Transcatheter Mitral Valve Repair/Replacement

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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

Mitral valve regurgitation (MVR) is the most prevalent form of heart valve disease. Transcatheter mitral valve repair/replacement (TMVR) is 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.

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.

POLICY POSITION

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 a 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:

- On-site 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		

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POLICY UPDATE HISTORY

<Date>	<Event>