Protocol

Transcatheter Aortic Valve Implantation for Aortic Stenosis

(701132)

Medical Benefit		**Effective Date**: 04/01/14	**Next Review Date**: 01/15
Preauthorization	Yes	**Review Dates**: 03/12, 01/13, 01/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Transcatheter aortic valve implantation (TAVI; also known as transcatheter aortic valve replacement or TAVR) is a potential alternative treatment for patients with severe aortic stenosis. Many patients with aortic stenosis are very elderly and/or have multiple medical comorbidities, thus indicating a high, often prohibitive, risk for surgery. This procedure is being evaluated as an alternative to open surgery for high-risk patients with aortic stenosis and as an alternative to nonsurgical therapy for patients with a prohibitive risk for surgery.

Background

Aortic stenosis. Aortic stenosis is defined as narrowing of the aortic valve opening, resulting in obstruction of blood flow from the left ventricle into the ascending aorta. Progressive calcification of the aortic valve is the most common etiology in North America and Europe, while rheumatic fever is the most common etiology in developing countries. (1) Congenital abnormalities of the aortic valve, most commonly a bicuspid valve, increase the risk for aortic stenosis, but aortic stenosis can also occur in a normal aortic valve. Risk factors for calcification of a congenitally normal valve mirror those for atherosclerotic vascular disease, including advanced age, male gender, smoking, hypertension, and hyperlipidemia. (1) Thus, the pathogenesis of calcific aortic stenosis is thought to be similar to that of atherosclerosis, i.e., deposition of atherogenic lipids and infiltration of inflammatory cells, followed by progressive calcification.

The natural history of aortic stenosis involves a long asymptomatic period, with slowly progressive narrowing of the valve until the stenosis reaches the severe stage. At this time, symptoms of dyspnea, chest pain, and/or dizziness/syncope often occur and the disorder progresses rapidly. Treatment of aortic stenosis is primarily surgical, involving replacement of the diseased valve with a bio-prosthetic or mechanical valve by open heart surgery.

Burden of illness. Aortic stenosis is a relatively common disorder of elderly patients and is the most common acquired valve disorder in the U.S. Approximately 2-4% of individuals older than 65 years of age have evidence of significant aortic stenosis, (1) increasing up to 8% of individuals by age 85 years. (2) In the Helsinki Aging Study, a population-based study of 501 patients aged 75-86 years, the prevalence of severe aortic stenosis by echocardiography was estimated to be 2.9%. (3) In the U.S., more than 50,000 aortic valve replacements are performed annually due to severe aortic stenosis.

Aortic stenosis does not cause substantial morbidity or mortality when the disease is mild or moderate in severity. By the time it reaches the severe stage, there is an untreated mortality rate of approximately 50% within two years. (4) Open surgical repair is an effective treatment for reversing aortic stenosis, and artificial valves have demonstrated good durability for periods of up to 20 years. (4) However, these benefits are

accompanied by a perioperative mortality of approximately 3-4% and substantial morbidity, (4) both of which increase with advancing age.

Unmet needs. Many patients with severe, symptomatic aortic stenosis are poor operative candidates. Approximately 30% of patients presenting with severe aortic stenosis do not undergo open surgery due to factors such as advanced age, advanced left ventricular dysfunction, or multiple medical comorbidities. (5) For patients who are not surgical candidates, medical therapy can partially alleviate the symptoms of aortic stenosis but does not affect the underlying disease progression. Percutaneous balloon valvuloplasty can be performed, but this procedure has less than optimal outcomes. (6) Balloon valvuloplasty can improve symptoms and increase flow across the stenotic valve but is associated with high rates of complications such as stroke, myocardial infarction (MI), and aortic regurgitation. In addition, restenosis can occur rapidly, and there is no improvement in mortality. As a result, there is a large unmet need for less invasive treatments for aortic stenosis in patients who are at increased risk for open surgery.

Transcatheter aortic valve implantation (TAVI). TAVI has been developed in response to this unmet need and is intended as an alternative treatment for patients in whom surgery is not an option due to prohibitive surgical risk or for patients who are at high risk for open surgery. The procedure is performed percutaneously, most often through the transfemoral artery approach. It can also be done through the subclavian artery approach and transapically using mediastinoscopy. Balloon valvuloplasty is first performed in order to open up the stenotic area. This is followed by passage of a bioprosthetic artificial valve across the native aortic valve. The valve is initially compressed to allow passage across the native valve and is then expanded and secured to the underlying aortic-valve annulus. The procedure is performed on the beating heart without the need for cardiopulmonary bypass.

There are at least two transcatheter aortic valve devices being tested. The Edwards SAPIEN heart-valve system™ (Edwards Lifesciences, Irvine, CA) is a tri-leaflet bioprosthetic porcine valve that is contained within a stainless steel frame. This device has been commercially available in Europe since 2007 but has not yet received U.S. Food and Drug Administration (FDA) approval in the U.S. There is currently a next generation version of this valve in testing, called the SAPIEN XT™ (Edwards Lifesciences, Irvine, CA), which has been redesigned with the intention of reducing procedural complications.

The Medtronic CoreValve ReValving System™ is a second transcatheter valve system under testing. This device is a porcine bioprosthetic valve that is sewn within a self-expanding nitinol frame. It is inserted via the transfemoral artery approach and has also been inserted via the subclavian artery approach. This device has also been approved for use in Europe since 2007 but has not yet received FDA approval in the U.S.

