

Policy Name:	Transcatheter Heart Valve Replacement and Repair Procedures
Effective Date:	12/15/2021

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member’s plan document for other specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Transcatheter aortic valve replacement (TAVR):

TAVR using an FDA approved system (e.g., Edwards SAPIEN™ system; CoreValve® system; Abbott Portico™ with FlexNav™) according to the FDA-approved indications is **COVERED** in individuals with severe symptomatic *native aortic valve stenosis* who have been determined an appropriate surgical candidate by a cardiac surgeon and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis. This includes individuals inoperable for, or at high or greater risk for, open aortic valve replacement.

TAVR using the CoreValve is **COVERED** in individuals with a *failed surgical bioprosthetic aortic valve* (stenosed, insufficient, or combined) when used according to the FDA-approved indications and who are judged to be at high or greater risk for open aortic valve replacement by a cardiac surgeon and in whom existing co-morbidities would not preclude the expected benefit from correction of the failed bioprosthetic valve.

TAVR using any other system and/or for any treatment indication not listed above is investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Percutaneous pulmonary valve implantation (PPVI):

PPVI using an FDA approved system (e.g., Melody® transcatheter pulmonary valve and delivery system; Edwards SAPIEN XT valve; Harmony™ transcatheter pulmonary valve) according to the FDA-approved indications is **COVERED** in children and adults with right ventricular outflow tract (RVOT) disorders who have been determined appropriate surgical candidates (i.e., moderate or greater pulmonary regurgitation) by a cardiac surgeon and in whom existing co-morbidities would not preclude the expected benefit from correction of the RVOT.

PPVI using any other system and/or for any treatment indications not listed above is investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Transcatheter mitral valve leaflet repair:

Transcatheter mitral valve leaflet repair using an FDA approved device (e.g., MitraClip®) used according to the FDA-approved indications is **COVERED** for percutaneous reduction of significant degenerative (i.e., primary) and functional (i.e., secondary) mitral regurgitation in individuals who have been determined an appropriate surgical candidate (i.e., moderate-to-severe or severe mitral valve regurgitation) by a cardiac surgeon and in whom existing co-morbidities would not preclude the expected benefit from correction of the mitral regurgitation.

Transcatheter mitral valve leaflet repair using any other system and/or for any treatment indication not listed above is investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

Transcatheter aortic valve replacement (TAVR):

TAVR is a nonsurgical, minimally invasive method to correct aortic valve dysfunction. TAVR is purported for use in patients with symptomatic heart disease due to either severe native calcific aortic stenosis or failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy.

TAVR involves delivering and implanting a bioprosthetic valve via a peripheral artery. There are two access routes for TAVR: (1) retrograde transfemoral arterial approach and (2) transapical antegrade approach. In the transfemoral approach, access via the aortic arch and through the stenotic valve is obtained via the femoral artery. The transapical approach utilizes direct left ventricular apical puncture via an anterolateral thoracotomy without cardiopulmonary bypass or sternotomy. Once the prosthetic valve is deployed, angiography or echocardiography is conducted to ensure successful implantation of the device.

Currently, there are three transcatheter valves in use in the United States: the Edwards SAPIENT™ Transcatheter Heart Valve (Edwards Lifesciences LLC), the CoreValve® System (Medtronic Inc.), and the Portico with FlexNav Transcatheter System (Abbott). The Edwards SAPIENT device is a balloon-expandable stainless steel frame that supports a valve created from bovine pericardial tissue. The CoreValve device is a self-expandable nitinol frame that supports a valve created from porcine pericardial tissue. Portico with FlexNav provides intra-annular leaflet positioning in a self-expanding valve, which results in early valve function and hemodynamic stability throughout the procedure.

Percutaneous pulmonary valve implantation (PPVI):

PPVI is a nonsurgical, minimally invasive method purported to correct right ventricular outflow tract (RVOT) dysfunction. The Melody® transcatheter pulmonary valve system (Medtronic, Inc.), the Edwards SAPIENT™ pulmonary valve, and the Harmony™ transcatheter pulmonary valve are commercially available in the United States. These bioprosthetic valves are derived from a bovine tissue and is attached to an expandable metal frame. The delivery system is available in different sizes to account for variability in patient physiology. A protective sheath covers the valve to facilitate delivery. Once the delivery system is placed within the RVOT conduit, the valve is fully deployed inside the conduit. The catheter is then retracted and fluoroscopy is used to ensure the valve is working correctly.

Transcatheter mitral valve leaflet repair:

Transcatheter mitral valve leaflet repair is a nonsurgical, minimally invasive method used as a treatment for degenerative (i.e., primary) and functional (i.e., secondary) mitral regurgitation using the MitraClip® system (Abbott Laboratories). The MitraClip procedure is intended to replicate the functional effects achieved by the Alfieri edge-to-edge surgical technique, whereby a surgeon sutures together the edges of the two opposing mitral valve leaflets at the center of the valve opening. This leaves two smaller openings on either side that close more completely than a single large opening. The MitraClip procedure replaces the sutures with a metal clip. The MitraClip system consists of a steerable guide catheter, including a clip delivery device, and the MitraClip implant. The MitraClip is a two-armed, flexible metal clip covered in polyester fabric.

To implant the MitraClip, a physician inserts the guide catheter into the femoral vein at the groin and threads it up to the heart into the right atrium under fluoroscopic guidance. To reach the mitral valve in the left atrium, the physician creates an opening in the septum through which the catheter is then advanced into the left atrium and through the mitral valve as the clip is expanded. Using Doppler ultrasound to identify the optimal location for clip placement to correct valve leaks, the physician grasps and fastens the edges of the valve leaflets together with the MitraClip.

