SUBJECT: **Transcatheter Aortic Valve Implantation (TAVI)/Replacement (TAVR)**
INDEX TITLE: **Medical Management**
ORIGINAL DATE: **January 2013**

This policy applies to the following MedStar Health lines of business:
(Check those that apply.)

COMMERCIAL	[ ] HMO	[ ] PPO	[ ] Fully Insured	[ ] Individual Product	[ ] Marketplace (Exchange)	[X] All
GOVERNMENT PROGRAMS	[ ] MA HMO	[ ] MA PPO	[ ] MA C-SNP	[ ] MA D-SNP	[X] MA All	
	[ ] Medicaid					
OTHER	[X] Self-funded/ASO					

I. POLICY

It is the policy of MedStar Health, Inc. to cover Transcatheter Aortic Valve Implantation (TAVI) and Transcatheter Aortic Valve Replacement (TAVR) when it is medically necessary (refer to CRM.015.MH Medical Necessity policy) and covered under the member's specific benefit plan.

All denials are based on medical necessity and appropriateness as determined by a MedStar Health, Inc. Medical Director (Medical Director).

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to provide the indications for coverage of TAVI and TAVR.

IV. SCOPE

This policy applies to various MedStar Health, Inc. departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description / Background

Many patients with severe symptomatic aortic stenosis are elderly and/or poor candidates for open valve replacement surgery as they are considered high risk for surgery or inoperable. Recently the new technology of TAVI/TAVR allows implantation of a bioprosthetic aortic valve into the orifice of the native aortic valve utilizing minimally invasive techniques. This new approach has been endorsed by the Centers for Medicare and Medicaid Services (CMS) as well as the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC). Complications of TAVI/TAVR include an increased risk for strokes and procedure associated adverse events such as vascular complications but in inoperable patients with severe aortic stenosis, the benefit is felt to be substantially greater than the risk.

The STS has established a risk calculator tool to assist in predicting the risk percentage of operative mortality/morbidity after adult cardiac surgery on the basis of patient demographic and clinical variables. This online tool can be accessed at the STS website – http://www.sts.org.

Edwards Lifesciences received FDA approval (P100041) on 11/2011 for their SAPIEN transcatheter aortic heart valve with RetroFlex balloon catheter system for use per transfemoral delivery**.** On 10/2012, the FDA expanded this coverage (P110021) to include the SAPIEN transcatheter aortic heart valve with Ascendra balloon catheter system for transapical use. InSeptember of 2013, the FDA approved removal of the access approach from the device labeling. Other devices are available such as Medtronic's Core Valve System (FDA approved January 17, 2014) and St. Jude's Portico catheter (still in clinical trial status).

B. Specific Indications

TAVI/TAVR for treatment of severe symptomatic calcified native aortic valve stenosis is covered when member meets all of the following criteria:

1. Ejection fraction greater than 20%
2. Without severe aortic insufficiency
3. Symptomatic from aortic valve stenosis as demonstrated by New York Heart Association (NYHA) functional class II or greater
4. Aortic stenosis with echocardiographically derived criteria of Aortic valve area of less than 0.8cm², mean aortic valve gradient greater than 40mmHg, or a jet velocity of greater than 4.0m/sec

TAVI/TAVR Transfemoral, Transapical, or Other Route Requirements:
TAVI/TAVR is covered when the following criteria are met:

1. Procedure furnished with a complete aortic valve and implantation system that has received FDA approval for that indication
2. Two cardiovascular surgeons have independently examined the patient face-to-face and determined:
    a. Patient is not a candidate for open aortic valve replacement (AVR) surgery and existing comorbidities would not preclude the expected benefit from correction of aortic stenosis or
    b. Patient is an operative candidate but deemed a high surgical risk as documented by STS score of ≥8 or Heart Team assessment of ≥15% risk of mortality with open surgical approach.

NOTE: The transfemoral route is the primary preferred route and other routes are only considered when the transfemoral route is precluded due to anatomic or other medical reasons.

Heart Team and hospital facility requirements:

- Heart teams and hospital facilities must comply with all CMS requirements per NCD 20.32 Transcatheter Aortic Valve Replacement (refer to Section H. References # 11) including participation in a prospective, national, audited registry.

C. Limitations/Exclusions:

a. Patients who cannot tolerate an anticoagulation/antiplatelet regimen.
b. History of active bacterial endocarditis or other active infection.
c. Evidence of an acute myocardial infarction ≤ 1 month prior to the implantation.
d. Aortic valve is a congenital unicuspid or bicuspid valve.
e. Non-calcified aortic annulus.
f. Evidence of intracardiac mass, thrombus or vegetation.
g. Re-do of TAVI/TAVR procedure would be considered off-label use but will require case by case review.

