

Cerebrovascular Interventions

A look at developments in physician reimbursement for cerebrovascular procedures over the last 20 years, including the latest CMS coverage updates.

BY ROSEANNE R. WHOLEY

The management of vascular disease is shifting toward less-invasive therapies. Physicians from interventional radiology, cardiology, vascular surgery, and other specialties have the expertise to perform endovascular procedures. Each vascular territory presents unique challenges.

Carotid artery angioplasty and stenting is an innovative procedure and is undergoing rapid change. Another area of intense investigation is the use of various protection devices and techniques to prevent embolization of debris. To understand the issues and reimbursement problems that have plagued the performance of these procedures, it is helpful to know more about the difficult journey.

HISTORY

As early as 1980, the Health Care Financing Administration (HCFA) Physicians Panel consensus was that percutaneous transluminal angioplasty (PTA) for noncoronary vessels was generally accepted and performed. There was no HCFA National Non-Coverage Policy. As a result, local Medicare intermediaries had discretion in determining coverage for these procedures. The trouble started in 1984 when, due to concerns regarding safety and efficacy, HCFA issued a National Non-Coverage Policy for PTA for the treatment of obstructive lesions of the aortic arch vessels. The policy was subsequently revised that year to cover obstructive lesions of a single coronary artery, the upper extremities (excluding head and neck vessels), the renal arteries, and arteriovenous dialysis fistulas and grafts.

The policy was revised again in 1993 to allow for the coverage of PTA for upper-extremity vessels, including the subclavian arteries, but concluded that PTA of the vessels for carotid, vertebral, and cerebral arteries remained investigational and, therefore, uncovered by Medicare.

In 1995, HCFA issued regulations related to Medicare coverage of certain devices with an investigational device exemption (IDE) approved by the FDA. HCFA permitted

“For 20 years, physicians have been trying to overturn the Medicare National Non-Payment Policy for carotid PTA and stenting.”

Medicare contractors to consider coverage on a local basis for category B devices with an IDE-approved clinical trial protocol. These devices and related services were to be covered by Medicare if all other applicable coverage requirements were met.

In 1997, the issue was analyzed by HCFA, and the conclusion was that the small, randomized studies lacked complete information and had limited outcomes and follow-up data. HCFA expressed their belief that the noncoverage policy should continue but that a randomized clinical trial would be the best mechanism for compiling data. It was decided that, due to the noncoverage status of the PTA, stents used during carotid PTA should not be covered either.

In July 2000, President Clinton issued a memorandum encouraging increased participation of Medicare beneficiaries in clinical trials. It explicitly authorized Medicare payment for routine patient care and costs due to complications associated with participation in clinical trials. On September 19, 2000, the Medicare Clinical Trials Coverage Policy went into effect. On December 18, 2000, HCFA internally generated a formal national coverage request for PTA of the carotid artery concurrent with stenting, which resulted in the conclusion that, as of July 1, 2001, Medicare would cover PTA of the carotid artery concurrent with stent placement when furnished in accordance with FDA-approved protocols governing category B, IDE-approved clinical trials. Performance of PTA in the carotid artery when used to treat obstructive lesions outside of approved protocols governing category B, IDE-approved

clinical trials remained a noncovered service. PTA of the vertebral and cerebral arteries also remained noncovered. There were no category I codes (CPT codes established by the American Medical Association (AMA) CPT editorial panel that have also gone through a formal valuation process) to describe the use of embolic protection devices. PTA of the carotid artery concurrent with stent placement was considered to be unproven in safety and efficacy and was, therefore, not covered.

PREVIOUS CPT CODES

Physicians performing carotid artery stenting as part of a clinical trial were required to report category III emerging technology codes that were set up for tracking the performance of the following procedures:

- 0005T Transcatheter placement extracranial cerebrovascular stent(s)—initial vessel
(This code includes the PTA procedure of the stented vessel and is reported one time regardless of the number of stents placed in the same vessel).
- 0006T Transcatheter placement extracranial cerebrovascular stent(s)—each additional vessel
- 0007T Supervision and interpretation of the above procedures (report separately for each vessel).

For claims processing, the physician had to provide the IDE number assigned by the FDA for the corresponding trial on the claim form.

NEW DEVELOPMENTS

On August 31, 2004, the FDA approved the Guidant RX Acculink Carotid Stent System (Indianapolis, IN) and RX Accunet Embolic Protection System, making it the first approved carotid artery stenting system in the US. The devices were approved for use in high-risk patients who have had neurologic symptoms referable to a carotid lesion of at least 50% or who have a carotid artery blockage of at least 80% but are asymptomatic, and who are not good candidates for endarterectomy. The FDA has recommended that physicians who use the device undergo special training; interventional physicians who are appropriately trained and credentialed may perform the procedures. They also recommended approval with conditions for the Cordis Precise Stent (a Johnson & Johnson company, Miami, FL) and AngioGuard Embolic Protection System.

