

Transcatheter Valve Procedures



INDEPENDENT CARE HEALTH PLAN

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Medical Coverage Policy

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Related Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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NCD	Transcatheter Aortic Valve Replacement ((TAVR)	20.32		
NCD	Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation	20.33		

Description

The transcatheter or percutaneous approach was developed as an alternative to traditional open-heart surgery for a number of interventions, including valve replacement or repair. The heart contains four valves which enable efficient circulation of blood: **aortic, mitral, pulmonary** and **tricuspid**.

Aortic Valve

The **aortic valve** closes off the left ventricle (lower chamber) that holds oxygenated blood before it pumps out to the body, then opens to allow the blood to exit the heart. Aortic stenosis (narrowing) and aortic regurgitation (leaking) may require valve replacement. Both conditions increase the workload of the heart and decrease function. The gold standard for preimplant planning for an eligible individual is computed tomography angiography (CTA) of the heart to measure the aortic annulus (fibrous ring at the aortic orifice). Transthoracic echocardiography (TTE) is used to determine left ventricular function, valve stenosis severity, presence of other valve disease or pulmonary hypertension. Transesophageal echocardiography (TEE) is an alternative to CTA for sizing the annulus in an individual with renal insufficiency.

In transcatheter aortic valve implantation (TAVI), also known as transcatheter aortic valve replacement (TAVR), a bioprosthetic valve is delivered by catheter through a peripheral artery and implanted into the existing valve. Once the prosthetic valve is deployed, angiography, CTA or echocardiography is conducted to ensure successful implantation of the device.

A number of transcatheter aortic valves have been developed for use in an individual with severe aortic stenosis and determined by a heart team (including a cardiac surgeon and an interventional cardiologist) to be at risk for open-heart surgery. Examples of US Food & Drug Administration (FDA)-approved transcatheter aortic valves for use at varying risk levels include, but may not be limited to:

- All risk levels (low, intermediate, high or prohibitive): Edwards Sapien Systems (Sapien 3, Sapien 3 Ultra, Sapien 3 Ultra Resilia) and Medtronic CoreValve Evolut Systems (Evolut FX, Evolut PRO+, Evolut R)^{92,93}
- High or prohibitive (inoperable) risk: Abbott TAVI Systems (Navitor, Portico)⁹⁷

Mitral Valve

The **mitral valve** closes the heart's left atrium (upper chamber) which collects the oxygenated blood from the lungs, then opens to allow blood to pass into the left ventricle (lower chamber). Mitral valve prolapse occurs when the flap-like leaflets of the valve bulge into the left atrium preventing even closure. In some cases, the prolapse results in regurgitation (blood leaks backward through the valve) which may cause a heart murmur. In mitral stenosis, the valve becomes narrowed and restricts blood flow from the left atrium to the left ventricle. Both mitral valve regurgitation and stenosis may require mitral valve repair if an individual is symptomatic.

Transcatheter edge-to-edge repair (TEER) of the mitral valve is indicated for the percutaneous reduction of symptomatic moderate-severe to severe mitral regurgitation (MR) in the individual who is deemed at prohibitive risk by a cardiac surgeon for open mitral valve surgical repair. During this procedure, a mechanical clip grasps and coapts the mitral valve leaflets resulting in fixed approximation of the mitral leaflets throughout the cardiac cycle. This repair occurs without the need for arresting the heart or cardiopulmonary bypass.⁹⁷ Examples of FDA-approved mitral valve TEER systems include, but may not be limited to, the MitraClip G4 System and the PASCAL Precision System. Depending upon the valve anatomy, it may be necessary to use more than one clip during the procedure.

Transcatheter mitral valve implantation (TMVI) or replacement is currently under investigation as an alternative to open surgical mitral valve replacement. The procedure is performed via a transcatheter approach including a transeptal puncture under general anesthesia. A stent-based prosthesis is implanted within the native mitral annulus via catheter threaded through the inferior vena cava to the right atrium where the septum is punctured to gain access to the left atrium. There are currently no FDA-approved devices for TMVI.

