



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Carotid Artery Stenting for Carotid Artery Stenosis**

**Effective Date ..... 10/15/2009**  
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## Hyperlink to Related Coverage Policies

Carotid Intima-Media Thickness Measurement  
 Computed Tomography Angiography (CTA)  
 Intravascular Ultrasound (IVUS)  
 Magnetic Resonance Angiography (MRA)

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

## Coverage Policy

**CIGNA covers carotid artery stenting using a U.S. Food and Drug Administration (FDA)-approved carotid stent system and embolic protection device, for carotid artery stenosis per the U.S. Food and Drug Administration (FDA) labeling as medically necessary when BOTH of the following criteria are met:**

- The individual is at high risk\* for adverse events from carotid endarterectomy and requires revascularization.
- The individual has **ONE** of the following, as demonstrated on ultrasound, magnetic resonance angiography, or arteriogram:
  - neurological symptoms and  $\geq 50\%$  stenosis of the common or internal carotid artery
  - no neurological symptoms and  $\geq 80\%$  stenosis of the common or internal carotid artery

\*See page two in the General Background for high-risk criteria

## General Background

Carotid artery disease occurs when atherosclerotic plaques decrease the carotid artery diameter (stenosis), thereby reducing blood flow to the brain. Treatment for carotid artery stenosis depends on the degree of carotid artery blockage and the presence of symptoms. Asymptomatic patients with stenosis are treated medically with

antiplatelet therapy (e.g., aspirin) to decrease the likelihood of a blood clot and decrease the risk of stroke. Patients with severe symptomatic stenosis are referred for surgery. The procedure, carotid endarterectomy (CEA), involves the surgical removal of stenotic plaque from the carotid artery. CEA is the reference standard for treatment of carotid artery stenosis. However, CEA is associated with increased mortality and morbidity in patients with significant comorbidity (e.g., coronary artery disease). Carotid artery angioplasty with stenting (CAS), with or without an embolic protection device, is an endovascular procedure that has been proposed as an alternative treatment to CEA in high risk patients with significant comorbidity and in patients with no contraindications to surgery but who have anatomically inaccessible lesions (Burton, et al., 2005).

### Description of Procedure

The purpose of carotid angioplasty is to compress the atherosclerotic plaque and expand the lumen in the target carotid artery(ies). Preoperatively, the patient has diagnostic studies which can include duplex ultrasonography with magnetic resonance angiography or plain angiogram of the neck and cerebral circulation. The stenosis is predilated with a balloon, and an embolic capture device is threaded through the predilated stenosis and placed in the distal extracranial internal carotid artery to capture emboli that may be dislodged during the procedure. When such devices are used, this procedure is called protected CAS or PCAS. Once again, the lesion is dilated in order to place a self-expanding stent, usually composed of nitinol, in the lesion with post-dilation using a balloon. The distal protection device in the internal carotid artery is retrieved and additional angiograms are done. (Institute for Clinical Systems Improvement [ICSI], 2006; Burton, et al., 2005).

Cerebral protection devices use different approaches to trap dislodged plaque particles: distal balloon occlusion, distal filter, and flow reversal (retrograde or proximal occlusion). The less complex filter approach has higher utilization compared to the other two approaches, since the device can trap particles while permitting continuous blood flow (Stafinski and Menon, 2005).

The technical success rate for CAS is 97%–99% for experienced operators. Complications such as emboli, carotid artery spasm, thrombosis, dissection, and hyperperfusion syndrome may occur but are uncommon. Other periprocedural (i.e., within 30 days after procedure performance) complications include minor stroke (5.3%), transient ischemic attack (TIA) (3.7%), and major stroke (0.7%). The low complication rate assumes the operators have experience performing CAS procedures. The periprocedural mortality rate for experienced CAS operators is 0.7%–0.8% (ICSI, 2006).

