Extracranial Carotid Angioplasty/Stenting

Policy # 00155
Original Effective Date: 05/23/2005
Current Effective Date: 10/01/2020

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 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 with associated stenting and embolic protection in patients 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 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% and <100% stenosis) or asymptomatic preocclusive disease (>80% and <100%) 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% 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*:**

- Patients 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

- 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 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. 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 sequelae (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. 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.

Extracranial Carotid Angioplasty/Stenting

Policy # 00155
Original Effective Date: 05/23/2005
Current Effective Date: 10/01/2020

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
W. L Gore & Associates, Inc Gore Carotid Stent	Gore Carotid Stent	P180010	Nov 2018

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
	carotid stents		
Guidant, now Abbott Vascular	Accunet and RX AccunetEmbolic protection system	K042218	Aug 2004

Guidant, now Abbott Vascular	Rx Accunet 2 Embolic Protection System	K042908	Nov 2004
Guidant, now Abbott Vascular	Rx Accunet Embolic Protection System	K052165	Aug 2005
Abbott Vascular	Emboshield®‡ embolic protection system	K052454	Sep 2005
Cordis Corp.	AngioGuardä XP and RX emboli capture guidewire systems	K062531	Sep 2006
Boston Scientific	FilterWire EZ™‡ embolic protection system	K063313	Dec 2006
EV3 Inc	Spiderx	K052659	Feb 2007
EV3 Inc	Spidefx	K063204	Nov 2007
GORE	GORE®‡ Flow Reversal System	K083300	Feb 2009
GORE	GORE®‡ Embolic Filter	K103500	May 2011
Medtronic/Invatec	Mo.Ma®‡ Ultra Proximal Cerebral Protection Device	K092177	Oct 2009
Silk Road Medical	ENROUTE™‡ Transcarotid Stent System and ENROUTE Transcarotid Neuroprotection System	K143072	Feb 2015
Gardia Medical	Wirion	K143570	Jun 2015
Abbott Vascular	Rx Accunet Embolic Protection System	K153086	Nov 2015
Silk Road Medical, Inc.	Enroute Transcarotid Neuroprotection System	K153485	Mar 2016
Gardia Medical Ltd.	Wirion	K180023	Mar 2018
Contego Medical, LLC	Paladin Carotid Post-Dilation Balloon System With Integrated Embolic Protection (Paladin System)	K181128	Sep 2018
Contego Medical,	Vanguard lep Peripheral Balloon Angioplasty	K181529	Dec 2018

LLC	System With Integrated Embolic Protection		
Abbott Vascular	Emboshield Nav6 Embolic Protection System, Barewire Filter Delivery Wires	K191173	Jul 2019

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.

The FDA-approved stents and EPDs differ in the deployment methods used once they reach the target lesion, with the rapid exchange devices designed for more rapid stent and filter expansion. The FDA has mandated postmarketing studies for EPDs, including longer follow-up for patients already reported to the FDA and additional registry studies, primarily to compare outcomes as a function of clinician training and facility experience. Each manufacturer's system is available in various configurations (eg, straight or tapered) and sizes (diameters and lengths) to match the vessel lumen that will receive the stent.

In 2015, the ENROUTE™‡Transcarotid Neuroprotection System was cleared for marketing by the FDA through the 510(k) process. ENROUTE™‡is a flow reversal device designed to be placed via direct carotid access.

FDA product codes: NIM (stents) and NTE (EPDs).

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, 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.

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.

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

American Stroke Association

The American Stroke Association (2011), with 13 other medical societies, issued guidelines on the management of extracranial carotid and vertebral artery diseases, which are summarized in Table 3.

Table 3. 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	I	B

Recommendation	COR[a]	LOE[b]
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)		
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 wk of the index event is reasonable rather than delaying surgery	IIa	B
Prophylactic CAS might be considered in highly selected patients with asymptomatic carotid stenosis (minimum 60% by angiography, 70% by validated Doppler ultrasound), but its effectiveness compared with medical therapy alone in this situation is not well established	IIb	B
In symptomatic or asymptomatic patients at high-risk of complications for carotid revascularization by either CEA or CAS because of comorbidities, the effectiveness of revascularization versus medical therapy alone is not well established	IIb	B
Carotid angioplasty and stenting might be considered when ischemic neurologic symptoms have not responded to antithrombotic therapy after acute carotid dissection	IIb	C

Recommendation	COR[a]	LOE[b]
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).

Society for Vascular Surgery
The Society for Vascular Surgery (2011) updated its guidelines on the management of the extracranial carotid disease. Recommendations from the guidelines are summarized in Table 4.

Table 4. Guidelines for Managing Extracranial Carotid Disease

Recommendation	GOE[a]	LOE[b]
In most patients with carotid stenosis who are candidates for intervention, CEA is preferred to CAS for reduction of all-cause and periprocedural death	I	B
CAS is preferred over CEA in symptomatic patients with >50% stenosis and tracheal stoma, situations where local tissues are scarred and fibrotic from prior ipsilateral surgery or external beam radiotherapy, prior cranial nerve injury, and lesions that extend proximal to the clavicle or distal to the C2 vertebral body	II	B
CAS is preferred over CEA in symptomatic patients with >50% stenosis and severe uncorrectable coronary artery disease, congestive heart failure, or chronic obstructive pulmonary disease	II	C

There are insufficient data to recommend CAS as primary therapy for neurologically asymptomatic patients with 70%-99% diameter stenosis. In properly selected asymptomatic patients, CAS is equivalent to CEA in the hands of experienced interventionalists with a combined stroke and death rate <3%	II	B

CAS: carotid artery angioplasty with stenting; CEA: carotid endarterectomy; GOE: grade of evidence; LOE: level of evidence.
[a] Grade I: benefit clearly outweighs risk; grade II: benefits and risks are more closely matched and are more dependent on specific clinical scenarios.
[b] Level B (moderate quality); level C (low quality).

