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Subject: Transcatheter Aortic Valve Replacement

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DESCRIPTION:

Transcatheter aortic valve replacement (TAVR) or implantation (TAVI) is a potential alternative treatment for patients with severe aortic stenosis as an alternative treatment for individuals that are not candidates for surgery due to prohibitive surgical risk or for patients who are at high risk for open valve replacement surgery. The procedure is performed percutaneously, most often through the transfemoral artery approach. It can also be done through the subclavian artery approach and trans-apically using mediastinoscopy.

Several transcatheter aortic valve device systems have received FDA approval (e.g., Edwards SAPIEN, Medtronic CoreValve).

Summary and Analysis of Evidence: An UpTo Date review on “Transcatheter aortic valve implantation: Periprocedural and postprocedural management” (Brecker) states that “Aortic valve replacement (AVR) is the mainstay of treatment of symptomatic severe aortic stenosis (AS). The role of transcatheter aortic valve implantation (TAVI; also known as transcatheter aortic valve replacement or TAVR) is an established alternative to surgical aortic valve replacement (SAVR). Candidates for TAVI should be evaluated for symptoms, aortic stenosis severity, and comorbid pathologies. The indication for valve intervention (surgical aortic valve replacement [SAVR] or TAVI), choice of therapy based upon potential risks (including absolute and relative contraindications for either procedure) and benefits of treatment option should be discussed with a multidisciplinary heart team. The transfemoral arterial approach is the most common and most favored method of TAVI delivery, and nearly all (>95 percent) cases can be performed via this route. When transfemoral access is not feasible, choice of alternative access route is based upon patient-specific anatomy and risk factors, operator and institutional practice and experience, and the type of valve delivery system used. Several types of stent-valve devices with various designs have been successfully implanted using the retrograde femoral approach. The most widely used types are balloon-expandable valves (SAPIEN 3 and SAPIEN 3 Ultra, which have replaced the Cribier-Edwards, SAPIEN, and SAPIEN XT valves) and self-expanding valves (e.g., Evolut PRO/PRO-PLUS, ACURATE neo, and Portico). Cerebral embolic protection (CEP) systems have been developed to capture or deflect debris released during TAVI to reduce the risk of stroke. However, a clinical benefit from CEP systems has not been established.”

POSITION STATEMENT:

Transcatheter aortic valve replacement with an FDA approved transcatheter heart valve system, performed via an approach consistent with the device's FDA approved labeling **meets the definition of medical necessity** for members with native valve aortic stenosis when **ALL** of the following conditions are present:

- Severe aortic stenosis with a calcified aortic annulus (see notes below); **AND**
- New York Heart Association (NYHA) heart failure Class II,III or IV symptoms; **AND**
- Member does not have unicuspid or bicuspid aortic valves.

Transcatheter aortic valve replacement performed with a transcatheter heart valve system with an FDA approved device approved for use for repair of a degenerated bioprosthetic valve (valve-in-valve) **meets the definition of medical necessity** when **ALL** of the following conditions are present:

- Failed (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; **AND**
- NYHA heart failure class II, III or IV symptoms; **AND**
- Member is not an operable candidate for open surgery, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon); or member is an operable candidate but is considered at increased surgical risk for open surgery (e.g., repeat sternotomy) due to a history of congenital vascular anomalies and/or has a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon) (see notes below).

Use of a cerebral embolic protection device (e.g., Sentinel) during transcatheter aortic valve replacement procedures is considered **experimental or investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

NOTES:

For the use of the SAPIEN or CoreValve devices, severe aortic stenosis is defined by **ONE OR MORE** of the following criteria:

- An aortic valve area of less than or equal to 1 cm^2;
- An aortic valve area index of less than or equal to 0.6 cm^2/m^2;
- A mean aortic valve gradient greater than or equal to 40 mm Hg;
- A peak aortic-jet velocity greater than or equal to 4.0 m/sec.

The U.S. Food and Drug Administration (FDA) definition of extreme risk or inoperable for open surgery:

- Predicted risk of operative mortality and/or serious irreversible morbidity 50% or higher for open surgery.

