

FEP 7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

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Related Policies: None

Transcatheter Aortic Valve Implantation for Aortic Stenosis

Description

Transcatheter aortic valve implantation (TAVI; also known as transcatheter aortic valve replacement) is a potential treatment for patients with severe aortic stenosis. Many patients with aortic stenosis are elderly and/or have multiple medical comorbidities, thus indicating a high, often prohibitive, risk for surgery. This procedure is being evaluated as an alternative to open surgery, or surgical aortic valve replacement (SAVR), for high-risk patients with aortic stenosis and as an alternative to nonsurgical therapy for patients with a prohibitive risk for surgery.

FDA REGULATORY STATUS

Two manufacturers have transcatheter aortic valve devices with Food and Drug Administration (FDA) approval. Regulatory status data for these devices are listed in Table 1.

Table 1 FDA-Approved Transcatheter Aortic Valve Device Systems

Device and Indication	Manufacturer	Date Cleared	PMA
Edwards SAPIEN Transcatheter Heart Valve System™	Edwards Lifesciences	11/11	P100041
<ul style="list-style-type: none"> Severe native aortic valve stenosis determined to be inoperable for open aortic valve replacement (transfemoral approach) 			
<ul style="list-style-type: none"> Expanded to include high-risk aortic stenosis (transapical approach) 		10/12	
<ul style="list-style-type: none"> Expanded to include replacement of bioprosthetic valve in high risk for death or severe complications of repeat surgery 		06/17	
<ul style="list-style-type: none"> Expanded to include severe aortic stenosis with intermediate surgical risk 		08/16	
Edwards SAPIEN XT Transcatheter Heart Valve (model 9300TFX) and accessories		07/14	P130009
<ul style="list-style-type: none"> Severe native aortic valve stenosis at high or greater risk for open surgical therapy 			
<ul style="list-style-type: none"> Expanded to include failure of bioprosthetic valve in high or greater risk for open surgical therapy 		10/15	P130009/S034
<ul style="list-style-type: none"> Expanded to include severe aortic stenosis with intermediate surgical risk 		08/16	
Medtronic CoreValve System™	Medtronic CoreValve	01/14	P130021
<ul style="list-style-type: none"> Severe native aortic stenosis at extreme risk or inoperable for open surgical therapy 			
<ul style="list-style-type: none"> Expanded to include high risk for open surgical therapy 		06/16	P130021/S002
<ul style="list-style-type: none"> Expanded to include intermediate risk for open surgical therapy 		07/17	P130021/S033
Medtronic CoreValve Evolut R System™		06/15	P130021/S014
<ul style="list-style-type: none"> Design iteration for valve and accessories 			

Original Policy Date: June 2012

Page: 1

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FEP 7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

<ul style="list-style-type: none"> Expanded to include intermediate risk for open surgical therapy 	07/17	P130021/S033
Medtronic CoreValve Evolut PRO System™	03/17	P130021/S029
<ul style="list-style-type: none"> Design iteration for valve and accessories 		
<ul style="list-style-type: none"> Expanded to include intermediate risk for open surgical therapy 	07/17	P130021/S033

FDA: Food and Drug Administration: PMA: postmarket approval.

Other transcatheter aortic valve systems are under development. The following repositionable valves are under investigation:

- Lotus™ Aortic Valve Replacement System (Boston Scientific)^Z
- Portico™ Transcatheter Aortic Valve (St. Jude Medical)
- JenaValve™ (JenaValve Technology); designed for transapical placement

Several embolic protection devices, which are designed to collect embolic debris distal to the transcatheter aortic valve implantation apparatus and to prevent ischemic stroke, are under investigation. No devices have FDA approval for use in the United States. Examples include the TriGuard (Keystone Heart) and the Sentinel Cerebral Protection System (Claret Medical).

POLICY STATEMENT

Transcatheter aortic valve replacement with an U.S. Food and Drug Administration (FDA)–approved transcatheter heart valve system, performed via an approach consistent with the device’s FDA-approved labeling, may be considered **medically necessary** for patients with native valve aortic stenosis when all of the following conditions are present:

- Severe aortic stenosis (see Policy Guidelines section) with a calcified aortic annulus; AND
- New York Heart Association heart failure class II, III, or IV symptoms; AND
- Left ventricular ejection fraction greater than 20%; AND
- 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 or intermediate risk for open surgery (see Policy Guidelines section).

