

Corporate Medical Policy

Transcatheter Heart Valve Implantation

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Description of Procedure or Service

As the proportion of older adults increases in the U.S. population, the incidence of degenerative heart valve disease also increases. Aortic stenosis and mitral regurgitation are the most common valvular disorders in adults aged 70 years and older. For patients with severe valve disease, heart valve replacement involving open heart surgery can improve functional status and quality of life. A variety of conventional mechanical and bioprosthetic heart valves are readily available. However, some individuals, due to advanced age or co-morbidities, are considered too high risk for open heart surgery. Alternatives to the open heart approach to heart valve replacement are currently being explored.

Transcatheter heart valve replacement is a relatively new interventional procedure involving the insertion of an artificial heart valve using a catheter, rather than through open heart surgery. The point of entry is typically either the femoral vein (antegrade) or femoral artery (retrograde), or directly through the myocardium via the apical region of the heart. An expandable prosthetic heart valve is crimped onto a catheter and then delivered and deployed at the site of the diseased native valve. The percutaneous heart valve replacement procedure usually takes less time to perform and is less invasive than open heart surgery. Potential disadvantages of transcatheter heart valve replacement include a greater risk for valve migration (since the valve is not sewn into place), complications associated with catheter-based delivery, and uncertain valve durability.

There are a number of products in use and in development. They include: CoreValve ReValving System™ (Medtronic, Inc.), Direct Flow Medical Valve (Direct Flow Medical, Inc.), Edwards SAPIEN® and SAPIEN XT (Edwards Lifescience, LLC), Melody® Valve (Medtronic, Inc.), and Lotus Valve™ (Sadra Medical).

The SAPIEN Transcatheter Heart Valve System™ 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.

The FDA approved the Medtronic Melody® Transcatheter Pulmonary Valve and Ensemble Delivery System under the Humanitarian Device Exemption (HDE) on January 25, 2010 for the treatment of adults and children with previously implanted, poorly functioning pulmonary valve conduits.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Transcatheter Heart Valve Implantation

Policy

Transcatheter Heart Valve Implantation may be considered medically necessary when the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Transcatheter Heart Valve Implantation is covered

Transcatheter pulmonary valve implantation (TPVI) may be considered medically necessary for patients with prior repair of congenital heart disease and right ventricular outflow tract (RVOT) dysfunction.

Transcatheter aortic valve implantation (TAVI) may be considered medically necessary for patients with aortic stenosis (AS) when **all** of the following conditions are present.

1. Severe aortic stenosis with a calcified aortic annulus defined as:
 - a. An aortic valve area of less than 0.8cm²
 - b. A mean aortic valve gradient greater than 40mmHg
 - c. A jet velocity greater than 4.0m/sec **and**
2. NYHA heart failure Class II, III or IV symptoms **and**
3. Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon)

When Transcatheter Heart Valve Implantation is not covered

Transcatheter aortic and pulmonary valve replacement is considered investigational for all other indications.

Policy Guidelines

To date, few groups in the United States have significant experience with percutaneous heart valve replacement and there is little U.S. based research. Although initial reports demonstrate that transcatheter heart valves can be implanted with short-term success, longer term survival, product durability, and complication rates are unknown. Reported complications include myocardial infarction or stroke, arrhythmia, perforation of the vessels or heart wall, and heart failure.

In patients who are not candidates for open surgery, or who are high-risk for surgery due to other medical comorbidities, alternative treatment options are limited. TAVI addresses an unmet need for patients with severe aortic stenosis who require intervention, but who are a high or prohibitive risk for open surgery. The Sapien Total Heart Valve System received FDA-approval in November 2011 for patients who are not operable candidates.

Regarding pulmonary valve replacement, use of the Melody valve should be especially beneficial to pediatric patients with right-sided valvular heart disease who may face several surgeries over their

Transcatheter Heart Valve Implantation

lifetimes. The Medtronic Melody valve FDA's approval was contingent upon the conduction of two post-approval studies to determine the long-term risks and benefits as well as to assess the physician specialization needed to perform the implantation procedure. One study will continue to follow 150 participants from the initial clinical trial for five years, and the second study will enroll more than 100 new participants to be evaluated over five years. Safety and benefit assessments will be part of both studies. The FDA also instructs Medtronic to compile a database of Melody recipients.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0256T, 0257T, 0258T, 0259T, 0262T

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Agency for Healthcare Research and Quality (AHRQ). Percutaneous Heart Valve Replacement. August 2010. Retrieved on November 19, 2010 from <http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=techbrief2>

