Transcatheter Procedures for Heart Valve Conditions

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➲ Instructions for Use

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Community Plan Policy

- Transcatheter Procedures for Heart Valve Conditions

Medicare Advantage Policy

- Cardiovascular Diagnostic and Therapeutic Procedures

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

➲ See Benefit Considerations

Aortic

Transcatheter aortic heart valve replacement is proven and medically necessary when performed according to U.S. Food and Drug Administration (FDA)–labeled indications, contraindications, warnings, and precautions and all the following criteria are met:

- Diagnosis of severe calcific native aortic valve stenosis, as indicated by **one** of the following:
  - Mean aortic valve gradient of ≥ 40 mm Hg; or
  - Peak aortic jet velocity of ≥ 4.0 m/s; or
  - Aortic valve area of ≤ 1.0 cm^2
- Individual is symptomatic [New York Heart Association (NYHA) class II or greater] and symptoms are due to aortic valve stenosis
- An interventional cardiologist and an experienced cardiothoracic surgeon have determined that the procedure is appropriate
- Individual has engaged in a Shared Decision-Making conversation with an interventional cardiologist and an experienced cardiothoracic surgeon
- Procedure is performed in a center that meets **all** the following criteria:
  - On-site heart valve surgery and interventional cardiology programs; and
  - Postprocedure intensive care unit, with personnel experienced in managing individuals who have undergone open heart valve procedures; and

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- Volume requirements consistent with the Centers for Medicare and Medicaid Services; for additional information, refer to the corresponding CMS National Coverage Determination and the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry

Transcatheter valve-in-valve replacement within a failed bioprosthetic aortic valve is proven and medically necessary for individuals at high or prohibitive surgical risk [Predicted Risk of Mortality (PROM) score of ≥ 8%] when performed according to FDA-labeled indications, contraindications, warnings, and precautions.

Note: Requests for transcatheter aortic heart valve replacement for low-flow/low-gradient aortic stenosis in individuals who do not meet the peak velocity, mean gradient, and valve area criteria listed above will be considered on a case-by-case basis. These requests will be evaluated using recommendations from the American College of Cardiology/American Heart Association Guideline for the Management of Patients With Valvular Heart Disease (Otto et al., 2021) when all the clinical evaluation has been facilitated by a transcatheter aortic heart valve replacement expert and after appropriate additional testing has been conducted.

Mitral

Transcatheter edge-to-edge repair of the mitral heart valve is proven and medically necessary when used according to FDA-labeled indications, contraindications, warnings, and precautions in individuals with one of the following clinical indications for intervention:

- Primary (degenerative) mitral regurgitation (MR) when **all** the following criteria are met:
  - Moderate to severe or severe MR (grade ≥ 3); and
  - Symptomatic NYHA class III or IV; and
  - Prohibitive surgical risk, as defined by **one** of the following:
    - PROM score of ≥ 8% for individuals deemed likely to undergo mitral valve replacement; or
    - PROM score of ≥ 6% for individuals deemed likely to undergo mitral valve repair; or
    - Predicted risk of death or major morbidity at 1 year of over 50%

    and
  - Care directed by a multidisciplinary heart team, which includes a heart failure specialist, interventional cardiologist, and cardiothoracic surgeon experienced in the evaluation and treatment of heart failure and mitral valve disease
- Secondary (functional) MR when **all** the following criteria are met:
  - Moderate to severe or severe MR (grade ≥ 3) with left ventricular ejection fraction ≥ 20 and ≤ 50; and
  - Symptomatic NYHA class II to IV (ambulatory); and
  - Optimal evidence-based management, which includes pharmacological therapy plus cardiac resynchronization therapy, as indicated; and
  - High surgical risk (PROM score of ≥ 8%); and
  - Care directed by a multidisciplinary heart team, which includes a heart failure specialist, interventional cardiologist, and cardiothoracic surgeon experienced in the evaluation and treatment of heart failure and mitral valve disease

Transcatheter mitral heart valve repair or reconstruction (e.g., annuloplasty), except where noted above, is unproven and not medically necessary due to insufficient evidence of efficacy.

Transcatheter mitral heart valve replacement is unproven and not medically necessary due to insufficient evidence of efficacy.

Note: Requests for transcatheter valve-in-valve replacement within a failed bioprosthetic mitral valve will be considered on a case-by-case basis.

Pulmonary

Transcatheter pulmonary heart valve replacement (including valve-in-valve) and related devices (e.g., Alterra) are proven and medically necessary when used according to FDA-labeled indications, contraindications, warnings, and precautions in individuals with right ventricular outflow tract dysfunction, with one of the following clinical indications for intervention:

- Moderate or greater pulmonary regurgitation; and/or
- Pulmonary stenosis with a mean right ventricular outflow tract gradient of ≥ 35 mm Hg

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Tricuspid

Transcatheter edge-to-edge repair of the tricuspid heart valve is proven and medically necessary when used according to FDA-labeled indications, contraindications, warnings, and precautions and the individual meets all the following criteria:

- Symptomatic Severe Tricuspid Regurgitation
- Receiving stable (≥ 30 days) guideline-directed medical therapy for heart failure
- Symptomatic NYHA class II or greater
- Pulmonary artery systolic pressure of < 70 mm Hg
- Intermediate or greater risk for surgery, as determined by the local heart team, which includes board-certified specialists in cardiac surgery, interventional cardiology, echocardiology, and heart failure

Transcatheter tricuspid heart valve repair or reconstruction (e.g., annuloplasty), except where noted above, is unproven and not medically necessary due to insufficient evidence of efficacy.

Transcatheter tricuspid heart valve replacement (including valve-in-valve) is unproven and not medically necessary due to insufficient evidence of efficacy.

Other Devices and Procedures

The following transcatheter heart valve devices and/or procedures are unproven and not medically necessary due to insufficient evidence of efficacy:

- Cerebral protection devices (e.g., SENTINEL™)
- Transcatheter superior and inferior vena cava prosthetic valve implantation

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

CMS Volume Requirements for Transcatheter Aortic Heart Valve Replacement:
To begin a transcatheter aortic heart valve replacement (TAVR) program for **hospitals without TAVR experience**, the hospital program must have the following:

- ≥ 50 open heart surgeries in the previous year prior to TAVR program initiation; and
- ≥ 20 aortic valve–related procedures in the 2 years prior to TAVR program initiation; and
- At least two physicians with cardiac surgery privileges; and
- At least one physician with interventional cardiology privileges; and
- ≥ 300 percutaneous coronary interventions per year

To begin a TAVR program for **heart teams without TAVR experience**, the heart team must include:

- Cardiovascular surgeon with ≥ 100 career open heart surgeries, of which ≥ 25 were aortic valve related; and
- Interventional cardiologist with:
  - Professional experience of ≥ 100 career structural heart disease procedures or ≥ 30 left-sided structural procedures per year; and
  - Device-specific training, as required by the manufacturer

For hospital programs with TAVR experience, the hospital program must maintain the following:

- ≥ 50 aortic valve replacements (TAVR or surgical aortic valve replacement) per year, including ≥ 20 TAVR procedures in the prior year; or
- ≥ 100 aortic valve replacements (TAVR or surgical aortic valve replacement) every 2 years, including ≥ 40 TAVR procedures in the prior 2 years; and
- At least two physicians with cardiac surgery privileges; and
- At least one physician with interventional cardiology privileges; and
- ≥ 300 percutaneous coronary interventions per year

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CMS National Coverage Determination (NCD) for TAVR.

New York Heart Association Heart Failure Classification (NYHA, 1994):
- I: No limitation of physical activity: ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain
- II: Slight limitation of physical activity; comfortable at rest: ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain
- III: Marked limitation of physical activity; comfortable at rest: less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain
- IV: Unable to carry on any physical activity without discomfort; symptoms of heart failure at rest: if any physical activity is undertaken, discomfort increases

Predicted Risk of Mortality: The Society of Thoracic Surgeons Predicted Risk of Mortality score is a predictor of 30-day mortality after cardiac procedures (Otto et al., 2021).

Shared Decision-Making: Shared Decision-Making is a process by which physicians and individuals work together to choose the treatment option that best reflects the clinical evidence and the individual's values and preferences (Coylewright et al., 2020).

Symptomatic Severe Tricuspid Regurgitation: Individuals with Symptomatic Severe Tricuspid Regurgitation (stage D) often have symptoms of fatigue, abdominal bloating, and peripheral edema. Criteria for stage D tricuspid regurgitation, as defined in joint guidelines from the American College of Cardiology and the American Heart Association, are noted below (Otto et al., 2021):
- Valve hemodynamics, including any of the following:
  - Central jet in the right atrium of ≥ 50%
  - Vena contracta width of ≥ 0.7 cm
  - Effective regurgitant orifice of ≥ 0.40 cm^2
  - Regurgitant volume of ≥ 45 mL
  - Dense continuous wave signal with triangular shape
  - Hepatic vein systolic flow reversal
- Right atrial and right ventricle dilation and elevated c-V wave
- Symptoms, including elevated venous pressure, dyspnea on exertion, fatigue, ascites, and edema

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

CPT Code	Description
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 (e.g., 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
0570T	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to code for primary procedure)

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CPT Code	Description
0646T	Transcatheter tricuspid valve implantation (TTVI)/replacement 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/or inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach
0806T	Transcatheter superior and/or inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach
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 (e.g., median sternotomy, mediastinotomy)
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., 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 (e.g., 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 (e.g., aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)
33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (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

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Description of Services

The four natural valves of the heart (aortic, pulmonary, mitral, and tricuspid) act as one-way valves to direct the flow of blood to the lungs and aorta. Heart valves with congenital defects or those that become diseased over time can result in either a leaky valve (regurgitation/incompetence/insufficiency) or a valve that does not open wide enough (stenosis).

Conventional treatment of structural heart valve disorders is surgical repair or replacement requiring open heart surgery using cardiopulmonary bypass. Transcatheter (percutaneous or catheter based) valve procedures use catheter technology to access the heart and manage heart valve disorders, without the need for open heart surgery and cardiopulmonary bypass. During the procedure, a compressed artificial heart valve or other device is attached to a wire frame and guided by a catheter to the heart. Once in position, the wire frame expands, allowing the device to fully open.

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Aortic Valve

The aortic valve directs blood flow from the left ventricle into the aorta. Flaps of tissue (cusps) on the valve open and close with each heartbeat and make sure that blood flows in the right direction. The aortic valve typically has three cusps. When only two cusps are present, the valve is referred to as bicuspid. Aortic valve stenosis, a common valvular disorder in older adults, is a narrowing or obstruction of the aortic valve that prevents the valve leaflets from opening normally. When the aortic valve does not open properly, the left ventricle has to work harder to pump enough blood through the narrowed opening to the rest of the body. Reduced blood flow can cause chest pain, shortness of breath, excess fluid retention, and other symptoms. Left untreated, severe aortic stenosis can lead to left ventricular hypertrophy and heart failure. The various stages of valvular aortic stenosis are addressed by Otto et al. (2021).

Transcatheter aortic valve replacement is a minimally invasive alternative to surgical valve replacement. Transcatheter aortic valves feature a metal, stent-like scaffold that contains a bioprosthetic valve. Depending on individual anatomy, possible access routes to the aortic valve include transfemoral (percutaneous or endovascular approach), transapical, subaxillary, and transaortic approaches. The procedure is done without removing the diseased native valve.

Mitral Valve

The mitral valve directs blood flow from the left atrium into the left ventricle. Mitral regurgitation (MR) occurs when the mitral valve does not close properly, allowing blood to flow backward from the ventricle to the atrium. MR is sometimes referred to as mitral incompetence or mitral insufficiency. Primary, or degenerative, MR is usually caused by damage to the valve components (e.g., leaflets, attached chords, adjacent supporting tissue). Secondary, or functional, MR is typically due to changes in the shape of the left ventricle that pull the leaflets apart, preventing complete closure. Left untreated, moderate to severe MR can lead to congestive heart failure. MR that cannot be managed conservatively may require surgical valve repair or replacement.

Transcatheter mitral valve replacement is a minimally invasive alternative to surgical valve replacement. Transcatheter mitral valves feature a metal, stent-like scaffold that contains a bioprosthetic valve. Depending on individual anatomy, possible access routes to the mitral valve include transfemoral (percutaneous or endovascular approach), transseptal, transapical, and transthoracic approaches. The procedure is done without removing the diseased native valve.

Transcatheter leaflet repair, percutaneous annuloplasty, artificial chordae tendineae, and annulus reconstruction are minimally invasive approaches to repair damaged mitral valves. Transcatheter leaflet repair keeps the two valve leaflets more closely fitted together, thereby reducing regurgitation. The procedure, based on the surgical edge-to-edge technique, creates a double orifice using a clip instead of a suture to secure the leaflets. The device consists of a steerable guide catheter, including a clip delivery device and a two-armed, flexible metal clip covered in polyester fabric. A transseptal puncture is required to implant the device in the left side of the heart. Access to the mitral valve is achieved via the femoral vein.

Percutaneous transcatheter annuloplasty attempts to replicate the functional effects of open surgical annuloplasty by reshaping the mitral annulus from within the coronary sinus. The coronary sinus is a large vein located along the heart's outer wall, between the left atrium and left ventricle, adjacent to the mitral valve.

Various artificial chordae tendineae and annulus reconstruction devices are in development.

Pulmonary Valve

The pulmonary valve directs blood flow from the right ventricle into the lungs. Disorders of the pulmonary valve are often due to congenital heart disease such as tetralogy of Fallot, pulmonary atresia, transposition of the great arteries, and double-outlet right ventricle. Surgery to replace the valve with a bioprosthesis may also include a conduit (graft) to open the right ventricular outflow tract. Over time, the valved conduit may fail, leading to pulmonary valve stenosis (narrowing), pulmonary valve regurgitation (incompetence/insufficiency), or a combination of the two. Because individuals undergoing this procedure are typically children or adolescents, the bioprosthetic valve will require revisions as the individual grows.

Transcatheter pulmonary valve implantation, a minimally invasive alternative to surgical valve repair or replacement, is designed to reduce the number of surgeries needed throughout an individual’s lifetime. Transcatheter pulmonary valves feature a metal, stent-like scaffold that contains a bioprosthetic valve. Access to the pulmonary valve is most often achieved via the femoral vein. Depending on the device, the replacement valve can be positioned in a native or surgically repaired right ventricular outflow tract.

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Tricuspid Valve

The tricuspid valve directs blood flow from the right atrium into the right ventricle. Tricuspid regurgitation (TR) occurs when the tricuspid valve does not close properly, allowing blood to flow backward from the ventricle to the atrium. TR is sometimes referred to as tricuspid incompetence or tricuspid insufficiency. The standard for treating tricuspid valve disease is surgical annuloplasty. Transcatheter edge-to-edge leaflet repair is a minimally invasive approach to repair damaged tricuspid valves. Transcatheter leaflet repair keeps the valve leaflets more closely fitted together, thereby reducing regurgitation. The procedure is based on the surgical edge-to-edge technique but uses a clip instead of a suture to secure the leaflets. Other devices/procedures for transcatheter tricuspid valve repair, reconstruction, and replacement are in development.

Caval valve implantation is an emerging technology for treating TR. In this procedure, a valve is placed in the inferior vena cava alone or in combination with a second valve in the superior vena cava to redirect regurgitant flow away from the tricuspid valve.