On September 1, 2004, CMS announced its intention to expand coverage of PTA of the carotid artery with placement of an FDA-approved carotid stent to permit coverage for patients in a large FDA-mandated, postapproval

study for the newly approved device. With this new coverage decision, Medicare is able to pay for carotid stenting performed in these postapproval studies that are being overseen by the FDA. CMS is also evaluating a separate request for a broader coverage expansion of PTA of the carotid artery concurrent with stent placement for patients at high risk for carotid endarterectomy. The CMS evidence-based review will involve public comment on a draft coverage decision and is scheduled to be complete by early 2005. CMS expects to finalize this decision and begin coverage shortly after the end of the required 30-day public comment period. This should coincide with the expected start date of enrollment of the postapproval trial.

“Correct coding for procedures is the burden of the performing physician who bears all responsibility for the accuracy of the claims submitted for payment.”

NEW CPT CODES

In November 2004, the AMA Current Procedural Terminology (CPT) Editorial Panel released two new 2005 category I codes for carotid stenting, one with distal protection (37215) and one without (37216) because there may be times when distal protection cannot be successfully completed. These codes have replaced the old category III codes and have been implemented for use as of January 2005. Both new codes are inclusive of selective carotid access, diagnostic imaging of the ipsilateral carotid, and supervision and interpretation. These codes can be used when billing for carotid stent/embolic protection procedures using either an FDA-approved device reported on the claim form with a PMSS (Post Market Surveillance Study) number, or a nonapproved device in a category B, IDE-approved clinical trial reported on the claim form with an IDE number. These codes are also appropriately used in non-trial patients for carriers other than CMS that have elected to cover carotid artery stenting.

The description and reimbursement of the new carotid stenting CPT codes is as follows:

- 37215 Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous, with distal embolic protection. Work RVU 18.71
- 37216 Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous, without distal embolic protection. Work RVU 17.98

If a diagnostic study is performed and carotid stenting is not indicated, the usual interventional radiology codes would be reported, including codes for catheter placement, diagnostic imaging, and supervision and interpretation. For example, if a physician performed a simple selective diagnostic catheterization of the right and left common carotids along with bilateral cerebral and bilateral cervical angiograms without carotid stenting/embolic protection in a hospital setting, it would be coded as follows:

- 36216RT Selective second-order catheter placement, arterial, thoracic or brachiocephalic, right side
- 36215LT Selective first-order catheter placement, arterial, thoracic or brachiocephalic, left side
- 75671-26 Angiography, carotid, cerebral, bilateral, radiological supervision and interpretation
- 75680-26 Angiography, carotid, cervical, bilateral, radiological supervision and interpretation

However, if the same bilateral diagnostic procedure were performed along with carotid stenting using embolic protection on the left side, the new bundled carotid stent code 36215-LT would be the only code used for the intervention. The diagnostic procedure performed on the right side would be coded as a unilateral cerebral and cervical angiogram as per the following:

- 37215-LT Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous, with distal embolic protection (includes catheterization, angiography, stent placement, PTA, EPD, follow-up images, and radiological supervision and interpretation of the entire procedure related to the left carotid system)
- 36216-RT Selective second-order catheter placement, arterial, thoracic or brachiocephalic, right side
- 75665-26 Angiography, carotid, cerebral, unilateral, radiological supervision and interpretation
- 75676-26 Angiography, carotid, cervical, unilateral, radiological supervision and interpretation

In July 2004, the AMA issued an early release of new 2005 category III codes describing non-FDA-approved carotid stent procedures that start their temporary tenure as of January 1, 2005. The category III codes previously used to describe carotid stenting have been deleted. New category III codes have been developed to describe carotid and vertebral artery stenting in anatomical sites that were not included in the national clinical research trials that have studied carotid stenting to date. The new category III

codes have also been structured to parallel the “bundled” codes approved for cervical carotid stenting approved for 2005. These new codes will allow for the collection of data for the following services:

- 0075T Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous, and initial vessel
- 0076T Each additional vessel (listed separately in addition to the code for the primary procedure).

If a category III code is available, this code must be used instead of an unlisted category I code (eg, 37799 unlisted procedure, vascular surgery). Recognition of category III codes is still not universal, and coding of these procedures may continue to have some carrier-dependency. Providers will need to check with the carrier prior to billing for these procedures. Because there are no relative value units assigned to these tracking codes, payment for these services is based on the policies of the payors and not on a yearly fee schedule. Providers should communicate with each carrier to determine level of payment for these codes. These procedures will be coded with category III codes until sufficient evidence is available to justify application for category I codes.

CONCLUSION

For 20 years, physicians have been trying to overturn the Medicare National Non-Payment Policy for carotid PTA and stenting. It appears as if there is a light at the end of the tunnel, but it is important to note that we are still operating under the National Non-Coverage Policy because it has not yet been lifted.

Correct coding for procedures is the burden of the performing physician who bears all responsibility for the accuracy of the claims submitted for payment. Physicians have been forced to become more knowledgeable about coding issues as well as the regulations of insurance carriers. Therefore, the provider should confirm payment policies with the various payor plans with regard to coding issues and remain educated regarding all policy changes such as those that have affected carotid stenting.

The good news is that patients who are considered to be at high surgical risk for a carotid endarterectomy may now have a minimally invasive alternative. This has been a remarkably complex journey for everyone involved. ■

Roseanne R. Wholey is the President of Roseanne R. Wholey and Associates, Pittsburgh, Pennsylvania. She may be reached at (412) 828-7010; rawholey@aol.com.