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:

- Failed (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; AND
- New York Heart Association heart failure class II, III, or IV symptoms; AND
- Left ventricular ejection fraction greater than 20%; AND
- 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 (see Policy Guidelines section).

Transcatheter aortic valve replacement is considered **not medically necessary** for all other indications.

POLICY GUIDELINES

The U.S. Food and Drug Administration (FDA) definition of extreme risk or inoperable for open surgery is:

- Predicted risk of operative mortality and/or serious irreversible morbidity 50% or higher for open surgery.

The FDA definition of high risk for open surgery is:

- Society of Thoracic Surgeons predicted operative risk score of 8% or higher; or
- Judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of 15% or higher for open surgery.

FEP 7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

The FDA definition of intermediate risk is:

- Society of Thoracic Surgeons predicted operative risk score of 3% to 7%.

For the use of the SAPIEN or CoreValve devices, severe aortic stenosis is defined by the presence of one or more of the following criteria:

- An aortic valve area of less than or equal to 1 cm²
- An aortic valve area index of less than or equal to 0.6 cm²/m²
- A mean aortic valve gradient greater than or equal to 40 mm Hg
- A peak aortic-jet velocity greater than or equal to 4.0 m/s.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have severe symptomatic aortic stenosis who are at prohibitive risk for open surgery who receive TAVI, the evidence includes an RCT comparing TAVI with medical management in individuals at prohibitive risk of surgery, a 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 on results for patients treated with TAVI by the transfemoral approach compared with continued medical care with or without balloon valvuloplasty. There was a large decrease in mortality for the TAVI patients at 1 year compared with medical care. This trial also reported improvements in 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 with 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, 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 vs open surgery in high-risk patients have reported no major differences in rates of mortality or stroke between the 2 procedures. Since the publication of the PARTNER A trial, the CoreValve High Risk Trial demonstrated noninferiority for survival at 1 and 2 years for the self-expanding prosthesis. This trial reported no significant differences in stroke rates between groups. In an RCT directly comparing the self-expandable with the balloon-expandable valve among surgically high-risk patients, the devices had similar 30-day mortality outcomes, although the self-expandable valve was associated with higher rates of residual aortic regurgitation and need for a new permanent pacemaker. Evidence from RCT and nonrandomized studies has suggested 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 support

FEP 7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

the superiority of one device over another in all patients. Two sex-specific studies were also identified in a literature search with the objective of observing mortality rates in women undergoing TAVI or SAVR. Results were varied, and further study is needed. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at intermediate risk for open surgery who receive TAVI, the evidence includes 3 RCTs comparing TAVI with surgical repair including individuals at intermediate surgical risk, 2 RCTs only in patients with intermediate risk, and multiple systematic reviews and nonrandomized cohort studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Five RCTs have evaluated TAVI in patients with intermediate risk for open surgery. Three of them, which included over 4000 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 RCT has suggested that the benefit of TAVI may be limited to patients who are candidates for transfemoral access. Although several RCTs have 2 years of follow-up postprocedure, it is uncertain how many individuals require reoperation. 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 low risk for open surgery who receive TAVI, the evidence includes 2 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 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; 17.2% 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.

For individuals who have valve dysfunction and aortic stenosis or regurgitation after aortic valve repair who receive transcatheter aortic “valve-in-valve” implantation, the evidence includes case series (largest with 459 patients) and systematic reviews of case series. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. These case series have reported high rates of technical success of valve implantation and improvement in heart failure symptoms for most patients. However, they have also reported high rates of short-term complications and high rates of mortality at 1 year postprocedure. There is a lack of evidence comparing valve-in-valve replacement with alternative treatment approaches. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Cardiology and American Heart Association

The American College of Cardiology and the American Heart Association (2014) published joint guidelines on the management of valvular heart disease.⁸¹ Both groups issued a joint focused update in

FEP 7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

2017.⁸² These guidelines made the following recommendations on the choice of surgical or transcatheter intervention for treatment of aortic stenosis (see Table 2).

