


<b>MEDICAL POLICY</b>	<b>Cardiac: Transcatheter Aortic Valve Replacement (TAVR) (All Lines of Business Except Medicare)</b>	
<b>Effective Date: 06/01/2020</b>   <div style="text-align: right;">6/1/2020</div>	Section: SUR	Policy No: 179
	Technology Assessment Committee Approved Date: 2/12 Medical Policy Committee Approved Date: 1/13; 6/13; 2/14; 9/15; 4/16; 5/17; 6/18; 10/18; 11/19; 05/2020	
Medical Officer	Date	

**See Policy CPT CODE section below for any prior authorization requirements**

**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

All lines of business

**BENEFIT APPLICATION**

Medicaid Members

*Oregon:* Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**POLICY CRITERIA**

**Aortic Stenosis**

I. Transcatheter aortic valve replacement (TAVR) for the treatment of severe symptomatic native calcific aortic stenosis may be considered **medical necessary and covered** when using an FDA-approved aortic valve and implantation system, performed via an approach consistent with the device’s FDA-approved labeling, and **all** of the following criteria are met (A. – C.):  
 Note: Please see the [Regulatory Status](#) section below for links to the most recent FDA labelling for FDA-approved systems.

A. Documented severe aortic valve stenosis with **one or more** of the following echocardiography derived criteria:

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1. Mean gradient >40 mm Hg; **or**
  2. Jet velocity > 4.0 m/s; **or**
  3. Aortic valve area (AVA) of < 0.8 cm<sup>2</sup>; **or**
  4. AVA index < 0.5 cm<sup>2</sup>/m<sup>2</sup>; **and**
- B. Symptomatic heart disease due to aortic valve stenosis as demonstrated by NYHA Functional Class ≥ II; **and**
- C. The subject, as judged by a heart team, including a cardiac surgeon and a cardiologist, is determined to be intermediate surgical risk (or greater) for open aortic valve replacement (i.e., Society of Thoracic Surgeons (STS) predicted risk of surgical mortality [PROM] ≥ 3% at 30 days). See [Policy Guidelines](#) section below on STS risk model.

Note: For a complete list of indications by device, please see the [Regulatory Status](#) section below.

- II. Transcatheter aortic valve replacement (TAVR) for the treatment of severe native calcific aortic stenosis is considered **investigational and not covered** when criterion I. above is not met, including, but not limited to when the following contraindications, precautions, or conditions are present:
- A. Known hypersensitivity or contraindication to anticoagulant/antiplatelet regimens
  - B. Active bacterial endocarditis or other active infections
  - C. Non-calcified aortic valve
  - D. Severe ventricular dysfunction with left ventricular ejection fraction of less than 20%
  - E. Congenital unicuspid or congenital bicuspid aortic valve
  - F. Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation > 3+)
  - G. Blood dyscrasias as defined: leukopenia (WBC <1000 cells/mm<sup>3</sup>), thrombocytopenia (platelet count <50,000 cells/mm<sup>3</sup>), history of bleeding diathesis or coagulopathy, or hypercoagulable states
  - H. Hypertrophic obstructive cardiomyopathy
  - I. Echocardiographic evidence of intracardiac mass, thrombus, or vegetation
  - J. Acute myocardial infarction within the previous month
  - K. Severe (>3+) mitral or aortic regurgitation
  - L. Transient ischemic attack or stroke within the previous 6 months
  - M. Life expectancy <12 months due to non-cardiac comorbid conditions

Note: For a complete list of the contraindications, warning and precautions by device please see the [Regulatory Status](#) section below.

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**Replacement of Degenerated Bioprosthetic Valve (Valve-in-Valve Procedure)**

III. Transcatheter aortic valve replacement (TAVR) when using an FDA-approved aortic valve and implantation system, performed via an approach consistent with the device’s FDA-approved labeling, for replacement of a degenerated bioprosthetic valve may be considered **medically necessary and covered** when **all** of the following criteria are met (A. – C.):

Note: Please see the [Regulatory Status](#) section below for links to the most recent FDA labelling for FDA-approved systems.

