

## Medical Coverage Policy | Carotid Angioplasty Without Associated Stenting and Embolic Protection



**EFFECTIVE DATE:** 04|07|2005

**POLICY LAST UPDATED:** 07|20|2022

### OVERVIEW

Carotid artery angioplasty with stenting (CAS) is a treatment for carotid stenosis that is intended to prevent future stroke. It is an alternative to medical therapy and a less invasive alternative to carotid endarterectomy (CEA).

### MEDICAL CRITERIA

Not applicable

### PRIOR AUTHORIZATION

Not applicable

### POLICY STATEMENT

#### Medicare Advantage Plans

Carotid angioplasty without associated stenting and embolic protection is not covered as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

#### Commercial Products

Carotid angioplasty without associated stenting and embolic protection is considered not medically necessary the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

### BACKGROUND

Carotid artery angioplasty with stenting is a treatment for carotid stenosis that is intended to prevent future stroke. It is an alternative to medical therapy and a less-invasive alternative to carotid endarterectomy.

Combined with optimal medical management, carotid angioplasty with or without stenting has been evaluated as an alternative to carotid endarterectomy (CEA). Carotid artery stenting (CAS) involves the introduction of coaxial systems of catheters, microcatheters, balloons, and other devices. The procedure is most often performed through the femoral artery, but a transcervical approach can also be used to avoid traversing the aortic arch. The procedure typically takes 20–40 minutes. Interventionalists almost uniformly use an embolic protection device (EPD) designed to reduce the risk of stroke caused by thromboembolic material dislodged during CAS. Embolic protection devices can be deployed proximally (with flow reversal) or distally (using a filter). Carotid angioplasty is rarely performed without stent placement.

Proposed advantages of CAS over CEA include:

- General anesthesia is not used (although CEA can be performed under local/regional anesthesia)
- Cranial nerve palsies are infrequent sequelae (although almost all following CEA resolve over time)
- Simultaneous procedures may be performed on the coronary and carotid arteries

A number of carotid artery stents and embolic protection devices (EPDs) have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval or the 510(k) process.

Each FDA-approved carotid stent is indicated for combined use with an EPD to reduce risk of stroke in patients considered at increased risk for periprocedural complications from carotid endarterectomy (CEA) who are symptomatic with greater than 50% stenosis, or asymptomatic with greater than 80% stenosis with degree of stenosis assessed by ultrasound or angiogram, with computed tomography angiography also used. Patients are considered at increased risk for complications during CEA if affected by any item from a list of anatomic features and comorbid conditions included in each stent system's Information for Prescribers.

The RX Acculink™ Carotid Stent System is also approved for use in conventional risk patients (not considered at increased risk for complications during CEA) with symptoms and 70% or more stenosis by ultrasound or 50% or more stenosis by angiogram, and asymptomatic patients with 70% or more stenosis by ultrasound or 60% or more stenosis by angiogram.

The FDA-approved stents and EPDs differ in the deployment methods used once they reach the target lesion, with the rapid exchange (RX) devices designed for more rapid stent and filter expansion. FDA has mandated postmarketing studies for EPDs, including longer follow-up for patients already reported to FDA and additional registry studies, primarily to compare outcomes as a function of clinician training and facility experience. Each manufacturer's system is available in various configurations (e.g., straight or tapered) and sizes (diameters and lengths) to match the vessel lumen that will receive the stent.

In 2015, the ENROUTE™ Transcarotid NPS was cleared for marketing by FDA through the 510(k) process. ENROUTE™ is a flow-reversal device designed to be placed via direct carotid access.

In 2007, a decision memo reaffirmed the Centers for Medicare and Medicaid Services (CMS) previous decision following a request to expand coverage while clarifying that "CAS is only covered when used with an embolic protection device and is, therefore, not covered if deployment of the distal embolic protection device is not technically possible." In 2008 in the sixth reconsideration, and on, in 2009 in the seventh reconsideration, CMS reaffirmed their prior coverage decisions.

Therefore, Carotid angioplasty without associated stenting and embolic protection is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial products as the evidence is insufficient to determine the effects of the technology on health outcomes.

#### **CODING**

The following code is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

**37216** Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; without distal embolic protection

#### **RELATED POLICIES**

Not applicable

#### **PUBLISHED**

Provider Update, September 2022

Provider Update, August 2021

Provider Update, July 2020

Provider Update, August 2019

Provider Update, Sep 2018

## REFERENCES

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