

Medical Coverage Policy



Transcatheter Aortic-Valve Implantation for Aortic Stenosis

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	1/1/2013	Policy Last Updated:	9/18/2012
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description

Transcatheter aortic valve implantation (TAVI) 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-risk, often prohibitive, 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.

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 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.

**Medical Criteria for BlueCHiP for Medicare Members:
CED Coverage Conditions with Registry Participation**

TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to an FDA approved indication and when all of the following conditions are met.

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.
4. 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.

Medical Criteria for All Members Other Than BlueCHiP for Medicare:

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 cm²

- 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)

Transcatheter aortic valve replacement is considered not medically necessary for all other indications, including but not limited to, patients at high risk for open surgery but who are operable candidates.

Policy:

TAVR is covered when the above medical criteria is met. Prior authorization is required for BlueCHIP for Medicare members and recommended for all others.

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber agreement, or Benefit Booklet for applicable surgery services coverage/benefits.

Coding:

The following codes are effective 1/1/2013:

33361
 33362
 33363
 33364
 33365
 33367
 33368
 33369

The following Category III CPT codes are deleted effective 1/1/2013:

0256T
0257T
0258T
0259T

Also Known As:

TAVR

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Brecker S, Baumbach A, Daniel T, Gray H, Mullen MJ. *Long-Term Outcomes After Transcatheter Aortic Valve Implantation in High-Risk Patients With Severe Aortic Stenosis: Title and subTitle BreakThe U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry*. Journal of American College of Cardiology;2011;58(20):2130-2138.

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