



FEP Medical Policy Manual

FEP 7.01.68 Extracranial Carotid Artery Stenting

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Original Policy Date: March 2012

Related Policies:

2.01.54 - Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Extracranial Carotid Artery Stenting

Description

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Carotid artery angioplasty with stenting and transcrotid artery revascularization are treatments for carotid stenosis that are intended to prevent a future stroke. They are an alternative to medical therapy and a less-invasive alternative to carotid endarterectomy.

OBJECTIVE

The objective of this evidence review is to determine whether the use of extracranial carotid artery stenting or transcrotid artery revascularization improves the net health outcome in individuals with carotid artery stenosis.

POLICY STATEMENT

Carotid angioplasty with the placement of a Food and Drug Administration (FDA) approved carotid stent with an FDA-approved or cleared embolic protection device may be considered **medically necessary** in individuals with:

- 50% to 99% stenosis (North American Symptomatic Carotid Endarterectomy Trial [NASCET] measurement); AND
- symptoms of focal cerebral ischemia (transient ischemic attack or monocular blindness) in the previous 120 days, symptom duration less than 24 hours, or nondisabling stroke; AND
- anatomic contraindication for carotid endarterectomy (eg, prior radiotherapy or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy).

Carotid angioplasty with associated stenting and embolic protection is considered **not medically necessary** for all other indications, including but not limited to, individuals with carotid stenosis who are suitable candidates for carotid endarterectomy and individuals with carotid artery dissection.

Carotid angioplasty without associated stenting and embolic protection is considered **not medically necessary** for all indications, including but not limited to, individuals with carotid stenosis who are suitable candidates for carotid endarterectomy and individuals with carotid artery dissection.

Transcarotid artery revascularization is considered **investigational** for all indications.

POLICY GUIDELINES

The intent of the second investigational policy statement is that carotid angioplasty with embolic protection but without stenting is investigational. There may be unique situations where the original intent of surgery was to perform carotid angioplasty with stenting and embolic protection, but anatomic or other considerations prohibited placement of the stent.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

A number of carotid artery stents and EPDs have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) or the 510(k) process. Table 1 lists the original PMAs with product code NIM and Table 2 lists 510(k) approvals with product code NTE.

Table 1. FDA Premarket Approvals for Carotid Artery Stents and Embolic Protection Devices

Manufacturer	Device	PMA	PMA Date
Cordis Corp.	Cordis Precise Nitinol Stent System	P030047	Sept 2006
Abbott Vascular	Acculink Carotid Stent System and Rx Acculink Carotid Stent System	P040012	Aug 2004
Abbott Vascular	XACT Carotid Stent System	P040038	Sep 2005

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

Boston Scientific Corp.	Carotid Wallstent Monorail Endoprosthesis	P050019	Oct 2008
Boston Scientific Corp.	Endotex Nexstent Carotid Stent and Delivery System and Endotex Carotid Stent and Monorail Delivery System	P050025	Oct 2006
Medtronic Vascular	Protege GPS and Protege Rx Carotid Stent Systems	P060001	Jan 2007
Medtronic Vascular	Exponent Self-Expanding Carotid Stent System with Over-the-Wire or Rapid-Exchange Delivery System	P070012	Oct 2007
Silk Road Medical, Inc.	Enroute Transcarotid Stent System	P140026	May 2015
	Enroute Transcarotid Stent System	P140026 S016	Apr 2022
W. L Gore & Associates, Inc Gore Carotid Stent	Gore Carotid Stent	P180010	Nov 2018
Contego Medical	Neuroguard IEP 3-in-1 Carotid Stent, Post-Dilation Balloon System with Integrated Embolic Protection	P240009	Oct 2024

FDA: Food and Drug Administration; PMA: Premarket approval.

Table 2. FDA 510(k) Carotid Artery Stents and Embolic Protection Devices

Manufacturer	Stents and Devices	510(k) Number	PMA/510(k) Date
Guidant, now Abbott Vascular	Accunet and RX Accunet Embolic protection system	K042218	Aug 2004
Guidant, now Abbott Vascular	Rx Accunet 2 Embolic Protection System	K042908	Nov 2004
Guidant, now Abbott Vascular	Rx Accunet Embolic Protection System	K052165	Aug 2005
Abbott Vascular	Emboshield embolic protection system	K052454	Sep 2005
Cordis Corp.	AngioGuard XP and RX emboli capture guidewire systems	K062531	Sep 2006
Boston Scientific	FilterWire EZ™ embolic protection system	K063313	Dec 2006
EV3 Inc	Spiderx	K052659	Feb 2007
EV3 Inc	Spidefx	K063204	Nov 2007
GORE	GORE Flow Reversal System	K083300	Feb 2009
GORE	GORE Embolic Filter	K103500	May 2011
Medtronic/Invatec	Mo.Ma Ultra Proximal Cerebral Protection Device	K092177	Oct 2009
Silk Road Medical	ENROUTE™ Transcarotid Stent System and ENROUTE Transcarotid Neuroprotection System	K143072	Feb 2015

