TITLE: TRANSCATHETER HEART VALVE REPLACEMENT AND REPAIR PROCEDURES

EFFECTIVE DATE: February 18, 2015

This policy was developed with input from specialists in cardiovascular/thoracic surgery and interventional cardiology and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE

To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of transcatheter aortic valve replacement. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

I. Definitions

A. Aortic stenosis is the obstruction of blood flow across the aortic valve due to narrowing of the lumen. Aortic stenosis has several etiologies, including calcific (due to degenerative changes), congenital (unicuspid or bicuspid valve), or rheumatic. Degenerative calcific aortic stenosis is the leading indication for aortic valve replacement.

B. Aortic Valve insufficiency is quantified using a graded scale. This is often determined following cardiac catheterization. A commonly accepted scale follows:
   1. Mild (grade 1+) : A small amount of contrast enters the left ventricle during diastole and clears with each systole.
   2. Moderate (grade 2+) : More contrast enters with each diastole and faint opacification of the entire left ventricular chamber occurs.
   3. Moderately severe (grade 3+) : Left ventricular chamber is well opacified and equal in density when compared with the ascending aorta.
   4. Severe (grade 4+) : Complete, dense opacification of the ventricular chamber on the first beat, and the left ventricle is more densely opacified than the ascending aorta.

C. Echocardiogram is a test that uses sound waves to create a moving picture of the heart. The technology provides a more detailed picture of the heart than that obtained with traditional x-ray imaging and does not require radiation exposure. The procedure allows clinicians to see the heart beating and to visualize the heart valves and other structures of the heart in real time. A contrast medium may be injected through an intravenous line to better visualize the inside of the heart. Very rarely, more invasive testing using specialized echocardiography probes may be required. An echocardiologist is a cardiologist with advanced training in all aspects of performing echocardiography and interpreting results seen on echocardiogram.

D. Kidney function classification is a system for categorizing progression of chronic kidney disease. Classification is based on glomerular filtration rate (GFR), which is a measure of how well the kidneys filter waste and is related to an individual’s overall kidney function. The stages of chronic kidney disease are:
   1. Stage 1: Signs of mild kidney disease but with normal or better GFR (greater than 90% kidney function).
2. Stage 2: Signs of mild kidney disease with reduced GFR (60% to 89% kidney function).
3. Stage 3: Signs of moderate chronic renal insufficiency (GFR indicates 40% to 59% kidney function).
4. Stage 4: Signs of severe chronic renal insufficiency (GFR indicates 15% to 29% kidney function).
5. Stage 5: Signs of end stage renal failure (GFR indicates less than 15% kidney function).

E. **Interventional cardiology** is the subspecialty within the practice of cardiology which employs catheter-based techniques to diagnosis and manage (medically, mechanically, and/or surgically) individuals with acute and chronic forms of cardiovascular disease. Examples of applicable technologies include, but are not limited to, balloon angioplasty, intracoronary stent deployment, intracoronary valve replacement, rotational atherectomy, extraction atherectomy, and peripheral angioplasty.

F. **Mitral regurgitation (MR),** also known as mitral insufficiency or mitral incompetence, is a disorder of the heart in which the mitral valve does not close properly. During systole, contraction of the left ventricle causes abnormal backflow of blood into the left atrium. MR is a common form of valvular heart disease. The symptoms associated with MR depend on degree of disease progression. Individuals with acute mitral regurgitation will have the signs and symptoms of decompensated congestive heart failure, as well as symptoms suggestive of a low cardiac output state. MR is quantified using a graded scale. A commonly accepted scale follows:
   1. Grade 1+: Mild MR.
   2. Grade 2+: Moderate MR.
   3. Grade 3+: Moderate-to-severe MR.
   4. Grade 4+: Severe MR.

G. **New York Heart Association (NYHA) functional classification** is classification of an individual’s extent of heart failure. It places the individual in one of four categories based on degree of limitation during physical activity, using the limitations/symptoms related to degrees of breathing difficulty, shortness of breath, and/or angina pain. The classification is:
   1. NYHA Class I: Cardiac disease, but no symptoms and no limitation in ordinary physical activity (e.g. shortness of breath when walking, climbing stairs, etc.).
   2. NYHA Class II: Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
   3. NYHA Class III: Marked limitation in activity due to symptoms, even during less-than-ordinary activity (e.g. walking short distances [20–100 m]). Comfortable only at rest.
   4. NYHA Class IV: Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

H. **Right ventricular outflow tract (RVOT) dysfunction** occurs when right ventricular outflow tract is blocked or obstructed due to a spectrum of disorders, including defects in the pulmonic valve, the supravalvar region, the infundibulum, or the pulmonary artery. Examples of resulting conditions include pulmonary atresia, pulmonary valve stenosis, and/or hypoplastic right heart syndrome.