Valve-in-Valve Procedures

Transcatheter heart valve implantation within an existing bioprosthetic valve, also called a valve-in-valve procedure, replaces a previously implanted bioprosthetic heart valve that has failed or degenerated over time.

Cerebral Protection

Transcatheter cerebral embolic protection devices are designed to filter and collect debris released during transcatheter aortic valve replacement procedures. These devices are intended to reduce the risk of stroke and decline in cognitive function following surgery.

Benefit Considerations

Some benefit documents allow coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for these services.

Clinical Evidence

Aortic Valve

Ueyama et al. (2021) assessed the impact of aortic valve replacement on survival in individuals with each subclass of low-gradient (LG) aortic stenosis and compared outcomes following surgical aortic valve replacement (SAVR) and transcatheter aortic heart valve replacement (TAVR). LG severe aortic stenosis includes a variety of pathophysiology, including classical low-flow (LF) LG; paradoxical LF-LG; and normal-flow LG aortic stenosis. The authors performed a pairwise meta-analysis comparing aortic valve replacement vs conservative management and a network meta-analysis comparing SAVR vs TAVR vs conservative management. Overall, 32 studies, with a total of 6,515 individuals and a median follow-up of 24.2 months, were included. The analysis showed that both SAVR and TAVR were associated with significant decreases in all-cause mortality compared with conservative management in all subclasses of LF-LG aortic stenosis. No significant difference was observed between SAVR and TAVR; however, all these comparisons were indirect, limiting the confidence in the findings.

In a meta-analysis of seven landmark randomized controlled trials (RCTs), Siontis et al. (2019) compared the safety and efficacy of TAVR vs those of SAVR across the entire spectrum of surgical risk individuals. Across the seven trials, 8,020 individuals with severe symptomatic aortic stenosis were enrolled: TAVR (n = 4,014) and SAVR (n = 4,006). The primary end point was all-cause mortality up to 2 years. The authors reported a lower risk of all-cause mortality (12% relative risk reduction) and stroke (19% relative risk reduction) regardless of underlying surgical risk, up to 2 years of follow-up. TAVR was linked to a higher risk of permanent pacemaker implantation and major vascular complications but a reduced risk of major bleeding, new-onset atrial fibrillation, and acute kidney injury. The following RCTs, which were previously summarized in this policy, are included in this meta-analysis:

- High risk:
  - PARTNER cohort A (Smith et al., 2011; Kodali et al., 2012; Mack et al., 2015)
  - U.S. CoreValve (Adams et al., 2014; Reardon et al., 2015; Deeb et al., 2016; Gleason et al., 2018)
- Intermediate risk:
  - PARTNER II cohort A (Leon et al., 2016); (Makkar et al., 2020, reported additional follow-up results after this meta-analysis was published)
  - SURTAVI (Reardon et al., 2017)

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- Low risk:
  - Evolut Low Risk (Popma et al., 2019); (Forrest et al., 2022, and Forrest et al., 2023, reported additional follow-up results after this meta-analysis was published)
  - PARTNER 3 (Mack et al., 2019); (Leon et al., 2025, Leon et al., 2021, and Mack et al., 2023, reported additional follow-up results after this meta-analysis was published)
- All risk: NOTION (Thyregod et al., 2015; Søndergaard et al., 2016; Thyregod et al., 2019); (Søndergaard et al., 2019, and Jørgensen et al., 2021, reported additional follow-up results after this meta-analysis was published)

Several systematic reviews and/or meta-analyses comparing TAVR and SAVR in intermediate-risk individuals with severe aortic stenosis reported similar clinical efficacy in the two groups (Lazkani et al., 2019; Singh et al., 2018; Sardar et al., 2017).

Witberg et al. (2018) conducted a systematic review and meta-analysis of RCTs and observational studies of TAVR vs SAVR in individuals at low surgical risk. The primary outcome was all-cause mortality. The secondary outcomes included stroke, myocardial infarction, bleeding, and various procedural complications. Six studies, which included 3,484 individuals, were included. The short-term mortality was similar with either TAVR or SAVR; however, TAVR was associated with an increased risk for intermediate-term mortality. TAVR was associated with a reduced risk of bleeding and renal failure but an increased risk of vascular complications and pacemaker implantation. The authors noted that until more data are available, SAVR should remain the treatment of choice for low-risk individuals.

Using registry data, Ribeiro et al. (2018) evaluated clinical outcomes and changes in left ventricular ejection fraction (LVEF) following TAVR in participants with classic LF-LG aortic stenosis. A total of 287 participants were included in the analysis. Clinical follow-up was obtained at 1 and 12 months and yearly thereafter. TAVR was associated with good periprocedural outcomes among participants with LF-LG aortic stenosis and reduced LVEF. However, approximately one-third of participants with LF-LG aortic stenosis who underwent TAVR had died by the 2-year follow-up, with pulmonary disease, anemia, and residual paravalvular leak associated with worse outcomes. LVEF improved following TAVR, but dobutamine stress echocardiography did not predict clinical outcomes or LVEF changes over time. Data from this multicenter registry support an expanding role for TAVR among individuals with LF-LG severe aortic stenosis and reduced LVEF. This study is registered under clinical trial number NCT01835028 on the ClinicalTrials.gov website.

Arora et al. (2017) performed a systematic review and meta-analysis comparing the 30-day risk of clinical outcomes between TAVR and SAVR in the lower surgical risk population. Four studies were included. Compared with SAVR, TAVR had a significantly lower risk of bleeding complications and acute kidney injury. However, a higher risk of vascular complications, moderate or severe paravalvular leak, and permanent pacemaker implantations was noted with TAVR. The authors noted that additional high-quality studies are needed to further explore the feasibility and long-term durability of TAVR in low-risk individuals.

In a large, multicenter registry of inoperable, high-risk, and intermediate-risk participants, Kodali et al. (2016) reported early outcomes following TAVR with the next-generation SAPIEN 3 valve. Participants with severe symptomatic aortic stenosis (583 high surgical risk or inoperable and 1,078 intermediate risk) were enrolled. All participants received the SAPIEN 3 valve via transfemoral (n = 1,443) and transapical or transaortic (n = 218) access routes. The rate of 30-day all-cause mortality was 2.2% in high-risk/inoperable participants [mean Society of Thoracic Surgeons (STS) score, 8.7%] and 1.1% in intermediate-risk participants (mean STS score, 5.3%). In high-risk/inoperable participants, the 30-day rate of major/disabling stroke was 0.9%, of major bleeding was 14.0%, of major vascular complications was 5.1%, and of a requirement for a permanent pacemaker was 13.3%. In intermediate-risk participants, the 30-day rate of major/disabling stroke was 1.0%, of major bleeding was 10.6%, of major vascular complications was 6.1%, and of a requirement for a permanent pacemaker was 10.1%. Overall, paravalvular regurgitation at 30 days was none/trace in 55.9% of participants, mild in 40.7%, moderate in 3.4%, and severe in 0.0%. The mean gradients among participants with paired baseline and 30-day or discharge echocardiograms decreased from 45.8 mm Hg at baseline to 11.4 mm Hg at 30 days, while the aortic valve area increased from 0.69 to 1.67 cm^2.

In cohort B of the PARTNER II multicenter RCT, Webb et al. (2015) evaluated the safety and effectiveness of the SAPIEN XT vs those of SAPIEN valve systems in participants with symptomatic severe aortic stenosis who were not candidates for surgery. The primary end point was a composite of all-cause mortality, major stroke, and rehospitalization. The secondary end points included cardiovascular death, New York Heart Association (NYHA) functional class, myocardial infarction, stroke, acute kidney injury, vascular complications, bleeding, 6-minute walk distance, and valve performance. A total of 560 participants were randomized to receive the SAPIEN (n = 276) or SAPIEN XT (n = 284) systems. At 1 year of follow-up, there was no difference in all-cause mortality, major stroke, or rehospitalization between SAPIEN and SAPIEN XT, but the SAPIEN XT was associated with less vascular complications and bleeding requiring transfusion. No differences in the secondary end points were found. The authors concluded that in inoperable participants with severe

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symptomatic aortic stenosis, the lower-profile SAPIEN XT system provided an incremental improvement from the prior generation of TAVR technology.

In a prospective, multicenter, nonrandomized study, Popma et al. (2014) evaluated the safety and efficacy of the CoreValve transcatheter heart valve for the treatment of severe aortic stenosis in participants at an extreme risk for surgery. Overall, 41 sites recruited 506 participants, of whom 489 underwent treatment with the CoreValve device. The rate of all-cause mortality or major stroke at 12 months was 26.0% vs 43.0%. Individual 30-day and 12-month events included all-cause mortality (8.4% and 24.3%, respectively) and major stroke (2.3% and 4.3%, respectively). Procedural events at 30 days included life-threatening/disabling bleeding (12.7%), major vascular complications (8.2%), and the need for permanent pacemaker placement (21.6%). The frequency of moderate or severe paravalvular aortic regurgitation was lower 12 months after self-expanding TAVR (4.2%) than at discharge (9.7%).

A meta-analysis of the adverse effects associated with TAVR included over 16,000 individuals in 49 studies. Khatri et al. (2013) found that the need for a permanent pacemaker was the most common adverse outcome (13.1%) and was five times more common with the CoreValve than the Edwards SAPIEN valve. Vascular complications were also common (10.4%) and were highest with the transarterial implantation of the Edwards SAPIEN valve (22.3%). Acute renal failure was the third most common complication, occurring in 4.9% of individuals. Overall, 30-day and 1-year survival after TAVR were 91.9% and 79.2%, respectively.

In cohort B of the PARTNER multicenter, open-label RCT, Leon et al. (2010) evaluated TAVR in participants with severe aortic stenosis who were not candidates for surgery. A total of 358 participants were randomized to standard therapy (including balloon aortic valvuloplasty; n = 179) or transfemoral transcatheter implantation of a balloon-expandable bovine pericardial valve (n = 179). At 1 year, the rate of death from any cause was 30.7% with TAVR compared with 50.7% with standard therapy [hazard ratio with transcatheter aortic valve implantation (TAVI), 0.55; 95% CI, 0.40-0.74; $p < 0.001$]. The rate of the composite end point of death from any cause or repeat hospitalization was 42.5% with TAVR compared with 71.6% with standard therapy. Among survivors at 1 year, the rate of cardiac symptoms (NYHA class III or IV) was lower among participants who had undergone TAVR than among those who had received standard therapy (25.2% vs 58.0%). At 30 days, TAVR compared with standard therapy was associated with a higher incidence of major strokes (5.0% vs 1.1%) and major vascular complications (16.2% vs 1.1%). In the year after TAVR, there was no deterioration in the functioning of the bioprosthetic valve. The authors concluded that in participants with severe aortic stenosis who were not suitable candidates for surgery, TAVR compared with standard therapy significantly reduced the rates of death from any cause, the composite end point of death from any cause or repeat hospitalization, and cardiac symptoms, despite the higher incidence of major strokes and major vascular events. Follow-up at 2 years showed that TAVR reduced the rates of death and hospitalization, with a decrease in symptoms and an improvement in valve hemodynamics (Makkar et al., 2012). Daubert et al. (2016) reported that valve performance and cardiac hemodynamics were stable 5 years after implantation of both the SAPIEN TAVR and SAVR valves.

Published results from several national TAVR registries indicate that the use of the SAPIEN and CoreValve devices was fairly equal and the transfemoral approach was used approximately three times as often as the transapical approach. Conversion to surgical valve replacement occurred in 0.4% to 4% of procedures. Procedural success was very high and ranged from 91% to 99%. Procedural mortality was low and ranged from 0.4% to 3%. Survival at 30 days ranged from 87% to 95% and at 1 year from 63% to 100%, depending on the device and approach used (Walther et al., 2015; Gilard et al., 2012; Ussia et al., 2012; Bosmans et al., 2011; Thomas et al., 2011; Eltchaninoff et al., 2011; Zahn et al., 2011; Moat et al., 2011; Rodés-Cabau et al., 2010).

Bicuspid Aortic Valve

Several systematic reviews and meta-analyses have been conducted to evaluate outcomes of TAVR in individuals with bicuspid aortic valve (BAV). While RCTs are lacking, evidence from observational or registry studies shows comparable outcomes of TAVR in BAV and tricuspid aortic valve stenosis. Further trials are needed to define which anatomical features of BAV are most suitable for TAVR and which implantation techniques offer optimal outcomes. While surgery remains the first-line treatment for the majority of individuals with BAV, TAVR, using the latest devices, may be a safe and reasonable alternative in individuals with an increased risk of surgery (Liu et al., 2026; Kang et al., 2024; Saeed Al-Asad et al., 2023; Chan et al., 2022; Chen et al., 2022; Zhang et al., 2022; Du et al., 2021; Quintana et al., 2020; Quintana et al., 2019; Kanjanahattakij et al., 2018).

Mitral Valve

Transcatheter Mitral Valve Replacement

There is insufficient quality evidence in the clinical literature demonstrating the long-term efficacy of catheter-delivered mitral valve prostheses for treating mitral disease. Most of the existing evidence is limited by a noncomparative design,

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high attrition rate, or short follow-up. Two observational comparative studies suggest inferior results for transcatheter mitral valve replacement (TMVR) compared with edge-to-edge repair and no benefit for mortality compared with standard of care.

An ECRI report concluded that although the available evidence from one small, single-center, retrospective comparison study and additional single-arm studies suggests that the Tendyne transcatheter mitral valve system may provide clinical benefits in individuals with mitral valve dysfunction, the studies provide very low-quality evidence that does not enable conclusions. Noted limitations include the retrospective design; single-center focus group; small sample size; and lack of control groups, randomization, and blinding (ECRI, 2025a).

Zorman et al. (2025) conducted a systematic review and meta-analysis evaluating early and mid-term outcomes of TMVR with contemporary dedicated devices in this population. Thirteen studies (n = 914) were included in the analysis: eight prospective studies, four retrospective studies, and one RCT. The mean age was 75.4 years, and 69.8% had functional or mixed mitral regurgitation (MR). Technical success was 96.3%. Residual MR was mild or less in 99% of individuals at 30 days and 98% at 1 year. All-cause mortality was 11.0% at 30 days and 26.4% at 1 year. Over a mean follow-up of 12.1 months, rates of heart failure hospitalizations, cerebrovascular events, and valve reinterventions were 26.2, 5.6, and 6.0 events per 100 patient-years, respectively. Compared with transapical, transseptal access was associated with lower morbidity and mortality. Mid-term rates of heart failure readmissions, major bleeding, and valve reinterventions were comparable between access routes. Well-designed, comparative studies, with larger cohorts, are needed to further understand the safety and clinical impact of TMVR.

The ENCIRCLE trial is an ongoing prospective, single-arm, multicenter study to assess the safety and effectiveness of the SAPIEN M3 TMVR system in treating adults with symptomatic, moderate to severe or severe MR who are not candidates for surgery or transcatheter edge-to-edge repair (TEER). The study comprises a main cohort of up to 300 participants, mitral annular calcification (MAC) registry of up to 100 participants, and failed TEER registry of up to 100 participants. Guerrero et al. (2025) reported the 1-year results in the main cohort (n = 299), with procedures performed at 56 centers in six countries. Follow-up data were available for 283 participants (95%) at 30 days and 243 (81%) at 1 year. The primary end point was a nonhierarchical composite of all-cause mortality and heart failure rehospitalization. At 1 year, percutaneous TMVR with the SAPIEN M3 system was associated with a composite rate of death or heart failure rehospitalization of 25.2%, which was significantly lower than the prespecified medical therapy–based performance goal of 45% (derived from the outcomes of two relevant RCTs of TEER). There were no intraprocedural deaths, no instances of left ventricular outflow tract obstruction causing hemodynamic compromise, and no conversions to surgery. The authors noted that while the SAPIEN M3 system represents a promising advancement in the landscape of TMVR, several technical, anatomical, and clinical limitations remain. The lack of randomization and a control group limits the conclusion that can be reached from this study. Long-term follow-up studies are essential for understanding the full impact of this device. This study is registered under clinical trial number NCT04153292 on the ClinicalTrials.gov website and is ongoing.

