INTRO | COVERAGE

HOSPITAL INPATIENT

HOSPITAL CHECKLIST

PHYSICIAN IMPLANTER

PHYSICIAN IMAGER PHYSICIAN CHECKLIST

HEALTH ECONOMICS & REIMBURSEMENT

TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

EFFECTIVE JANUARY 1, 2023

REFERENCES



TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

Effective January 1, 2023

INTRODUCTION

The TAVI Coding Guide is intended to provide reference material related to the reimbursement of Abbott products when used consistently with their labeling.

REIMBURSEMENT HOTLINE

In addition, Abbott offers a reimbursement hotline, which provides live coding and reimbursement information from dedicated reimbursement specialists. Coding and reimbursement support is available from 8 a.m. to 5 p.m. Central Time, Monday through Friday at (855) 569-6430 or ReimbursementHelp@abbott.com. This guide and all supporting documents are available at https://www.cardiovascular.abbott/us/en/hcp/reimbursement/sh/transcatheter-valve-solutions.html. Coding and reimbursement assistance is provided subject to the disclaimers set forth in this guide.

DISCLAIMER

This material and the information contained herein is for general information purposes only and is not intended, and does not constitute, legal, reimbursement, business, clinical, or other advice. Furthermore, it is not intended to and does not constitute a representation or guarantee of reimbursement, payment, or charge, or that reimbursement or other payment will be received. It is not intended to increase or maximize payment by any payer. Similarly, nothing in this document should be viewed as instructions for selecting any particular code, and Abbott does not advocate or warrant the appropriateness of the use of any particular code. The ultimate responsibility for coding and obtaining payment/reimbursement remains with the customer. This includes the responsibility for accuracy and veracity of all coding and claims submitted to third-party payers. In addition, the customer should note that laws, regulations, and coverage policies are complex and are updated frequently, and, therefore, the customer should check with its local carriers or intermediaries often and should consult with legal counsel or a financial, coding, or reimbursement specialist for any questions related to coding, billing, reimbursement or any related issues. This update reproduces information for reference purposes only. It is not provided or authorized for marketing use.

REFERENCES PAGE 2 OF 15



TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

MEDICARE COVERAGE

CMS provides coverage for Transcatheter Aortic Valve Implantation (TAVI) under Coverage with Evidence Development⁶. Among the coverage criteria specified in this National Coverage Determination (NCD):

- 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.
- Both a cardiac surgeon and an interventional cardiologist have independently examined the patient face-to-face and evaluated the patient's suitability for surgical aortic valve replacement (SAVR, TAVR or medical or palliative therapy).
- · The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
- · All TAVR cases must be enrolled in the national transcatheter valve therapy (TVT) registry.

Other institutional and operator requirements apply based on multi-society guidelines. Refer to the NCD 20.32 and MLN Matters Number (MM8168 and MM8255) for additional details and requirements.^{6,7}

PRIVATE PAYERS

- · Private payer plans vary significantly in coverage and compliance requirement for TAVR.
- · Private payers should be consulted in advance of the procedure to verify terms and conditions of coverage.
- · Please check with your payer regarding appropriate coding and payment information.
- · Commercial payer payment methods vary for reimbursing inpatient services including case rates, percent of billed charges, DRGs, and device carve outs.
- · Commercial payer policies vary on details such as:
 - prior authorization requirements
 - co-surgeon requirements

Please consult the private payer directly to ensure complete understanding of any relevant coverage polices and billing requirements.

MEDICARE ADVANTAGE

Medicare Advantage plan must cover TAVR therapy consistent with the national coverage determination (NCD):

- · Medicare Advantage plans may not impose more restrictive coverage criteria than detailed in the NCD
- · Medicare Advantage plans may use prior authorization/precertification to ensure compliance with the NCD

Please reach out directly to Medicare Advantage plan administrators to understand any specific prior authorization/pre-certification requirements that may apply.

REFERENCES PAGE 3 OF 15

TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

FY 2023 Hospital Inpatient Reimbursement - Medicare

NATIONAL AVERAGE REIMBURSEMENT INFORMATION

TAVI procedures are assigned to MS-DRG 266/267: Endovascular Cardiac Valve Replacement and Supplement Procedures. Reimbursement rates for FY2023 show a slight decrease of approximately 4% for the DRG family. The rates in the table below are the national average reimbursement rates. For hospital specific rates, please contact your local Abbott representative.