The U.S. Food and Drug Administration (FDA) definition of high risk for open surgery:

- Society of Thoracic Surgeons predicted operative risk score of 8% or higher; **or**
- Judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, the individual has an expected mortality risk of 15% or higher for open surgery.

The U.S. Food and Drug Administration (FDA) definition of intermediate risk for open surgery:

- Society of Thoracic Surgeons predicted operative risk score of 3% to 7%.

Individuals with Society of Thoracic Surgeons predicted operative risk score of less than 3% or 4% are considered at low risk for open surgery.

BILLING/CODING INFORMATION:

CPT Coding

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 artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (List separately in addition to code for primary procedure)
33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (e.g., femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)
33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (e.g., aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)
33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catherization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure) (**investigational**)

LOINC Codes:

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made

			six months or fewer before starting date of service for the claim.
Plan of treatment	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Laboratory studies	26436-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Transcatheter Aortic Valve Replacement (TAVR) (20.32) located at cms.gov. No Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

DEFINITIONS

Aortic stenosis: a narrowing of the aortic valve opening, resulting in obstruction of blood flow from the left ventricle into the ascending aorta. Treatment of aortic stenosis is primarily surgical, involving replacement of the diseased valve with a bio-prosthetic or mechanical valve by open heart surgery.

Mediastinoscopy: a surgical procedure that allows physicians to view areas of the mediastinum, the cavity behind the breastbone that lies between the lungs. The organs in the mediastinum include the heart and its vessels, the lymph nodes, trachea, esophagus, and thymus.

New York Heart Association (NYHA) Functional Classification of heart failure symptoms: A classification for the extent of heart failure. Places patients in one of four categories based on the patient's physical activity limitations. These limitations/symptoms are relevant to normal breathing and varying degrees in shortness of breath and or angina pain:

NYHA Class	
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

RELATED GUIDELINES:

None applicable.

OTHER:

Other names used to report transcatheter aortic valve replacement:

Transcather aortic valve implantation

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Acurata TA (Symetis)

CoreValve (Medtronic)

Edwards SAPIEN

Engager (Medtronic)

JenaValve (JenaValve Technology)

Navitor Transcatheter Aortic Valve Implantation System (Abbott)

Nordic Aortic Valve

Portico (St. Jude Medical)

Portico Transcatheter Aortic Valve Implantation System (Abbott)

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 04/25/24.

GUIDELINE UPDATE INFORMATION:

07/15/12	New Medical Coverage Guideline.
01/15/13	Annual CPT/HCPCS coding update; added 0318T, 33361-33369; deleted 0276T-0279T.
04/15/13	Revision of Position Statement; references updated; formatting changes; Program Exceptions section updated.
01/01/14	Annual CPT/HCPCS coding update; added 33366 and deleted 0318T.
04/15/14	Annual review; Position Statement reformatted; additional reformatting; references updated.
12/15/15	Revision; added Medtronic CoreVale device to description and “with an FDA approved device” to position statement. Updated and reformatted references.
10/15/16	Revision; Revised position statement for transcatheter aortic valve replacement for aortic stenosis. Added position statement for transcatheter aortic valve replacement for repair of a degenerated bioprosthetic valve. Deleted transcatheter aortic valve replacement experimental or investigational indications. Upated New York Heart Association (NYHA) functional classification of heart failure symptoms.

06/15/18	Revision; added “or intermediate” to position statement. Added position statement for other indications. Updated description and references.
05/15/19	Review; no change to position statement. Removed investigational from code (33363, 33364, 33365, 33368, 33369). Updated references.
04/15/20	Review/revision. Added an exclusion for members with unicuspid or bicuspid aortic valve for native valve aortic stenosis. Added valve-in-valve to repair of a degenerated bioprosthetic valve and operative risk score for low risk for open surgery. Updated references.
04/15/21	Review/revision. Deleted statement related to member is not an operable candidate for open surgery. Revised statement for low risk for open heart surgery. Updated references.
07/15/23	Review; added cerebral embolic protection device and code 33370. Updated references.
05/15/24	Review/revision. Deleted left ventricular ejection fraction greater than 20% criteria. Added statement for consideration of individuals who may be at increased surgical risk for open heart surgery. Updated references.