- A. Documented presence of symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve); **and**
- B. Symptomatic heart disease as demonstrated by NYHA Functional Class  $\geq$  II; **and**
- C. The subject, as judged by a heart team, including a cardiac surgeon and a cardiologist, is determined to be at high risk (or greater) for open surgery (i.e., predicted risk of surgical mortality [PROM]  $\geq$  8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities).

See [Policy Guidelines](#) section below on the STS risk model.

IV. Transcatheter aortic valve replacement (TAVR) for replacement of a degenerated bioprosthetic valve is considered **investigational and not covered** when criterion III. above is not met.

Link to [Policy Summary](#)

**POLICY GUIDELINES**

Society of Thoracic Surgeons (STS) Risk Calculator <sup>1,2</sup>

The Society of Thoracic Surgeons (STS) cardiac surgery risk model for isolated valve surgery is a risk assessment tool that adjusts cardiac surgery outcomes for preoperative patient characteristics and disease severity. This tool is an online tool that can be used to assess the risk of open surgical valve replacement and is included as part of the FDA indications for FDA-approved aortic valve replacement systems. The online risk calculator is publicly available from [The Society of Thoracic Surgeons website](#).<sup>3</sup>

Per the Society of Thoracic Surgeons website, below is the list of the weighted variables contained in the STS isolated aortic valve replacement model:

Age	Cerebrovascular disease	Cardiogenic shock
Sex	Peripheral artery disease	Intra-Aortic Balloon Pump (IABP)
Height Weight	Diabetes	Receipt of IV inotropic agents before surgery
Ejection Fraction	Hypertension	Previous cardiac interventions
Heart failure within 2 weeks	Immunocompromise	Valve disease (aortic and mitral)

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Race	Endocarditis	Valve insufficiency (mitral, tricuspid, aortic)
Renal failure/dialysis	Coronary anatomy/disease status	Incidence of surgery (first, second, etc.)
Last creatinine level	Surgery status (elective, urgent, etc.)	Cardiogenic shock
Cardiac presentation/symptoms	Resuscitation	Intra-Aortic Balloon Pump (IABP)

According to the American College of Cardiology/American Heart Association guidelines for the management of patients with valvular heart disease, the STS risk score generates a predicted risk of mortality (PROM) that falls into one of the following categories:<sup>4</sup>

- Low risk: <4%
- Intermediate risk: 4-8%
- High risk: >8%
- Prohibitive risk: Predicted risk with surgery of death or major morbidity (all-cause) >50% at 1 y

**CPT CODES**

<b>All Lines of Business Except Medicare</b>	
No Prior Authorization Required	
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)
33367	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)
33368	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)

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33369	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)
<b>Unlisted Codes</b>	
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then <b>prior-authorization is required.</b>	
33999	Unlisted procedure, cardiac surgery
93799	Unlisted cardiovascular service or procedure

**DESCRIPTION**

Transcatheter aortic valve replacement (TAVR), also known as transcatheter aortic valve implantation (TAVI), is a newer, minimally invasive procedure which is an emerging alternative to open surgery, or surgical aortic valve replacement (SAVR), for patients with aortic stenosis who fall into one of several risk categories for open heart surgery. These prosthetic aortic valves are delivered percutaneously, and are intended to replace a patient’s aortic heart valve. These risk categories are based on the definitions found in the FDA labelling information for devices approved for TAVR, and are as follows:

Extreme risk or inoperable for open heart surgery:

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

High Risk for open heart surgery:

- 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.

Intermediate risk:

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

During the TAVR procedure, a catheter is inserted at a suitable access point (e.g., femoral, apical, aortic) that allows the introduction of an expandable prosthetic heart valve, which is then delivered to the stenosed native valve. The most common approaches include a transfemoral (TF) or transapical (TA) approach. However, other approaches may be used.

Recently, several devices have been FDA-approved to replace bioprosthetic valves that are failing or have failed. This is also referred to as the valve-in-valve (ViV) approach.

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Please see the [Regulatory Status](#) section below for more detail on the indications and contraindications of the FDA-approved devices for the replacement of native valves and failed bioprosthetic valves.

**REVIEW OF EVIDENCE**

A number of transcatheter aortic valve replacement (TAVR) devices currently being studied have not been approved by the Food & Drug Administration (FDA). Examples of these devices include the Acurate TA transaortic valve replacement system, the Engager system; and the JenaValve system. The health plan considers devices that are not FDA-approved to be investigational and not covered. The following evidence review is only focused on FDA-approved devices.

