()	Medicare Supplement ()			
DPW-MA:				
Health Choices ()	Voluntary ()			All ()
CMS-MA:				
OH ()	WV ()	PA ()	All (X)	Other ()
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()	PFFS ()
PID-CHIP:				
Free ()	Sub ()	Full ()	All ()	
APPLICABLE TO:				
Community Care ()	Work Partners ()			

I. POLICY

It is the policy of UPMC Health Plan to recognize coverage for services mandated through Medicare regulations. Based on review of clinical literature available, the effectiveness of Intracranial Percutaneous Transluminal Angioplasty (PTA) with stenting has not yet been established, UPMC Health Plan considers this to be experimental/investigational and, therefore, **UPMC Health Plan covers Intracranial PTA Stenting when performed for the treatment of Cerebral Artery Stenosis only for Medicare and Commercial members as outlined in this policy.**

Coverage for Medicare and Commercial members will be considered, after review on an individual basis, for the specific indications detailed in this policy and covered under the member's benefit plan.

Based on review of the clinical literature available the MERCI Clot Retriever and the modified MERCI Clot Retriever have not been medically proven to be effective and are considered to be experimental/investigational and, therefore, not a covered benefit for all products.

II. DEFINITIONS

Intracranial arteries – Arteries located within the skull and comprised of branches of the carotid and vertebral arteries that supply blood to the brain (e.g., anterior, middle and posterior cerebral, vertebrobasilar or basilar).

Percutaneous transluminal angioplasty (PTA) – Insertion of a balloon catheter into a narrow or occluded blood vessel to dilate the vessel by inflating the balloon.

Stent – A mechanical device used to support and keep open various bodily structures such as an artery.

III. PURPOSE

The purpose of this policy is to define the criteria for coverage of intracranial stenting.

IV. SCOPE

This policy applies to various UPMC Health Plan departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to: Medical Management, Benefit Configuration and Claims departments.

V. PROCEDURE

A. Background/Medical Description

Atherosclerosis of the major intracranial arteries is a significant cause of ischemic stroke. Treatment of symptomatic intracranial atherosclerosis falls into two categories: prevention of recurrent events in members with completed stroke or resolution of transient ischemic attacks (TIA) and treatment of acute ischemic stroke. Current medical intervention consists of antiplatelet therapy or anticoagulation or both and modification of risk factors and can still leave many patients at risk for another stroke. Alternate treatment methods include re-establishing the blood flow by mechanically opening the atherosclerotic blockage or by surgically bypassing the affected area. As a result of the recent successes in cardiovascular disease, there are now cardiovascular devices that have been modified for use in intracranial artery disease and intracranial balloon angioplasty and stenting are now used to treat and prevent stroke. Clinical trials are also ongoing for use of intracranial balloon angioplasty for patients following aneurismal subarachnoid hemorrhage.

The Food and Drug Administration (FDA) approved the Wingspan Stent System with Gateway PTA Balloon Catheter on January 9, 2004 with Humanitarian Device Exemption Number H050001. This device is manufactured by Boston Scientific. The device is a self expanding, neurovascular stent and delivery system and balloon catheter that consist of;

- Wingspan Stent
- Wingspan Delivery System and
- Gateway PTA Balloon Catheter.

The Wingspan device is indicated for improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease refractory to pharmacotherapies and in intracranial vessels with greater than or equal to 50% stenosis that is accessible to the system.

The NEUROLINK System was FDA approved in 2002 with Humanitarian Device Exemption Number H010004 and was indicated for treatment of patients 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 equal to or greater than 50% stenosis that are accessible to the stent system.

In October of 2005, the American Society of Interventional and Therapeutic Neuroradiology, the Society of Interventional Radiology and the American Society of Neuroradiology issued a position statement regarding intracranial angioplasty and stenting for cerebral atherosclerosis. The statement reviewed a number of case series and also the SSYLVA (NeuroLink system) study and Wingspan multi-institutional studies and concluded that evidence existed to recommend that intracranial angioplasty with or without stenting be offered to symptomatic patients with intracranial stenosis greater than 50 % who have failed medical therapy.

