Extracranial Carotid Angioplasty/Stenting

Policy # 00155
Original Effective Date: 05/23/2005
Current Effective Date: 07/19/2017

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.

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;
  - Congestive heart failure (New York Heart Association [NYHA] class III/IV) and/or left ventricular ejection fraction < 30%;
  - Open heart surgery needed within 6 weeks;
  - Recent myocardial infarction (> 24 hours and < 4 weeks);
  - Unstable angina (Canadian Cardiovascular Society [CCS] class III/IV);
  - Severe chronic obstructive pulmonary disease;
  - Contralateral carotid occlusion requiring treatment;
  - 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;
  - Restenosis after carotid endarterectomy (CEA);
  - Stenosis secondary to arterial dissection;
  - Stenosis secondary to fibromuscular dysplasia;
  - Stenosis secondary to Takayasu arteritis;
  - 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 carotid endarterectomy (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
Carotid angioplasty with or without associated stenting has been investigated as a less invasive alternative to open CEA, currently considered the standard treatment for patients with significantly obstructing carotid atherosclerosis (stenosis). Note that either alternative is added to optimal medical management for these patients. Carotid angioplasty and stenting (CAS) involves the introduction of coaxial systems of catheters, microcatheters, balloons, and other devices through the femoral artery and into the carotid artery. The procedure typically takes 20–40 minutes and is performed with the patient fully awake and without sedation. At present, most practitioners also use a distally placed embolic protection device (EPD) that is designed to reduce the risk of peri-procedural stroke caused by thromboembolic material dislodged during CAS. Carotid angioplasty rarely is performed without stent placement.

Proposed advantages of CAS in contrast to CEA include the following:
- General anesthesia is not required
- Cranial nerve palsies are infrequent sequelae
- Simultaneous procedures may be performed on the coronary and carotid arteries

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
The U.S. FDA has approved carotid artery stents and EPDs from various manufacturers. Examples include:
- Acculink™ and RX Acculink™ carotid stents and Accunet™ and RX Accunet™ cerebral protection filters, Guidant Corp, now Abbott Vascular (approved August 2004);
- Xact® RX carotid stent system and Emboshield® embolic protection system, Abbott Vascular Devices (approved September 2005);
- Precise® nitinol carotid stent system and AngioGuard™ XP and RX emboli capture guidewire systems, Cordis Corp. (approved September 2006);
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- NexStent®‡ carotid stent over-the-wire and monorail delivery systems, Endotex Interventional Systems; and FilterWire EZ™ embolic protection system, Boston Scientific Corp. (approved October 2006);
- ProtegeRx® and SpideRx®‡, ev3 Inc, Arterial Evolution Technology. (approved January 2007);
- Carotid Wallstent®‡, Boston Scientific Corp. (approved October 2008);
- GORE® Flow Reversal System (clearance February 2009); GORE® Embolic Filter (clearance May 2011)

Each FDA-approved carotid stent is indicated for combined use with an EPD to reduce risk of stroke in patients considered to be at increased risk for periprocedural complications from CEA who are symptomatic with greater than 50% stenosis, or asymptomatic with greater than 80% stenosis—degree of stenosis being assessed by ultrasound or angiogram with computed tomography (CT) angiography also sometimes 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% stenosis by ultrasound or ≥ 50% stenosis by angiogram, and asymptomatic patients with ≥ 70% stenosis by ultrasound or ≥ 60% stenosis by angiogram.

U.S. FDA approved stents and EPDs differ in the deployment methods used once they reach the target lesion, with the RX (rapid exchange) devices designed for more rapid stent and filter expansion. The Precise and AngioGuard devices were studied in a randomized, controlled trial (RCT) (the SAPHIRE trial; see Rationale section). Other devices were approved based on uncontrolled, single-arm trials or registries and comparison to historical controls. The FDA has mandated postmarketing studies for these devices, 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 (e.g., straight or tapered) and sizes (diameters and lengths) to match the vessel lumen that will receive the stent.

In February 2015, FDA cleared for marketing the Enroute Transcarotid Neuroprotection System, or Enroute Transcarotid NPS (Silk Road Medical, Sunnyvale, CA), through the 510(k) process. The Enroute is a flow-reversal device designed to be placed via direct carotid access. Clearance was based on results of the Roadster trial (NCT01685567), a single-arm phase 3 pivotal trial to evaluate outcomes after CAS with the Enroute device among 283 subjects with symptomatic or asymptomatic carotid stenosis. Full results of the Roadster trial have not yet been published. The manufacturer has also submitted a premarket approval application for the Enroute transcarotid stent system, an optimized stent delivery system for use with the Enroute NPS.
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Centers for Medicare and Medicaid Services (CMS)
From March 2001, Medicare’s national coverage policy restricted coverage for CAS to patients participating in a clinical trial with Category B Investigational Device Exemption (IDE) designation from the FDA. Percutaneous transluminal angioplasty (PTA) of the vertebral and cerebral arteries remained noncovered.

When FDA approved the first (Guidant) devices, Medicare coverage under the IDE trial policy was no longer available for that manufacturer’s devices and was not applicable to FDA-required post-approval studies. Thus, on October 12, 2004, Medicare broadened its national coverage policy and “determined that the evidence is adequate to conclude that 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 EPD 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 policy, 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 value in supporting post-approval 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.”

The CMS provides a continually updated listing of facilities eligible for Medicare reimbursement that met CMS’s minimum facility standards for performing carotid artery stenting for high-risk patients.

On March 17, 2005, CMS determined that CAS with EPD is reasonable and necessary for patients at high risk for CEA who also have symptomatic carotid artery stenosis equal to or greater than 70%. The CMS limited coverage for these patients to procedures performed using 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 equal to or greater than 80%, to FDA-approved Category B IDE clinical trials for unapproved devices, or to FDA-required post-approval 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. The list of CMS-certified facilities for CAS with EPD is now available online at https://www.cms.gov/MedicareApprovedFacilities/CASF/list.asp.

The paragraph below provides CMS’ reasoning for this change in coverage policy:

“Considering the evidence and clinical situation, there appears to be sufficient evidence to infer that CAS with embolic protection can improve health outcomes for patients with severe symptomatic stenosis ≥ 70% who are also at high risk for CEA, if performed with the same expertise and rate of adverse events as demonstrated in the published clinical trials. Since patients with severe symptomatic stenosis ≥ 70% are at high risk for stroke, carotid interventions to reduce the risk of stroke should be considered. Although the published studies on CAS have various potential biases, we feel that the need for an alternative treatment to CEA for patients who are truly at high risk for CEA should be factored...
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into the coverage decision, unlike the Blue Cross and Blue Shield Association technology assessment program (BCBS TEC) report, which did not consider this circumstance. By not covering this group, symptomatic patients who also are at high risk for surgery may be left with no other treatment options. The risk benefit consideration may be similarly influenced. However, having mentioned this situation, the high risk CAS studies compared CAS to CEA and found that CEA can be performed as well as CAS in a group classified as high risk. Therefore, two comparable options exist for patients with symptomatic stenosis ≥ 70% who are at high risk."

On April 30, 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.” On October 14, 2008 in the sixth reconsideration, and on December 9, 2009 in the seventh reconsideration, CMS reaffirmed their prior coverage decisions.

On January 25, 2012 CMS convened a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) panel to consider "Management of Carotid Atherosclerosis." 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 not judged to reach a level of certainty to provide allow determining 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

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 “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
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 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 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
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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.

Next Scheduled Review Date: 07/2018

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 2016 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:

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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:
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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;
   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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