

Extracranial Carotid Angioplasty/Stenting

Policy # 00155

Original Effective Date: 05/23/2005

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms) is addressed separately in medical policy 00198.

Note: Endovascular Therapies for Extracranial Vertebral Artery Disease is addressed separately in medical policy 00466.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider carotid artery angioplasty for **symptomatic** carotid artery stenosis to be **eligible for coverage**** when **ALL** of the following criteria are met:

- Request is for carotid artery angioplasty with the placement of a Food and Drug Administration (FDA) approved carotid stent with an FDA-approved or cleared embolic protection device; **AND**
- Documented is severe carotid artery stenosis with 50-99% stenosis; **AND**
- Symptoms of focal cerebral ischemia ipsilateral to the carotid stenosis:
 - Transient ischemic attack or monocular blindness in the previous 180 days with symptom duration less than 24 hrs; **OR**
 - Nondisabling stroke in the previous 180 days (modified Rankin scale score less than 3 at least 30 days after onset); **AND**
- Individual is considered high risk for carotid endarterectomy (CEA) due to a documented history of **ANY** of the following significant comorbidities or anatomic risk factors:
 - Prior radiotherapy or neck surgery; **OR**
 - Lesion is surgically inaccessible; **OR**
 - High bifurcation requiring mandibular dislocation; **OR**
 - Spinal immobility; **OR**
 - Tracheostomy; **OR**

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- Age greater than 80 years; **OR**
- Congestive heart failure (New York Heart Association [NYHA]) class III/IV and/or left ventricular ejection fraction less than 30%; **OR**
- Open heart surgery needed within 6 weeks; **OR**
- Recent myocardial infarction within the preceding 4 weeks; **OR**
- Unstable angina (Canadian Cardiovascular Society [CCS]) class III/IV; **OR**
- Severe chronic obstructive pulmonary disease; **OR**
- Contralateral carotid occlusion requiring treatment; **OR**
- Contralateral laryngeal nerve palsy; **OR**
- Significant tandem lesion that may require endovascular therapy; **OR**
- Restenosis after CEA; **OR**
- Stenosis secondary to fibromuscular dysplasia; **OR**
- Stenosis secondary to Takayasu arteritis; **OR**
- Carotid pseudoaneurysm.

Based on review of available data, the Company may consider carotid artery angioplasty for **asymptomatic** carotid artery stenosis to be **eligible for coverage**** when **ALL** of the following criteria are met:

- Request is for carotid angioplasty with the placement of a Food and Drug Administration (FDA) approved carotid stent with an FDA-approved or cleared embolic protection device; **AND**
- Documented is severe carotid artery stenosis with 70-99% stenosis; **AND**
- Carotid stenosis is asymptomatic with no medical history of stroke, transient ischemic attack (TIA), or amaurosis fugax ipsilateral to the carotid stenosis within 180 days; **AND**
- No prior medical history of disabling stroke (modified Rankin scale score 3 or higher at least 30 days after onset); **AND**
- Documented treatment meets **ONE** of the following:
 - Individuals are treated with intensive medical therapy including **ALL** of the following: aggressive management of high blood pressure (target systolic blood pressure of less than 130 mmHg), low-density lipoprotein cholesterol (target LDL cholesterol level of less than 70 mg per deciliter), diabetes, and smoking cessation (if applicable); **OR**
 - Individuals have documented contraindications to optimal medical therapy; **AND**
- Shared decision-making is documented, and individuals are informed of the risk of revascularization including risk of procedural harm (stroke and death risk).

(Note: Only small proportion of patients with asymptomatic carotid stenosis will develop symptoms despite the use of optimal medical therapy).

When Services Are Considered Not Medically Necessary

The use of carotid artery angioplasty with associated stenting and embolic protection for carotid stenosis in an individual when criteria are not met is considered to be **not medically necessary**** including but not limited to **ANY** of the following:

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- Individuals with symptomatic carotid stenosis who are suitable candidates for carotid endarterectomy (CEA); **OR**
- Complete occlusion (100% stenosis) of the relevant carotid artery; **OR**
- Carotid angioplasty without associated stenting and embolic protection, except for unique situations where the original intent was to perform stenting but anatomic or other considerations prohibited placement of the stent (coverage criteria must still be met); **OR**
- Symptomatic stenosis associated with an intracranial vascular malformation; **OR**
- Individual with a significant contraindication to angiography; **OR**
- Carotid stenosis with angiographically visible intraluminal thrombus; **OR**
- Carotid stenosis that cannot be safely reached or crossed by endovascular approach.

Policy Guidelines

Modified Rankin Scale (mRS) measures functional independence on a seven-grade scale. The mRS has been used as a measure of stroke-related handicap in many interventional trials. It has a particular focus on ambulation and is better characterized as a global measure of the functional impact of stroke.

Score	Description
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent, and requiring constant nursing care and attention
6	Dead

Background/Overview

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 to 40 minutes. Interventionalists almost uniformly use an embolic protection device (EPD) to reduce the risk of stroke caused by thromboembolic material dislodged during CAS. Embolic protection devices can

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be deployed proximally (with flow reversal) or distally (using a filter). Carotid angioplasty is rarely performed without stent placement.