National Institute for Clinical Excellence (NICE). Transcatheter aortic valve implantation for aortic stenosis. Interventional procedure guidance 266. June 2008. Retrieved on November , 19, 2010 from <http://www.nice.org.uk/nicemedia/live/11914/41020/41020.pdf>

National Institutes of Health (NIH). THE PARTNER TRIAL: Placement of AoRTic TraNscathetER Valve Trial. NCT00530894. Retrieved on November 19, 2010 from <http://www.clinicaltrials.gov/ct2/results?term=NCT00530894>

National Institutes of Health (NIH). Transcatheter Compared to Surgical Valve Implantation in Patients With Severe Aortic Valve Stenosis (TAVIvsSAVR). NCT01057173. Retrieved on November 19, 2010 from <http://www.clinicaltrials.gov/ct2/results?term=NCT01057173>

Coeytaux RR, Williams Jr. JR, Gray, RN; Wang A. Narrative Review: Percutaneous Heart Valve Replacement for Aortic Stenosis: State of the Evidence. *Ann Intern Med.* 2010 Sep 7;153(5):314-24. Retrieved on November 19, 2010 from <http://www.annals.org/content/153/5/314.long>

Food and Drug Administration (FDA) Approval letter for Medtronic Melody® Transcatheter Pulmonary Valve (Model PB 10) and Medtronic Ensemble® Transcatheter Valve Delivery System. H080002. January 25, 2011. Retrieved on May 26, 2011 from http://www.accessdata.fda.gov/cdrh_docs/pdf8/H080002a.pdf

National Institutes of Health (NIH). Melody Transcatheter Pulmonary Valve Study: Post Approval Study of the Original IDE Cohort (Melody IDE). NCT00740870. Retrieved on May 26, 2011 from <http://clinicaltrials.gov/ct2/show/NCT00740870>

National Institutes of Health (NIH). Melody® Transcatheter Pulmonary Valve Post-Approval Study.

Transcatheter Heart Valve Implantation

NCT01186692. Retrieved on May 26, 2011 from <http://clinicaltrials.gov/ct2/show/NCT01186692>

Hillebrenner MG, Swain JA, Zuckerman B. Valve Academic Research Consortium (VARC) Consensus Report: The FDA Perspective. J. Am. Coll. Cardiol. 2011;57:270-271. Retrieved on May 26, 2011 from <http://content.onlinejacc.org/cgi/reprint/57/3/270.pdf>

Specialty Matched Consultant Advisory Panel review 6/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.131, 11/10/11

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.132, 12/8/11

Medical Director review 3/2012

Policy Implementation/Update Information

1/4/11 New policy implemented. Transcatheter Heart Valve Implantation is not covered for any clinical indication including mitral or aortic valve replacement or by any approach. This includes percutaneous/endovascular access or by transapical/transventricular access.(mco)

7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. Added new coverage criteria for the Medtronic Melody® Transcatheter Pulmonary Valve and Ensemble Delivery System. Policy revised to state: “Transcatheter Heart Valve Implantation may be considered medically necessary as a replacement for a pulmonary heart valve that has been previously repaired. Transcatheter Heart Valve Implantation is considered investigational for aortic or mitral valve replacement. BCBSNC does not provide coverage for investigational services or procedures.” Added the following statement to the “When Covered” section: “Transcatheter Heart Valve Implantation may be considered medically necessary as a replacement for a pulmonary heart valve that has been previously repaired.” References updated. Policy Guidelines updated. Added new code effective July 1, 2011: 0262T (mco)

3/30/12 Added new coverage criteria for Transcatheter Aortic Valve Implantation (TAVI.) “When Covered” section revised to state: “Transcatheter pulmonary valve implantation (TPVI) may be considered medically necessary for patients with prior repair of congenital heart disease and right ventricular outflow tract (RVOT) dysfunction. Transcatheter aortic valve implantation (TAVI) is considered medically necessary for patients with aortic stenosis (AS) when **all** of the following conditions are present. Severe aortic stenosis with a calcified aortic annulus defined as: a. An aortic valve area of less than 0.8cm², b. A mean aortic valve gradient greater than 40mmHg, c. A jet velocity greater than 4.0m/sec **and** 2. NYHA heart failure Class II, III or IV symptoms **and** 3. Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon)” “Description” section and “Policy Guidelines” section updated. Reference updated. Medical Director review 3/2012.

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.