



**Kaiser Foundation Health Plan  
of Washington**

**Clinical Review Criteria**

**Transcatheter Aortic or Pulmonary Valve Replacement (TAVR/TPVI)**

- Valve-in Valve Transcatheter Aortic Valve Implantation (VI-TAVI) in Failed Bioprosthetic Aortic Valves Transcatheter Valve-in Valve Implantation (TAVIV)
- Transcatheter Aortic Valve in Surgical Aortic Valve (TAV-in-SAV)
- Transcatheter Pulmonary Valve Implantation (TPVI)

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**Criteria**

**For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	<a href="#">Transcatheter Aortic Valve Replacement (TAVR) (20.32)</a>
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance for transcatheter valve-in-valve replacement or transcatheter pulmonary valve implantation, Kaiser Permanente has chosen to use their own Clinical Review Criteria, <b>Valve-in-Valve Transcatheter Aortic Valve Implantation and Transcatheter Pulmonary Valve Implantation (TPVI)</b> for medical necessity determinations. Refer to the Non-Medicare criteria below.

**For Non-Medicare Members**

**I. Transcatheter Aortic Valve Replacement (TAVR)**

- A. Transcatheter aortic valve replacement is medically necessary when **ALL of the following** are true:
  1. Use of an FDA approved device
  2. Documentation of severe, symptomatic aortic valve stenosis
  3. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. The heart team includes the following:
    - a. Cardiac surgeon and an interventional cardiologist experienced in the care and treatment of aortic stenosis who have:
      - I. independently examined the patient face-to-face, evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy;
      - II. documented and made available to the other heart team members the rationale for their clinical judgment.
    - b. Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel and administrators.

4. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
5. TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
  - a. On-site heart valve surgery and interventional cardiology programs,
  - b. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,
  - c. Appropriate volume requirements per the applicable qualifications below:

There are two sets of qualifications; the first set outlined below is for hospital programs and heart teams without previous TAVR experience and the second set is for those with TAVR experience.

Qualifications to begin a TAVR program for hospitals without TAVR experience:

The hospital program must have the following:

- a.  $\geq 50$  open heart surgeries in the previous year prior to TAVR program initiation, and;
- b.  $\geq 20$  aortic valve related procedures in the 2 years prior to TAVR program initiation, and;
- c.  $\geq 2$  physicians with cardiac surgery privileges, and;
- d.  $\geq 1$  physician with interventional cardiology privileges, and;
- e.  $\geq 300$  percutaneous coronary interventions (PCIs) per year.

Qualifications to begin a TAVR program for heart teams without TAVR experience:

The heart team must include:

- a. Cardiovascular surgeon with:
  - i.  $\geq 100$  career open heart surgeries of which  $\geq 25$  are aortic valve related; and,
- b. Interventional cardiologist with:
  - i. Professional experience of  $\geq 100$  career structural heart disease procedures; or,  $\geq 30$  left-sided structural procedures per year; and,
  - ii. Device-specific training as required by the manufacturer

Qualifications for hospital programs with TAVR experience:

The hospital program must maintain the following:

- a.  $\geq 50$  AVRs (TAVR or SAVR) per year including  $\geq 20$  TAVR procedures in the prior year ; or,
- b.  $\geq 100$  AVRs (TAVR or SAVR) every 2 years, including  $\geq 40$  TAVR procedures in the prior 2 years; and,
- c.  $\geq 2$  physicians with cardiac surgery privileges; and,
- d.  $\geq 1$  physician with interventional cardiology privileges, and
- e.  $\geq 300$  percutaneous coronary interventions (PCIs) per year; and,

Participation in the STS/ACC TVT Registry is required.

All other indications are not covered as there is insufficient evidence to support effectiveness.

## II. Valve-in-Valve Transcatheter Aortic Valve Implantation

- A. Valve in Valve TAVR is medically necessary when **ALL of the following** are met:
  1. Use of an FDA approved device
  2. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals.
  3. Documentation of a failed aortic tissue prosthesis resulting in symptomatic stenosis or regurgitation.

