New Century Health

Cardio Policy:

Trans Catheter Aortic Valve Replacement (TAVR)

POLICY NUMBER UM CARDIO_1295	**SUBJECT** Trans Catheter Aortic Valve Replacement (TAVR)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 5**
DATES COMMITTEE REVIEWED 05/24/16, 11/28/16, 10/10/17, 03/08/19, 04/25/19, 08/12/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22	**APPROVAL DATE** September 14, 2022	**EFFECTIVE DATE** September 30, 2022	**COMMITTEE APPROVAL DATES** 05/24/16, 11/28/16, 10/10/17, 03/08/19, 04/25/19, 08/12/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

Indications for determining medical necessity for Trans Catheter Aortic Valve Replacement (TAVR).

II. DEFINITIONS

The most common valvular abnormality in the United States is aortic stenosis (AS), with an incidence of approximately five of every 10,000 adults. Patients with severe symptomatic aortic stenosis (native or previous bioprosthetic aortic valve) do not undergo aortic valve replacement due to various co-morbidities and are considered as high risk or prohibitive risk (STS Score ≥ 8 or at a ≥ 50% risk of mortality at one year) for conventional open-heart surgery. TAVR has allowed for the delivery of heart valves via catheter as an alternative to open surgical valve replacement in these high-risk patient group. TAVR treats the stenotic heart valve by displacing and functionally replacing the native aortic valve with a bioprosthetic valve delivered on a catheter via a percutaneous approach through a peripheral artery (e.g., the femoral artery), a trans-aortic approach through a limited sternotomy, or a trans-apical approach through a limited lower thoracotomy in non-surgical candidates.

Severe AS (Stage D1/D2/D3) is defined as an aortic velocity ≥ 4.0 m/s or mean pressure gradient ≥ 40 mm Hg with a valve area ≤ 1.0 cm2 or an indexed valve area ≤ 0.6 cm2/m2on trans-thoracic echocardiogram.

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
D1	Symptomatic severe high gradient AS	Severe leaflet calcification OR severely reduced leaflet opening	Aortic Vmax ≥4 m/s or mean PG≥ 40 mm H , AVA ≤1.0 cm^2	LV diastolic dysfunction -LV hypertrophy -Pulmonary hypertension may be present	Exertional dyspnea/ decreased exercise tolerance /angina / syncope or presyncope
D2	Symptomatic severe low-flow/low-gradient AS with reduced LVEF	Severe leaflet calcification and severely reduced leaflet motion	- AVA ≤1.0 cm^2 with **resting** aortic Vmax <4m/s - Dobutamine stress echo- AVA ≤1.0 cm^2 with Vmax≥ 4 m/s at any flow rate	LV diastolic dysfunction -LV hypertrophy - LVEF <50%	HF Angina Syncope or presyncope
D3	Symptomatic severe low-gradient AS with normal LVEF or paradoxical low-flow severe AS	Severe leaflet calcification and severely reduced leaflet motion	-Aortic Vmax ≥4 m/s or mean PG≥ 40 mm Hg, AVA ≤1.0 cm2 - Indexed AVA ≤0.6 cm^2 /m^2 and Stroke volume index ≤35 ml/m^2	-Increased LV wall thickness - Small LV chamber with low stroke volume -Restrictive diastolic filling --LVEF 50%	HF Angina Syncope or presyncope

A. Society of Thoracic Surgeons (STS) Score: It is used to calculate a patient's risk of mortality and other morbidities, such as long length of stay, risk of stroke, risk of prolonged ventilation, infection and renal failure etc. The STS score risk calculator incorporates the STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity.

Risk Assessment Combining STS Risk Estimate, Frailty, Major Organ System Dysfunction, and Procedure-Specific Impediments

	Low Risk (Must Meet ALL Criteria in This	Intermediate Risk (Any 1 Criterion in This Column)	High Risk (Any 1 Criterion in This Column)	Prohibitive Risk (Any 1 Criterion in This Column)
STS PROM*	<4% **AND**	4% to 8% **OR**	**>8% OR**	***Predicted risk with surgery of death or major morbidity (all-cause) >50% at 1 y*** **OR**
Frailty†	None **AND**	1 Index (mild) **OR**	≥2 Indices (moderate to severe) **OR**	
Major organ system compromise not to be improved postoperatively‡	None **AND**	1 Organ system **OR**	No more than 2 organ systems **OR**	≥3 Organ systems **OR**
Procedure-specific impediment§	None	Possible procedure- specific impediment	Possible procedure-specific impediment	Severe procedure-specific impediment

*Use of the STS PROM (Predictive Risk of Mortality) is to predict risk in a given institution with reasonable reliability is appropriate only if institutional outcomes are within 1 standard deviation of STS average observed/expected ratio for the procedure in question.

†Seven frailty indices: Katz Activities of Daily Living (independence in feeding, bathing, dressing, transferring, toileting, and urinary continence) and independence in ambulation (no walking aid or assist required or 5- meter walk in <6 s). Other scoring systems can be applied to calculate no, mild-, or moderate-to-severe frailty.