The proposed advantages of CAS over CEA include:

- General anesthesia is not used (although CEA can be performed under local or 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.

Transcarotid artery revascularization (TCAR) is another option among individuals with carotid stenosis who were defined as high risk (includes both clinical and anatomic characteristics). The procedure involves a stenting technique that incorporates direct cervical carotid artery exposure and flow-reversal embolic protection.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of CAS 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 PMA's 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

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	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 ^{TM†} 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 ^{TM†} 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

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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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Description

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.

Summary of Evidence

For individuals who 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 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

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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. 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; 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.

Brott et al (2025) published results of the Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial (CREST-2; NCT02089217) to elucidate whether CEA or CAS plus contemporary intensive medical management is superior in preventing stroke beyond medical management alone. CREST-2 consists of 2 parallel clinical trials enrolling patients with high-grade ($\geq 70\%$) asymptomatic carotid stenosis. Notably, CAS and CEA were not directly compared. One trial compared intensive medical management alone to medical management plus CAS. The other trial compared intensive medical management alone to medical management plus CEA. The primary outcome consists of the composite of stroke and death within 44 days of randomization and incidence of ipsilateral stroke through 4 years. A total of 1245 patients were randomized in the CAS trial and 1240 in the CEA trial. Demographic and risk factor profiles were similar among the groups in both studies. The primary outcome was significantly reduced with CAS plus medical management compared to medical management alone (2.8% vs 6.0%; absolute risk difference 3.2%; 95% CI, 0.6 to 5.9; $p=.02$; relative risk, 2.13; 95% CI, 1.15 to 4.39). However, there was no significant difference between CEA plus medical management compared to medical management alone (3.7% vs 5.3%; absolute risk difference, 1.6%; 95% CI, -1.1 to 4.3; $p=.24$; relative risk, 1.43; 95% CI, 0.7 to 2.8). In the first 44 days of the CAS trial, no strokes or deaths occurred in the medical therapy group, but 7 strokes and 1 death occurred in the CAS group. In the first 44 days of the CEA trial, 3 strokes occurred in the medical therapy group, but 9 strokes occurred in the CEA group. Conclusions regarding the comparative efficacy of CEA and CAS from the CREST-2 trials are difficult given that the treatments were not directly compared. Editorial noted that it is reasonable to advise patients with asymptomatic carotid stenosis to start intensive medical therapy immediately and to delay revascularization until such time as symptoms develop, which will occur in only a small proportion of patients. Exceptions would then be made for patients who prefer to take the risk of

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revascularization or who cannot take medical therapy — in which case, stenting would be the choice for suitable patients at a center with skilled and experienced interventionists.

Additional Information

Based on limited data, clinical input, a chain of evidence, and unmet medical need, CAS may be considered a reasonable treatment option in recently symptomatic patients when CEA cannot be performed due to anatomic reasons. For this population, CAS may be considered medically necessary. It is considered investigational for all other indications.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2009 Input

In response to requests, input was received from 4 physician specialty societies (6 reviewers) and 4 academic medical centers while this policy was under review in 2009. (Also, an unsolicited response from a specialty society was received.) Input strongly supported the use of carotid artery stenting (CAS) in recently symptomatic patients where surgical carotid endarterectomy cannot be performed due to anatomic reasons, although acknowledging the limited evidence about this subgroup. The lack of alternative treatments for recently symptomatic patients and the established increased risk of stroke were factors supporting this opinion.

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). 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.

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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 ($\geq 70\%$) 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 $\geq 70\%$ 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 $\gg \gg$ risk; Class IIa: benefit $\gg$ risk; Class IIb: benefit $\geq$ 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).

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Society for Vascular Surgery

The Society for Vascular Surgery published updated guidelines for management of extracranial cerebrovascular disease in 2022. They recommended CEA over 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.

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

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Recommendation	COR ^a	LOE ^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).

Medicare National Coverage

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

"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 ≥50%; and
- B. Patients with asymptomatic carotid artery stenosis ≥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.

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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."

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 5.

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Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT07054060	Endarterectomy Versus Stenting in Patients With Symptomatic Severe Carotid Stenosis - 2	600	Mar 2028
NCT07204678	Post Market Clinical Follow-up Study of the Precise Pro Rx Nitinol Stent System in the Treatment of Carotid Artery Disease (REAL-PRECISE)	187	Jan 2026
ISRCTN97744893	European Carotid Surgery Trial 2 (ECST-2): a randomized controlled trial	429	Mar 2025
NCT05623904	Carotid Revascularization Versus Best Medical Treatment for Asymptomatic Carotid Stenosis: a Multicenter, Open, Randomized Controlled Trial in Chinese Population	1056	Dec 2025
NCT05465122	Long-Term Observational Extension of Participants in CREST-2 (C2LOE)	2480	Feb 2026
NCT02850588	TransCarotid Revascularization Surveillance Project of the Society for Vascular Surgery Vascular Quality Initiative (VQI-TCAR)	60000	Dec 2027

ISRCTN: International Standard Randomized Controlled Trial Number; NCT: national clinical trial.