The multicenter CHOICE-MI registry performed a retrospective study of outcomes following TMVR for MR. The primary end points included mortality, heart failure hospitalization rates, procedural complications, residual MR, and functional status. Ludwig et al. (2023a) reported 2-year results in all 400 patients with symptomatic MR treated with TMVR. Technical success was achieved in 95.2% of patients. MR reduction to ≤ 1+ was observed in 95.2% at discharge, with durable results at 1 and 2 years. NYHA functional class had improved significantly at 1 and 2 years. All-cause mortality was 9.2% at 30 days, 27.9% at 1 year, and 38.1% at 2 years after TMVR. The authors noted that optimized selection of individuals and improved access site management are mandatory to improve outcomes. The findings are limited by the lack of a comparison group and large loss to follow-up.

Using propensity-matched scoring, Ludwig et al. (2023b) compared outcomes after TMVR and TEER for the treatment of secondary MR. Overall, 235 TMVR individuals were compared with 411 TEER individuals. All-cause mortality was 6.8% after TMVR and 3.8% after TEER at 30 days and 25.8% after TMVR and 18.9% after TEER at 1 year. While postprocedural mortality tended to be higher after TMVR, no significant differences in mortality were found beyond 30 days.

Ludwig et al. (2023c) compared outcomes after TMVR and guideline-directed medical therapy (GDMT) for the treatment of secondary MR. After propensity score matching, 97 patient pairs undergoing TMVR vs GDMT were compared. At 1 and 2 years, residual MR was ≤ 1+ in all patients in the TMVR group compared with 6.9% and 7.7%, respectively, in those receiving GDMT alone. Over a 2-year follow-up period, TMVR in patients with secondary MR was associated with a significant reduction in MR, symptomatic improvement, less frequent hospitalizations for heart failure, and similar mortality compared with GDMT. Inherent limitations of registry data include the lack of randomization, incomplete follow-up, and missing or incomplete data. This study is registered under clinical trial number NCT04688190 on the ClinicalTrials.gov website.

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A Hayes report concluded that there is insufficient evidence to draw conclusions regarding the effectiveness and safety of TMVR for treating individuals with MR. Substantial uncertainty remains due to a small body of evidence and lack of studies comparing TMVR with clinical alternatives (Hayes, 2021; updated 2024).

In a multicenter global registry, Guerrero et al. (2016) evaluated the outcomes of TMVR in individuals with severe MAC. Overall, 64 individuals in 32 centers underwent TMVR with compassionate use of balloon-expandable valves. The mean age was 73 ±13 years, 66% were female, and the mean STS score was 14.4% ±9.5%. The mean mitral gradient was 11.45 ±4.4 mm Hg, and the mean mitral area was 1.18 ±0.5 cm^2. SAPIEN valves were used in 7.8%, SAPIEN XT in 59.4%, SAPIEN 3 in 28.1%, and Inovare in 4.7%. Access was transatrial in 15.6%, transapical in 43.8%, and transseptal in 40.6%. Technical success was achieved in 46 individuals (72%), primarily limited by the need for a second valve in 11 (17.2%). Six (9.3%) had left ventricular outflow tract obstruction with hemodynamic compromise. The mean mitral gradient post procedure was 4 ±2.2 mm Hg, and paravalvular regurgitation was mild or absent in all. The 30-day all-cause mortality was 29.7%. In total, 84% of the survivors with follow-up data available were in NYHA functional class I or II at 30 days (n = 25). The authors concluded that TMVR with balloon-expandable valves in individuals with severe MAC is feasible but may be associated with significant adverse events. This study is limited by a retrospective design, lack of a comparison group, short-term follow-up, and small sample size.

Puri et al. (2016) conducted a systematic review of TMVR for inoperable, severely calcified native mitral valve disease. Nine publications describing 11 individuals (82% severe mitral stenosis; 18% severe MR) were identified. The procedural success rate was 73%, without residual paravalvular leaks. Successful immediate redeployment of a second valve was needed in two instances following significant paravalvular leak detection. All individuals survived the procedure, with two non–cardiac-related deaths reported on days 10 and 41 post TMVR. The mid-term follow-up, reported in eight individuals, revealed that six individuals were alive at 3 months, with much improved functional status. Further studies, with a larger number of individuals and longer follow-up, are warranted.

Transcatheter Edge-to-Edge Mitral Valve Leaflet Repair

D'Amario et al. (2024) performed a systematic review and meta-analysis to compare percutaneous mitral valve repair approaches for treating severe MR. Outcomes of interest were divided into three categories: efficacy, safety, and procedural. The clinical efficacy end points were all-cause mortality, major adverse cardiovascular events, and a postprocedural NYHA functional class of < 3. The echocardiographic efficacy end point was a postintervention residual MR of less than moderate. Safety and procedural end points were also assessed. Eight of the 11 observational studies compared the MitraClip with PASCAL (n = 1,662). The authors found that PASCAL was as safe and clinically effective as the MitraClip in treating individuals with MR.

An ECRI report concluded that evidence from one RCT and four retrospective studies showed that PASCAL worked as well as the MitraClip, which ECRI has independently assessed and found to be safe and effective for correcting MR and improving physical function and quality of life through 1 year of follow-up in individuals with severe MR who are at a high surgical risk. Evidence from a noncomparative meta-analysis of five studies and two additional studies (a case series and patient registry) also supported PASCAL's safety and effectiveness (ECRI, 2022a).

In a registry-based cohort study in 19,088 individuals with isolated, moderate to severe or severe, degenerative MR, Makkar et al. (2023) evaluated the outcomes of transcatheter edge-to-edge mitral valve repair using the MitraClip device. The primary end point was defined as moderate or less residual MR and a mean mitral gradient of less than 10 mm Hg. The authors reported that the procedure was safe and resulted in successful repair in 88.9% of individuals. The lowest mortality was observed in individuals with mild or less residual MR and low mitral gradients. Compared with unsuccessful repair, successful valve repair was associated with lower mortality and heart failure hospitalization over 1 year. The findings are limited by the observational nature of the study.

Lim et al. (2022) conducted a prospective, multicenter, randomized controlled pivotal trial (CLASP IID) to evaluate the safety and effectiveness of the PASCAL system compared with those of the MitraClip system in participants with degenerative MR. Participants with 3+ or 4+ degenerative MR at prohibitive surgical risk were assessed and randomized 2:1 (PASCAL:MitraClip). The primary safety end point was the composite major adverse event rate at 30 days. The primary effectiveness end point was the proportion of participants with MR of ≤ 2+ at 6 months. A prespecified interim analysis in 180 participants demonstrated noninferiority of the PASCAL system vs the MitraClip system for the primary safety and effectiveness end points of major adverse event rate (3.4% vs 4.8%) and MR of ≤ 2+ (96.5% vs 96.8%), respectively. Functional and quality-of-life outcomes significantly improved in both groups. The proportion of participants with MR of ≤ 1+ was durable in the PASCAL group from discharge to 6 months. The CLASP IID trial demonstrated the safety and effectiveness of the PASCAL system and met noninferiority end points. Two-year outcomes showed favorable survival and significant and sustained MR reduction, with functional and quality-of-life improvements (Makkar et al., 2025). This study is registered under clinical trial number NCT03706833 on the ClinicalTrials.gov website.

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Marmagkiolis et al. (2019) performed a meta-analysis to evaluate the safety and efficacy of percutaneous mitral valve repair for the management of functional MR (FMR). Seven studies (two RCTs and five observational studies) comparing percutaneous mitral valve repair using the MitraClip device (n = 1,174) against conservative therapy (n = 1,015) for the management of FMR were included. The 12-month mortality rate in the MitraClip group was 18.4% compared with 25.9% in the medical therapy group. The rate of readmission at 12 months was 29.9% in the MitraClip group compared with 54.1% in the medical therapy group.

The multicenter, randomized controlled COAPT study enrolled participants with heart failure and moderate to severe or severe secondary MR who remained symptomatic despite the use of maximal doses of GDMT. Participants were randomly assigned to transcatheter mitral valve repair plus medical therapy (device group) or medical therapy alone (control group). Of the 614 participants who were enrolled in the trial, 302 were assigned to the device group and 312 to the control group. The primary effectiveness end point was all hospitalizations for heart failure within 24 months of follow-up. The primary safety end point was freedom from device-related complications at 12 months. Transcatheter mitral valve repair resulted in a lower rate of hospitalization for heart failure (hazard ratio, 0.53; 95% CI, 0.40-0.70; $p < 0.001$) and lower all-cause mortality (hazard ratio, 0.62; 95% CI, 0.46-0.82; $p < 0.001$) within 24 months of follow-up than medical therapy alone. The rate of freedom from device-related complications (96.6%) exceeded a prespecified safety threshold (Stone et al., 2018). With extended follow-up through 36 months, there was no loss of effectiveness with MitraClip treatment, and no new safety concerns emerged. Additionally, among 58 participants assigned to medical therapy alone who crossed over and were treated with the MitraClip, the subsequent composite rate of mortality or hospitalizations for heart failure was reduced compared with those who continued on medical therapy alone (Mack et al., 2021). Stone et al. (2023) reported that TEER of the mitral valve was safe, led to a lower rate of hospitalization for heart failure than medical therapy alone, and prolonged survival during 5 years of follow-up. This study is registered under clinical trial number NCT01626079 on the ClinicalTrials.gov website.

In the MITRA-FR study, participants with severe secondary MR were randomly assigned to undergo percutaneous mitral valve repair plus medical therapy (n = 152) or medical therapy alone (n = 152). Severe secondary MR was defined as an effective regurgitant orifice area of > 20 mm^2 or a regurgitant volume of > 30 mL per beat; an LVEF between 15% and 40%; and symptomatic heart failure. Among participants with severe secondary MR, the rate of death or unplanned hospitalization for heart failure at 1 year did not differ significantly between the two groups. The rate of death from any cause was 24.3% (37 of 152 participants) in the intervention group and 22.4% (34 of 152 participants) in the control group. The rate of unplanned hospitalization for heart failure was 48.7% (74 of 152 participants) in the intervention group and 47.4% (72 of 152 participants) in the control group (Obadia et al., 2018). As in the 12-month results, the addition of percutaneous mitral valve repair to medical therapy did not significantly decrease the rate of death or unplanned hospitalization for heart failure at 24 months (Iung et al., 2019). This study is registered under clinical trial number NCT01920698 on the ClinicalTrials.gov website.

Bail (2015) performed a meta-analysis of the safety and efficacy of the MitraClip device. Overall, 26 observational studies (n = 3,821) were included in the analysis. Based on the analysis, the authors reported that treatment with the MitraClip was associated with good short-term success and low mortality and that the procedure was safe and effective for individuals with limited surgical options. The results were comparable with open mitral valve repair, but individuals were markedly older and had a higher risk profile than individuals who underwent open mitral valve repair. These findings are limited by the lack of randomization of the included studies.

The EVEREST II multicenter RCT and registry evaluated the safety and efficacy of endovascular mitral valve repair using the MitraClip device compared with those of conventional mitral valve surgery in participants with moderate to severe MR. With results up to 5 years, the randomized arm found that both groups had improved left ventricular size, NYHA functional class, and quality-of-life measures compared with baseline. Although percutaneous repair was less effective at reducing MR than conventional surgery at 12 and 24 months, the procedure was associated with a lower adverse event rate and similar improvements in clinical outcomes (Feldman et al., 2011; Mauri et al., 2013; Feldman et al., 2015). The high-risk registry arm found that the MitraClip device reduced MR in a majority of participants deemed at high risk of surgery, which resulted in improvement in clinical symptoms and significant left ventricular reverse remodeling (Whitlow et al., 2012; Glower et al., 2014; Kar et al., 2019).

Maisano et al. (2013) and Reichenspurner et al. (2013) reported early outcomes from the ACCESS-EU trial. The prospective, multicenter, single-arm, postapproval study enrolled 567 participants with MR. Maisano et al. reported an implant success rate of 99.6%. Overall, 19 participants (3.4%) died within 30 days after the MitraClip procedure. Survival at 1 year was 81.8%. In total, 36 participants (6.3%) required mitral valve surgery within 12 months after the implant procedure. There was improvement in the severity of MR at 12 months compared with baseline. In a subset of 117 participants with severe degenerative MR, Reichenspurner et al. reported that the MitraClip procedure resulted in significant reductions in MR and improvements in clinical outcomes at 12 months. Limitations of this study include the lack

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of randomization, absence of a control group, and short-term follow-up. Additionally, participant selection criteria varied at participating centers.

Cohort studies have compared the MitraClip procedure in high-risk individuals with conventional surgery in individuals at normal risk. A study by Conradi et al. (2013) enrolled 171 individuals with secondary MR and found that after 6 months, the MitraClip procedure was associated with lower survival (87% vs 96% of individuals) and lower freedom from moderate or severe MR (88% vs 97% of individuals). These differences may have been due to the poorer health status of individuals who underwent the MitraClip procedure. Adjustment for these differences eliminated the statistically significant difference in survival. Similar results were obtained by Taramasso et al. (2012) in a cohort study that enrolled 143 individuals and preferentially assigned higher-risk individuals to the MitraClip procedure. At 1 year of follow-up, there were no significant differences between the treatment groups in individuals' survival, but the MitraClip group was more likely to have moderate or severe MR (21% vs 6% of individuals). Again, these differences may have been due to the poorer health status of individuals who underwent the MitraClip procedure.

The EVEREST multicenter, prospective, single-arm study evaluated the feasibility, safety, and efficacy of the MitraClip percutaneous mitral valve repair system for treating MR. Overall, 107 participants with moderate to severe (grade 3-4+) MR or compromised left ventricular function (if asymptomatic) underwent percutaneous valve repair with the MitraClip device. Ten (9%) had a major adverse event, including one nonprocedural death. Freedom from clip embolization was 100%. Partial clip detachment occurred in 10 participants (9%). Overall, 74% of participants achieved acute success, and 64% were discharged with MR of ≤ 1+. Overall, 32 participants (30%) had mitral valve surgery during the 3.2 years after clip procedures. When repair was planned, 84% (21 of 25) were successful. Thus, surgical options were preserved. Overall, 50 of 76 successfully treated participants (66%) were free from death, mitral valve surgery, or MR > 2+ at 12 months (primary efficacy end point). Kaplan-Meier freedom from death was 95.9%, 94.0%, and 90.1%, and Kaplan-Meier freedom from surgery was 88.5%, 83.2%, and 76.3% at 1, 2, and 3 years, respectively. The findings are limited by the lack of a comparison group (Feldman et al., 2009).

Percutaneous Annuloplasty

There is insufficient quality evidence in the clinical literature demonstrating the long-term efficacy of coronary sinus annuloplasty devices for treating MR. Existing studies are limited by the large loss to follow-up or lack of a relevant comparison group.