Annuloplasty (annulus reconstruction) is a surgical procedure to tighten, reshape or reinforce the mitral annulus (ring around the valve) to enable effective leaflet function. Flexible rings or bands may be implanted to improve the structure of the valve. Transcatheter approaches and devices (eg, Carillon Mitral Contour System) are under investigation as an alternative to surgical annuloplasty. A percutaneously deployed annuloplasty device is placed into the mitral valve annulus through the coronary sinus to purportedly reduce mitral regurgitation. There are currently no devices approved by the FDA for transcatheter annuloplasty.

The mitral valve contains **chordae tendineae** (thread-like bands of fibrous tissue) which serve to anchor the leaflets in place. During some types of mitral valve repair procedures, chordae tendineae may be transplanted or artificial replacements may be implanted.

Pulmonary Valve

The **pulmonary** or **pulmonic valve** opens and closes the heart's right ventricle (lower chamber) to pump blood via the pulmonary artery from the heart to the lungs where it is oxygenated. The pulmonary valve may require replacement for pulmonary stenosis (narrowing) or regurgitation (leaking). **Transcatheter pulmonary valve implantation (TPVI)** devices are used to prolong the life span of failing prosthetic pulmonary conduits in an individual with congenital heart defects. The TPVI is not expected to replace the initial open-heart surgery for placement of a pulmonary conduit, but it is expected to reduce the total number of open-heart right ventricular outflow tract (RVOT) procedures over an individual's lifetime. Harmony and Melody transcatheter pulmonary valves are examples of FDA-approved devices.

Tricuspid Valve

The **tricuspid valve** closes the right atrium (upper chamber) where blood enters from the body, then opens to allow blood to flow to the right ventricle (lower chamber), while preventing backflow when pumped out of the ventricle. Tricuspid regurgitation (leaking) or stenosis (narrowing) may result from an improperly functioning tricuspid valve. Tricuspid annuloplasty (valve repair), reconstruction or replacement via transcatheter approach is being studied as a treatment for tricuspid regurgitation. This is currently in preclinical or early clinical trials and not yet available for general use. **Transcatheter tricuspid valve repair**

or replacement generally includes right heart catheterization, temporary pacemaker insertion and selective right ventricular or right atrial angiography during the procedure.

Transcatheter caval valve implantation (CAVI) is an investigational technique proposed to relieve the symptoms of severe tricuspid regurgitation (eg, ascites, dyspnea, fatigue, lower extremity edema) without repairing or replacing the tricuspid valve. This is accomplished by implanting a valve in the inferior vena cava (IVC) alone or in combination with a second valve in the superior vena cava (SVC) to redirect the regurgitant blood flow from the failing tricuspid valve. There are no FDA-approved CAVI devices available for general use.

Paravalvular leaks may occur as a complication of surgical or transcatheter aortic or mitral valve replacement, when the seal between the valve annulus and the prosthetic valve becomes separated. Regurgitation of blood may occur, and large leaks could lead to heart failure or endocarditis. Percutaneous transcatheter repair of paravalvular leaks has been successfully performed; however, there are currently no FDA-approved devices for this indication.

Valve-in-valve (V-in-V) procedures are performed to replace previously implanted surgical or transcatheter cardiac valves that have failed or degenerated over time. These may be replaced using transcatheter access.

Examples of FDA-approved devices for V-in-V procedures for the individual deemed at high or greater risk for surgical valve replacement include, but may not be limited to:

- **Aortic:** CoreValve systems (Evolut FX, Evolute PRO+, Evolut R), Sapien 3, Sapien 3 Ultra, Sapien 3 Ultra Resilia
- **Mitral:** Sapien 3, Sapien 3 Ultra, Sapien 3 Ultra Resilia
- **Pulmonic/Tricuspid:** No FDA-approved devices.

Coverage Determination

iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance for **TAVR and TEER**.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Transcatheter Aortic Valve Procedures

TAVI or TAVR will be considered medically reasonable and necessary when [NCD 20.32](#) requirements and any of the following severe aortic stenosis definition requirements are met:

- Severe symptomatic native calcific aortic stenosis as indicated by **ANY** of the following⁴:

- Aortic valve area less than 1.0 cm²; **OR**
- Aortic valve area index less than or equal to 0.6 cm²m²; **OR**
- Mean aortic valve gradient greater than or equal to 40 mmHg; **OR**
- Peak aortic jet velocity greater than or equal to 4.0 m/s

Transcatheter Edge-to-Edge Repair

Please refer to the above [Medicare guidance](#) for **transcatheter edge-to-edge repair (TEER) for mitral valve regurgitation**.