References

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3. MRC European Carotid Surgery Trial: interim results for symptomatic patients with severe (70-99%) or with mild (0-29%) carotid stenosis. European Carotid Surgery Trialists' Collaborative Group. *Lancet*. May 25 1991; 337(8752): 1235-43. PMID 1674060
4. Mayberg MR, Wilson SE, Yatsu F, et al. Carotid endarterectomy and prevention of cerebral ischemia in symptomatic carotid stenosis. Veterans Affairs Cooperative Studies Program 309 Trialist Group. *JAMA*. Dec 18 1991; 266(23): 3289-94. PMID 1960828
5. Endarterectomy for asymptomatic carotid artery stenosis. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. *JAMA*. May 10 1995; 273(18): 1421-8. PMID 7723155
6. Randomised trial of endarterectomy for recently symptomatic carotid stenosis: final results of the MRC European Carotid Surgery Trial (ECST). *Lancet*. May 09 1998; 351(9113): 1379-87. PMID 9593407

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04/05/2005	Medical Director review
04/19/2005	Medical Policy Committee review
05/23/2005	Managed Care Advisory Council approval
08/03/2005	Medical Director review
08/16/2005	Medical Policy Committee review. Coverage eligibility revised to consider “coverage for carotid artery angioplasty and stent placement (CAS) in patients who can be safely treated or crossed by this approach and have no angiographically visible intramural thrombus.”
08/24/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. Coverage eligibility unchanged. CMS information added to governmental regulatory approval, rationale updated.
04/02/2008	Medical Director review

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04/16/2008	Medical Policy Committee approval. No change to coverage eligibility.
04/02/2009	Medical Director review
04/15/2009	Medical Policy Committee approval. No change to coverage eligibility.
04/08/2010	Medical Policy Committee approval
04/21/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2011	Medical Policy Committee review
04/13/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/23/2013	Coding updated
04/04/2013	Medical Policy Committee review
04/24/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2014	Medical Policy Committee review
04/23/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/07/2015	Medical Policy Committee review
05/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
03/24/2016	Coding update: codes 37238 and 37239 will be removed from this policy
05/05/2016	Medical Policy Committee review
05/18/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. For symptomatic, severe stenosis (>50% stenosis) or asymptomatic preocclusive disease (>80%), “in patients with anatomic contraindication for carotid endarterectomy (e.g., prior radiotherapy or neck surgery, lesions surgically inaccessible,” and “spinal immobility, or tracheostomy” was added to the first coverage criteria bullet. For symptomatic, severe stenosis (>50% stenosis) or asymptomatic preocclusive disease (>80%) in a patient with significant medical disease that would make the patient high risk for surgery, removed “lesions distal or proximal to the usual location” from the criteria. For symptomatic, severe stenosis (>50%) or asymptomatic preocclusive disease (>80%), removed the second coverage criteria bullet, “Radiation-induced stenosis (following radiation to the neck or radical neck dissection)”. For the use of carotid artery angioplasty and stent placement, “Patients with carotid stenosis who are suitable candidates for carotid endarterectomy” was added to the investigational indications.

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07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2019	Coding update
05/13/2019	Coding update
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Added “with associated stenting and embolic protection” regarding carotid artery angioplasty for all statements applicable in the coverage section. Added an upper limit of <100% to the Patient Selection Criteria for both symptomatic severe stenosis and asymptomatic preocclusive disease. Added second and third bullets to the investigational indications as follows: • Complete occlusion (100% stenosis) of the relevant carotid artery; OR • Carotid angioplasty <u>without</u> associated stenting and embolic protection, except for unique situations where the original intent was to perform stenting but anatomic or other considerations prohibited placement of the stent (coverage criteria must still be met); OR
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/07/2022	Medical Policy Committee review
07/13/2022	Medical Policy Implementation Committee approval. Transcarotid artery revascularization (TCAR) added to the body of this policy.
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/03/2025	Medical Policy Committee review
07/09/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2026	Medical Policy Committee review
07/08/2026	Medical Policy Implementation Committee review
07/16/2026	Medical Quality Management Committee approval. First coverage statement for carotid artery angioplasty revised with criteria for symptomatic carotid artery stenosis. Coverage with criteria added for carotid artery angioplasty for asymptomatic carotid artery stenosis. Carotid artery angioplasty with associated stenting and embolic protection for carotid stenosis with criteria changed from investigational to not medically necessary. Asymptomatic stenosis of any degree, except when coverage criteria are met was removed from the not medically

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necessary criteria. Symptomatic stenosis removed from the not medically necessary criteria bullet for an individual with a significant contraindication to angiography. Policy Guidelines section added with the Modified Rankin Scale (mRS).

Next Scheduled Review Date: 07/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	37215, 37216, 37217
HCPCS	Add codes effective 10/01/2026: C1876, C1884
ICD-10 Diagnosis	All related Diagnoses

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services

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at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.