FEP Medical Policy Manual

FEP 7.01.68 Extracranial Carotid Artery Stenting

Annual Effective Policy Date: October 1, 2024

Original Policy Date: March 2012

Related Policies:

2.01.54 - Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)
7.01.148 - Endovascular Therapies for Extracranial Vertebral Artery Disease

Extracranial Carotid Artery Stenting

Description

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Carotid artery angioplasty with stenting and transcarotid 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 transcarotid artery revascularization improves the net health outcome in individuals with carotid artery stenosis.

POLICY STATEMENT

Carotid angioplasty with associated stenting and embolic protection 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
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	jProtege 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

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 AccunetEmbolic 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
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.

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 CEA who are symptomatic with greater than 50% stenosis, or asymptomatic with greater than 80% stenosis with the 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 devices designed for more rapid stent and filter expansion. The FDA has mandated postmarketing studies for EPDs, including longer follow-up for patients already reported to the 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 (eg, straight or tapered) and sizes (diameters and lengths) to match the vessel lumen that will receive the stent.

In 2015, the ENROUTE™ Transcarotid Neuroprotection System was cleared for marketing by the FDA through the 510(k) process. ENROUTE is a flow reversal device designed to be placed via direct carotid access. In April 2022, the ENROUTE Transcarotid Stent System received expanded approval for use in the treatment of individuals at standard risk of complications from CEA. For those with neurological symptoms, criteria include 70% or more stenosis by ultrasound or 50% or more stenosis by angiogram. For asymptomatic individuals, criteria include 70% or more stenosis by ultrasound or 60% or more stenosis by angiogram. The carotid bifurcation location must be a minimum of 5 cm above the clavicle to allow for the placement of the ENROUTE Transcarotid Neuroprotection System.

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 was found between TCAR and CEA for reduction in composite incidence of stroke, death, or myocardial infarction; a reduction in incidence of myocardial infarction and cranial nerve injury was found with TCAR versus CEA. Another systematic review comparing TCAR and CAS found no statistically significant differences were observed 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).[78,] 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 6.

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.[79,] 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.[80,81,82,]

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% (360)	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	IIa	B
It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery	IIa	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	IIa	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	IIb	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	IIb	B
Carotid angioplasty and stenting might be considered when ischemic neurologic symptoms have not responded to antithrombotic therapy after acute carotid dissection	IIb	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 IIa benefit >> risk; class IIb 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).[83,]

Medicare National Coverage

The Center for Medicaid & Medicare Services (CMS; 2001) issued national coverage policy that restricted coverage for carotid angioplasty and stenting to patients participating in a clinical trial with category B investigational device exemption (IDE) designation from the U.S. Food and Drug Administration (FDA). Percutaneous transluminal angioplasty of the vertebral and cerebral arteries remained noncovered.

When the FDA approved the first (Guidant) devices, Medicare coverage under the IDE was no longer available for that manufacturer"s devices and was not applicable to the FDA-required postapproval studies. Thus, in 2004, Medicare broadened its national coverage policy and "determined that the evidence is adequate to conclude that percutaneous transluminal angioplasty with carotid stent placement is reasonable and necessary when performed consistent with the FDA approval of the carotid stent device and in an FDA required post-approval study." For unapproved stents and embolic protection devices, the prior policy remained in effect and restricted coverage to patients participating in an FDA-approved category B IDE trial of stent placement in the cervical carotid artery.

While the Medicare decision differed from the conclusions of this evidence review, Medicare made a public policy decision "that making available new, effective therapies aimed at addressing treatment and prevention of cerebrovascular disease was important to Medicare beneficiaries." Medicare also noted that it recognized the value in supporting postapproval studies as "the collected data may provide an opportunity for practitioners to determine which patients are most appropriate for carotid artery stenting and to reinforce IDE trial data on health outcomes and adverse events."

CMS provides a continually updated listing of facilities eligible for Medicare reimbursement that meet CMS's minimum facility standards for performing CAS for high-risk patients.

In 2005, CMS determined that CAS with embolic protection devices was reasonable and necessary for patients at high risk for CEA who also have symptomatic carotid artery stenosis 70% or more.[84,]The CMS limited coverage for these patients to procedures performed using the FDA-approved devices. The CMS also limited coverage for patients at high risk for CEA with symptomatic carotid artery stenosis between 50% and 70%, and for patients at high risk for CEA with asymptomatic stenosis 80% or more, to the FDA-approved category B, IDE clinical trials for unapproved devices, or to the FDA-required postapproval studies for approved devices. The CMS defined patients at high-risk for CEA as having significant comorbidities and/or anatomic risk factors (ie, recurrent stenosis and/or previous radical neck dissection) who would be poor candidates for CEA in the opinion of a surgeon.

In 2007, a decision memo reaffirmed CMS"s 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 a sixth reconsideration, and in 2009, in a seventh reconsideration, CMS reaffirmed its prior coverage decisions.

In 2012, CMS convened a Medicare Evidence Development & Coverage Advisory Committee panel to consider management of carotid atherosclerosis. Medicare Evidence Development & Coverage Advisory Committee panel members voted on specific questions using a scale of 1 (low confidence) to 5 (high confidence). For symptomatic patients not considered at high risk, the mean scores to the question of whether CAS is the favored treatment strategy in this population was 1.85, and for CEA 3.6. For asymptomatic patients not considered high-risk, the evidence was judged to have not reached a level of certainty to determine a favored treatment.

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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).