



INTRACRANIAL STENTING AND ANGIOPLASTY HS-017



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

WellCare of Kentucky, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

Intracranial Stenting and Angioplasty

Policy Number: HS-017

Original Effective Date: 3/13/2008

Revised Date(s): 7/7/2011; 5/3/2012

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

In the United States, approximately 70,000 or 10% of all strokes are due to intracranial atherosclerotic disease (ICAD), blockage of the small arteries of the brain by fatty deposits. The risk of recurrent stroke remains high in patients who have severe ICAD despite optimal medical therapy, which has led to a search for new techniques to increase blood flow through partially blocked intracranial arteries.

CMS National Coverage Determination, December 9, 2009

The Centers for Medicare and Medicaid Services (CMS) has determined, based on the Food and Drug Administration (FDA) clearance of new embolic protection devices, to revise the national coverage determination (NCD) language regarding embolic protection devices as follows in section B3 and B4 of the NCD: Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or cleared embolic protection device for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. CMS determines that coverage of PTA of the carotid artery is reasonable and necessary in these circumstances.

Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent for the following:

- Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis $\geq 70\%$. Coverage is limited to procedures performed using FDA-approved carotid artery stenting systems and FDA-approved or cleared embolic protection devices. *If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is not covered by Medicare;*
- Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on carotid artery stenting (CAS) post-approval studies (Medicare NCD Manual 20.7B);
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis $\geq 80\%$, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on CAS post-approval studies (Medicare NCD Manual 20.7B).

Wingspan® Stent System (Boston Scientific Corp.)

The Wingspan® Stent System is a self-expanding metal stent that was designed specifically for use in brain arteries. To use this device, a catheter is threaded through the femoral artery in the groin and all the way to the region of the brain that has the blocked artery. After the Gateway® PTA Balloon Catheter is used to compress the blockage, the Wingspan stent is deployed across the length of the blockage. This procedure is performed in an angiography suite by a specialist in endovascular surgical neuroradiology or interventional neuroradiology with the patient under general anesthesia or local anesthesia and conscious sedation. Patients are typically monitored in an intensive care unit overnight, and discharged after approximately 5 days on anticoagulating agents. Intracranial stenting is usually reserved for patients who have more than 50% blockage of the affected artery and symptoms despite anticoagulating treatment.

The literature search identified 3 uncontrolled case series that evaluated the Wingspan Stent System. Results of these studies do not provide reliable evidence of the safety or efficacy of the Wingspan Stent System for ICAD. Although initial stent placement was successful in 96% to 99% of all cases, 1% to 3% of patients died shortly after

treatment and partial or complete re-blockage occurred in 8% to 30% of patients less than 1 year after treatment. Studies that compare stenting with optimal drug treatment and that involve long-term assessment of patients after treatment are needed to determine whether the Wingspan Stent System is a safe and effective treatment for ICAD (Hayes Rating-D).

Clinical Trial Findings

SSYLVA Trial

The SSYLVA trial (Stenting of Symptomatic atherosclerotic Lesions in the Vertebral or Intracranial Arteries) was a multi-center, non-randomized, prospective feasibility study, which evaluated the NeuroLink intracranial stent system (Guidant Corp, Indianapolis, IN) for treatment of vertebral or intracranial artery stenosis. Patients were 18–80 years of age, with symptoms attributed to a single target lesion of >50% stenosis. In 61 patients enrolled, 43 (70.5%) had an intracranial stenosis and 18 (29.5%) had an extracranial vertebral artery stenosis. In the first 30 days, 6.6% had strokes and there was 0% mortality. Successful stent placement was achieved in 58/61 (95%) of cases. At 6 months post-procedure, angiographic re-stenosis of >50% occurred in 12/37 cases (32.4%) of the intracranial arteries and 6/14 (42.9%) of the extracranial vertebral arteries. Seven (39%) patients had recurrent stenosis and were symptomatic. Four of 55 patients (7.3%) had strokes later than 30 days. Based upon this study, the FDA granted a humanitarian device exemption to treat patients with significant intracranial and extracranial atherosclerotic disease by balloon angioplasty and stent placement.

WINGSPAN Trial

The results of treatment by a combination of balloon dilatation, followed by the deployment of a self-expanding microstent were reported in 15 symptomatic patients with intracranial atherosclerotic stenosis despite medical treatment. An anatomically and clinically adequate result was achieved in all patients. The mean initial degree of stenosis was 72%. Balloon dilatation resulted in a mean residual stenosis of 54% which was reduced further to a mean of 38% after stent deployment. All patients were either stable or improved 4 weeks after the treatment. Recurrent TIA did not occur in any patient. Forty-five medically refractory patients with recurrent stroke, attributable to intracranial atherosclerotic stenosis >50% were treated in this prospective, multicenter study and results included an ipsilateral stroke or death rate of 4.4% at 30-days and 7.1% at 6-months.