‡Examples of major organ system compromise: Cardiac—severe LV systolic or diastolic dysfunction or RV dysfunction, fixed pulmonary hypertension; CKD stage 3 or worse; pulmonary dysfunction with FEV1 <50% or DLCO2 <50% of predicted; CNS dysfunction (dementia, Alzheimer's disease, Parkinson's disease, CVA with persistent physical limitation); GI dysfunction—Crohn's disease, ulcerative colitis, nutritional impairment, or serum albumin <3.0; cancer—active malignancy; and liver—any history of cirrhosis, variceal bleeding, or elevated INR in the absence of VKA therapy.

§Examples: tracheostomy present, heavily calcified ascending aorta, chest malformation, arterial coronary graft adherent to posterior chest wall, or radiation damage.

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. The ultimate objective of AUC is to improve patient care and health outcomes in a cost – effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. TAVR is recommended in patients who meet an indication for aortic valve replacement (AVR) but have a prohibitive risk for conventional surgical AVR and have a predicted post- TAVR survival greater than 12 months. **(AUC Score 9)**[1,2,3]

B. TAVR can be performed as an alternative to surgical AVR in patients with symptomatic severe AS (Stage D1) with preserved LVEF and have high surgical risk. **(AUC Score 9)**[1,2,3]

C. TAVR is reasonable alternative to surgical AVR for symptomatic patients with severe AS (Stage D1) with preserved EF and intermediate surgical risk. **(AUC Score 8)**[1,2,3]

D. TAVR is reasonable alternative to surgical AVR in patients with severe symptomatic low flow- low gradient AS (Stage D2), with flow reserve on dobutamine echo, LVEF 20-49% and have high or intermediate surgical AVR risk. **(AUC Score 8)**[1,2,3]

E. TAVR is reasonable alternative to surgical AVR in patients with severe symptomatic low flow-low gradient (Stage D3), LVEF ≥50% and have high or intermediate surgical AVR risk. **(AUC Score 8)**[1,2,3]

F. TAVR is preferred over surgical AVR in patients with severe symptomatic AS/AR with degenerative surgical bioprosthesis size ≥23mm with high surgical AVR risk. **(AUC Score 8)**[1,2,3]

Limitations:

Following are the exclusion criteria for TAVR

A. Life expectancy < 12 months due to non-cardiac co-morbid conditions.

B. Evidence of an acute myocardial infarction ≤ 1 month before the intended treatment or evidence of intracardiac mass, thrombus, or vegetation.

C. Congenital unicuspid or bicuspid non-calcified Aortic Valve.

D. Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation) and or severe mitral insufficiency.

E. Native aortic annulus size < 18mm or > 25mm as measured by echocardiogram.

F. Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater; marked tortuosity (hyper acute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe “unfolding” and tortuosity of the thoracic aorta (applicable for transfemoral patients only).

G. Bulky calcified aortic valve leaflets near coronary ostia. Any therapeutic invasive cardiac procedure performed within 30 days of the index procedure, (or 6 months if the procedure was a drug eluting coronary stent implantation).

H. Untreated clinically significant coronary artery disease requiring revascularization.

I. Hemodynamic instability requiring inotropic support or mechanical heart assistance.

J. Iliofemoral vessel with severe obstructive calcification, severe tortuosity or vessels size less than 7 mm in diameter (applicable for transfemoral approach only).

K. Active bacterial endocarditis or other active infections

L. Hypertrophic cardiomyopathy with or without obstruction (HOCM).

M. Severe ventricular dysfunction with LVEF < 20%.

N. Blood dyscrasias as defined: leukopenia (WBC < 3000 mm^3), acute anemia (Hb < 9 mg %), thrombocytopenia, (platelet count < 50,000 cells/mm^3), history of bleeding diathesis or coagulopathy.

O. Active peptic ulcer or upper GI bleeding within the prior 3 months.

P. A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated.

Q. Patient has been offered surgery but has refused surgery.

R. Recent (within 6 months) cerebrovascular accident (CVA) or a transient ischemic attack (TIA).

S. Renal insufficiency (creatinine > 3.0) and/or end stage renal disease requiring chronic dialysis.

T. Need for emergency surgery for any reason

U. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:

   1. Interventional Cardiologist and or Cardiothoracic Surgeon progress note that prompted request
   2. Most recent ECHO, TEE, Cardiac Cath, CT aorta reports

B. Primary codes appropriate for this service:

1. TAVR with percutaneous femoral approach-33361
2. TAVR with open femoral approach-33362
3. TAVR with open axillary artery approach-33363
4. TAVR with open illiac artery approach -33364
5. TAVR with trans-aortic approach-33365
6. TAVR with trans-apical approach-33366

C. Place/Site of Service: Inpatient hospital (21)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) (20.32). Transcatheter Aortic Valve Replacement (TAVR). Retrieved from https://www.cms.gov April 25th, 2019.
2. Bonow et al. ACC/AATS/AHA/ASE/EACTS/ HVS/SCA/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for the Treatment of Patients with Severe Aortic Stenosis. JACC VOL. 70, NO. 20, 2017. NOVEMBER 14/21, 2017:2566 – 9 8
3. Rick A. Nishimura, et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. March 2017. Volume 135, Number 25,Pages e1159-e1195.
4. NCQA UM 2022 Standards and Elements.