D'Amario et al. (2024) performed a systematic review and meta-analysis to compare percutaneous mitral valve repair approaches for treating severe MR. The outcomes of interest were divided into three categories: efficacy, safety, and procedural. The clinical efficacy end points were all-cause mortality, major adverse cardiovascular events, and a postprocedural NYHA functional class of < 3. The echocardiographic efficacy end point was a postintervention residual MR that was less than moderate. Safety and procedural end points were also assessed. Two of the 11 observational studies compared the MitraClip with Carillon® (n = 195), but the authors were not able to draw conclusions due to a lack of robust data.

An ECRI report concluded that Carillon is a safe procedure that may provide clinical benefits in some individuals with FMR; however, the evidence is too limited in quality to support conclusions. The studies reported moderate improvements in physical function and quality of life and modest cardiovascular risk reduction after 1 year; however, the findings are at a high risk of bias from high attrition in the RCT, a lack of randomization, and a small sample or single-center focus in other studies. How Carillon placement compares with medical therapy and other transcatheter mitral valve repair systems is unclear because relevant studies assessed too few individuals. Large, multicenter RCTs comparing Carillon with conventional mitral repair surgery (in eligible individuals), optimal medical therapy (in individuals ineligible for surgery), TEER, and other transcatheter annuloplasty devices are needed to validate the available data and determine Carillon's optimal place in MR treatment (ECRI, 2023).

Giallauria et al. (2020) performed a meta-analysis of individual participant data from the TITAN, TITAN II, and REDUCE FMR studies (n = 209). The studies compared transcatheter mitral valve repair with the Carillon device with optimal medical therapy alone in individuals with FMR. The measured outcomes included MR severity/grade, left ventricular remodeling, functional status, and heart failure–related outcomes in individuals with heart failure and reduced ejection fraction. At the 1-year follow-up, the authors reported that the Carillon device was more effective than optimal medical therapy alone for improving MR grade in individuals with FMR; however, ventricular ejection fraction improvement did not differ significantly between the two groups. NYHA functional status improved more with Carillon than with medical therapy alone. Heart failure–related hospitalizations occurred less frequently among Carillon recipients than among control group individuals. Two of the three trials were small and lacked randomization and a control; the third was randomized but had high attrition of individuals. Furthermore, Carillon was not compared with other proven transcatheter or surgical

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approaches to MR. The study by Siminiak et al. (2012), previously discussed in this policy, was included in this meta-analysis.

In the REDUCE FMR trial, Witte et al. (2019) evaluated the effects of the Carillon device on MR severity and left ventricular remodeling. In this blinded, randomized, proof-of-concept, sham-controlled trial, participants receiving optimal heart failure medical therapy were assigned to a coronary sinus–based mitral annular reduction approach for FMR or sham. The primary end point was change in mitral regurgitant volume at 12 months, measured by echocardiography. Participants (n = 120) were randomized to either the treatment (n = 87) or the sham-controlled (n = 33) arm. There were no significant differences in baseline characteristics between the groups. In the treatment group, 73 of 87 (84%) had the device implanted. The primary end point was met, with a statistically significant reduction in mitral regurgitant volume in the treatment group compared with the control group. Additionally, there was a significant reduction in left ventricular volumes in participants receiving the device vs those in the control group. This study was not powered to evaluate clinical end points. Carillon was not compared with other proven transcatheter or surgical approaches to MR. Studies are underway to assess the effect of this approach on mortality and hospitalization in individuals with FMR. This study is registered under clinical trial number NCT02325830 on the ClinicalTrials.gov website.

Schofer et al. (2009) evaluated participants with moderate heart disease who were enrolled in AMADEUS (Carillon Mitral Annuloplasty Device European Union Study). Percutaneous mitral annuloplasty was achieved through the coronary sinus with the Carillon Mitral Contour System™. Of the 48 participants enrolled in the trial, 30 received the Carillon device. Overall, 18 participants did not receive a device because of access issues, insufficient acute FMR reduction, or coronary artery compromise. Echocardiographic FMR grade, exercise tolerance, NYHA class, and quality of life were assessed at baseline and 1 and 6 months. The major adverse event rate was 13% at 30 days. At 6 months, the degree of FMR reduction among five different quantitative echocardiographic measures ranged from 22% to 32%. Six-minute walk distance improved from 307 ±87 m at baseline to 403 ±137 m at 6 months. Quality of life, measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ), improved from 47 ±16 points at baseline to 69 ±15 points at 6 months. The authors concluded that percutaneous reduction in FMR with a novel coronary sinus–based mitral annuloplasty device is feasible in individuals with heart failure, associated with a low rate of major adverse events, and associated with improvement in quality of life and exercise tolerance. Study limitations include the lack of a randomized, blinded control group to compare safety and efficacy results.

Other Minimally Invasive Mitral Valve Repair Devices

Several other minimally invasive mitral valve repair devices are in development. Larger, prospective studies, with long-term follow-up, are needed to establish their clinical role.

Small case series from a single research group reported early results with the Harpoon expanded polytetrafluoroethylene chordal implantation system. The results were promising; however, larger, prospective studies, with long-term follow-up, are needed to establish their clinical role (Gammie et al., 2021; Gammie et al., 2016; Gammie et al., 2018).

Messika-Zeitoun et al. (2019) reported the 1-year outcomes in 60 consecutive individuals with moderate or severe secondary MR who underwent the Cardioband™ procedure. At 1 year, most individuals had moderate or less MR and experienced significant functional improvements. There were two in-hospital deaths (no device related), one stroke, two coronary artery complications, and one tamponade. Anchor disengagement, observed in 10 individuals, resulted in device inefficacy in five individuals and led to device modification halfway through the study to mitigate this issue. Study limitations include the lack of randomization and a control group and short-term follow-up.

Colli et al. (2018) reported early results of the NeoChord mitral valve repair system for treating degenerative MR. In a consecutive case series of individuals, 213 individuals were enrolled in the NeoChord Independent International Registry. All individuals presented with severe MR. The primary end points were procedural success; freedom from mortality, stroke, reintervention, recurrence of severe MR, and rehospitalization; and a decrease of at least one NYHA functional class at 1 year of follow-up. Procedural success was achieved in 206 individuals (96.7%). At the 1-year follow-up, overall survival was 98% ±1%. The composite end point was achieved in 84% ±2.5% in the overall population. Study limitations include the lack of randomization and a control group and short-term follow-up.

Pulmonary Valve

An ECRI evidence review concluded that individuals treated with transcatheter pulmonary valve replacement (TPVR) had reduced long-term mortality, shorter hospital stays, and reduced noncardiac adverse events compared with individuals treated with surgical pulmonary valve replacement. The review also reported similar short-term mortality, pulmonary regurgitation, reintervention rates, and short-term infective endocarditis incidence with TPVR compared with surgical pulmonary valve replacement. However, individuals treated with TPVR had an increased risk of infective endocarditis at

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more than the 18-month follow-up. The review included three systematic reviews of nonrandomized studies. While the evidence is limited by a lack of RCTs, results were consistent across the systematic reviews (ECRI, 2025b).

Dimas et al. (2024) reported 2-year outcomes from the main cohort of the ALTERRA prospective, single-arm, multicenter pivotal trial using the 29-mm SAPIEN 3 transcatheter heart valve. The system was evaluated in participants with moderate or greater pulmonary valve regurgitation. The primary end point was valve dysfunction at 6 months, defined as a composite of right ventricular outflow tract (RVOT)/pulmonary valve reintervention, moderate or greater total pulmonary regurgitation, and mean RVOT/pulmonary valve gradient of 35 mm Hg or greater. Of the 97 participants screened, 60 underwent implantation. No participants had valve dysfunction at 6 months. At 2 years, the majority of participants (92.5%) had mild or less pulmonary valve regurgitation, with no reports of coronary compression, stent fractures warranting reintervention, or endocarditis. Of the 21 participants (34.4%) who experienced early (days 0-1) arrhythmias, 12 had episodes of nonsustained ventricular tachycardia that resolved with medication. One participant underwent reintervention secondary to an iatrogenic RVOT obstruction. There were no deaths or explanations through 2 years.

Gillespie et al. (2023) presented 1-year outcomes in a pooled cohort of clinical trial participants from three earlier studies of the Harmony™ transcatheter pulmonary heart valve. The Harmony device continued to demonstrate favorable clinical and hemodynamic outcomes across studies and valve types through 1 year. At 3 to 5 years, the Harmony valve resulted in sustained valve competence, beneficial cardiac remodeling, and improved quality of life (Morray et al., 2025). Continued follow-up in this participant cohort through 10 years will allow long-term evaluation of valve performance and durability.

A Hayes report concluded that there is insufficient evidence to draw conclusions regarding the effectiveness and safety of percutaneous pulmonary valve implantation using SAPIEN 3 and SAPIEN XT valves for the treatment of RVOT. Substantial uncertainty exists regarding the long-term durability and efficacy compared with open heart surgery (Hayes, 2022; updated 2025).

McElhinney et al. (2022) evaluated mid- and long-term outcomes after TPVR in a large, multicenter cohort using international registry data from 2,476 individuals. The analysis found that survival and freedom from reintervention or surgery after TPVR are generally comparable to outcomes of surgical conduit/valve replacement across a wide range of ages of individuals.

Ribeiro et al. (2020) performed a systematic review and meta-analysis of 18 studies comparing transcatheter with surgical pulmonary valve replacement. The primary end point was early mortality after replacement. The secondary end points included procedure-related complications, length of hospital stay, mortality during follow-up, infective endocarditis, need for reintervention, postreplacement transpulmonary peak systolic gradient, and significant pulmonary regurgitation. No significant difference was observed in the primary end point of early mortality between the groups. At the mid-term follow-up, the transcatheter technique was comparable to the surgical procedure in terms of repeat intervention but was associated with an increased risk of infective endocarditis. In selected individuals, the transcatheter technique was found to have a shorter length of hospital stay and fewer procedure-related complications.

Benson et al. (2020) reported 3-year clinical and hemodynamic outcomes in a follow-up to the Bergersen et al. (2017) feasibility study. Of the original 20 implanted participants, 17 completed the 3-year follow-up. Results showed good valve function in most and the absence of moderate/severe paravalvular leak and significant late frame fractures. Two participants developed significant neointimal tissue ingrowth requiring valve-in-valve (ViV) treatment, while all others had no clinically significant RVOT obstruction. The authors noted that these results are encouraging, but further follow-up is required. At 5 years, Gillespie et al. (2021) reported, in a letter to the editor, sustained valve function with freedom from moderate to severe valve or perivalvular leak and no reports of endocarditis. Two participants underwent surgical explant. There were three catheter-based reinterventions performed in two participants who both ultimately underwent Melody™ ViV procedures. One participant died shortly after the 3-year follow-up assessment. These and the original publication described below are limited by the lack of a comparison group undergoing a different therapeutic approach.

Kenny et al. (2018) reported 3-year follow-up results of the COMPASSION (Congenital Multicenter Trial of Pulmonic Valve Regurgitation Studying the SAPIEN Transcatheter Heart Valve) trial. Participants with moderate to severe pulmonary regurgitation and/or RVOT conduit obstruction were implanted with the SAPIEN transcatheter heart valve. Overall, 57 of the 63 eligible participants were accounted for at the 3-year follow-up visit from a total of 69 implantations in 81 enrolled participants. Indications for implantation were pulmonary stenosis (7.6%), regurgitation (12.7%), or both (79.7%). A functional improvement in NYHA functional class was observed in 93.5% of participants. The mean peak conduit gradient decreased from 37.5 ±25.4 mm Hg to 17.8 ±12.4 mm Hg, and the mean right ventricular systolic pressure decreased from 59.6 ±17.7 mm Hg to 42.9 ±13.4 mm Hg. Pulmonary regurgitation was mild or less in 91.1% of participants. When implanted in participants with moderate to severe pulmonary regurgitation and/or RVOT conduit obstruction, the SAPIEN

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valve was associated with favorable outcomes at 3 years, with low rates of all-cause mortality, reintervention, and endocarditis and no stent fractures.

Chatterjee et al. (2017) performed a systematic review and meta-analysis of observational studies evaluating transcatheter pulmonary valve implantation. Overall, 19 studies (n = 1,044), which included five or more individuals and at least 6 months of follow-up, were included. In total, 13 studies used the Melody valve, three used the Edwards SAPIEN or SAPIEN XT valves, and three used both the Melody and Edwards valve systems. The procedural success rate was 96.2%, with a conduit rupture rate of 4.1% and coronary complication rate of 1.3%. The authors reported favorable updated estimates of procedural and follow-up outcomes after transcatheter pulmonary valve implantation. They also noted that widespread adoption of prestenting has improved long-term outcomes in these individuals. (This systematic review includes Cheatham et al., 2015, Armstrong et al., 2014, Butera et al., 2013, and Eicken et al., 2011, previously cited in this policy.) Note: These versions of the SAPIEN valve are no longer commercialized.

Bergersen et al. (2017) reported clinical outcomes from an early feasibility study to assess the self-expanding Harmony transcatheter pulmonary valve. Of 66 enrolled participants, 21 were approved for the implant, and 20 received the Harmony device. Most participants had been diagnosed with tetralogy of Fallot and had augmented RVOTs or transannular patch repairs. Clinical assessments were collected at baseline and after the 1-month, 3-month, and 6-month follow-ups. In the 20 implanted participants, the device was implanted in the intended location; however, proximal migration occurred in one participant during delivery system removal. Two devices were surgically explanted. Premature ventricular contractions related to the procedure were reported in three participants; two were resolved without treatment. One participant had ventricular arrhythmias that required treatment and were later resolved. Overall, 18 participants returned for the 3- and 6-month follow-up assessments. Echocardiographic data remained consistent with those observed at the 1-month visit. Compared with baseline, participants had significant improvements in pulmonary regurgitation. By the 6-month follow-up, there were minimal changes in incidence of paravalvular leak, mean RVOT gradient, and tricuspid regurgitation (TR). Study limitations include the lack of randomization and a control group and small sample size. Additionally, enrollment was limited to three sites, each with an experienced catheterization cardiologist performing the procedure. The authors noted that further studies, with larger populations of individuals, are needed to assess the long-term durability, function, and safety of the Harmony device.

McElhinney et al. (2010) conducted a single-arm multicenter trial in 136 participants (median age, 19 years) who underwent catheterization for intended Melody valve implantation. Implantation was attempted in 124 participants. In the other 12, transcatheter pulmonary valve placement was not attempted because of the risk of coronary artery compression (n = 6) or other clinical or protocol contraindications. There was one death and one explanted valve after conduit rupture. The median peak RVOT gradient was 37 mm Hg before implantation and 12 mm Hg immediately after implantation. Before implantation, pulmonary regurgitation was moderate or severe in 92 participants. No participant had more than mild pulmonary regurgitation early after implantation or during follow-up. Freedom from stent fracture was 77.8% ±4.3% at 14 months. Freedom from valve dysfunction or reintervention was 93.5% ±2.4% at 1 year. A higher RVOT gradient at discharge and younger age were associated with shorter freedom from dysfunction. The results demonstrated an ongoing high rate of procedural success and encouraging short-term valve function. All reinterventions in this series were for RVOT obstruction, highlighting the importance of participant selection, adequate relief of obstruction, and measures to prevent and manage stent fracture. Jones et al. (2022) reported on 58 participants at 10 years. The estimated freedom from mortality was 90%, from reoperation was 79%, and from any reintervention was 60%. The 10-year freedom from transcatheter pulmonary valve dysfunction was 53% and was significantly shorter in children than in adults. Estimated freedom from transcatheter pulmonary valve–related endocarditis was 81% at 10 years, with an annualized rate of 2.0% per patient-year. This study is registered under clinical trial number NCT00740870 on the ClinicalTrials.gov website.