### III. Transcatheter Pulmonary Valve Implantation (TPVI)

- A. Transcatheter pulmonary valve implantation is considered medically necessary for patients with congenital heart disease and current right ventricular outflow tract obstruction (RVOT) 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 **OR**
  - Individuals with native or patched RVOT with at least moderate pulmonic regurgitation **OR**
  - Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg) **OR**
  - Individuals with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg)

All other indications are not covered as there is insufficient evidence to support effectiveness.

#### **If requesting these services, please send the following documentation to support medical necessity:**

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Aortic stenosis (AS) is one of the most frequent degenerative valve diseases in developed countries with a prevalence of approximately 5% in individuals over the age of 75 years. The absolute numbers continue to increase with the increase in life expectancy. Aortic stenosis has a long latency period followed by a rapid progression after the appearance of symptoms. It is estimated that up to 2.9% of adults between the ages of 75 and 86 years have severe aortic stenosis, and that the two-year mortality among adults with severe symptoms is as high as 50% (Leon 2010, Rajani 2011, Amonn 2012).

Currently, surgical aortic valve replacement (SAVR) is the treatment of choice in patients with symptomatic severe aortic stenosis in the absence of severe co-morbid conditions. It is the only treatment that has been shown to reduce symptoms and improve functional status and survival in patients with severe aortic stenosis. The conventional surgical aortic valve replacement is performed via sternotomy using cardiopulmonary bypass. The procedure is associated with low operative mortality; however, at least 30% of the patients with severe symptomatic aortic valve stenosis are not suitable candidates for open SAVR due to advanced age, left ventricular dysfunction, concomitant coronary artery disease, and/or other pre-existing conditions. Historically these high surgical risk patients were treated with palliative medical therapy or aortic valve balloon valvuloplasty (BAV) (Leon 2010, Rajani 2011, Amonn 2012, Staubach 2012).

Transcatheter aortic valve replacement (TAVR) has emerged as an alternative minimally invasive treatment option for elderly patients with aortic stenosis who are at high surgical risk. The first transcatheter aortic valve implantation in humans was performed by Alain Cribier in France ten years ago and has developed rapidly and tremendously since then. Over 50,000 patients in 500 European centers have undergone the procedure after two prosthetic valves (Edwards SAPIEN and Medtronic CoreValve) was approved by the Conformité Européenne (CE) in 2007. TAVR involves the insertion of a bioprosthetic aortic valve through a catheter and implanting it within the diseased native aortic valve. Patients are treated off-pump i.e. on a beating heart, and the new prosthesis is implanted within the calcified native valve leaflets that remain in place while being squeezed aside. In most patients the prosthetic valve is inserted through the groin and advanced to the heart using X-ray guidance (retrograde approach). In patients who cannot undergo catheterization of the femoral artery due to vessel disease, the valve can be delivered from the left ventricular apex (antegrade approach) through a small chest incision between the ribs (Amonn 2012, Walther 2012).

Currently, TAVR is indicated for the management of high-risk patients with severe aortic stenosis who are not candidates for open surgical valve replacement. However, some patients are at too high risk even for TAVR, and patient selection plays a crucial role in the success of the procedure. Patients have to be evaluated thoroughly for their risk and anatomical suitability for the procedure. A heart team comprised of clinical cardiologists, cardiac

surgeons, interventionalists, anesthesiologists, geriatricians, and imaging specialists, is essential for the patient selection and performance of the procedure. The collaboration of such a multidisciplinary team is reported to be a key to the success of the procedure and achievement of optimal clinical outcomes (Piazza 2012, Vahanian 2012).