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of transcatheter aortic valve replacement (TAVR) as a treatment for aortic stenosis of native valves and failing bioprosthetic valves. Below is a summary of the available evidence identified through April of 2020. Due to the large body of recent evidence published on the use of TAVR for aortic stenosis, the following review is primarily focused on high-quality systematic reviews.

Prohibitive/Extreme Risk for Open Surgery

*Systematic Reviews*

In 2011, Figulla et al. published the results of a systematic review that compared TAVR with medical therapy in patients with severe aortic valve stenosis who were not eligible for surgical aortic valve replacement (SAVR), including 20 studies (N=1995 patients).<sup>5</sup> Only three of the studies included were comparative. The reviewers reported a significantly improved mean one-year rate survival in TAVR patients compared to nonsurgical management.

*Randomized Controlled Trials (RCTs)*

Recent publications from the PARTNER B randomized controlled trial (RCT) comparing TAVR with continued or best medical care have reported decreased mortality rates in patients who underwent TAVR compared with medical care at 1-, 2- and 3-year follow-up.<sup>6-9</sup> Although increased risk of stroke at 3-years follow-up has been reported in TAVR patients, improvements in clinically relevant outcomes, including NYHA class symptoms and overall survival, demonstrates that treatment with TAVR leads to a net improvement of health outcomes when compared to current or best non-surgical medical management in this patient population.

High Risk for Open Surgery

A large number of recent systematic reviews have been published comparing TAVR with SAVR in patients with high risk for open surgery (N = 1494 - 38, 253 patients). These reviews typically included a combination of RCTs (such as the PARTNER 1A and CoreValve High Risk trials) and observational

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studies.<sup>10-17</sup> Most reviews have reported similar perioperative (30-day) and long-term (1-5 years) all-cause mortality rates between TAVR and SAVR in high-risk patients with aortic stenosis. In addition, TAVR is associated with significantly lower 30-day stroke and myocardial infarction rates, as well as decreased bleeding complications compared to SAVR. Reports on renal impairment or injury rates were inconsistent. Although, pacemaker implantation rates were higher in TAVR-treated patients, reviews have consistently reported an overall net improvement in health outcomes in patients who underwent TAVR compared with SAVR.

Intermediate Risk for Open Surgery

Recent systematic reviews have been published comparing TAVR with SAVR in patients with intermediate risk for open surgery (N = 2312 – 5841 patients). These reviews primarily included large observational studies, and a limited number of RCTs (such as the PARTNER 2A trial).<sup>10,17,18</sup> These reviews have reported similar perioperative (30-day) and one-year all-cause mortality between TAVR and SAVR in intermediate patients with aortic stenosis. In addition, consistent significant decreases in post-procedural acute renal failure/injury and bleeding complications have been reported in TAVR patients of intermediate surgical risk. Reports on stroke, myocardial infarction and atrial fibrillation rates were inconsistent but trended towards favoring TAVR compared to SAVR. Although, pacemaker implantation rates and vascular complications were higher in TAVR-treated patients, improvements in clinically relevant outcomes demonstrates that treatment with TAVR leads to a net improvement of health outcomes when compared to SAVR in this patient population.

Low Risk for Open Surgery

*Systematic Reviews*

Recent systematic reviews have been published comparing TAVR with SAVR in patients with low risk for open surgery (N = 2252 patients). These reviews primarily included large observational studies, and a limited number of RCTs (such as the NOTION trial). However, it is important to note that currently, TAVR using any FDA-approved device, it not approved for use in patients considered to be at low risk for open surgery. Therefore, TAVR in this population is considered investigational.

In 2017, Arora et al. published the results of a systematic review that included four studies (one RCT and three propensity-matched cohort studies) reported that TAVR had a significantly lower risk of bleeding complications and acute kidney injury.<sup>19</sup> Thirty-day mortality trended in favor of TAVR compared to SAVR, but the confidence intervals were wide, indicating the sample sizes were too small to make meaningful conclusions. However, a substantially higher risk of vascular complications (RR 11.72, 95% CI 3.75, 36.64), moderate or severe paravalvular leak (RR 5.04, 95% CI 3.01, 8.43), and permanent pacemaker implantations (RR 4.62, 95% CI 2.63, 8.12) was noted for TAVR. The reviewers concluded that although “TAVR and SAVR appear to be comparable in short term outcomes, additional high quality studies among patients classified as low risk are needed to further explore the feasibility of TAVR.” The reviewers noted significant heterogeneity between studies, possible publication bias and small study number as limitations. No mid- to long-term outcomes were assessed in the included studies.

