



MASSACHUSETTS

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## Medical Policy Carotid Stent Placement

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### Policy Number: 219

BCBSA Reference Number: 7.01.68 (For Plan internal use only)

### Related Policies

Endovascular Therapies for Extracranial Vertebral Artery Disease, #[730](#)

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms) #[323](#)

### Policy<sup>1</sup>

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

##### Extracranial Stent Placement

Extracranial carotid artery stent (CAS) placement performed by a percutaneous transfemoral approach or by direct access to the carotid artery (transcarotid arterial revascularization, TCAR) is considered **MEDICALLY NECESSARY** for individuals who meet **EITHER categories A or B** of the following criteria **and** can be safely treated by this approach **and** who have no angiographically visible intraluminal thrombus:

- A. Symptomatic stenosis equal to or greater than 50%, **or** asymptomatic stenosis equal to or greater than 80%; **and one or more** of the following conditions which render the individual a *high risk* for carotid endarterectomy (CEA):
  1. Congestive heart failure (New York Heart Association Class III/IV) or left ventricular ejection fraction less than 30%; **or**
  2. Open heart surgery needed within the next 6 weeks; **or**
  3. Recent myocardial infarction (less than 4 weeks); **or**
  4. Severe chronic obstructive pulmonary disease; **or**
  5. Unstable angina (Canadian Cardiovascular Society Class III/IV)
  6. Inability to move the neck to a suitable position for surgery; **or**
  7. Tracheostomy.

**or**
- B. Symptomatic stenosis equal to or greater than 50%, **or** asymptomatic stenosis equal to or greater than 80%; **and one or more** of the following conditions:
  1. Contralateral laryngeal nerve palsy; **or**
  2. Existence of lesions distal or proximal to the carotid bulb and bifurcation of the common carotid; **or**
  3. Carotid pseudoaneurysm; **or**

4. Radiation-induced stenosis following previous radiation therapy to the neck **or**
5. Prior major neck surgery (e.g. thyroidectomy, radical neck dissection); **or**
6. Restenosis after prior CEA; **or**
7. Severe tandem lesions that may require endovascular therapy; **or**
8. Stenosis secondary to arterial dissection; **or**
9. Stenosis secondary to fibromuscular dysplasia; **or**
10. Stenosis secondary to Takayasu arteritis; **or**
11. Stenosis that is surgically difficult to access (e.g., high bifurcation requiring mandibular dislocation); **or**
12. Stenosis associated with contralateral carotid artery occlusion; **or**
13. Inability to move the neck to a suitable position for CEA; **or**
14. Presence of tracheostomy.

*Note:* If, in exceptional circumstances, extracranial carotid artery angioplasty is performed without stent placement, the above medically necessary criteria must still be met. In addition, any stent delivery system utilized must include embolic protection.

Carotid artery stent placement (CAS) and TCAR are considered **NOT MEDICALLY NECESSARY** in individuals with **any** of the following conditions:

- Carotid stenosis with angiographically visible intraluminal thrombus; **or**
- A stenosis that cannot be safely reached or crossed by an endovascular approach; **or**
- Circumferential carotid calcification; **or**
- Complete occlusion (100% stenosis) of the relevant carotid artery; **or**
- Severe carotid stenosis in individuals who are candidates for standard CEA; **or**
- Symptomatic stenosis less than 50% of the relevant carotid artery; **or**
- Asymptomatic stenosis less than 80% of the relevant carotid artery.

Extracranial carotid artery stent (CAS) placement performed by a percutaneous transfemoral approach or by direct access to the carotid artery (transcarotid arterial revascularization, TCAR) under any other circumstances except as noted above is considered **INVESTIGATIONAL**.

## Prior Authorization Information

### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

### Outpatient

- For services described in this policy, see below for situations where prior authorization might be required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>not required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>not required</b> .

## CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

## CPT Codes

CPT codes:	Code Description
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous; with distal embolic protection

## Description

### Description of Disease

Approximately 795,000 people in the U.S. experience a stroke every year, and 34% of those hospitalized for stroke are under the age of 65. Stroke is currently the fifth leading cause of death in the U.S. Stenosis of one or both of the cervical internal carotid arteries is a leading risk factor, accounting for 8-11% of ischemic strokes. Treatment of carotid artery stenosis includes risk factor modification, such as smoking cessation, weight reduction, lowering cholesterol levels, exercise, reduction of elevated blood pressure, glycemic control, medication (eg, statins and antiplatelet therapy), and, in some cases, surgical intervention (CEA or CAS).

Fibromuscular dysplasia is a nonatherosclerotic, noninflammatory disease of the blood vessels that most commonly affects the internal carotid and renal arteries. The condition is rare, and the cause is unknown, although cigarette smoking, and a history of hypertension may increase the risk. The severity of symptoms varies widely and may result in arterial stenosis, aneurysms, and dissection (separation of the layers of the vessel wall) that result in significant morbidity. Therapy may include drug therapy (to treat hypertension that results from renal artery involvement), surgical revascularization, and/or angioplasty.

### Description of Technology

Traditional surgical treatment for clinically significant internal carotid arterial stenosis in the neck entails an open CEA. The carotid artery is exposed through a large neck incision, and the atherosclerotic plaque causing the narrowing is removed surgically. Over the past 20 years, CAS has emerged as an alternative to open surgery. Initially, only a balloon angioplasty of the carotid stenosis was performed. Currently, angioplasty is followed by insertion of a stent in order to support the arterial wall and thus prevent restenosis. Insertion of a distal embolic protection filter should generally accompany stent placement. This filter consists of a small wire mesh or basket to capture any embolic debris that may dislodge from the stenotic lesion. This device thus decreases the risk of an ischemic event in the brain due to embolic occlusion of the smaller intracranial arteries. In certain settings of fibromuscular dysplasia and in other rare situations where stent placement is technically not feasible, angioplasty alone may be performed.

Transcarotid artery revascularization (TCAR) represents an alternative to standard transfemoral CAS. During a TCAR procedure, the common carotid artery is accessed directly through a small incision in the neck. However, the TCAR catheter does not deploy a distal embolic protection device *per se*. Instead, carotid and cerebral arterial bloodflow is temporarily reversed through a special cannula and is redirected into the femoral vein. As a result, any fragments of plaque or thrombus dislodged during the subsequent angioplasty and stent deployment are diverted away from the brain. The TCAR approach thus avoids manipulation of the aortic arch and origin of the common carotid. It also obviates the risk of smaller embolic particles passing through or around conventional distal embolic filters. In theory, therefore, the TCAR approach should diminish the risk of an ischemic cerebral event during CAS.

## Summary

### Extracranial Carotid Artery Angioplasty with Stent Placement (CAS) for Treatment of Atherosclerotic Stenosis of the Extracranial Carotid Arteries:

Carotid endarterectomy (CEA) remains the established procedure for individuals with symptomatic or significant asymptomatic carotid artery stenosis. However, this is an invasive surgical procedure associated with well-defined complications, including the risk of major and minor strokes, cranial nerve injuries as well as myocardial ischemia. An endovascular approach to carotid artery lesions is attractive,

since this minimally invasive technique has been applied successfully in the coronary and lower limb arteries. Although much less invasive than CEA, the risk of serious complications, including stroke and death, remain an issue for CAS.

For individuals with have carotid artery stenosis who receive carotid artery stenting (CAS), the evidence includes randomized controlled trials and systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. A substantial body of randomized controlled trial evidence has compared outcomes of CAS with CEA for symptomatic and asymptomatic individuals with carotid stenosis. The evidence does not support the use of CAS in carotid artery disease for the *average-risk* patient because early adverse events are higher with CAS and long-term outcomes are similar between the two procedures. Data from randomized controlled trials and large database studies have established that the risk of death or stroke with CAS exceeds the threshold considered acceptable to indicate overall benefit from the procedure. In addition, several of the randomized controlled trials and systematic reviews reported higher carotid restenosis rates following CAS compared to CEA. Therefore, for individuals with carotid stenosis who are suitable candidates for CEA, CAS does not improve health outcomes. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome. Therefore, coverage for CAS is limited to individuals deemed *high risk* for CEA due to either medical or local anatomic contraindications as delineated above.

