

Medical Policy Manual

Topic: Extracranial Carotid Angioplasty/Stenting

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Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Carotid angioplasty with stenting (CAS) is a treatment for carotid stenosis that is intended to prevent future stroke. The procedure is proposed as an alternative to medical therapy and a less invasive alternative to carotid endarterectomy (CEA). CAS involves the insertion of a stent (wire-mesh tube) into a narrowed carotid artery. A catheter (a long hollow tube) is inserted into the groin artery and guided through the arteries to the narrowing in the carotid artery. A balloon at the end of the catheter is inflated to push open the narrowed area, and a metal stent is inserted to keep this area from narrowing again. The procedure is performed with the patient fully awake and without sedation. At present, most practitioners also use a distally placed embolic protection (DEP) device that is designed to reduce the risk of stroke caused by thromboembolic material dislodged during CAS. Carotid angioplasty is rarely performed without stent placement.

Regulatory Status

The U.S. Food and Drug Administration (FDA) has approved several carotid artery stents and DEP devices from various manufacturers. The FDA has mandated postmarketing studies for these devices. Each FDA-approved carotid stent system is indicated for combined use with a DEP device.

Note: This policy does not address percutaneous angioplasty and stenting of intracranial or venous vessels, which are addressed in separate policies (see Cross References below).

MEDICAL POLICY CRITERIA

- I. Carotid angioplasty with associated stenting and embolic protection may be considered **medically necessary** when all of the following criteria are met:
 - A. Documented 50-99% stenosis; AND
 - B. Symptoms with duration less than 24 hours of focal ischemia (transient ischemic attack or monocular blindness) in previous 120 days, or nondisabling stroke; AND
 - C. One or more of the following anatomic contraindications for carotid endarterectomy (CEA) are present:
 1. Tissue changes from prior extensive ipsilateral neck radiation
 2. Prior ipsilateral radical neck resection
 3. Anatomical malformation that prevents collateral circulation to the brain during open carotid endarterectomy (CEA)
 4. Lesions surgically inaccessible (such as high internal carotid lesion that cannot be accessed from the neck)
 5. Spinal immobility preventing open carotid endarterectomy (CEA)
 6. Tracheostomy
- II. Except as defined in I. A, B, and C above, carotid angioplasty with associated stenting and embolic protection, is considered **investigational**.

SCIENTIFIC EVIDENCE^[1]

Evidence from well-designed, well-conducted randomized controlled trials (RCTs) is necessary to establish the safety and efficacy of carotid angioplasty with stenting (CAS) compared with carotid endarterectomy (CEA) for treatment of carotid stenosis.

Literature Appraisal

Agency for Healthcare Research and Quality (AHRQ) Technology Assessment

A 2012 AHRQ report evaluated the evidence from 60 eligible studies of treatment strategies for patients with asymptomatic carotid artery stenosis.^[2,3] The report noted that the definitions of “asymptomatic” patients were heterogeneous across the evaluated studies (i.e., patients without symptoms, patients with symptoms present for > 6 months before their enrollment in the study but recently [within 6 months] asymptomatic, or patients with symptoms in a vascular territory other than ipsilateral carotid [e.g., vertebrobasilar territory]). The report focused on evidence for the following treatments:

- Medical therapy alone
- CEA and medical therapy compared with medical therapy alone
- CAS and medical therapy compared with medical therapy alone
- CAS and medical therapy compared with CEA and medical therapy.

For evidence on CAS and medical therapy compared with CEA and medical therapy, the review concluded that

- “One recent large trial (CREST) reported higher rates of postprocedural ipsilateral stroke (including any periprocedural stroke) and its composite primary endpoint in the CAS[group], as compared with CEA, but this did not reach statistical significance in patients with asymptomatic carotid stenosis. The CREST and the SAPHIRE trials randomized patients with symptomatic and asymptomatic carotid stenosis stratified according to symptom status. Therefore, the treatment assignment was randomized among the subgroup of patients with asymptomatic carotid stenosis. However, neither trial was powered to detect a significant difference in the primary composite endpoint among subgroups of patients with asymptomatic carotid stenosis. The failure to find a significant difference does not rule out the possibility that real difference exists between the intervention modalities tested.”
- “Future trials should focus not only on whether CAS is equivalent or superior to CEA, but also on whether an invasive interventional procedure is likely to translate into any significant benefit to the patient treated with current best medical therapy.”