FDA Approval

TAVR:

Edwards Lifesciences LLC has received FDA approval on multiple systems under the name Edwards Sapien, including but not limited to:

1. Edwards SAPIEN Transcatheter Heart Valve was approved in November 2011, for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis (P100041). It is indicated for patients with severe symptomatic native aortic valve stenosis, who have been determined to be inoperable for open aortic valve replacement and in whom existing comorbidities would not preclude the expected benefit from correction of the aortic stenosis.
2. Edwards SAPIEN XT was approved in June 2014, for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis, and with native anatomy appropriate for the 23-, 26-, or 29-mm valve system, who are at high or greater risk for open surgical therapy (P130009).
3. Edwards SAPIEN 3 was approved in June 2015, based on early data from the Placement of Aortic Transcatheter Valves II (PARTNER II) trial. It is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged to be at high or greater risk for open surgical therapy (P140031). SAPIEN 3 is approved for use in high-risk and intermediate risk individuals.

Medtronic has received FDA approval on multiple systems under the name of CoreValve, including but not limited to:

1. CoreValve system (Medtronic Inc.) received FDA approval in January, 2014, for correction of aortic stenosis in individuals with severe symptomatic aortic stenosis and who are not candidates for conventional surgery. On March 30, 2015, CoreValve was granted additional FDA approval for patients with symptomatic heart disease due to a failed, surgically implanted bioprosthetic aortic valve who are judged to be at high or greater risk for open surgical therapy (P130021/S010).
2. In June 2015, the FDA approved the CoreValve® Evolut-R system for high-risk patients with severe aortic stenosis who are unable undergo surgery. In July 2017, the system received additional FDA approval for individuals with symptomatic severe aortic stenosis who are at intermediate risk for open surgical aortic valve replacement.

Abbott received FDA approval in September 2021 for the Portico with FlexNav Transcatheter aortic valve replacement system for individuals with symptomatic, severe aortic stenosis who are at high or extreme risk for open heart surgery.

PPVI:

Multiple systems have received FDA approval for PPVI, including but not limited to:

1. The Melody Transcatheter Pulmonary Valve and Delivery System received FDA approval in 2010 through a Humanitarian Device Exemption (HDE) approval. In January 2015, FDA granted the Melody TPV and the Ensemble Transcatheter Valve Delivery System full premarket approval. The device is approved as an adjunct to surgery in the management of pediatric and adult patients with one of the following clinical conditions:
 - a. Existence of a full (circumferential) right ventricular outflow tract (RVOT) conduit equal to or greater than 16 mm in diameter when originally implanted.
 - b. Dysfunctional RVOT conduit with a clinical indication for intervention, and one or more of the following:

- i. Regurgitation classified as moderate or greater
 - ii. Stenosis with a mean RVOT gradient of at least 35 mmHg.
2. The Edwards SAPIEN XT valve received FDA approval in March 2016 for pulmonic valve replacement procedures. It is approved for the treatment of symptomatic adult and pediatric patients who have either:
 - a. A narrowed pulmonary valve
 - b. Moderate or greater pulmonary regurgitation caused by congenital heart disease.
3. The Harmony Transcatheter Pulmonary Valve System received FDA approval in March 2021 as the first nonsurgical heart valve to treat pulmonary-valve regurgitation in pediatric and adult patients with a native or surgically repaired right ventricular outflow tract (RVOT).

Other transcatheter systems are currently under clinical evaluation.

Mitral valve leaflet repair:

In October 2013, Abbott Vascular, Inc. received FDA approval for the MitraClip Clip Delivery System (P100009). The device was approved for the percutaneous reduction of significant symptomatic mitral regurgitation due to primary abnormality of the mitral apparatus in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral valve regurgitation. In March 2019, MitraClip was FDA approved for treatment of individuals with normal mitral valves who develop heart failure symptoms and moderate-to-severe or severe mitral regurgitation because of diminished left heart function (commonly known as secondary or functional mitral regurgitation) despite being treated with optimal medical therapy.

The Carillon device (Cardiac Dimensions) has received the CE mark for both a first and second generation device. As of 2014, Cardiac Dimensions had not announced plans for additional U.S. clinical trials or a timeline for pursuing U.S. marketing approval. Other transcatheter mitral systems are currently under clinical evaluation.

Transcatheter Tricuspid Valve Repair Systems

As of October 2021, no transcatheter tricuspid valve repair system has received FDA approval. Devices under clinical trial in the United States include the TriClip Tricuspid Valve Repair System (Abbott Vascular) and the PASCAL System (Edwards Lifesciences). Results are pending.

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

- **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)

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- **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)
- **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)
- **33418** - Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis
- **33419** - Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)
- **33477** - Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed
- **93799** – Unlisted cardiovascular service or procedure
- **0345T** - Transcatheter mitral valve repair percutaneous approach via the coronary sinus
- **0483T** - Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed
- **0484T** - Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (eg, thoracotomy, transapical)
- **0543T** - Transapical mitral valve repair, including transthoracic echocardiography, when performed, with placement of artificial chordae tendineae
- **0544T** - Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture
- **0545T** - Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach
- **0569T** – Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis

Original Effective Date: 12/16/2015

Re-Review Date(s): 1/4/2016 – administrative update; codes added
1/1/2018 – administrative update; codes added
12/19/2018
7/17/2019
3/16/2020 – administrative update; format
11/16/2020 – administrative update; FDA for TriClip
12/15/2021
4/1/2022 – administrative update; code added
4/12/2022 – administrative update; word correction