PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) (NCD 20.7)

Guideline Number: MPG239.03

Table of Contents

INSTRUCTIONS FOR USE ......................................... 1
POLICY SUMMARY .................................................... 1
APPLICABLE CODES ..................................................... 3
REFERENCES ............................................................. 4
GUIDELINE HISTORY/REVISION INFORMATION .............. 4

Related Medicare Advantage Policy Guideline
- Category III CPT Codes

Related Medicare Advantage Reimbursement Policy
- Global Surgery

Related Medicare Advantage Coverage Summaries
- Experimental Procedures and Items, Investigational Devices and Clinical Trials
- Percutaneous Transluminal Angioplasty and Stenting

INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY SUMMARY

Overview
This broad NCD addresses the treatment of various vessels, however, the focus for this policy is those that are performed for the following:
- Concurrent with Carotid Stent Placement in Food and Drug Administration (FDA)-Approved Category B Investigational Device Exemption (IDE) Clinical Trials.
- Concurrent with Intracranial Stent Placement in FDA-Approved Category B IDE Clinical Trials.

This procedure involves inserting a balloon catheter into a occluded or narrow blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of 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 renal, peripheral, and coronary arteries.
**Guidelines**

Medicare covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service when provided in the context of such a clinical trial.

Medicare covers PTA and stenting of 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. CMS determines that coverage of intracranial PTA and stenting is reasonable and necessary under these circumstances.

**Other Guidelines**

**Treatment of Atherosclerotic Obstructive Lesions**

In the lower extremities, i.e., the iliac, femoral, and popliteal arteries, or in the upper extremities, i.e., the innominate, subclavian, axillary, and brachial arteries. The upper extremities do not include head or neck vessels.

- Of a single coronary artery for patients for whom the likely alternative treatment is coronary bypass surgery and who exhibit the following characteristics:
  - Angina refractory to optimal medical management;
  - Objective evidence of myocardial ischemia; and
  - Lesions amenable to angioplasty.

- Of the renal arteries for patients in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative. PTA for this group of patients is an alternative to surgery, not simply an addition to medical management.

- Of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

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

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. The Centers for Medicare & Medicaid Services (CMS) determines that coverage of PTA of the carotid artery is reasonable and necessary in these circumstances.

**Concurrent with Carotid Stent Placement in Patients at High Risk for Carotid Endarterectomy (CEA)**

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

- Patients who are at high risk for CEA and who also have symptomatic carotid artery stenosis ≥70%. Coverage is limited to procedures performed using FDA-approved carotid artery stenting (CAS) 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 National Coverage Determination (NCD) Manual 310.1), or in accordance with the NCD on CAS post-approval studies (Medicare NCD Manual 20.7);

- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥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 20.7).

Coverage is limited to procedures performed using an FDA-approved CAS, stents and FDA-approved or cleared embolic protection devices.

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.

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.

Symptoms of carotid artery stenosis include carotid transient ischemic attack (distinct focal neurological dysfunction persisting less than 24 hours), focal cerebral ischemia producing a nondisabling stroke (modified Rankin scale < 3 with symptoms for 24 hours or more), and transient monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale ≥ 3) shall be excluded from coverage.

The determination that a patient is at high risk for CEA and the patient’s symptoms of carotid artery stenosis shall be available in the patient medical records prior to performing any procedure.

The degree of carotid artery stenosis shall be measured by duplex Doppler ultrasound or carotid artery angiography and recorded in the patient’s medical records. If the stenosis is measured by ultrasound prior to the procedure, then the degree of stenosis must be confirmed by angiography at the start of the procedure. If the stenosis is determined to be <70% by angiography, then CAS should not proceed.

In addition, CMS has determined that CAS with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. Standards to determine competency include specific physician training standards, facility support requirements and data collection to evaluate outcomes during a required reevaluation.

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 CAS for high-risk patients.

**Nationally Non-Covered Indications**

All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain noncovered.

All other indications for PTA without stenting for which CMS has not specifically indicated coverage remain noncovered.

**Other**

CMS has created facility standards in order to receive coverage for carotid artery stenting in high risk patients. A list of certified facilities is available and viewable at: [Carotid Artery Stenting Facilities](#).

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>37215</td>
<td>Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection</td>
</tr>
<tr>
<td>37799</td>
<td>Unlisted procedure, vascular surgery</td>
</tr>
</tbody>
</table>

*CPT® is a registered trademark of the American Medical Association*

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>FB</td>
<td>Item provided without cost to provider, supplier or practitioner, or full credit received for replaced device (examples, but not limited to, covered under warranty, replaced due to defect, free samples)</td>
</tr>
<tr>
<td>Q0</td>
<td>Investigational clinical service provided in a clinical research study that is in an approved clinical research study</td>
</tr>
<tr>
<td>Q1</td>
<td>Routine clinical service provided in a clinical research study that is in an approved clinical research study</td>
</tr>
</tbody>
</table>
ICD-10 Diagnosis Codes

NCD 20.7 ICD-10 Dx Coding.xlsx

ICD-10 Procedure Codes

NCD 20.7 ICD-10 Proc Coding.xlsx

REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 20.7 Percutaneous Transluminal Angioplasty (PTA)
Related NCD: NCD 310.1 Routine Costs in Clinical Trials

CMS Claims Processing Manual
Chapter 32: § 68 Investigational Device Exemption (IDE), § 69 Qualifying Clinical Trials, § 160 PTA for Implanting the Carotid Stent § 161 Intracranial PTA with Stenting

CMS Transmittals
Transmittal 1537, Change Request 9252, Dated 08/21/2015, (ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations (NCDs)--3rd Maintenance CR)
Transmittal 1580, Change Request 9252, Dated 12/03/2015, (ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations (NCDs)--3rd Maintenance CR)
Transmittal 1665, Change Request 9631, Dated 05/13/2016, (Coding Revisions to National Coverage Determinations (NCDs))
Transmittal 1672, Change Request 9631, Dated 06/03/2016, (Coding Revisions to National Coverage Determinations (NCDs))
Transmittal 1708, Change Request 9751, Dated 08/19/2016, (Coding Revisions to National Coverage Determination (NCDs))
Transmittal 1753, Change Request 9751, Dated 11/17/2016, (Coding Revisions to National Coverage Determination (NCDs))

MLN Matters
Article MM3489, Percutaneous Transluminal Angioplasty (PTA)
Article MM5022, Clarification on Billing Requirements for Percutaneous Transluminal Angioplasty (PTA) Concurrent with the Placement of an FDA-approved Carotid Stent
Article MM9751, Revised, Coding Revisions to National Coverage Determination (NCDs)
Article SE1119, National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7)

Others
Mandatory Reporting of National Clinical Trial (NCT) Identifier, CMS Website

GUIDEline HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/08/2017</td>
<td>• Annual review; no changes</td>
</tr>
</tbody>
</table>