

Corporate Medical Policy

Surgical Management of Transcatheter Heart Valves

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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 repair or 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 and repair are relatively new interventional procedures involving the insertion of an artificial heart valve or repair device using a catheter, rather than through open heart surgery, or surgical valve replacement (SAVR). 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. For pulmonic and aortic valve replacement surgery, an expandable prosthetic heart valve is crimped onto a catheter and then delivered and deployed at the site of the diseased native valve. For valve repair, a small device is delivered by catheter to the mitral valve where the faulty leaflets are clipped together to reduce regurgitation.

The percutaneous heart valve surgery procedure usually takes less time to perform and is less invasive than open heart surgery. Potential disadvantages of transcatheter heart valve surgery include a greater risk for valve migration (since the valve is not sewn into place), complications associated with catheter-based delivery, and uncertain valve/device durability.

Regulatory Status

There are a number of heart valve products in use and in development, including: Edwards SAPIEN™ and SAPIEN XT (Edwards Lifescience, LLC), CoreValve Valve Systems™ (Medtronic CoreValve, Inc.), Direct Flow Medical Valve (Direct Flow Medical, Inc.), Melody® Valve (Medtronic, Inc.), and MitraClip (Abbott Vascular). See descriptions below.

Transcatheter Aortic Valve

Multiple manufacturers have received approval from the Food and Drug Administration (FDA) for transcatheter aortic valve devices for aortic stenosis with expanded indications.

- The Edward SAPIEN Transcatheter Heart Valve System™ (Edwards LifeSciences) received FDA approval in November 2011. Approval was granted through the premarket approval process for patients with severe native aortic stenosis determined to be inoperable for open aortic valve replacement (transfemoral approach).

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- October of 2012, indications were expanded to include patients with high risk aortic stenosis (transapical approach)
- August of 2016, the FDA expanded indications to include severe aortic stenosis with intermediate risk for open surgery.
- June of 2017, indications were expanded to include replacement of bioprosthetic valve in high risk for death or severe complications of repeat surgery.
- In July 2014, the Edward SAPIEN XT Transcatheter Heart Valve (model 9300TFX) was approved by the FDA.
 - October 2015, FDA expanded the indication to include failure of bioprosthetic valve in high or greater risk for open surgical therapy.
 - October 2015, indication was expanded to include failure of bioprosthetic valve in high or greater risk for open surgical therapy.
 - August 2016, the FDA again expanded indications to include severe aortic stenosis with intermediate surgical risk. (ie, predicted risk of surgical mortality $\geq 3\%$ at 30 days based on the Society of Thoracic Surgeons [STS] Risk Score and other clinical co-morbidities unmeasured by the STS Risk Calculator).
 - August 2019, the FDA expanded indications to include severe aortic stenosis with low surgical risk.

Medtronic CoreValve System™ (Medtronic CoreValve) received FDA approval in January 2014, through the premarket approval process for patients with severe native aortic stenosis at extreme risk or inoperable for open surgical therapy.

- June 2015, FDA expanded the indications to include high risk for open surgical therapy.
- July 2017, indications were expanded to include intermediate risk for open surgical therapy.
- Medtronic CoreValve Evolut R System™, received FDA approval in June 2015.
 - July 2017, FDA expanded indications to include patients at intermediate risk for open surgical therapy.
 - August 2019, FDA expanded indications to include severe aortic stenosis with low surgical risk.
- Medtronic CoreValve Evolut PRO system received FDA approval, through the premarket approval process to include porcine pericardial tissue wrap.
 - July 2017, FDA expanded indications to include intermediate risk for open surgical therapy. labeling indicates that the device can be delivered via femoral, subclavian/axillary, or ascending aortic access. In March 2017, the FDA approved the CoreValve Evolut PRO System™. All three devices received approval for expanded indications to include intermediate risk for open surgery.
 - August 2019, FDA expanded indications to include severe aortic stenosis with low surgical risk.
- LOTUS Edge Valve System received FDA approval, through the premarket approval process for severe aortic stenosis at high or greater risk for open surgical therapy in April 2019.

Transcatheter Pulmonary Valve

Devices for transcatheter pulmonary valve implantation were initially cleared from marketing by the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption (HDE) process. Approval was then granted by FDA through the premarket approval process between 2015 and 2016.