\*Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors and would be poor candidates for CEA in the opinion of a surgeon (CMS, 2005). A list of comorbid conditions and/or anatomic features which can be found in each of the manufacturers' U.S. Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data for their CAS system. Conditions that were used to determine patients at high risk for CEA are found in the prior CAS trials and studies (e.g., ARCHER, CABERNET, SAPPHIRE). In order for patients to qualify as a high-risk or nonsurgical candidate in any of the three ARCHER trials, two or more of the criteria listed in a-e **OR** one or more of the criteria listed in f-q had to be met (FDA, 2004).

Significant anatomic features and/or comorbid conditions include but are not limited to:

- a) knowledge of two or more proximal or major diseased coronary arteries with  $\geq 70\%$  stenosis that have not or cannot be revascularized
- b) unstable angina defined as rest angina with electrocardiogram (ECG) changes
- c) MI within the previous 30 days and current need for carotid artery revascularization
- d) concurrent requirement for aortocoronary bypass or cardiac valve surgery within 30 days
- e) contralateral occlusion of the internal carotid artery
- f) currently on a list for major organ transplantation (i.e., heart, lung, liver, kidney) or is being evaluated for such
- g) ejection fraction  $< 30\%$  or New York Heart Association (NYHA) Functional Class III or higher
- h)  $FEV_1 < 30\%$  (predicted)
- i) dialysis-dependent renal failure
- j) uncontrolled diabetes defined as fasting glucose  $> 400$  mg/dl and ketones  $> 2+$
- k) restenosis after previous CEA
- l) patient is status/post-radiation treatment to the neck

- m) patient is status/post-radical neck surgery
- n) surgically inaccessible lesions (e.g., lesions above the level of C2 or below the clavicle, lesions obstructed by tumors in the neck)
- o) spinal immobility (i.e., inability to flex neck beyond neutral or kyphotic deformity)
- p) presence of tracheostomy stoma
- q) contralateral laryngeal nerve paralysis

### **U.S. Food and Drug Administration (FDA)**

The FDA has approved CAS systems and distal embolic protection devices from various manufacturers. The FDA-approved stents and distal embolic protection devices differ in the deployment methods once they reach the targeted lesion. The FDA-approved stents and distal embolic protection devices were approved based on either randomized controlled trials (RCTs) (i.e., Precise and AngioGuard) or the devices were approved based on uncontrolled trials, single-arm trials or registries, and comparison to historical controls. The FDA mandates post-marketing studies for these devices.

On August 31, 2004, the FDA announced their approval of the first carotid stenting system for use in individuals with  $\geq 50\%$  symptomatic stenosis of the common or internal carotid artery or in individuals with  $\geq 80\%$  asymptomatic stenosis of the common or internal carotid artery by ultrasound or angiography. The individuals were viewed by their treating surgeon as being at high risk for CEA due to anatomic risks or medical comorbidities. Since 2004, various carotid stenting devices have been approved. The carotid stenting systems were often approved in conjunction with carotid embolic protection systems.

FDA-approved stents and distal embolic protection devices include, but are not limited to:

- The ACCULINK™ Carotid Stent System and the RX ACCULINK™ Carotid Stent System (Guidant Corporation, Santa Clara, CA), used in conjunction with carotid embolic protection systems (ACCUNET™ and RX ACCUNET™ Embolic Protection Systems, Guidant Corporation, Santa Clara, CA), received FDA approval in August 2004. The approval of the Guidant devices was based on the submission of the results of the ACCULINK for Revascularization of Carotids in High-Risk Patients (ARCHEr 1, 2 and 3) clinical trials. The ongoing clinical trial, CREST (Carotid Revascularization Endarterectomy versus Stent Trial) is utilizing the Guidant devices (FDA, 2004).
- The Xact® Carotid Stent System (Abbott Vascular Devices, Redwood City, CA) with Abbott Vascular Devices Emboshield® Protection System received FDA approval in September 2005 (FDA, 2005). The approval of the Xact® Carotid Stent System was based on the Registry Study to Evaluate the Neuroshield Bare Wire Cerebral Protection System and Xact Stent in Patients at High Risk for Carotid Endarterectomy (SECURITY) (FDA, 2005a).
- The Liberté™ Monorail™ and Over-the-Wire Coronary Stent System (Boston Scientific Corp., Maple Grove, MN) received FDA approval in April 2005 (FDA, 2005b).
- The Cordis Corporation (Warren, NJ) received FDA approval in September 2006 for the Cordis PRECISE™ OTW Nitinol Stent System and is used in conjunction with an embolic protection system (ANGIOGUARD™). These devices were studied in the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial (FDA, 2006a).