Cochrane Reviews

The 2007 and 2009 Cochrane Reviews assessed the risks and benefits of endovascular treatment (CAS) compared to open carotid endarterectomy (CEA). The reviews included 12 and 10 randomized controlled trials respectively.^[4,5]

The review found the data from these studies to be conflicting and difficult to interpret. Several flaws undermine the validity of the study findings:

- The overall estimates of effect were imprecise and difficult to interpret due to substantial heterogeneity among the trials such as different patient populations, outcome measures, endovascular procedures, and durations of follow-up. In addition, stopped and completed trials were analyzed together.
- Some studies were stopped early due to recruitment, safety, or futility issues. The early termination may have led to an overestimate of the risk or the benefit of the treatment.
- No intention-to-treat (ITT) or partial ITT analyses were carried out, which may have biased the estimates of treatment effect.
- Use of antiplatelet medications before, during, and after the treatment may have confounded the study findings.
- Long-term efficacy was difficult to assess because outcome measures and length of follow-up differed greatly among the studies

The review concluded that “the data are insufficient to support a change from routine clinical practice in the types of patient for which carotid endarterectomy is the current standard treatment.”

Follow-up of the Trials Included in the Cochrane Reviews

Subsequent to the publication of the Cochrane reviews, two long-term follow-up reports of the CAVATAS trial were published.^[6,7] Both reports summarize the long-term effects of CAS compared to CEA on restenosis and/or the risk of stroke and other major adverse events. Although both reports found CEA to lead to more favorable outcomes, the findings are unreliable due to at least one of the following flaws:

- No intention-to-treat (ITT) was carried out, which may have biased the estimates of treatment effect.
- Heterogenous patient populations (e.g. patients with and without stent placement) may have led to biased estimations of treatment effects.
- The study was underpowered (not able to detect reliably clinically important differences between the treatment groups).

BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC) Assessments

The 2007 and the 2010 BCBSA TEC assessments did not identify reliable evidence in support of CAS.^[8,9]

Five major randomized trials of CAS vs. CEA were reviewed in the TEC Assessments (SPACE, EVA-3S, SAPPHERE, ICSS, and CREST) and all had significant limitations, including but not limited to:

- Early termination (SPACE and EVA-3S)
Subsequent to the publication of the first EVA-3S report and the BCBSA TEC assessment, additional analyses of the same data have been published.^[10] However, any findings based on the EVA-3S data are unreliable due to the bias introduced by early termination.
- Disproportionally small number of symptomatic vs. asymptomatic patients enrolled (≤ 50) in each treatment arm (SAPPHERE)
- Follow-up still ongoing and only interim safety results have been reported (ICSS).^[11]
The ICSS interim safety analysis measured the 120-day rate of stroke, death, or procedural myocardial infarction. The interim findings suggest that CEA is safer than CAS for the treatment of symptomatic patients. However, long-term follow-up is needed to reliably establish the difference between the two treatments.
- Significant loss to follow-up (only 13% of the original study population available) (CREST).^[12]
- Study was underpowered to reliably detect differences between treatment arms in the whole study population as well as in the subanalyses (CREST).^[12]
Subsequent to the publication the first CREST report^[12] and the BCBSA TEC assessment, additional analyses of the CREST data were published.^[13-15] Some of these analyses focus on comparisons of the safety of CAS vs. CEA in the different subgroups of the study population, such as by symptomatic status or gender.^[14,15] However, any findings based on the CREST data are unreliable due to the biases introduced by the loss to follow-up and inadequate statistical power.

Other Meta-analyses

In addition to the Cochrane reviews and TEC Assessments, several other meta-analyses of the studies that compare carotid angioplasty/stenting (CAS) with endarterectomy (CEA) have been published.^[16-22] These analyses reported inconsistent findings, some in favor of CAS and others in favor of CEA. In either case, the reliability of the conclusions from these meta-analyses is limited by pooling results from

unreliable, heterogeneous primary studies (different patient samples, endovascular procedures, duration of follow-up and/or completion status of the trials).

Non-randomized Trials, Case Series and Registries

A number of non-randomized trials, case series and registries on carotid angioplasty and stenting (CAS) have been published.^[23-36] While these studies contribute to the body of knowledge by providing direction for future research, evidence from these studies is unreliable due to inherent design flaws which introduce significant bias, such as non-random allocation of treatment and lack of appropriate comparison groups. In addition, registry data may be unreliable due to incomplete reporting. Finally, the technology under investigation may change over time, further limiting the ability to carry out reliable comparisons based on the registry data.

