Intracranial Percutaneous Transluminal Angioplasty (PTA) with Stenting

[For the list of services and procedures that need preauthorization, please refer to www.mcs.com.pr. Go to "Comunicados a Proveedores", and click "Cartas Circulares".]

Medical Policy: MP-SU-01-10
Original Effective Date: April 22, 2010
Reviewed: December 7, 2013

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider’s contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member’s benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

DESCRIPTION

The concept of using stents along with PTA for intracranial arterial stenosis comes from the cardiac intervention experience. Coronary balloon angioplasty is accompanied by abrupt closure secondary to elastic recoil and vessel dissection in approximately 5% of patients. In the presence of thrombus the risk of abrupt closure increases to 7.2 to 27.8%. While such closure may be tolerable in the cardiac system it is not tolerable in a basilar artery without significant posterior communicating artery collateral flow. The use of stents for the management of intracranial arterial disease has been limited by the interventionalist's inability to negotiate the relatively stiff balloon/stent assembly through the tortuous carotid and vertebral artery systems without damaging the vessel in the process. Recent advances in coronary stents, however, have made delivery of more flexible systems possible (UPNS, 2013).

Currently, there are 2 FDA approved devices for intracranial arterial stenosis:

- The Neurolink® System, which 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 (FDA, 2002); and

- The Wingspan™ Stent System, which was FDA approved in 2005 as a Humanitarian Use Device (HDE) for patients with treatment-resistant (refractory) intracranial atherosclerotic disease who have 50 percent or greater narrowing in the intracranial arteries. However, the FDA announced in 2012 to health care providers and patients that the indications for use and labeling for the Wingspan™ stent have changed to limit the use of Wingspan™ to a narrow, select group of patients and conditions (FDA, 1/31/13). Wingspan™ is now indicated for use only in patients between 22 and 80 years of age who meet 4 specific criteria. The criteria include two or more strokes even after aggressive medical management, no stroke within the seven days before planned Wingspan™ treatment, 70% to 90% stenosis of the intracranial artery related to the recurrent strokes, and a history of good recovery from previous strokes with a modified Rankin score ≤3 before Wingspan™. Contraindications now include the treatment of stroke with...
symptom onset within the seven days before treatment and the treatment of transient ischemic attacks (ECRI, 8/24/12).

This medical policy addresses medical necessity criteria for intracranial stenting and angioplasty for the treatment of cerebral artery stenosis.

**COVERAGE**

Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits and coverage.

**INDICATIONS**

Medical Card System, Inc. (MCS) will consider medically necessary the use of Intracranial PTA and Stenting for the treatment of cerebral artery stenosis (≥50%) under the following circumstances:

1. In patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials (CMS NCD 20.7, 2013).

**LIMITATIONS**

1. MCS WILL NOT cover any other indication for Intracranial Percutaneous Transluminal Angioplasty with Stenting. The safety and efficacy of these procedures are not established (CMS NCD 20.7, 2013).

**CODING INFORMATION**

CPT® Codes (List may not be all inclusive)

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>61630</td>
<td>Balloon angioplasty, intracranial (eg., atherosclerotic stenosis), percutaneous</td>
</tr>
<tr>
<td>61635</td>
<td>Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed</td>
</tr>
<tr>
<td>61640</td>
<td>Balloon dilation of intracranial vasospasm, Percutaneous; initial vessel</td>
</tr>
<tr>
<td>+61641</td>
<td>Balloon dilation of intracranial vasospasm, Percutaneous; each additional vessel in same vascular family (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>+61642</td>
<td>Balloon dilation of intracranial vasospasm, Percutaneous; each additional vessel in different vascular family (List separately in addition to code for primary procedure)</td>
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ICD-9 CM® Diagnosis Codes (List may not be all inclusive)

<table>
<thead>
<tr>
<th>ICD-9 CM® CODES</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>434.00</td>
<td>Cerebral thrombosis without mention of cerebral infarction</td>
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<tr>
<td>434.01</td>
<td>Cerebral thrombosis with cerebral infarction</td>
</tr>
<tr>
<td>434.10</td>
<td>Cerebral embolism without mention of cerebral infarction</td>
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<tr>
<td>434.11</td>
<td>Cerebral embolism with cerebral infarction</td>
</tr>
<tr>
<td>434.90</td>
<td>Cerebral artery occlusion, unspecified without mention of cerebral infarction</td>
</tr>
<tr>
<td>434.91</td>
<td>Cerebral artery occlusion, with cerebral infarction</td>
</tr>
<tr>
<td>437.0</td>
<td>Cerebral atherosclerosis</td>
</tr>
<tr>
<td>V70.7</td>
<td>Examination of participant in clinical trial</td>
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REFERENCES