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In 2018, a larger review was published that included six studies (two RCTs and four propensity-matched studies, N = 3,484 patients) and included follow-up that ranged from three months to three years (median two years).<sup>20</sup> The reviewers reported that short-term mortality was similar between TAVR and SAVR; however, TAVR was associated with a significantly increased risk for intermediate-term mortality. In terms of periprocedural complications, results similar to the Arora et al. study above were reported.<sup>19</sup> The reviewers concluded that “in patients who are at low surgical risk, TAVR seems to be associated with increased mortality risk. Until more data in this population is available, SAVR should remain the treatment of choice for these patients.”

*Randomized Controlled Trials (RCTs)*

No additional RCTs have been published since the systematic reviews described above. Trials are currently underway for the Medtronic CoreValve and the Edwards valves (PARTNER 3 trial) and results are expected to be forthcoming in an attempt to expand the FA indications for TAVR devices.

Valve-in-Valve (ViV) TAVR

A 2016 systematic review by Phan et al. evaluated VIV approach compared to reoperative conventional aortic valve replacement in patients considered inoperable or at high risk, including 18 studies (N = 823 patients).<sup>21</sup> The review reported that VIV TAVR achieved similar hemodynamic outcomes (mean gradient and peak gradient) and similar peri-operative mortality rates, compared with reoperative valve replacement. However, ViV was found to have lower risk of stroke and bleeding, but significantly higher para-valvular leaks compared to surgical reoperation. Large randomized controlled trials (RCTs) and prospective registries are essential to compare the long-term effectiveness of transcatheter VIV with surgical redo. Three additional systematic reviews published in 2018 have reported similar results for perioperative and short-term (30-day) outcomes.<sup>22-24</sup> In addition, two of the more recent reviews reported longer-term mortality rates (1-year and 18-month) to be comparable between ViV and surgical reoperation.<sup>23,24</sup>

Although, para-valvular leaks were higher in ViV-treated patients, improvements in clinically relevant outcomes demonstrates that ViV leads to a net improvement of health outcomes when compared to surgical reoperation in patients considered to be inoperable or high-risk for open surgery.

Studies reporting on the use of ViV-TAVR in patient populations at intermediate and low risk for surgery were not identified, and the use of ViV-TAVR is not approved for use in patients considered to be at intermediate or low risk for surgical reoperation. Therefore, ViV in these populations are considered investigational.

**CLINICAL PRACTICE GUIDELINES**

American College of Cardiology collaborated with the American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, European Association for Cardio-



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Thoracic Surgery, Heart Valve Society, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons (ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS)

In 2018, the ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS published the first Appropriate Use Criteria (AUC) for the treatment of patients with severe aortic stenosis.<sup>25</sup> The AUC were developed by multiple panels in multidisciplinary working groups to identify and categorize common clinical scenarios for patients with severe AS, based on common scenarios in clinical practice, current literature and guidelines. Seventeen rating panelists scored the clinical scenarios, and an in-person meeting was convened wherein discrepancy in scoring and the evidence base or guidelines could be worked out. Multiple rounds of review and revision ensued. The scoring system resulted in SAVR and TAVR recommendations for specific clinical scenarios, and no differentiation was made between the two options.

American College of Cardiology (ACC) / American Heart Association (AHA)

In 2017, the ACC/AHA published updated guidelines for the management of patients with valvular heart disease<sup>26</sup> made the following recommendations regarding transcatheter valve replacement (TAVR):

*TAVR:*

- “SAVR or TAVR is recommended for symptomatic patients with severe AS (Stage D) and high risk for surgical AVR, depending on patient-specific procedural risks, values, and preferences.” This was a strong recommendation (Class I) based on high quality evidence from studies reporting long-term follow-up.
- “TAVR is recommended for symptomatic patients with severe AS (Stage D) and a prohibitive risk for surgical AVR who have a predicted post-TAVR survival greater than 12 months.” This was a strong recommendation (Class I), based on high quality evidence from recent randomized controlled trials (RCTs).
- “TAVR is a reasonable alternative to surgical AVR for symptomatic patients with severe AS (Stage D) and an intermediate surgical risk, depending on patient-specific procedural risks, values, and preferences.” This was a moderate strength recommendation, based on RCTs of moderate quality.
- “TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS.” This was a strong recommendation based on moderate quality evidence.

