**Extracranial Carotid Angioplasty/Stenting**

**Published:** 11/01/2017

**Next Review:** 09/2018

**Last Review:** 09/2017

**Medicare Link(s) Revised:** 11/01/2017

---

**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 MCGTM 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)*

Carotid angioplasty with stenting (CAS) is a treatment for carotid stenosis, intended to prevent future stroke. CAS involves the insertion of a stent (wire-mesh tube) into a narrowed carotid artery, and is proposed as an alternative to medical therapy and a less invasive alternative to carotid endarterectomy (CEA).
Note: This policy does not address percutaneous angioplasty and stenting of intracranial or venous vessels, which are addressed in separate policies (see Cross References below).

<table>
<thead>
<tr>
<th>CMS Coverage Manuals*</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Coverage Determinations (NCDs)*</td>
<td>Percutaneous Transluminal Angioplasty (PTA) (20.7)</td>
</tr>
</tbody>
</table>

Note: Carotid artery percutaneous transluminal angioplasty (PTA) and stenting may fall under one of the categories noted below. Be sure to determine which section of the NCD applies to the PTA and stenting procedure being performed:

- For PTA of the carotid artery concurrent with carotid stent placement furnished in accordance with the FDA-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials, see Section B.2.

- For PTA of the carotid artery concurrent with placement of an FDA-approved carotid stent and an FDA-approved or -cleared embolic protection device (EPD) in FDA-Approved post approval studies, see Section B.3.

- For PTA of the carotid artery concurrent with placement of an FDA-approved carotid stent with embolic protection device in patients at high risk for carotid endarterectomy (CEA), see Section B.4.

- For PTA of the carotid artery concurrent without placement of an embolic protection device (CPT 37216), see Section B.4, where it reads, “The use of an FDA-approved or cleared embolic protection device is required. If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is not covered by Medicare.”

To identify Medicare-approved trials, registries, facilities, and IDE studies, see “References” below.[4-6]
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 planned treatment, including the location of the target areas and technique to be used;
- The name of the trial, registry, or study;
- The name of the device;
- Facility where services will be rendered;
- The six-digit IDE number that begins with a "G" (i.e., G123456);
- For an IDE study approved prior to January 1, 2015, documentation to support the IDE study was approved by the local MAC must be submitted. While not mandatory, a copy of the FDA-approval letter provided to the sponsor or manufacturer of the device is also beneficial and may help to expedite claim processing. The category assignment (Category A or Category B IDE) should be represented on this FDA letter.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has approved several carotid artery stents and DEP devices from various manufacturers. The FDA has mandated postmarketing studies for these devices. Each FDA-approved carotid stent system is indicated for combined use with a DEP device.

CROSS REFERENCES

Clinical Trials and Investigational Device Exemption (IDE) Studies, Medicine, Policy No. M-150

Percutaneous Angioplasty and Stenting of Veins, Surgery, Policy No. M-109

Percutaneous Transluminal Angioplasty of Intracranial Atherosclerotic Stenoses With or Without Stenting, Surgery, Policy No. N-141

REFERENCES

1. MLN Matters Article “Clarification on Billing Requirements for Percutaneous Transluminal Angioplasty (PTA) Concurrent with the Placement of an FDA-approved Carotid Stent”
2. MLN Matters Article “Clarification of Percutaneous Transluminal Angioplasty (PTA) Billing Requirements Issued in CR 3811”
3. Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, §160 – PTA for Implanting the Carotid Stent (See the various subsections of this reference)
4. Medicare-Approved Carotid Artery Stenting (CAS) Investigational Studies
5. Medicare-Approved IDE Studies
6. Medicare-Approved Carotid Artery Stenting Facilities (facilities are listed alphabetically by name)

**CODING**

**NOTE:** CPT code 37216 is a Medicare Status “N” code, and therefore, is non-covered by Medicare and Medicare Advantage.\(^{(1)}\)

Effective January 1, 2008, all claims submitted for patient care in clinical research studies must use the –Q0 or –Q1 modifiers for routine and investigational clinical services. This includes “studies that are certified under the Medicare Clinical Research Policy, Investigational Device Exemption (IDE) trials, and studies required under a coverage with evidence development (CED) national coverage determination (NCD).”\(^{(7)}\)

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>37215</td>
<td>Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection</td>
</tr>
<tr>
<td></td>
<td>37216</td>
<td>Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; without distal embolic protection ((\text{Non-covered by Medicare}))</td>
</tr>
<tr>
<td></td>
<td>37217</td>
<td>Transcatheter placement of an intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, via open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation</td>
</tr>
<tr>
<td></td>
<td>37246</td>
<td>Transluminal balloon angioplasty (except lower extremity artery(ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; initial artery</td>
</tr>
<tr>
<td></td>
<td>37247</td>
<td>; each additional artery (list separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>HCPCS</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

*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.