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In January 2010, the Melody® and the Ensemble® Transcatheter Delivery System (Medtronic) were approved by FDA under the HDE program for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

- Existence of a full (circumferential) right ventricular outflow tract (RVOT) conduit that was 16 mm or greater in diameter when originally implanted, and
- Dysfunctional RVOT conduits with clinical indication for intervention, and either:
 - Regurgitation: moderate-to-severe regurgitation, or
 - Stenosis: mean RVOT gradient ≥ 35 mm Hg

The Melody® Transcatheter Pulmonary Valve (TPV) and the Ensemble® Transcatheter Valve Delivery System were approved to be used for percutaneous replacement of a dysfunctional pulmonary valve. The Melody® Valve consists of a section of bovine jugular vein with an intact native venous valve. The valve and surrounding tissue are sutured within a platinum-iridium stent scaffolding. The transcatheter delivery system consist of a balloon-in-balloon catheter with a retractable sheath and distal cup into which the valve is placed. The procedure is performed on a beating heart without the use of cardiopulmonary bypass.

In January 2015, approval of the Melody® system was amended to a premarket approval (PMA) because FDA determined that the device represents a breakthrough technology. The PMA was based, in part, on 2 prospective clinical studies, the Melody® TPV Long-term Follow-up Post Approval Study (PAS) and the Melody TPV New Enrollment PAS. In February 2017, approval was expanded for the Melody® system to include patients with a dysfunctional surgical bioprosthetic valve (valve in valve).

The Edwards Sapien XT™ Transcatheter Heart Valve (Pulmonic) (Edwards Lifesciences) is composed of a stainless steel frame with bovine pericardial tissue leaflets and available in 23- and 26-mm sizes. It includes a delivery accessories system. In February 2016, it was approved by FDA as a supplement “for use in pediatric and adult patients with dysfunctional, noncompliant Right Ventricular Outflow Tract (RVOT) conduit with a clinical indication for intervention, along with pulmonary regurgitation \geq moderate and/or mean RVOT gradient ≥ 35 mmHg.

The approval for the pulmonic valve indication is a supplement to the 2014 PMA for use of the Edwards SAPIEN XT™ Transcatheter Heart Valve (THV) System, for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis and who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (ie, Society of Thoracic Surgeons operative risk score $\geq 8\%$ or at a $\geq 15\%$ risk of mortality at 30 days).

Transcatheter Mitral Valve

In October 2013, the MitraClip® Clip Delivery System (Abbott Vascular) was approved by FDA through the premarket approval process for treatment of “significant symptomatic mitral regurgitation (MR $\geq 3+$) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at a prohibitive risk for mitral valve surgery by a heart team.”

In March 2019, FDA approved a new indication for MitraClip, for “treatment of patients with normal mitral valves who develop heart failure symptoms and moderate-to-severe or severe mitral regurgitation because of diminished left heart function (commonly known as secondary or functional mitral regurgitation) despite being treated with optimal medical therapy. Optimal medical therapy includes combinations of different heart failure medications along with, in certain patients, cardiac resynchronization therapy and implantation of cardioverter defibrillators.”

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*****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.**

Policy

Surgical Management of Transcatheter Heart Valves 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 Surgical Management of Transcatheter Heart Valves is covered

Transcatheter mitral valve repair with a device approved by the Food and Drug Administration for use in mitral valve repair may be considered medical necessary for patients with symptomatic, primary mitral regurgitation who are considered at prohibitive risk for open surgery.

“Prohibitive risk” for surgery may be determined based on:

- Presence of a Society for Thoracic Surgeons predicted mortality risk of 12% or greater; **and/or**
- Presence of a logistic EuroScore of 20% or greater.

Transcatheter mitral valve repair with a device approved by the U.S. Food & Drug Administration may be considered medically necessary for patients with heart failure and moderate-to-severe or severe symptomatic secondary mitral regurgitation despite the use of maximally tolerated guideline-directed medical therapy.

Moderate to severe or severe mitral regurgitation (MR) may be determined by:

- Grade 3+ (moderate) or 4+ (severe) MR confirmed by echocardiography
- New York Heart Association (NYHA) functional class II, III or IVa (ambulatory) despite the use of stable maximal doses of guideline-directed medical therapy and cardiac resynchronization therapy (if appropriate) administered in accordance with guidelines of professional societies.

Transcatheter pulmonary valve implantation (TPVI) may be considered medically necessary for patients with congenital heart disease and current right ventricular outflow tract (RVOT) obstruction or regurgitation including the following indications:

- Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation;
- Individuals with native or patched right ventricular outflow tract (RVOT) with at least moderate pulmonic regurgitation;
- Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35mm Hg); **or**
- Individuals with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35mm Hg).

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

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1. Severe aortic stenosis with a calcified aortic annulus as defined by one or more of the following criteria:
 - An aortic valve area of less than 0.8cm²
 - A mean aortic valve gradient greater than 40mmHg
 - A jet velocity greater than 4.0m/sec **and**
2. NYHA heart failure Class II, III or IV symptoms **and**
3. Left ventricular ejection fraction >20%; **and**
4. Patient does not have unicuspid or bicuspid aortic valves.