*Valve-In-Valve (ViV):*

The following moderate strength recommendations were made based on well-designed nonrandomized studies:

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- “For severely symptomatic patients with bioprosthetic aortic valve stenosis judged by the heart team to be at high or prohibitive risk of reoperation, and in whom improvement in hemodynamics is anticipated, a transcatheter ViV procedure is reasonable.”
- “For severely symptomatic patients with bioprosthetic aortic valve regurgitation judged by the heart team to be at high or prohibitive risk for surgical therapy, in whom improvement in hemodynamics is anticipated, a transcatheter ViV procedure is reasonable.”

The guidelines stated “in nonrandomized studies and a systematic review comparing outcomes and safety of the transcatheter ViV procedure with repeat SAVR, the ViV procedure was found to have similar hemodynamic outcomes, lower stroke risk, and reduced bleeding risk as compared with repeat surgery. No data are available yet on the durability and long-term outcomes after transcatheter ViV procedures.”

National Institute for Health and Care Excellence (NICE)

*TAVR:*

In 2017, NICE published an updated guidance document addressing TAVR for aortic stenosis<sup>27</sup>, recommending the following:

- “Current evidence on the safety and efficacy of transcatheter aortic valve implantation (TAVI) for aortic stenosis is adequate.
- Patient selection should be carried out by an experienced multidisciplinary team, which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging and, when appropriate, a cardiac anesthetist and a specialist in elderly medicine. The multidisciplinary team should determine the risk level for each patient and the TAVI device most suitable for them.
- TAVI is a technically challenging procedure that should only be done in specialized centers and only by clinicians and teams with special training and experience in complex endovascular interventions. Units doing this procedure should have both cardiac and vascular surgical support for the emergency treatment of complications and subsequent patient care.”

*Valve-In-Valve (ViV):*

In 2014, NICE published a guidance document addressing transcatheter aortic valve implantation (ViV-TAVI) for aortic bioprosthetic valve dysfunction<sup>28</sup>, recommending the following:

- “For patients with aortic bioprosthetic valve dysfunction for whom surgical aortic valve replacement (SAVR) is considered to be unsuitable, the evidence on the safety and efficacy of ViV-TAVI is adequate.
- For patients with aortic bioprosthetic valve dysfunction for whom SAVR is considered to be suitable but to pose a high risk, the evidence on the safety and efficacy of ViV-TAVI is inadequate.

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- For patients with aortic bioprosthetic valve dysfunction for whom SAVR is considered to be suitable and not to pose a high risk, the evidence on the safety and efficacy of ViV-TAVI is inadequate. For these patients, ViV-TAVI should only be used in the context of research.
- ViV-TAVI is a technically challenging procedure that should only be done by clinicians and teams with special training and experience in complex endovascular cardiac interventions, including regular experience in the use of TAVI. Units doing this procedure should have both cardiac and vascular surgical support for emergency treatment of complications.”

**POLICY SUMMARY**

There is sufficient evidence that transcatheter aortic valve replacement (TAVR) is both safe and effective as a treatment for symptomatic native aortic stenosis in patients considered to be at intermediate risk or higher for open surgery (based on a Society of Thoracic Surgeons predicted operative risk score of 3% or higher). In addition, the use of TAVR in these patients is supported by strong recommendations published in 2017 by the American College of Cardiology/American Heart Association and the National Institute for Health and Care Excellence (NICE).

There is insufficient evidence that transcatheter aortic valve replacement (TAVR) is safe or effective as a treatment for native aortic stenosis when the medical necessity criteria above are not met. This includes, but is not limited to patients with comorbidities/conditions published in the FDA indications for use for TAVR devices, patients who are asymptomatic, and patients considered to be at low risk for open surgery. Furthermore, the use of TAVR in these patients is not supported by the recent guidelines published by the American College of Cardiology/American Heart Association and the National Institute for Health and Care Excellence (NICE).

