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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Transcatheter Heart Valve Procedures Policy Indication/Usage:

Transcatheter Aortic Valve Replacement (TAVR-also known as TAVI-transcatheter aortic valve implantation):
Aortic stenosis affects 3% of persons older than 65 years of age and is the most significant cardiac valve disease in developed countries. Aortic stenosis has a prolonged latent period, during which progressive worsening of left ventricular (LV) outflow obstruction leads to compensatory hypertrophic changes in the LV myocardium. The resultant increase in LV systolic function helps maintain adequate systemic pressures. However, LV hypertrophy may also lead to diastolic dysfunction and increased resistance to LV filling. Thus, a strong left atrial contraction may be needed to provide sufficient LV diastolic filling and to support adequate stroke volume. As aortic stenosis worsens, these adaptations become inadequate to overcome the outflow obstruction and maintain systolic function. Impaired systolic function, alone or combined with diastolic dysfunction, may lead to clinical heart failure. Aortic valve replacement is the only effective treatment for symptomatic, hemodynamically severe aortic stenosis. (Grimard, 2016). TAVR uses a bioprosthetic valve inserted percutaneously using a catheter and implanted in the in

the opening of the native aortic valve for patients who are poor candidates for conventional surgery (Centers for Medicare & Medicaid Services, 2012)

Transcatheter Closure of Paravalvular Leaks of prosthetic aortic valve:

According to Webb (as cited in Hayes, 2016), following aortic valve (AV) replacement, up to 5% of patients may develop early, clinically significant paravalvular leaks (PVL According to Smolka et al. (as cited in Hayes, 2016) hemodynamically significant leaks may lead to heart failure and an increased risk for endocarditis, while smaller leaks can lead to intravascular hemolysis and subsequent anemia. Reoperation is associated with higher mortality and an excess risk of recurrent paravalvular insufficiency. Transcatheter repair has been proposed as a minimally invasive procedure intended to access and repair the symptomatic defect (Smolka, 2016).

Transcatheter Mitral Valve Repair (TMVR):

Severe mitral regurgitation (MR) is a debilitating disease that develops over many years and has an annual mortality rate of at least 5% (Feldman &Young, 2014). It has been estimated that nearly one in 10 people aged 75 and above will be affected by this condition. But for the elderly and those with certain comorbidities, the standard-of-care treatment – open heart surgery – may be too risky to perform. Proponents of transcatheter mitral valve repair (TMVR), however, believe this technique provides a safer way to treat patients who are unsuitable for surgery. The MitraClip® Clip Delivery System (CDS), the only percutaneous TMVR system approved by the U.S. Food and Drug Administration (FDA), involves clipping together a portion of the mitral valve leaflets. This in turn is hoped to improve recovery of the heart from overwork, enhance function, and possibly halt the progression of heart failure (Centers for Medicare and Medicaid Services [CMS], 2014). A catheter is used to insert the device through the femoral vein and guide it into the heart. It is then positioned by grasping both leaflets of the mitral valve. Once the MitraClip device is in place the delivery catheter is removed (FDA, 2015).

Transcatheter Closure of Paravalvular Leaks of Prosthetic Mitral Valve:

According to Hayes (2016) it is estimated that from 5% to 17% of patients who have received an implanted prosthetic valve may develop some degree of regurgitation or leak. Surgical repair, the gold standard, has been associated with significant morbidity and mortality related to reoperation, sternotomy, tissue friability, and possible calcification and inflammation of the prosthetic valve. Percutaneous transcatheter procedures offer a minimally invasive procedure intended to access the defective valve through a transseptal, antegade, or retrograde approach and deploy a plug to repair the defect.

Transcatheter Pulmonary Valve Implantation or replacement:

Acquired pulmonary valve disease in adults is rare, with regurgitation in the setting of pulmonary hypertension being the most frequent cause. In patients with congenital heart disease, pulmonary valve dysfunction is common and frequently occurs following tetralogy of Fallot repair.

Percutaneous pulmonary valve replacement is indicated for congenital pulmonary stenosis and pulmonary stenosis and regurgitation in a patient with congenital heart disease who has previously undergone right ventricular outflow track surgery as is could avoid the morbidity and discomfort accompanying repeated open-heart surgery. (Satpathy, 2015).