Transcatheter aortic valve replacement with a transcatheter heart valve system approved for use for repair and/or replacement of a degenerated bioprosthetic valve (valve-in-valve) may be considered **medically necessary** when all of the following conditions are present:

1. Failed (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; **and**
2. NYHA heart failure class II, III or IV symptoms; **and**
3. Left ventricular ejection fraction >20%; **and**
4. Patient is not an operable candidate for open surgery, as judged by at least 2 cardiovascular specialists (cardiologist and/or cardiac surgeon); or patient is an operable candidate but is at high risk for open surgery

When Surgical Management of Transcatheter Heart Valves is not covered

Transcatheter mitral valve repair is considered investigational for all other indications not listed above.

Transcatheter pulmonary valve implantation is considered investigational for all other indications.

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

Transcatheter tricuspid valve repair or replacement is considered investigational for all indications.

Policy Guidelines

Transcatheter aortic valve implantation (TAVI)

For individuals who have severe symptomatic aortic stenosis who are at prohibitive risk for open surgery who receive TAVI, the evidence includes 1 randomized controlled trial (RCT) comparing TAVI with medical management in individuals at prohibitive risk of surgery, 1 single-arm prospective trial, multiple case series, and multiple systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. For patients who are not surgical candidates due to excessive surgical risk, the PARTNER B trial reported results for patients treated with TAVI by the transfemoral approach compared with continued medical care with or without balloon valvuloplasty. There was a large decrease in mortality for the TAVI patients at 1 year compared with medical care. This trial also reported improvements on other relevant clinical outcomes for the TAVI group. There was an increased risk of stroke and vascular complications in the TAVI group. Despite these concerns, the overall balance of benefits and risks from this trial indicate that health outcomes are improved. For

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patients who are not surgical candidates, no randomized trials have compared the self-expandable valve to best medical therapy. However, results from the single arm CoreValve Extreme Risk Pivotal Trial met the authors prespecified objective performance goal. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at high risk for open surgery who receive TAVI, the evidence includes 2 RCTs comparing TAVI with surgical repair in individuals at high risk for surgery and 1 RCT comparing two types of valves, multiple nonrandomized comparative studies, and systematic reviews of these studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. For patients who are high risk for open surgery and are surgical candidates, the PARTNER A trial reported noninferiority for survival at 1 year for the balloon-expandable valve compared with open surgery. In this trial, TAVI patients also had higher risks for stroke and vascular complications. Nonrandomized comparative studies of TAVI versus open surgery in high-risk patients have reported no major differences in rates of mortality or stroke between the two procedures. Since the publication of the PARTNER A trial, the CoreValve High Risk Trial demonstrated noninferiority for survival at 1 and 2 years for the self-expanding prosthesis. This trial reported no significant differences in stroke rates between groups. In an RCT directly comparing the self-expandable with the balloon-expandable valve among surgically high-risk patients, the devices had similar 30-day mortality outcomes, although the self-expandable valve was associated with higher rates of residual aortic regurgitation and requirement for a new permanent pacemaker. Evidence from RCT and nonrandomized studies suggest that TAVI with a self-expanding device is associated with higher rates for permanent pacemakers postprocedure. However, survival rates appear to be similar between device types, and the evidence does not clearly support the superiority of one device over another in all patients. Two gender-specific studies were also identified in a literature search with the objective of observing mortality rates in women undergoing TAVI or SAVR. Results were varied, and further study is needed. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at intermediate risk for open surgery who receive TAVI, the evidence includes 3 RCTs comparing TAVI with surgical repair including individuals at intermediate surgical risk, 2 RCTs only in patients with intermediate risk, and multiple systematic reviews and nonrandomized cohort studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Five RCTs, have evaluated TAVI in patients with intermediate risk for open surgery. Three of them, which included over 4,000 patients combined, reported noninferiority of TAVI vs SAVR for their composite outcome measures (generally including death and stroke). A subset analysis of patients (n=383) with low and intermediate surgical risk from a fourth trial reported higher rates of death at 2 years for TAVI vs SAVR. The final study (N=70) had an unclear hypothesis and reported 30-day mortality rates favoring SAVR (15% vs 2%, p=0.07) but used a transthoracic approach. The rates of adverse events differed between groups, with bleeding, cardiogenic shock, and acute kidney injury higher in patients randomized to open surgery and permanent pacemaker requirement higher in patients randomized to TAVI. Subgroup analyses of meta-analyses and the transthoracic arm of the Leon and colleagues RCT, suggest that the benefit of TAVI may be limited to patients who are candidates for transfemoral access. Although several RCTs have two years of follow-up post-procedure, it is uncertain how many individuals require reoperation. The evidence is sufficient to determine that the technology results in meaningful improvements in the net health outcomes.

