IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured’s benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Percutaneous transluminal angioplasty (PTA) “involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of percutaneous transluminal angioplasty (PTA) is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased. With the development and use of balloon angioplasty for treatment of atherosclerotic and other vascular stenoses, PTA (with and without the placement of a stent) is a widely used technique for dilating lesions of peripheral, renal, and coronary arteries.” (National Coverage Determination 20.7) A stent (wire-mesh tube) may be inserted to keep the artery open or to block off an aneurysm.
**Note:** Intracranial vessels on which angioplasty has been performed include, but are not limited to, anterior, middle, and posterior cerebral arteries, vertebral artery (distal), carotid siphon, and internal carotid.

This policy does not address percutaneous angioplasty and stenting of extracranial carotid arteries or venous vessels, or the use of mechanical embolectomy or thrombectomy devices which are addressed in separate policies (see Cross References below).

<table>
<thead>
<tr>
<th>Procedure(s):</th>
<th>CMS Coverage Manuals, National Coverage Determinations (NCD)*</th>
<th>Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCD) and Articles (LCA)*</th>
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<tbody>
<tr>
<td><em>PTA with</em> stenting in the treatment of <em>cerebral artery stenosis in patients with intracranial atherosclerotic disease</em></td>
<td>Percutaneous Transluminal Angioplasty (PTA) <em>(20.7)</em></td>
<td><em>(See Section B.5.)</em></td>
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<tr>
<td><em>PTA with or without</em> stenting in the treatment of <em>other obstructive lesions of the vertebral and cerebral arteries</em></td>
<td>Percutaneous Transluminal Angioplasty (PTA) <em>(20.7)</em></td>
<td><em>(See Section C)</em></td>
</tr>
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<td><em>PTA without</em> stenting not specifically addressed in NCD 20.7 Section B.1-5</td>
<td>Percutaneous Transluminal Angioplasty (PTA) <em>(20.7)</em></td>
<td><em>(See Section C)</em></td>
</tr>
<tr>
<td>Stenting using the <em>Neuroform® stent for ischemic disease, including but not limited to ischemic stroke</em></td>
<td>Non-Covered Services <em>(L35008)</em></td>
<td><strong>Scroll to the “Public Version(s)” section at the bottom of the LCD for links to prior versions if necessary.</strong></td>
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**Scroll to the “Public Version(s)” section at the bottom of the LCD for links to prior versions if necessary.**
For **PTA with stenting not specifically addressed by NCD Section B.1-5** (e.g., PTA with stenting for intracranial aneurysms or for ischemic stroke when using a stent **other than the Neuroform® stent**)

Medicare coverage guidance is not available in the health plan’s service area for PTA with stenting for intracranial aneurysms or for PTA with stenting for ischemic stroke when using a stent other than the Neuroform® stent. NCD 20.7 states coverage eligibility is at the individual local contractor discretion for PTA with stenting not specifically addressed by NCD Section B.1-5. Other than the non-coverage LCD for Neuroform® stent placement for ischemic disease above, Noridian does not have other LCDs or LCAs to address PTA services with stenting. Therefore, PTA and stenting of intracranial vessels for these indications may be considered medically necessary for Medicare Advantage.
REQUIRED DOCUMENTATION

The information below must be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Description of the condition being treated (stenosis, aneurysm, stroke, etc.);
- Location (i.e., specific vessel) of lesion or obstruction;
- Description of planned treatment, including the type of stent that will be used (if applicable);
- Documentation of the Medicare-approved clinical trial as required by the Medicare NCD 20.7, also if applicable.

REGULATORY STATUS

Currently, approval of intracranial stents by the U.S. Food and Drug Administration (FDA) has been 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; 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.

Stents for Intracranial Atherosclerosis

There are currently two devices that have received FDA approval for humanitarian use in the treatment of intracranial atherosclerosis. Their labeled indications are as follows:

- NEUROLINK® System (Guidant) 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."[1]

- Wingspan™ Stent System with Gateway™ PTA Balloon Catheter (Boston Scientific) 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.”[2] The Wingspan Stent System consists of a highly flexible, microcatheter delivered self-expanding nitinol stent, which may be suitable for lesions in the distal internal carotid and middle cerebral arteries. These arteries are difficult to access with a balloon-mounted stent, such as the
Stents for Intracranial Aneurysm

Endovascular Stents for Use with Coils

The following devices have received FDA approval for humanitarian use with embolic coils in the treatment of unruptured wide-neck intracranial aneurysms:

- The Neuroform™ Microdelivery Stent System (Boston Scientific) (H020002)
- The Enterprise™ Vascular Reconstruction Device and Delivery System (Cordis Neurovascular, Inc./DePuy Companies) (H060001)
- The LVIS® or LVIS® Jr. Low-Profile Visualized Intraluminal Support Device (MicroVention®, Inc.) (H130005)

The Solitaire AB retrievable stent (Covidien) has not received FDA approval for use in the United States outside the clinical trial setting.

Flow-Diverting Stents

- In 2011, the Pipeline® Embolization Device (Covidien eV3 Neurovascular), which falls into a new device category called “intracranial aneurysm flow diverters,” or flow-diverting stent, received FDA premarket approval for endovascular treatment of large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments in adult patients aged 22 years or older. The Pipeline device is a braided, wire mesh device that is placed within the parent artery of an aneurysm to redirect blood flow away from the aneurysm with the goal of preventing aneurysm rupture and possibly decreasing aneurysm size.
- The SILK Reconstruction device (Balt Extrusion) and the Surpass Flow Diverting Stent (Stryker) have not received FDA approval for use in the United States.
<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>37799</td>
<td>Unlisted procedure, vascular surgery</td>
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<tr>
<td></td>
<td>61630</td>
<td>Balloon angioplasty, intracranial (e.g., atherosclerotic stenosis), percutaneous</td>
</tr>
<tr>
<td></td>
<td>61635</td>
<td>Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed</td>
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**HCPCS** None

*IMPORTANT NOTE: Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan’s web control as these sites are not maintained by the health plan.*