Extracranial Carotid Angioplasty/Stenting

Policy # 00155
Original Effective Date: 05/23/2005
Current Effective Date: 07/11/2018

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 and stent placement in patients 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 and stent placement in patients who have no angiographically visible intramural thrombus will be considered for coverage when the following criteria are met:

- Symptomatic, severe stenosis (> 50% stenosis) or asymptomatic preocclusive disease (> 80%) in patients 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
- 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, 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%) or asymptomatic preocclusive disease (> 80%) and one of the following conditions:
  - Significant tandem lesion that may require endovascular therapy; or

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- 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 and stent placement for all other indications, including but not limited to the following, to be investigational*:

- Patients with carotid stenosis who are suitable candidates for CEA; or
- 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 a patient with a subacute cerebral infarction; or
- Symptomatic stenosis in a patient 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 a patient 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 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. EPDs 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 sequela (although almost all following CEA resolve over time)
- Simultaneous procedures may be performed on the coronary and carotid arteries.

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. FDA through the premarket approval or the 510(k) process. Examples are provided in Table 1.
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Table 1. FDA-Approved Carotid Artery Stents and Embolic Protection Devices

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Stents and Devices</th>
<th>PMA/510(k) Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidant, now Abbott Vascular</td>
<td>Acculink™‡ and RX Acculink™‡ carotid stents</td>
<td>Aug 2004</td>
</tr>
<tr>
<td>Guidant, now Abbott Vascular</td>
<td>Accunet™‡ and RX Accunet™‡ cerebral protection filters</td>
<td>Aug 2004</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>Xact®‡ RX carotid stent system</td>
<td>Sep 2005</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>Emboshield®‡ embolic protection system</td>
<td>Sep 2005</td>
</tr>
<tr>
<td>Cordis Corp.</td>
<td>Precise®‡ nitinol carotid stent system</td>
<td>Sep 2006</td>
</tr>
<tr>
<td>Cordis Corp.</td>
<td>AngioGuard™† XP and RX emboli capture guidewire systems</td>
<td>Sep 2006</td>
</tr>
<tr>
<td>EndoTex Interventional Systems</td>
<td>NexStent®† carotid stent over-the-wire and monorail delivery systems</td>
<td>Oct 2006</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>FilterWire EZ™† embolic protection system</td>
<td>Oct 2006</td>
</tr>
<tr>
<td>ev3, Arterial Evolution Technology</td>
<td>Protégé®† Rx and SpideRx®†</td>
<td>Jan 2007</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>Carotid Wallstent®†</td>
<td>Oct 2008</td>
</tr>
<tr>
<td>GORE</td>
<td>GORE®‡ Flow Reversal System</td>
<td>Feb 2009</td>
</tr>
<tr>
<td>GORE</td>
<td>GORE®‡ Embolic Filter</td>
<td>May 2011</td>
</tr>
<tr>
<td>Medtronic/Invatec</td>
<td>Mo.Ma®‡ Ultra Proximal Cerebral Protection Device</td>
<td>Oct 2009</td>
</tr>
<tr>
<td>Silk Road Medical</td>
<td>ENROUTE™‡ Transcarotid Stent System and ENROUTE™‡ Transcarotid Neuroprotection System</td>
<td>May 2015</td>
</tr>
</tbody>
</table>

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 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.

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. FDA has mandated postmarketing studies for EPDs, including longer follow-up for patients already reported to 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 (e.g., 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 FDA through the 510(k) process. ENROUTE is a flow reversal device designed to be placed via direct carotid access.

FDA product codes: NIM (stents) and NTE (EPDs).
Centers for Medicare and Medicaid Services (CMS)

In 2001, the CMS 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 FDA. Percutaneous transluminal angioplasty of the vertebral and cerebral arteries remained noncovered.

When 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 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 (PTA) with carotid stent placement is reasonable and necessary when performed consistent with FDA approval of the carotid stent device and in an FDA required post-approval study.” For unapproved stents and EPDs, 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 CAS 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 EPD was reasonable and necessary for patients at high-risk for CEA who also have symptomatic carotid artery stenosis 70% or more. CMS limited coverage for these patients to procedures performed using FDA-approved devices. 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 FDA-approved category B IDE clinical trials for unapproved devices, or to FDA-required postapproval studies for approved devices. CMS defined patients at high-risk for CEA as having significant comorbidities and/or anatomic risk factors (i.e., 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 EPD and is, therefore, not covered if deployment of the distal EPD 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).
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.

Rationale/Source
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References
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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
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.

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
04/12/2012 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
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.
01/23/2017 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.

07/05/2018 Medical Policy Committee review

Next Scheduled Review Date: 07/2019
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
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<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
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<tbody>
<tr>
<td>CPT</td>
<td>0075T, 0076T, 36221, 36222, 36223, 36224, 36225, 36226, 36227, 36228, 37215, 37216, 37217, 37218</td>
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<tr>
<td>HCPCS</td>
<td>No Codes</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>I63.031-I63.039 I63.131-I63.139 I65.231-I65.239 I63.59 I65.21-I65.29 I65.8</td>
</tr>
</tbody>
</table>

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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;
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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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