Transcatheter Valve-in-Valve Implantation:
A bioprosthetic aortic or mitral valve may fail over time due to stenosis, when the valve narrows and causes the heart to work harder to pump blood, regurgitation, when the valve does not close completely and blood leaks backwards, or a combination of both. Treatment would normally require repeat open heart surgery, which causes a high or greater risk of complications for certain patient. Valve-in-valve procedures offer an alternative to repeat surgery, since the replacement valve is inserted inside the failing surgical bioprosthetic valve through a patient's blood vessel or a small cut in a patient's chest. The FDA evaluated data from the Transcatheter Valve Therapy Registry, a partnership of the American College of Cardiology and the Society of Thoracic Surgeons. The registry collects clinical data on the safety and effectiveness of transcatheter valve replacement procedures performed in a real world setting. The outcome data used to support the marketing application consisted of 314 patients who had undergone aortic valve-in-valve procedures and 311 patients who had undergone mitral valve-in-valve procedures. The registry data showed that more than 85 percent of patients who underwent aortic or mitral valve-in-valve procedures experienced clinically meaningful improvement in their heart failure symptoms 30 days after the procedure, as shown by their New York Heart Association (NYHA) Classifications. (FDA, 2017)

Medical Indications for Authorization

Transcatheter Aortic Valve Replacement (TAVR or TAVI):
SummaCare considers transcatheter aortic valve replacement with the use of an FDA approved aortic valve **medically necessary** when existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis and the below criteria are met:

- Severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency
- Ejection fraction is greater than 20%
- Inoperable for open aortic valve replacement or who are operative candidates but have a Society of Thoracic Surgeons operative risk score greater than or equal to 8% or are judged to be at 15% or greater risk of mortality.

Transcatheter Mitral Valve Repair:
SummaCare considers percutaneous mitral valve repair (PMVR) by means of an FDA approved device medically necessary for persons with grade 3+ to 4+ symptomatic degenerative mitral regurgitation or moderate to severe heart failure despite maximal dosage of medical therapy and at high-risk for conventional open-heart mitral valve surgery.

Transcatheter Pulmonary Valve Replacement:
SummaCare considers transcatheter pulmonary valve replacement proven and **medical necessary**, when using an FDA approved device, in patient with dysfunctional right ventricular outflow (RVOT) conduits when the follow criteria is met:

- Existence of a full (circumferential) dysfunctional RVOT conduit that was equal to **or** greater than 16 mm in diameter when originally implanted, **and**
- Dysfunctional RVOT conduit with one of the following clinical indications for intervention: Moderate or greater pulmonary regurgitation, **or** ○ Pulmonary stenosis with a mean RVOT gradient ≥ 35 mmHg **or** ○ Dysfunctional non-conduit patch repair RVOT **or** ○ Members with pulmonary insufficiency with progressive R ventricular dilation who have failed pulmonary valvulectomy

Transcatheter Valve-in-Valve Replacement:
SummaCare considers transcatheter valve replacement with the use of a FDA-approved valve medically necessary for valve-in-valve replacement for persons with a degenerated bioprosthetic valve who require another valve replacement but who have a greater than or equal to 8% or greater risk of mortality for surgical valve replacement

Limitations

Transcatheter Aortic Valve Replacement is not indicated for patients and considered experimental and investigational for patients:

- Who can safely undergo open-heart surgery (low risk patients).
- Ongoing sepsis including endocarditis.
- TAVR and left atrial appendage occlusion.
- Who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen.
- Blood clots present at the intended site of implant or blood clots in vessels through which access to the defect is gained.
- All other indications because its effectiveness of the indications has not been established.
- Have a life expectancy of less than 1 year.

Transcatheter Mitral Valve Repair is not indicated for patients and considered experimental and investigational for patients:

- Who can safely undergo open-heart surgery.
- Who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen.
- Active endocarditis of the mitral valve..
- Rheumatic mitral valve disease
- Blood clots present at the intended site of implant or blood clots in vessels through which access to the defect is gained.
- Any other indications because the effectiveness has not been established.

- Who have a life expectancy of less than 1 year.