TAVR is not without complications; the increased risk of stroke is a significant safety concern of the procedure. Other major vascular complications, valve embolization, complete heart block, and moderate to severe paravalvular aortic regurgitation have also been reported. In addition, once the transcatheter aortic valve is implanted, it cannot be removed, and may lead to performing other risky procedures. Researchers are investigating different approaches to reduce the occurrence of these TAVR-related complications e.g. through better screening of the candidates for the intervention; refinement of the implantable devices and their delivery systems; improving the techniques in valve sizing and positioning; use of embolic protection devices as cerebral filters, carotid filters, or membrane covering of the carotid ostia; modification of periprocedure and postoperative antiplatelet strategies; use of antiarrhythmic treatment, and others (Vahanian 2012, Cribier 2012).

Over the years, different prostheses have become available for performing TAVR. The Edward SAPIEN (Edwards Lifesciences, Irvine, CA, USA) prosthesis consists of bovine pericardial leaflets mounted on a balloon-expandable cobalt-chromium stent. It is available in 2 sizes (23 mm and 26 mm) and can be inserted by either the retrograde or antegrade approach. The prosthesis was approved by the US Food and Drug Administration in 2011 based on data from the inoperable cohort of PARTNER study, for its use patients with severe aortic stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement, and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis (FDA website). The FDA requested two post-approval studies to assess the long-term safety and effectiveness of the TAVR, as well as adherence to the indication of SAPIEN utilization. Other devices including the COREValve® (Medtronic, Minneapolis, MN, USA), ACURATE TATM valve, and JenaValve™, have received CE approval, but have not been approved by the USA FDA to date.

## Medical Technology Assessment Committee (MTAC)

### ***Transcatheter Aortic Valve Replacement (TAVR)***

**6/18/2012: MTAC REVIEW**

#### **Evidence Conclusion:**

Conclusion: PARTNER Cohort A showed that transcatheter aortic valve replacement was non-inferior to open heart surgical aortic valve replacement for all-cause mortality at one year in patients with severe aortic stenosis at high-risk of operation. PARTNER Cohort B showed a 19% absolute mortality reduction at one year after transcatheter aortic valve replacement (number needed to treat of 5) when compared to standard medical therapy in patients with severe aortic stenosis and symptoms who are not suitable candidates for surgery. In the two cohorts TAVR was associated with a higher risk of neurological and cardiovascular events. The follow-up duration in the two cohorts of PARTNER may be insufficient to determine long-term safety and durability of the prosthesis, and whether the benefits observed with TAVR will be sustained over time.

**Articles:** The literature search revealed several publications on the PARTNER trial; another small trial (STACCATO trial); a meta-analysis that pooled the results of 16 heterogeneous studies; and a large number of case series, feasibility studies, and registry data. The pivotal PARTNER trial was selected for critical appraisal. The STACCATO study, a randomized controlled trial conducted on operable elderly patients with aortic stenosis, was not selected for critical appraisal due to its small size and premature termination. The meta-analysis was not reviewed further due to the heterogeneity of studies it included. The following studies were critically appraised: Leon MB, Smith CR, Mack M, for the PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med.* 2010; 363:1597-607. See [Evidence Table](#) Smith CR, Leon MB, Mark MJ, for the PARTNER trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med.* 2011;364:2187-2198. See [Evidence Table](#)

The use of TAVR does meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

### ***Valve-in Valve Transcatheter Aortic Valve Implantation (VI-TAVI) in Failed Bioprosthetic Aortic Valves [Transcatheter Valve-in Valve Implantation (TAVIV), transcatheter aortic valve in surgical aortic valve (TAV-in-SAV)]***