Transcatheter edge-to-edge repair (TEER) for mitral valve regurgitation will be considered medically reasonable and necessary when [NCD 20.33](#) requirements, and either of the following moderate-severe to severe mitral regurgitation definition requirements are met:

- Chronic degenerative (primary) moderate-severe to severe (greater than or equal to 3+) MR when determined by a heart team (including a cardiac surgeon and an interventional cardiologist) to be at [prohibitive surgical risk*](#); **OR**
- Chronic functional (secondary) moderate-severe to severe (greater than or equal to 3+) MR with symptomatic ([New York Heart Association Class III or IV](#)) heart failure despite optimal individualized [guideline-directed medical therapy \(GDMT\)](#) and LVEF 20% – 50%

*Prohibitive surgical risk is defined as **one or more** of the following risk factors:

- [STS predicted risk of operative mortality \(STS PROM\) score](#) greater than or equal to 8% for isolated open surgical mitral valve (MV) replacement^{61,100}; **OR**
- [STS PROM score](#) greater than or equal to 6% for isolated open surgical MV repair^{61,100}; **OR**
- Presence of one or more clinical features not captured in the STS-PROM risk calculator algorithm that adds heightened open surgical risk (eg, abnormal chest anatomy, frailty, porcelain aorta, severe liver disease with [Model for End-stage Liver Disease \[MELD\] score](#) greater than 12, severe pulmonary hypertension [mPAP greater than 20 mmHg and/or pulmonary vascular resistance greater than 2 Wood units])^{14,75,96,97}

TRANSCATHETER PULMONARY VALVE IMPLANTATION (TPVI)

TPVI will be considered medically reasonable and necessary when the requirements are met for one of the following valve systems:

Harmony Transcatheter Pulmonary Valve System:

- Dysfunctional native or surgically repaired RVOT conduit with a clinical indication for intervention as indicated by **EITHER** of the following:
 - Pulmonary regurgitant fraction greater than or equal to 30% on cardiac magnetic resonance imaging;**OR**

- Severe pulmonary regurgitation on echocardiogram (regurgitant jet width greater than 50% of pulmonic valve annulus)^{17,78}; **OR**

Melody Transcatheter Pulmonary Valve System:

- Dysfunctional RVOT conduit with a clinical indication for intervention as indicated by:
 - Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted;

AND either of the following

- Regurgitation: greater than or equal to moderate (regurgitant jet width less than 50% of pulmonic valve annulus)^{17,78} on echocardiogram; **OR**
- Stenosis: mean RVOT gradient greater than or equal to 35 mmHg

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

Transcatheter Aortic Valve Procedures

Please refer to the above [Medicare guidance](#) for **transcatheter aortic valve procedures**.

Transcatheter Edge-to-Edge Repair

Please refer to the above [Medicare guidance](#) for **transcatheter edge-to-edge repair (TEER) for mitral valve regurgitation**.

Transcatheter Pulmonary Valve Procedures

The following **transcatheter pulmonary valve** procedures and/or devices will not be considered medically reasonable and necessary:

- Sapien 3 valve; **OR**
- Transcatheter implantation or replacement of previously implanted pulmonary valves that have failed (V-in-V); **OR**
- Transcatheter repair of paravalvular leak of pulmonary valves

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management for these indications.

Transcatheter Tricuspid Valve Procedures

The following **transcatheter tricuspid valve procedures** will not be considered medically reasonable and necessary:

- Transcatheter caval valve implantation (CAVI); **OR**
- Transcatheter implantation or replacement of previously implanted tricuspid valves that have failed (V-in-V); **OR**
- Transcatheter repair of paravalvular leak (PVL) of tricuspid valves; **OR**
- Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus device; **OR**
- Transcatheter tricuspid valve repair or replacement