I. **Transcatheter aortic valve replacement/implantation (TAVR / TAVI)** is a nonsurgical, minimally invasive method to correct aortic stenosis. The native aortic valve is approached via a balloon catheter guided to the replacement site. Once the instrumentation is in place, the artificial valve is inserted over the diseased aortic valve. Two transcatheter aortic heart valves have received U.S. Food and Drug Administration (FDA) approval. The Edwards SAPIEN valve system (Edwards Lifesciences LLC) was granted FDA approval in November 2011, while the CoreValve system (Medtronic Inc.) received FDA approval in January 2014. Other transcatheter systems are currently under clinical evaluation.


K. **Transcatheter, percutaneous pulmonary valve implantation (PPVI)** is a minimally invasive method purported to correct right ventricular outflow tract (RVOT) dysfunction. The Melody® Transcatheter Pulmonary Valve system (Medtronic, Inc.) was granted a Humanitarian Device Exemption (HDE) for certain indications by the FDA in 2010. It is currently the only FDA-approved commercially available PPVI in the United States. The delivery system is inserted into the femoral vein and guided into the RVOT, whereupon the balloon is inflated until the valve is fully deployed. Another system, the Sapien Transcatheter Heart Valve platform (Edwards Lifesciences), is currently commercially available only in Europe, but clinical trials are ongoing in the U.S.
A. Aortic stenosis is the most common valvular abnormality in the United States, with approximately five of every 10,000 (one of every 2,000) U.S. adults displaying the condition. Prevalence is highest in older subsets of the population. In one large study (Carabello, 2009), 26% of participants over the age of 65 displayed some degree of aortic stenosis. Progression from aortic sclerosis with no obstruction in ventricular blood outflow to aortic stenosis with serious outflow obstruction causing sickness and death can be estimated, but much variability exists in the rate of progression. Furthermore, it is not currently possible to predict rate of progression on an individual basis. Symptomatic, severe aortic stenosis displays a poor prognosis, with average survival being two to three years after development of severe symptoms. There is also an increased risk of sudden death.

B. Surgical aortic valve replacement has traditionally been the gold standard for treatment in adults with severe symptomatic aortic stenosis. Recently, due to technological advances in the percutaneous delivery of heart valves via catheter, transcatheter aortic valve replacement (TAVR) has been introduced. The first human trials were initiated in 2002. Currently, the Edwards SAPIEN® prosthesis and the CoreValve® prosthesis are available for implantation in the United States.

C. In the United States, the Centers for Medicare and Medicaid Services (CMS) allows for coverage of TAVR for individuals meeting specified clinical criteria only when the individual’s condition is managed by a comprehensive, multidisciplinary care team, TAVR is performed in a specialized heart center meeting defined practice parameters, and outcomes are reported to the joint Society of Thoracic Surgeons/American College of Cardiology Registry database. (Note: See the Coverage Issues and References section of this document).

MEDICAL NECESSITY CRITERIA EQR
TRANSCATHETER AORTIC VALVE REPLACEMENT/IMPLANTATION (TAVR / TAVI)

I. Prior authorization is required for initial TAVR/TAVI. It is considered medically necessary when documentation in the medical record indicates that all of the following criteria are met:

A. TAVR/TAVI is to be performed using an FDA approved system (e.g., Edwards SAPIEN™ system; CoreValve system).

B. The individual demonstrates severe, symptomatic, calcified native aortic valve stenosis without severe aortic insufficiency, as documented by all of the following:
   1. New York Heart Association (NYHA) functional classification of II or higher.
   2. Echocardiogram or magnetic resonance imaging (MRI) results documenting an ejection fraction greater than or equal to 20%.
   3. Echocardiogram or MRI results documenting one of the following:
      a. Mean gradient greater than 40 mm HG or
      b. Jet velocity greater than 4.0m/s and one of the following:
         1) An initial aortic valve area of less than 0.8 cm2
         2) An indexed effective orifice area (EOA) less than 0.5 cm2/m2.

C. The individual is being evaluated by a multidisciplinary team, which includes both of the following:
   1. A cardiologist
   2. A cardiac surgeon.

D. The multidisciplinary team concurs and has documented all of the following:
   1. The individual is inoperable or at high risk for open aortic valve replacement (e.g., high probability of death or serious irreversible morbidity)
   2. Existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis.

D. No documented contraindications present as indicated by all of the following:
   1. No active bacterial endocarditis or other active infections within 6 months of surgery.
   2. No acute coronary syndrome (e.g., MI, unstable angina pectoris), transient ischemic attack or stroke within one month of surgery.
   3. No mixed aortic valve disease (e.g., aortic stenosis and aortic regurgitation with predominant aortic regurgitation greater than 3+).
   4. No evidence on echocardiogram of intracardiac mass, thrombus, or vegetation.
   5. No kidney dysfunction classification greater than stage 3.
   6. No non-cardiac condition which limits life expectancy to less than 12 months.