Tricuspid Valve

The international TriValve Registry (n = 312) was developed to evaluate several transcatheter tricuspid valve interventions in high-risk individuals with severe TR (predominantly functional). Interventions included leaflet repair, annulus repair, coaptation, and replacement. Implanted devices included the MitraClip (n = 210), Trialign (n = 18), TriCinch first generation (n = 14), caval valve implantation (CAVI; n = 30), FORMA (n = 24), Cardioband (n = 13), NaviGate (n = 6), and PASCAL (n = 1). Preliminary results of transcatheter tricuspid valve interventions were promising in terms of safety and feasibility. Mid-term survival was favorable in this high-risk population. However, long-term outcomes and better selection of individuals are needed to better understand the clinical role of these procedures for treating TR (Taramasso et al., 2019).

Transcatheter Tricuspid Valve Replacement

There is insufficient quality evidence in the clinical literature demonstrating the long-term safety and efficacy of transcatheter tricuspid valve replacement (TTVR) for treating tricuspid valve disease. Data from one RCT showed

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promising results, with improvements in functional status and quality of life, but early (< 3 months) mortality and severe bleeding are concerning. Longer follow-up is needed to assess whether these early unfavorable findings are compensated with later favorable results. Furthermore, confidence in findings of this RCT is limited by the open-label design. Other publications are limited by a single-arm and observational design.

An ECRI report concluded that the EVOQUE transcatheter tricuspid valve works as intended to treat TR and improves functional and quality-of-life outcomes in individuals with severe symptomatic TR compared with medical therapy alone; however, individuals treated with EVOQUE experienced higher rates of bleeding events and permanent pacemaker implantation following the procedure. Whether EVOQUE reduces mortality compared with medical therapy at the 1-year follow-up remains unclear. Evidence from one systematic review of 20 single-arm studies at a high risk of bias is too limited in quality to determine how well EVOQUE works compared with other interventional treatment options or TTVR systems. Additional controlled studies, with longer-term follow-up, are needed to fully evaluate EVOQUE's risk-benefit profile and compare EVOQUE with other TTVR devices, transcatheter valve repair, and surgical valve repair and replacement (ECRI, 2026).

Hatab et al. (2025) performed a meta-analysis of clinical outcomes data following TTVR in individuals with severe or torrential TR. Overall, 20 studies (n = 1,017) evaluating various valve systems were included. There was considerable heterogeneity across studies in terms of populations of individuals, device platforms, delivery routes, procedural techniques, and outcome definitions. At baseline, 97.0% of individuals had TR graded as greater than or equal to severe, and 85.6% were classified as NYHA functional class III or IV. At follow-up, the weighted in-hospital and 30-day mortality rates across platforms were 1.37% and 2.49%, respectively. New permanent pacemaker implantation occurred in 7.98% of individuals, with the highest rates observed in EVOQUE recipients (11.64%). Overall, 3% of individuals had residual TR greater than or equal to severe, and only 12% remained in NYHA functional class III/IV. The pooled estimate of thrombotic and bleeding events was 1.66% and 8.93%, respectively. Most included studies were small, nonrandomized, and conducted in early feasibility or compassionate use settings. Robust, long-term RCTs, with standardized outcome reporting and clinical end points, are needed to define durable clinical benefit and guide optimal device selection in this population of individuals. (This study is included in the ECRI, 2026, report summarized above. Kodali et al., 2023, and Webb et al., 2022, previously cited in this policy, are included in this meta-analysis.)

Hahn et al. (2024) conducted the TRISCEND II international, multicenter, randomized pivotal trial that evaluated the EVOQUE TTVR in participants with severe symptomatic TR. The trial used a two-phase design, based on the U.S. Food and Drug Administration Breakthrough Device Designation program. Investigators evaluated 30-day safety and 6-month effectiveness end points for the first 150 participants in the initial phase and a 1-year safety and effectiveness end point for the full cohort of 400 participants in the second phase. Participants were predominantly older (mean age, 79.2 years), with a high prevalence of comorbidities. Study limitations include the open-label design, reliance on participant-reported outcomes, and short-term follow-up.

In phase 1 of TRISCEND II, the first 150 participants were randomized to TTVR with optimal medical therapy (n = 96) or medical therapy alone (n = 54). Early data from phase 1 showed a major adverse event rate of 27.4% at 30 days and significant reductions in TR, with 98.8% of participants achieving moderate or less TR and 93.8% achieving mild or less TR at 6 months. Additionally, there were improvements in quality-of-life and functional outcomes at 6 months for the composite end point, including improvements in the KCCQ Overall Summary (KCCQ-OS) score, NYHA functional class, and 6-minute walk distance.

In phase 2 in the full TRISCEND II cohort, 400 participants were randomized in a 2:1 ratio to undergo either TTVR with medical therapy (n = 267) or medical therapy alone (n = 133). The primary end point was a hierarchical composite outcome, including death from any cause, need for a right ventricular assist device or heart transplant, additional tricuspid valve interventions, hospitalization for heart failure, improvement of ≥ 10 points on the KCCQ-OS, improvement of at least one NYHA functional class, and a ≥ 30-m improvement on the 6-minute walk test. At 1 year, TTVR was associated with a slightly lower mortality rate (12.6%) compared with the control group (15.2%). TTVR recipients experienced a lower hospitalization rate for heart failure (20.9%) than the control group (26.1%). Improvement in KCCQ-OS scores by at least 10 points was achieved in 66.4% of TTVR recipients vs 36.5% in the control group. TTVR recipients had marked improvement in NYHA class, with 78.9% achieving at least one functional class improvement, compared with 24.0% in the control group. Improvement in the 6-minute walk test was observed in 47.6% of TTVR recipients compared with 31.8% in the control group. Additionally, TTVR significantly reduced TR severity, with 95.3% of participants achieving mild or less TR at 1 year, compared with only 16.1% in the control group. TTVR adverse events included severe bleeding in 15.4% of participants vs 5.3% in the control group and new permanent pacemaker implantation in 17.4% of participants compared with 2.3% of controls. Arnold et al. (2025) performed an analysis of the health status of participants enrolled in the study and reported that TTVR with medical therapy resulted in substantial improvement in symptoms, function, and quality of life

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at 1 year. In a post hoc analysis, Lurz et al. (2025) evaluated outcomes by baseline TR severity. (This study is included in the ECRI, 2026, report summarized above.)

A Hayes report found minimal support for the use of the EVOQUE Tricuspid Valve Replacement System to treat individuals with severe (or greater) TR, despite optimal medical therapy, who are not candidates for transcatheter repair or open heart surgery and have poor prognosis. Longer-term follow-up data are expected from ongoing studies. Higher-quality RCTs comparing EVOQUE with other replacement valve options are needed (Hayes, 2024; updated 2025).

An ECRI report on the safety and effectiveness of TTVR for treating TR found that the evidence is inconclusive. RCTs reporting on clinical outcomes and comparing TTVR with medical treatment, transcatheter tricuspid valve repair, and prosthetic valves from different manufacturers are needed to address evidence gaps (ECRI, 2022b).

Buğan et al. (2022) completed a systematic review and meta-analysis to evaluate the feasibility of orthotopic TTVR devices, echocardiographic, functional improvements, and mortality rates following replacement in individuals with significant tricuspid valve regurgitation. The authors systematically searched for the studies evaluating the efficacy and safety of TTVR for significant tricuspid valve regurgitation. The efficacy and safety outcomes were the improvements in NYHA functional class, 6-minute walk distance, all-cause death, and periprocedural and long-term complications. In addition, a random-effects meta-analysis was performed, comparing outcomes before and after TTVR. Nine studies, with 321 individuals, were included in this study. The mean age was 75.8 years, and the mean European System for Cardiac Operative Risk Evaluation II score was 8.2% (95% CI, 6.1%-10.3%). Severe, massive, and torrential tricuspid valve regurgitation was diagnosed in 95% of individuals (95% CI, 89%-98%), and 83% (95% CI, 73%-90%) of individuals were in NYHA functional class III or IV. At a weighted mean follow-up of 122 days, NYHA functional class (risk ratio, 0.20; 95% CI, 0.11-0.35; $p < 0.001$) and 6-minute walk distance (mean difference, 91.1 m; 95% CI, 37.3-144.9 m; $p < 0.001$) improved. The prevalence of severe or greater tricuspid valve regurgitation was reduced after TTVR (baseline risk ratio, 0.19; 95% CI, 0.10-0.36; $p < 0.001$). In total, 28 individuals (10%; 95% CI, 6%-17%) died. Pooled analyses failed to show significant differences in hospital and 30-day mortality and > 30-day mortality than predicted operative mortality (risk ratio, 1.03; 95% CI, 0.41-2.59; $p = 0.95$ and risk ratio, 1.39; 95% CI, 0.69-2.81; $p = 0.35$, respectively). The authors concluded that TTVR could be an emerging treatment option for individuals with severe TR who are not eligible for transcatheter repair or surgical replacement because of a high surgical risk. Limitations include a potential for bias, as the analysis only included single-arm interventional studies, case series, and no RCTs. Moderate heterogeneity was found in the consistency of results. In addition, there are no specific guideline recommendations for the selection of individuals for TTVR; therefore, this meta-analysis is limited by the lack of uniformity in the definition of procedural success.

Transcatheter Edge-to-Edge Tricuspid Valve Leaflet Repair

Kritya et al. (2025) performed a systematic review and meta-analysis evaluating the safety and efficacy of tricuspid TEER (T-TEER) compared with those of GDMT. The outcomes assessed were all-cause mortality, heart failure hospitalization, cardiovascular mortality, residual TR, NYHA class improvement, stroke, and new permanent pacemaker implantation. Two RCTs and five observational studies (n = 4,220) were included in the analysis. The follow-up duration was uniform across all studies, with the exception of the TRILUMINATE trial that had 2-year data for all-cause mortality and heart failure rehospitalization. The pooled analysis showed that T-TEER was associated with a significant reduction in all-cause mortality and heart failure hospitalization compared with GDMT. Cardiovascular mortality and risk of stroke did not differ significantly between the two groups. T-TEER significantly improved TR severity and reduction in NYHA functional class, without increasing the risk of new permanent pacemaker implantation. Limitations include the use of observational data and short-term follow-up. Further research, with longer follow-up and refined selection of individuals, is warranted to better clarify the long-term impact of T-TEER (Sorajja et al., 2023, and Kar et al., 2025, from the TRILUMINATE study, noted below, are included in this analysis.)

In the TRILUMINATE study, 572 participants were randomly assigned to receive either T-TEER with the TriClip™ device plus medical therapy (n = 285) or medical therapy alone (n = 287). After 1 year, 142 participants in the control group were allowed to cross over prior to the 2-year follow-up. At 2 years, T-TEER significantly reduced heart failure hospitalizations compared with medical therapy alone, without affecting mortality. Freedom from all-cause mortality, tricuspid valve surgery, and tricuspid valve intervention through 2 years was significantly higher with T-TEER than in the control group; however, this was driven by participants in the control group crossing over to T-TEER between 1 and 2 years. Safety at 2 years was also maintained. The study also demonstrated sustained improvements in TR severity and quality of life through the 2-year follow-up (Kar et al., 2025).

Rehan et al. (2024) performed a systematic review and meta-analysis to assess echocardiographic parameters and clinical outcomes in individuals undergoing T-TEER for moderate to severe (grade III-V), isolated TR. One RCT and 14 observational studies were included. A GRADE (Grading of Recommendations Assessment, Development, and Evaluation) assessment was performed, and studies were assessed for risk of bias and publication bias. The authors

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reported promising results in terms of TR grade and volume, NYHA class, and 6-minute walk distance. T-TEER procedural success was 97%. No significant differences in LVEF, fractional area change, and tricuspid annular plane systolic excursion were observed. Most of the studies in this review were single-arm, prospective, observational studies or retrospective analyses, with moderate sample sizes, that lacked a control group and randomization. This publication's data analyses are limited to prior to/post comparison, without comparison to a concurrent group undergoing a different intervention. Further large-scale RCTs comparing the efficacy of T-TEER with that of traditional therapeutic strategies are needed to establish T-TEER as a first-line treatment option for individuals with TR. (Sorajja et al., 2023, and Lurz et al., 2021, summarized below, are included in this systematic review.)

An ECRI report on the TriClip device for treating TR in individuals at an intermediate to high risk of tricuspid valve surgery concluded that TriClip is safe and improves quality of life and functional status more than best-available medical therapy alone at up to the 2-year follow-up in individuals with moderate- or higher-grade TR. While ECRI deemed the evidence favorable, the report also noted that the studies reported too few events and too short of follow-up to enable conclusions about whether TriClip reduces mortality rates compared with best-available medical therapy. Additional studies are needed to validate findings. T-TEER with TriClip presents a treatment option for individuals with symptomatic TR whose symptoms persist despite best-available medical care. Ongoing clinical trials may validate the findings and address evidence gaps (ECRI, 2024).

The TRILUMINATE single-arm study was an international, prospective, multicenter study designed to evaluate the safety and effectiveness of the TriClip T-TEER system in participants with symptomatic, moderate or greater TR who were at a high risk for surgery and had valve anatomies suitable for T-TEER. Of 97 participants who met the inclusion criteria, the first 85 were enrolled and underwent successful TriClip implantation. The primary safety end point was a composite of major adverse events at 6 months. The primary efficacy end point was a reduction in TR severity by at least one grade at 30 days. Clinical status was assessed using NYHA functional class, KCCQ score, and the 6-minute walk test. At 6 months, Nickenig et al. (2019) reported that both primary end points were met. The procedure effectively reduced TR and significantly improved clinical symptoms and exercise capacity. The study also showed that reduction in TR with the TriClip device was associated with significant right heart remodeling and improved right ventricular function; however, it was unclear that a reduction of TR was associated with reduced morbidity and mortality. T-TEER using the TriClip implant was found to be safe and effective, with sustained benefits at 1, 2, and 3 years (Lurz et al., 2021; von Bardeleben et al., 2023; Nickenig et al., 2024). This study was limited by the lack of randomization and a control group and small sample size.

The prospective, open-label, randomized TRILUMINATE pivotal trial evaluated the safety and effectiveness of T-TEER in symptomatic participants with severe TR. A total of 350 participants were randomly assigned in a 1:1 ratio to receive either T-TEER with the TriClip device (n = 175) or medical therapy alone (n = 175). The primary end point was a hierarchical composite that included death from any cause or tricuspid valve surgery, heart failure hospitalization, and improved quality of life, as measured with the KCCQ at 1 year. The secondary end points were freedom from major adverse events within 30 days (T-TEER group only), a change from baseline in KCCQ score at the 1-year follow-up, a reduction in TR severity to moderate or less by the 30-day follow-up, and a change from baseline in the 6-minute walk distance at the 1-year follow-up. The mean participant age was 78 years, and 54.9% of participants were women. Results showed that T-TEER was safe (only three major adverse events occurred within 30 days) and effectively reduced TR severity (TR grade of ≤ 2+ at 30 days was present in 87.0% of the T-TEER group vs 4.8% of the control group). However, the incidence of death or tricuspid valve surgery and the rate of hospitalization for heart failure did not appear to differ between the groups. The difference in the primary outcome was driven by a significantly greater increase in KCCQ score from baseline to follow-up in the T-TEER–assigned group (mean improvement 12.3 vs 0.6 points), which could have been biased by a lack of participant masking. NYHA class was also improved with T-TEER, although the difference in 6-minute walk distance from baseline to follow-up was not significantly different between groups (Sorajja et al., 2023). This study is registered under clinical trial number NCT03904147 on the ClinicalTrials.gov website.