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Gardia Medical	Wirion	K143570	Jun 2015
Abbott Vascular	Rx Accunet Embolic Protection System	K153086	Nov 2015
Silk Road Medical, Inc.	Enroute Transcarotid Neuroprotection System	K153485	Mar 2016
Gardia Medical Ltd.	Wirion	K180023	Mar 2018
Contego Medical, LLC	Paladin Carotid Post-Dilation Balloon System With Integrated Embolic Protection (Paladin System)	K181128	Sep 2018
Contego Medical, LLC	Vanguard Iep Peripheral Balloon Angioplasty System With Integrated Embolic Protection	K181529	Dec 2018
Abbott Vascular	Emboshield Nav6 Embolic Protection System, Barewire Filter Delivery Wires	K191173	Jul 2019
Cardiovascular Systems	Wirion	K200198	Mar 2020
Cardiovascular Systems	Wirion Embolic Protection System	K210282	Mar 2021
Cordis Corporation	Angioguard Xp Emboli Capture Guidewire, Angioguard Rx Emboli Capture Guidewire	K220654	Apr 2022
Contego Medical Inc.	Paladin Carotid Post-Dilation Balloon System With Integrated Embolic Protection	K221339	Jun 2022
Silk Road Medical	Enroute Transcarotid Neuroprotection System	K230402	Apr 2023

FDA: Food and Drug Administration; PMA: premarket approval.

FDA product codes: NIM (stents) and NTE (EPDs).

RATIONALE

Summary of Evidence

For individuals who have carotid artery stenosis who receive carotid artery stenting (CAS), the evidence includes randomized controlled trials (RCTs) and systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. A substantial body of RCT evidence has compared outcomes of CAS with carotid endarterectomy (CEA) for symptomatic and asymptomatic patients 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 2 procedures. Data from RCTs 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. Therefore, for patients with carotid stenosis who are suitable candidates for CEA, CAS does not improve health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have carotid artery stenosis who receive transcarotid artery revascularization (TCAR), the evidence includes systematic reviews, nonrandomized trials, and observational studies. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. There is a lack of a body of evidence comprised of RCTs. The evidence on the effectiveness and safety of TCAR procedures is limited to nonrandomized and observational studies. A systematic review found no statistically significant difference between TCAR and CEA for reduction in composite incidence of stroke, death, or myocardial infarction (MI); a reduction in incidence of MI and cranial nerve injury was found with TCAR versus CEA. Another systematic review comparing TCAR and CAS found no statistically significant differences for rates of stroke or death, stroke, or stroke/death/MI with TCAR; however, the risk of death alone was significantly elevated with TCAR. Key nonrandomized trials also highlighted safety outcomes of the TCAR procedure, and observational comparative studies found similar results to what the systematic reviews reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association and American Stroke Association

The American Heart Association and the American Stroke Association (2021) issued guidance for the prevention of stroke in patients with stroke and transient ischemic attack (TIA).⁷⁷ They recommended that, for patients with severe extracranial carotid artery stenosis ipsilateral to a nondisabling stroke or TIA, the choice between carotid endarterectomy (CEA) and CAS in patients who are candidates for intervention should be patient specific. Specific recommendations for CAS or CEA are summarized in Table 3.

