I. Policy: Percutaneous Heart Valve Replacement

II. Purpose/Objective:
To provide a policy of coverage regarding Percutaneous Heart Valve Replacement

III. Responsibility:
A. Medical Directors
B. Medical Management Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and

the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.
DESCRIPTION:
Percutaneous (transcatheter) heart valve replacement (PHV) is catheter-based technology that allows for implantation of a prosthetic valve without open-heart surgery. The prosthetic heart valve is delivered via a catheter inserted either through a vein or artery (femoral vein; femoral, subclavian, or axillary arteries; or the ascending aorta) or through the apex of the heart via an incision in the chest wall (transapical approach).

INDICATIONS:

Aortic Valve Replacement:
Transcatheter aortic valve replacement (TAVR) may be considered medically necessary when all of the following criteria are met:

- Diagnosis of severe aortic stenosis defined by a mean aortic valve gradient greater than 40mmHg or a jet velocity greater than 4.0m/sec, with a calcified aortic annulus
- Severe symptoms known to be secondary to the severe aortic stenosis:
  - NYHA Class III or IV heart failure; or
  - Syncope/ risk of sudden cardiac death; or
  - Refractory angina
- Member is not a candidate for open aortic valve replacement verified by two cardiovascular specialists
- No other co-morbidities limiting life expectancy to less than 1 year

For Medicare/Medicaid Business Segment:
The Center for Medicare & Medicaid Services (CMS) provides coverage for transcatheter aortic valve repair (TAVR) under Coverage with Evidence Development (CED) for the treatment of symptomatic aortic valve stenosis with all of the following conditions:

- The transcatheter aortic valve repair system has received FDA premarket approval (PMA); and
- Surgeon, cardiologist and hospital requirements are met per CMS Decision Memo CAG-00430R; and
  and
- The physician and facility are participating in a prospective, national, audited registry that meets the requirements of the CMS Decision Memo

Transcatheter Aortic Valve Replacement for Degenerated Bio-prosthetic Valves ("Valve-In-Valve")
TAVR for repair of a degenerated bio-prosthetic valve using an FDA-approved transcatheter heart valve system is considered medically necessary when ALL the of following criteria are met:
The member

- has a failed previous surgical bioprosthetic aortic valve; and
- is not a candidate for open surgery, or is at high risk for open surgery as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon); and
- has NYHA heart failure class II, III or IV symptoms; and
- has a left ventricular ejection fraction greater than 20 percent

Pulmonary Valve Replacement:
Transcatheter pulmonary valve replacement may be considered medically necessary when the following criteria are met:

- Prior repair of congenital heart disease and right ventricular outflow tract dysfunction
- Member is not a candidate for open repair due to concomitant co-morbidities

Mitral Valve Repair:
Transcatheter mitral valve repair may be considered medically necessary when the following criteria are met:
The member

- Significant (Class III or IV) symptomatic, degenerative mitral regurgitation; and
- Has been determined to be at prohibitive risk as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon) and as evidenced by a Society of Thoracic Surgeons (STS) predicted operative risk score of 12 percent or greater; or the presence of a logistic EuroSCORE of 20 percent or greater.

For Medicare/Medicaid Business Segment:
The Center for Medicare & Medicaid Services (CMS) provides coverage for transcatheter mitral valve repair (TMVR) under Coverage with Evidence Development (CED) with all of the following conditions:

- The transcatheter mitral valve repair system has received FDA premarket approval (PMA); and
- Surgeon, cardiologist and hospital requirements are met per CMS Decision Memo CAG-00438N; and
- The physician and facility are participating in a prospective, national, audited registry that meets the requirements of the CMS Decision Memo

Transcatheter Mitral Valve Replacement for Degenerated Bio-prosthetic Valves ("Valve-In-Valve")

TMVR for repair of a degenerated bio-prosthetic valve using an FDA-approved transcatheter heart valve system is considered medically necessary when ALL the of following criteria are met:
The member

- has a failed previous surgical bioprosthetic mitral valve; and
- is not a candidate for open surgery, or is at high risk for open surgery as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon)

EXCLUSIONS:

With the exception of mandated for coverage by CMS under a Coverage with Evidence Development (CED) program, the Plan does NOT provide coverage for percutaneous transcatheter closure of paravalvular leaks because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these procedures on health outcomes when compared to established procedures or technologies.

The Plan does NOT provide coverage for Transcatheter tricuspid valve repair (TVR) because it is considered experimental/investigational and, therefore, not covered. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these procedures on health outcomes when compared to established procedures or technologies.

Coding Associated With: Percutaneous Heart Valve Replacement

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

Aortic valve

33361 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
33362 open femoral artery approach
33363 open axillary artery approach
33364 open iliac artery approach
33365 transaortic approach
33366 transapical exposure

Mitral valve

33418 Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed
33419 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 (MitraClip)
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)

Pulmonary valve
33477 Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

Paravalvular leak repair
93590 Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve
93591 Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve
93592 Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device

Associated coding
33367 cardiopulmonary bypass support with percutaneous peripheral artery and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure
33368 cardiopulmonary bypass support with open peripheral artery and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure
33369 cardiopulmonary bypass support with open central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure
0569T TRANSCATHETER TRICUSPID VALVE REPAIR, PERCUTANEOUS APPROACH; INITIAL PROSTHESIS
0570T TRANSCATHETER TRICUSPID VALVE REPAIR, PERCUTANEOUS APPROACH; EACH ADDITIONAL PROSTHESIS DURING SAME SESSION (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

ICD10 Codes
I34.0, I34.1, Z00.6


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


Stone GW, Lindenfield J, et al. Transcatheter Mitral-Valve Repair in Patients with Heart Failure. NEJM Sept 23, 2018

Society of Thoracic Surgeons. Short-term risk calculators.: 
http://riskcalc.sts.org/STSWebRiskCalc273/About%20the%20STS%20Risk%20Calculator%20v2.73.pdf


Hayes Inc. Online. Comparative effectiveness review. Percutaneous Mitral Valve Repair. April 13, 2018


This policy will be revised as necessary and reviewed no less than annually.

Devised: 12/10

Revised: 5/12 (add indications), 9/14, 9/16; 1/17 (added exclusion), 12/17 (added exclusions), 12/18 (add indications)

Reviewed: 1/12, 5/13, 5/14, 9/15, 8/17, 12/19