An ECRI report found very low-quality evidence for percutaneous tricuspid valve repair for treating TR in individuals who are ineligible for surgery. Study results were at a high risk of bias due to a small sample size and lack of controls and randomization (ECRI, 2022c).

Bocchino et al. (2021) performed a meta-analysis to assess the pooled clinical and echocardiographic outcomes of different isolated transcatheter tricuspid valve repair strategies for moderate or greater TR in individuals who were ineligible for surgery. Fourteen observational studies (n = 771) were included. At a mean follow-up of 212 days, 209 individuals (35%) were in NYHA functional class III or IV compared with 586 individuals (84%) at baseline. Six-minute walk distance significantly improved by a mean of 50 m. Overall, 147 individuals (24%) had severe or greater TR after isolated transcatheter tricuspid valve repair compared with 616 (96%) at baseline. The included studies are at a high risk

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of bias due to several factors: a small sample size, single-center focus, retrospective design, and/or lack of controls, randomization, and blinding. Further results from prospective RCTs are needed to confirm these findings.

Caval Valve Implantation

There is insufficient quality evidence in the clinical literature demonstrating the long-term safety and efficacy of CAVI for treating tricuspid valve disease. Identified publications are limited by short-term follow-up, an open-label design, and small sample sizes.

Using data from the TricBicaval registry, Sánchez-Recalde et al. (2025) assessed the safety and efficacy of the TricValve® system. The multicenter registry retrospectively enrolled 204 consecutive patients with severe TR. The authors reported reductions in peripheral edema, ascites, hospitalizations for heart failure, and diuretic dosing at 1 year. Functional status significantly improved, with 19.8% of patients in NYHA functional class I or II at baseline vs 81.5% after a median follow-up period of 8.8 months. The study is limited by the lack of a comparison group.

Blasco-Turrión et al. (2024) reported 1-year clinical results in a combined cohort of participants enrolled in the TRICUS (n = 9) and TRICUS EURO (n = 35) studies. Both studies were prospective, nonblinded, nonrandomized, single-arm trials representing early experience with the TricValve system in participants with symptomatic severe TR despite optimal medical treatment; an NYHA functional class of III or IV; and ineligibility for open heart surgery. The primary end points were quality of life and functional status. Clinical improvement at 1 year was achieved in 42 participants (95.5%). There were three deaths (6.8%), and the heart failure rehospitalization rate was 29.5%. Limitations of both studies include the nonrandomization, small sample size, lack of a control group, and short-term follow-up. Well-designed, comparative studies, with larger cohorts and long-term follow-up, are needed to further understand the safety and clinical impact of CAVI with the TricValve system.

Badwan et al. (2023) performed a meta-analysis of studies evaluating clinical outcomes after CAVI for severe symptomatic TR. Fifteen studies (n = 142) were included, eight of which were case reports or case series. The median follow-up duration ranged from 61 to 350 days. The authors found that CAVI was associated with a high procedural success rate and significant reductions in NYHA functional class and TR severity but noted several limitations, including a small sample size, short-term follow-up, and dissimilar definitions of procedural success. Also, multiple CAVI systems were incorporated into the pooled analysis. While hemodynamic and functional improvements are encouraging, larger-scale, prospective studies, with longer follow-up, are needed.

In the TRICAVAL prospective, open-label, single-center, randomized trial, Dreger et al. (2020) compared the impact of a balloon-expandable transcatheter valve into the inferior vena cava (CAVI) on exercise capacity with that of optimal medical therapy in participants with severe TR and high surgical risk. Overall, 28 participants were randomized to optimal medical therapy (n = 14) or CAVI (n = 14). The primary end point was maximal oxygen uptake at 3 months. The secondary end points included the 6-minute walk test, NYHA functional class, N-terminal pro–brain natriuretic peptide levels, right heart function, unscheduled heart failure hospitalization, and quality of life. Participants underwent follow-up examinations 1, 3, 6, and 12 months after randomization. Maximal oxygen uptake did not change significantly in either group after 3 months, and there was no difference between the medical therapy and CAVI groups. Compared with baseline, CAVI improved NYHA class, dyspnea, and quality of life after 3 months. However, there were no statistically significant differences in the secondary end points between the groups. CAVI did not result in a superior functional outcome compared with medical therapy. Due to an unexpectedly high rate of valve dislocations, the study was stopped for safety reasons, resulting in a low number of enrolled participants. The study may have been underpowered to detect clinically significant differences between groups.

Valve-in-Valve Procedures

There is insufficient quality evidence in the clinical literature demonstrating the long-term efficacy of ViV procedures for mitral and tricuspid valves. Identified evidence is limited by the observational design of the studies. The evidence for these procedures is still evolving.

Aortic

Al-Abcha et al. (2021) performed a meta-analysis to compare the clinical outcomes of ViV TAVR vs those of redo SAVR in failed bioprosthetic aortic valves. Twelve observational studies were included (n = 8,430). Compared with redo SAVR, ViV TAVR was associated with a similar risk of all-cause mortality, cardiovascular mortality, myocardial infarction, permanent pacemaker implantation, and rate of moderate to severe paravalvular leakage. However, the rates of major bleeding, stroke, procedural mortality, and 30-day mortality were significantly lower in the ViV group. Randomized clinical trials are needed to confirm the safety and efficacy of ViV TAVR in individuals with failed bioprosthetic aortic valves.

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Gozdek et al. (2018) performed a systematic review and meta-analysis to compare redo SAVR with ViV TAVR in individuals with failed aortic bioprostheses. Five observational studies (n = 342) were included in the analysis. Although there was no statistical difference in procedural mortality, 30-day mortality, and cardiovascular mortality at a mean follow-up period of 18 months, cumulative survival analysis favored surgery. ViV procedures were associated with a significantly lower rate of permanent pacemaker implantations and shorter intensive care unit and hospital stays. Redo SAVR offered superior echocardiographic outcomes, lower incidence of individual-prosthesis mismatch, fewer paravalvular leaks, and lower mean postoperative aortic valve gradients. The authors concluded that the ViV approach is a safe, feasible alternative to conventional surgery that may offer an effective, less invasive treatment for individuals with failed surgical aortic bioprostheses who are inoperable or at a high risk but that SAVR should remain the standard of care, particularly in the low-risk population, because it offers superior hemodynamic outcomes, with low mortality rates.

Tam et al. (2018) performed a systematic review and meta-analysis to determine the safety and efficacy of ViV TAVR vs those of redo SAVR for the treatment of previously failed aortic bioprostheses. Four unadjusted (n = 298) and two propensity-matched (n = 200) observational studies were included. Despite a higher predicted surgical risk in ViV individuals, there was no difference in perioperative mortality (4.4% vs 5.7%) or late mortality, reported at a median of 1 year of follow-up. The incidence of permanent pacemaker implantation (8.3% vs 14.6%) and dialysis (3.2% vs 10.3%) was lower with ViV. There was a reduction in the incidence of severe individual-prosthesis mismatch (3.3% vs 13.5%) and mild or greater paravalvular leak (5.5% vs 21.1%) in the redo SAVR group compared with ViV.

Using patient data from the STS/American College of Cardiology Transcatheter Valve Therapy Registry, Tuzcu et al. (2018) evaluated the safety and effectiveness of ViV TAVR for failed surgically implanted bioprostheses by comparing it with the benchmark of native valve (NV) TAVR. Patients who underwent ViV TAVR (n = 1,150) were matched 1:2 to patients undergoing NV TAVR (n = 2,259). An unadjusted analysis revealed lower 30-day mortality (2.9% vs 4.8%), stroke (1.7% vs 3.0%), and heart failure hospitalizations (2.4% vs 4.6%) in the ViV TAVR than the NV TAVR group. An adjusted analysis revealed lower 30-day mortality, 1-year mortality, and hospitalization for heart failure in the ViV TAVR group. Patients in the ViV TAVR group had a higher post-TAVR mean gradient (16 vs 9 mm Hg) but less moderate or severe aortic regurgitation (3.5% vs 6.6%). Post-TAVR gradients were highest in small SAVRs and stenotic SAVRs.

Deeb et al. (2017) evaluated the safety and effectiveness of the CoreValve in participants with failed surgical aortic bioprostheses. The CoreValve U.S. Expanded Use Study was a prospective nonrandomized study that enrolled 233 participants with symptomatic surgical valve failure who were deemed unsuitable for reoperation. Participants were treated with the CoreValve and evaluated for 30-day and 1-year outcomes after the procedure. Surgical valve failure occurred through stenosis (56.4%), regurgitation (22.0%), or a combination (21.6%). A total of 227 participants underwent attempted TAVR, and successful TAVR was achieved in 225 participants (99.1%). Participants were elderly (76.7 ±10.8 years), had an STS Predicted Risk of Mortality score of 9.0% ±6.7%, and were severely symptomatic (86.8% NYHA functional class III or IV). The all-cause mortality rate was 2.2% at 30 days and 14.6% at 1 year; the major stroke rate was 0.4% at 30 days and 1.8% at 1 year. Moderate aortic regurgitation occurred in 3.5% of participants at 30 days and 7.4% of participants at 1 year, with no severe aortic regurgitation. The rate of new permanent pacemaker implantation was 8.1% at 30 days and 11.0% at 1 year. The mean valve gradient was 17.0 ±8.8 mm Hg at 30 days and 16.6 ±8.9 mm Hg at 1 year.

Webb et al. (2017) evaluated 30-day and 1-year outcomes in high-risk participants undergoing ViV TAVR using the SAPIEN XT valve. Participants with symptomatic degeneration of surgical aortic bioprostheses at a high risk (≥ 50% major morbidity or mortality) for reoperative surgery were prospectively enrolled in the multicenter PARTNER 2 ViV trial and continued-access registries. ViV procedures were performed in 365 participants (96 initial registry; 269 continued-access participants). The mean age was 78.9 ±10.2 years, and the mean STS score was 9.1% ±4.7%. At 30 days, all-cause mortality was 2.7%, stroke was 2.7%, major vascular complication was 4.1%, conversion to surgery was 0.6%, coronary occlusion was 0.8%, and new pacemaker insertion was 1.9%. The 1-year all-cause mortality was 12.4%. Mortality fell from the initial registry to the subsequent continued-access registry, both at 30 days (8.2% vs 0.7%, respectively) and at 1 year (19.7% vs 9.8%, respectively). At 1 year, the mean gradient was 17.6 mm Hg, and the effective orifice area was 1.16 cm^2, with greater than mild paravalvular regurgitation of 1.9%. LVEF increased (50.6% to 54.2%), and mass index decreased (135.7 to 117.6 g/m^2), with reductions in both mitral (34.9% vs 12.7%) and tricuspid (31.8% vs 21.2%) moderate or severe regurgitation.

Phan et al. (2016) conducted a systematic review to compare the outcomes and safety of transcatheter ViV implantation with those of reoperative conventional aortic valve replacement. Overall, 18 relevant observational studies (823 individuals) were included. A pooled analysis suggests that transcatheter ViV implantation achieved similar hemodynamic outcomes, with a lower risk of strokes and bleeding but higher rates of paravalvular leaks compared with reoperative conventional aortic valve replacement. The authors noted that future randomized studies and prospective registries are essential to compare the effectiveness of these procedures.

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Using VIVID registry data, Dvir et al. (2014) determined the survival of participants after transcatheter aortic ViV implantation inside failed surgical bioprosthetic valves. Correlates for survival were evaluated using a multinational registry that included 459 participants with degenerated bioprosthetic valves undergoing ViV implantation. Modes of bioprosthesis failure were stenosis (n = 181), regurgitation (n = 139), and combined (n = 139). The stenosis group had a higher percentage of small valves (37% vs 20.9% and 26.6% in the regurgitation and combined groups, respectively). Within 1 month following ViV implantation, 35 participants (7.6%) died, eight (1.7%) had major stroke, and 313 (92.6%) of surviving participants had good functional status (NYHA class I/II). The overall 1-year survival rate was 83.2%, with 62 death events and 228 survivors. Participants in the stenosis group had worse 1-year survival (76.6%; 34 deaths; 86 survivors) than the regurgitation group (91.2%; 10 deaths; 76 survivors) and the combined group (83.9%; 18 deaths; 66 survivors). Similarly, participants with small valves had worse 1-year survival (74.8%; 27 deaths; 57 survivors) vs those with intermediate-sized valves (81.8%; 26 deaths; 92 survivors) and with large valves (93.3%; seven deaths; 73 survivors). Factors associated with mortality within 1 year included having a small surgical bioprosthesis (≤ 21 mm) and baseline stenosis (vs regurgitation). In a follow-up study, Bleiziffer et al. (2020) assessed long-term survival and reintervention outcomes after transcatheter aortic ViV procedures. A total of 1,006 aortic ViV procedures were included in the analysis. The primary end point was participant survival, and the main secondary end point was all-cause reintervention. Results showed that the size of the original failed valve may influence long-term mortality, and the type of transcatheter valve may influence the need for reintervention after aortic ViV procedures.

Mitral

Ismayl et al. (2023) conducted a systematic review and meta-analysis of observational studies comparing ViV TMVR vs redo surgical mitral valve replacement in a degenerated bioprosthetic mitral valve. The outcomes included in-hospital, 30-day, 1-year, and 2-year mortality, stroke, bleeding, acute kidney injury, arrhythmias, permanent pacemaker insertion, and hospital length of stay. In total, six observational studies (n = 707) were included. ViV TMVR was associated with better outcomes than redo surgical mitral valve replacement, including lower complication rates and shorter hospital length of stay, with no significant difference in mortality rates. The findings are limited by the observational nature of the included studies, which could have led to biased estimates. Large-scale, randomized trials are needed to confirm these findings.

A single-center retrospective cohort study by Taha et al. (2022) was performed to evaluate the feasibility and safety of TMVR in patients with a high surgical risk with degenerated mitral bioprostheses (TMViV), failed surgical rings (TMViR), and MAC (TMViMAC). Patients with a high surgical risk who underwent TMVR from February 2017 to September 2020 were enrolled in this study. The TMVR procedure was performed using Edwards SAPIEN 3 valves through the transseptal approach. Overall, 64 patients aged 62.7 ±16.1 years, with an STS score of 9.2% ±3.7%, underwent TMVR [35 (55%) TMViV; 16 (25%) TMViR; 13 (20%) TMViMAC]. Mitral stenosis was more frequent in TMViV, MR was more frequent in TMViR, and combined mitral stenosis and regurgitation was more frequent in TMViMAC ($p < 0.05$). The mitral valve gradient was 14.3 ±5.3 mm Hg, and the mitral valve area was 1.5 ±0.6 cm^2. The 29-mm valve was frequently used in TMViV and TMViMAC, while the 23-mm valve was frequently used in TMViR ($p = 0.003$). The procedural and fluoroscopy times were 58.7 ±8.9 and 41.1 ±8.2 minutes, respectively. Technical success was reported in 62 patients (98.4%); one TMViR patient experienced valve embolization and salvage surgery, and one TMViMAC patient experienced slight valve malposition. At 3 months, two patients (3.1%) had valve thrombosis (treated with anticoagulation), and one patient (1.6%) developed a paravalvular leak (underwent surgical mitral valve replacement). At 6 months, three patients (4.7%) had valve degeneration (underwent surgical mitral valve replacement). Throughout follow-up, no patient exhibited mortality. The authors concluded that TMVR is a feasible and safe approach in individuals with a high surgical risk. TMViV and TMViR are reasonable as the first treatment approaches, and TMViMAC seems encouraging. Limitations include the lack of comparison with other therapeutic approaches, small sample size (n = 64), short duration of follow-up (6 months), and single-center design. Further research is needed to determine the clinical relevance of these findings.

