Public Statement:

1) Carotid artery angioplasty with stenting and distal protection device is covered for patients with significant carotid artery stenosis who have increased risk of surgical mortality from surgical carotid endarterectomy.

2) Stent placement for intrathoracic carotid arteries is considered investigational and is not covered.

Medical Policy Statement:

Carotid artery angioplasty with stenting and distal protection device is considered medically necessary for patients with:

- Carotid artery stenosis of 50% or greater who have evidence of central nervous system embolic disease who have increased risk of surgical mortality from surgical carotid endarterectomy. OR
- Carotid artery stenosis of 80% or greater who have increased risk of surgical mortality from surgical carotid endarterectomy.

Significant comorbid conditions include but are not limited to congestive heart failure, class III/IV; left ventricular ejection fraction of < 30%; unstable angina; contra lateral carotid occlusion; recent myocardial infarction; previous carotid endarterectomy with recurrent stenosis; and prior radiation treatment to neck.
Limits:

The following services are considered investigational because there is a lack of scientific evidence of effectiveness:

- Carotid angioplasty or carotid angioplasty with stenting (with or without distal protective device) for patients who do not meet the above criteria (because of increased morbidity compared to carotid endarterectomy or the procedure is the subject of ongoing clinical trials to determine safety and efficacy).
- Carotid artery stenting of the intrathoracic carotid artery.

Background:

Carotid angioplasty with or without associated stenting has been investigated as an alternative to carotid endarterectomy (CEA), currently considered the standard treatment for patients with significantly obstructing carotid atherosclerosis (stenosis). 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. Interventionalists almost uniformly use a distally placed embolic protection (DEP) device designed to reduce the risk of periprocedural stroke caused by thromboembolic material dislodged during CAS. Carotid angioplasty rarely is performed without stent placement.

Proposed advantages of CAS as opposed to carotid endarterectomy include:

- General anesthesia is not required (although CEA can be performed under local/regional anesthesia)
- Cranial nerve palsies are infrequent sequelae
- Simultaneous procedures may be performed on the coronary and carotid arteries

The U.S. Food and Drug Administration (FDA) has approved carotid artery stents and DEP devices from various manufacturers:

- ACCULINK™ and RX ACCULINK™ carotid stents and ACCUNET™ and RX ACCUNET™ cerebral protection filters, Guidant Corp. (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); and
- 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)
- ProtégéRx® and SpideRx®, ev3 Inc, Arterial Evolution Technology. (approved January 2007)
- Carotid Wallstent®, Boston Scientific Corp. (approved October 2008); and

Each FDA-approved carotid stent system is indicated for combined use with a DEP device to reduce risk of stroke in patients at high risk for perisurgical complications from CEA who are symptomatic with >50% stenosis, or asymptomatic with >80% stenosis. Patients are considered at high risk for CEA complications if affected by any item from a list of anatomic features and comorbid conditions included in each stent system’s Information for Prescribers. CAS with these devices for patients outside those indications is an unlabeled use.

FDA-approved stents and DEP devices 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 (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.

References:


The SPACE Collaborative Group.(2006) 30 day results from the SPACE trial of stent protected angioplasty versus carotid endarterectomy in symptomatic patients. Lancet, 2006; 368:1239-47.


Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

Last modified by: Date: