Medical Coverage Policy | Transcatheter Aortic-Valve Implantation for Aortic Stenosis

EFFECTIVE DATE: 01|01|2013
POLICY LAST UPDATED: 12|17|2013

OVERVIEW

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

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial:
Prior Authorization is required for BlueChiP for Medicare and recommended for all other lines of business

POLICY STATEMENT

BlueCHiP for Medicare and Commercial:
TAVR is covered when the below medical criteria is met. For all other indications TAVR is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial:
Transcatheter aortic valve replacement, performed via the transfemoral approach, is considered **medically necessary** for patients with aortic stenosis when all of the following conditions are present.

- Severe aortic stenosis as defined by one or more of the following criteria **with** a calcified aortic annulus
  - An aortic valve area of less than 0.8 cm^2
  - A mean aortic valve gradient greater than 40 mmHg
  - A jet velocity greater than 4.0 m/sec
- NYHA heart failure Class II, III or IV symptoms

Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon)

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 2 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.

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.

Transcatheter aortic-valve implantation (TAVI) is a treatment for patients with severe aortic stenosis who require intervention, but who are a high or prohibitive risk for open surgery. There is currently one transcatheter aortic valve that is FDA-approved, the Edwards SAPIEN™ valve (Edwards LifeSciences, Irvine, CA).

For patients who are not surgical candidates due to excessive surgical risk, the PARTNER B trial reported results for patients treated with TAVI by the transfemoral approach compared to continued medical care with or without balloon valvuloplasty. There was a large decrease in mortality for the TAVI patients at 1 year compared to medical care. This trial also reported improvements on other relevant clinical outcomes for the TAVI group. There was an increased risk of stroke and vascular complications in the TAVI group. Despite these concerns, the overall balance of benefits and risks from this trial indicate that health outcomes are improved. Therefore, TAVI may be considered medically necessary for patients with severe aortic stenosis (AS) who are not surgical candidates when performed by the transfemoral approach.

For patients who are high risk for open surgery, but are operable candidates, the PARTNER A trial reported non-inferiority for survival at 1 year compared to open surgery. In this trial, TAVI patients also had higher risks for stroke and vascular complications. In 2012, the FDA expanded indications for TAVI to include patients who are at high risk for surgery, as defined by a Society of Thoracic Surgery (STS) risk score of $\geq$8%, or judged by a heart team to have a risk for operative mortality that is $\geq$15%. Based on the results of the PARTNER A trial and the FDA approval, TAVI for patients who are operable candidates but at high risk for open surgery may be considered medically necessary. The PARTNER A trial also included a subgroup analysis comparing the transfemoral and transapical approaches and reported no outcome differences between the 2 approaches. The 2012 FDA approval also expanded indications to include the transapical route in patients who were high risk for open surgery. Based on the available evidence and the 2012 FDA approval, TAVI performed by the transapical approach may be considered medically necessary in patients who are operable candidates but at high risk for open surgery.

TAVI has also been used as a "valve-in-valve" treatment for degenerated bio-prosthetic valves and for failed transcatheter valves. The evidence on this indication consists only of case series and is insufficient to determine whether outcomes are improved compared to alternatives. As a result, TAVI used for a "valve-in-valve" approach is considered not medically necessary as there is no proven efficacy.

Additional information for BlueCHiP for Medicare:

CR7879, from which this article is taken announces that on May 1, 2012, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) covering TAVR under Coverage with Evidence Development (CED) and only when specific requirements are met.

CED Coverage Conditions with Registry Participation

CMS covers TAVR for the treatment of symptomatic aortic valve stenosis under CED with the following conditions:

1. It is furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the following conditions are met:
    a. It is furnished with a complete aortic valve and implantation system that has received FDA Premarket Approval (PMA) for that system's FDA approved indication;

b. 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 this rationale is available to the heart team;
c. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals that embodies collaboration and dedication across medical specialties to offer optimal patient-centered care;
d. It is furnished in a hospital with the appropriate infrastructure that includes (but is not limited to):

- On-site heart valve surgery program;
- Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging;
- Non-invasive imaging such as echocardiography, vascular ultrasound, Computed Tomography (CT) and Magnetic Resonance (MR);
- Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications;
- Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures; and
- Appropriate volume requirements per the applicable qualifications (specifically, for hospitals without TAVR experience and for those with experience performing the procedure), which follow.

2. Required qualifications for the hospitals and heart teams performing the procedure.

Hospitals <u>without</u>TAVR experience must have the following qualifications to begin a TAVR program:

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

Heart Teams <u>without</u>TAVR experience must include the following to begin a TAVR program:

a. A cardiovascular surgeon with: 1) ≥ 100 career AVRs including 10 high-risk patients; or, 2) ≥ 25 AVRs in one year; or, 3) ≥ 50 AVRs in 2 years; and which include at least 20 AVRs in the last year prior to TAVR initiation; and,
b. An interventional cardiologist with: 1) Professional experience with 100 structural heart disease procedures lifetime; or, 2) 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; as well as
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.

Hospital programs <u>with</u>TAVR experience must have the following qualifications:

a. Maintain ≥ 2 physicians with cardiac surgery privileges;
b. Perform ≥ 20 AVRs per year or ≥ 40 AVRs every 2 years; and
c. Perform ≥ 1000 catheterizations per year, including ≥ 400 Percutaneous Coronary Interventions (PCIs) per year.

Heart teams <u>with</u> TAVR experience must have the following qualifications

a. Include a cardiovascular surgeon and an interventional cardiologist whose combined experience maintains: 1) ≥ 20 TAVR procedures in the prior year, or 2) ≥ 40 TAVR procedures in the prior 2 years;
b. Include additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers; and
c. The interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

In addition, the heart team and hospital must be participating in a prospective, national, audited registry. The complete list of requirements for a qualifying registry can be found in the NCD, which is available at **http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R147NCD.pdf** on the CMS website. To date, CMS has approved one registry, the Transcatheter Valve Therapy Registry operated by the Society of Thoracic Surgeons and the American College of Cardiology.

CED Coverage Conditions with Clinical Studies

For indications that are not approved by the FDA, CMS covers TAVR under CED when patients are enrolled in qualifying clinical studies. The clinical study requirements are available in the NCD, which is available at **http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R147NCD.pdf** on the CMS website. Approved studies are listed at **http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Transcatheter-Aortic-Valve-Replacement-TAVR-.html** on the CMS website.

COVERAGE

BlueCHiP for Medicare and Commercial

Benefits may vary between groups and/or contracts. Please refer to the appropriate evidence of coverage, subscriber agreement, or member certificate for the applicable surgery benefits/coverage.

CODING

BlueCHiP for Medicare and Commercial

33361, 33362, 33363, 33364, 33365, 33366, 33367, 33368, 33369

RELATED POLICIES

None

PUBLISHED

Provider Update	Feb 2014
Provider Update	Jan 2013

REFERENCES

Freeman RV, Otto CM. Spectrum of calcific aortic valve disease: pathogenesis, disease progression, and treatment strategies. Circulation 2005; 111(24):3316-26.

2. Coeytaux RR, Williams JW, Jr., Gray RN et al. Percutaneous heart valve replacement for aortic stenosis: state of the evidence. Ann Intern Med 2010; 153(5):314-24.

3. Lindroos M, Kupari M, Heikkila J et al. Prevalence of aortic valve abnormalities in the elderly: an echocardiographic study of a random population sample. J Am Coll Cardiol. 1993; 21(5):1220-5.

4. Bonow RO, Carabello BA, Kanu C et al. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease): developed in collaboration with the Society of Cardiovascular Anesthesiologists: endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons. Circulation 2006; 114(5):e84-231.

5. Iung B, Cachier A, Baron G et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? Eur Heart J 2005; 26(24):2714-20.
6. Lieberman EB, Bashore TM, Hermiller JB et al. Balloon aortic valvuloplasty in adults: failure of procedure to improve long-term survival. J Am Coll Cardiol 1995; 26(6):1522-8.
7. Food and Drug Administration. Summary of Safety and Effectiveness for the Edwards SAPIEN Transcatheter Heart Valve (PMA P11021). 2012. Available online at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM307195.pdf. Last accessed November 26, 2012.
8. Piazza N, Grube E, Gerckens U et al. Procedural and 30-day outcomes following transcatheter aortic valve implantation using the third generation (18 Fr) corevalve revalving system: results from the multicentre, expanded evaluation registry 1-year following CE mark approval. EuroIntervention 2008; 4(2):242-9.
9. Rodes-Cabau J, Webb JG, Cheung A et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience. J Am Coll Cardiol 2010; 55(11):1080-90.
10. Figulla L, Neumann A, Figulla HR et al. Transcatheter aortic valve implantation: evidence on safety and efficacy compared with medical therapy. A systematic review of current literature. Clin Res Cardiol 2011; 100(4):265-76.