II. Prior authorization is required for surgical revision or bioprosthesis replacement following initial TAVR/TAVI. It is considered medically necessary when documentation in the medical record indicates that one of the following criteria is met:
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**A. Complication due to failure of optimal device placement and/or prosthetic dysfunction** (e.g., malpositioning, valve migration/embolization, postdilation of the prosthesis, paravalvular leak)

**B. Significant vascular complication** (e.g., vascular dissection, perforation, access-site hematoma, bleeding, transfusion, paravalvular aortic regurgitation, atrioventricular heart block, new-onset atrial fibrillation).

**Note:** All requests for surgical revision or bioprosthesis replacement require Medical Director review.

**TRANSCATHETER MITRAL VALVE LEAFLET REPAIR**

**I. Prior authorization is required** for initial transcatheter mitral valve leaflet repair. It is considered medically necessary when documentation in the medical record indicates that **all of the following** criteria are met:

- **A. Procedure** is to be performed using an FDA approved system (e.g., MitraClip®).
- **B. The individual** demonstrates severe mitral regurgitation due to primary abnormality of the mitral apparatus, as demonstrated by **all of the following**:
  1. NYHA functional classification of II or higher
  2. Mitral regurgitation grade 3+ or higher.
- **C. The individual** is being evaluated by a multidisciplinary team, which includes **both of the following**:
  1. A cardiologist
  2. A cardiac surgeon.
- **D. The multidisciplinary team** concurs and has documented **all of the following**:
  1. The individual is inoperable or at high risk for open mitral valve replacement (e.g., high probability of death or serious irreversible morbidity)
  2. Existing co-morbidities would not preclude the expected benefit from correction of the MR.
- **E. No documented contraindications** present as indicated by **all of the following**:
  1. No active bacterial endocarditis or other active infections within 6 months of surgery
  2. No pre-existing prosthetic heart valve failure (e.g., mechanical; animal-based) or prosthetic ring in any position
  3. No acute coronary syndrome (e.g., MI, unstable angina pectoris), transient ischemic attack or stroke within one month of surgery
  4. No evidence on echocardiogram of intracardiac mass, thrombus, or vegetation
  5. No kidney dysfunction classification greater than stage 3.

**II. Prior authorization is required for surgical revision or bioprosthesis replacement following initial transcatheter mitral valve leaflet repair.** It is considered medically necessary when documentation in the medical record indicates that **one of the following** criteria are met:

- **Complication due to failure of optimal device placement and/or prosthetic dysfunction** (e.g., malpositioning, valve migration/embolization, postdilation of the prosthesis, paravalvular leak)
- **Significant vascular complication** (e.g., perforation, access-site hematoma, bleeding, transfusion, atrioventricular heart block, new-onset atrial fibrillation).

**Note:** All requests for surgical revision or bioprosthesis replacement require Medical Director review.

**MEDICAL NECESSITY CRITERIA FOR PERCUTANEOUS PULMONARY VALVE IMPLANTATION (PPVI):**

**I. Indications for initial PPVI:**

- When the Melody® transcatheter pulmonary valve and delivery system (Medtronic, Inc.) is indicated for use:
  - Refer to the Utilization Management policy: **Humanitarian Device Exemption** policy, for appropriate coverage criteria.
- When another PPVI is indicated for use: See Coverage Issues section, below, for related information.

**II. Indications for surgical revision or bioprosthesis replacement following initial Melody PPVI implantation:**

**All** requests for surgical revision or bioprosthesis replacement of the Melody transcatheter pulmonary valve and delivery system require Medical Director Review.

**COVERAGE ISSUES**

1. **Prior authorization is required** for transcatheter aortic valve replacement/implantation (TAVR/TAVI) using an FDA approved system (e.g., Edwards SAPIEN™ system; CoreValve® system).
2. TAVR/TAVI using any non-FDA approved TAVR/TAVI system and/or for any indication not outlined above is investigative and therefore not covered.
3. Transcatheter/percutaneous replacement of a pulmonary valve is investigative and therefore not covered. This does not apply to transcatheter/percutaneous replacement using a heart valve having an approved humanitarian device exemption. The Melody® transcatheter pulmonary valve and delivery system has been granted an HDE for treatment of right ventricular outflow threshold (RVOT) disorders for patients who meet device exemption indications. Refer to the Utilization Management: **Humanitarian Device Exemption** policy for details on coverage.

Effective Date: February 18, 2015
4. Coverage may vary according to the terms of the member’s plan document.

5. For Medicare members, refer to the following, as applicable:

6. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.

7. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be reviewed by the medical director or an external reviewer. Practitioners are reminded of the appeals process in their Medica Provider Administrative Manual.

References


24. Hayes, Inc. Hayes Search and Summary: Melody Transcatheter Pulmonary Valve (Medtronic) for Patients with Tetralogy of Fallot. August 2013. Lansdale, PA.


