Sentara Health Plans

Commercial

Percutaneous Antegrade Transseptal Transcatheter Mitral Valve Implantation

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Effective Date	11/2022
Next Review Date	1/15/2024
Coverage Policy	Surgical 136
Version	2

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.

Purpose:

This policy addresses the medical necessity of Percutaneous Antegrade Transseptal Transcatheter Mitral Valve Implantation.

- **Medical Director review is required**

Description & Definitions:

Percutaneous Antegrade Transseptal Transcatheter Mitral Valve Implantation is a Transcatheter mitral valve implantation/replacement is a procedure using a balloon-expandable transcatheter heart valve to replace a heart valve with an artificial valve for three circumstances such as failed mitral valve bioprostheses (TMVI-VIV, "valve-in-valve"), failed mitral annuloplasty ring (TMVI-R), and advanced native mitral annular calcification (TMVI-MAC).

Criteria:

Percutaneous antegrade transseptal transcatheter mitral valve implantation is considered medically necessary for **All** of the following:

- **Open Mitral valve repair or replacement** is either contraindicated or is felt to be higher risk than Percutaneous antegrade transseptal transcatheter mitral valve implantation after evaluation by Heart Team at a highly experienced center.
- **Mitral regurgitation**, as indicated by **All** of the following:
  - Severe primary mitral regurgitation correction procedure appropriate as indicated by **All** of the following:
    - Primary mitral regurgitation ranked as severe as indicated by **2 or more** of the following:
      - Central jet of mitral regurgitation more than 40% of left atrial area
      - Holosystolic eccentric jet mitral regurgitation
      - Vena contracta width of 0.7 cm or more
      - Regurgitant volume 60 mL per beat or greater
      - Regurgitant fraction 50% or greater
      - Effective regurgitant orifice area 0.40 cm2 or greater

        - Mitral regurgitation graded as 3+ or greater on angiography
    - Correction of regurgitation clinically appropriate, as indicated by **1 or more** of the following:
        - Individual has symptoms attributable to mitral regurgitation (eg, decreased exercise tolerance, exertional dyspnea, heart failure)
        - Left ventricular ejection fraction less than or equal to 60%
        - Left ventricular end-systolic diameter (LVESD) greater than or equal to 40 mm
        - Left ventricular ejection fraction greater than 60% and LVESD less than 40 mm and **1 or more** of the following:
            - Progressive decrease in left ventricular ejection fraction over at least 3 serial measurements
            - Progressive increase in LVESD over at least 3 serial measurements
        - Left ventricular ejection fraction greater than 60% and LVESD less than 40 mm and **ALL** of the following:
            - Procedure to be performed by highly experienced center and physician (eg, Comprehensive Valve Center)
- **Individual with 1 or more** of the following:
    - Failed mitral valve bioprostheses (TMVI-VIV, “valve-in-valve”)
    - Failed mitral annuloplasty ring (TMVI-R)
    - Advanced native mitral annular calcification (TMVI-MAC)

Percutaneous Antegrade Transseptal Transcatheter Mitral Valve Implantation is considered **not medically necessary** for any use other than those indicated in clinical criteria.

Coding:

Medically necessary with criteria:

Coding	Description
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 (eg, thoracotomy, transapical)

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2023: August

Reviewed Dates:

- 2023: August

Effective Date:

- November 2022

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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(2023). Retrieved Aug 7, 2023, from UpToDate: https://www.uptodate.com/contents/search?search=Percutaneous%20Antegrade%20Transseptal%20Transcatheter%20Mitral%20Valve%20Implantation&sp=0&searchType=PLAIN_TEXT&source=USER_INPUT&searchControl=TOP_PULLDOWN&searchOffset=1&autoComplete=false&language=en&ma

Contemporary Review of Transcatheter Mitral Valve Interventions for Mitral Regurgitation. (2023, June 25). Retrieved Aug 4, 2023, from MDPI: https://www.mdpi.com/2075-1729/13/7/1511

National Coverage Determination (NCD) Transcatheter Mitral Valve Repair (TMVR) 20.33. (2021, Jan 19). Retrieved Aug 4, 2023, from CMS - NCD: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=363&ncdver=1

Percutaneous Mitral Valve Repair for Secondary (Functional) Mitral Valve Regurgitation in High-Risk Adults - Annual Review: Mar 28, 2023. (n.d.). Retrieved Aug 4, 2023, from Hayes: https://evidence.hayesinc.com/report/dir.pmvrsecondary4954

Procedure Fee Files & CPT Codes. (2023). Retrieved Aug 5, 2023, from Department of Medical Assistance Services: https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/ & https://www.dmas.virginia.gov/for-providers/cardinal-care-transition/

Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

SHP Percutaneous Antegrade Transseptal Transcatheter Mitral Valve Implantation, SHP Surgical 136, Mitral regurgitation, failed mitral valve bioprostheses, TMVI-VIV, valve-in-valve, failed mitral annuloplasty ring, TMVI-R, advanced native mitral annular calcification, TMVI-MAC