For individuals who have severe symptomatic aortic stenosis who are at low risk for open surgery who receive TAVI, the evidence includes two RCTs comparing TAVI with surgical repair in individuals selected without specific surgical risk criteria but including patients at low surgical risk and RCTs enrolling low surgical risk patients, systematic reviews, and nonrandomized cohort studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Two RCTs (Evolut Low Risk Trial and PARTNER 3) have been

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conducted exclusively in patients at low surgical risk and 1 RCT (NOTION) included predominantly patients at low surgical risk. In the Evolut Low Risk Trial, TAVR was noninferior to SAVR with respect to the composite outcome of death or disabling stroke at 24 months. In the PARTNER 3 trial, the rate of the composite of death, stroke, or rehospitalization at 1 year was significantly lower with TAVI than SAVR. In the NOTION trial, the risk of the composite outcome of death from any cause, stroke, or MI at 5 years was similar for TAVI and SAVR. TAVR showed less structural valve deterioration than SAVR at 6 years. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Clinical input supported the use of transcatheter aortic “valve-in-valve” replacement for individuals who have degeneration of a surgically implanted aortic valve and who are at high or prohibitive risk for open repair.

Transcatheter pulmonary valve implantation (TPVI)

The evidence for TPVI with an FDA-approved device according to FDA indications in patients who have a history of CHD and current RVOT obstruction, includes prospective, interventional, noncomparative studies and multiple prospective and retrospective case or cohort series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity and mortality. The results of the case series indicate that there is a high rate of procedural success and low procedural mortality, although the rates of serious procedural adverse events reported ranges from 3.0% to 7.4%. Most valves demonstrate competent functioning by Doppler echocardiography at 6- to 12-month follow-up, but complications (eg. stent fractures, need for reinterventions) were reported in an FDA analysis to occur at rates of 18% and 7%, respectively. Other publications with longer follow-up have reported stent fractures in up to 26% of patients; however, most stent fractures have not required reintervention. Studies with follow-up extending to a maximum of 7 years postprocedure have suggested that the functional and hemodynamic improvements are durable, but a relatively high proportion of patients, roughly 20-30% require reintervention on the pulmonary valve. No comparative studies were identified, and there is no direct evidence to demonstrate that TPVI leads to a reduction in future open heart procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for TPVI with a non-FDA-approved indication or device in patients who have a history of CHD and current RVOT obstruction includes case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity and mortality. There is limited published evidence on the off-label use of TPVI, including implantation of a non-FDA-approved valve, or use of an approved valve for a non-FDA-approved indication. The published evidence consists of relatively small case series with few enrolled patient that are heterogeneous in terms of the device used and the indications for TPVI. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical evidence in 2011 demonstrates short-term success and supports TPVI for patients who are not candidates for open repair or who are at high risk for open repair, due to limited alternative treatment options. In 2018, clinical evidence indicates meaningful improvement in net health outcomes in the use of TPVI for individuals with any of the following:

- right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation;
- native or patched RVOT with at least moderate pulmonic regurgitation;
- With right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35mm Hg);
- Native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 34mmg Hg).

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Transcatheter mitral valve (MV) repair

The evidence for patients with symptomatic primary MR and at prohibitive risk for open surgery who receive TMVR using MitraClip, includes a single-arm prospective cohort with historical cohort and registry studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment related morbidity. The primary evidence includes the pivotal EVEREST II HRR and EVEREST II REALISM studies and Transcatheter Valve Therapy Registry studies. These studies demonstrate that MitraClip implantation is feasible with a procedural success rate greater than 90%, 30-day mortality ranging from 2.3% to 6.4% (less than predicted STS mortality risk score for MR repair or replacement; range, 9.5%-13.2%), postimplantation MR severity grade of 2+ or less in 82% to 93% of patients, and a clinically meaningful gain in quality of life (5- to 6-point gains in 36-Item Short-Form Health Survey scores). At 1-year, freedom from death and MR more than 2+ was achieved in 61% of patients but the 1-year mortality or heart failure hospitalization rates remain considerable high (38%). Conclusions related to the treatment effect on mortality based on historical controls cannot be made because the control groups did not provide unbiased or precise estimates of the natural history of patients eligible to receive MitraClip. Given that primary MR is a mechanical problem and there is no effective medical therapy, a randomized controlled trial (RCT) comparing MitraClip with medical management is not feasible or ethical. The postmarketing data from the United States is supportive that MitraClip surgery is being performed with short-term effectiveness and safety in select patient populations. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome. mortality rates in

