

# FDA Expands Indication for CAS

BY THE ENDOVASCULAR TODAY STAFF  
WITH COMMENTARY FROM WILLIAM A. GRAY, MD

**A**bbott Vascular (Santa Clara, CA) announced that the US Food and Drug Administration (FDA) expanded the approval of the RX Acculink carotid stent system for use in the endovascular treatment of patients with carotid artery disease who are at standard risk for adverse events from carotid endarterectomy (CEA). RX Acculink was previously indicated for patients at high risk for adverse events from surgery. RX Acculink is intended for use with the RX Accunet embolic protection system.

According to the company, this expanded indication is supported by the results of the CREST (Carotid Revascularization Endarterectomy Versus Stenting Trial) study, which the company submitted to the FDA. CREST is

the largest prospective study conducted to date comparing carotid artery stenting (CAS) to CEA. CREST was sponsored by the National Institute of Neurological Disorders and Stroke, part of the National Institutes of Health, and was partially funded by Abbott. The trial demonstrated that CAS and CEA had similar safety and long-term outcomes for standard-risk patients with symptomatic and asymptomatic carotid artery disease.

Abbott stated that it intends to seek expanded Medicare coverage for CAS based on the CREST results. In addition, the company plans to initiate a postapproval study of the RX Acculink carotid stent system in patients at standard surgical risk later this year. The study is planned to assess clinical outcomes at 30 days and annually for 3 years. ■

## COMMENTARY



### What does the expanded indication mean for CAS?

In general, this is a large accomplishment for a therapy that, in its dedicated form (embolic protection devices and nitinol stents), has been around for less than a decade and has matched a 60-year-old surgical alternative—in a very difficult political and reimbursement environment.

### What does it mean for other approved carotid stents?

The approval gives Abbott another indication (standard risk patients) for which they can market the stent. Although other stent manufacturers have approval for stents in high-surgical-risk patients, they will not be permitted to promote them for the standard-risk population because it would be off-label.

### What do you think CMS will do and when?

Given the results of CREST (a \$50 million NINDS/NIH trial), which is prototypical of the type of evidence-based medicine that has been so prominently promoted in this and other countries, along with the accompanying FDA approval and recent multisociety guidelines that have

endorsed CAS as an acceptable alternative to CEA, I am hopeful that CMS will understand the imperative to give patients and their treating physicians the choice as to the accepted carotid treatment they receive and not have therapeutic limitations imposed from a federal level.

Coverage becomes a public health issue given that there are clearly ways of using CEA and CAS in a complementary fashion to reduce procedural complications and therefore increase the overall benefit to the at-risk population.

There will likely be a request to CMS to reopen the coverage decision this summer, and from that point forward, there is a 9-month process period allowed by Congress. It is not usually shorter.

*William A. Gray, MD, is Associate Professor of Clinical Medicine and Director of Endovascular Services, Center for Interventional Vascular Therapy, New York-Presbyterian Hospital/Columbia University Medical Center in New York. He has disclosed that he participated in the CREST trial as a Principal Investigator and as a member of the International Management Committee and that he is a paid consultant to Abbott Vascular. Dr. Gray may be reached at wg2131@columbia.edu.*