U.S. Preventive Services Task Force Recommendations
Not applicable.

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

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

While the Medicare decision differed from the conclusions of this evidence review, Medicare made a public policy decision "that making available new, effective therapies aimed at addressing treatment and prevention of cerebrovascular disease was important to Medicare beneficiaries."

Medicare also noted that it recognized the value in supporting postapproval studies as "the collected data may provide an opportunity for practitioners to determine which patients are most appropriate for carotid artery stenting and to reinforce IDE trial data on health outcomes and adverse events."

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

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

In 2007, a decision memo reaffirmed CMS’s previous decision following a request to expand coverage while clarifying that “CAS is only covered when used with an embolic protection device and is, therefore, not covered if deployment of the distal embolic protection device is not technically possible.” In 2008, in a sixth reconsideration, and in 2009, in a seventh reconsideration, CMS reaffirmed its prior coverage decisions.

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

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 5. There are no ongoing or direct comparisons of CAS with CEA in patients at increased risk for CEA complications. Particularly problematic is the lack of adequate data, from either randomized or nonrandomized studies, to separately compare outcomes of the alternatives (CAS vs CEA vs current optimal medical management) in symptomatic and asymptomatic increased-risk subgroups.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02538276	Carotid Endarterectomy and Carotid Artery Stenting in Brazil	500	Jul 2019 (Unknown status)
NCT00883402	Asymptomatic Carotid Surgery Trial-2 (ACST-2): an International Randomised Trial to Compare Carotid Endarterectomy With Carotid Artery Stenting to Prevent Stroke	3600	Dec 2019
ISRCTN78592017	Stent-protected angioplasty in asymptomatic carotid artery stenosis vs endarterectomy: two two-arm clinical trials (SPACE-2)	5000	Jul 2020
NCT02089217	Carotid revascularization and medical management for asymptomatic carotid stenosis trial (CREST-2)	2480	Dec 2020
ISRCTN97744893	European Carotid Surgery Trial 2 (ECST-2): a randomized controlled trial	2000	Mar 2022

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

References

1. Anthem: An Independent licensee of the Blue Cross and Blue Shield Association, "Carotid, Vertebral and Intracranial Artery Stent Placement with or without Angioplasty", CG-SURG-76, April 15, 2020.
2. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Extracranial Carotid Artery Stenting", 7.01.68, June 2020.
3. Blue Cross and Blue Shield Association. Angioplasty and Stenting of the Cervical Carotid Artery with Distal Embolic Protection of the Cerebral Circulation. TEC Assessment, February 2005; 19(15).
4. Ecker RD, Brown RD, et al. Cost of Treating High-Risk Symptomatic Carotid Artery Stenosis: Stent Insertion and Angioplasty Compared with Endarterectomy. J of Neurosurg. 2004; 101(6):904-7.
5. Kovacic JC, Roy PR, et al. Percutaneous Carotid Artery Stenting: A Strategy in Evolution. Int Med J. 2005; 35(3):143-50.
6. Levy EI, Hanel RA, et al. Frequency and Management of Recurrent Stenosis after Carotid Artery Stent Implantation. J Neurosurg.2005; 102(1):29-37.
7. Hobson RW 2nd, Howard VJ, et al. Carotid Artery Stenting is associated with Increased Complications in Octogenarians: 30-day Stroke and Death Rates in the CREST Lead-In Phase. J Vasc Surg. 2004; 40(6):1106-11.
8. Lin PH, Bush RL, et al. Carotid Artery Stenting with Routine Cerebral Protection in High-Risk Patients. Am J Surg. 2004; 188(6):644-52.
9. ALhaddad IA. Carotid Artery Surgery vs. Stent: A Cardiovascular Perspective. Catheter Cardiovasc Interv. 2004; 63(3):377-84.
10. Faries PL, Dayal R, et al. Continuity in the Treatment of Carotid Artery Disease: Results of a Carotid Stenting Program Initiated by Vascular Surgeons. Ann Vasc Surg. 2004; 18(6):669-76.
11. Barr J, Connors III JJ, et al. Quality Improvement Guidelines for the Performance of Cervical Carotid Angioplasty and Stent Placement. J Vasc Interv Radiol. 2003; 14:S321-S335.
12. Sacco RL, Adams R, Albers G et al. Guidelines for prevention of stroke in patients with ischemic stroke or transient ischemic attack: a statement for healthcare professionals from the American Heart Association/American Stroke Association Council on Stroke: co-sponsored by the Council on Cardiovascular Radiology and Intervention: the American Academy of Neurology affirms the value of this guideline. Stroke 2006; 37(2):577-617.

Extracranial Carotid Angioplasty/Stenting

Policy # 00155
Original Effective Date: 05/23/2005
Current Effective Date: 10/01/2020

Policy History

Original Effective Date: 05/23/2005
Current Effective Date: 10/01/2020

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 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.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2019	Coding update

Extracranial Carotid Angioplasty/Stenting

Policy # 00155
Original Effective Date: 05/23/2005
Current Effective Date: 10/01/2020

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

Next Scheduled Review Date: 07/2021

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 2019 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

Extracranial Carotid Angioplasty/Stenting

Policy # 00155
Original Effective Date: 05/23/2005
Current Effective Date: 10/01/2020

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.

CPT is a registered trademark of the American Medical Association.

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	I63.031-I63.139, I63.59, I65.21-I65.29, I65.81-I65.89

*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;
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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.