The NexStent® Carotid Stent and Monorail® Delivery System (Endotex Interventional Systems, Inc., Cupertino, CA) received FDA approval in October 2006. It is also compatible with the FilterWire EZ™ Embolic Protection System. FDA approval for the FilterWire EZ Embolic Protection System, as well as for the two associated CAS systems, was based on a prospective, nonrandomized multicenter clinical trial (Carotid Artery revascularization using the Boston Scientific EPI FilterWire EX and the EndoTex NExStent [CABERNET]) (FDA, 2006b). In June 2008, the FDA issued a recall of the NexStent Carotid Stent and Monorail Delivery System. It was noted that the tip of this stent system had a tendency to detach during the procedure. The concern was that this may lead to increased procedure time, cause vessel wall damage, stroke and/or emergency surgery to remove the detached tip (FDA, 2008).

- The Protégé® GPS™ and Protégé® RX Carotid Stent Systems used with the SpiderRX™ Embolic Protection Device (ev3 Inc., Plymouth, MN) received FDA approval in January 2007. This CAS system was evaluated via the Carotid Revascularization with ev3 Inc. Arterial Technology Evolution (CREATE) Trial (FDA, 2007a).
- The Exponent® Self-Expanding Carotid Stent System and Delivery System (Medtronic, Inc., Santa Rosa, CA) received FDA approval in October 2007 (FDA, 2007b).

Each CAS system and distal embolic protection device has an FDA Summary of Safety and Effectiveness Data which lists similar contraindications, including the following:

- contraindication to anticoagulant and/or antiplatelet therapy
- severe vascular tortuosity or anatomy that would preclude the safe introduction of a guide catheter, sheath, embolic protection system, or stent system
- known hypersensitivity to nickel-titanium
- uncorrected bleeding disorders
- lesions in the ostium of the common carotid artery

### Literature Review

CAS placement with an FDA-approved carotid stent system and embolic protection device has become an accepted alternative for treating a subset of individuals who are at high risk for adverse events from CEA and are anatomically good candidates for CAS. The preponderance of the evidence supports the conclusion that CAS with embolic protection is not inferior to CEA in either symptomatic or asymptomatic patients at increased risk for surgical complications of CEA (White, et al., 2008). Individuals with surgical high risk features (anatomic and comorbid) for CEA have been proven to have outcomes similar to CEA. This was reported in a randomized controlled trial (SAPPHIRE). The SAPPHIRE study is an accepted study by the FDA as evidence supporting CAS device approval (Yadov, et al., 2004). Three year outcomes data from the SAPPHIRE study have confirmed the long-term safety and efficacy in this high risk subset of patients. The author reported that 73.8% of patients in the stenting group and 69.7% in the endarterectomy group were free of major adverse events at three years (the pre-specified major end point, defined as death, myocardial infarction, or stroke within 30 days or death or ipsilateral stroke between 31 days and 1080 days). A total of 80.0% of patients in the stenting group and 75.8% in the endarterectomy group were alive at three years. A total of 92.0% of patients in the stenting group and 93.3% in the endarterectomy group were free of stroke at three years (defined as stroke within 30 days or ipsilateral stroke between 31 days and 1080 days) (Gurm, et al., 2008b).

Several large, non-randomized, prospective registry studies (e.g., BEACH, ARCHeR, SECURITY) have reported the safety and efficacy of CAS with embolic protection in individuals who have stenosis of the common or internal carotid artery who are symptomatic with neurological symptoms and ( $\geq 50\%$  stenosis) and those individuals with no neurological symptoms ( $\geq 80\%$  stenosis) (Eisenhauer, 2008; Gray, et al, 2007; Katzen, et al., 2007; White, et al., 2006; FDA, 2004).

