



## Extracranial Carotid Angioplasty/Stenting

**Policy #** 00155

**Original Effective Date:** 05/23/2005

**Current Effective Date:** 08/14/2023

*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.*

*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 with associated stenting and embolic protection in individuals who can be safely treated or crossed by this approach and have no angiographically visible intramural thrombus to be **eligible for coverage.\*\***

### Patient Selection Criteria

The use of carotid artery angioplasty with associated stenting and embolic protection in individuals who have no angiographically visible intramural thrombus will be considered for coverage when the following criteria are met:

- Symptomatic, severe stenosis (>50% and <100% stenosis) or asymptomatic preocclusive disease (>80% and <100%) in individuals with anatomic contraindication for carotid endarterectomy (CEA) (e.g., prior radiotherapy or neck surgery, lesions surgically inaccessible, high bifurcation requiring mandibular dislocation, spinal immobility, or tracheostomy); **OR**

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- Symptomatic, severe stenosis (>50% and <100% stenosis) or asymptomatic preocclusive disease (>80% and <100%) in an individual with significant medical disease that would make the individual high risk for surgery, including **ONE OR MORE** of the following conditions:
  - Age >80 years; **OR**
  - Congestive heart failure (New York Heart Association [NYHA] class III/IV) and/or left ventricular ejection fraction <30%; **OR**
  - Open heart surgery needed within 6 weeks; **OR**
  - Recent myocardial infarction (>24 hours and <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.
- Symptomatic, severe stenosis (>50% and <100%) or asymptomatic preocclusive disease (>80% and <100%) and **ONE** of the following conditions:
  - Significant tandem lesion that may require endovascular therapy; **OR**
  - Restenosis after CEA; **OR**
  - Stenosis secondary to arterial dissection; **OR**
  - Stenosis secondary to fibromuscular dysplasia; **OR**
  - Stenosis secondary to Takayasu arteritis; **OR**
  - Pseudoaneurysm.

## When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers use of carotid artery angioplasty with associated stenting and embolic protection for all other indications, including but not limited to **ANY** the following, to be **investigational\***:

- Individuals with carotid stenosis who are suitable candidates for 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**

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- Asymptomatic stenosis of any degree, except when patient selection criteria are met; **OR**
- Symptomatic stenosis associated with an intracranial vascular malformation; **OR**
- Symptomatic stenosis in an individual with a subacute cerebral infarction; **OR**
- Symptomatic stenosis in an 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; **OR**
- Carotid stenosis in an individual when patient selection criteria are not met.

### **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 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.

Extracranial carotid artery angioplasty with stenting (CAS) or without stenting has been investigated as a minimally invasive alternative to the current standard of care, that being carotid endarterectomy (CEA). CAS can be performed percutaneously (that is, passage of a balloon catheter into the lesion via a femoral or brachial artery, followed by dilatation of the blocked segment and stent placement) or through a small incision in the neck (that is, transcarotid artery revascularization [TCAR]). TCAR

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employs a flow reversal system to provide continuous embolic protection throughout the CAS procedure for extracranial carotid artery stenosis.

## **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<br>Acculink Carotid Stent System   | P040012 | Aug 2004  |
| Abbott Vascular         | XACT Carotid Stent System   | P040038 | Sep 2005  |
| Boston Scientific Corp. | Carotid Wallstent Monorail<br>Endoprosthesis  | P050019 | Oct 2008  |
| Boston Scientific Corp. | Endotex Nexstent Carotid Stent and<br>Delivery System and Endotex Carotid<br>Stent and Monorail Delivery System | P050025 | Oct 2006  |
| Medtronic Vascular      | jProtege GPS and Protege Rx Carotid<br>Stent Systems  | P060001 | Jan 2007  |
| Medtronic Vascular      | Exponent Self-Expanding Carotid<br>Stent System with Over-the-Wire or<br>Rapid-Exchange Delivery System         | P070012 | Oct 2007  |
| Silk Road Medical, Inc. | Enroute Transcarotid Stent System   | P140026 | May 2015  |
|                         | Enroute Transcarotid Stent System   | P140026 | Apr 2022  |

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| W. L Gore & Associates, Inc<br>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 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 <sup>®†</sup> embolic protection system                 | K052454       | Sep 2005        |
| Cordis Corp.                 | AngioGuard <sup>®</sup> XP and RX emboli capture guidewire systems | K062531       | Sep 2006        |
| Boston Scientific            | FilterWire EZ <sup>™†</sup> embolic protection system              | K063313       | Dec 2006        |
| EV3 Inc                      | Spiderx  | K052659       | Feb 2007        |
| EV3 Inc                      | Spidefx  | K063204       | Nov 2007        |
| GORE                         | GORE <sup>®†</sup> Flow Reversal System                            | K083300       | Feb 2009        |
| GORE                         | GORE <sup>®†</sup> Embolic Filter                                  | K103500       | May 2011        |
| Medtronic/Invatec            | Mo.Ma <sup>®†</sup> Ultra Proximal Cerebral Protection Device      | K092177       | Oct 2009        |

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|                         |  |         |          |
|-------------------------|--|---------|----------|
| Silk Road Medical       | ENROUTE <sup>TM†</sup> 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 <sup>®†</sup> Transcarotid Neuroprotection System  | K230402 | Apr 2023 |

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

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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 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<sup>TM†</sup> 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<sup>TM‡</sup> 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).

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### **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 federal regulations, other plan medical policies, and accredited national guidelines.

### **Description**

Carotid artery angioplasty with stenting is a treatment for carotid stenosis that is intended to prevent a future stroke. It is an alternative to medical therapy and a less-invasive alternative to carotid endarterectomy (CEA).

