Transcatheter Aortic Valve Replacement

Indications for Use

The Edwards SAPIEN Transcatheter Heart Valve (THV), sizes 23mm and 26mm, is currently indicated for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis who have been determined to be inoperable for open aortic valve replacement and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis.

Contraindications

The bioprosthesis and delivery system are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

CMS Coverage

The Centers for Medicare & Medicaid Services (CMS) covers transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED) for the treatment of symptomatic aortic valve stenosis when all of the following conditions are met:

- The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) 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 (AVR) 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 cohesive and multi-disciplinary heart team.
About the Complex Heart Valve Service at OHSU

The Complex Heart Valve Service at OHSU offers high quality care for patients with advanced heart valve disease. Our multidisciplinary team is composed of sub-specialty cardiologists and cardiac surgeons with special expertise in valvular heart disease. The heart valve team extends into the OHSU hospital system, where cardiovascular anesthesiologists, cardiac nurses, and critical care specialists all work together to care for patients with valvular heart disease. Throughout the clinic visits, hospitalization or procedures, we are committed to keeping the patients’ primary care physician and primary cardiologist up to date.

We care for high-risk patients and/or those who require complex care or who have existing health concerns in addition to cardiac issues. An interventional cardiologist and cardiac surgeon see patients jointly, along with an on-site heart valve team that includes ICU, cardiothoracic surgery, cardiac imaging and cardiac anesthesia. Having relevant specialties all in one place allows the team to formulate a patient’s treatment plan within a single visit, which is then communicated to the patients and referring providers. A patient care coordinator manages patient appointments.

OHSU’s Heart Valve Team

Coordinated, state-of-the-art multidisciplinary evaluation and care provided by disciplines including cardiac surgery, interventional cardiology, cardiac imaging and interventional radiology.

- Saurabh Gupta, M.D., FACC
- Matt Slater, M.D.
- Joaquin Cigarroa, M.D.
- Howard Song, M.D.
- Steve Heitner, M.D.
- Kevin Wei, M.D.