Transcatheter Mitral Valve Repair/Replacement

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Application:	All participating hospitals and providers
Page Number(s):	1 of 9

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary benefits.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Transcatheter Mitral Valve Repair/Replacement (TMVR) – A minimally invasive procedure that uses catheter-based technology that emulates surgical annuloplasty and edge-to-edge repair of regurgitant mitral valves. TMVR is performed on a beating heart with no cardiopulmonary bypass.

POLICY POSITION

Prior authorization is required.

TMVR with a device approved by the United States (U.S.) Food and Drug Administration (FDA) for use in mitral valve repair may be considered medically necessary when individual meets ALL of the following criteria:

- Symptomatic primary mitral valve regurgitation:
  - New York Heart Association (NYHA) Class III to IV with severe primary mitral regurgitation (stage D) (see tables below); and
- Individual is considered prohibitive high risk for surgery; and
- Has failed optimal guideline directed medical therapy for heart failure; and
- Has favorable anatomy for the procedure as well as a reasonable life expectancy.

TMVR with a device approved by the U.S. FDA may be considered medically necessary for individuals with heart failure and moderate-to-severe or severe symptomatic secondary mitral regurgitation despite the use of maximally tolerated guideline-directed medical therapy.

- Moderate to severe or severe MR may be determined by EITHER:
  - Grade 3+ (moderate) or 4+ (severe) MR confirmed by echocardiography; or
  - New York Heart Association (NYHA) functional class II, III, or IVa (ambulatory) despite the use of stable maximal doses of guideline-directed medical therapy and cardiac resynchronization therapy (if appropriate) administered in accordance with guidelines of professional societies.

TMVR for repair of a degenerated bio-prosthetic valve (valve-in-valve) with a device approved by U.S. FDA may be considered medically necessary when ALL of the following criteria are met:

- The individual has a failed (i.e., stenosed, insufficient, and/or combined) previous surgical bio-prosthetic mitral valve; and
- At the discretion of the Heart Team specialists, the individual is EITHER:
  - Not an operable candidate for open surgery; or
  - Is an operable candidate but at high risk for open surgery (i.e. STS score of 8% or higher or have an expected mortality risk of 15% or greater for open surgery).

TMVR not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

REQUIREMENTS

The professional team must meet ALL of the following requirements:

- Both a cardiothoracic surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease; and
- Each interventional cardiologist performs greater than 50 structural procedures per year including atrial septal defects (ASD), patent foramen ovale (PFO) and trans-septal punctures; and
- Interventional cardiologist(s) must receive prior suitable training on the devices to be used; and
- The interventional cardiologist(s) must be board-certified in interventional cardiology or board-certified/eligible in pediatric cardiology or similar boards from outside the United States; and
- The cardiothoracic surgeon(s) must be board-certified in thoracic surgery or similar foreign equivalent.

TMVR must be performed by an interventional cardiologist or a cardiothoracic surgeon. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVR as appropriate.

The facility must meet ALL of the following requirements:

- Onsite active valvular heart disease surgical program with greater than or equal to two (2) hospital-based cardiothoracic surgeons experienced in valvular surgery; and
- A surgical program that performs greater than or equal to 25 total mitral valve surgical procedures for severe mitral regurgitation (MR) per year of which at least 10 must be mitral valve repairs; and
- An interventional cardiology program that performs greater than or equal to 1000 catheterizations per year, including greater than or equal to 400 percutaneous coronary interventions (PCIs) per year, with acceptable outcomes for conventional procedures compared to National Cardiovascular Data Registry (NCDR) benchmarks; and
- Cardiac catheterization laboratory or hybrid operating room/catheterization laboratory equipped with a fixed radiographic imaging system with flat-panel fluoroscopy offering catheterization laboratory-quality imaging; and
- Post-procedure intensive care facility with personnel experienced in managing individuals who have undergone open-heart valve procedures.

NEW YORK HEART ASSOCIATION (NYHA) CLASSIFICATION OF HEART FAILURE

Class	Description
Class I	No limitation of physical activity. Ordinary physical activity does not cause undue breathlessness, fatigue, or palpitations.
Class II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in undue breathlessness, fatigue, or palpitations
Class III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary physical activity results in undue breathlessness, fatigue, or palpitations.
Class IV	Unable to carry on any physical activity without discomfort. Symptoms at rest can be present. If any physical activity is undertaken, discomfort is increased.

STAGES OF SECONDARY MITRAL REGURGITATION (MR)

Grade	Definition	Symptoms
A	At risk of MR	Symptoms due to coronary ischemia or HF may be present that respond to revascularization and appropriate medical therapy.
B	Progressive MR	Symptoms due to coronary ischemia or HF may be present that respond to revascularization and appropriate medical therapy.
C	Asymptomatic severe MR	Symptoms due to coronary ischemia or HF may be present that respond to revascularization and appropriate medical therapy.
D	Symptomatic severe MR	HF symptoms to MR persist even after revascularization and optimization of medical therapy, decreased exercise tolerance, exertional dyspnea.