### **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 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 sufficient to determine that the technology is unlikely to improve the net health outcome.

### **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, including carotid artery dissection.

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Transcarotid artery revascularization (TCAR) was recently introduced as a novel CAS option that circumvents several of the high embolic-risk maneuvers found in transfemoral CAS and employs a flow reversal system that provides continuous embolic protection throughout the procedure. According to this review article, early results from this technique have shown low stroke/death rates comparable to CEA while maintaining the minimally invasive benefits of CAS. It is reported that TCAR has a strong potential to become the preferred method of performing CAS in the near future and may challenge CEA as the preferred carotid artery revascularization method.

As of Feb. 23, 2021 the FDA issued a Class II device recall for affected lots of the ENROUTE Transcarotid Stent System which is under investigation for the following:

Action: On 01/13/2021, the firm sent an "URGENT: MEDICAL DEVICE RECALL" Notification via email to customers informing them that product complaints have been received where the tip/nose cone detached from the stent delivery system during use and it is possible the resulting patient harm can range from minor intervention required to retrieve the detached tip/nose cone to embolization or stroke if the device failure goes undetected.

According to the web site for the Society for Vascular Surgery (SVS), the following information is noted:

Transcarotid Artery Revascularization (TCAR) is a clinically proven, minimally invasive procedure to treat carotid artery disease and help prevent future strokes. TCAR is unique in that blood flow is temporarily reversed during the procedure so that any bits of plaque that may break off are diverted away from the brain.

In an updated SVS guideline for management of extracranial cerebrovascular disease, the following is excerpted:

Carotid endarterectomy (CEA) remains favored over transfemoral carotid artery stenting (TF-CAS) for most anatomically suited low/standard risk patients with indications for carotid revascularization. Transcarotid artery revascularization (TCAR) is a newer hybrid CAS procedure that places the stent through a small neck incision. In observational studies, TCAR had a lower risk of perioperative stroke compared with TF-CAS, and lower rates of myocardial infarction or cranial nerve injury compared with CEA. For these reasons, the SVS now considers

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TCAR preferable to TF-CAS or CEA in high surgical risk patients such as those with high-risk carotid or other anatomy, or unacceptably high medical risk.

Available data from pre-clinical studies, prospective single-arm studies, and comparative analyses of registry data have demonstrated similar major outcomes from TFCAS and TCAR procedures for carotid stenosis, with lower adverse event rates from TCAR. Investigators have called for a well-controlled randomized trial with careful oversight to be prioritized to obtain level 1 evidence and further validate these preliminary findings.

### **Supplemental Information**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

#### **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

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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.

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

| Recommendation  | COR <sup>a</sup> | LOE <sup>b</sup> |
|---|------------------|------------------|
| 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 $\geq 70$ 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  | 2a               | C-LD             |

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| surgery (such as radiation-induced stenosis or restenosis after CEA) it is reasonable to choose CAS to reduce the periprocedural complication rate.   |    |   |
| 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.

<sup>a</sup> Class I: benefit  $\gg \gg$  risk; Class IIa: benefit  $\gg$  risk; Class IIb: benefit  $\geq$  risk.

<sup>b</sup> 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  $\geq 1$  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. 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.

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### 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 <sup>a</sup> | LOE <sup>b</sup> |
|---|------------------|------------------|
| 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 <sup>a</sup> | LOE <sup>b</sup> |
|--|------------------|------------------|
| 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.

<sup>a</sup> Class I: benefit >>> risk; class IIa benefit >> risk; class IIb benefit ≥ risk; class III: no benefit.

<sup>b</sup> 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; 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

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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 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 carotid endarterectomy (CEA) who also have symptomatic carotid artery stenosis 70% or more. 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.

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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.

### Ongoing and Unpublished Clinical Trials

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

**Table 5. Summary of Key Trials**

| NCT No.        | Trial Name   | Planned Enrollment | Completion Date |
|----------------|--|--------------------|-----------------|
| NCT05416853    | Radial Versus Femoral Access For Carotid Artery Stenting In Patients With Carotid-Artery Stenosis: a Prospective, Randomized, Multicenter, Noninferiority Trial (RACE-CAS) | 2688               | Aug 2024        |
| NCT02089217    | Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial (CREST-2)   | 2480               | Feb 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   | 1056               | Dec 2025        |

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|             |  |       |          |
|-------------|--|-------|----------|
|             | Multicenter, Open, Randomized Controlled Trial in Chinese Population   |       |          |
| NCT05465122 | Long-Term Observational Extension of Participants in CREST-2 (C2LOE)   | 1500  | May 2026 |
| NCT02850588 | TransCarotid Revascularization Surveillance Project of the Society for Vascular Surgery Vascular Quality Initiative (VQI-TCAR) | 60000 | Dec 2026 |

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

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## **Policy History**

Original Effective Date: 05/23/2005

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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<br>“coverage for carotid artery angioplasty and stent placement (CAS) in patients who<br>can be safely treated or crossed by this approach and have no angiographically<br>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<br>rationale/source. Coverage eligibility unchanged.  |
| 04/04/2007 | Medical Director review  |
| 04/18/2007 | Medical Policy Committee approval. Coverage eligibility unchanged. CMS<br>information added to governmental regulatory approval, rationale updated.  |
| 04/02/2008 | Medical Director review  |
| 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  |

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## Extracranial Carotid Angioplasty/Stenting

Policy # 00155

Original Effective Date: 05/23/2005

Current Effective Date: 08/14/2023

|            |   |
|------------|---|
| 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 |

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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.

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 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

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

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07/12/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2024

### **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2022 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.*

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

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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            | No Codes              |
| ICD-10 Diagnosis | All related Diagnoses |

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**\*Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

**\*\*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 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.

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