POSITION STATEMENT

Intracranial stenting and angioplasty **can be considered for treatment of cerebral artery stenosis** if ALL of the following criteria are met:

- Member has cerebral artery stenosis $\geq 50\%$; **AND**,
- Member has a diagnosis of intracranial atherosclerotic disease; **OR**,
- Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis $\geq 70\%$. Coverage is limited to procedures performed using FDA-approved carotid artery **STENTING** systems and FDA-approved or cleared embolic protection devices. *If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is not covered by Medicare;*
- Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on carotid artery **STENTING** (CAS) post-approval studies (Medicare NCD Manual 20.7B);
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis $\geq 80\%$, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under

the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on CAS post-approval studies (Medicare NCD Manual 20.7B) **OR**;

- Member is enrolled in a Category B Investigational Device Exemption (IDE) clinical trial cleared by the Food and Drug Administration (FDA)

CODING

Covered CPT® Codes

- 61630** Balloon Angioplasty, intracranial (e.g., atherosclerotic stenosis) percutaneous
61635 Transcatheter placement of intravascular stent(s) intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed
61640 Balloon dilation of intracranial vasospasm, percutaneous, initial vessel
61641+ Balloon dilation of intracranial vasospasm, percutaneous, each additional vessel in same vascular family
+(List separately in addition to code for primary procedure.)
61642+ Balloon dilation of intracranial vasospasm, percutaneous, each additional vessel in different vascular family
+(List separately in addition to code for primary procedure.)

Covered ICD-9-CM Procedure Codes

- 00.62** Percutaneous angioplasty or atherectomy intracranial vessel(s)
00.65 Percutaneous insertion of intracranial vascular stent(s)

Code also any: **00.45 - 00.48** Code for Number of vascular stents inserted
00.40 - 00.43 Code for Number of vessels treated

Draft ICD-10-CM Procedure Code Effective October 1, 2013

- 03UG3JZ** Med/Surg Upper Arteries Supplement; Intracranial; Percutaneous Synthetic Substitute
Putting in or on a biological or synthetic material that physically reinforces and/or augments the function of the body part.

Applicable HCPCS Level II Codes

- C1725** Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)
C1876 Stent, non-coated/non-covered, with delivery system

Covered ICD-9-CM Diagnosis codes if all of the above criteria are met.

- 434.00 - 434.90** Occlusion of cerebral arteries
437.0 - 437.1 Cerebral atherosclerosis; arteriosclerosis; Atheroma of Cerebral arteries, Acute and Chronic
V70.7 Participant in FDA approved Category B Investigational Device Exemption (IDE) Clinical Trial

Draft ICD-10-CM Diagnosis Codes Effective October 1, 2013

- I66.01 – I66.9** Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction
I67.2 Cerebral aneurysm, nonruptured
I67.8 Other specified cerebrovascular diseases; acute cerebrovascular insufficiency; chronic cerebral ischemia
Z00.6 Encounter for examination for normal comparison and control in clinical research program

*Current Procedural Terminology (CPT) 2012 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

1. Hayes Directory. (2008, November 25). Wingspan® stent system with Gateway® PTA balloon catheter (Boston Scientific Corp.) for intracranial atherosclerotic disease (ICAD) (archived December 25, 2011). Retrieved from <http://www.hayesinc.com>

Government Agencies, Professional and Medical Organizations

1. Centers for Medicare and Medicaid Services. (2009, December 9). National coverage determination for percutaneous transluminal angioplasty (PTA) (20.7). Retrieved from <http://www.cms.hhs.gov/mcd/search.asp>
2. Centers for Medicare and Medicaid Services. (2008, May 12). Decision memo for intracranial stenting and angioplasty (CAG-00085R5). Retrieved from <http://www.cms.hhs.gov/mcd/search.asp>
3. Institute for Clinical Systems Improvement. (2006, June). Technology assessment report: carotid, vertebral and intracranial artery angioplasty and stenting. Retrieved from <http://www.icsi.org>
4. American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, & American Society of Neuroradiology. (2005, October). Intracranial angioplasty and stenting for cerebral atherosclerosis: a position statement. *American Journal of Neuroradiology*, 26, 2323-2327.

HISTORY AND REVISIONS

Date	Action
5/3/2012	<ul style="list-style-type: none">• Approved by MPC. No changes.
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
7/7/2011	<ul style="list-style-type: none">• Approved by MPC.