	FY 2023 ²	
MS-DRG	266/267	
With MCCs	\$45,278	
Without MCCs	\$35,399	
Weighted Average	\$38,857	

Weighted average using MS-DRG breakdown of TAVI cases in 2021 Acclaim Data Analytics 35% w/ MCCs, 65% w/o MCCs

FY2023 Payment Rates Effective October 1, 2022 - September 30, 2023

INPATIENT ONLY PROCEDURE

The TAVI procedure is designated by CMS as an Inpatient Only Procedure. Therefore, the two-midnight rule for Medicare does not apply. In addition, there is no designated APC payment for the TAVI procedure nor a C-Code for the TAVI device.

REFERENCES PAGE 4 OF 15

PHYSICIAN

IMAGER



HEALTH ECONOMICS & REIMBURSEMENT

PAGE 1 = PAGE 2 = PAGE 3 = PAGE 4

TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

PROCEDURE CODES

ICD-10-PCS PROCEDURE CODE⁴	DESCRIPTOR
02RF38Z	Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach

DIAGNOSIS CODES

Below are potential ICD-10-CM codes for the TAVI procedure.³ It is the responsibility of the hospital and physician to determine the appropriate diagnosis code(s) for each patient. As discussed above, participation in the TVT Registry is a requirement of TAVI coverage. Secondary ICD-10-CM Diagnosis Code Z00.6 should be used to denote clinical trial participation for these TAVI claims.^{3,5}

POTENTIAL ICD-10-CM DIAGNOSIS CODES 3,5	DESCRIPTOR
I35.0	Nonrheumatic aortic (valve) stenosis
Z00.6	Encounter for exam for normal comparison and control in clinical research program

REFERENCES PAGE 5 OF 15

TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

DOCUMENTATION OF PATIENT COMORBIDITIES

Patient complications and comorbidities should be identified on admission. Ensure the documentation addresses the acuity, treatment of the comorbidity while in the hospital, and the status on discharge. Always use the most detailed and appropriate code available versus defaulting to an "unspecified" code. It is the responsibility of the hospital or physician to determine appropriate coding for a particular patient and/or procedure.

For reference, below are the common major complications and comorbidities on TAVI claims⁸.

ICD-10-CM	DESCRIPTION
E43	Unspecified severe protein-calorie malnutrition
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I50.23	Acute on chronic systolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
J96.01	Acute respiratory failure with hypoxia
J96.21	Acute and chronic respiratory failure with hypoxia
N17.0	Acute kidney failure with tubular necrosis
N18.6	End stage renal disease
R57.0	Cardiogenic shock

REFERENCES PAGE 6 OF 15

TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

ADDITIONAL REQUIREMENTS

Additional coding requirements are necessary for TAVI cases enrolled in the TVT Registry.

ADDITIONAL REQUIRED INFORMATION 3,5	NOTES
NCT 01737528	National Clinical Trial Number is required for cases enrolled in the TVT Registry. ² For Form UB-04 paper claims, enter 01737528 in the value amount, value code D4. For 837I electronic claims, enter 01737528 in Loop 2300 REF02 (REF01 = P4).
Condition Code 30	Condition Code is required for cases enrolled in the TVT Registry.
Revenue Code 278	Medical/Surgical supplies and devices: Other Implants. A revenue code must be included on all TAVI inpatient claims.
Bill Type 11x	Hospital Inpatient

For additional considerations for private payer and Medicare Advantage plans, please reference the coverage section of this guide

REFERENCES PAGE 7 OF 15



TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

HOSPITAL CLAIM CHECKLIST

This checklist is provided as a summary of the information used to process claims for TAVI procedures per the CMS NCD 20.32⁶. This list includes the most commonly used codes and is not all-inclusive. It is the responsibility of the hospital and/or physician to determine appropriate coding for a particular patient and/or procedure. Any claim should be coded appropriately and supported with adequate documentation in the medical record.

