

Percutaneous Transluminal Angioplasty and Stenting

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- [Routine Costs in Clinical Trials \(NCD 310.1\)](#)

Coverage Guidelines

Percutaneous transluminal angioplasty (PTA) is covered when Medicare coverage criteria are met.

Percutaneous transluminal angioplasty (PTA) is covered when used under the following conditions:

- 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. The 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 Food and Drug Administration (FDA)-approved category B investigational device exemption (IDE) clinical trials:
 - Effective July 1, 2001, Medicare covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the Food and Drug Administration (FDA)-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials. The 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 only when provided in the context of such a clinical trial.
- Concurrent with carotid stent placement in FDA-approved post approval studies:
 - Effective October 12, 2004, 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 (effective December 9, 2009) for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. CMS determines that coverage of PTA of the carotid artery is reasonable and necessary under these circumstances.
- Concurrent with carotid stent placement in patients at high risk for carotid endarterectomy (CEA):
 - Effective March 17, 2005, Medicare cover PTA concurrent with the placement of an FDA-approved carotid stent with embolic protection for the following:
 - Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis >70%. Coverage is limited to procedures performed using FDA-approved carotid artery stenting systems and embolic protection devices; and FDA-approved or -cleared (effective December 9, 2009) 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 (Effective December 9, 2009);

- 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 [Refer to the [National Coverage Determination \(NCD\) for Routine Costs in Clinical Trials \(310.1\)](#)], or in accordance with the NCD on carotid artery stenting (CAS) post-approval studies (Refer to [Concurrent with Carotid Stent Placement in FDA-Approved Post Approval Studies](#)). (Accessed March 8, 2021)
- 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 [Refer to the [NCD for Routine Costs in Clinical Trials \(310.1\)](#)], or in accordance with the NCD on CAS post-approval studies (Refer to [Concurrent with Carotid Stent Placement in FDA-Approved Post Approval Studies](#)). (Accessed March 8, 2021)

Notes:

- 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.
- Coverage is limited to procedures performed using FDA-approved carotid artery stenting systems 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.
- All facilities must meet CMS's standards for carotid artery stenting in high risk patients. The list of CMS approved Carotid Artery Stenting Facilities is available at <http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Carotid-Artery-Stenting-Facilities.html>. (Accessed March 8, 2021)
- Concurrent with intracranial stent placement in FDA-approved category B IDE clinical trials:
 - Effective November 6, 2006, Medicare covers the treatment of cerebral artery stenosis >50% in patients with intracranial atherosclerotic disease with intracranial percutaneous transluminal angioplasty (PTA) and stenting when furnished in accordance with the Food and Drug Administration (FDA)-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials.
 - For clarification of high risk patients and further information on clinical trials criteria refer to the [NCD for Percutaneous Transluminal Angioplasty \(20.7\)](#). (Accessed March 8, 2021)

Refer to the [NCD for Percutaneous Transluminal Angioplasty \(20.7\)](#). (Accessed March 8, 2021)

A list of Medicare approved facilities for Carotid Artery Stenting is available at <http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Carotid-Artery-Stenting-CAS-Investigational-Studies.html>. (Accessed March 8, 2021)

Definitions

Carotid Artery Stenosis: An abnormal constriction or narrowing of the carotid artery; carotid stenosis accounts for 20% of the morbidity and mortality associated with stroke, the third leading cause of death in the United States. Treatment for carotid artery stenosis depends on the degree of blockage and the presence of symptoms. Hayes Technology Directory Report: Carotid Angioplasty and Stenting for Carotid Artery Stenosis (Publication Date: September 29, 2009); updated October 10, 2013. (Accessed March 8, 2021)

Carotid Artery Stents and Stenting (CAS): An endovascular treatment to remove atherosclerotic plaques in the carotid artery in patients with symptomatic or asymptomatic carotid artery stenosis. The goal of the procedure is to improve blood flow, reduce the chance of embolization to the brain, and prevent stroke and the recurrence of stenosis. Hayes Technology Directory Report: Carotid Angioplasty and Stenting for Carotid Artery Stenosis (Publication Date: September 29, 2009); updated October 10, 2013. (Accessed March 8, 2021)

Modified Rankin Scale:

- 0 No symptoms at all
- 1 No significant disability despite symptoms; able to carry out all usual duties and activities

- 2 Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
- 3 Moderate disability; requiring some help, but able to walk without assistance
- 4 Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
- 5 Severe disability; bedridden, incontinent and requiring constant nursing care and attention
- 6 Dead

Hayes Technology Directory Report: Carotid Angioplasty and Stenting for Carotid Artery Stenosis (Publication Date: September 29, 2009); updated October 10, 2013; based on Rankin (1957) and later modifications (Bonita et al, 1986; Van Swieten et al, 1988). (Accessed March 8, 2021)

Policy History/Revision Information

Date	Summary of Changes
05/01/2021	Template Update <ul style="list-style-type: none"> • Reformatted policy; transferred content to new template
03/16/2021	Definitions <ul style="list-style-type: none"> • Removed definition of “Percutaneous Transluminal Angioplasty”

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The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

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