Transcatheter Cardiac Procedures

Policy Number: HS-249

Original Effective Date: 5/1/2014
Revised Date(s): 4/2/2015

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

Clinical Coverage Guideline

Original Effective Date: 5/1/2014 - Revised: 4/2/2015
BACKGROUND

Transcatheter aortic valve implantation (TAVI) (or Transcatheter Aortic Valve Replacement [TAVR]) is a nonsurgical treatment for severe aortic stenosis. This procedure involves delivering and implanting a bioprosthetic valve via a peripheral artery.

Percutaneous Pulmonary Valve Implantation (PPVI) devices may extend the life span of members with failing prosthetic pulmonary conduits and congenital heart defects. PPVI is not expected to replace the initial open heart surgery for placement of a pulmonary conduit, but it is expected to reduce the total number of open heart right ventricular outflow tract (RVOT) procedures over a patient’s lifetime.1

Transcatheter mitral valve repair (TMVR) is an option for members that are not favorable candidates for surgical repair in the treatment of mitral regurgitation.2 While some companies are developing catheter-based devices (e.g., Abbott Vascular’s MitraClip Mitral Valve Repair System) for the treatment of mitral valve disorders, the FDA has not issued any approvals.

Professional Organizations

The United States Food and Drug Administration (FDA) classifies transcatheter aortic valve implantation (TAVI) devices as Class III under the designation “aortic valve, prosthesis, percutaneously delivered” (PMA product code NPT). Of the 2 TAVI devices used in the United States, only 1 has received marketing approval. The Edwards SAPIEN Transcatheter Heart Valve (Edwards Lifesciences LLC) was approved on November 2, 2011, for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis. The SAPIEN Transcatheter Heart Valve is indicated for 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 comorbidities would not preclude the expected benefit from correction of the aortic stenosis. The SAPIEN valve is available in 2 sizes: 23 and 26 millimeters (mm).

The FDA Advisory Panel approved a Premarket Approval Application on October 19, 2012, for the SAPIEN valve, using both the transfemoral and transapical routes of delivery, for patients with severe, symptomatic aortic valve stenosis who are at a high surgical risk. The other TAVI device used in the United States, CoreValve System (Medtronic Inc.), received approval for its Investigational Device Exemption application on October 15, 2010 (Medtronic Inc., 2010). The CoreValve System has been approved for use in Europe since 2007 (Medtronic Inc., 2011). Recently, Medtronic received approval for an extended investigation of CoreValve under the FDA’s Continued Access Policy to continue enrolling extreme risk patients.3,4

The American College of Cardiology (ACC), Society of Thoracic Surgeons (STS), American Association of Thoracic Surgeons (AATS), and Society for Cardiovascular Angiography and Interventions (SCAI) released an expert consensus document to provide important guidance on the use of TAVI.5,6 The consensus document outlines key recommendations for the successful employment of TAVI, including:

- Careful patient selection.
- Team-based approach given the complexity of TAVI coupled with the high-risk profile of suitable patients, many of whom have extensive comorbid conditions that require ongoing management.
- Specialized heart centers and physicians with expertise in treating valve disorders; this includes use of...
proctors as needed to serve on the heart care team during the first few cases, as well as proper facilities (hybrid operating rooms or modified catheterization laboratories).

- TAVI screening tests to inform treatment decisions.
- Enhanced patient and family education in the risk and benefits of this procedure.
- Ongoing evaluation and participation in national TAVI registry to assess real-world outcomes.

The organizations also provided additional expert consensus recommendations for patient selection, screening, and post-procedural care. TAVR is recommended for members who have:

- Severe, symptomatic, calcific stenosis of a tri-leaflet aortic valve;
- Aortic and vascular anatomy suitable for TAVR and a predicted survival of 12 months; and
- A prohibitive surgical risk as defined by an estimated ≥ 50% risk of mortality or irreversible morbidity at 30 days or other factors such as frailty, prior radiation therapy, porcelain aorta, and severe hepatic or pulmonary disease.

TAVR is a reasonable alternative to SAVR in patients at high surgical risk. Further recommendations include:

- Implementation of standardized screening protocols for every TAVI evaluation (e.g., metrics to calculate STS score, comorbid conditions, cognitive impairment, imaging data, arterial mapping);
- Expertise of team (> 50 SAVR surgeries in past year, experience with balloon aortic valvuloplasty, proctored experience with all device approaches);
- Setting (cardiac catheterization laboratories or hybrid room)
- Proper postprocedural care and rehabilitation; and
- Participation in national registries.

**POSITION STATEMENT**

**Applicable To:**
- ☑ Medicaid
- ☑ Medicare

Transcatheter aortic valve implantation (TAVI) or transcatheter aortic heart valve replacement (TAVR) is **considered medically necessary and a covered benefit** with devices that have received U.S. Food and Drug Administration (FDA) approval (e.g., Edwards SAPIEN™ Transcatheter Heart Valve [Edwards Lifesciences, LLC, Irvine, CA]) and when the following are met:

- Member has severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency;
  
  **AND,**

- An ejection fraction of ≥ 20%;
  
  **AND either of the following:**

- EITHER of the following:
  
  - Member is deemed inoperable per cardiac team (including a cardiac surgeon and a cardiologist), and existing comorbidities would not impede the expected benefit from correction of the aortic stenosis;
  
  **AND/OR,**

- Member is a candidate for aortic valve replacement however, the predicted Society of Thoracic Surgeons
operative risk score is ≥ 8%, or are deemed by the heart team to have a ≥ 15% risk of mortality for surgical aortic valve replacement.

