

TAVR!

WHAT IT IS, WHO IT HELPS, AND HOW TO GET PAID FOR IT

WHAT IS IT?

Transcatheter Aortic Valve Replacement, or TAVR, has been on the rise as a treatment option for patients suffering from senile aortic valve stenosis in the United States following the PARTNER trial's successful deployment of the Edwards Sapien Aortic Valve among nonsurgical candidates in 2010. The minimally invasive treatment delivers an artificial valve into the heart through a catheter. The collapsed valve is then inflated using a balloon inside the native valve, where it resumes the work the narrowed valve can no longer perform almost immediately. Although higher rates of stroke and aortic insufficiency are seen in conjunction with TAVR, the procedure provides an alternative for patients deemed inoperable or high risk by a multidisciplinary team of practitioners.

TAVR relies heavily on echocardiography to provide the most accurate view of heart valves from diagnosis to post-procedure.

Although cardiac catheterization was traditionally considered to be the most appropriate technique for quantifying aortic stenosis, it has been eclipsed by Doppler echocardiography as the gold standard for identifying aortic stenosis over the course of the past decade; this is owing in part to the convenience and widespread applicability of transthoracic echocardiograms (TTE). Echocardiography enables physicians to assess the anatomy of the valve, to quantify the severity of the stenosis and calculate the size of the aortic valve area, and to determine whether the valve leaks, all before the procedure begins. Physicians typically use 3-dimensional TTE or, when image quality is suboptimal, transesophageal echocardiography (TEE), to perform this preprocedural diagnostic workup of patients with AS.



WHY IS THIS CONDITION ON THE RISE?

Senile aortic valve stenosis is a degenerative disease that affects the elderly. Approximately 300,000 patients in the United States have aortic stenosis, and nearly 30% of these are too old or have too many comorbidities to survive surgical replacement. As the average age of populations in the developed world rises, these numbers will increase. Because TAVR is a less invasive approach than open heart surgery, it provides hope for this growing older cohort.



WHO PERFORMS TAVR?

Because the preprocedural evaluations necessary to determine whether a patient is a candidate for TAVR are complex, a heart team is required to provide interdisciplinary care and expertise. According to Centers for Medicare and Medicaid Services regulations, this team must include a cardiovascular surgeon who has performed a high volume of Aortic Valve Replacements, an interventional cardiologist with vast experience in structural heart disease procedures, echocardiographers and imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers. Each member of the team must have received device-specific training from the manufacturer.

WHAT ARE THE CURRENT RULES ON MEDICARE AND MEDICAID REIMBURSEMENT FOR TAVR PROCEDURES?

On May 1st, 2012, the Center for Medicare and Medicaid Services (CMS) determined that it would cover TAVR under the Coverage with Evidence Development. This development is used for procedures that are not considered “reasonable and necessary for the diagnosis or treatment of illness” under typical national coverage determinations; this statutory provision is often used for novel techniques that would traditionally lack sufficient medical and scientific evidence required for them to qualify for Medicare payment. This victory followed a National Coverage Decision request from the American College of Cardiology (ACC) and the Society of Thoracic Surgeons (STS) in late 2011.

In order to receive Medicare/Medicaid coverage for TAVR, a series of conditions must be met.

These include the following «

- ♥ The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval for that system’s FDA approved indication
- ♥ Two cardiac surgeons have independently examined the patient face-to-face and evaluated the patient’s suitability for open aortic valve replacement surgery; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.
- ♥ The patient (preoperatively and postoperatively) is under the care of a heart team.
- ♥ The heart team’s interventional cardiologist(s) and the cardiac surgeon(s) must jointly participate in the intraoperative technical aspects of TAVR.
- ♥ The heart team and hospital participate in a prospective, national, audited registry that consecutively enrolls TAVR patients, accepts all manufactured devices, follows the patient for at least 1 year and complies with regulations for protecting human research subjects. *Currently, the only FDA-approved transcatheter valve is manufactured by Edwards.*

WHAT CRITICISMS DO THESE REQUIREMENTS ELICIT FROM PHYSICIANS, AND WHAT EFFECT MIGHT THEY HAVE ON PATIENT CARE?

