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

Carotid artery disease accounts for 20% of the morbidity and mortality associated with stroke, the third leading cause of death in the United States. Therefore, any treatment or procedure that prevents or reverses critical cerebrovascular stenoses has great importance. Treatment for carotid artery stenosis depends on the degree of blockage and the presence of symptoms. Asymptomatic patients with < 70% stenosis receive best medical treatment to decrease blood clot formation and the risk of stroke. Symptomatic (³ 70%) and severe asymptomatic patients (³ 80%) are referred for surgery. The procedure, carotid endarterectomy (CEA), involves the surgical removal of stenotic plaques from the carotid artery. CEA was associated with reduced risk of stroke and death compared with medical treatment alone. However, CEA can also lead to increased morbidity and mortality in patients with significant comorbidity (e.g., coronary artery disease).

Carotid angioplasty and stenting (CAS) is an endovascular treatment to remove atherosclerotic plaques in the carotid artery, and has been proposed as a less invasive alternative to CEA for patients with symptomatic or asymptomatic carotid artery stenosis. CAS involves balloon-mediated pneumatic dilatation of a stenotic atherosclerotic lesion with the subsequent placement of a distensible metal mesh, or stent, designed to assure vascular patency. Cerebral embolic protection devices (EPDs) may be used with CAS to reduce the risk of distal embolization during the angioplasty procedure (from Hayes, 2007).

High Risk Assessment

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA. Significant comorbid conditions include but are not limited to:

- Congestive heart failure (CHF) class III/IV;
- Left ventricular ejection fraction (LVEF) < 30%;
- Unstable angina;
- Contralateral carotid occlusion;
- Recent myocardial infarction (MI);
- Previous CEA with recurrent stenosis;
- Prior radiation treatment to the neck; and
- Other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

CMS Facility Standards

The CMS has created a list of minimum standards modeled in part on professional society statements on competency. All facilities must at least meet CMS’s standards in order to receive coverage for carotid artery stenting for high risk patients.

- Facilities must have necessary imaging equipment, device inventory, staffing, and infrastructure to support a dedicated carotid stent program. Specifically, high-quality x-ray imaging equipment is a critical component of any carotid interventional suite, such as high resolution digital imaging systems with the capability of subtraction, magnification, road mapping, and orthogonal angulation.
Advanced physiologic monitoring must be available in the interventional suite. This includes real time and archived physiologic, hemodynamic, and cardiac rhythm monitoring equipment, as well as support staff who are capable of interpreting the findings and responding appropriately.

Emergency management equipment and systems must be readily available in the interventional suite such as resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation capability, and anesthesia support.

Each institution shall have a clearly delineated program for granting carotid stent privileges and for monitoring the quality of the individual interventionalists and the program as a whole. The oversight committee for this program shall be empowered to identify the minimum case volume for an operator to maintain privileges, as well as the (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation. Committees are encouraged to apply published standards from national specialty societies recognized by the American Board of Medical Specialties to determine appropriate physician qualifications. Examples of standards and clinical competence guidelines include those published in the December 2004 edition of the American Journal of Neuroradiology, and those published in the August 18, 2004 Journal of the American College of Cardiology.

To continue to receive Medicare payment for CAS under this decision, the facility or a contractor to the facility must collect data on all carotid artery stenting procedures done at that particular facility. This data must be analyzed routinely to ensure patient safety. This data must be made available to CMS upon request. The interval for data analysis will be determined by the facility but shall not be less frequent than every 6 months.

Since there currently is no recognized entity that evaluates CAS facilities, CMS has established a mechanism for evaluating facilities. Facilities must provide written documentation to CMS that the facility meets one of the following:

1. The facility was an FDA approved site that enrolled patients in prior CAS IDE trials, such as SAPPHIRE, and ARCHER;
2. The facility is an FDA approved site that is participating and enrolling patients in ongoing CAS IDE trials, such as CREST;
3. The facility is an FDA approved site for one or more FDA post approval studies; or
4. The facility has provided a written affidavit to CMS attesting that the facility has met the minimum facility standards.

Facilities must recertify every two (2) years in order to maintain Medicare coverage of CAS procedures. Recertification will occur when the facility documents that and describes how it continues to meet the CMS standards.