Table 2 Recommendations on Surgical or Transcatheter Intervention for Aortic Stenosis

Recommendation	COR	LOE
"Surgical AVR is recommended in patients who meet an indication for AVR with low or intermediate surgical risk."	I	A
"For patients in whom TAVR or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care"	I	C
"TAVR is recommended for symptomatic patients with severe AS and high risk for SAVR, depending on patient-specific procedural risks, values and preferences."	I	A
"TAVR is recommended for symptomatic patients with severe AS, prohibitive risk for SAVR and a predicted post-TAVR survival >12 mo."	I	A
"TAVR is a reasonable alternative to SAVR for symptomatic patients with severe AS and intermediate surgical risk, depending on patient-specific procedural risks, values and preferences"	IIa	B
"For severely symptomatic patients with bioprosthetic stenosis or regurgitation at high or prohibitive risk for reoperation, and in whom improvement in hemodynamics is anticipated, valve-in-valve TAVR is reasonable"	IIa	B
"Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS."	IIb	C
"TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS."	III	B

AS: aortic stenosis; AVR: aortic valve replacement; COR: class of recommendation; LOE: level of evidence; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement.

European Society for Cardiology and European Association for Cardio-Thoracic Surgery

The European Society for Cardiology and the European Association for Cardio-Thoracic Surgery (2017) published joint guidelines on the management of valvular heart disease.⁸³ These guidelines made the following recommendations on the use of TAVI (see Table 3).

Table 3 Recommendations on Surgical or Transcatheter Intervention for Aortic Stenosis

Recommendation	COR	LOE
"TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team."	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II \geq 4% or logistic EuroSCORE I \geq 10% or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics, with TAVI being favoured in elderly patients suitable for transfemoral access."	I	B

COR: class of recommendation; LOE: level of evidence; SAVR: surgical aortic valve replacement; STS: Society of Thoracic Surgeons; TAVI: transcatheter aortic valve implantation.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services published a decision memo on the use of TAVR in 2012.⁸⁴ This memo indicated that the Centers for Medicare & Medicaid Services covers TAVI when used according to FDA indications when the following conditions are met:

- Device has FDA approval
- Two cardiac surgeons agree with indications for the procedure
- The patient is "under the care of a heart team," and the hospital meets qualifications for performing TAVR.

FEP 7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

The memo also stated that TAVR could be covered for non-FDA-approved indications under the Coverage with Evidence Development program. The following is a summary of the main conditions required for Coverage with Evidence Development:

- TAVI is performed within a clinical study that has the following characteristics:
- “The clinical study must adhere to the ... standards of scientific integrity and relevance to the Medicare population.”
- The study must address quality of life and adverse events at follow-up periods of 1 year or longer.

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FEP 7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

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FEP 7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

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FEP 7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

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FEP 7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

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POLICY HISTORY

Date	Action	Description
December 2012	New Policy	
March 2013	Update Policy	Policy updated with literature review, references 7, 15, 16, 18, 20, 22-27, 29 added. Medically necessary indications added for patients who are at high risk for open surgery using the transfemoral approach, and patients who are at high risk for open surgery using the transapical approach. Not medically necessary statement added for treatment of degenerated bio-prosthetic valve or failed TAVI (Valve-in- Valve approach), and for vascular approaches other than transfemoral or transapical.
March 2014	Update Policy	Policy updated with literature review, adding references 8, 18, 19, 22, 23, 27. Policy statement revised to include medically necessary indication for TAVI by the transapical approach for patients who are not suitable candidates for open surgery.
December 2014	Update Policy	Policy updated with literature review through September 1, 2014, and the results of clinical input. References 9-10, 15-17, 23, 28-34, 36, 41-43, 45, 47, 49-52, and 57-59 added. Policy statement revised to remove statement that "procedures performed via the transaxillary, transiliac, transaortic, or other approaches" are investigational, to reflect the approval of the CoreValve device that is labeled for use via transaxillary, transfemoral, and transaortic approaches. A statement was added to the policy statement that devices should be used according to their FDA approved indication
September 2016	Update Policy	Policy updated with literature review, references 8-10, 15, 21, 25- 27, 30, 36, 41-45, 48, 54-56, 58, 74-75, and 78 added. Medically necessary policy statement added for valve-in-valve implantation in patients at high or prohibitive risk for open surgery. Policy statements revised to include intermediate risk of surgical mortality based on expansion of FDA approvals of Sapien 3 and Sapien XT valves.
June 2018	Update Policy	Policy updated with literature review through February 2, 2018; references 19-20, 26, 31-34, 37, 42-55, 58-60, 68, 82-83 and 85 added.

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FEP 7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy statements changed to add patients at intermediate surgical risk to first medically necessary statement. Transcatheter aortic valve replacement corrected from investigational to not medically necessary for all other indications due to FDA PMA approval status.
