



CAROTID and INTRACRANIAL ARTERY STENTING

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I. DESCRIPTION

Carotid artery angioplasty with stenting (CAS) is an endovascular procedure that has been proposed as an alternative treatment to Carotid Endarterectomy (CEA) in high-risk patients and in patients with contraindications to surgery. Percutaneous access to the carotid artery is gained through the femoral or brachial arteries. A balloon catheter is passed into the carotid artery under fluoroscopic guidance. Once the catheter has reached the area of blockage, the balloon is inflated to open the blocked artery. To keep the artery open, a semi-rigid tube-like device, or stent, is placed in the carotid artery. The increased dislocation of microemboli during CAS is thought to be the underlying cause for the increased risk of neurologic complications. This risk may be reduced with the use of embolic protection devices, intravessel filtration systems designed to retain the stenotic debris.

The Food and Drug Administration (FDA) approved the first carotid stent/companion carotid embolic protection device system in early September 2004-The RX ACCULINK™ Carotid Stent System and RX ACCUNET™ Embolic Protection System. This device is available only to participants in a multicenter post-approval study sponsored in the practices of physicians at both academic and private hospitals, who will have a mixture of high, medium and low annual carotid stent implant volumes. The post-approval study will gather data on patient outcomes including death, stroke, myocardial infarction and rare adverse events.

Background:

Stroke is the third leading cause of death in the United States and the number one cause of disability in adults. In the United States, about 700,000 people have a new or recurrent stroke each year, and 280,000 will die. Cerebral infarctions account for about 80% to 85% of all strokes. Of all cerebral infarctions, about 20% to 30% are due to atherothrombosis or thromboembolism from the extracranial or intracranial vessels including the carotid arteries. Lifetime cost of stroke exceeds \$90,000 per patient in the United States.

Treatment for carotid artery stenosis depends on the degree of blockage and the presence of symptoms. Asymptomatic patients with less than 70% 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 ($\geq 70\%$) are referred for surgery. The procedure, carotid endarterectomy

(CEA), involves the surgical removal of stenotic plaque from the carotid artery. A multicenter randomized controlled trial (NASCET; the North American Symptomatic Carotid Endarterectomy Trial) demonstrated that CEA significantly improved outcome and reduced the risk of stroke and death compared with medical treatment alone. 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) is an endovascular procedure that has been proposed as an alternative treatment to CEA in these patients and in patients with contraindications to surgery. Percutaneous access to the carotid artery is gained through the femoral or brachial arteries. A balloon catheter is passed into the carotid artery under fluoroscopic guidance. Once the catheter has reached the area of blockage, the balloon is inflated to open the blocked artery. To keep the artery open, a semi-rigid tube-like device, or stent, is placed in the carotid artery. The proponents of this modality suggest that CAS may reduce the risk and side effects associated with general anesthesia. Furthermore, CAS may reduce the risk of complications for patients with significant comorbidities and may be an alternative for patients with contraindications to surgery or who have anatomically inaccessible lesions. However, early clinical studies reported stroke and death rates ranging from 10% to 12%. This rate did not compare favorably with the CEA stroke and death rate reported in the NASCET trial (5.8%), and raised concerns about the relative safety of the procedure. The increased dislocation of microemboli during CAS is thought to be the underlying cause for the increased risk of neurologic complications. This risk may be reduced with the use of embolic protection devices, intravessel filtration systems designed to retain the stenotic debris.

Yadav JS, Wholey MH, Kuntz RE, et al. Protected carotid-artery stenting versus endarterectomy in high-risk patients. N Engl J Med. 2004;351(15):1493-1501. In this pivotal randomized trial, carotid endarterectomy (n=151) was no more effective than carotid artery angioplasty with stent placement performed with an embolic protection device (n=159) in reducing the incidence of major cardiovascular events among patients with severe carotid artery stenosis who also had at least one coexisting condition associated with increased risk for complications from endarterectomy. The Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial enrolled symptomatic patients with 50% carotid artery stenosis or asymptomatic patients with 80% luminal diameter loss who were poor candidates for endarterectomy. However, only those patients judged by study investigators, both surgeons and interventional physicians, not to be at higher risk for stroke or death if treated with either one of the two procedures were eligible for randomization to undergo endarterectomy or stenting. Therefore, patients determined to be unsuitable for endarterectomy but for whom stenting was considered feasible were excluded from randomization and enrolled in a stent registry-type study. Baseline characteristics were well balanced between treatment arms with a few exceptions. A significantly greater percentage of patients allocated to receive a stent, than those assigned to undergo endarterectomy, had coronary disease and a history of previous coronary

angioplasty. The primary measure of efficacy was a composite endpoint, including 30-day cumulative incidence of death, stroke, or myocardial infarction (MI), or incidence of death *or* ipsilateral stroke between 31 and 365 days postprocedure. This outcome did not statistically differ between treatment groups in intention-to-treat analysis, and occurrence favored stenting in analysis of those actually treated despite significantly more patients with coronary disease and a history of angioplasty. In addition, target vessel revascularization rates, as well as incidence of major ipsilateral stroke within 1 year of treatment, were significantly lower in the stent versus endarterectomy group. The SAPPHERE trial was not sufficiently powered to detect significant mortality differences between the two treatment arms. Due to low patient enrollment, the trial was ended early. Authors suggest that the advent of carotid stent registries made the procedure more readily available to patients and hampered recruitment for the randomized comparison with endarterectomy. It seems unlikely that future randomized head-to-head studies would have greater success with enrollment, and the data provided by SAPPHERE may be among the best published evidence available. Findings support carotid stenting and endarterectomy equivalence in high-risk patients, even hinting that the less invasive treatment may have an edge over the standard surgical approach.