There is sufficient evidence that valve-in-valve (ViV) TAVR is both safe and effective as a treatment of bioprosthetic valve failure in patients considered to be at high risk for open surgical reoperation. This is based on a Society of Thoracic Surgeons predicted operative risk score of 8% or higher; or when judged by a heart team to have an expected mortality risk of 15% or higher for open surgery. In addition, the use of ViV-TAVR in these patients is supported by recommendations published in 2017 by the American College of Cardiology/American Heart Association and 2014 recommendations by the National Institute for Health and Care Excellence (NICE).

There is insufficient evidence that valve-in-valve (ViV) TAVR is safe or effective as a treatment of bioprosthetic valve failure in patients considered to be at low risk for surgical reoperation. Furthermore, the use of ViV-TAVR in these patients is not supported by the recent guidelines published by the American College of Cardiology/American Heart Association and the National Institute for Health and Care Excellence (NICE).

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## INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

## REGULATORY STATUS

### U.S. Food & Drug Administration (FDA)

FDA Product Code: NPT.

#### *EDWARDS SAPIEN XT (Edwards Lifesciences LLC.)*

- Originally approved through the PMA process on 06/16/2014 (P130009) for TAVR for select patients at high or greater risk for open surgical therapy.
- Valve-in-valve (ViV): On 10/09/2015, approval was expanded to include aortic ViV procedures in high- or extreme-risk candidates to replace a failing bioprosthetic valve.
- On 08/18/2016, approval was expanded to include patients with intermediate surgical risk for aortic valve replacement.
- A complete list of contraindications, warnings and precautions for this device can be found in the most current version of the FDA labeling information:  
[https://www.accessdata.fda.gov/cdrh\\_docs/pdf13/P130009S057d.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S057d.pdf).<sup>29</sup>

#### *EDWARDS SAPIEN 3 (Edwards Lifesciences LLC.)*

- Originally approved through the PMA process on 06/17/2015 (P140031) for TAVR for select patients at high or greater risk for open surgical therapy.
- On 08/18/2016, approval was expanded to include patients with intermediate surgical risk for aortic valve replacement.
- ViV: On 06/05/2017, approval was expanded to include aortic ViV procedures in high- or extreme-risk candidates to replace a failing bioprosthetic valve.
- A complete list of contraindications, warnings and precautions for this device can be found in the most current version of the FDA labeling information:  
[https://www.accessdata.fda.gov/cdrh\\_docs/pdf14/P140031S028c.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S028c.pdf).<sup>30</sup>

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*CoreValve (Medtronic)*

- Originally approved through the PMA process on 01/17/2014 (P130021) for TAVR for select patients at extreme risk or inoperable for open surgical therapy.
- On 06/12/2014, the indications were expanded to include patients at high or greater risk for open surgical therapy.
- ViV: On 03/30/2015, the indications were expanded to allow for ViV replacement in selected high-surgical risk patients with a degenerated bioprosthetic aortic valve who require another valve replacement procedure.
- On 07/10/2017, indications were to include patients with intermediate surgical risk for aortic valve replacement.
- A complete list of contraindications, warnings and precautions for this device can be found in the most current version of the FDA labeling information:  
[https://www.accessdata.fda.gov/cdrh\\_docs/pdf13/P130021S033c.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130021S033c.pdf).<sup>31</sup>

*LOTUS Edge™ Valve System (Boston Scientific)*

- Originally approved through the PMA process on 04/23/2019 (P180029)
- The device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area [AVA] of  $\leq 1.0$  cm<sup>2</sup> or index of  $\leq 0.6$  cm<sup>2</sup>/m<sup>2</sup>) who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality  $\geq 8\%$  at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).
- The approval order, Summary of Safety and Effectiveness, and most up to date product labeling and supplemental approvals can be found at the FDA listing for this device:  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180029>.<sup>32</sup>

The following devices have not been FDA approved and are currently considered investigational:

- ACURATE TA™ system (Boston Scientific)
- Engager TAVI system (Medtronic)
- JenaValve transapical (TAVI) system (JenaValve Technology)
- Portico™ Transcatheter Aortic Valve (St. Jude Medical)

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

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