Clinical Practice Guidelines

American Heart Association/American Stroke Association Council on Stroke (AHA/ASA)

The 2011 update of the evidence-based guideline on stroke prevention from the AHA/ASA includes the following recommendations:

Asymptomatic Carotid Stenosis ^[37]

- Selection of asymptomatic patients for carotid revascularization should be guided by the following:
 - An assessment of comorbid conditions and life expectancy
 - Other individual factors
 - A thorough discussion of the risks and benefits of the procedure with an understanding of patient preferences (Class I; Level of Evidence C defined as useful/effective based on consensus opinion, case studies, limited populations studied).
- Prophylactic CEA performed with <3% morbidity and mortality can be useful in highly selected patients with an asymptomatic carotid stenosis (minimum 60% by angiography, 70% by validated Doppler ultrasound) (Class IIa; Level of Evidence A defined as reasonable based on data from multiple RCTs with conflicting evidence or meta-analyses; additional focused studies needed).
 - Note: The benefit of surgery may now be lower than anticipated based on RCT results, and the cited 3% threshold for complication rates may be high because of interim advances in medical therapy.
- Prophylactic CAS might be considered in highly selected patients with an asymptomatic carotid stenosis. The advantage of revascularization over current medical therapy alone is not well established (Class IIb; Level of Evidence B defined as may be considered, but efficacy is less well established and evidence is conflicting; additional broad studies needed).

Stenosis is defined as at least one of the following:

 - >60% on angiography
 - >70% on validated Doppler ultrasonography
 - >80% on computed tomographic angiography or MRA if the stenosis on ultrasonography was 50% to 69%).

- The usefulness of CAS as an alternative to CEA in asymptomatic patients at high risk for the surgical procedure is uncertain (Class IIb; Level of Evidence C defined as may be considered, but efficacy is less well established with only diverging expert opinion or case series; additional focused studies needed).

Symptomatic Carotid Stenosis^[38]

- CEA is recommended for the following patients with recent (i.e., in the past 6 months) transient ischemic attack (TIA) or ischemic stroke if the perioperative morbidity and mortality risk is estimated to be less than 6%:
 - With severe ipsilateral carotid stenosis (between 70% and 90% of the lumen diameter), (Class I; Level of Evidence A defined as a strong recommendation based on sufficient evidence from multiple RCTs or meta-analyses)
 - With moderate carotid stenosis (50% to 69% of the vessel lumen), depending on patient-specific factors such as age, gender, and comorbidities. (Class I; Level of Evidence B defined as recommended based on evidence from a single RCT or non-randomized studies)
 - When indicated, CEA is reasonable within 2 weeks if there are no contraindications to early revascularization (Class IIa; Level of Evidence B defined as reasonable procedure; some conflicting evidence from single RCT or non-randomized studies)
- CAS is indicated as an alternative to CEA for symptomatic patients at low risk of complications associated with endovascular intervention with severe stenosis defined as >70% by noninvasive imaging or >50% by angiography (Class I; Level of Evidence B defined as recommended based on evidence from a single RCT or non-randomized studies)
- CAS may be considered for patients with symptomatic severe stenosis (>70%) when performed by operators with established periprocedural morbidity and mortality rates of 4% to 6% in the following circumstances:
 - Stenosis that is difficult to access surgically, or
 - Medical conditions that greatly increase the risk for surgery, or
 - Other specific circumstances exist (e.g., radiation-induced stenosis or restenosis after prior CEA) (Class IIb; Level of Evidence B defined as may be considered; greater conflicting evidence from a single RCT or non-randomized studies)
- When the degree of stenosis is <50%, there is no indication for carotid revascularization by either CEA or CAS (Class III; Level of Evidence A defined as not helpful based on sufficient evidence from multiple RCTs or meta-analyses)

ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS

The 2011 Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease^[39] specifies the circumstances in which CAS may be indicated as an alternative to CEA, as well as the circumstances when it may be reasonable to choose CAS over CEA. However, the recommendations are based on B level of evidence, the lower level of evidence defined in the guideline as derived from a single randomized trial or non-randomized studies. Further, the specific randomized

trials referenced for these determinations are the CREST and SAPHIRE trials. The findings from these trials are considered unreliable due to significant study limitations as explained above.

Summary

There is a substantial body of evidence from randomized controlled trials comparing carotid artery angioplasty and stenting (CAS) with carotid endarterectomy (CEA) for the treatment of carotid artery stenosis. The evidence does not support CAS for the average risk patient since CAS has a higher rate of early adverse events than CEA but has not been shown to provide superior long-term outcomes. However, in a group of highly selected patients with carotid artery stenosis, CEA is not performed as it carries unacceptably high risks. In these patients, CAS may provide an improvement in health outcomes that could not otherwise be achieved. Therefore, except in a select group of patients identified in the policy criteria, CAS is considered investigational.

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CROSS REFERENCES

[Percutaneous Angioplasty and Stenting of Veins](#), Surgery, Policy No. 109

[Endovascular Angioplasty and/or Stenting for Intracranial Arterial Disease \(Atherosclerotic and Aneurysms\)](#), Surgery, No. 141

CODES	NUMBER	DESCRIPTION
CPT	37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection
	37216	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; without distal embolic protection
	0075T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel
	0076T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; each additional vessel (list separately in addition to code for primary procedure)
HCPCS	None	