II. POLICY/CRITERIA

Priority Health will cover, carotid artery stenting for *either* of the following (A or B):

A. Participants who meet eligibility criteria for the post-approval *CREST (Carotid Revascularization Endarterectomy vs. Stent Trial) study, including both of the following:

1. Patients who meet either of the following criteria:
 - a. neurological symptoms and $\geq 50\%$ stenosis of the common or internal carotid artery by ultrasound or angiogram, *or*
 - b. patients without neurological symptoms and $\geq 80\%$ stenosis of the common or internal carotid artery by ultrasound or angiogram

AND

2. Patients must have a reference vessel diameter within the range of 4.0 mm and 9.0 mm at the target lesion.

*The CREST study is available in network. The embolic protection device is available only in an FDA approved trial.

B. Patients at high risk** for adverse events from carotid endarterectomy who meet both of the following:

1. Patients with either of the following:
 - a. neurological symptoms and $\geq 50\%$ stenosis of the common or internal carotid artery by ultrasound or angiogram, **OR**
 - b. patients without neurological symptoms and $\geq 80\%$ stenosis of the common or internal carotid artery by ultrasound or angiogram

AND

2. Patients must have a reference vessel diameter within the range of 4.0 mm and 9.0 mm at the target lesion.

Note: The embolic protection device is not available for patients at high risk who do not meet inclusion criteria for a trial. However, the carotid artery stent is FDA approved for use outside of a trial.

** High-risk for this population² is defined as any of the following:

1. Clinically significant cardiac disease (congestive heart failure, abnormal stress test, or need for open-heart surgery)
2. Severe pulmonary disease
3. Contralateral carotid occlusion
4. Contralateral laryngeal-nerve palsy
5. Previous radical neck surgery or radiation therapy to the neck
6. Recurrent stenosis after endarterectomy
7. Age >80 yr

The following additional criteria must be met for carotid artery stenting.

- Must be performed by an interventional cardiologist, interventional radiologist, or vascular surgeon who has completed a specialized training course and is qualified to perform this procedure.
- Patients must have significant contraindications for standard carotid endarterectomy surgery and/or general anesthesia.

Limitations and Exclusions include:

- Patients who are candidates for carotid endarterectomy and in whom surgery is **not** contraindicated.
- Patients with contraindications to angiography and/or endovascular treatment
- Patients who can be treated medically or surgically.

Coverage for Self-funded Members —Participation in the CREST or other clinical trials is not a covered benefit. Patients who meet the high-risk criteria are eligible for coverage for coronary artery stenting.

Intracranial Angioplasty and Stenting: Intracranial angioplasty, with or without stenting for the treatment of atherosclerotic lesions, intracranial vasospasm, or any other indication, is considered investigational and not a covered benefit.

III. MEDICAL NECESSITY REVIEW

Required Not Required Not Applicable

IV. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS).*
- ❖ **MEDICAID:** *Coverage is determined by the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html.*
- ❖ **MICHILD:** *For MICHILD members, this policy will apply unless MICHILD certificate of coverage limits or extends coverage.*

V. CODING INFORMATION

ICD-9 Codes that may support medical necessity:

- 433.10 Occlusion and stenosis of precerebral arteries, without mention of cerebral infarction
- 433.11 Occlusion of the carotid artery with infarct
- 433.30 Occlusion and stenosis of carotid artery, multiple and bilateral, without mention of cerebral infarction
- 433.31 Occlusion and stenosis of carotid artery, multiple and bilateral, with infarct

CPT/HCPCS Codes:

- 37215 Transcatheter Placement Of Intravascular Stent(S), Cervical Carotid Artery, Percutaneous; With Distal Embolic Protection (*Not covered for Self-Funded products*)

- 37216 Transcatheter Placement Of Intravascular Stent(S), Cervical Carotid Artery, Percutaneous; Wo Distal Embolic Protection (*Not covered for PriorityMedicare*)
- 0075T Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel (*Not covered for Medicaid*)
- 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) (*Not covered for Medicaid*)

Not Covered:

- 61630 Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous
- 61635 Transcatheter placement of intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed
- 61640 Balloon dilatation of intracranial vasospasm, percutaneous; initial vessel
- 61641 Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in same vascular family (List separately in addition to code for primary procedure)
- 61642 Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in different vascular family (List separately in addition to code for primary procedure)

Special Note: Priority Health's Technology Assessment Committee reviewed Carotid Artery Stenting on December 3, 2004. This medical policy follows the recommendations of the committee.

VI. REFERENCES

- "Carotid Artery Stenting for Carotid Artery Disease", Hayes, Inc, March 2004
- Yadav JS, Wholey MH, Kuntz RE, et al. Protected carotid-artery stenting versus endarterectomy in high-risk patients. *N Engl J Med.* 2004;351(15):1493-1501.
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Decision Memo for Intracranial Stenting and Angioplasty, Centers for Medicare and Medicaid Services, May 12, 2008. Available on the World Wide Web @ <https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=214&>

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