



MEDICAL COVERAGE POLICY

SERVICE: Transcatheter Valve Replacement or Repair

Policy Number: 204

Effective Date: 05/01/2025

Last Review: 04/14/2025

Next Review: 04/14/2026

Important note: Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.

SERVICE: Transcatheter valve replacement or repair (TAVR, TPVI and TMVR)

PRIOR AUTHORIZATION: Required

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). [NCD 20.32 Transcatheter Aortic Valve Replacement \(TAVR\)](#), [NCD 20.33 Transcatheter Mitral Valve Repair \(TMVR\)](#). Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the [Texas Medicaid Provider Procedures Manual | TMHP](#) (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

BSWHP may consider transcatheter aortic valve replacement (TAVR) with devices and indications approved by the FDA medically necessary for members with symptomatic aortic valve stenosis:

- For commercial plans, please review using InterQual®
- For Medicare, please review using criteria set forth in [NCD 20.32 Transcatheter Aortic Valve Replacement \(TAVR\)](#). See [Medicare Approved Facilities/Trials/Registries](#) for additional requirements.

Transcatheter aortic valve replacement is considered experimental, investigational and/or unproven for all other indications.

BSWHP may consider transcatheter pulmonary valve implantation (TPVI) medically necessary for members with prior repair of congenital heart disease and right ventricular outflow tract dysfunction, who are not good candidates for open repair due to one or more of the following conditions:

- High-risk for surgery due to concomitant medical comorbidities; OR
- Poor surgical candidate due to multiple prior thoracotomies for open heart surgery.

Transcatheter pulmonary valve implantation is considered experimental, investigational and/or unproven for all other indications.



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BSWHP may consider transcatheter mitral valve repair (TMVR) with a device approved by the FDA medically necessary for patients with symptomatic mitral regurgitation who are considered at high risk for traditional open-heart mitral valve surgery.

- For Commercial and Medicare lines of business, please review using [NCD 20.33 Transcatheter Mitral Valve Repair \(TMVR\)](#). See [Medicare Approved Facilities/Trials/Registries](#) for additional requirements for Medicare lines of business.

BSWHP considers transcatheter mitral valve implantation/replacement (TMVI) experimental, investigational and/or unproven for ALL indications.

BACKGROUND:

Aortic stenosis is the most commonly acquired valvular heart disease in the Western world. Surgical aortic valve replacement is currently the gold-standard treatment for patients with severe symptomatic aortic stenosis. Without surgery, the prognosis is extremely poor, with a 3-year survival rate of less than 30%. (Sambu N, Curzen N. Transcatheter aortic valve implantation: The state of play. *Future Cardiol.* 2010; 6(2):243-254.) However, due to age and/or other co-morbidities not everyone is a suitable candidate for invasive surgery. Thus, a number of less invasive techniques for valvular replacement and repair, have been developed.

Transcatheter aortic valve implantation or replacement (TAVI/TAVR) may be an alternative treatment for patients with severe aortic stenosis. It is not expected to replace current surgical care for aortic valve replacement, but may be an alternative to non-surgical therapy for patients with a prohibitive risk for surgery. According to the American Heart Association TAVI/TAVR repairs the valve without removing the old, damaged valve. Instead, it wedges a replacement valve into the aortic valve's place.

Transcatheter mitral valve repair is used in the treatment of mitral regurgitation. A TMVR device involves clipping together a portion of the mitral valve leaflets as treatment for reducing mitral regurgitation. Currently, Abbott's MitraClipR, an edge-to-edge leaflet repair device is currently the only one with United States Food & Drug Administration (FDA) approval for TMVR. The Mitraclip is currently FDA approved for commercial use only in patients with moderate-severe or severe primary (degenerate) MR.

Candidates for Transcatheter Mitral Valve Repair – a multidisciplinary dedicated heart team approach (including primary [general] cardiologists, interventional cardiologists, cardiac surgeons, imaging specialists, valve and heart failure specialists, and cardiac anesthesiologists) is recommended for the evaluation and care of potential candidates for TMVR.

MANDATES:

There are no mandated benefits or regulatory requirements for BSWHP to provide coverage for these services.



