



For Immediate Release

STS, ACC Receive FDA Approval for IDE to Study Alternative Access for TAVR

IDE Study Will be Performed in STS/ACC TVT Registry

STS Press Release

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CHICAGO—The Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) have received a unique investigational device exemption (IDE) from the U.S. Food and Drug Administration (FDA) to study “alternative access” approaches for transcatheter aortic valve replacement (TAVR) using the STS/ACC TVT Registry™. The IDE is believed to be a first for any medical specialty society.

TAVR is a minimally invasive catheter-based option available to patients with aortic stenosis who are deemed inoperable or at high risk during conventional surgical therapy.

Currently, only the transfemoral (via the leg) approach to TAVR using the Edwards SAPIEN valve has been approved for inoperable patients. Both the transfemoral and apical approaches (via the heart muscle) have been approved for high risk patients. An estimated 1 in 4 patients is ineligible for these procedures because of inadequate vessel size, vessel disease, or other considerations. The new STS/ACC study protocol, as approved by CMS, allows Medicare reimbursement for alternative access to the aortic valve via the heart muscle or the aorta (transaortic approach) in inoperable patients involved in the study.

“The goal of this study is controlled off-label use of an approved device,” said Michael Mack, MD, Past President of STS and Chair of the STS/ACC TVT Registry Steering Committee. “Specifically, we hope to gain complete and accurate information regarding off-label use that may ultimately lead to label expansion. The IDE approval represents the next step in the collaboration among professional societies, CMS, the FDA, and medical device manufacturers that resulted in the STS/ACC TVT Registry. The process required all parties to be flexible and innovative while navigating these ‘uncharted waters.’ This is an iterative process that we hope will allow the safe and timely introduction of new medical device technology to our patients.”

The trial will be conducted in the TVT Registry, and the 180 sites currently using the TVT Registry will have the opportunity to participate.

“The collaboration and use of registries for research in this pilot can be a model for specialty societies, industry and federal regulators,” said ACC President William Zoghbi, MD, FACC. “We have aligned our efforts to ensure patient access to a new technology in a safe and cost-effective way.”

Last year, STS and the ACC worked collaboratively with the FDA and the Centers for Medicare & Medicaid Services (CMS) to streamline the approach required for device approval and subsequent Medicare coverage for TAVR through a National Coverage Determination (NCD), a process that STS Immediate Past President Jeffrey B. Rich, MD described as a “phenomenal” effort by everyone involved.

Dr. Rich added that the NCD helps to ensure the best care for patients because the “pre-operative evaluation, inter-operative deployment of the valve, and post-operative care must be jointly shared by cardiologists and cardiothoracic surgeons, utilizing the heart team approach.”

The TAVR NCD requires that a treating heart team and hospital participate in a prospective, national, audited registry that consecutively enrolls TAVR patients, accepts all manufactured devices, follows patient outcomes for at least 1 year, and complies with relevant patient privacy protections.

“Using registries for this kind of study has the potential to make new technology available in a timely manner while protecting patient safety,” said ACC Immediate Past President David Holmes.

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About The Society of Thoracic Surgeons

Founded in 1964, STS is a not-for-profit organization representing more than 6,600 cardiothoracic surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. The Society’s mission is to enhance the ability of cardiothoracic surgeons to provide the highest quality care through education, research and advocacy.

www.sts.org

About the American College of Cardiology

The mission of the American College of Cardiology is to transform cardiovascular care and improve heart health. The College is a 40,000-member medical society comprised of physicians, surgeons, nurses, physician assistants, pharmacists and practice managers. The College is a leader in the formulation of health policy, standards and guidelines. The ACC provides professional education, operates national registries to measure and improve quality of care, disseminates cardiovascular research, and bestows credentials upon cardiovascular specialists who meet stringent qualifications. For more information, visit www.cardiosource.org/ACC.

About The STS/ACC TVT Registry™

The TVT Registry is a benchmarking tool developed to track patient safety and real-world outcomes related to the TAVR procedure. Created by STS and ACC, the TVT Registry is designed to monitor the safety and efficacy of TAVR for the treatment of aortic stenosis. www.tvtregistry.org