Table 3. Guidelines for CAS/CEA in Extracranial Carotid Stenosis

Recommendation	COR ^a	LOE ^b
In patients with a TIA or nondisabling ischemic stroke within the past 6 months and ipsilateral severe (70%-99%) carotid artery stenosis, CEA is recommended to reduce the risk of future stroke, provided that perioperative morbidity and mortality risk is estimated to be <6%.	1	A
In patients with recent TIA or ischemic stroke and ipsilateral moderate (50%-69%) carotid stenosis as documented by catheter-based imaging or noninvasive imaging, CEA is recommended to reduce the risk of future stroke, depending on patient-specific factors such as age, sex, and comorbidities, if the perioperative morbidity and mortality risk is estimated to be <6%.	1	B-R
In patients ≥70 years of age with stroke or TIA in whom carotid revascularization is being considered, it is reasonable to select CEA over CAS to reduce the periprocedural stroke rate.	2a	B-R
In patients in whom revascularization is planned within 1 week of the index stroke, it is reasonable to choose CEA over CAS to reduce the periprocedural stroke rate.	2a	B-R
In patients with symptomatic severe stenosis (≥70%) in whom anatomic or medical conditions are present that increase the risk for surgery (such as radiation-induced stenosis or restenosis after CEA) it is reasonable to choose CAS to reduce the periprocedural complication rate.	2a	C-LD
In symptomatic patients at average or low risk of complications associated with endovascular intervention, when the ICA stenosis is ≥70% by noninvasive imaging or >50% by catheter-based imaging and the anticipated rate of periprocedural stroke or death is <6%, CAS may be considered as an alternative to CEA for stroke prevention, particularly in patients with significant cardiovascular comorbidities predisposing to cardiovascular complications with endarterectomy.	2b	A

CAS: carotid artery angioplasty with stenting; CEA: carotid endarterectomy; COR: class of recommendation; ICA: internal carotid artery; LOE: level of evidence; TIA: transient ischemic attack.

^a Class I: benefit >>> risk; Class IIa: benefit >> risk; Class IIb: benefit ≥ risk.

^b Level A (data derived from multiple randomized controlled trials, meta-analyses of high-quality RCTs, or RCT corroborated by high-quality registry study); level B-R (data derived from ≥1 randomized controlled trial of moderate quality or meta-analysis of such trials); level C-LD (randomized or nonrandomized observational or registry studies with limitations of design or execution, meta-analyses of such studies, or physiological or mechanistic studies in human subjects).

Society for Vascular Surgery

The Society for Vascular Surgery published updated guidelines for management of extracranial cerebrovascular disease in 2022.⁷⁸ They recommended CEA over transfemoral CAS (TF-CAS) in low- and standard-risk patients with more than 50% symptomatic artery stenosis (strong evidence of high quality). The guidelines note that while present data are inadequate to make a recommendation on the role of transcarotid arterial

revascularization (TCAR) in low surgical risk patients with symptomatic carotid stenosis, TCAR is superior or preferable to TF-CAS or CEA for patients with high anatomic and/or physiologic surgical risk.

American Stroke Association

The American Stroke Association (2011), along with 13 other medical societies, issued guidelines on the management of extracranial carotid and vertebral artery diseases, which are summarized in Table 4.^{79,80,81}

Table 4. Guidelines for Managing Patients With Extracranial Carotid and Vertebral Artery Disease

Recommendation	COR ^a	LOE ^b
CAS is indicated as an alternative to CEA for symptomatic patients at average or low-risk of complications associated with endovascular intervention when the diameter of the lumen of the internal carotid artery is reduced by >70%, as documented by noninvasive imaging or >50% as documented by catheter angiography and the anticipated rate of periprocedural stroke or mortality is <6%	I	B
Selection of asymptomatic patients for carotid revascularization should be guided by an assessment of comorbid conditions, life expectancy, and other individual factors and should include a thorough discussion of the risks and benefits of the procedure with an understanding of patient preferences	I	C
It is reasonable to choose CEA over CAS when revascularization is indicated in older patients, particularly when arterial pathoanatomy is unfavorable for endovascular intervention	Ila	B
It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery	Ila	B
When revascularization is indicated for patients with TIA or stroke and there are no contraindications to early revascularization, intervention within 2 week of the index event is reasonable rather than delaying surgery	Ila	B
Prophylactic CAS might be considered in highly selected patients with asymptomatic carotid stenosis (minimum 60% by angiography, 70% by validated Doppler ultrasound), but its effectiveness compared with medical therapy alone in this situation is not well established	Ilb	B
In symptomatic or asymptomatic patients at high-risk of complications for carotid revascularization by either CEA or CAS because of comorbidities, the effectiveness of revascularization versus medical therapy alone is not well established	Ilb	B
Carotid angioplasty and stenting might be considered when ischemic neurologic symptoms have not responded to anti-thrombotic therapy after acute carotid dissection	Ilb	C
Except in extraordinary circumstances, carotid revascularization by either CEA or CAS is not recommended when atherosclerosis narrows the lumen by <50%	III	A
Carotid revascularization is not recommended for patients with chronic total occlusion of the targeted carotid artery	III	C
Carotid revascularization is not recommended for patients with severe disability caused by cerebral infarction that precludes preservation of useful function	III	C

CAS: carotid artery angioplasty with stenting; CEA: carotid endarterectomy; COR: class of recommendation; LOE: level of evidence; TIA; transient ischemic attack.