**POSITION STATEMENT**

**Applicable To:**
- Medicaid – All Markets
- Medicare – All Markets

Percutaneous transluminal angioplasty (PTA) is considered medically necessary when used under the following conditions:

1. Treatment of atherosclerotic obstructive lesions:
   a. Of the lower extremities (i.e. iliac, femoral, and popliteal arteries); OR,
   b. Of the upper extremities (i.e. innominate, subclavian, axillary, and brachial arteries. NOTE: The upper extremities DO NOT INCLUDE head and neck vessels); OR,
   c. Of a single coronary artery for members for whom the likely alternative treatment is coronary bypass surgery who exhibit ALL of the following characteristics:
      - Angina refractory to optimal medical management; AND,
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- Objective evidence of myocardial ischemia; **AND,**
- Lesions amenable to angioplasty.
  d. Of the renal arteries for members in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative; **OR,**
  e. Of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

**OR;**

2. Concurrent with Carotid Stent Placement in FDA-Approved Category B Investigational Device Exemption (IDE) Clinical Trial

**OR;**

3. Concurrent with Carotid Stent Placement in FDA-Approved Post Approval Studies

**OR;**

4. Concurrent with Carotid Stent Placement in Members at High Risk for Carotid Endarterectomy (CEA). PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent with embolic protection for the following may be medically necessary and a covered benefit:
  a. Members who are at high risk for CEA and who also have symptomatic carotid artery stenosis ≥ 70%; **OR,**
  b. Members who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, as a routine cost under the clinical trials policy; **OR,**
  c. Members who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥ 80% as a routine cost under the clinical trials policy.

5. Concurrent with Intracranial Stent Placement in FDA-Approved Category B IDE Clinical Trials when:
   a. The member exhibits intracranial atherosclerotic disease with cerebral artery stenosis ≥50%.

**NOTE:** Coverage is limited to procedures performed using an FDA-approved carotid artery stent and embolic protection devices. The use of a distal embolic protection device is required. If deployment of the distal embolic protection device is not technically possible, then the procedure should be aborted given the risks of CAS without distal embolic protection.

**CODING**

**Covered CPT® Codes – NCCI Edits apply**

- **35470** Deleted Code to report See 37228 - 37235
- **35471** Transluminal balloon angioplasty, percutaneous; renal or visceral artery
- **35472** Transluminal balloon angioplasty, percutaneous; aortic
- **35473** Deleted Code to report See 37220 – 37227
- **35474** Deleted Code to report See 37220 – 37227
- **35475** Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel
- **35476** Transluminal balloon angioplasty, percutaneous; venous
- **36120** Introduction of needle or intracatheter; retrograde brachial artery
- **36140** Introduction of needle or intracatheter; extremity artery
- **36147** Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); initial access with complete radiological evaluation of dialysis access, including fluoroscopy, image documentation and report (includes access of shunt, injection(s) of contrast, and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava.
- **36148** Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); initial access with complete radiological evaluation of dialysis access, including fluoroscopy, image documentation and report (includes access of shunt, injection(s) of contrast, and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava.

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imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava; each additional access for therapeutic intervention
List separately in addition to code for primary procedure.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>36245</td>
<td>Place catheter in artery</td>
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<td>36246</td>
<td>Place catheter in artery</td>
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<tr>
<td>36247</td>
<td>Place catheter in artery</td>
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<tr>
<td>37220</td>
<td>Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel, with transluminal angioplasty</td>
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<td>37221</td>
<td>Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel, with transluminal stent placement(s), includes angioplasty within the same vessel, when performed</td>
</tr>
<tr>
<td>37222+</td>
<td>Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; With transluminal angioplasty (List separately in addition to code for primary procedure)</td>
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<td>37223+</td>
<td>Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; With transluminal stent placement(s), includes angioplasty within the same vessel, when performed. (List separately in addition to code for primary procedure)</td>
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<tr>
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<td>Revascularization, endovascular, open or percutaneous femoral, popliteal artery(s), unilateral; With transluminal angioplasty</td>
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<tr>
<td>37225</td>
<td>Revascularization, endovascular, open or percutaneous femoral, popliteal artery(s), unilateral; With atherectomy, includes angioplasty within the same vessel, when performed</td>
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<tr>
<td>37226</td>
<td>Revascularization, endovascular, open or percutaneous femoral, popliteal artery(s), unilateral; With transluminal stent placement(s), includes angioplasty within the same vessel, when performed</td>
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<td>37227</td>
<td>Revascularization, endovascular, open or percutaneous femoral, popliteal artery(s), unilateral; With transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed</td>
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<td>Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; With transluminal angioplasty</td>
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<tr>
<td>37229</td>
<td>Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; With atherectomy, includes angioplasty within the same vessel, when performed</td>
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<td>37230</td>
<td>Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; With transluminal stent placement(s), includes angioplasty within the same vessel, when performed</td>
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<td>37231</td>
<td>Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; With transluminal stent placement(s), includes angioplasty within the same vessel, when performed</td>
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<td>37232+</td>
<td>Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedures)</td>
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<td>37233+</td>
<td>Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedures)</td>
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<tr>
<td>37234+</td>
<td>Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)</td>
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<tr>
<td>37235+</td>
<td>Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)</td>
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<tr>
<td>75962</td>
<td>Transluminal balloon angioplasty, peripheral artery; Radiological Supervision &amp; Interpretation, each vessel</td>
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<tr>
<td>75964+</td>
<td>Transluminal balloon angioplasty, each additional peripheral artery; Radiological Supervision &amp; Interpretation, each vessel</td>
</tr>
<tr>
<td>75966</td>
<td>Transluminal balloon angioplasty, renal or other visceral artery; Radiological Supervision &amp; Interpretation, each vessel</td>
</tr>
<tr>
<td>75968+</td>
<td>Transluminal balloon angioplasty, each additional visceral artery; Radiological Supervision &amp; Interpretation, each vessel</td>
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</tbody>
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75978 Transluminal balloon angioplasty, venous (e.g. subclavian stenosis); Radiological Supervision & Interpretation