POLICY HISTORY

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION</th>
<th>COMMENT</th>
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<tbody>
<tr>
<td>April 22, 2010</td>
<td>Origination of Policy</td>
<td>The following indication was modified:</td>
</tr>
</tbody>
</table>
| November 17, 2011 | Revised     | - Patients must be enrolled in a Category B Investigational Device Exemption (IDE) clinical trial cleared by the Food and Drug Administration (FDA); **AND**
- Patients must have a diagnosis of intracranial atherosclerotic disease: **AND**
- Patients must have cerebral artery stenosis ≥ 50%  
- For recurrent stroke, refractory to medical therapy, and symptomatic intracranial stenosis ≥50 %.
Indication Modified to read:
For intracranial arteries for the treatment of cerebral artery stenosis ≥50% in patients with intercranial artherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. |
| December 7, 2013 | Revised     | References updated. New references were added, numbers 1, 5-6, 9-12, &15.                                                                    |
|                 |             | To the Description Section:                                                                                                           |
|                 |             | - Deleted: Intracranial arterial stenosis is a major risk factor for stroke. According to the American Society of Neuroradiology hardening of the arteries in the brain causes 40,000 to 60,000 strokes about 10% of all strokes. Stenosis develops in the intracranial arteries for the same reasons that blockages form in arteries in the heart and other vascular beds. Treatment of symptomatic intracranial atherosclerosis falls into two categories: 1. Prevention of recurrent events in members with completed stroke; & 2. Resolution of transient ischemic attacks |
and treatment of acute ischemic stroke. Medical therapy with blood thinners such as aspirin, dipyridamole, other anti-platelet agents, or warfarin have been a standard stroke prevention strategy for patients at increased risk of stroke with the goal of preventing a blood clot from completely blocking a narrowed brain artery. These treatments can still leave many patients at risk for another stroke, therefore alternate treatment methods have been attempted such as: re-establishing the blood flow by mechanically opening the atherosclerotic blockage or by surgically bypassing the affected area. As a result, there are now cardiovascular devices that have been modified for use in intracranial balloon angioplasty and stenting are now used to treat and prevent stroke. Currently, two devices have received FDA approval through the humanitarian device exemption (HDE) process. This form of FDA approval is available for devices used in the treatment or diagnosis of conditions that affect fewer than 4,000 individuals in the United States per year and the FDA only requires data showing “probable safety and effectiveness”. An approved HDE authorizes marketing of the humanitarian use device (HUD). However, an HUD may only be used after an internal review board (IRB) approval has been obtained for the use of the device for the FDA approved indication. The labeling for an HUD must state that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated. The two devices and their labeled indications are as follows:

- NEUROLINK® System, which 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 greater than or equal to 50% stenosis and that are accessible to the stent system; &
- Wingspan™ Stent System with Gateway™ PTA Balloon Catheter, which is indicated for improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with greater than or equal to 50% stenosis that are accessible to the system.

**Added:** The concept of using stents along with PTA for intracranial arterial stenosis comes from the cardiac intervention experience. Coronary balloon angioplasty is accompanied by abrupt closure secondary to elastic recoil and vessel dissection in approximately 5% of patients. In the presence of thrombus the risk of abrupt closure increases to 7.2 to 27.8%. While such closure may be tolerable in the cardiac system it is not tolerable in a basilar artery without significant posterior communicating artery collateral flow. The use of stents for the management of intracranial arterial disease has been limited by the interventionalist’s inability to negotiate the relatively stiff balloon/stent assembly through the tortuous carotid and vertebral artery systems without damaging the vessel in the process. Recent advances in coronary stents, however, have made delivery of more flexible systems possible (UPNS, 2013).

**Also added:** Currently, there are 2 FDA approved devices for intracranial arterial stenosis: The Neurolink® System, which 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 (FDA, 2002); and The WingspanTM Stent System, which was FDA approved in 2005 as a Humanitarian Use Device (HDE) for patients with treatment-resistant (refractory) intracranial atherosclerotic disease who have 50 percent or greater narrowing in the intracranial arteries. However, the FDA announced in 2012 to health care providers and patients that the indications for use and labeling for the WingspanTM stent have changed to limit the use of WingspanTM to a narrow, select group of patients and conditions (FDA, 1/31/13). WingspanTM is now indicated for use only in patients between 22 and 80 years of age who meet 4 specific criteria. The criteria include two or more strokes even after aggressive medical management, no stroke within the seven days before planned WingspanTM treatment, 70% to 90% stenosis of the intracranial artery related to the recurrent strokes, and a history of good recovery from previous strokes with a modified Rankin score ≤3 before WingspanTM. Contraindications now include the treatment of stroke with symptom onset within the seven days before treatment and the treatment of transient ischemic attacks (ECRI, 8/24/12).

To the Indications Section:

- Deleted: For 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.

- Revised and rewrote Indications Statement: Medical Card System, Inc. (MCS) will consider medically necessary the use of Intracranial PTA and Stenting for the treatment of cerebral artery stenosis (≥50%) under the following circumstances: 1. In patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials (CMS NCD 20.7, 2013).

To the Limitations Section:

- To Limitation #1 added: The safety and efficacy of these procedures are not established (CMS NCD 20.7, 2013).
This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member’s plan in effect as of the date services are rendered. Medical Card System, Inc., (MCS) medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Medical Card System, Inc., (MCS) reserves the right to review and update its medical policies at its discretion. Medical Card System, Inc., (MCS) medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan’s ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.