#### **BACKGROUND**

Degenerative aortic stenosis is one of the most common and most serious acquired valvular heart diseases among adults. Surgical aortic valve replacement (SAVR) has been the standard treatment for symptomatic severe aortic stenosis for over forty years. SAVR is an open-heart procedure that involves removing the

diseased aortic valve and replacing it with either a man-made mechanical valve or a biological valve. Mechanical valves are strong and long-lasting, but patients receiving them will need to use a blood thinning medication for the rest of their lives. In the last two decades, there has been a shift toward the use of biological (bioprosthetic) valve implants rather than mechanical valves. These are tissue valves made from human aortic valves (homografts) or more commonly from animal tissue (xenografts). The latter are made from porcine valve leaflets, bovine pericardium, or less frequently from porcine pericardium. Surgical bioprostheses are commonly stratified into stented and stentless valves. Compared with mechanical valves, bioprosthetic valves are associated with a lower risk of thromboembolic events and do not require long-term anticoagulation. However, these tissue valves have a limited durability, and the majority deteriorates within 10-20 years leading to structural dysfunction. Valve failure may present as stenosis due to calcification, pannus or thrombosis; regurgitation secondary to wear and tear or infection; or as a combination of both stenosis and regurgitation (Seiffert 2010, Bapat 2012, Webb 2013, Dvir 2014).

Treatment of patients with failed bioprosthetic valve is a clinical challenge. Re-operation is considered the standard of care, but a repeat cardiac surgery is associated with high risk of morbidity and mortality, not only of the complexity of the procedure, but also because of the comorbidities and advanced age of the patients who usually need it. The operative mortality for elective redo valve surgery is reported to range from 2-7% and may increase to more than 30% among those at high-risk. Patients who are considered inoperable have no other effective treatment option; supportive medical therapy is associated with poor prognosis, and balloon valvuloplasty is not recommended for stenotic bioprosthetic valves due to the high risk of tearing of the leaflets (Seiffert 2010, Bapat 2012, Dvir 2014).

Transcatheter aortic valve replacement (TAVR), also known as transcatheter aortic valve implantation (TAVI) has become an alternative less invasive treatment modality for patients with severe native aortic valve stenosis who are at high surgical risk due to advanced age, significant comorbidities, frailty, prior chest radiation and other factors. The current widespread use and success of TAVI in high-risk patients together with the major complications of redo aortic valve surgery in these patients; have led to considering the valve-in-valve TAVI (VIV-TAVI) (also referred to as TAV-in-SAV) approach as an option for patients with degenerated failed bioprosthetic heart valve. TAVI is performed with a beating heart and avoids the risks associated with using cardioplegia and cardiopulmonary bypass during redo surgery. Currently, the main transcatheter valves used for valve-in-valve procedures are the Edwards SAPIEN or SAPIEN XT (Edwards Lifesciences, Irvine, California), and the CoreValve (Medtronic, Minneapolis, Minnesota) (Eggebrecht 2011, Linke 2012, Dvir 2014).

Edwards SAPIEN XT Transcatheter Heart Valve (SAPIEN XT THV) system consists of a transcatheter aortic valve and the accessories used to implant it. The valve is made of cow tissue attached to a balloon-expandable, cobalt-chromium frame for support, and comes in three sizes: 23 mm, 26 mm, and 29 mm. The valve is compressed and placed on the end of a balloon catheter, which is then inserted through either the femoral artery or a small cut between the ribs and advanced through the blood vessels until it reaches the failed valve. The SAPIEN XT valve is then expanded with the balloon until it anchors to the failed valve (valve-in-valve). Once the new valve is in place, it opens and closes properly, allowing the blood to flow in the correct direction. According to the FDA The Edwards SAPIEN XT THV is indicated for patients with symptomatic heart disease due to either severe native calcific aortic stenosis, or more recently (in 2015) due failure of a surgical bioprosthetic aortic valve who are judged by a heart team to be at high or greater risk for open surgical therapy (i.e. Society of Thoracic Surgeons operative risk score  $\geq 8\%$  or at a  $\geq 15\%$  risk of mortality at 30 days). It is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen, have a mechanical artificial aortic valve, or have active bacterial endocarditis or other active infections in the heart or elsewhere (FDA and the manufacturer's webpages).