Eleid et al. (2021) conducted a systematic review of observational studies to evaluate outcomes after transcatheter mitral ViV implantation for the treatment of degenerated mitral bioprostheses. Five studies (n = 2,684) were included in the review. Procedural technical success ranged from 94% to 98%, with 1% to 3% rates of periprocedural death, 0% to 2% of stroke, and 1% to 5% of risk of left ventricular outflow tract obstruction. The 30-day postprocedure mean mitral prosthetic gradient ranged from 6 to 7 mm Hg, and residual MR was mild or less in 96% to 100% of individuals. The 30-day survival and 1-year survival ranged from 93% to 97% and 83% to 89%, respectively. Further longitudinal studies are needed to assess long-term outcomes. The findings are limited by the lack of comparison groups.

Eleid et al. (2017) reported 1-year outcomes of percutaneous balloon-expandable transcatheter heart valve implantation in a failed mitral bioprosthesis (n = 60), previous ring annuloplasty (n = 15), and severe MAC (n = 12). Acute procedural success was achieved in 97% of the ViV group and 74% in the valve-in-ring/valve-in-MAC group. The 30-day survival free of death and cardiovascular surgery was 95% in the ViV subgroup and 78% in the valve-in-ring/valve-in-MAC group. The 1-year survival free of death and cardiovascular surgery was 86% in the ViV group compared with 68%. At 1 year, 90% had NYHA functional class I or II symptoms, no participants had more than mild residual mitral prosthetic or periprosthetic

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regurgitation, and the mean transvalvular gradient was 7 ±3 mm Hg. The procedure for failed annuloplasty rings and severe MAC was feasible but associated with significant rates of left ventricular outflow tract obstruction, a need for a second valve, and/or cardiac surgery. This study reflects very early results with the procedure and is limited by a small sample size and lack of randomization. Further studies in a larger number of individuals treated using similar techniques and with longer follow-up duration will be necessary to continually assess the outcomes of this novel therapy.

In an observational study, Yoon et al. (2017) evaluated the outcomes of TMVR in 248 individuals with failed mitral bioprosthetic valves (ViV) and annuloplasty rings. The TMVR procedure provided acceptable outcomes in high-risk individuals with degenerated bioprostheses or failed annuloplasty rings, but mitral valve in ring was associated with higher rates of procedural complications and mid-term mortality than mitral ViV. This study is limited by the lack of randomization and a control group. Further studies evaluating the long-term outcomes in individuals undergoing TMVR for degenerated bioprostheses or failed annuloplasty rings are needed.

Pulmonary

In the prospective, single-arm, multicenter COMPASSION S3 study (n = 58), Lim et al. (2023) evaluated the safety and effectiveness of the SAPIEN 3 transcatheter heart valve for treating participants with a dysfunctional RVOT conduit or surgical valve in the pulmonary position. The primary end point was a composite of valve dysfunction at 1 year, comprising RVOT reintervention, at least moderate total pulmonary regurgitation, and a mean RVOT gradient of > 40 mm Hg. Prestenting was performed 53% of the time. At discharge, the device success was 98%. At 30 days, there were no major adverse clinical events. At 1 year, the composite primary end point of valve dysfunction occurred in 4.3% of participants. No mortality, endocarditis, thrombosis, or stent fractures were reported at 1 year. Long-term follow-up to determine the durability of these results will continue.

Cerebral Protection

There is insufficient quality evidence in the clinical literature demonstrating the efficacy of transcatheter cerebral embolic protection (CEP) devices in improving stroke, neurological, and cognitive outcomes following TAVR. Two large RCTs failed to show a benefit for stroke. Combined observational and randomized studies meta-analyses suggest benefit, but observational studies could be subject to biases.

In the BHF PROTECT-TAVI prospective, open-label, multicenter RCT, Kharbanda et al. (2025) evaluated the routine use of the SENTINEL CEP device to prevent stroke in individuals with aortic valve stenosis undergoing TAVR. Overall, 7,635 participants with aortic stenosis were randomly assigned in a 1:1 ratio to undergo TAVR with a CEP device (CEP group; n = 3,815) or TAVR without a CEP device (control group; n = 3,820). The primary outcome was stroke within 72 hours after TAVR or before discharge from the hospital (if discharge occurred sooner). Stroke occurred in 81 of 3,795 participants (2.1%) in the CEP group and in 82 of 3,799 participants (2.2%) in the control group. There were no substantial differences between the groups with respect to severe stroke, disabling stroke, or death. Overall access site complications were similar in the two groups (8.1% in the CEP group and 7.7% in the control group). In total, 24 serious adverse events occurred in 22 of 3,798 participants (0.6%) in the CEP group, and 13 serious adverse events occurred in 13 of 3,803 participants (0.3%) in the control group. Results showed that the routine use of CEP did not decrease the incidence of stroke within 72 hours. These results are consistent with reported results from the PROTECTED TAVR trial (Kapadia et al., 2022), which also showed no evidence of a treatment effect with CEP for the primary outcome of stroke. In a secondary analysis of the BHF PROTECT-TAVI population, Kennedy et al. (2025) evaluated the impact of CEP on neurocognitive function after TAVR and reported that CEP did not impact cognition after TAVR.

A prospective, postmarket, multicenter RCT was conducted by Kapadia et al. (2022) to evaluate the SENTINEL CEP device in participants with aortic stenosis undergoing transfemoral transcatheter TAVR. A total of 3,000 participants with aortic stenosis across North America, Europe, and Australia underwent randomization in a 1:1 ratio to undergo transfemoral TAVR with CEP (CEP group) or without CEP (control group); 1,501 were assigned to the CEP group and 1,499 to the control group. The primary end point was stroke within 72 hours after TAVR or before discharge (whichever came first) in the intention-to-treat population. Disabling stroke, death, transient ischemic attack, delirium, major or minor vascular complications at the CEP access site, and acute kidney injury were also assessed. A neurology professional examined all enrolled study participants at baseline and again after TAVR. A CEP device was successfully deployed in 1,406 of the 1,489 participants (94.4%) in whom an attempt was made. The incidence of stroke within 72 hours after TAVR or before discharge did not differ between the CEP group and the control group (2.3% vs 2.9%; difference, -0.6 percentage points; 95% CI, -1.7 to 0.5; p = 0.30). Disabling stroke occurred in 0.5% of the participants in the CEP group and in 1.3% of those in the control group. There were no sizeable differences between the CEP group and the control group in the percentage of participants who died (0.5% vs 0.3%); had a stroke, a transient ischemic attack, or delirium (3.1% vs 3.7%); or had acute kidney injury (0.5% vs 0.5%). One participant (0.1%) had a vascular complication at the CEP access site. The authors concluded that among participants with aortic stenosis undergoing transfemoral TAVR, the

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use of CEP did not influence the incidence of periprocedural stroke; however, based on the 95% CI around this outcome, the results may not rule out a benefit of CEP during TAVR. Limitations include a greater percentage of female participants in the CEP group, despite randomization, and a large number of enrolled participants. Female sex has been reported to be a risk factor for stroke with TAVR. Granular data on clinical outcomes were restricted to a small number of end points, with only short-term follow-up. In addition, the trial results apply only to the SENTINEL CEP device and cannot be generalized to other CEP devices.

In a letter to the editor, Radwan et al. (2021) performed a meta-analysis of studies evaluating the safety and efficacy of the SENTINEL Cerebral Protection System (CPS) during TAVR. Three RCTs and four observational studies were included (n = 117,329). The SENTINEL group was associated with a lower risk of 30-day stroke, mortality, and major bleeding. These short-term results were mainly driven from observational data, as a subgroup analysis from the RCTs showed a trend toward benefit, without statistical significance. The rate of major vascular complications was similar between the two groups. Results from large RCTs are needed to confirm these results.

Ndunda et al. (2020) performed a systematic review and meta-analysis to compare the clinical outcomes following TAVR with and without the use of the SENTINEL CPS. Four studies (three RCTs and one propensity score–matched cohort study) comparing individuals undergoing TAVR with SENTINEL CPS (n = 606) with those without any embolic protection device (n = 724) were included. SENTINEL CPS use was associated with lower rates of 30-day mortality, 30-day symptomatic stroke, and major or life-threatening bleeding. There was no significant difference between the two arms in the incidence of acute kidney injury and major vascular complications. The authors noted limitations for the analyzed studies, including lack of a control group in some studies, small sample sizes, lack of individual-level data, and missing outcomes data. Furthermore, not all included studies were randomized.

An ECRI product brief on the SENTINEL device reported that the evidence suggests that device placement is relatively safe, but whether it benefits individuals undergoing TAVR is unclear. Studies reported inconsistent findings on the device's impact on reducing stroke risk, and too few data are available on the long-term neurocognitive burden of brain microinfarction in individuals treated with the device. Additional controlled studies that report on these outcomes are needed to assess the device's effectiveness (ECRI, 2017; updated 2022d).

Bagur et al. (2017) performed a systematic review and meta-analysis evaluating the impact of embolic protection devices on cerebrovascular events during TAVR. Sixteen studies (five RCTs and 11 observational studies), involving 1,170 individuals (865/305 with/without embolic protection devices), were included. The embolic protection device delivery success rate was reported in all studies and was achieved in 94.5% of individuals. Meta-analyses comparing the two methods showed no significant differences between individuals undergoing TAVR, with or without embolic protection devices, with respect to clinically evident stroke and 30-day mortality. Embolic protection during TAVR may be associated with a smaller volume of silent ischemic lesions and smaller total volume of silent ischemic lesions. However, it may not reduce the number of new single, multiple, or total number of lesions.

In an observational cohort study, Seeger et al. (2017) evaluated the impact of CEP on stroke-free survival in 802 consecutive participants undergoing TAVR for severe aortic stenosis. The SENTINEL CEP device was used in 34.9% (n = 280) of participants. In the remaining group of participants, TAVR was performed without CEP. In participants undergoing TAVR, use of a CEP device demonstrated a significantly higher rate of stroke-free survival than unprotected TAVR. This study is limited by the lack of randomization.

In two RCTs (Kapadia et al., 2017; Van Mieghem et al., 2016), the primary efficacy end point was reduction in the volume of new cerebral lesions on diffusion-weighted magnetic resonance imaging (diffusion-weighted evaluation) up to 7 days post TAVR, a surrogate end point for cerebral damage. This end point was not met in either trial, although both trials demonstrated a nonsignificant numerical reduction in new cerebral lesions favoring the SENTINEL device over no transcatheter CEP. In addition, both trials were limited by small sample sizes and poor compliance with diffusion-weighted magnetic resonance imaging follow-up, which was missing for 21% of SENTINEL trial participants (Kapadia et al., 2017) and 43% of MISTRAL-C trial participants (Van Mieghem et al., 2016).

In the Claret Embolic Protection and TAVI (CLEAN-TAVI) trial, Haussig et al. (2016) evaluated the effect of a cerebral protection device on the number and volume of cerebral lesions in participants undergoing TAVR. Overall, 100 participants were randomly assigned to undergo TAVR with a cerebral protection device (filter group; n = 50) or without a cerebral protection device (control group; n = 50). Brain magnetic resonance imaging was performed at baseline, 2 days, and 7 days after TAVR. The use of a cerebral protection device reduced the frequency of ischemic cerebral lesions in potentially protected regions. The number of new lesions was 4.00 in the filter group and 10.00 in the control group. New lesion volume after TAVR was 242 mm^3 in the filter group and 527 mm^3 in the control group. One participant in the control group died prior to the 30-day visit. Life-threatening hemorrhages occurred in one participant in the filter group and one in

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the control group. Major vascular complications occurred in five participants in the filter group and six participants in the control group. One participant in the filter group and five in the control group had acute kidney injury, and three participants in the filter group had a thoracotomy. Larger studies, with longer follow-up, are needed to assess the effect of cerebral protection device use on neurological and cognitive function after TAVR. This study is registered under clinical trial number NCT01833052 on the ClinicalTrials.gov website.

Giustino et al. (2016) conducted a systematic review and meta-analysis of four RCTs (n = 252) that tested the safety and efficacy of embolic protection during TAVR. Use of embolic protection was associated with lower total lesion volume and a smaller number of new ischemic lesions. Embolic protection was associated with a trend toward lower risk for deterioration in National Institutes of Health Stroke Scale score at discharge and higher Montreal Cognitive Assessment score. Risk for overt stroke and all-cause mortality were not significantly lower in the embolic protection group. The authors noted that the findings are subject to the inherent limitations of the included trials due to study design, length of follow-up, imaging, and neurocognitive assessment dropout. Some of the end points were not available in all the included trials. Most of the valves used were first-generation TAVR devices. Given the substantial limitations of the included studies, the results are only hypothesis generating. Further prospective, adequately powered RCTs are needed to establish the role of embolic protection during TAVR.

Clinical Practice Guidelines

American College of Cardiology (ACC) et al.

The ACC/American Heart Association guidelines for the management of patients with valvular heart disease (Otto et al., 2021) make the following recommendations regarding transcatheter valve therapies.

Aortic

In patients with an indication for aortic valve replacement, the choice of prosthetic valve should be based on a shared decision-making process that accounts for the patient's values and preferences and includes discussion of the indications for and risks of anticoagulant therapy and the potential need for and risks associated with valve reintervention. In patients with BAV and symptomatic severe aortic stenosis, TAVR may be considered as an alternative to SAVR after consideration of patient-specific procedural risks, values, trade-offs, and preferences and when the surgery is performed at a Comprehensive Valve Center. RCTs are needed to obtain full clarity on the optimal use of TAVR in this population as well as long-term outcomes.

Mitral

In severely symptomatic patients (NYHA class III or IV) with primary severe MR and a high or prohibitive surgical risk, TEER is reasonable if mitral valve anatomy is favorable for the repair procedure and the patient's life expectancy is at least 1 year.

In patients with chronic, severe secondary MR related to left ventricular systolic dysfunction (LVEF < 50%) who have persistent symptoms (NYHA class II, III, or IV) while on optimal guideline-directed management and therapy for heart failure, TEER is reasonable in patients with appropriate anatomy, as defined on transesophageal echocardiography, and with an LVEF between 20% and 50%, left ventricular end-systolic dimension of ≤ 70 mm, and pulmonary artery systolic pressure of ≤ 70 mm Hg.

Pulmonary

TPVR is outside the scope of these guidelines. Refer to Gurvitz et al. (2025).

Tricuspid

The guideline does not address the transcatheter approach for tricuspid valve replacement.

Valve-in-Valve

For severely symptomatic patients with bioprosthetic aortic valve stenosis and a high or prohibitive surgical risk, a transcatheter ViV procedure is reasonable when performed at a Comprehensive Valve Center.

