



MEDICAL COVERAGE POLICY

TOPIC: Transcatheter Valve Replacement or Repair

Policy Number: 204

Effective Date: 07/01/2023

Last Review: 05/25/2023

Next Review Date: 05/25/2024

Important note:

Unless otherwise indicated, this policy will apply to all lines of business.

Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

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.

For Medicare plans, please refer to appropriate Medicare LCD (Local Coverage Determination). If there is no applicable LCD, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM.

Transcatheter aortic valve replacement (TAVR) with devices and indications approved by the FDA may be considered 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](#). See Medicare [registry / clinical study approvals](#) for additional requirements.

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

Transcatheter pulmonary valve implantation (TPVI) may be considered 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.

Transcatheter mitral valve repair (TMVR) with a device approved by the FDA may be considered 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](#). For Medicare lines of business, see Medicare [registry / clinical study approvals](#) for additional requirements.

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Transcatheter mitral valve implantation/replacement (TMVI) is considered experimental, investigational and/or unproven for ALL indications.

OVERVIEW:

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.

Technical Assessment: Reviewed at TAC in March 2012

CMS: NCD TAVR 20.32 (1/7/2013) and NCD TMVR 20.33 (4/6/2015)

LCD L32691 (6/20/2013) contains category III codes.

CAG-00430R

CODES:

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

POLICY HISTORY:

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

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

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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. Kallenbach 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.
10. Lazar HL. Transcatheter aortic valves -- Where do we go from here? N Engl J Med. 2010; 363(17):1667-1668.
11. Clavel MA, Webb JG, Rodés-Cabau J, et al. Comparison between transcatheter and surgical prosthetic valve implantation in patients with severe aortic stenosis and reduced left ventricular ejection fraction. Circulation. 2010; 122(19):1928-1936.
12. Dworakowski R, MacCarthy PA, Monaghan M, et al. Transcatheter aortic valve implantation for severe aortic stenosis-a new paradigm for multidisciplinary intervention: A prospective cohort study. Am Heart J. 2010; 160(2):237-243.
13. Zahn R, Gerckens U, Grube E, et al; German Transcatheter Aortic Valve Interventions-Registry Investigators. Transcatheter aortic valve implantation: First results from a multi-centre real-world registry. Eur Heart J. 2011; 32(2):198-204.
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.
17. Kalavrouziotis D, Rodés-Cabau J, Bagur R, et al. Transcatheter aortic valve implantation in patients with severe aortic stenosis and small aortic annulus. J Am Coll Cardiol. 2011; 58(10):1016-1024.
18. Georgiadou P, Kontodima P, Sbarouni E, et al. Long-term quality of life improvement after transcatheter aortic valve implantation. Am Heart J. 2011; 162(2):232-237.



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20. Food and Drug Administration. FDA approves first artificial aortic heart valve placed without open-heart surgery. FDA: Silver Spring, MD. November 2, 2011. Available at: <https://www.prnewswire.com/news-releases/fda-approves-first-artificial-aortic-heart-valve-placed-without-open-heart-surgery-133108353.html> Last accessed 10/15/2017
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 Plans.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSA's. Individual HMO plans are offered through FirstCare in West Texas.