

Medical Necessity Guidelines: Transcatheter Mitral Valve Repair (TMVR)

Effective: November 18, 2020

Prior Authorization Required If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<p>Applies to: COMMERCIAL Products <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617.972.9409 <input checked="" type="checkbox"/> Tufts Health Freedom Plan products; Fax: 617.972.9409 • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</p> <p>TUFTS HEALTH PUBLIC PLANS Products <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404 <input checked="" type="checkbox"/> Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304 *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</p> <p>SENIOR Products • Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List • Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List</p>	

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

OVERVIEW

Tufts Health Plan may cover FDA approved mitral valve system for Members who meet specific guidelines. Mitral regurgitation (MR) is a backflow of blood from the left ventricle to the left atrium due to mitral valve insufficiency. Transcatheter mitral valve repair is sometimes recommended for primary mitral valve disease (MVD) e.g., degenerative mitral regurgitation (DMR), which is usually due to direct damage or wear of the MV leaflets, attached chords, or adjacent supporting tissues. The procedure involves clipping together a portion of the mitral valve leaflets as a treatment for reducing MR with the intended outcome to improve recovery of the heart from overwork, improve function, and potentially halt the progression of heart failure.

CLINICAL COVERAGE CRITERIA

Tufts Health Plan may authorize an elective transcatheter mitral valve repair when **ALL** of the following are met:

- The Member has NYHA class III or IV functional capacity due to Mitral Valve Disease.
- A cardiologist has documented that the Member remains severely symptomatic in spite of optimal medical management, and recommends an interventional procedure.
- A cardiothoracic surgeon has documented that the Member is a prohibitive risk for an **open** mitral valve operation.

*New York Heart Association Classification System⁷

Functional Capacity	Objective Assessment
Class I. Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	A. No objective evidence of cardiovascular disease.

Functional Capacity	Objective Assessment
Class II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	B. Objective evidence of minimal cardiovascular disease.
Class III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.	C. Objective evidence of moderately severe cardiovascular disease.
Class IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	D. Objective evidence of severe cardiovascular disease.

LIMITATIONS

- Tufts Health Plan does not cover TMVR for Members who have moderate or severe mitral valve (MV) regurgitation but are suitable candidates for conventional open MV repair surgery.

CODES

The following CPT codes require prior authorization:

Code	Description
33418	Transcatheter mitral valve repair, percutaneous approach, including transeptal puncture when performed; initial prosthesis
33419	Transcatheter mitral valve repair, percutaneous approach, including transeptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus

REFERENCES

1. Center for Medicare and Medicaid Services (CMS). Proposed Decision Memo for Transcatheter Mitral Valve (TMV) Procedures (CAG-00438N) 2014. Available online at: [cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=273](https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=273). Accessed January 27, 2015.
2. FDA. Summary of Safety and Effectiveness Data: Mitral Valve Repair Device. 2013. Available online at: accessdata.fda.gov/cdrh_docs/pdf10/P100009b.pdf.
3. Feldman T., Foster E., Glower D.D., et al; Percutaneous repair or surgery for mitral regurgitation. N Engl J Med. 2011;364:1395-1406.
4. Hayes Inc. Hayes Medical Technology Directory. Percutaneous mitral valve repair. February 20, 2014. Lansdale, PA: Hayes, Inc.; Updated February 25, 2015.
5. Lim DS, Reynolds MR, Feldman T, et al. Improved functional status and quality of life in prohibitive surgical risk patients with degenerative mitral regurgitation following transcatheter mitral valve repair with the MitraClip^(R) system. J Am Coll Cardiol 2013.
6. Nishimura RA, Otto CM, Bonow RO et al. 2014 AHA/ACC Guideline for the management of patients with valvular heart disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2014; 129(23):2440-92.
7. *The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. 9th ed. Boston, Mass: Little, Brown & Co; 1994:253-256.
8. Whitlow P.L., Feldman T., Pedersen W.R., et al; Acute and 12-month results with catheter-based mitral valve leaflet repair: the EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study. J Am Coll Cardiol. 2012;59:130-139.

APPROVAL HISTORY

March 11, 2015: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC) for an effective date of January 1, 2016

Subsequent endorsement date(s) and changes made:

- December 9, 2015: Reviewed by IMPAC, renewed without changes
- May 12, 2016: Administrative update

- December 14, 2016: Reviewed by IMPAC, renewed without changes
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- December 13, 2017: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated
- November 14, 2018: Reviewed by IMPAC, renewed without changes
- November 20, 2019: Reviewed by IMPAC, renewed without changes
- November 18, 2020: Reviewed by IMPAC, renewed without changes
- December 8, 2020: Fax number for Unify updated

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.

[Provider Services](#)