For individuals who have heart failure and symptomatic secondary MR despite the use of maximally tolerated guideline-directed medical therapy who receive TMVR using MitraClip, the evidence includes two RCTs. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The trials had conflicting results, but the larger trial, with a longer duration and patients selected for nonresponse to maximally tolerated therapy, found a significant benefit for MitraClip after 2 years compared to medical therapy alone. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have symptomatic primary or secondary MR and are surgical candidates who receive TMVR using MitraClip, the evidence includes one RCT. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The RCT found that MitraClip did not reduce MR as often or as completely as the surgical control, although it could be safely implanted and was associated with fewer adverse events at 1 year. Long-term follow-up from the RCT showed that significantly more MitraClip patients required surgery for MV dysfunction than conventional surgery patients. For these reasons, this single trial is not definitive in demonstrating improved clinical outcomes with MitraClip compared with surgery. Additional RCTs are needed to corroborate these results. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have symptomatic primary or secondary MR who receive TMVR using devices other than MitraClip, the evidence includes primarily noncomparative feasibility studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The body of evidence consists only of very small case series and case reports. Controlled studies, preferably RCTs, are needed to draw conclusions about the net health benefit. The evidence is insufficient to determine the effects of the technology on health outcomes.

The American College of Cardiology (ACC), American Association for Thoracic Surgery, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons released a position statement on transcatheter therapies for MR in 2014. This statement outlines critical components for successful transcatheter MR therapies and recommends ongoing research and inclusion of all patients treated with transcatheter MR therapies in a disease registry.

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In 2017, the Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) released guidelines on the management of valvular heart disease.

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.bcbssc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0483T, 0484T, 0569T, 0570T

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

For Policy titled Transcatheter Heart Valve Implantation

Agency for Healthcare Research and Quality (AHRQ). Percutaneous Heart Valve Replacement. August 2010. Retrieved 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 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 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 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 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 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 from <http://clinicaltrials.gov/ct2/show/NCT00740870>

National Institutes of Health (NIH). Melody® Transcatheter Pulmonary Valve Post-Approval Study. NCT01186692. Retrieved 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 from <http://content.onlinejacc.org/cgi/reprint/57/3/270.pdf>

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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

Specialty Matched Consultant Advisory Panel review 6/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.131, 11/8/12

National Institutes of Health (NIH). A Comparison of Transcatheter Heart Valves in High Risk Patients with Severe Aortic Stenosis: The CHOICE trial. NCT 01645202. Retrieved from <http://clinicaltrials.gov/ct2/show/NCT01645202?term=NCT01645202&rank=1>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.132, 12/10/12

Specialty Matched Consultant Advisory Panel review 6/2013

Medical Director review 6/2013

For Policy re-titled Surgical Management of Transcatheter Heart Valves

Food and Drug Administration (FDA) Approval letter for Medtronic MitraClip Clip Delivery System PMA#P100009. http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100009a.pdf

Jilaihawi H, Hussaini A, Kar S. MitraClip: a novel percutaneous approach to mitral valve repair. J Zhejiang Univ Sci B. 2011 August; 12(8): 633–637. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3150716/>

National Institutes of Health (NIH). Pivotal Study of a Percutaneous Mitral Valve Repair System (EVERESTIIIRCT). NCT 00209274. <http://clinicaltrials.gov/ct2/show/NCT00209274>

Medical Director review 11/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.131, 11/14/13

Li X, Kong M, Jiang D et al. Comparison 30-day clinical complications between transfemoral versus transapical aortic valve replacement for aortic stenosis: a meta-analysis review. J Cardiothorac Surg 2013; 8:168. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3722124/>

Food and Drug Administration (FDA). FDA press release. FDA expands approved use of Sapien artificial heart valve. 2013. <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm323478.htm>.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.132, 12/12/13

Medical Director review 1/2014

Wan B, Rahnavardi M, Tian DH, Phan K, Munkholm-Larsen S, Bannon PG, Yan TD. A meta-analysis of MitraClip system versus surgery for treatment of severe mitral regurgitation. Ann Cardiothorac Surg. 2013 Nov;2(6):683-92.