Eckstein et al. (2008) reported no significant differences with regard to clinical endpoints for up to two years after either CAS or CEA. Patients who were successfully treated with stent-protected angioplasty had a similar low risk of secondary cerebrovascular events as patients who were treated with endarterectomy. These results were from the completed SPACE trial which was a large (n=1214), randomized study of CAS and CEA for the secondary prevention of carotid artery stenosis in patients with symptomatic, severe ( $\geq 70\%$ ) CAS.

In a prospective, multicenter study (BEACH), Iyer et al. (2008) reported that in high-surgical-risk patients who meet indications for carotid revascularization, CAS with emboli protection is not inferior to CEA at one year.

Additional supporting evidence in the published, peer-reviewed scientific literature for CAS in individuals with high risk for adverse events from CEA include meta-analyses (Gurm, et al, 2008a; Burton, et al., 2005) and systematic reviews (Zahn, et al., 2005; Groschel et al., 2005). Results of large ongoing randomized controlled trials are needed before CAS can be used in a broad perspective.

### Technology Assessments

The Institute for Clinical Systems Improvement (ICSI) Technology Assessment Committee reported the following conclusions on CAS: "CAS, especially using an embolic protection device, is a relatively safe

procedure when performed by providers experienced with the technology. A number of short-term studies have shown CAS to be generally equivalent to CEA (the reference standard) in safety and efficacy, especially in populations at increased risk for surgery (i.e., SAPHIRE trial). However, lack of longer-term follow-up does not permit conclusions regarding CAS in terms of long-term (i.e., greater than one year) efficacy. Results of ongoing randomized trials may provide further clarity in this area” (ICSI, 2006).

In 2006, the National Institute for Health and Clinical Excellence (NICE) issued interventional procedure guidance on carotid artery stent placement for carotid stenosis. NICE guidance states, “Current evidence states that stent placement is safe and efficacious in the short term. However, long-term efficacy in terms of stroke prevention and restenosis is unknown, and there are uncertainties about the benefits for asymptomatic patients.”

### **Professional Societies/Organizations**

The Society for Vascular Surgery (SVS) appointed a committee of experts to formulate evidence-based clinical guidelines for the management of carotid stenosis. In formulating clinical practice recommendations, the committee used systematic reviews to summarize the best available evidence and the GRADE scheme to grade the strength of recommendations (GRADE 1 for strong recommendations; GRADE 2 for weak recommendations) and rate the quality of evidence (high, moderate, low, and very low quality). In symptomatic and asymptomatic patients with low-grade carotid stenosis (< 50% in symptomatic and < 60% in asymptomatic patients), optimal medical therapy rather than revascularization is recommended (GRADE 1 recommendation, high quality evidence). In symptomatic patients with moderate to severe carotid stenosis (more than 50%), CEA plus optimal medical therapy is recommended (GRADE 1 recommendation, high quality evidence). In symptomatic patients with moderate to severe carotid stenosis (> 50%) and high perioperative risk, CAS as a potential alternative to CEA is suggested (GRADE 2 recommendation, low quality evidence). In asymptomatic patients with moderate to severe carotid stenosis (> 60%), CEA plus medical management as long as the perioperative risk is low is recommended (GRADE 1 recommendation, high quality evidence). CAS for asymptomatic patients with moderate to severe (> 60%) carotid artery stenosis is not recommended (GRADE 1 recommendation, low quality evidence). A possible exception includes patients with > 80% CAS and high anatomic risk for CEA (Hobson, et al., 2008).

In 2007, the American College of Cardiology (ACC) issued a joint expert consensus document on CAS (Bates, et al., 2007). The document states, “Carotid artery stenting is a reasonable alternative to CEA, particularly in patients at high risk for CEA. Although there are no randomized studies comparing CAS with and without embolic protection devices, the use of embolic protection devices appears to be important in reducing the risk of stroke during CAS. Careful neurological assessment is required before and after CAS. At the present time, there is insufficient evidence to support CAS in high-risk patients with asymptomatic stenosis less than 80% or in any patient without high-risk features. Operators should previously have achieved a high level of proficiency in catheter-based intervention, complete dedicated training in CAS, and be credentialed at their hospital.”