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CODES:

Important note: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes	33361 - TAVR with prosthetic valve; percutaneous femoral artery approach 33362 - TAVR with prosthetic valve; open femoral artery approach 33363 - TAVR with prosthetic valve; open axillary artery approach 33364 - TAVR with prosthetic valve; open iliac artery approach 33365 - TAVR with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy) 33366 - TAVR with prosthetic valve; transapical exposure (eg, left thoracotomy) 33418 - Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis 33477 - Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site 0345T - Transcatheter mitral valve repair percutaneous approach via the coronary sinus (MitraClip)
CPT Codes Not Covered	0483T - Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous 0484T Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic
ICD-10 Codes	I06.0 - Rheumatic aortic stenosis I08.0 - Rheumatic disorders of both mitral and aortic valves I34.0 - I34.9 Mitral valve disorders (symptomatic degenerative mitral regurgitation) I35.0 - I35.9 Nonrheumatic aortic valve disorders (stenosis) T82.01x+ Breakdown (mechanical) of heart valve prosthesis (degenerated bioprosthetic aortic valve) T82.03x+ Leakage of heart valve prosthesis (degenerated bioprosthetic aortic valve) T82.857+ Stenosis of cardiac prosthetic devices, implants and grafts (degenerated bioprosthetic aortic valve) I06.x - Rheumatic aortic valve disease I05.x - Rheumatic mitral valve disease Q23.2 - Q23.8 – Congenital mitral valve disease Z95.2 - Presence of prosthetic heart valve

POLICY HISTORY:

Status	Date	Action
New	11/29/2012	New policy after review at TAC March 2012
Review	07/11/2013	Minor updates
Review	11/14/2013	ICD10 codes added
Review	11/06/2014	Criteria updated based on current NCD language

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Review	10/22/2015	Added TMVR coverage
Review	11/17/2016	Updated policy language
Review	10/17/2017	Updated "Overview." Confirmed criteria.
Review	09/25/2018	Updated language. Added criteria for pulmonary valve
Review	11/21/2019	Updated to align with new CMS guidelines
Updated	05/28/2020	Reviewed and aligned for FirstCare and SWHP
Review	05/27/2021	No changes
Review	05/26/2022	Updated language for Medicare coverage
Review	05/25/2023	No changes
Review	06/10/2024	Formatting changes, added hyperlinks to CMS and TMPPM resources, beginning and ending note sections updated to align with CMS requirements and business entity changes.
Review	04/14/2025	No changes

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Kallenchbach K, Karck M. Percutaneous aortic valve implantation - contra. Herz. 2009; 34(2):130-139.
2. Bleiziffer S, Ruge H, Mazzitelli D, et al. Survival after transapical and transfemoral aortic valve implantation: Talking about two different patient populations. J Thorac Cardiovasc Surg. 2009; 138(5):1073-1080.
3. Sambu N, Curzen N. Transcatheter aortic valve implantation: The state of play. Future Cardiol. 2010; 6(2):243-254.
4. Rodés-Cabau J, Webb JG, Cheung A, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: Acute and late outcomes of the multicenter Canadian experience. J Am Coll Cardiol. 2010; 55(11):1080-1090.
5. Ye J, Cheung A, Lichtenstein SV, et al. Transapical transcatheter aortic valve implantation: Follow-up to 3 years. J Thorac Cardiovasc Surg. 2010; 139(5):1107-1113.
6. Attias D, Himbert D, Ducrocq G, et al. Immediate and mid-term results of transfemoral aortic valve implantation using either the Edwards Sapien transcatheter heart valve or the Medtronic CoreValve System in high-risk patients with aortic stenosis. Arch Cardiovasc Dis. 2010; 103(4):236-245.
7. Rajani R, Buxton W, Haworth P, et al. Prognostic benefit of transcatheter aortic valve implantation compared with medical therapy in patients with inoperable aortic stenosis. Catheter Cardiovasc Interv. 2010; 75(7):1121-1126.
8. Avanzas P, Muñoz-García AJ, Segura J, et al. Percutaneous implantation of the CoreValve self-expanding aortic valve prosthesis in patients with severe aortic stenosis: Early experience in Spain. Rev Esp Cardiol. 2010; 63(2):141-148.
9. Leon MB, Smith CR, Mack M, et al; PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010; 363(17):1597-1607.
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12. Dworakowski R, MacCarthy PA, Monaghan M, et al. Transcatheter aortic valve implantation for severe aortic stenosis-a



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 14. Buellesfeld L, Gerckens U, Schuler G, et al. 2-year follow-up of patients undergoing transcatheter aortic valve implantation using a self-expanding valve prosthesis. J Am Coll Cardiol. 2011; 57(16):1650-1657.
 15. Smith CR, Leon MB, Mack MJ, et al; PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011; 364(23):2187-2198.
 16. Thomas M, Schymik G, Walther T, et al. One-year outcomes of cohort 1 in the Edwards SAPIEN aortic bioprosthesis European outcome (SOURCE) registry: The European Registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve. Circulation. 2011; 124(4):425-433.
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 21. Armstrong, Ehrin J, Foster, Elyse Transcatheter mitral valve repair. Up-to-Date. September 15, 2017. Topic 99943, Version 9.0.
 22. Prof. Luc Pierard, FESC, Transcatheter Aortic Valve Implantation: Indications; European Society of Cardiology Vol.14,N°1 - 12 Jan 2016
 23. CMS CAG-00430R published October, 2019

Note:

Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSA's; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.