CODES / MODIFIERS / OTHER	WHEN USED?	INCLUDED
DIAGNOSIS CODES		
Z00.6 Examination of a participant in a clinical trial	All cases - required to indicate inclusion in TVT Registry	
I35.0 Nonrheumatic aortic (valve) stenosis	When appropriate	
ICD-10-PCS CODE		
02RF38Z: Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach	All cases	
BILL TYPE		
11x - Inpatient	All cases	
CONDITION CODE		
30 – Qualifying clinical trial	All cases	
NCT NUMBER		
01737528	All cases	
REVENUE CODE		
0278: Medical/Surgical supplies and devices, other implants	All cases	

REFERENCES PAGE 8 OF 15

CODING AND REIMBURSEMENT FOR TAVI

IMPLANTING PHYSICIAN¹

			NATIONAL MEDICARE RATE	
CPT [‡] CODE	DESCRIPTION Output Description Output Description Output Description Descr	WORK RVU	FACILITY RATE	MODIFIER -62
TRANSCA	THETER AORTIC VALVES IMPLANTATION			
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	22.47	\$1,168	\$730
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	24.54	\$1,273	\$796
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	25.47	\$1,318	\$824
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	25.97	\$1,318	\$824
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)	26.59	\$1,377	\$861
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)	11.88	\$589	NA
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)	14.39	\$713	NA
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)	19.00	\$942	NA
INTRACARDIAC ECHOCARDIOGRAPHY (ICE)				
+93662	Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure)	1.44	\$71	NA

^{(+) =} Indicates add-on code. List add-on code separately in addition to code for primary procedure.

Effective Dates: January 1, 2023 - December 31, 2023

REFERENCES PAGE 9 OF 15

^{*}Modifier 62 Payment = 62.5% of Facility Payment⁷.

^{**33367-33369} are add-on codes for cardiopulmonary bypass support to be used by cardiac surgeon, when performed as applicable. These codes do not require usage of the 62 modifier.





CODING AND REIMBURSEMENT FOR TAVI

CODING MODIFIERS AND ADDITIONAL REQUIREMENTS

REQUIREMENTS FOR BILLING 3,5	NOTES
Modifier -Q0	Use for physician claims for cases enrolled in the TVT Registry.
Modifier -62	Use for physician claims for TAVR procedure to indicate participation of two surgeons/co-surgeons.
Place of Service 21	Inpatient hospital
NCT 01737528	National Clinical Trial Number is required for cases enrolled in the TVT Registry. For Form CMS-1500 paper claims, enter 'CT' followed by 01737528 in Field 19. For 837P electronic claims, enter 01737528 (no 'CT') in Loop 2300 REF02 (REF01 = P4).
Diagnosis code Z00.6	Encounter for the examination for normal comparison and control in clinical research program – required for inclusion in TVT Registry

REFERENCES PAGE 10 OF 15



PAGE 1 = PAGE 2 = PAGE 3

TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

DIAGNOSIS CODES

Below are potential ICD-10-CM codes for the TAVI procedure.³ It is the responsibility of the hospital and physician to determine the appropriate diagnosis code(s) for each patient. As discussed above, participation in the TVT Registry is a requirement of TAVI coverage. Secondary ICD-10-CM Diagnosis Code Z00.6 should be used to denote clinical trial participation for these mitral TAVI claims.^{3,5}

ICD-10-CM DIAGNOSIS CODES 3,5	DESCRIPTOR
I35.0	Nonrheumatic aortic (valve) stenosis
Z00.6	Encounter for exam for normal comparison and control in clinical research program

For additional considerations for private payer and Medicare Advantage plans, please reference the coverage section of this guide.

REFERENCES PAGE 11 OF 15

CODING AND REIMBURSEMENT FOR TAVI

PROCEDURAL IMAGING¹

CPT [‡] CODE	DESCRIPTION	WORK RVU	NATIONAL FACILITY	MEDICARE RATE NON FACILITY
TRANSE	OPHAGEAL ECHOCARDIOLOGY (TEE)			
93355*	Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (e.g., TAVR, transcathether pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intraprocedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D	4.66	\$217	NA

^{*} Note that 93355 is bundled and not separately payable when reported on the same physician claim as the primary procedure or with anesthesia services²

Effective Dates: January 1, 2023 - December 31, 2023

REFERENCES PAGE 12 OF 15

CODING AND REIMBURSEMENT FOR TAVI

FOR IMPLANTING PHYSICIAN(S):

This checklist is provided as a summary of the information used to process claims for TAVI procedures per CMS's NCD 20.32.6 It is the responsibility of the hospital and/or physician to determine appropriate coding for a particular patient and / or procedure. Any claim should be coded appropriately and supported with adequate documentation in the medical record.