The document outlines the high-risk criteria for CEA into anatomical criteria and medical comorbidities. Anatomical criteria includes: lesion at C-2 or higher, lesion below clavicle, prior radical neck surgery or radiation, prior ipsilateral CEA, contralateral laryngeal nerve palsy, and tracheostoma. Medical comorbidities include: age  $\geq$  80 years, Class III/IV congestive heart failure, Class III/IV angina pectoris, left main/ $\geq$  two vessel coronary disease, urgent (<30 days) heart surgery, left ventricle ejection fraction  $\leq$  30%, recent (<30 days) MI, severe chronic lung disease, and severe renal disease.

The updated guideline on stroke prevention from the American Heart Association/American Stroke Association Council on Stroke (Sacco, et al., 2006) includes recommendations on interventional approaches for patients with extracranial carotid artery atherosclerosis. The guideline recommends that CAS may be considered a reasonable alternative to CEA for patients with symptomatic severe stenosis (>70%), in whom the risk of surgery, or when other specific circumstances exist (e.g., radiation-induced stenosis or restenosis after prior CEA), provided it is performed by operators with established periprocedural morbidity and mortality rates of 4–6%, similar to that observed in trials of CEA and CAS.

Carotid stenting is a technically complex procedure. Minor embolic events can lead to major complications (ICSI, 2006). The Society of Cardiac Angiography and Interventions (SCAI), the Society for Vascular Medicine and Biology (SVMB), and the Society for Vascular Surgery (SVS) issued a clinical competence statement on carotid stenting addressing the training and credentialing for carotid stenting. This multispecialty consensus

recommendation states that physicians who perform carotid stenting with embolic protection must meet or exceed minimum qualifications deemed necessary to offer safe and effective therapy. The qualifications must include proficiency in the cognitive, technical, and clinical skills necessary to care for patients with carotid artery disease (Rosenfield, et al., 2005).

### U.S. Preventive Services Task Force (USPSTF)

The USPSTF clinical guidelines on screening for carotid artery stenosis (Wolff, et al., 2007), stenting for carotid artery stenosis is discussed as an emerging issue. The guidelines states that CAS has emerged as a potential alternative to CEA for patients who are not candidates for CEA because of high-risk comorbid conditions. The USPSTF reports that based on the evidence they cannot determine whether the benefits of stenting differ from those of CEA.

### Summary

There is some evidence that carotid artery stenting (CAS) is safe and effective in treating severe (50–70%) carotid artery stenosis in high-risk symptomatic patients. There is also evidence, although more limited, that CAS can reduce severe (>80%) stenosis in patients who have not yet begun to experience neurological symptoms. Results of the few available randomized comparative trials suggest clinical equipoise of CAS and CEA; however, these findings need to be confirmed in additional prospective, randomized clinical trials. Furthermore, the added benefit of embolic protection devices remains to be proven, and questions regarding optimal patient and device selection criteria remain. Ongoing, randomized clinical trials are investigating the role of CAS in different patient populations.

## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

CPT <sup>®*</sup> Codes	Description
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous: with distal embolic protection
37216	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous: without distal embolic protection
0075T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel
0076T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; each additional vessel (List separately in addition to code for primary procedure)

ICD-9-CM Diagnosis Codes	Description
433.10	Occlusion and stenosis of precerebral arteries; carotid artery without mention of cerebral infarction
433.11	Occlusion and stenosis of precerebral arteries; carotid artery with cerebral infarction
433.30	Occlusion and stenosis of precerebral arteries, multiple and bilateral, without mention of cerebral infarction
433.31	Occlusion and stenosis of precerebral arteries, multiple and bilateral, with cerebral infarction

\*Current Procedural Terminology (CPT<sup>®</sup>) © 2008 American Medical Association: Chicago, IL.

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## Policy History

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<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	10/15/2007	0101	Carotid Artery Stenting
Great-West Healthcare	4/30/2007	05.280.02	Carotid Artery Stenting

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.