The CoreValve system consists of a catheter-based artificial aortic heart valve and the accessories used to implant it. The valve is made of pig tissue attached to a flexible, self-expanding, nickel-titanium frame for support. The CoreValve is compressed and placed on the end of a delivery catheter, which is then inserted through the femoral artery. If the femoral arteries are not suitable, the valve can be inserted through other arteries or through the aorta. The catheter is pushed through the blood vessels until it reaches the diseased aortic valve. The valve is then released from the catheter, expands on its own and anchors to the diseased valve. The CoreValve functions the same as a normal valve, allowing the blood flow in the correct direction. The CoreValve System had been previously approved by the FDA to treat patients whose native aortic valve has become severely narrowed as a result of calcium buildup and who are considered to be at "extreme risk" or "high risk" for surgical aortic valve replacement. In March 2015 the FDA expanded the use of CoreValve system for aortic valve-in valve replacement inpatients who need replacement of a failed tissue aortic valve but are at extreme or high risk of death or serious complications from traditional open-heart surgery based on the

judgement of a heart medical team. The CoreValve System use is contraindicated in patients with a mechanical aortic heart valve, have any infection, cannot tolerate blood thinning medicines; or have sensitivity to titanium or nickel or contrast media (FDA News Release March 30, 2015).

Reported adverse events with of VIV-TAVI include death, stroke, acute kidney injury, myocardial infarction, major bleeding, and the need for a permanent pacemaker. Other limitations associated with VIV-TAVI are the increase risk of coronary obstruction (especially in patients with stentless valves); high residual gradients which may result from under expansion of the result transcatheter heart valve in smaller surgical bioprosthesis; and paravalvular leaks between the surgical and transcatheter valves. Successful outcome of the VIV procedure is thus dependent on patient selection, knowledge of prior cardiac surgery, internal diameter and material of the degenerated bioprosthetic valve as well as mode of valve failure, anticipation of complication, procedural planning, and experience of the cardiac team with TAVI (Bapat 2012, Webb 2013, Verhoye 2015, Phan 2016)

In 2015, the US Food and Drug administration (FDA) expanded the approved use of the SAPIEN XT (Edwards Lifesciences) and CoreValve System (Medtronic) to include "valve-in-valve" repair in patients who failed surgical bioprosthetic heart and are at high or extreme risk for complications associated with traditional open-heart surgery.

### **06/20/2016: MTAC REVIEW**

#### **Evidence Conclusion:**

##### **Conclusion:**

- There is fair evidence from a number of observational studies that valve-in-valve implant in a failed aortic prosthetic valve is feasible and relatively safe.
- There is insufficient direct evidence to determine whether the outcomes of valve-in-valve implantation in a failed aortic prosthetic valve are equivalent or superior to the outcomes of a redo conventional operation to replace the valve.
- There is insufficient published evidence to determine the long-term efficacy and durability of valve-in-valve implant in a failed aortic prosthetic valve.

