

**TRANSCATHETER HEART VALVE PROCEDURES**

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**Review Dates:** 4/12, 4/13, 5/14, 5/15, 5/16, 5/17, 5/18, 5/19

**Date Of Origin:** April 11, 2012

**Status:** Current

**I. POLICY/CRITERIA**

- A. Transcatheter Aortic Valve Replacement (TAVR)** may be a covered benefit according to InterQual®. All of the following also apply:
1. Device must FDA approved and used per labeled indications.
  2. For Medicare members: procedure is performed at a center approved by the Centers for Medicare & Medicaid Services (CMS) under the CMS Coverage with Evidence Development (CED) criteria
  3. None of the following:
    - a) Evidence of an acute myocardial infarction  $\leq$  1 month before the intended treatment
    - b) Aortic valve is a congenital unicuspid or congenital bicuspid valve, or is non-calcified.
    - c) Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation  $>3+$ ).
    - d) Any therapeutic invasive cardiac procedure performed within 30 days of the index procedure, (or 6 months if the procedure was a drug eluting coronary stent implantation).
    - e) Severe mitral annular calcification (MAC), severe (greater than 3+) mitral insufficiency, or Gorelin syndrome
    - f) Blood dyscrasias as defined: leukopenia (WBC  $<$  3000 mm<sup>3</sup>), acute anemia (Hb  $<$  9 mg%), thrombocytopenia (platelet count  $<$  50,000 cells/mm<sup>3</sup>), history of bleeding diathesis or coagulopathy.
    - g) Untreated clinically significant coronary artery disease requiring revascularization.
    - h) Hemodynamic instability requiring inotropic support or mechanical heart assistance.
    - i) Need for emergency surgery for any reason.
    - j) Hypertrophic cardiomyopathy with or without obstruction (HOCM).
    - k) Severe ventricular dysfunction with LVEF  $<$  20.
    - l) Echocardiographic evidence of intracardiac mass, thrombus or vegetation.
    - m) Active peptic ulcer or upper GI bleeding within the prior 3 months.
    - n) A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated.

- o) Native aortic annulus size < 18mm or > 25mm as measured by echocardiogram.
- p) Patient has been offered surgery but has refused surgery.
- q) Recent (within 6 months) cerebrovascular accident (CVA) or a transient ischemic attack (TIA).
- r) Chronic Kidney Disease (creatinine > 3.0) and/or end stage renal disease requiring chronic dialysis.
- s) Life expectancy < 12 months due to non-cardiac co-morbid conditions.
- t) Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5cm or greater; marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [ $> 5$  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 (applicable for transfemoral patients only).
- u) Iliofemoral vessel characteristics that would preclude safe placement of 22F or 24F introducer sheath such as severe obstructive calcification, severe tortuosity or vessels size less than 7 mm in diameter (applicable for transfemoral patients only).
- v) Currently participating in an investigational drug or another device study.
- w) Active bacterial endocarditis or other active infections.
- x) Bulky calcified aortic valve leaflets in close proximity to coronary ostia.”

**B. Transcatheter Pulmonary Valve Implantation (TPVI) with an FDA-approved device (e.g. Melody<sup>®</sup> Transcatheter Pulmonary Valve, Sapien XT) may be covered for the management of pediatric and adult patients when both of the following are met:**

1. Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted, **AND**
2. Dysfunctional RVOT conduits with a clinical indication for intervention, **AND** either of the following:
  - regurgitation:  $\geq$  moderate regurgitation, **AND/OR**
  - stenosis: mean RVOT gradient  $\geq$  35 mm Hg

**C. Mitral Valve (MV) Repair.** Percutaneous repair of the mitral valve (e.g. MitraClip system) is considered experimental and investigational and not a covered benefit. An exception to allow coverage may be made in high-risk patients who have moderate or severe MV regurgitation but are not candidates for conventional open MV repair surgery if either of the following apply:

1. The procedure is performed at a center approved by the Centers for Medicare & Medicaid Services (CMS) under the CMS Coverage with Evidence Development (CED) criteria; **OR**

2. The procedure is performed as part of a clinical trial and meets the criteria of the *Priority Health “Clinical Trials” medical policy*.