In 2004 the FDA approved the MERCI Retrieval System (mechanical embolus removal in cerebral ischemia) for mechanical retrieval of clots following a stroke. Criteria included patients with profound neurologic deficits ineligible for treatment with tPA or who failed tPA treatment. Overall mortality with this procedure was 44%. A more recent version of this device called the Modified MERCI Clot Retriever was also FDA approved in February 2007 for the same criteria. Overall mortality with this device was shown to be slightly less (34%), but long term randomized data and outcome results are not available.

B. Specific Indications

Intracranial stenting devices are indicated for use in improving cerebral artery lumen diameter in patients with all of the following criteria:

1. Symptomatic intracranial atherosclerotic disease with signs and symptoms of recurring profound neurological deficits (acute ischemic stroke) which are refractory to medical therapy; and
2. Angiographic demonstration of a thrombotic occlusion in the intracranial vessels with equal to or greater than 50% stenosis that is accessible to the stent system; and
3. Age > 18 years; and
4. Evaluation and recommendations from a consulting Neurologist.

C. Limitations

- A stenosis that cannot be safely reached or crossed by endovascular approach.

- All other indications other than listed above for intracranial PTA and stenting are non-covered.

The surgical device used in the procedure is subject to the Food and Drug Administration (FDA) approved protocol governing Category B Investigational Device Exemption (IDE)/Humanitarian Device Exemption (HDE) clinical trials.

D. Information Required for Review

In order for medical necessity to be established for intracranial PTA and stenting, the treating physician will need to furnish adequate clinical information. Necessary information includes, but is not limited to, the following:

- A physician's letter of medical necessity or documentation indicating the diagnosis of intracranial atherosclerotic disease, medical therapy attempted and the percentage of cerebral artery stenosis present.

E. Review Process

1. The Medical Management staff assigned to review obtains the clinical information to determine if there is adequate clinical information. If the case does not meet the established criteria, it is referred to a UPMC Health Plan Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan.

F. Variations

This policy applies to the Medicare and Commercial products only.

I. Records Retention

Records Retention for UPMC Health Plan documents, regardless of medium are provided within the UPMC Health System Policy and as indicated in the UPMC Insurance Services Division Policy and Procedure.

J. References

1. Centers for Medicare and Medicaid Services, NCD 20.7, *Percutaneous Transluminal Angioplasty*, 08/11/2008
2. Centers for Medicare and Medicaid Services, Pub 100-03 NCD, *Intracranial Percutaneous Transluminal Angioplasty with Stenting*, 01/05/2007
3. Centers for Medicare and Medicaid Services, MLN MM6137, *Intracranial Percutaneous Transluminal Angioplasty (PTA) with Stenting*, 05/12/2008
4. Aetna, Clinical Policy Bulletin :0276, *Angioplasty/Stenting of Extra-Cranial and Proprietary and Confidential Information of UPMC Health Plan*

- Intra-Cranial Arteries*, Last review 06/03/2008
5. BlueCross of California, Medical Policy SURG.00001, *Carotid, Vertebral and*
 6. *Intracranial Artery Angioplasty with or without Stent Placement*, Last review date 12/07/2006
 7. BlueCross BlueShield of North Carolina, Corporate Medical Policy SUR6120, *Cerebral Angioplasty*, Last review date 05/2007
 8. The Regence Group, Medical Policy 141, *Percutaneous Transluminal Angioplasty of Intracranial Atherosclerotic Stenosis With or Without Stenting*, Effective date 05/01/2008
 9. *Intracranial stenting reduces stroke risk in stenosis*, MD Consult, 02/23/2007,
 10. *Stenting gives stroke patients uneven aid*, H.A. Abella, Diagnostic Imaging, April 2007
 11. ECRI- Target database *Mechanical thrombectomy for ischemic stroke*, February 2007, www.target.ecri.org
 12. Excellus Health Plan, Medical Policy 7.01.70, *Angioplasty, stenting and mechanical embolectomy of intracranial arteries*, Revision date 09/20/07
 13. ECRI Institute, *Combined Angioplasty and Stenting for Intracranial Atherosclerosis*, 07/14/2006

Disclaimer:

UPMC Health Plan medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of UPMC Health Plan and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

UPMC Health Plan reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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