

Transcatheter Aortic Valve Replacement

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Medical Guideline Disclaimer

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Definition

Transcatheter aortic valve replacement (TAVR), also known as transcatheter aortic valve implantation (TAVI) is a minimally invasive procedure for the treatment of aortic stenosis. A bioprosthetic valve is implanted percutaneously in the orifice of the native aortic valve. There are two access routes for TAVI—transfemoral and transapical (involving thoracotomy).

Guideline

- A. Members are eligible for TAVR coverage when the method of insertion and clinical indication are commensurate with the FDA's approval of the device and when the following criteria are met:
 1. Severe native valve aortic stenosis or failure defined by ≥ 1 of the following:
 - a. Mean aortic valve gradient ≥ 40 mmHg
 - b. Peak jet velocity ≥ 4.0 m/s
 - c. Aortic valve area (AVA) < 0.8 cm²
 - d. AVA Index < 0.6 cm²/m²
 2. Presence of New York Heart Association (NYHA) symptoms \geq class II
 3. Inoperable or at high-risk for open heart surgery, as determined by two cardiovascular specialists (cardiologist and/or cardiac surgeon)

Limitations/Exclusions

TAVR is not considered medically necessary for members with existing co-morbidities that would preclude the expected benefit from correction of the aortic stenosis.

Requests for TAVR as a repair to a previously implanted bio-prosthetic valve ("valve-in-valve"), which has degenerated, will be case-by-case reviewed.

Revision History

11/21/2016 — removed provider and facility credentialing prerequisite.

Applicable Procedure Codes

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 (eg, median sternotomy, mediastinotomy)
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy) New code effective 1/1/2014
33367	Transcatheter aortic valve replacement (TAVR/TAVI) 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	Transcatheter aortic valve replacement (TAVR/TAVI) 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	Transcatheter aortic valve replacement (TAVR/TAVI) 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)

Applicable ICD-10 Diagnosis Codes

I06.0	Rheumatic aortic stenosis
I06.2	Rheumatic aortic stenosis with insufficiency
I06.8	Other rheumatic aortic valve diseases
I06.9	Rheumatic aortic valve disease, unspecified
I08.0	Rheumatic disorders of both mitral and aortic valves
I08.8	Other rheumatic multiple valve diseases
I08.9	Rheumatic multiple valve disease, unspecified
I35.0	Nonrheumatic aortic (valve) stenosis
I35.2	Nonrheumatic aortic (valve) stenosis with insufficiency
Q23.0	Congenital stenosis of aortic valve

References

American College of Cardiology (ACC) Website. ACCF/AATS/SCAI/STS Expert Consensus Statement on Transcatheter Aortic Valve Replacement. <http://www.acc.org/search#q=consensus%20statement%20transcatheter&sort=relevancy> March 2012. Accessed November 17, 2017.

American College of Cardiology (ACC) Website. AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease. 2014. <http://content.onlinejacc.org/article.aspx?articleid=1838843>. Accessed November 17, 2017.

CMS National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR). January 2013. [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355&ncdver=1&NCAid=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+\(TAVR\)&bc=ACAAAAACAAAAA%3D%3D&](http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355&ncdver=1&NCAid=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+(TAVR)&bc=ACAAAAACAAAAA%3D%3D&). Accessed November 17, 2017.

Hayes, Winifred S. Directory Report. Transcatheter aortic valve implantation for aortic stenosis. October 2013; annual review April 2015. <http://www.hayesinc.com>. Accessed November 17, 2017.

Hayes, Winifred S. Search and Summary. Transapical aortic valve implantation using the Edwards Sapien transcatheter 9000 TFX heart valve and Ascendra balloon aortic valvuloplasty catheter. June 2014. <http://www.hayesinc.com>. Accessed November 17, 2017.

Sambu N, Curzen N. Transcatheter aortic valve implantation: The state of play. *Future Cardiol.* 2010;6(2):243-254.

Specialty matched clinical peer review.

US Food and Drug Administration (FDA) Website. FDA approves SAPIEN 3 THV artificial heart valve. June 2015. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm451678.htm>. Accessed November 17, 2017.

US Food and Drug Administration (FDA) Website. Medtronic CoreValve System—P130021/S010. April 2015. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=p130021S010>. Accessed November 17, 2017.

US Food and Drug Administration (FDA) Website. News Release. September 2013. FDA approval expands access to artificial heart valve for inoperable patients. <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm369510.htm>. Accessed November 17, 2017.

US Food and Drug Administration (FDA) Website. Edwards Sapien XT transcatheter heart valve. June 2014. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm405068.htm>. Accessed November 17, 2017.

US Food and Drug Administration (FDA) Website. Medtronic CoreValve System — P130021. January 2014. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=p130021>. Accessed November 17, 2017.