**Articles:** The literature search for studies on valve-in-valve transcatheter aortic valve replacement in high risk patients with failed bioprosthetic valves identified a number of observational studies and case series from single institutions as well as registries for patients receiving a VIV-TAVI in various countries (Canadian registry, German registry, Italian registry, Germany/Switzerland registry, and a global registry that collects data form more than 60 countries worldwide). A recent systematic review with meta-analyses (Chen 2016) pooled the results of studies reporting on clinical outcomes of transcatheter VIV in failed surgical bioprosthetic aortic and mitral valves. Two other systematic reviews (with no meta-analyses) that summarized the results of studies on VIV-TAVI published through July 2014 were also identified (Tourmousoglou, et al, 2015, and Raval et al, 2014). To date, there are no published randomized controlled trials that directly compared the VIV-TAVI to surgical reoperation in patients with failed bioprosthetic aortic valves. The search identified a recent systematic review and meta-analysis (Phan, et al, 2016) that indirectly compared VIV-TAVI versus surgical valve redo operation (i.e. TAV-in-SAV versus SAV-in-SAV), and Erlebach et al, 2015 study that compared retrospective data on postoperative outcomes for patients with failing bioprosthetic valve who received a VIV-TAVI or underwent a redo aortic surgery in a single center in the period from January 2001 through October 2014. The two United States pivotal studies that were the basis of the FDA approvals of the systems are not published to data but are available at the FDA website. The meta-analysis that pooled the results of the cohort studies on VIV-TAVI and the analysis that compared VIV-TAVI with reoperation, as well as the global VIVID registries and the two pivotal studies submitted to the FDA were selected for critical appraisal. Chen HL, Liu K. Clinical outcomes for transcatheter valve-in-valve in treating surgical bioprosthetic dysfunction: A meta-analysis. *Int J Cardiol.* 2016 Mar 18; 212:138-141. ([See Evidence Table 1](#)) Phan K, Zhao DF, Wang N, et al. Transcatheter valve-in-valve implantation versus re-operative conventional aortic valve replacement: a systematic review. *J Thorac Dis.* 2016 Jan; 8 (1): E83-93. ([See Evidence Table 2](#)) Dvir D, Webb JG, Bleiziffer S, et al. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. *JAMA.* 2014 Jul; 312(2):162-170. ([See Evidence Table 3](#)).

The use of Valve-in Valve Transcatheter Aortic Valve Implantation does meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

### **01/13/2020: MTAC REVIEW**

#### **Evidence Conclusion:**

- Overall the results of the two pivotal RCTs (PARTNER 3 and Evolut Low Risk trial) that compared the outcomes of TAVR with those of SAVR in low-surgical risk patients with

severe aortic stenosis (excluding those with a bicuspid valve) show that TAVR is non-inferior to surgical valve replacement with respect to the primary composite endpoint as defined in each trial. PARTNER 3 trial defined the primary endpoint as a composite of death from any cause, stroke, or rehospitalization at 1 year after the procedure, while Evolut Low Risk trial defined it as a composite of all-cause mortality or disabling stroke in TAVR vs. SAVR at 24 months.

- PARTNER 3 trial is the only published trial, to date, that suggests that TAVR is superior to SAVR in reducing the composite rate of death from any cause, stroke, or rehospitalization at 1-year in low-surgical risk patients with severe aortic stenosis. However, there was no significant difference between the two procedures when each of the components was considered individually.
- The published results of Evolut Low-Risk trial are for interim analysis; the 1-year and 2-year event rates were derived from estimates not true observed incidence.
- Meta-analyses pooling the results of the two pivotal trials with NOTION study and with or without SURTAVI/low risk showed conflicting results: Anantha-Narayana et al's analysis showed that all-cause mortality was significantly lower with TAVR at 30 days, but not with long-term follow-up, Al-Abdoun et al, also found no statistically significant difference between TAVR and SAVR in all-cause mortality at one year, while Kolte et al's analysis showed a significantly lower rate of all-cause mortality at one year with TAVR vs. SAVR.
- The overall 1-year results of trials in low-risk patients indicate that compared to surgery, TAVR is associated with significantly lower risk of stages II & III acute kidney injury, new onset atrial fibrillation and life threatening or disabling bleeding. However, it is associated with a statistically significant higher risk of the need for permanent pacemaker implantation, and moderate -severe paravalvular leak compared to SAVR.
- The trials had strict legibility criteria that may limit generalization of their results.
- There is no long-term follow-up data from large RCTs to determine the long-term efficacy and safety of TAVR, the performance and durability of the TAV, potential formation of subclinical leaflet thrombosis, and long-term difference between the surgical and transcatheter valves with respect to their durability and structural degeneration.
- To date the only published long-term follow-up data is provided by the 5-year results of NOTION trial that shows no difference between TAVR and SAVR in the composite primary endpoint of all-cause mortality, stroke or myocardial infarction in mostly low surgical risk patients. The trial was small, and the lack of statistically significant differences does not indicate that the two interventions are equivalent. In addition, the study used the first generation CoreValve as well as earlier SAVR techniques, which may limit generalization of the results.
- The rapid progress in technology and continuous improvements in the design of the devices as well as the surgical and implant techniques, would be a common limitation for the pivotal studies with planned 10-year follow-up, as well as any other interventional study with 5-10 years follow-up duration.

