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
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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses Percutaneous Antegrade Transseptal Transcatheter Mitral Valve Implantation.

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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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

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Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by

medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

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