^a Class I: benefit >>> risk; class Ila benefit >> risk; class Ilb benefit ≥ risk; class III: no benefit.

^b Level A (data derived from multiple randomized controlled trials or meta-analyses; multiple populations evaluated); level B (data derived from a single randomized controlled trial or nonrandomized studies; limited populations evaluated); level C (only consensus opinion of experts, case studies, or standard of care; very limited populations evaluated).

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force recommends against screening for asymptomatic carotid artery stenosis in the general adult population (Grade D; reaffirmed in 2021).⁸²

Medicare National Coverage

The Center for Medicaid & Medicare Services (CMS) updated their national coverage policy in 2023 to state the following⁸³:

"CMS finds that coverage of percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting is reasonable and necessary with the placement of a Food and Drug Administration (FDA) approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries under the following conditions:

- A. Patients with symptomatic carotid artery stenosis $\geq 50\%$; and
- B. Patients with asymptomatic carotid artery stenosis $\geq 70\%$.

For both A and B above:

1. Neurological assessment by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after carotid artery stenting (CAS) must be performed.
2. First-line evaluation of carotid artery stenosis must use duplex ultrasound.
3. Computed Tomography angiography or magnetic resonance angiography, if not contraindicated, must be used to confirm the degree of stenosis and provide additional information about the aortic arch, and extra- and intracranial circulation.
4. Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results, or in lieu of computed tomography angiography or magnetic resonance angiography if these are contraindicated.

Prior to furnishing CAS, the practitioner must engage in a formal shared decision-making interaction with the beneficiary. The shared decision-making interaction must include:

- Discussion of all treatment options including carotid endarterectomy (CEA), CAS (which includes transcarotid artery revascularization (TCAR)), and optimal medical therapy (OMT).
- Explanation of risks and benefits for each option specific to the beneficiary's clinical situation.
- Integration of clinical guidelines (e.g., patient comorbidities and concomitant treatments).
- Discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan.

Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. These standards must at least include and ensure the following:

- Facilities have a clearly delineated program for granting carotid stent privileges and for monitoring patient outcomes for individual physicians and the program as a whole.
- The oversight committee for this program shall be empowered to identify the minimum case volume for a physician to maintain privileges, as well as the (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation. Committees are encouraged to apply published standards from specialty societies and widely-used, published professional society guidelines to determine appropriate physician qualifications.
- Facilities have appropriately trained staff capable of fulfilling roles and responsibilities as delineated under the dedicated carotid stent program.
- Facilities have appropriate supporting personnel and equipment for imaging, emergency management, advanced physiologic monitoring, and other ancillary care.
- Facilities must ensure continuous quality improvement by assessing procedural outcomes and making necessary programmatic adjustments to assure patient safety."

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2012	New policy	
June 2013	Replace policy	Policy updated with literature review; References added, renumbered, and some removed. Carotid dissection added to policy as investigational, clarified policy statement to read that CAS is investigational for those who are suitable candidates for CEA.
June 2014	Replace policy	Policy update with literature review, adding reference 12. Added transcervical approach to background. Policy statements unchanged.
June 2015	Replace policy	Policy updated with literature review adding references 24, 28-29, 35-37, 49-50 and 53. Policy statement is unchanged.
September 2016	Replace policy	Policy updated with literature review; references 30, 34, 38-39, and 54 added. Policy statements unchanged.
September 2018	Replace policy	Policy updated with literature review through March 5, 2018; references 52, 60, 69, 73, and 75 added. Investigational policy statements separated for carotid angioplasty with or without associated stenting. Policy statements otherwise unchanged.
September 2019	Replace policy	Policy updated with review of literature through March 20, 2019; international guidelines removed, 2019 PMA information added; no references added. Policy statements unchanged except "investigational" changed to "not medically necessary" due to FDA PMA status.
September 2020	Replace policy	Policy updated with review of literature through March 13, 2020; references added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through March 23, 2021; references added. Policy statements unchanged.
September 2022	Replace policy	Policy updated with literature review through March 14, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
September 2023	Replace policy	Policy updated with literature review through April 3, 2023; references added. Minor editorial refinements to policy statements; intent unchanged.
September 2024	Replace policy	Policy updated with literature review through April 9, 2024; references added. New PICO added. Refinements to policy statements made (due to additional PICO added).
March 2026	Replace policy	Policy updated with literature review through November 4; references added. Minor revision to medically necessary policy statement to include "with the placement of a Food and Drug Administration (FDA) approved carotid stent with an FDA-approved or cleared embolic protection device".

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