MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

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PA.088.MH – Transcatheter Aortic Valve Implantation

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Transcatheter Aortic Valve Implantation (TAVI), Transcatheter Aortic Valve Replacement (TAVR)** and **Transcatheter Pulmonary Valve (TPV) Therapy** for treatment of severe symptomatic native aortic valve stenosis medically necessary for the following indications:

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 0.8cm^2, or mean aortic valve gradient greater than 40mmHg at rest or during dobutamine stress echo, or aortic valve area (AVA) index is less than 0.5 cm^2/m^2, 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. The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication
2. Two cardiac 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.

Pulmonary Valve
Transcatheter Pulmonary heart valve replacement is intended for use as an adjunct to surgery in the management of pediatric and adult patient with the following clinical conditions:

- Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted,
- Dysfunctional RVOT conduit with a clinical indication for intervention:
- Regurgitation: ≥ moderate regurgitation, AND/OR
- Stenosis: mean RVOT gradient ≥ 35 mmHg.

Limitations/Exclusions

Aortic Valve

1. TAVR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis
2. Patients who cannot tolerate an anticoagulation/antiplatelet regimen.
3. History of active bacterial endocarditis or other active infection.
4. Evidence of an acute myocardial infarction ≤ 1 month prior to the implantation.
5. Aortic valve is a congenital unicuspid or bicuspid valve.
6. Non-calcified aortic annulus.
7. Evidence of intracardiac mass, thrombus or vegetation.
8. Re-do of TAVI/TAVR procedure would be considered off-label use but will require a case by case review.
9. Known allergy/sensitivity to nickel or titanium
10. Sensitivity to contrast media used during the procedure

TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:

- On-site heart valve surgery program,
- Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging,
- Non-invasive imaging such as echocardiography, vascular ultrasound, computed tomography (CT) and magnetic resonance (MR),
- Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications,
- Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,

- Appropriate volume requirements per the applicable qualifications listed in CMS NCD 20.32, including heart team requirements, hospital team requirements, and registry requirements.

Pulmonary Valve:

1. The intended lifetime for the Melody® device is 2 years.
2. Venous anatomy unable to accommodate a 22 Fr size introducer sheath;
3. Implantation in left heart;
4. Unfavorable right ventricular outflow tract for good stent anchorage;
5. Severe right ventricular outflow obstruction, which cannot be dilated by balloon;
6. Obstruction of the central veins;
7. Clinical or biological signs of infection;
8. Active endocarditis;
9. Known allergy to aspirin or heparin;
10. Pregnancy.

Background

TAVR, or TAVI, is a new technology for use in treating aortic stenosis. A bioprosthetic valve is inserted intravascularly using a catheter and implanted in the orifice of the native aortic valve. The procedure is performed in a cardiac catheterization lab or a hybrid operating room/cardiac catheterization lab with advanced quality imaging and with the ability to safely accommodate complicated cases that may require conversion to an open surgical procedure. The interventional cardiologist and cardiothoracic surgeon jointly participate in the intra-operative technical aspects of TAVR.

On May 1, 2012, the Centers for Medicare & Medicaid Services (CMS) issued a NCD covering TAVR under Coverage with Evidence Development (CED). When the procedure is furnished for the treatment of symptomatic aortic stenosis and according to a Food and Drug Administration (FDA) approved indication for use with an approved device, CED requires that each patient be entered into a qualified national registry. In addition, prior to receiving TAVR, face-to-face examinations of the patient are required by two cardiac surgeons to evaluate the patient's suitability for open aortic valve replacement (AVR). The NCD lists criteria for the physician operators and hospitals that must be met prior to beginning a TAVR program and after a TAVR program is established.

Codes:

CPT Codes	
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
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels)
33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels)
33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery)
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

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