PROFESSIONAL STATEMENTS AND SOCIETAL POSITIONS GUIDELINES

National Institute For Health And Care Excellence–2019

In June 2019, the National Institute For Health And Care Excellence published interventional procedures guidance [IPG653] regarding valve-in-valve TAVI for aortic bioprosthetic valve dysfunction. The guidance was informed by an Interventional procedure overview described previously. The guidance recommendation is that "Current evidence on the safety and efficacy of valve-in-valve transcatheter aortic valve implantation (ViVâ€'TAVI) 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 American College of Cardiology and the American Heart Association–2017.

The American College of Cardiology and the American Heart Association in the 2017 guidelines on the management of valvular heart disease provider recommendations in 2 categories for Mitral Valve repair. Primary Mitral Valve disease: Transcatheter mitral valve repair may be considered for severely symptomatic patients (New York Heart Association (NYHA) class III to IV with chronic severe primary mitral regurgitation who have favorable anatomy for the repair procedure and a reasonable life expectancy but who have a prohibitive surgical risk because of severe comorbidities and remain severely symptomatic despite optimal guideline directed medical therapy for heart failure.

Secondary Mitral Regurgitation: Mitral valve surgery is reasonable for patients with chronic severe secondary mitral regurgitation who are undergoing Coronary Artery Bypass Graft or Atrial Valve Repair. Also Mitral valve repair or replacement may be considered for severely symptomatic patients (NYHA class III to IV) with chronic severe mitral regurgitation who have persistent symptoms despite optimal guideline directed medical therapy for heart failure.

ELIGIBLE PROCEDURE CODES

CPT Codes	Description
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).
93590	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve.
93592	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (list separately in addition to code for primary procedure).

ELIGIBLE DIAGNOSIS CODES FOR PROCEDURE CODES 33418, 33419, 93590 AND 93592

Codes						
I34.0	I34.1	I34.2	I34.8	I34.9		

References

Ramlawi B, Gammie J. Mitral valve surgery: Current minimally invasive and transcatheter options. Methodist DeBakey Cardiovasc J. 2016;12(1):20–26.

Nishimura R, Otto CM, Bonow RO, et al. 2017 AHA/ACC focused update of the 2014 AHA/ACC guidelines for the management of patients with valvular heart disease. J Am Coll Cardiol. 2017; 70(2)252-289.

Lazam S, Vanoverschelde J, Tribouilloy C, et al. Twenty-year outcome after mitral repair versus replacement for severe degenerative mitral regurgitation. Analysis of a large, prospective, multicenter international registry. Circulation. 2016;116.

Sorajja P, Mack M, Vemulapalli S, et al. Initial experience with commercial transcatheter mitral valve repair in the United States. J Am Coll Cardiol. 2016;67(10):1129-1140.

Alozie A, Paranskaya L, Westphal B, et al. Clinical outcomes of conventional surgery versus MitraClip® therapy for moderate to severe symptomatic mitral valve regurgitation in the elderly population: An institutional experience. BMC Cardiovasc Disord. 2017; 17:85.

Hayes, Inc., Hayes Health Technology Assessment. Minimally invasive thoracotomy for mitral valve replacement. Lansdale, PA: Hayes, Inc.; Published Nov 2014, Annual Review 11/2018. Accessed 7/9/2019.

Hayes, Inc., Hayes Evidence Analysis Research Brief. MitraClip for the treatment of children with congenital mitral valve cleft. Lansdale, PA: Hayes, Inc. Published April 2019.

Mkalaluh S, Szczeckowicz M, Karck M, Weyman A. Failed MitraClip therapy: surgical revision in high-risk patients. J Cardiothorac Surg. 2019; 14:75

Nishimura RA, O'Gara PT, Bavaria JE, Brindis RG, et al. 2019 AATS/ACC/ASE/SCAI/STS expert consensus systems of care document: a proposal to optimize care for patients with valvular heart disease: A joint report of the American Association for Thoracic Surgery, American College of Cardiology, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol 2019;73(20):2609-2635.

Stone GW, Lindenfeld JA, Abraham WT, et al. Transcatheter mitral-valve repair in patients with heart failure. N Engl J Med. 2018; 379:2307-18.

Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2017;38(36):2739-2791.

Hayashida K, Yasuda S, Matsumoto T, et al. AVJ-514 Trial- baseline characteristics and 30-day outcomes following MitraClip ® Treatment in a Japanese cohort. Circ J. 2017;81(8):1116-1122.

Sorajja P, Vemulapalli S, Feldman T, et al. Outcomes With transcatheter mitral valve repair in the United States: An STS/ACC TVT Registry Report. J Am Coll Cardiol. 2017;70(19):2315-2327.