Regulatory Status

The Sapien Transcatheter Heart Valve System™ (Edwards LifeSciences, Irvine, CA) received original FDA approval in November 2011 for patients with severe aortic stenosis who are not eligible for open-heart procedures and have a calcified aortic annulus. In 2012, an additional FDA premarket approval (PMA) was granted for the Edwards SAPIEN™ transcatheter heart valve Model 9000TFX (Edwards LifeSciences, Irvine, CA) with expanded indications for use. (7) Approval was granted for both the transfemoral and transapical approach. For the transfemoral approach, patient indications were broadened to include patients who are at high risk for open surgery. For the transapical approach, approval was granted for patients who are at high risk for open surgery. In September 2013, the FDA expanded the indications for the transapical approach to include both inoperable patients and patients who are at high risk for open surgery. (8) As a result, as of September 2013, the Sapien Transcatheter Heart Valve System™ is approved for both high risk and inoperable patients when used by either the transapical or transfemoral approach.

Policy (Formerly Corporate Medical Guideline)

Transcatheter aortic valve replacement, performed via the transfemoral or transapical approach, may be considered **medically necessary** for patients with aortic stenosis when all of the following conditions are present:

- Severe aortic stenosis (see Policy Guidelines) with a calcified aortic annulus
- NYHA [New York Heart Association] heart failure Class II, III or IV symptoms;
- Left ventricular ejection fraction > 20%; AND
- Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon); or patient is an operable candidate but is at high risk for open surgery (see Policy Guidelines).

Transcatheter aortic valve replacement is considered **investigational** for all other indications, including but not limited to:

- Patients with a degenerated bio-prosthetic valve ("Valve-in-Valve" implantation)
- Procedures performed via the transaxillary, transiliac, transaortic, or other approaches.

Policy Guideline

Severe aortic stenosis is defined by one or more of the following criteria:

- An aortic valve area of less than 0.8cm^2
- A mean aortic valve gradient greater than 40mm Hg
- A jet velocity greater than 4.0m/sec.

FDA definition of high risk for open surgery:

- Society of Thoracic Surgeons predicted operative risk score of $\geq$ 8% or higher; or
- Judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of $\geq$ 15% or higher for open surgery.

Medicare Advantage

Transcatheter aortic valve replacement (TAVR) may be **medically necessary** for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (FDA)-approved indication when all of the following conditions are met under under Coverage with Evidence Development (CED).

1. 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.
2. 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.
3. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.

TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:

a. On-site heart valve surgery program,

b. Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging,
c. Non-invasive imaging such as echocardiography, vascular ultrasound, computed tomography (CT) and magnetic resonance (MR),
d. Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications,
e. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart VALVE procedures,
f. Appropriate volume requirements per the applicable qualifications below.

There are two sets of qualifications; the first set outlined below is for hospital programs and heart teams without previous TAVR experience and the second set is for those with TAVR experience.

1. Qualifications to begin a TAVR program for hospitals without TAVR experience:

   The hospital program must have the following:

   a. ≥ 50 total AVRs in the previous year prior to TAVR, including 10 high-risk patients, and;
   b. ≥ 2 physicians with cardiac surgery privileges, and;
   c. ≥ 1000 catheterizations per year, including 400 percutaneous coronary interventions (PCIs) per year.

2. Qualifications to begin a TAVR program for heart teams without TAVR experience:

   The heart team must include:

   a. Cardiovascular surgeon with:
      i. ≥ 100 career AVRs including 10 high-risk patients; or,
      ii. ≥ 25 AVRs in one year; or,
      iii. ≥ 50 AVRs in two years; and

      which include at least 20 AVRs in the last year prior to TAVR initiation; and,
   b. Interventional cardiologist with:
      i. Professional experience with 100 structural heart disease procedures lifetime; or,
      ii. 30 left-sided structural procedures per year of which 60% should be balloon aortic valvuloplasty (BAV). Atrial septal defect and patent foramen ovale closure are not considered left-sided procedures; and,
   c. Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers; and,
   d. Device-specific training as required by the manufacturer.

1. Qualifications for hospital programs with TAVR experience:

   The hospital program must maintain the following:

   a. ≥ 20 AVRs per year or ≥ 40 AVRs every two years; and,
   b. ≥ 2 physicians with cardiac surgery privileges; and,
   c. ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year.

2. Qualifications for heart teams with TAVR experience:

   The heart team must include:

   a. cardiovascular surgeon and an interventional cardiologist whose combined experience maintains the following:
      i. ≥ 20 TAVR procedures in the prior year, or,

ii. ≥ 40 TAVR procedures in the prior two years; and,

b. Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers.

3. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
4. The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TAVR patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 CFR Part 46 and 21 CFR Parts 50 & 56. The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient, practitioner and facility level variables that predict each of these outcomes:
   i. Stroke;
   ii. All cause mortality;
   iii. Transient Ischemic Attacks (TIAs);
   iv. Major vascular events;
   v. Acute kidney injury;
   vi. Repeat aortic valve procedures;
   vii. Quality of Life (QoL).

The registry should collect all data necessary and have a written executable analysis plan in place to address the following questions:

- When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
- How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?
- What is the long term (five year) durability of the device?
- What are the long term (five year) outcomes and adverse events?
- How do the demographics of registry patients compare to the pivotal studies?

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

TAVR may be eligible for uses that are not expressly listed as an FDA-approved indication when performed within an eligible clinical trial. These situations would be billed to Original Medicare fee-for-service, not Medicare Advantage.

TAVR is **investigational** for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced

procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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