



CMS Coverage

of Carotid Artery Stenting

Marcel E. Salive, MD, Director, Division of Medical and Surgical Services at CMS, discusses the current status of Medicare reimbursement coverage for CAS.

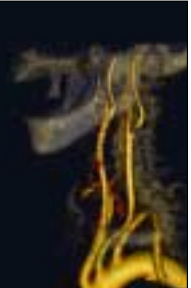
On August 17, 2004, the Centers for Medicare & Medicaid Services (CMS) held a Town Hall Meeting at its facility in Baltimore, Maryland, regarding potential facility qualifications for carotid artery stenting (CAS) procedures. The stated purpose of the meeting was to elicit information on the appropriate experience requirements for facilities intending to offer CAS procedures, suggestions for training programs, and limitations to ensure appropriate use of this procedure.

On September 1, 2004, CMS announced its intention to expand coverage of percutaneous transluminal angioplasty (PTA) of the carotid artery with placement of Guidant's (Indianapolis, IN) newly approved carotid stent system to permit coverage for participants in a large FDA-mandated postapproval study.

CMS stated that the purpose of the study is to produce data that will indicate which patients are most likely to benefit from the procedure and to develop information on which clinical practices are associated with the best outcomes when using the system. The postapproval studies are also designed to provide an understanding of whether the results of earlier trials used for FDA approval can be generalized to other populations, settings, treatment regimens, and outcomes.

Endovascular Today: Does this announcement cover reimbursement solely for the postmarket surveillance studies?

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Marcel Salive, MD: Yes.

EVT: What is the plan with respect to items that are not part of the postmarket surveillance?

MS: We are continuing to look at the broader issue. We expect to complete that in the next several months and then post a draft decision that can be commented upon and implemented about 3 months after the draft is posted.

EVT: So, this is only a draft announcement?

MS: Yes. It's our new process for coverage decisions that the Congress mandated in the Medicare Modernization Act: to issue a draft decision for public comment for 30 days and then finalize it within 3 months.

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EVT: What is the process with respect to procedures that are performed during the time period while this announcement has not been finalized? Are they reimbursed, or does that reimbursement not begin until after that final announcement?

MS: When we issue the final instruction, the procedures can be reimbursed. We currently have a policy of noncoverage, and we would have to issue those final instructions to alter that noncoverage to cover most approvable studies.

EVT: Will it only affect procedures from the date of the final announcement, or will it affect those procedures performed during the time period from now until then?

MS: We don't issue retroactive instructions. We issue forward-looking instructions.

EVT: So at present, the noncoverage will still be in place until such time as there is a final judgement there?

MS: Yes, but we understand that the study is not yet started so there is a little bit of leg work that the study has to go through. They have other hurdles that they have to pass. They have IRB approvals and other investigator training that they have to do.

EVT: What is an IRB approval?

MS: An IRB is an ethical review by the institutional review board and the institution participating in these postapproval studies. Most research studies are required to go through IRB review.

EVT: How are compassionate and emergency use cases addressed in the context of something like this? Obviously, they are outside the high-risk criteria but if the FDA approves someone for compassionate use, under the CMS guidelines, are they still considered to be part of the reimbursement group?

MS: Well, we have a noncoverage decision on this, and it is fairly tight. Frankly, we haven't heard of compassionate use of this device.

EVT: Does CMS plan to address accreditation guidelines in the context of its final decision?

MS: Certainly, that is the reason that we had the town hall meeting, and we're reviewing and considering all of the input we received during that as part of this coverage analysis.

EVT: Is that something that has been unique to carotid stenting? Has the CMS previously discussed accreditation in terms of approval for other procedures?

MS: Yes. We've considered facility issues for other coverage decisions for treatments such as the lung volume reduction surgery and the implantation of a left ventricular-assist device for end-stage congestive heart failure.

EVT: What type of facility issues did they involve?

MS: The capabilities to perform surgery, members of the team, and experience in the procedure were some of the topics we considered in those prior issues.

EVT: So it wasn't purely an equipment decision. It actually gets into the faculty's level of expertise?

MS: Yes.

CMS expects to finalize its 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. To view the proposed coverage policy in its entirety, please visit www.cms.hhs.gov/coverage. ■

Marcel E. Salive, MD, is Director, Division of Medical and Surgical Services at CMS. He may be reached at msalive@cms.hhs.gov.