Surgical Management of Transcatheter Heart Valves

National Institutes of Health (NIH). EVEREST II Pivotal Study High Risk Registry (HRR). NCT01940120. <http://clinicaltrials.gov/ct2/show/study/NCT01940120?term=REALISM&rank=4>

Food and Drug Administration (FDA). Press Release. FDA approval expands access to artificial heart valve for inoperable patients. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369510.htm>

Food and Drug Administration (FDA). Approval Letter -- Medtronic CoreValve System (P130021). 2014. http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130021a.pdf.

Nishimura RA, Otto CM, Bonow RO et al. 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2014.

Specialty Matched Consultant Advisory Panel review 6/2014

Medical Director review 6/2014

O'Gara PT, Calhoun JH, Moon MR, Tommaso CL; American College of Cardiology; American Association for Thoracic Surgery; Society for Cardiovascular Angiography and Interventions Foundation; Society of Thoracic Surgeons. Transcatheter therapies for mitral regurgitation: a professional society overview from the American College of Cardiology, The American Association for Thoracic Surgery, Society for Cardiovascular Angiography and Interventions Foundation, and The Society of Thoracic Surgeons. J Thorac Cardiovasc Surg. 2014 Mar;147(3):837-49.

Vahanian A, Alfieri O et al. Guidelines on the management of valvular heart disease (version 2012): The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Eur Heart J 2012; 33(19):2451-96.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.30, 7/10/14

Medical Director review 8/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.131, 11/13/14

Specialty Matched Consultant Advisory Panel review 6/2015

Medical Director review 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.30, 10/15/15

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.131, 11/12/2015

U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data: Melody™ Transcatheter Pulmonary Valve. 2015; http://www.accessdata.fda.gov/cdrh_docs/pdf14/p140017b.pdf. Accessed January 26, 2015.

Cheatham JP, Hellenbrand WE, Zahn EM, et al. Clinical and hemodynamic outcomes up to 7 years after transcatheter pulmonary valve replacement in the US melody valve investigational device exemption trial. Circulation. Jun 2 2015;131(22):1960-1970. PMID 25944758

Surgical Management of Transcatheter Heart Valves

Armstrong AK, Balzer DT, Cabalka AK, et al. One-year follow-up of the Melody transcatheter pulmonary valve multicenter post-approval study. *JACC Cardiovasc Interv.* Nov 2014;7(11):1254-1262. PMID 25459038

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.30, 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.131, 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.132, 6/2016

Puls M, Lubos E, Boekstegers P, et al. One-year outcomes and predictors of mortality after MitraClip therapy in contemporary clinical practice: results from the German transcatheter mitral valve interventions registry. *Eur Heart J.* Feb 21 2016;37(8):703-712. PMID 26614824

Lesevic H, Sonne C, Braun D, et al. Acute and Midterm Outcome After MitraClip Therapy in Patients With Severe Mitral Regurgitation and Left Ventricular Dysfunction. *Am J Cardiol.* Sep 1 2015;116(5):749-756. PMID 26160468

Velazquez EJ, Samad Z, Al-Khalidi HR, et al. The MitraClip and survival in patients with mitral regurgitation at high risk for surgery: A propensity-matched comparison. *Am Heart J.* Nov 2015;170(5):1050-1059 e1053. PMID 26542516

Feldman T, Kar S, Elmariah S, et al. Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation: 5-Year Results of EVEREST II. *J Am Coll Cardiol.* Dec 29 2015;66(25):2844-2854. PMID 26718672

De Bonis M, Lapenna E, Buzzatti N, et al. Optimal results immediately after MitraClip therapy or surgical edge-to-edge repair for functional mitral regurgitation: are they really stable at 4 years? *Eur J Cardiothorac Surg.* Mar 23 2016. PMID 27009105

US Food and Drug Administration. Summary of Safety and Effectiveness Data: Medtronic CoreValve. 2015; http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130021S010b.pdf. Accessed September, 2016.

Kapadia SR, Tuzcu EM, Makkar RR, et al. Long-term outcomes of inoperable patients with aortic stenosis randomly assigned to transcatheter aortic valve replacement or standard therapy. *Circulation.* Oct 21 2014;130(17):1483-1492. PMID 25205802

Reardon MJ, Adams DH, Kleiman NS, et al. 2-year outcomes in patients undergoing surgical or self-expanding transcatheter aortic valve replacement. *J Am Coll Cardiol.* Jul 14 2015;66(2):113-121. PMID 26055947

Blackstone EH, Suri RM, Rajeswaran J, et al. Propensity-matched comparisons of clinical outcomes after transapical or transfemoral transcatheter aortic valve replacement: a placement of aortic transcatheter valves (PARTNER)-I trial substudy. *Circulation.* Jun 2 2015;131(22):1989-2000. PMID 25832034