**Articles:** The literature search revealed the recently published trials: PARTNER 3 trial, Evolut Low Risk trial, and the 5-year follow-up of NOTION trial, as well as 3 meta-analyses of RCTs comparing TAVR vs SAVR in low-risk patients with symptomatic severe aortic stenosis. Three other meta-analyses identified by the search pooled the results of RCTs and observational studies on TAVR for patients with low-intermediate risk. The PARTNER 3 and Evolut Low Risk trials were selected for critical appraisal. The NOTION trial and the three meta-analyses of trials in low-risk patients were summarized. The meta-analyses including observational studies and /or trials on intermediate- risk patients were excluded. See [Evidence Table](#).

The use of Transcatheter aortic valve replacement (TAVR) for low-surgical risk patients with aortic valve stenosis does meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## Applicable Codes

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

### Transcatheter aortic valve replacement (TAVR/TAVI)

CPT®	Description
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<b>Codes</b>	
<b>33361</b>	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
<b>33362</b>	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
<b>33363</b>	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
<b>33364</b>	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
<b>33365</b>	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)
<b>33366</b>	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)
<b>33367</b>	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)
<b>33368</b>	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)
<b>33369</b>	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)

**Transcatheter pulmonary valve implantation (TPVI)**

<b>CPT® Codes</b>	<b>Description</b>
<b>33477</b>	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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<b>Date Created</b>	<b>Date Reviewed</b>	<b>Date Last Revised</b>
07/03/2012	07/03/2012 <sup>MDCRPC</sup> , 05/07/2013 <sup>MDCRPC</sup> , 09/03/2013 <sup>MPC</sup> , 07/01/2014 <sup>MPC</sup> , 05/05/2015 <sup>MPC</sup> , 03/01/2016 <sup>MPC</sup> , 09/02/2016 <sup>MPC</sup> , 04/04/2017 <sup>MPC</sup> , 06/05/2018 <sup>MPC</sup> , 06/04/2019 <sup>MPC</sup> , 06/02/2020 <sup>MPC</sup> , 06/01/2021 <sup>MPC</sup> , 06/07/2022 <sup>MPC</sup> , 06/06/2023 <sup>MPC</sup> , 04/02/2024 <sup>MPC</sup>	06/01/2021

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee

<sup>MPC</sup> Medical Policy Committee

<b>Revision History</b>	<b>Description</b>
05/05/2015	Changed ejection fraction from >15% to >20%
03/01/2016	Added two indications to criteria
08/02/2016	Added MTAC review for Valve-in Valve Transcatheter Aortic Valve Implantation
09/06/2016	New policy for Valve-in-Valve Implantation was adopted
04/04/2017	Added indication for TAVR to clarify risk score and the ability for 2 cardiac surgeons to override risk scoring
12/03/2019	MPC approved to adopt the updated Medicare indication requiring one cardiologist and one interventional cardiologist for commercial members, however KPWA will retain the high-risk restriction.



02/04/2020	MPC approved to adopt clinical indications for Transcatheter Pulmonary Valve Implantation
03/03/2020	MPC approved to endorse coverage policy for TAVR for low-surgical risk patients with aortic valve stenosis. Added January 2020 MTAC review.
05/05/2020	MPC approved to adopt updates to the clinical indications for Non-Medicare. Requires 60-day notice, effective date 9/1/2020.
06/01/2021	Retitled to include TPVI.