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; supporting documentation must be submitted to Use Management.* 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) is a potential alternative treatment for patients with severe aortic stenosis (AS). Many patients with AS 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 AS and as an alternative to non-surgical therapy for patients with a prohibitive risk for surgery.

Background

Aortic stenosis

Aortic stenosis (AS) 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 (AoV) 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 AoV, most commonly a bicuspid valve, increase the risk for AS, but AS 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 AS 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 AS 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 AS is primarily surgical, involving replacement of the diseased valve with a bio-prosthetic or mechanical valve by open heart surgery.

Burden of illness

AS is a relatively common disorder of elderly patients and is the most common acquired valve disorder in the United States. Approximately 2–4% of individuals older than 65 years of age have evidence of significant AS, (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 US, more than 50,000 aortic valve replacements are performed annually due to severe AS.

AS 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 AS, and artificial valves have demonstrated good
durability for periods up to 20 years. However, these benefits are accompanied by a perioperative mortality of approximately 3-4% and substantial morbidity, both of which increase with advancing age.

Unmet needs

Many patients with severe, symptomatic AS are poor operative candidates. Approximately 30% of patients presenting with severe AS do not undergo open surgery due to factors such as advanced age, advanced left ventricular dysfunction, or multiple medical comorbidities. For patients who are not surgical candidates, medical therapy can partially alleviate the symptoms of AS, but does not affect the underlying disease progression. Percutaneous balloon valvuloplasty can be performed, but this procedure has less than optimal outcomes. 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 AS 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 US. 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 US.

Regulatory Status

The Sapien Transcatheter Heart Valve System™ (Edwards LifeSciences, Irvine, CA) received FDA approval in November 2011. Approval was granted for patients with severe aortic stenosis who are not eligible for open-heart procedures, and have a calcified aortic annulus. The product labeling also advises that a heart surgeon should be involved in determining whether a patient is an acceptable candidate for transcatheter valve replacement. Exclusion criteria are patients who are candidates for an open procedure, patients with congenital heart abnormalities, patients with an infection in the heart, and/or cannot tolerate anticoagulation/antiplatelet therapy post-implantation.

Corporate Medical Guideline

Transcatheter aortic valve replacement, performed via the transfemoral approach, is considered medically necessary for patients with aortic stenosis (AS) when all of the following conditions are present:
• Severe aortic stenosis (see Policy Guidelines) with a calcified aortic annulus
• 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 investigational for all other indications, including but not limited to, patients at high risk for open surgery but who are operable candidates.

Policy Guideline

Severe aortic stenosis is defined by one or more of the following criteria:
• An aortic valve area of less than 0.8cm²
• A mean aortic valve gradient greater than 40mmHg
• A jet velocity greater than 4.0m/sec.

Medicare Advantage

For Medicare Advantage medical necessity will be considered based on the FDA approved indication of delivery in patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon 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.

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.
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