D. Information Required for Review

In order to assess medical necessity for TAVI/TAVR adequate information must be furnished by requesting physician. Necessary documentation includes but is not limited to the following:

1. Member's clinical history/physical including documentation of critical aortic valve disease as documented by the following:

- Aortic valve area of less than 0.8cm² , mean aortic valve gradient greater than 40mmHg or a jet velocity of greater than 4.0m/sec and
- New York Heart Association class II, III, or IV heart failure symptoms or other symptoms secondary to severe aortic stenosis such as syncope or chest pain.

2. Treatment history
3. Pertinent diagnostic/imaging tests
4. Statements and documentation from both cardiovascular surgeons stating rationale for the procedure and confirmation that patient is not a candidate for open aortic valve surgery or is a candidate but is at high risk of mortality per documentation of STS risk assessment score or Heart Team assessment.

E. Review Process

1. The Medical Management Ancillary Service staff reviews the request. If the case does not meet the established criteria, it is referred to a MedStar Health, Inc. Medical Director (Medical Director).
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management Ancillary Service staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan.

F. Variations

N/A

G. Records Retention

Records Retention for documents, regardless of medium, are provided within the MedStar Health, Inc., and as indicated in the MedStar Health, Inc. Division Policy and Procedure CORP.028.MH Records Retention.

H. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Applicable CPT Coding:

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

I. References

Medical Literature/Clinical Information:

1. The Society of Thoracic Surgeons. Reporting Transcatheter Aortic Valve Replacement (TAVR) Procedures in 2013, Issued 2013. http://www.sts.org/sites/default/files/documents/pdf/advocacy/ReportingTAVRin2013.pdf
2. Edwards Lifesciences Corp.. SAPIEN Transcatheter Heart Valve. ©2013, Edwards Lifesciences Corp. http://www.edwards.com/products/transcathetervalve/pages/sapienthv.aspx?sapienmedia=1
3. Hu, P.P., TAVR and SAVR: Current Treatment of Aortic Stenosis, Clinical Medicine Insights: Cardiology, 2012 Aug 23, 6: 125-139. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3431975/
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5. Society of Thoracic Surgeons. Press Release: Society of Thoracic Surgeons and American College of Cardiology support national coverage determination for transcatheter aortic valve replacement. Feb. 3, 2012. http://www.sts.org/news/sts-and-acc-support-national-coverage-analysis-transcatheter-aortic-valve-replacement
6. The Society of Thoracic Surgeons and the American College of Cardiology. Formal Request for a Medicare National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) Procedures. September 22, 2011.

http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id257.pdf

7. The Society of Thoracic Surgeons. STS Adult Cardiac Surgery Database Risk Model Variables - Data Version 2.73. Fall 2007, http://riskcalc.sts.org/STSWebRiskCalc273/About%20the%20STS%20Risk%20Calculator%20v2.73.pdf
8. Bonow RO, Carabello BA, Chatterjee K, et al. 2008 Focused update incorporated into the ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease): endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons . Circulation, 2008 Oct 7;118(15):e523-661. doi: 10.1161/CIRCULATIONAHA.108.190748. Epub 2008 Sep 26 . http://circ.ahajournals.org/content/118/15/e523.full.pdf+html

Regulatory/Government Source:

1. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No., L31686. Services That Are Not Reasonable and Necessary. (Contractor: Novitas Solutions, Inc.) Revision Effective Date: 07/08/2013. http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=31686&ContrId=165&ver=17&ContrVer=2&Date=06%2f13%2f2012&DocID=L31686&SearchType=Advanced&bc=KAAAAAgAAAAAAA%3d%3d&
2. Centers for Medicare and Medicaid Services: Medicare Learning Network Matters (MM8168) National Coverage Determination (NCD)- Transcatheter Aortic Valve Replacement (TAVR) Coding Update/Policy Clarification. Effective January 1, 2013. http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8168.pdf
3. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) No. 20.32. Transcatheter Aortic Valve Replacement (TAVR). Effective date: 05/01/2012 Implementation date: 01/07/2013. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355&ncdver=1&DocID=20.32&SearchType=Advanced&bc=IAAAAAgAAAAAAA%3d%3d&
4. United States Food and Drug Administration: FDA News Release- FDA Approval Expands Access to Artificial Heart Valve for Inoperable Patients. September 23, 2013. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369510.htm
5. U.S. Food and Drug Administration (FDA). September 2013 PreMarket Approvals. Updated June 17, 2014.

http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/ucm380991.htm

6. U.S. Food and Drug Administration (FDA). Expanded Approval Letter: Edwards SAPIEN Transcatheter Heart Valve (THV) – P110021. Oct. 19, 2012. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327342.htm
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