10/22/2015 Important note
Even though this policy may indicate that a particular service or supply maybe considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the following website: http://cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp

SERVICE: Transcatheter valve replacement or repair (TAVR, TPVI and TMVR)

PRIOR AUTHORIZATION: Required

POLICY:

Transcatheter aortic valve replacement (TAVR) may be considered medically necessary for members with native valve aortic stenosis when ALL of the following conditions are met:
1. Severe aortic stenosis (aortic valve area of ≤1 cm², or aortic valve area index of ≤ 0.6 cm /m, or aortic valve gradient ≥40 mm Hg, or peak aortic-jet velocity ≥4.0 m/sec) with a calcified aortic annulus; AND
2. New York Heart Association (NYHA) heart failure Class II, III or IV symptoms; AND
3. Left ventricular ejection fraction >20%; AND
4. Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and cardiac surgeon); or patient is an operable candidate but is at intermediate or higher risk for open surgery.

For Medicare lines of business, see NCD 20.32

Transcatheter aortic valve replacement may be considered medically necessary for members with a degenerated bioprosthetic valve when ALL of the following conditions are met:
1. Failed (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; AND
2. NYHA heart failure class II, III or IV symptoms; AND
3. Left ventricular ejection fraction greater than 20%; AND
4. Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and cardiac surgeon); or patient is an operable candidate but is at high risk for open surgery.

For Medicare lines of business, see NCD 20.32

Transcatheter aortic valve replacement is considered experimental, investigational and/or unproven for all other indications.

Transcatheter pulmonary valve implantation (TPVI) may be considered medically necessary for members with prior repair of congenital heart disease and right ventricular outflow tract dysfunction, who are not good candidates for open repair due to one or more of the following conditions:
- High-risk for surgery due to concomitant medical comorbidities; or
- Poor surgical candidate due to multiple prior thoracotomies for open heart surgery.
Transcatheter pulmonary valve implantation is considered experimental, investigational and/or unproven for all other indications.

Transcatheter mitral valve repair (TMVR) with a device approved by the FDA may be considered medically necessary for patients with symptomatic, degenerative mitral regurgitation who are considered at high risk for traditional open heart mitral valve surgery. For Medicare lines of business, see NCD 20.33 for additional requirements.

Transcatheter mitral valve implantation/replacement (TMVI) is considered experimental, investigational and/or unproven for ALL indications.

OVERVIEW:

Aortic stenosis is the most commonly acquired valvular heart disease in the Western world. Surgical aortic valve replacement is currently the gold-standard treatment for patients with severe symptomatic aortic stenosis. Without surgery, the prognosis is extremely poor, with a 3-year survival rate of less than 30%. (Sambu N, Curzen N. Transcatheter aortic valve implantation: The state of play. Future Cardiol. 2010; 6(2):243-254.) However, due to age and/or other co-morbidities not everyone is a suitable candidate for invasive surgery. Thus, a number of less invasive techniques for valvular replacement and repair, have been developed.

Transcatheter aortic valve implantation or replacement (TAVI/TAVR) may be an alternative treatment for patients with severe aortic stenosis. It is not expected to replace current surgical care for aortic valve replacement, but may be an alternative to non-surgical therapy for patients with a prohibitive risk for surgery. According to the American Heart Association TAVI/TAVR repairs the valve without removing the old, damaged valve. Instead, it wedges a replacement valve into the aortic valve’s place.

Transcatheter mitral valve repair is used in the treatment of mitral regurgitation. A TMVR device involves clipping together a portion of the mitral valve leaflets as treatment for reducing mitral regurgitation. Currently, Abbott’s MitraClip, an edge-to-edge leaflet repair device is currently the only one with United States Food & Drug Administration (FDA) approval for TMVR. The MitraClip, as well as the CARILLON mitral annuloplasty device, has CE Mark approval. (The CARILLON mitral annuloplasty device is considered to be an investigational technology). The Mitraclip is currently FDA approved for commercial use only in patients with moderate-severe or severe primary (degenerate) MR.

Candidates for Transcatheter Mitral Valve Repair – a multidisciplinary dedicated heart team approach (including primary [general] cardiologists, interventional cardiologists, cardiac surgeons, imaging specialists, valve and heart failure specialists, and cardiac anesthesiologists) is recommended for the evaluation and care of potential candidates for TMVR.

MANDATES:

There are no mandated benefits or regulatory requirements for SWHP to provide coverage for these services.

Technical Assessment: Reviewed at TAC in March 2012
MEDICAL COVERAGE POLICY

TOPIC: Transcatheter Valve Replacement or Repair

Policy Number: 204
Effective Date: 12/01/2018
Last Review: 09/18/2018
Next Review Date: 09/18/2019

CMS: NCD TAVR 20.32 (1/7/2013) and NCD TMVR 20.33 (4/6/2015)
LCD L32691 (6/20/2013) contains category III codes.

CODES:

CPT Codes:
33361 TAVR with prosthetic valve; percutaneous femoral artery approach
33362 TAVR with prosthetic valve; open femoral artery approach
33363 TAVR with prosthetic valve; open axillary artery approach
33364 TAVR with prosthetic valve; open iliac artery approach
33365 TAVR with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)
33366 TAVR with prosthetic valve; transapical exposure (eg, left thoracotomy)
33367 TAVR with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)
33368 TAVR with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)
33369 TAVR with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure.)
33477 Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed
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

CPT Not Covered:
0345T Transcatheter mitral valve repair percutaneous approach via the coronary sinus (MitraClip)
0483T Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous
0484T Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic

ICD-10 codes
I06.0 Rheumatic aortic stenosis
I08.0 Rheumatic disorders of both mitral and aortic valves
I34.0 - I34.9 Mitral valve disorders (symptomatic degenerative mitral regurgitation)
I35.0 - I35.9 Nonrheumatic aortic valve disorders (stenosis)
Q23.0 Congenital stenosis of aortic valve
T82.01x+ Breakdown (mechanical) of heart valve prosthesis (degenerated bioprosthetic aortic valve)
T82.03x+ Leakage of heart valve prosthesis (degenerated bioprosthetic aortic valve)
T82.857+ Stenosis of cardiac prosthetic devices, implants and grafts (degenerated bioprosthetic aortic valve)
I06.x - Rheumatic aortic valve disease
I35.0 - I35.8 Non-rheumatic aortic valve disease
Q23.0 - Q23.1 Congenital stenosis/insufficiency aortic valve
I05.x - Rheumatic mitral valve disease
MEDICAL COVERAGE POLICY

TOPIC: Transcatheter Valve Replacement or Repair
Policy Number: 204
Effective Date: 12/01/2018
Last Review: 09/18/2018
Next Review Date: 09/18/2019

Q23.2 - Q23.8 – Congenital mitral valve disease
Z95.2 - Presence of prosthetic heart valve

POLICY HISTORY:

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<tr>
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<td>07/11/2013</td>
<td>Minor updates</td>
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<td>Updated language. Added criteria for pulmonary valve</td>
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REFERENCES

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.


22. Prof. Luc Pierard, FESC, Transcatheter Aortic Valve Implantation: Indications; European Society of Cardiology Vol.14,N°1 - 12 Jan 2016