Surgical Management of Transcatheter Heart Valves

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.

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

- The SAPIEN Transcatheter Heart Valve System™ (Edwards LifeSciences, Irvine, CA) received FDA approval in November 2011. Approval was granted through the premarket approval process for patients with severe aortic stenosis who are not eligible for open-heart procedures and have a calcified aortic annulus. Approval was granted for both the transfemoral and transapical approach, and in October of 2012, indications were expanded to include patients who are at high risk for open surgery. In 2016, the FDA expanded indications to include intermediate risk for open surgery and as a result, the SAPIEN Transcatheter Heart...
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Valve System™ is approved for both high risk, inoperable and intermediate risk patients when used by either the transapical or transfemoral approach.

- In June 2014, the next-generation SAPIEN XT Transcatheter Heart Valve (model 9300TFX) was approved by the FDA for use with the NovaFlex+ delivery system. In October 2015, FDA expanded the indication for the SAPIEN XT valve to include treatment of a failed surgical bioprosthesis (TAV-in-SAV or “valve-in-valve”). In August 2016, the FDA again expanded indications for the SAPIEN XT valve and introducers to include individuals at intermediate surgical risk for open aortic valve replacement (ie, predicted risk of surgical mortality ≥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).

- The CoreValve Transcatheter Aortic Valve Replacement System™ (Medtronic, Minneapolis, MN) received FDA approval in January 2014, through the premarket approval process for patients with symptomatic heart disease due to severe native calcific aortic stenosis and with native aortic annulus diameters between 18 and 29 mm who are judged by a heart team, including a cardiac surgeon, to be at extreme risk or inoperable for open surgical therapy. In March 2015, FDA further expanded the indications for the CoreValve™ to include treatment of a failed surgical bioprosthesis (TAV-in-SAV or “valve-in-valve”). A second-generation CoreValve device, the CoreValve Evolut R System™, received FDA approval in June 2015. In June 2016, FDA expanded indications for the CoreValve™ to include patients at high risk for open surgery. The FDA 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.

- In June 2017, the FDA approved an expanded indication for replacement of the SAPIEN Transcatheter Heart Valve (THV) for patients with symptomatic heart disease due to failure of a previously placed bioprosthetic aortic or mitral valve whose risk of death or severe complications from repeat surgery is high or greater.

On January 25, 2010, the Melody® Transcatheter Pulmonary Valve (TPV) and the Ensemble® Transcatheter Valve Delivery System (Medtronic, Minneapolis, MN) were approved by the U.S. Food and Drug Administration (FDA) under the Humanitarian Device Exemption Program. Approval was 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 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 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
Surgical Management of Transcatheter Heart Valves

Right Ventricular Outflow Tract (RVOT) conduit with a clinical indication for intervention, along with pulmonary regurgitation ≥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 ≥8% or at a ≥15% risk of mortality at 30 days.

In October 2013, the MitraClip® Clip Delivery System (Abbott Vascular, Menlo Park, CA) was approved by FDA through the premarket approval process for treatment of “significant symptomatic mitral regurgitation (MR ≥ 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. The FDA’s approval was based on data from 1 randomized controlled trial (RCT) and 2 patient registry databases.

***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, degenerative 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;
- Presence of a logistic EuroScore of 20% or greater.

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).
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**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.

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 0.8 cm²
   - A mean aortic valve gradient greater than 40 mmHg
   - A jet velocity greater than 4.0 m/sec 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 two cardiovascular specialists (cardiologist and/or cardiac surgeon) or patient is an operable candidate but is at high or intermediate risk for open surgery (see Policy Guidelines)

Transcatheter aortic valve replacement with a transcatheter heart valve system approved for use for repair and/or replacement of a degenerated bioprosthetic 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.

**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 to continued medical care with or without balloon valvuloplasty. There was a large decrease in mortality for the TAVI patients at 1 year compared to medical care. This trial also reported
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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 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 multiple nonrandomized comparative studies and systematic reviews of these studies. Relevant outcomes are overall survival, symptoms, morbidity, 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 the 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, morbidity, 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, systematic reviews, and nonrandomized cohort studies. Relevant outcomes are overall
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survival, symptoms, morbid events, and treatment-related mortality and morbidity. Limited data are available comparing SAVR with TAVI in patients who had severe aortic stenosis with low risk for open surgery. A systematic review including the low surgical risk patients of these 2 RCTs, and 4 observational studies, with propensity score matching, reported that the 30-day and in-hospital mortality rates were similar for TAVI (2.2%) and SAVR (2.6%). However, TAVI was associated with increased risk of mortality with longer follow-up (median, 2 years; 17.5% vs 12.7%). TAVI was associated with reduced risk for bleeding, renal failure and, an increase in vascular complications and pacemaker implantation compared with SAVR. The evidence is insufficient to determine the effects of the technology on health outcomes.