HCPCS © Codes
C1725 Catheter, Transluminal, Angioplasty, Non-laser (May include Guidance, Infusion/Perfusion Capability)
C1760 Closure Device, Vascular (Implantable/Insertable)
C1769 Guide wire
C1874 Stent, Coated/Covered, With Delivery System
C1875 Stent, Coated/Covered, Without Delivery System
C1876 Stent, Non-coated/Non-covered With Delivery System
C1877 Stent, Non-coated/Non-covered Without Delivery System
C1884 Embolization Protective System
C1885 Catheter, Transluminal Angioplasty, Laser
C1887 Catheter, Guiding (May Include Infusion/Perfusion Capability)

Covered ICD-9 Procedure Codes 39.50 Angioplasty or atherectomy of other non-coronary vessel(s)
39.90 Insertion of non-drug eluting peripheral vessel stent(s)
00.40 Procedure on single vessel; number of vessels, unspecified
00.41 Procedure on two vessels
00.42 Procedure on three vessels
00.43 Procedure on four or more vessels
00.45 Insertion of one vascular stent; number of stents, unspecified
00.46 Insertion of two vascular stents
00.47 Insertion of three vascular stents
00.48 Insertion of four or more vascular stents
00.61 Percutaneous Angioplasty or atherectomy of precerebral (extracranial) vessel(s); carotid artery(s)
00.63 Percutaneous Insertion of carotid artery stent(s)

DRAFT 2014 ICD-10-PCS Codes
Refer to the following ICD-10-PCS table(s) for specific PCS code assignment based on physician documentation.
NOTE: Per ICD-10-PCS Coding Guidelines, "ICD-10-PCS codes are composed of seven characters. Each character is an axis of classification that specifies information about the procedure performed. Within a defined code range, a character specifies the same type of information in that axis of classification. One of 34 possible values can be assigned to each axis of classification in the seven-character code".

027 Medical/Surgical, Heart and great vessels, dilation
037 Medical/Surgical, Upper arteries, dilation

Covered ICD-9-CM Diagnosis Codes
414.00-414.01 Coronary Atherosclerosis; ASHD; native artery or graft
414.2 Chronic total occlusion of coronary artery; complete / total occlusion
414.3 Coronary Atherosclerosis due to lipid rich plaque
433.10 Occlusion and stenosis of pre-cerebral arteries; carotid artery without mention of cerebral infarction
433.11 Occlusion and stenosis of pre-cerebral arteries; carotid artery with cerebral infarction
433.30 Occlusion and stenosis of pre-cerebral arteries, multiple and bilateral, without mention of cerebral infarction
433.31 Occlusion and stenosis of pre-cerebral arteries, multiple and bilateral, with cerebral infarction
440.20-440.28 Atherosclerosis of extremities; with intermittent claudication; with rest pain; with ulceration; with gangrene
440.1 Atherosclerosis of Renal Artery
440.4 Chronic total occlusion of artery of the extremities; Complete occlusion of artery of extremities.

Draft 2014 ICD-10-CM Diagnosis Codes
I25.10 – I25.110, I25.119 Atherosclerotic heart disease of native coronary artery without angina pectoris
I25.82 Chronic total occlusion of coronary artery
I25.83 Coronary atherosclerosis due to lipid rich plaque
I63.139 Cerebral infarction due to embolism of unspecified carotid artery
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I63.239  Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid arteries
I65.21 - I65.29  Occlusion and stenosis of unspecified carotid artery
I63.031-I63.039, I63.131 – I63.139, I63.231-I63.239  Occlusion and stenosis of pre-cerebral arteries; carotid artery with cerebral infarction
I65.8  Occlusion and stenosis of other precerebral arteries
I63.59  Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
I70.1  Atherosclerosis of renal artery
I70  Unspecified atherosclerosis of native arteries of extremities
I70.92  Chronic total occlusion of artery of the extremities


REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
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<th>Action</th>
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<td>10/2/2014</td>
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<td>10/3/2013</td>
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</tr>
<tr>
<td>10/4/2012</td>
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<tr>
<td>12/1/2011</td>
<td>New template design approved by MPC.</td>
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