Transcatheter Pulmonary Valve Implantation/Replacement:

- Limited size selection for treatment of young children and patients with dilated right ventricular outflow tract.
- Positioning of the devices is a challenge but may be assisted with preprocedure imaging.
- It should be performed as part of a clinical trial in order to gather data.
- Test angioplasty might be indicated to detect preexisting coronary artery compression, which could lead to a fatal outcome.
- Pre-stenting decreases chances of stent fracture.

Transcatheter Closure of Paravalvular Leaks in prosthetic valves is not indicated for patients and considered experimental and investigational for patients: Who can safely undergo open-heart surgery (low risk patients) Ongoing sepsis including endocarditis.

- Who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen.
- Blood clots present at the intended site of repair or blood clots in vessels through which access to the defect is gained.
- Have a life expectancy of less than 1 year.

Transcatheter valve-in-valve Replacement valves is not indicated for patients and considered experimental and investigational for patients:

- Who can safely undergo open-heart surgery (low risk patients).
- Ongoing sepsis including endocarditis.
- Who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen.
- Blood clots present at the intended site of replacement or blood clots in vessels through which access to the defect is gained.
- Have a life expectancy of less than 1 year.

Transcatheter valve-in-valve Replacement valves is not indicated for patients and considered experimental and investigational for patients:

- Who can safely undergo open-heart surgery (low risk patients).
- Ongoing sepsis including endocarditis.
- Who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen.
- Blood clots present at the intended site of replacement or blood clots in vessels through which access to the defect is gained. Have a life expectancy of less than 1 year.

Medicare Members

CMS NCD ID Transcatheter Aortic Valve Replacement (TAVR)

Indications and Limitations of Coverage

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED) with the following conditions:

A. TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (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. 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 patientcentered care. The heart team includes the following:
    a. Cardiac surgeon and an interventional cardiologist experienced in the care and treatment of aortic stenosis who have:
        i. Independently examined the patient face-to-face, evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy;
        ii. Documented and made available to the other heart team members the rationale for their clinical judgment.
    b. Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel and administrators.
3. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

4. TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
    a. On-site heart valve surgery and interventional cardiology programs,
    b. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,
    c. 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.

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

The hospital program must have the following:

a. $\geq$ 50 open heart surgeries in the previous year prior to TAVR program initiation, and;

b. ≥ 20 aortic valve related procedures in the 2 years prior to TAVR program initiation, and;
c. ≥ 2 physicians with cardiac surgery privileges, and;
d. ≥ 1 physician with interventional cardiology privileges, and;
e. ≥ 300 percutaneous coronary interventions (PCIs) per year.

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

The heart team must include:

a. Cardiovascular surgeon with:
   i. ≥ 100 career open heart surgeries of which ≥ 25 are aortic valve related; and,
b. Interventional cardiologist with:
   i. Professional experience of ≥ 100 career structural heart disease procedures; or, ≥ 30 left-sided structural procedures per year; and, ii. Device-specific training as required by the manufacturer.

Qualifications for hospital programs with TAVR experience:

The hospital program must maintain the following:

a. ≥ 50 AVRs (TAVR or SAVR) per year including ≥ 20 TAVR procedures in the prior year ; **or**
b. ≥ 100 AVRs (TAVR or SAVR) every 2 years, including ≥ 40 TAVR procedures in the prior 2 years; **and**
c. ≥ 2 physicians with cardiac surgery privileges; **and**
d. ≥ 1 physician with interventional cardiology privileges, **and**
e. ≥ 300 percutaneous coronary interventions (PCIs) per year; **and**

5. 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:

   - Stroke
   - All-cause mortality
   - Transient Ischemic Attacks (TIAs)

- Major vascular events
- Acute kidney injury
- Repeat aortic valve procedures
- New permanent pacemaker implantation
- Quality of Life (QoL)

6. The registry shall collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary). Specifically, for the CED question iv, this must be addressed through a composite metric. For the below CED questions (i-iv), the results must be reported publicly as described in CED criterion k.

    - When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
    - What is the long term durability of the device?
    - What are the long term outcomes and adverse events?
    - What morbidity and procedure-related factors contribute to TAVR patients outcome?

No National Coverage Determination (NCD) for transcatheter pulmonary valve, mitral valve, implantation/replacement was identified on the CMS website. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

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