Priority Health’s Technology Assessment Committee reviewed Transcatheter Heart Valves in March 2012; this policy is based on recommendations of the committee.

**II. MEDICAL NECESSITY REVIEW**

Required                       Not Required                       Not Applicable

**III. APPLICATION TO PRODUCTS**

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945\\_42542\\_42543\\_42546\\_42551-159815--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html). If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945\\_5100-87572--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html), the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

**IV. DESCRIPTION**

Transcatheter aortic valve implantation (TAVI) is an alternative to current care, open heart, aortic valve replacement (AVR) in patients with severe aortic stenosis who are at high or prohibitive risk for operative mortality. Approximately 50,000 AVR procedures are performed annually in the United States, and the surgery is associated with significant improvement in the quality of life and prolonged

survival. An estimated 32% of patients with severe aortic stenosis, however, are currently considered unsuitable candidates for open surgery. The prognosis for survival is poor in this patient subset. A recent study estimates that the 1- and 5-year survival rates are 62% and 32%, respectively, in nonsurgically managed patients with severe aortic stenosis.

The U.S. pivotal PARTNER trial evaluated TAVI with the Sapien THV in two distinct patient populations: high-operative-risk patients (Cohort A) and medically inoperable patients (Cohort B). The randomized controlled trial (RCT) compared TAVI-TF or TAVI-TA (transapical) with surgical AVR in Cohort A, and TAVI-TF with current care nonsurgical management in Cohort B.

PARTNER results represent the only published RCT outcomes of TAVI with the Sapien valve. In Cohort B, TAVI-TF was significantly superior to nonsurgical therapy in reducing the 1-year mortality rates (31% versus 51%, respectively) and the combined endpoint of death or repeat hospitalization (43% versus 72%, respectively). TAVI-TF statistically bettered nonsurgical therapy in cardiac symptom improvement, but also was associated with a higher 30-day incidence of major vascular events. In Cohort A, TAVI was noninferior to AVR; 1-year mortality rates did not statistically differ (24.2% and 26.8%, respectively). However, rates of all neurologic events were significantly higher in the TAVI versus AVR groups at 30 days (5.5% versus 2.4%, respectively) and at 1 year (8.3% versus 4.3%, respectively). Major bleeding events and new-onset atrial fibrillation were significantly more frequent for AVR than for TAVI.

The Melody Transcatheter Pulmonary Valve and the Ensemble Transcatheter Delivery System received FDA approval in 2014.

Mitral Valve Repair (Hayes, Inc):

Although a large randomized controlled trial (RCT) found that patient survival and reduction in MV regurgitation were similar for the MitraClip procedure versus conventional open surgery at 4 years follow-up, MitraClip implantation was associated with a statistically significant 4.2-fold increase in need for additional mitral valve surgery, which suggests that conventional surgery should be used instead of the MitraClip procedure, if possible.

## V. CODING INFORMATION

**ICD-10 Codes** that may apply:

I05.1	Rheumatic mitral insufficiency
I34.0	Nonrheumatic mitral (valve) insufficiency
I35.0 – I35.9	Nonrheumatic aortic valve disorders
I37.0 – I37.9	Nonrheumatic pulmonary valve
Q22.1	Congenital pulmonary valve stenosis

**CPT/HCPCS Codes:**

- 33361 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
- 33362 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
- 33363 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
- 33364 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
- 33365 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)
- 33366 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)
  
- 33477 Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

**Not separately payable**

- 33367 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)
- 33368 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)
- 33369 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)
  
- 93355 Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D

**Not covered**

- 0345T Transcatheter mitral valve repair percutaneous approach via the coronary sinus
- 0483T Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed
- 0484T Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (eg, thoracotomy, transapical)

*Covered for Medicare only, under CED rules and criteria*

- 33418 Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis
- 33419 Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)

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