



MEDICAL COVERAGE POLICY

TOPIC: Transcatheter Valve Replacement or Repair

Policy Number: 204

Effective Date: 07/01/2021

Last Review: 05/27/2021

Next Review Date: 05/27/2022

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) may be considered medically necessary for members with aortic stenosis when the requirements set forth in CMS CAG-00430R are fully met.

A copy of decision summary is attached starting on page 6. The full CMS Decision Memo can be found here: <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=293&type=Closed&bc=ACAAAAAAQAAA&>

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, degenerative mitral regurgitation who are considered at high risk for traditional open-heart mitral valve surgery.

For Medicare lines of business, see NCD 20.33 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, as well as the CARILLON mitral annuloplasty device, has CE Mark approval. (The CARILLON mitral annuloplasty device is considered to be an investigational technology). 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 SWHP 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
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	<p>33364 TAVR with prosthetic valve; open iliac artery approach</p> <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>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>Q23.0 Congenital stenosis of aortic valve</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>I35.0 - I35.8 Non-rheumatic aortic valve disease</p> <p>Q23.0 - Q23.1 Congenital stenosis/insufficiency aortic valve</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

REFERENCES

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the



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published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP 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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19. Ussia GP, Barbanti M, Cammalleri V, et al. Quality-of-life in elderly patients one year after transcatheter aortic valve implantation for severe aortic stenosis. *EuroIntervention*. 2011; 7(5):573-579.
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
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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

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Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Decision Summary

The Centers for Medicare & Medicaid Services (CMS) will cover Transcatheter Aortic Valve Replacement (TAVR) for the treatment of symptomatic aortic valve stenosis through Coverage with Evidence Development (CED).

A. TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the following conditions are met:

1. The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication.
2. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. The heart team includes the following:
 - a. Cardiac surgeon and an interventional cardiologist experienced in the care and treatment of aortic stenosis who have:
 - i. independently examined the patient face-to-face, evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy;
 - ii. documented and made available to the other heart team members the rationale for their clinical judgment.
 - b. Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel and administrators.
3. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
4. TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
 - a. On-site heart valve surgery and interventional cardiology programs,
 - b. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,
 - c. Appropriate volume requirements per the applicable qualifications below:

There are two sets of qualifications; the first set outlined below is for hospital programs and heart teams without previous TAVR experience and the second set is for those with TAVR experience.

Qualifications to begin a TAVR program for hospitals without TAVR experience:

The hospital program must have the following:

- a. \geq 50 open heart surgeries in the previous year prior to TAVR program initiation, and;
- b. \geq 20 aortic valve related procedures in the 2 years prior to TAVR program initiation, and;
- c. \geq 2 physicians with cardiac surgery privileges, and;
- d. \geq 1 physician with interventional cardiology privileges, and;
- e. \geq 300 percutaneous coronary interventions (PCIs) per year.

Qualifications to begin a TAVR program for heart teams without TAVR experience:



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The heart team must include:

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

Qualifications for hospital programs with TAVR experience:

The hospital program must maintain the following:

- a. ≥ 50 AVRs (TAVR or SAVR) per year including ≥ 20 TAVR procedures in the prior year ; or,
 - b. ≥ 100 AVRs (TAVR or SAVR) every 2 years, including ≥ 40 TAVR procedures in the prior 2 years; and,
 - c. ≥ 2 physicians with cardiac surgery privileges; and,
 - d. ≥ 1 physician with interventional cardiology privileges, and
 - e. ≥ 300 percutaneous coronary interventions (PCIs) per year; and,
5. The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TAVR patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 CFR Part 46 and 21 CFR Parts 50 & 56.

The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient, practitioner and facility level variables that predict each of these outcomes:

- i. Stroke;
 - ii. All-cause mortality;
 - iii. Transient Ischemic Attacks (TIAs);
 - iv. Major vascular events;
 - v. Acute kidney injury;
 - vi. Repeat aortic valve procedures;
 - vii. New permanent pacemaker implantation;
 - viii. Quality of Life (QoL).
6. The registry shall collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary). Specifically, for the CED question iv, this must be addressed through a composite metric. For the below CED questions (i-iv), the results must be reported publicly as described in CED criterion k.
- i. When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
 - ii. What is the long term durability of the device?
 - iii. What are the long term outcomes and adverse events?
 - iv. What morbidity and procedure-related factors contribute to TAVR patients outcomes?

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

B. TAVR is covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the following:

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1. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
2. As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient's quality of life pre- and post-TAVR (minimum of 1 year), but must also address at least one of the following questions:
 - What is the incidence of stroke?
 - What is the rate of all-cause mortality?
 - What is the incidence of new permanent pacemaker implantation?
 - What is the incidence of transient ischemic attacks (TIAs)?
 - What is the incidence of major vascular events?
 - What is the incidence of acute kidney injury?
 - What is the incidence of repeat aortic valve procedures?
3. The clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:
 - a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
 - b. The rationale for the study is well supported by available scientific and medical evidence.
 - c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
 - d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
 - e. The study is sponsored by an organization or individual capable of completing it successfully.
 - f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and /or services, and the use and eventual disposition of the collected data
 - g. All aspects of the research study are conducted according to appropriate standards of scientific integrity.
 - h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
 - i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
 - j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
 - k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessible manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
 - l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.



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m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that meet the above-listed standards and address the above-listed research questions.

The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed, and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS Website.

Director, Coverage and Analysis Group
Re: TAVR CED
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

Email address for protocol submissions: clinicalstudynotification@cms.hhs.gov
Email subject line: "CED [NCD topic (i.e. TAVR)] [name of sponsor/primary investigator]"