Specialty Matched Consultant Advisory Panel review 6/2016

Medical Director review 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.132, 8/2016

Medical Director review 9/2016

Surgical Management of Transcatheter Heart Valves

Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med.* Apr 28 2016;374(17):1609-1620. PMID 27040324

Siemieniuk RA, Agoritsas T, Manja V, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at low and intermediate risk: systematic review and meta-analysis. *BMJ.* Sep 28 2016;354:i5130. PMID 27683246

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.132, 2/2017

Medical Director review 2/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.30, 5/2017

Medical Director review 5/2017

Specialty Matched Consultant Advisory Panel review 6/2017

Medical Director review 6/2017

Food and Drug Administration (FDA). Press Release. FDA approval expands use of Sapien 3 artificial heart valve for high-risk patients, June 5, 2017.

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm561924.htm>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.132, 4/2018

Medical Director review 4/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.30, 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.131, 5/2018

Specialty Matched Consultant Advisory Panel review 6/2018

Medical Director review 6/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.30, 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.132, 3/2019

Specialty Matched Consultant Advisory Panel review 6/2019

Medical Director review 6/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.132, 1/2020

Medical Director review 1/2020

Policy Implementation/Update Information

For Policy titled Transcatheter Heart Valve Implantation

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)

Surgical Management of Transcatheter Heart Valves

- 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.
- 7/10/12 Specialty Matched Consultant Advisory Panel review 6/2012. No changes to Policy Statements. (mco)
- 1/1/13 Deleted CPT codes 0256T, 0257T, 0258T, 0259T, 0262T and added 0318T, 33361, 33362, 33363, 33364, 33365, 33367, 33368, 33369 to Billing/Coding section. No changes to Policy Statements. References updated. (mco)
- 1/29/13 Description section updated. “When Covered” section revised to include coverage for transapical surgical approach. Added “Left Ventricular Ejection Fraction >20%” as a criterion for coverage in the “When Covered” section. “When not Covered” section revised to state: “Transcatheter pulmonary valve implantation is considered investigational for all other indications. Transcatheter aortic valve replacement is considered investigational for all other indications, including but not limited to: patients with a degenerated bio-prosthetic valve (“Valve-in-Valve” implantation); procedures performed via the transaxillary, transiliac, transaortic, or other approaches.” Policy Guidelines updated. References updated. Medical Director review 1/2013. (mco)
- 2/12/13 Added code 0262T to Billing/Coding section. (mco)
- 7/16/13 Specialty Matched Consultant Advisory Panel review 6/2013. Medical Director review 6/2013. (mco)
- 11/12/13 Updated “When Covered” section to state “Severe aortic stenosis with a calcified aortic annulus as defined by one or more of the following criteria...” Removed statement “Severe aortic stenosis with a calcified aortic annulus defined as...” (mco)

For Policy re-titled Surgical Management of Transcatheter Heart Valves

Surgical Management of Transcatheter Heart Valves

- 12/31/13 Policy title changed from “Transcatheter Heart Valve Implantation” to “Surgical Management of Transcatheter Heart Valves.” Coding updated. Removed CPT code 0318T. Added 0342T, 0343T, 0344T, 0345T and 33666 to Billing/Coding section. Added the following statement to “When not Covered” section: “Transcatheter mitral valve implantation is considered investigational.” Description section updated. Policy Guidelines updated. References updated. Medical Director review 11/2013. (mco)
- 2/11/14 Description section updated. Policy Statements for Transcatheter Aortic Valve Implantation (TAVI) updated to include transapical approach as medically necessary with the same clinical indications as transfemoral approach. Policy Guidelines updated. References updated. Medical Director review 1/2014. (mco)
- 7/15/14 Specialty Matched Consultant Advisory Panel review 6/2014. Medical Director review 6/2014. Deleted 0342T from Billing/Coding section. References updated. Policy Guidelines updated. Deleted the following statement from the “When not Covered” section: “Transcatheter aortic valve replacement is considered investigational for all other indications, including but not limited to... procedures performed via the transaxillary, transiliac, transaortic, or other approaches.” Added the Medtronic Core Valve System as new FDA approved aortic valve device. Description section updated. (mco)
- 9/9/14 Policy Guidelines updated. References updated. Medical Director review 8/2014. No changes to Policy Statements. (mco)
- 12/30/14 Added CPT codes 33418, and 33419 to the Billing/Coding section effective 1/1/15. (td)
- 2/10/15 Reference added. Policy Guidelines section Transcatheter Pulmonary Valve Implantation section updated. Policy Statement remains unchanged. (td)
- 9/1/15 Specialty Matched Consultant Advisory Panel review 6/2015. Medical Director review 6/2015. When Not Covered statement updated to state: “Transcatheter mitral valve repair is considered investigational in all situations.” Policy Statement remains unchanged. (td)
- 12/30/15 Description section updated. When Covered section updated to state transcatheter mitral valve repair considered medically necessary for degenerative mitral regurgitation in patients at prohibitive surgical risk. When Not Covered section updated. Billing/Coding section updated to delete code 0262T and add code 33477 effective 1/1/16. Policy Guidelines section updated. References updated. (td)
- 4/1/16 Description section updated. Policy Guidelines section updated. References updated. (td)
- 7/26/16 Policy Guidelines and references updated. Specialty Matched Consultant Advisory Panel review 6/2016. Medical Director review 6/2016. (jd)
- 9/30/16 When Covered section for TAVI, updated to include coverage of the following: “Transcatheter aortic valve replacement with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve may be considered **medically necessary** when all of the following conditions are present”; When Not Covered section revised to remove the following from investigational as it is now considered medically necessary: “patients with a bio prosthetic valve (“Valve in Valve” implantation). Description section and Policy Guidelines extensively revised for TAVI to support policy statement. References updated. Medical Director review 9/2016. (jd)