Obadia JF, Messika-Zeitoun D, Leurent G, et al. Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation. N. Engl. J. Med. 2018;379(24).

Atianzar, KK, Zhang, MM, Newhart, ZZ, Gafoor, SS. Why did COAPT win while MITRA-FR failed? Defining the appropriate patient population for MitraClip. Interv Cardiol, 2019;14(1).

Nishimura RA, Bonow RO. Percutaneous Repair of Secondary Mitral Regurgitation – A tale of two trials. N Engl J Med. 2018;379(24): 2374-2376.

Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused update of the 2013 ACCF/AHA Guideline for the management of heart failure. J Card Fail. 2017;23(8):628-651.

Takagi H, Ando T, Umemoto T, et al. A review of comparative studies of Mitraclip versus surgical repair for mitral regurgitation. Int J Cardiol. 2017; 228:289-294.

Takagi H, Hari Y, Kawai N, Ando T, ALICE (All-Literature Investigation of Cardiovascular Evidence) Group. A meta-analysis of valve-in-valve and valve-in-ring transcatheter mitral valve implantation. J Interv Cardiol. 2018;31(6):899-906.

Hu J, Chen Y, Cheng S, et al. Transcatheter mitral valve implantation for degenerated mitral bioprostheses or failed surgical annuloplasty rings: A systematic review and meta-analysis. J Card Surg. 2018;33(9):508-519.

Novitas Solutions, Inc., LCD L35448. Revised 09/26/2019 (R16).

Novitas Solutions, Inc., LCA A53252. Revised 07/01/2020 (R25), 09/24/2020 (R26).

InterQual® Level of Care Criteria 2019. Acute Care Adult. Change Healthcare, LLC.

Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the management of patients with valvular heart disease: A report of the American college of cardiology/American heart association task force on clinical practice guidelines. J Am Coll Cardiol. 2017;70(2):252-289.

Kumar A, Al-Khafaji J, Shariff M, et al. Percutaneous mitral valve repair for secondary mitral valve regurgitation: A systematic review and meta-analysis. Eur J Intern Med. 2020.

Obadia JF, Messika-Zeitoun D, Leurent G, et al. Percutaneous repair or medical treatment for secondary mitral regurgitation. N Engl J Med. Dec 13, 2018;379(24):2297-2306.

Lung B, Armoiry X, Vahanian A, et al. Percutaneous repair or medical treatment for secondary mitral regurgitation: outcomes at 2 years. Eur J Heart Fail. 2019;21(12):1619-1627.

Nishimura RA, Bonow RO. Percutaneous Repair of Secondary Mitral Regurgitation - A Tale of Two Trials. N Engl J Med. 2018; 379(24):2374-2376.

Buzzatti N, Van Hemelrijck M, Denti P, et al. Transcatheter or surgical repair for degenerative mitral regurgitation in elderly patients: A propensity-weighted analysis. J Thorac Cardiovasc Surg. 2019;158(1):86-94. e1.

Kapadia SR, Huded CP, Kodali SK, et al. Stroke after surgical versus transfemoral transcatheter aortic valve replacement in the partner trial. J. Am. Coll. Cardiol. 2018;72(20).

Baron SJ, Arnold SV, Reynolds MR, et al. Durability of quality-of-life benefits of transcatheter aortic valve replacement: Long-term results from the CoreValve US extreme risk trial. Am Heart J. 2017; 194:39-48.

Panoulas VF, Francis DP, Ruparelia N, et al. Female-specific survival advantage from transcatheter aortic valve implantation over surgical aortic valve replacement: Meta-analysis of the gender subgroups of randomised controlled trials including 3758 patients. Int J Cardiol. 2018; 250:66-72.

Deeb GM, Reardon MJ, Chetcuti S, et al. 3-year outcomes in high-risk patients who underwent surgical or transcatheter aortic valve replacement. J Am Coll Cardiol. 2016;67(22):2565-2574.

Conte JV, Hermiller J, Jr., Resar JR, et al. Complications after self-expanding transcatheter or surgical aortic valve replacement. Semin Thorac Cardiovasc Surg. 2017;29(3):321-330.

Gleason TG, Reardon MJ, Popma JJ, et al. 5-Year Outcomes of Self-Expanding Transcatheter Versus Surgical Aortic Valve Replacement in High-Risk Patients. J Am Coll Cardiol. 2018;72(22).

Food and Drug Administration. Summary Of Safety and Effectiveness Data (SSED): LOTUS EdgeTM Valve System. https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180029B.pdf. Accessed March 09, 2021.

Arora S, Strassle PD, Ramm CJ, et al. Transcatheter versus surgical aortic valve replacement in patients with lower surgical risk scores: a systematic review and meta-analysis of early outcomes. Heart Lung Circ. 2017;26(8):840-845.