For patients with severe heart failure symptoms caused by bioprosthetic valve regurgitation who are at a high to prohibitive surgical risk, a transcatheter ViV procedure is reasonable when performed at a Comprehensive Valve Center.

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Congenital Heart Disease

Joint guidelines on the management of adults with congenital heart disease address interventions for patients with RVOT dysfunction. Interventions include surgical replacement, percutaneous stenting, and/or transcatheter valve placement. Patients with moderate or greater conduit regurgitation or stenosis who have worsening exercise capacity or sustained arrhythmias (atrial or ventricular) can benefit from surgical or transcatheter conduit intervention, by an operator with adult congenital heart disease expertise, to relieve stenosis and/or regurgitation. Transcatheter stent implantation and pulmonary valve replacement may be performed with high procedural success and low mortality rates, and the procedure may improve cardiovascular status, such as improved hemodynamics and exercise capacity. Surgical conduit replacement carries a higher risk for periprocedural complications, with good long-term outcomes. Predictors of conduit dysfunction and reoperation include placement of small-diameter conduits; therefore, insertion of conduits with the largest possible diameter should be attempted, with the anticipation of possible subsequent transcatheter valve replacement, such as ViV (Gurvitz et al., 2025).

Low-Flow, Low-Gradient Aortic Stenosis

A multisociety group published appropriate use criteria for the treatment of severe aortic stenosis that include criteria for patients with LF-LG aortic stenosis (Bonow et al., 2017).

Institutional Requirements

A multisociety group released an expert consensus statement outlining operator and institutional recommendations and requirements for creating and maintaining transcatheter aortic valve replacement programs. The recommendations are aimed at ensuring optimal patient care (Bavaria et al., 2018). The same organizations released similar statements addressing transcatheter therapies for mitral valve procedures (Bonow et al., 2020) and pulmonary valve procedures (Hijazi et al., 2015).

European Society of Cardiology (ESC)

The ESC guidelines for the management of adult congenital heart disease state that transcatheter pulmonary valve implantation techniques are an alternative to open heart surgery in patients with RVOT conduit stenosis/regurgitation. Transcatheter replacement, when technically feasible, provides outcomes comparable to those with surgical pulmonary valve replacement and is intended to extend the lifetime of a conduit, reducing the number of reoperations during a patient's lifetime. The guidelines also note that future replacement of a dysfunctional valve could be performed by a transcatheter ViV procedure (Baumgartner et al., 2020).

European Society of Cardiology (ESC)/European Association for Cardio-Thoracic Surgery (EACTS)

In a joint guideline for the management of valvular heart disease, the ESC and EACTS (Praz et al., 2025) recommend the following with regard to transcatheter heart valve procedures.

Aortic

The guideline recommends that the selection of the most appropriate mode of intervention for aortic stenosis should take into account clinical characteristics, such as age, estimated life expectancy, concomitant conditions, access and valve anatomy, and surgical risk as well as repeat procedure options and risks (lifetime management).

The guideline recommends SAVR in younger patients with aortic stenosis who are at a low risk for surgery (< 70 years and with a low surgical risk) or in patients who are operable and unsuitable for transfemoral TAVI. TAVI is recommended in older patients (≥ 70 years with a tricuspid aortic valve), if the patient's anatomy is suitable and transfemoral access is feasible, to reduce the risk of early adverse outcomes and to accelerate recovery. SAVR or TAVI is recommended for remaining patients, according to procedural risk based on anatomical characteristics and comorbidities, expected outcomes, lifetime management considerations, and patient preference.

For aortic regurgitation, the guideline states that TAVI may be considered at experienced centers for selected patients with aortic regurgitation who are ineligible for surgery. The guideline notes that the use of nondedicated transcatheter valves for this indication is off label and associated with an increased risk of valve malpositioning and residual aortic regurgitation, along with higher rates of second valve implantation (approximately 10%) or surgical conversion, compared with TAVI in aortic stenosis. Additionally, dedicated devices appear to minimize the risk of valve migration and residual aortic regurgitation in select patients; however, they are also associated with a high new permanent pacemaker implantation rate in 24% of cases. The guideline concludes that current transcatheter options for aortic regurgitation are limited and applicable only in patients who are ineligible for surgery.

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Mitral

According to the guideline, surgical mitral valve repair is the preferred method of treatment in severe primary MR, while TEER is recommended in those patients who are inoperable or high risk. Surgical mitral valve repair is also the procedure of choice for asymptomatic patients with primary MR and signs of cardiac damage, including moderate or more MR. In patients with ventricular secondary MR, GDMT is the initial and essential treatment step, while mitral TEER is recommended in symptomatic patients without coronary artery disease needing revascularizaton.

Tricuspid

The guideline indicates that tricuspid valve repair using an annuloplasty ring is preferred over replacement, whenever technically feasible, especially in low-risk patients with suitable anatomy; however, tricuspid valve replacement may be necessary in cases of advanced disease with marked annular dilation and leaflet tethering. In isolated, severe tricuspid regurgitation without severe right ventricular dysfunction, surgery should be performed at an early stage in patients at low operative risk, while T-TEER or transcatheter replacement should be considered to improve quality of life and right ventricular remodeling in the absence of severe right ventricular dysfunction or precapillary pulmonary hypertension in isolated, severe cases in patients with severe tricuspid regurgitation at increased surgical risk.

Valve-in-Valve

According to the guideline, implanting a transcatheter aortic valve inside a surgical or prior transcatheter valve is associated with lower periprocedural risk than a redo SAVR. However, ViV implantation increases the risk of severe prosthesis-patient mismatch, and it immobilizes the leaflets of the failed prosthesis in an open position, which creates a covered tube that may cause direct coronary obstruction in those with shallow sinuses of Valsalva or indirect coronary flow obstruction due to sinus sequestration if the ascending aorta is narrow and the neoskirt reaches the sinotubular junction.

The guideline states that transcatheter ViV implantation in the tricuspid position has been reported to be performed with satisfactory results and, in the case of biological heart valve degeneration, transcatheter ViV procedures are good alternatives to re-replacement. The guideline also states that decisions about the treatment modality for valve repair (redo surgery or transcatheter ViV implantation) should be made within the interdisciplinary heart team, depending on reoperation risk and anatomical reconsiderations, including the risk of coronary obstruction as well as prosthesis type and size; additionally, when considering a ViV procedure for a degenerated aortic biological heart valve, the possibility of creating a prosthetic-patient mismatch in small valves should be anticipated and may impact intervention or valve selection. Given the larger sizes of biological heart valves in mitral and tricuspid positions, the guideline states that transfemoral/transseptal ViV implantation represents an attractive alternative to redo open surgery. With mitral ViV, the risk of left ventricular outflow tract obstruction should be ruled out, especially in patients with small and hypertrophic ventricles.

National Institute for Health and Care Excellence (NICE)

NICE published an interventional procedures guidance (IPG) for transcatheter tricuspid valve annuloplasty for tricuspid regurgitation, in which they state that the evidence on the efficacy of transcatheter tricuspid valve annuloplasty is limited in quantity and quality and that the evidence on safety shows that there are serious but well-recognized complications when this procedure is done in people with severe and symptomatic tricuspid regurgitation. For people with mild or moderate tricuspid regurgitation, the evidence is inadequate in quantity and quality for the safety and efficacy of this procedure (NICE, 2022a).

In another IPG published by NICE that addresses transcatheter tricuspid valve leaflet repair for tricuspid regurgitation, NICE states that the evidence on the efficacy of transcatheter valve leaflet repair is limited in quantity and quality for people with severe and symptomatic tricuspid regurgitation. The IPG also states that the evidence on its safety shows that there are serious but well-recognized complications. For people with mild or moderate tricuspid regurgitation, the IPG states that the evidence is inadequate in quantity and quality for the safety and efficacy of transcatheter tricuspid valve leaflet repair (NICE, 2022b).

NICE published an overarching guideline for heart valve disease presenting in adults. In the evidence review supporting documentation for the guideline, NICE states that transcatheter valve interventions may allow for quicker recovery if the procedure is uncomplicated and notes that the abnormal valve is not removed using the transcatheter approach; rather, the abnormal valve is pushed aside to allow for the prosthetic valve to be implanted.

For aortic valve disease, this guideline states that TAVI is clinically effective for patients defined as intermediate or low risk for cardiac surgery for aortic valve disease. For aortic stenosis, the guideline states that transcatheter interventions are currently only indicated for symptomatic patients; however, for aortic regurgitation, there is no current accepted

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transcatheter intervention. The guideline also states that there is no evidence for TAVI valve durability beyond 6 to 7 years and that there is evidence of valve leaflet deterioration due to crimping, which cannot be avoided when a valve is implanted through a catheter.

With regard to mitral stenosis, this guideline on heart valve disease in adults recommends transcatheter valvotomy for adults with rheumatic severe mitral stenosis if the valve is suitable for the procedure or surgical mitral valve replacement when the transcatheter valvotomy is not suitable. TEER is recommended, if suitable, for adults with severe primary MR and symptoms when surgery is unsuitable and for adults with heart failure and severe secondary MR if surgery is unsuitable and the patient remains symptomatic on medical management.

The guideline does not include any guidance for transcatheter tricuspid valve repair for tricuspid regurgitation (NICE, 2021a).

A NICE guidance document states that the current evidence on the safety of transapical transcatheter mitral ViV implantation for a failed surgically implanted mitral valve bioprosthesis shows some serious but well-recognized complications. Evidence on its efficacy is limited in quality. This procedure should only be used with special arrangements for clinical governance, consent, and audit or research (NICE, 2021b).

A NICE IPG on the transapical transcatheter mitral valve-in-ring implantation procedure states that the evidence on the safety of this procedure after failed mitral valve repair surgery is adequate and shows some serious but well-recognized complications. It also states that the evidence on this procedure's efficacy is limited in quality and that the procedure should only be used with special arrangements for clinical governance, consent, and audit or research (NICE, 2021c).

A NICE guidance document states that the evidence on the safety and efficacy of ViV TAVR for aortic bioprosthetic dysfunction is adequate to support the use of this procedure, provided that standard arrangements are in place for clinical governance, consent, and audit. The report also notes that long-term evidence for ViV TAVR is from earlier-generation devices. The technology is evolving, and longer-term evidence is needed (NICE, 2019a).

A NICE guidance document states that transcatheter insertion of a cerebral protection device to prevent cerebral embolism during TAVR raises no major safety concerns other than those associated with the TAVR procedure. However, the evidence on efficacy for preventing TAVR-related stroke is inconclusive. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research (NICE, 2019b).

A NICE guidance document states that evidence on the safety and efficacy of percutaneous mitral valve leaflet repair for MR is adequate to support the use of this procedure in patients for whom open surgery is contraindicated following risk assessment, provided that standard arrangements are in place for clinical governance, consent, and audit (NICE, 2019c).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Aortic

FDA approval status for transcatheter aortic valve prostheses can be found by searching the FDA's Premarket Approval database using product code NPT: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm.
(Accessed December 30, 2025)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130021
- Evolut™ FX (Medtronic)
- Evolut PRO (Medtronic)
- Evolut R (Medtronic)

(Accessed December 30, 2025)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190023
- Navitor™ (Abbott)

(Accessed December 30, 2025)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031
- SAPIEN 3 Ultra RESILIA (Edwards Lifesciences)
- SAPIEN 3 Ultra (Edwards Lifesciences)

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- SAPIEN 3 (Edwards Lifesciences)

(Accessed December 30, 2025)

Mitral

FDA approval status for transcatheter mitral valve prostheses can be found by searching the FDA's Premarket Approval database using product code NPU: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed December 30, 2025)

FDA approval status for transcatheter mitral valve repair devices can be found by searching the FDA's Premarket Approval database using product code NKM: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed December 30, 2025)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100009

- MitraClip (Abbott)

(Accessed December 30, 2025)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P220003

- PASCAL (Edwards Lifesciences)

(Accessed December 30, 2025)

Pulmonary

FDA approval status for transcatheter pulmonary valve prostheses and related devices can be found by searching the FDA's Premarket Approval database using product code NPV: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed December 30, 2025)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200046

- Harmony (Medtronic)

(Accessed December 30, 2025)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140017

- Melody (Medtronic)

(Accessed December 30, 2025)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200015

- SAPIEN 3 (Edwards Lifesciences)
- SAPIEN 3 with Alterra Adaptive Prestent (Edwards Lifesciences)

(Accessed December 30, 2025)

Tricuspid

FDA approval status for transcatheter tricuspid valve prostheses can be found by searching the FDA's Premarket Approval database using product code NPW: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed December 30, 2025)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230013

- EVOQUE (Edwards Lifesciences)

(Accessed December 30, 2025)

FDA approval status for transcatheter tricuspid valve repair devices can be found by searching the FDA's Premarket Approval database using product code NPS: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed December 30, 2025)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230007

- TriClip (Abbott)

(Accessed December 30, 2025)

Cerebral Protection

FDA approval status for cerebral embolic protection devices used during transcatheter intracardiac procedures can be found by searching the FDA's De Novo or 510(k) Premarket Notification database using product code PUM:

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https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm or https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

- SENTINEL (Boston Scientific)

(Accessed December 30, 2025)

Additional Products

The following products may not have full FDA approval:

- AltaValve™
- Cardioband
- Carillon Mitral Contour System
- Harpoon
- Intrepid™ (Medtronic)
- NeoChord
- TricValve
- TriGUARD 3™ (Keystone Heart)

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Policy History/Revision Information

Date	Summary of Changes
07/01/2026	**Coverage Rationale** ***Mitral*** • Replaced language indicating: ○ "Transcatheter mitral heart valve repair (e.g., annuloplasty), except where noted [as proven and medically necessary in the policy], is unproven and not medically necessary" with "transcatheter mitral heart valve repair *or reconstruction* (e.g., annuloplasty), except where noted [as proven and medically necessary in the policy], is unproven and not medically necessary" ○ "Transcatheter mitral heart valve r*econstruction or* replacement is unproven and not medically necessary" with "transcatheter mitral heart valve replacement is unproven and not medically necessary" • Added notation to indicate requests for transcatheter valve-in-valve replacement within a failed bioprosthetic mitral valve will be considered on a case-by-case basis ***Pulmonary*** • Added language to clarify transcatheter pulmonary heart valve replacement *(including valve-in-valve)* and related devices (e.g., Alterra) are proven and medically necessary when used according to FDA-labeled indications, contraindications, warnings, and precautions in individuals with right ventricular outflow tract dysfunction, with one of the [listed] clinical indications for intervention ***Tricuspid*** • Added language to indicate transcatheter tricuspid heart valve repair or reconstruction (e.g., annuloplasty), except where noted [as proven and medically necessary in the policy], is unproven and not medically necessary due to insufficient evidence of efficacy • Replaced language indicating "transcatheter tricuspid heart valve *reconstruction or* replacement is unproven and not medically necessary due to insufficient evidence of efficacy" with "transcatheter tricuspid heart valve replacement *(including valve-in-valve)* is unproven and not medically necessary due to insufficient evidence of efficacy" ***Other Devices and Procedures*** • Revised list of unproven and not medically necessary devices/procedures; removed "valve-in-valve replacement within a failed bioprosthesis for mitral, pulmonary, or tricuspid valves" **Definitions** • Updated definition of "CMS Volume Requirements for Transcatheter Aortic Heart Valve Replacement"

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Date	Summary of Changes
	Supporting Information • Updated *Benefit Considerations*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version 2026T0557EE

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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