Transfemoral and transapical delivery approaches to transcatheter aortic heart valve replacement are the only approaches with FDA approval. All other delivery approaches (e.g., subaxillary, subclavian, transaortic) are considered experimental and investigational.

Pediatric and adult members may be eligible using an FDA-approved device (e.g., Medtronic Melody® Transcatheter Pulmonary Valve) in lieu of surgery when the following are met:¹

- Existence of a full (circumferential) right ventricular outflow tract (RVOT) conduit that was equal to or greater than 16 mm in diameter when originally implanted; AND,
- Dysfunctional RVOT conduit with a clinical indication for intervention; AND,

**ONE of the following:**

- Regurgitation is greater than or equal to moderate; OR,
- Stenosis: mean RVOT gradient greater than or equal to 35 mmHg.

Alternatives to TAVI include surgical aortic valve replacement (SAVR). Providers should educate the member of the risks and benefits of SAVR.

**Exclusions**

**TAVI is considered experimental and investigational** for the following, but is not limited to:

- Mitral valve repair
- Active infections (e.g., bacterial endocarditis)
- Acute myocardial infarction (MI) less than or equal to one month of planned TAVR
- Aortic valve stenosis that can be treated by surgical aortic valve replacement
- Cannot tolerate anticoagulation or an antiplatelet regimen
- Congenital bicuspid or unicuspid aortic valve, or is noncalcified
- Echocardiographic evidence of intracardiac mass, thrombus or vegetation
- Hypertrophic cardiomyopathy with or without obstruction
- Life expectancy of less than or equal to 12 months due to noncardiac comorbid conditions
- Magnetic Resonance Imaging (MRI) confirmed cerebral vascular accident (CVA) or transient ischemic attack (TIA) within six months of planned TAVR
- Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation greater than 3+)
- Renal insufficiency (creatinine greater than 3.0 mg/dL) and/or end-stage renal disease requiring chronic dialysis
- Severe left ventricular dysfunction with left ventricular ejection fraction (LVEF) less than or equal to 20 percent
- Severe mitral regurgitation
- Severe pulmonary hypertension and right ventricular dysfunction
- Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter five cm or greater, marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [greater than five mm], protruding or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe “unfolding” and tortuosity of the thoracic aorta;6 OR
- Transapical, transventricular, or any approach other than transfemoral.
- All other indications not listed above.
In addition, the following devices are considered experimental and investigational:

- CoreValve transcatheter device
- JenaValveTM transapical transcatheter device
- Leaflet repair (e.g., MitraClip®)
- Percutaneous annuloplasty (e.g., Carillon® Mitral Contour System™)

### CODING

#### CPT® Codes

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>33361</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) w/ prosthetic valve; percutaneous femoral artery approach</td>
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<tr>
<td>33362</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach</td>
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<td>33363</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach</td>
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<td>33364</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach</td>
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<td>33365</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median Sternotomy, mediastinotomy)</td>
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<tr>
<td>33366</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)</td>
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<td>33367</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels)</td>
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<tr>
<td>33368</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels)</td>
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<tr>
<td>33369</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery)</td>
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<tr>
<td>37241</td>
<td>Vascular embolization or occlusion, inclusive of all radiological supervision and interpretations, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (e.g., congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)</td>
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<td>0262T</td>
<td>Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach</td>
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#### ICD-9 Procedure

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<td>35.05</td>
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<td>35.06</td>
<td>Transapical replacement of aortic valve</td>
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<tr>
<td>35.07</td>
<td>Endovascular replacement of pulmonary valve</td>
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<td>35.08</td>
<td>Transapical replacement of pulmonary valve</td>
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#### HCPCS®* Codes – No applicable codes.

### Covered ICD-9-CM Diagnosis Codes

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<tr>
<td>424.1</td>
<td>Aortic valve disorders</td>
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<td>396.0</td>
<td>Mitral valve stenosis and aortic valve stenosis</td>
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<td>396.1</td>
<td>Mitral valve stenosis and aortic valve insufficiency</td>
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<td>396.2</td>
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### Covered Draft 2014 ICD-10-CM Diagnosis Codes

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<td>I08.8</td>
<td>Other rheumatic multiple valve diseases</td>
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<td>I08.9</td>
<td>Rheumatic multiple valve disease, unspecified</td>
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I35.0 Nonrheumatic aortic (valve) stenosis
I35.1 Nonrheumatic aortic (valve) insufficiency
I35.2 Nonrheumatic aortic (valve) stenosis with insufficiency
I35.8 Other nonrheumatic aortic valve disorders
I35.9 Nonrheumatic aortic valve disorder, unspecified


REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<td>4/2/2015</td>
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<tr>
<td>5/1/2014</td>
<td>Approved by MPC. New.</td>
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