Arora S, Vaidya SR, Strassle PD, et al. Meta-analysis of transfemoral TAVR versus surgical aortic valve replacement. Catheter Cardiovasc Interv. 2017.

Garg A, Rao SV, Visveswaran G, et al. Transcatheter aortic valve replacement versus surgical valve replacement in low-intermediate surgical risk patients: a systematic review and metaanalysis. J Invasive Cardiol. 2017;29(6):209-216.

Singh K, Carson K, Rashid MK, et al. Transcatheter aortic valve implantation in intermediate surgical risk patients with severe aortic stenosis: a systematic review and meta-analysis. Heart Lung Circ. 2018;27(2):227-234.

Gozdek M, Raffa GM, Suwalski P, et al. Comparative performance of transcatheter aortic valvein-valve implantation versus conventional surgical redo aortic valve replacement in patients with degenerated aortic valve bioprostheses: systematic review and meta-analysis. Eur J Cardiothorac Surg. 2018;53(3):495-504.

Khan SU, Lone AN, Saleem MA, et al. Transcatheter vs surgical aortic-valve replacement in lowto intermediate- surgical-risk candidates: A meta-analysis and systematic review. Clin Cardiol. 2017;40(11):974-981.

Tam DY, Vo TX, Wijeysundera HC, et al. Transcatheter vs surgical aortic valve replacement for aortic stenosis in low-intermediate risk patients: a meta-analysis. Can J Cardiol. 2017;33(9):1171- 1179.

Witberg G, Lador A, Yahav D, et al. Transcatheter versus surgical aortic valve replacement in patients at low surgical risk: A meta-analysis of randomized trials and propensity score matched observational studies. Catheter Cardiovasc Interv. 2018.

Ueshima D, Fovino LN, D'Amico G et al. Transcatheter versus surgical aortic valve replacement in low- and intermediate-risk patients: an updated systematic review and meta-analysis. Cardiovasc Interv Ther. 2018;34(3).

Zhou Y, Wang Y, Wu Y, et al. Transcatheter versus surgical aortic valve replacement in low to intermediate-risk patients: A meta-analysis of randomized and observational studies. Int J Cardiol. 2016; 228:723-728

Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2016;374(17):1609-1620.

Kondur A, Briasoulis A, Palla M, et al. Meta-Analysis of transcatheter aortic valve replacement versus surgical aortic valve replacement in patients with severe aortic valve stenosis. Am J Cardiol. 2016;117(2):252- 257.

Siemieniuk RA, Agoritsas T, Manja V, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at low and intermediate risk: systematic review and meta-analysis. BMJ. 2016;354: i5130.

Sondergaard L, Steinbruchel DA, Ihlemann N, et al. Two-year outcomes in patients with severe aortic valve stenosis randomized to transcatheter versus surgical aortic valve replacement: the all-comers Nordic aortic valve intervention randomized clinical trial. Circ Cardiovasc Interv. 2016;9(6).

Thyregod HGH, Ihlemann N, Jorgensen TH, et al. Five-year clinical and echocardiographic outcomes from the nordic aortic valve intervention (notion) randomized clinical trial in lower surgical risk patients. Circ. 2019.

Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2017;376(14):1321-1331.

National Institute for Health and Care Excellence. Interventional procedure overview of valve-invalve TAVI for aortic bioprosthetic valve dysfunction (IP 1013/2 [IPG653]). June 2019. https://www.nice.org.uk/guidance/ipg653/evidence/overview-final-pdf-6834685357. Accessed March 09, 2021.

Phan K, Zhao DF, Wang N, Huo YR, Di Eusanio M, Yan TD. Transcatheter valve-in-valve implantation versus reoperative conventional aortic valve replacement: a systematic review. J Thorac Dis. 2016;8(1): E83-93.

National Institute for Health and Care Excellence.Valve-in-valve TAVI for aortic bioprosthetic valve dysfunction, Interventional procedures guidance [IPG653]. June 2019. https://www.nice.org.uk/guidance/ipg653. Accessed March 08, 2021.

Centers for Medicaid and Medicare Services. Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R). https://www.cms.gov/medicare-coveragedatabase/details/nca-decision-memo.aspx?NCAId=293&bc=ACAAAAAAQAAA&. Accessed March 08, 2021.

Hayes, Inc. Hayes Medical Technology Directory Report. Comparative effectiveness review of transcatheter aortic valve implantation (tavi) and surgical aortic valve replacement (SAVR) for Aortic Stenosis in Lower Risk Patients. Lansdale, PA: Hayes, Inc.; September 2020.

POLICY UPDATE HISTORY

10/08/2021	Approved in medical policy committee
08/24/2022	Annual review; approved in medical policy committee
09/13/2022	Approved in QI-UM
10/10/2022	Approved in Governance