

CMS Proposes Expanded Carotid Stenting Coverage

BY MARY ELLEN SCHNEIDER
New York Bureau

Officials at the Centers for Medicare and Medicaid Services are proposing to expand coverage for carotid artery stenting to patients younger than 80 years old who are at high risk for carotid endarterectomy and have asymptomatic carotid artery stenosis of 80% or greater.

Under the proposed national coverage determination, a surgeon would perform a consultation to ascertain a patient's high-risk status.

The proposal also spells out coverage for patients 80 years of age and older with either symptomatic stenosis of 70% or greater or asymptomatic stenosis of 80% or greater. Because of safety concerns, carotid artery stenting would be allowed in this group only when it is performed in a Food and Drug Administration Category B Investigational Device Exemption trial, an FDA-approved postapproval study, or under Medicare clinical trial policy.

If finalized the proposal would replace the current CMS coverage policy under which patients at high risk for carotid endarterectomy (CEA) with asymptomatic carotid artery stenosis of greater than 80% can be covered only when carotid artery stenting procedures are performed in an FDA Category B Investigational Device Exemption trial, an FDA-approved postapproval study, or in accordance with Medicare clinical trial policy.

"CMS is committed to providing broader access to appropriate and innovative care to our beneficiaries in the management of their carotid artery disease," Leslie Norwalk, acting CMS administrator, said in a statement.

Over the last 6 years, CMS officials have expanded coverage of percutaneous transluminal angioplasty and carotid artery stenting in three separate national coverage decisions. Most recently, in No-

vember 2006, CMS established Medicare coverage for percutaneous transluminal angioplasty and stenting of intracranial vessels for the treatment of cerebral artery stenosis of 50% or greater in patients with intracranial atherosclerotic disease as part of an FDA-approved Category B clinical trial.

In proposing the expansion of coverage for patients with asymptomatic carotid artery stenosis, CMS relied on evidence

from external and internal technology assessments, clinical reviews, and postapproval studies.

Two postapproval studies (CAPTURE and CAS-ES-PMS) showed that carotid artery stenting outcomes were similar by provider experience and in settings outside clinical trials. The trials also did not raise safety concerns about carotid artery stenting in asymptomatic patients with stenosis of 80% or greater,

according to CMS.

CMS officials concluded that the evidence is "sufficient" to find that percutaneous transluminal angioplasty with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery and have asymptomatic carotid artery stenosis of 80% or greater. However, carotid artery stenting is not covered in the absence of distal embolic protection, even when technical difficulties prevent it from being deployed, according to CMS.

The American Association of Neurological Surgeons was still reviewing the proposed coverage decision at press time. However, in comments to CMS in 2004, the group raised concerns about expanding Medicare coverage for carotid stenting to asymptomatic patients. At that time, the group said that the available data suggested that carotid angioplasty and stenting may be inferior to medical treatment for the prevention of stroke in asymptomatic patients.

At press time, the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions (SCAI) were both also reviewing the CMS coverage proposal. However, Dr. Michael J. Cowley, cochair of the carotid and neurovascular interventions committee for SCAI, said he sees the expansion of coverage as a step in the right direction.

However, he expects that the SCAI committee may have concerns about some aspects of the proposal.

The proposed coverage expansion was also praised by Boston Scientific, which markets the NexStent Carotid Stent and the FilterWire EZ Embolic Protection System. However, the company also said it would like to see broader coverage for high-risk symptomatic patients.

CMS, which is reviewing public comments received prior to the March 3 deadline for comments, is expected to issue a final decision sometime in May. ■

National Provider Identifier Sign-Up Deadline is May 23

BY MARY ELLEN SCHNEIDER
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The clock is ticking for physicians to sign up for a National Provider Identifier, the new 10-digit number that will be used by Medicare, Medicaid, and many private health plans to process claims.

The deadline for registering for an NPI number is May 23.

Physicians who are not using an NPI after that date could experience cash flow disruptions, according to the Centers for Medicare and Medicaid Services.

The transition to a single identifier that can be used across health plans is required under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. Most health plans and all health care clearinghouses must begin using NPIs to process physicians' claims in standard transactions by May 23. Small health plans have another year to become compliant.

"The NPI is the new standard identifying number for all healthcare billing transactions, not just for billing Medicare or Medicaid. National standards like the NPI will make electronic data exchanges a viable and preferable alternative to paper processing for healthcare providers and health plans alike," said Aaron Hase, a CMS spokesman.

As of Jan. 29, more than 1.6 million NPIs had been assigned, according to CMS.

Physicians and other health care providers can apply for an NPI online or by using a paper application. In addition, organizations like hospitals or profes-

sional associations can submit applications for several physicians in an electronic file.

Officials at CMS are urging physicians who haven't yet signed up to do so soon. A physician who submits a properly completed electronic application could have his or her NPI in 10 days. However, it can take 120 days to do the remaining work to use it, Mr. Hase said. The preparation includes working on internal billing systems; coordinating with billing services, vendors, and clearinghouses; and testing the new identifier with payers, he said.

So far, the process of obtaining an NPI has been relatively easy, said Brian Whitman, senior analyst for regulatory and insurer affairs at the American College of Physicians. The application process itself takes only about 10 minutes, he said.

But one thing to be aware of is that you may already have an NPI. Because some large employers may have already registered their providers, physicians may be surprised to learn that they already have a number, Mr. Whitman said.

As the May deadline approaches and more and more physicians get registered, the next question is how widely CMS plans to disseminate the NPIs. CMS officials have said they are considering creating some type of directory of NPIs that could be available to physicians and office staff. ■

Physicians can apply for an NPI online at <https://nppes.cms.hhs.gov> or call 800-465-3203 to request a paper application.

Could Facial Capture Software Be The Next Patient Safety Technology?

WASHINGTON — Electronic bar codes and radiofrequency microchips are all the rage in medical error prevention, but one research team thinks avoiding mistakes may be as easy as snapping a photo.

Researchers with the MedStar Health network here are experimenting with facial-capture software that they say could quickly and inexpensively help busy nurses and physicians avoid mistakes.

The software can pick human faces out of any photo image in less than a second. It's tied into a \$120 Web camera mounted behind the nurse's triage desk, and anyone who approaches the desk automatically has his or her face captured.

Nurses "don't have to pick up a camera, they don't have to make them say cheese, they don't have to put them in a special location. All they have to do is click on the patient's face," Dr. Michael Gillam, director of the Medical Media Lab at MedStar, said at the annual symposium of the American Medical Informatics Association. "The problem with a bar code is that it's not human readable," Dr. Gillam said in an interview.

MedStar developers say their software

could be used to tack the right face to any medication order, blood product, or device before it goes into a patient.

"Anyone can look and see that that blood doesn't match, because that's not the right person," Dr. Gillam said.

The Medical Media Lab tested the software prototype and found that it captured the smiling faces of all 22 racially diverse adults who approached a MedStar triage desk. But the system has yet to be put into practice to see if it really enhances patient safety.

Dr. Gillam said the automatic system could be especially useful in overwhelmed emergency departments. "Suddenly 30 patients show up ... at one time from a bus accident. You can imagine trying to take each picture," he said.

But as with most identity technology, privacy is a concern. After all, no one wants to have his or her face on permanent file simply for asking directions to the rest room. Dr. Gillam said that although the system would photograph all comers, images are quickly erased if nurses don't attach them to a medical record.

—Todd Zwillich

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