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. The rate of serious procedural adverse events reported in these series ranges from 3.0% to 7.4%. At 6- to 12-month follow-up, there is evidence that most valves demonstrate competent functioning by Doppler echocardiography, 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 currently 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 use of TPVI for individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis or with at least moderate pulmonic regurgitation, as well as, for use in individuals with native or patched RVOT with pulmonic stenosis or with at least moderate pulmonic regurgitation, provides meaningful improvement in net health outcomes.

Transcatheter mitral valve (MV) repair

The evidence for the use of MitraClip in patients with symptomatic degenerative mitral regurgitation (DMR) or functional mitral regurgitation (FMR) and at prohibitive risk for open
Surgical Management of Transcatheter Heart Valve surgery who receive transcatheter mitral valve repair (TMVR) using MitraClip, includes single-arm cohort studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment related morbidity. Several single-arm studies have demonstrated that MitraClip implantation is feasible, with high rates (at least 70% to 90%) of short-term reductions in MR grade to 2+ or less, and has a reasonable safety profile. A nonrandomized analysis matching patients in the EVEREST registries to similar non-surgically treated patients found significantly lower 1-year mortality rates in MitraClip-treated patients. However, the lack of concurrent control groups, especially in randomized trials, makes it difficult to draw conclusions about whether there is a net health benefit compared with alternative therapies in this population. There are no strong barriers to conducting controlled trials, including RCTs that compare MitraClip with continued medical management. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the use of MitraClip in patients with symptomatic DMR or FMR who are considered surgical candidates for TMVR with MitraClip, includes a systematic review, 1 RCT (EVEREST II) and multiple comparative and noncomparative cohort studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The RCT had some methodologic limitations, including a wide noninferiority margin and permissibility of crossing over to surgery and still considered to have a positive outcome. This trial does not definitively demonstrate improved clinical outcomes with MitraClip compared with surgery. Additional RCTs are needed to corroborate these results. A subsequent nonrandomized controlled trial, which attempted to verify the finding of the RCT, did not find the same low rates of long-term MR control in MitraClip patients with an initially positive response to treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the use of transcatheter mitral valve repair devices other than the MitraClip for patients with DMR or FMR 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 transcathether 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 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) released guidelines on the management of valvular heart disease. These guidelines do not address transcathether MV repair.

Billing/Coding/Physician Documentation Information

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

Applicable service codes: 0345T, 0483T, 0484T, 33361, 33362, 33363, 33364, 33365, 33366, 33367, 33368, 33369, 33418, 33419, 33477

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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Scientific Background and Reference Sources

For Policy titled Transcatheter Heart Valve Implantation


Medical Director review 3/2012

Specialty Matched Consultant Advisory Panel review 6/2012


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Specialty Matched Consultant Advisory Panel review 6/2013

Medical Director review 6/2013

For Policy re-titled Surgical Management of Transcatheter Heart Valves


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3150716/


Medical Director review 11/2013


http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm323478.htm


http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369510.htm


Specialty Matched Consultant Advisory Panel review 6/2014
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Medical Director review 6/2014


Medical Director review 8/2014


Specialty Matched Consultant Advisory Panel review 6/2015

Medical Director review 6/2015


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Medical Director review 6/2016

Medical Director review 9/2016


Medical Director review 2/2017

Medical Director review 5/2017
Specialty Matched Consultant Advisory Panel review 6/2017
Medical Director review 6/2017
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https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm561924.htm

Medical Director review 4/2018


Specialty Matched Consultant Advisory Panel review 6/2018

Medical Director review 6/2018

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 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)
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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


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)


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)
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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)


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)

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 Transcather Pulmonary Valve devices. When Covered section for Transcatheter Pulmonary Valve added the following to “implantation
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(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 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)

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