Some physicians feel that the minimum experience the heart team must meet in order to participate in a Medicare-covered TAVR program will restrict access to TAVR too severely, preventing sick patients from accessing this life-saving procedure. These critics view the stipulation that interventional cardiologists must have performed 50 TAVR procedures as an arbitrary requirement that does little to identify individuals who are capable of performing TAVR successfully. Conversely, proponents of the requirements feel that there are sufficient numbers of high-volume PCI physicians with long-term experience in structural interventions who will meet the CMS requirements that there will not be holes in access to TAVR across the country. Proponents of these requirements include ASE advocacy committee chair David Wiener, MD, FASE who writes:

ASE supports the emphasis on quality which is embodied in CMS’ decision on TAVR. The TAVR team approach is in line with the latest guidelines for surgical and percutaneous interventions promulgated by our sister cardiovascular societies. ASE also affirms the concept that specific numbers of procedures must be performed in order to achieve and maintain competence, an idea that permeates the medical literature as well as ASE’s own guidelines. We further endorse the requirement to enroll patients in a registry, as registries allow quality to be judged on clinical rather than claims data, and provide a fruitful source for future research.

THESE SENTIMENTS ARE ECHOED BY ASE ADVOCACY COMMITTEE MEMBER MICHAEL MAIN, MD, FASE WHO WRITES:

I believe the CMS heart team and operator experience requirements for TAVR are well-founded and will maximize the prospects for positive patient outcomes. Patient candidates for TAVR are extremely complex – elderly and frail, with multiple co-morbidities, and oftentimes difficult vascular access issues. Appropriate patient selection and procedural success are dependent on multi-disciplinary collaboration amongst cardiac surgeons,

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interventional cardiologists, cardiac anesthesiologists, and echocardiographers. The current CMS requirements for TAVR in the only group so far approved for commercial use (patients with severe symptomatic aortic stenosis who are deemed inoperable) nicely balance patient safety and access to care issues.



As these informed opinions illustrate, finding a balance between establishing a high level of expertise required for those performing this complicated procedure while allowing new startup sites to qualify to perform TAVR is both complex and nuanced. Indeed, in a recent interview with *Cardiac Interventions Today*, Ted E. Feldman, MD, director of the Cardiac Catheterization Laboratory at Evanston Hospital in Evanston, IL, sums up the issue in saying:

The fundamental question is, how many sites in the United States can be sustained with current indications for the procedure? At the extreme, it is clear that we cannot have all 1,000-plus cath and surgery programs doing TAVR and expect operators to maintain volumes that are adequate to keep them performing at a highly confident level. At the other end, we cannot have criteria that are so restrictive that the procedure is not available.^[i]

The efficacy of surgery programs performing TAVR to provide insight into clinical practice patterns and patient outcomes under the CMS's requirements will be monitored through registry participation.

HOW WILL THE CMS'S APPROVAL CRITERIA IMPROVE PATIENT CARE?

The requirement that a heart team work in concert to prepare for, perform, and monitor TAVR pre-, peri-, and postoperatively will ensure the best outcome for patients undergoing this procedure. This model of providing care is particularly appealing to those who are eager to see formal collaboration between practitioners with different areas of expertise rather than a turf war. Experts suggest that there is tangible benefit in having representatives of different specialties work together in the evaluation and treatment of patients with AS. The multidisciplinary approach the CMS requires is appropriate to a procedure as complex as TAVR, especially in patients with numerous comorbidities.



WHAT'S NEXT FOR TAVR?

Under current CMS regulations, reimbursement for TAVR is only approved for inoperable patients. On June 13th of this year, however, the FDA's Circulatory Systems Device Panel voted 11-0 with 1 abstention to recommend the Edwards SAPIEN valve for approval in high-risk surgical aortic valve replacement candidates. If the FDA adopts this recommendation, which, in all likelihood it will, the Edwards SAPIEN valve will be approved for candidates who face a >15% risk of mortality from surgical AVR. The FDA will decide whether to follow the recommendation in the next several months. ASE will be monitoring this issue closely and will keep you informed.

The PARTNER 2 trial is currently underway at 50 sites nationwide to evaluate the success of TAVR in intermediate risk patients (> 4% risk of mortality from surgical AVR). Results from this trial could be available as early as December 2014.

Additionally, a series of new valves are currently in trial both in the United States and abroad. Valves from Medtronic (CoreValve®), St. Jude Medical (Portico), and Direct Flow Medical (DFM) are currently under development domestically. These 2nd and 3rd generation valves theoretically present a number of advantages over the SAPIEN valve that will help to improve patient outcomes: first, the valves under development have a lower delivery profile (18 French catheter vs. the 22 French catheter that is commercially approved). Second, the new valves are repositionable, ensuring that they are accurately placed. Third, these valves incorporate a variety of mechanisms to limit paravalvular leakage, helping to eliminate insufficiency, which remains a primary shortcoming of today's equipment. TAVR technology and the skills of those who perform it will continue to grow in effectiveness and ability, making this procedure the appropriate option for an increasing number of patients. ♥

[i] "The TAVR National Coverage Decision: How will this record announcement affect your patients and practice?" *Cardiac Interventions Today*. June 2012.