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- 3/31/17 Description section updated with expanded indications for SAPIEN XT. Policy guidelines and references updated. No change to policy intent. Medical Director review 2/2017. (jd)
- 6/30/17 When Covered section, replaced “cleared” with “approved”, no change to policy intent. Policy guidelines and references updated. Medical Director review. (jd)
- 7/28/17 Description section updated with recent FDA expanded coverage for replacement of SAPIEN 3 Transcatheter Heart Valve (THV) for patients with symptomatic heart disease due to failure of a previously placed bioprosthetic aortic or mitral valve. When Covered section revised to include “replacement” of a degenerated bioprosthetic. References updated. No change to policy intent. Specialty Matched Consultant Advisory Panel review 6/2017. Medical Director review 6/2017. (jd)
- 12/29/17 Codes 0483T, 0484T added to code section, effective 1/1/18. (jd)
- 5/11/18 Description section updated and Regulatory Status section added. FDA expanded indications added to Regulatory Status section to include severe aortic stenosis in individuals with intermediate surgical risk for aortic valve replacement. When Covered section revised under section - **Transcatheter aortic valve implantation (TAVI)**, item 4 to include medically necessary indication for patients with intermediate risk for open surgery as follows: “Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon) or patient is an operable candidate but is at high or intermediate risk for open surgery.” Policy guidelines extensively revised for TAVI for aortic stenosis. References updated. Medical Director review 4/2018. (jd)
- 7/27/18 Regulatory Status updated for Transcatheter Pulmonary Valve devices. When Covered section for **Transcatheter Pulmonary Valve** added the following to “implantation (TPVI) may be considered medically necessary for patients with congenital heart disease and **current** right ventricular outflow tract (RVOT) **obstruction or regurgitation including the following indications:**”, followed by the the noted 4 bullets. No change to policy intent. Policy guidelines extensively updated. References updated. Specialty Matched Consultant Advisory Panel review 6/2018. Medical Director review 6/2018. (jd)
- 7/1/19 Regulatory status section revised to better clarify the different valve repairs. Policy guidelines and references updated. Billing/Coding section, added the following CPT codes 0543T, 0544T, 0545T effective 7/1/19. Specialty Matched Consultant Advisory Panel review 6/2019. Medical Director review 6/2019. (jd)
- 2/11/20 Added the following statement under the When Covered section of the TAVI, item 4: “does not have unicuspid or bicuspid aortic valves.”; removed the following statement from that section, “Patient is not an operable candidate for open surgery, as judged by at least 2 cardiovascular specialists (cardiologist and/or cardiac surgeon); or patient is an operable candidate but is at high risk for open surgery.” The following statement was added to the When Not Covered section: “**Transcatheter tricuspid valve** repair is considered investigational for all indications”. Regulatory status updated to include the following expanded indications for the SAPIEN XT and Medtronic CoreValve Evolut R System and Evolut PRO “August 2019, the FDA expanded indications to include severe aortic stenosis with low surgical risk.” The LOTUS Edge Valve System was added to this section as an FDA approved device, as well. Policy guidelines and references updated. The following codes were removed from the Billing/Coding section effective 10/1/19: 33361, 33362, 33363, 33364, 33365, 33366, 33367, 33368, 33369, 33418, 33419, 33477,

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0345T, 0543T, 0544T, 0545T. The following codes were added to the Billing/Coding section effective 1/1/2020: 0569T, 0570T. Medical Director review. (jd)

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