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Summary of Evidence

Evidence from one small single-arm feasibility study assessing the **Sapien 3** with the Alterra Adaptive prenent for TPVI is too small and the risk of bias is too high to determine the safety and efficacy for treating severe pulmonary regurgitation.³⁵ The study has small sample size and lack of controls, randomization and blinding. Available study results are insufficient to determine the value, long-term durability and reintervention rates of the Sapien 3 for severe pulmonary regurgitation due to limited comparison of pretreatment and posttreatment clinical outcomes, lack of direct comparison with open surgery and insufficient long-term follow-up.⁴⁷

A review of the medical literature indicates a lack of evidence supporting **transcatheter pulmonary V-in-V** and **transcatheter pulmonary PVL repair**. Studies are limited to nonrandomized and single-center studies at risk of bias due to lack of sufficient sample size, controls, randomization and blinding. Long-term follow-up with larger randomized, sham-controlled, blinded studies is needed to properly assess the efficacy and safety of these procedures for clinical management.^{4,78}

A very low-quality, insufficient body of evidence is available to assess the safety and efficacy of **transcatheter tricuspid valve procedures** to treat severe tricuspid regurgitation. How well these transcatheter procedures treat tricuspid regurgitation cannot be determined from the available evidence due to the high risk of bias from small sample size, lack of controls and randomization and comparison to

open surgical procedures.^{31,32} Limited clinical trial studies indicate that transcatheter tricuspid procedures may be an emerging treatment option for an individual with severe tricuspid regurgitation who is ineligible for open surgical replacement; however, findings need validation from randomized controlled trials reporting on clinical outcomes to determine the safety and efficacy of these procedures.⁴⁵

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
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)	
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	
33999	Unlisted procedure, cardiac surgery	
93355	Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D	
93590	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve	
93591	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve	
93592	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)	
93799	Unlisted cardiovascular service or procedure	
CPT® Category III Code(s)	Description	Comments
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 transeptal 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	
0570T	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to code for primary procedure)	
0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	
0805T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach	
0806T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach	
HCPCS Code(s)	Description	Comments
No code(s) identified		

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Appendix

Appendix A

New York Heart Association (NYHA) Functional Classification System⁷

Classification	Symptoms
Class I (mild)	Individual with cardiac disease, but without resulting limitations on physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.
Class II (mild)	Individual with cardiac disease resulting in slight limitations on physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.
Class III (moderate)	Individual with cardiac disease resulting in marked limitations on physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
Class IV (severe)	Individual with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increases.

Class IV (ambulatory)	Individual with class IV heart failure and no active acute coronary syndrome, no inotropes and on GDMT *7
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Appendix B

Guideline-directed medical therapy (GDMT) for heart failure⁷

Left ventricular ejection fraction (LVEF)	Medication	Duration
Less than or equal to 40%	<ul style="list-style-type: none"> • Beta blocker • Diuretic • Mineralocorticoid receptor agonist (MRA) • Sodium-glucose cotransporter-2 inhibitor (SGLT2i) • One of the following: <ul style="list-style-type: none"> ○ Angiotensin-converting enzyme inhibitor (ACEi) ○ Angiotensin receptor blocker (ARB) ○ Angiotensin receptor-neprilysin inhibitor (ARNi) 	<ul style="list-style-type: none"> • 3 months • Greater than 1 month • Greater than 1 month • Greater than 1 month • Greater than 1 month
41 – 49%	<ul style="list-style-type: none"> • Beta blocker • Diuretic • Mineralocorticoid receptor agonist (MRA) • Sodium-glucose cotransporter-2 inhibitor (SGLT2i) • One of the following: <ul style="list-style-type: none"> ○ ACEi ○ ARB ○ ARNi 	<ul style="list-style-type: none"> • Greater than 1 month • Greater than 1 month • Greater than 1 month • Greater than 1 month • Greater than 1 month
Greater than or equal to 50%	<ul style="list-style-type: none"> • Diuretic • Mineralocorticoid receptor agonist (MRA) • Sodium-glucose cotransporter-2 inhibitor (SGLT2i) • One of the following: <ul style="list-style-type: none"> ○ ACEi ○ ARB ○ ARNi 	<ul style="list-style-type: none"> • Greater than 1 month • Greater than 1 month • Greater than 1 month • Greater than 1 month

Change Summary

- 01/01/2024 New Policy.

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