### Role of TCAR

Schermerhorn et al. recently published an outcomes comparison between transcarotid artery revascularization (TCAR) and CAS by the traditional percutaneous transfemoral route. The authors performed a propensity score-matched analysis of prospectively collected data from the Vascular Quality Initiative Transcarotid Artery Surveillance Project and Carotid Stent Registry of both asymptomatic and symptomatic individuals in the United States and Canada undergoing transcarotid artery revascularization and transfemoral carotid artery stenting for carotid artery stenosis between 2016-2019. 3286 matched pairs of individuals who underwent either transcarotid artery revascularization or transfemoral carotid artery stenting were identified. Transcarotid artery revascularization was associated with a significantly lower risk of stroke or death in-hospital (1.6% vs 3.1%), 30-days (1.9% vs. 3.7%) later, and one year later (5.1% vs. 9.6% by Kaplan-Meier life-table estimation) compared to the transfemoral approach. Moreover, transcarotid artery revascularization was associated with significantly lower rates of technical failure (0.5% vs 1.2%), embolic protection placement failure (0.3% vs 5.8%), and required significantly less contrast dye and radiation exposure to complete the stenting procedure compared to the transfemoral approach. There was no statistically significant difference in the risk of perioperative myocardial infarction between the two cohorts (0.2% for transcarotid vs 0.3% for transfemoral approach) or overall bleeding rates at the access site (3.5% for transcarotid vs 3.8% for transfemoral approach). However, transcarotid artery revascularization was associated with a somewhat higher risk of access site bleeding resulting in interventional treatment (1.3% vs 0.8%). The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

To date, no prospective randomized controlled trials of transcarotid artery revascularization versus standard carotid endarterectomy have been published. The principal benefit of the former over the latter procedure would be to mitigate the risk of cranial nerve injury. Two recent retrospective, propensity-matched analyses suggested no significant difference between the two procedures in stroke rate, myocardial infarction, or overall death rate at one month postoperatively. As expected, transcarotid artery revascularization was associated with a significantly lower risk of cranial nerve injury (0.3% vs 3.8% for carotid endarterectomy). The evidence is insufficient to determine that transcarotid artery revascularization should be preferred over standard carotid endarterectomy for the *average risk* patient with significant carotid stenosis at this time. (Yee EJ 2020) (Kashyap VS 2019)

### Policy History

Date	Action
6/2022	Annual policy review. References added. Policy remains unchanged.
5/2021	Policy updated with literature review through April 2021. No references added. Policy statements unchanged.

1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
10/2020	New medically necessary indications described for TCAR when all the policy criteria for Extracranial Carotid Stent Placement are met. Clarified coding information. Effective 10/1/2020.
6/2020	Policy clarified to remove duplicate statement on percutaneous intracranial artery stent placement with or without angioplasty. For coverage information, see medical policy 323.
5/2018	Policy criteria clarified. Effective 5/1/2018.
3/2017	New medically necessary indications described. Title changed. Clarified coding information. Effective 3/1/2017.
7/2016	Annual policy review. New references added
12/2015	Added coding language.
9/2015	Clarified coding information.
1/2015	Clarified coding information.
5/2014	Annual policy review. New references added. Added transcervical approach to background.
1/2014	Updated to add new CPT codes 37217, 37238 and 37239.
5/2013	Annual policy review. New references added.
2/2013	Annual policy review. Changes to policy statement. Effective 2/4/2013.
1/2013	Updated to add new CPT codes 36221-36228.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
12/2011	Annual policy review. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
8/1/2010	New policy, effective 8/1/2010, describing covered and non-covered indications.
8/2008	Annual policy review. No changes to policy statements.
3/2008	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
7/2007	Annual policy review. No changes to policy statements.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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## Endnotes

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<sup>1</sup> Based on expert opinion