CODES / MODIFIERS / OTHER	WHEN USED?	INCLUDED	NA
DIAGNOSIS CODES ²			
I35.0: Nonrheumatic aortic (valve) stenosis	When appropriate		
Applicable secondary diagnosis codes	When appropriate		
CPT [‡] CODES			
33361: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	Femoral artery approach cases		
+93662: Intracardiac echocardiography during therapeutic/diagnostic intervention	When appropriate		
CPT [‡] CODE MODIFIERS			
-Q0: Investigational / Routine clinical service provided in a clinical research study that is in an approved clinical research study.	All cases		
-62: When two surgeons work together as primary surgeons performing distinct part(s) of a procedure.	When two surgeons/co-surgeons perform the procedure. Supporting documentation is required to show medical necessity for co-surgeons.		
NCT NUMBER			
01737528	All cases		

(+) = Indicates add-on code. List add-on code separately in addition to code for primary procedure.

REFERENCES PAGE 13 OF 15

Abbott

PAGE 1 = PAGE 2

CODING AND REIMBURSEMENT FOR TAVI

FOR ECHOCARDIOGRAPHER:

This checklist is provided as a summary of the information used to process claims for TAVI procedures per CMS's NCD 20.32.6 It is the responsibility of the hospital and/or physician to determine appropriate coding for a particular patient and / or procedure. Any claim should be coded appropriately and supported with adequate documentation in the medical record.

CODES / MODIFIERS / OTHER	WHEN USED?	INCLUDED	NA
DIAGNOSIS CODES ²			
I35.0: Nonrheumatic aortic (valve) stenosis	When appropriate		
Applicable secondary diagnosis codes	When appropriate		
CPT [‡] CODES			
93355: TEE for intraprocedural monitoring	All cases		
CPT‡ CODE MODIFIERS			
-Q0: Investigational / Routine clinical service provided in a clinical research study that is in an approved clinical research study.	All cases		
NCT NUMBER			
01737528	All cases		

REFERENCES PAGE 14 OF 15



References

- 1. Physician Prospective Payment-Final rule with Comment Period and Final CY2023 Payment Rates. CMS-1770-F: https://www.cms.gov/medicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1770-f
- 2. Hospital Inpatient Prospective Payment-FY 2023 Final Rule CMS-1771-F: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-final-rule-home-page
- 3. CMS 2023 ICD-10-CM: https://www.cms.gov/medicare/icd-10/2023-icd-10-cm
- 4. CMS 2023 ICD-10-PCS Procedure Coding System and Index: https://www.cms.gov/medicare/icd-10/2023-icd-10-pcs
- 5. MLN Matters® Articles 2013 Transmittals Transcatheter Aortic Valve Replacement (TAVR) (MM8168, MM8255), https://www.cms.gov/Regulations-and-Guidance/Guidance/Guidance/Transmittals/2013-Transmittals
- 6. CMS National Coverage Determination for Transcatheter Aortic Valve Replacement (TAVR) 20.32, https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=355&ncdver=2&keyword=TAVR&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAAA&KeyWordLookUp=Doc&KeyWordSearchType=Exact
- 7. Medicare Claims Processing Manual, Chapter 12, Section 40.8, Section B Billing instructions, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf
- 8. Medicare Inpatient Hospital Standard Analytical Files. 2021 MEDPAR file. Data set on file.

Abbott

3200 Lakeside Dr., Santa Clara, CA 95054 USA Tel: 1.800.227.9902

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

www.cardiovascular.abbott

©2023 Abbott. All rights reserved. MAT-2106409 v6.0 | Item approved for U.S. use only.

HE&R approved for non-promotional use only.

Abbott

<u>references</u>