

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.
- 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.
 - 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 2016, 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.

Portico™ with FlexNav™ (Abbott Medical) received FDA approval in September 2021, through the premarket approval process for severe native aortic stenosis at high or greater risk for open surgical therapy.

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.

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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

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) was approved by the FDA in 2016 “for use in pediatric and adult patients with a 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 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).

The Harmony™ Transcatheter Pulmonary Valve (Medtronic) received breakthrough technology status in 2019 and PMA in 2021. This device is indicated “for use in pediatric and adult patients with severe pulmonary regurgitation (determined by echocardiography and/or pulmonary regurgitant fraction $\geq 30\%$ by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement.”

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.”

In September 2022, the FDA approved the PASCAL Precision Transcatheter Valve Repair System 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

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patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team."

*****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 individuals with symptomatic, primary mitral regurgitation (MR) 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 individuals 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 with a Food and Drug Administration-approved valve for individuals 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).

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

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. Individual 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. Failure (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. Individual is not an operable candidate for open surgery, as judged by at least 2 cardiovascular specialists (cardiologist and/or cardiac surgeon); or individual 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 Placement of AorRTic TraNscathetER Valve Trial Edwards SAPIEN Transcatheter Heart Valve (PARTNER B) trial reported results for patients treated with TAVI by the transfemoral approach compared with

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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 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 trialists' 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 Portico valve with other FDA-approved valves found an increase in safety outcomes with Portico at 30 days but no major differences at 2 years. Gender-specific meta-analyses have found improved mortality with TAVI compared with SAVR in women. 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 et al (2010) 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 RCTs comparing TAVI with surgical repair in individuals selected without specific surgical risk criteria but including patients at low surgical risk and RCTs enrolling only 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 the Study to Establish the Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients

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Who Have Severe, Calcific, Aortic Stenosis Requiring Aortic Valve Replacement [PARNTER 3]) have been conducted exclusively in patients at low surgical risk and 1 RCT, Nordic Aortic Intervention Trial 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 PARNTER 3 trial, the rate of the composite of death, stroke, or rehospitalization at 1 year was significantly lower with TAVI than SAVR. In the Nordic Aortic Intervention 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. In the publicly sponsored UK TAVI trial, which was conducted in patients aged 70 years or older with predominantly low surgical risk, TAVI was noninferior to SAVR with respect to all-cause mortality at 1 year. 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 a systematic review of retrospective comparative studies, prospective, interventional, noncomparative studies and a multicenter registry of 2,476 individuals who underwent TPV replacement with a Melody (82%) or Sapien (18%) valve between July 2005 and March 2020. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity and mortality. Overall, the evidence suggests that TPVI is associated with high rates of short-term technical success and improvements in heart failure-related symptoms and hemodynamic parameters. Most valves demonstrate competent functioning by Doppler echocardiography at 6- to 12-month follow-up. Other publications with longer follow-up have reported stent fractures in up to 26% of patients; however, most stent fractures did not require reintervention. Studies with follow-up extending to a maximum of 8 years postprocedure have suggested that the functional and hemodynamic improvements are durable. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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 patients 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); or
- native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 34mm 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 considerably 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.

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 as well as multiple observational studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The trials had discrepant results potentially related to differences in primary outcomes. The larger trial, with patients selected for nonresponse to maximally tolerated therapy, found a significant benefit for MitraClip after 2 years compared to medical therapy alone. Improvements in MR severity, quality of life measures, and functional capacity persisted to 36 months in patients who received TMVR. 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 a systemic review, one RCT and a retrospective comparative observational study in individuals ≥ 75 years. 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 observational study in individuals ≥ 75 years found that although MitraClip was associated with improved 1-year survival and a lower rate of all acute complications compared with surgical repair, it had lower 5-year survival and greater MR reoccurrence. 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 or PASCAL, the evidence includes a randomized study, nonrandomized prospective studies, and noncomparative feasibility studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. A head-to-head RCT comparing the direct leaflet repair devices, PASCAL and MitraClip, is ongoing. Prospective nonrandomized trials demonstrate promising efficacy and safety results for the PASCAL direct leaflet repair device. A small open-label head-to-head comparison trial

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between PASCAL and MitraClip (Gercek et al 2021) demonstrated similar safety and efficacy between the 2 systems. Data from the ongoing RCT is 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.

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, 0646T, 0805T, 0806T

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.

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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)
- 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

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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

- 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)

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- 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)
- 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)

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- 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, 0345T, 0543T, 0544T, 0545T. The following codes were added to the Billing/Coding section effective 1/1/2020: 0569T, 0570T. Medical Director review. (jd)
- 6/30/20 References updated. Specialty Matched Consultant Advisory Panel review 6/2020. Medical Director review 6/2020. (jd)

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- 7/1/21 Minor update to policy guidelines and references updated. Added the following to the policy statement under the When Covered section for Transcatheter Pulmonary Valve Implantation - may be considered medically necessary “with a Food and Drug Administration-approved valve”. No change to policy intent. The following code was added to the Billing/Coding section effective 7/1/21: 0646T. Specialty Matched Consultant Advisory Panel review 6/2021. Medical Director review 6/2021. (jd)
- 7/12/22 Minor updates to regulatory status and policy guidelines. Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. (jd)
- 6/30/23 Regulatory Status, Policy Guidelines and References sections updated. When Covered section edited for clarity, no change to policy statement. Codes 0805T and 0806T added to Billing/Coding section, effective 7/1/23. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023 (tm)

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