2019
Billing and Coding Guide
Transcatheter Aortic Valve Replacement (TAVR) Procedures

Contents

See page 11 for important information about the uses and limitations of this document.

Reimbursement Overview

The table below provides an overview of coding, coverage and payment for TAVR procedures, across sites-of-service and by payer.

Element	Description	Examples	TAVR
Coding Diagnosis and Procedure Codes	**What happened? Why?**	• Procedure Codes (CPT® Codes, ICD-10 Procedure Codes) • Diagnosis Codes (ICD-10 Diagnosis Codes)	• See hospital and physician sections for specific codes to be used.
Coverage National Coverage Determinations, Local Coverage Determinations, Coverage Policies	**Was it medically necessary and therefore payers may cover the procedure?**	• National Coverage Determinations (NCDs) from Medicare • Local Coverage Determinations (LCDs) from Medicare • Coverage Policies from Commercial/Private Payers	• The Medicare National Coverage Determination (NCD) 20.32 was established in 2013. • Private payer coverage varies by payer policy for TAVR procedures. Check with local payers for their coverage policies.
Facility Payment Inpatient, outpatient, ASC, physician office payments	**What do hospitals, ambulatory surgery centers or physician offices get paid for the procedure?**	• MS-DRGs (inpatient payment) • APCs (outpatient payment) • ASC payments (~90% of APC for device-intensive procedures, ~60% of APC payment for many other procedures) • Non-facility payments (physician offices)	• The TAVR procedure is conducted on an inpatient only basis. The most common mappings are MS-DRG 266 (endovascular cardiac valve replacement with MCC) and MS DRG 267 (endovascular cardiac valve replacement w/o MCC). • See hospital section of this guide for specific payments.
MD Payment Physician Fees	**What do physicians get paid for the procedure?**	• Physician payments	• See physician section of this guide for specific payments.

National Coverage Determination (NCD)

Transcatheter aortic valve replacement (TAVR - also known as TAVI or transcatheter aortic valve implantation) is used in the treatment of aortic stenosis. The Centers for Medicare & Medicaid Services (CMS) covers TAVR under Coverage with Evidence Development (CED) for the treatment of symptomatic aortic valve stenosis furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the conditions outlined in the NCD are met.[1]

Most TAVR patients are Medicare beneficiaries (90% of all TAVR procedures conducted in 2016 were for Medicare patients)[2]. Below are highlights of the National Coverage Determination (NCD) that the Centers for Medicare and Medicaid Services (CMS) implemented in 2013 for TAVR procedures. Note, this NCD is under revision. On June 27, 2018, the Centers for Medicare and Medicaid Services (CMS) opened up a National Coverage Analysis (NCA) to re-examine the requirements of the NCD. CMS will update and change the NCD in 2019. For private payers, coverage varies by payer policy. Check with local payers for their TAVR procedure coverage policies.

Highlights of the current Medicare NCD include:

Coverage for ALL Medicare Beneficiaries

- Variations exist for Medicare Advantage plans

Procedure Volume Requirements for Hospitals and Physicians

To gain/maintain Medicare coverage and start/continue to offer a TAVR program:

- Physicians AND hospitals must meet procedure volume requirements
- New AND existing physicians and sites must meet procedure volume requirements

Registry Participation Mandatory

- Participation is a must in the TVT and NCDR registries

Heart Team Approach

- The heart team must be involved in all cases. It includes at least two physicians, an interventional cardiologist and a cardiovascular surgeon as well as other members.

[1] Source: https://www.cms.gov/medicare-coverage-database/details/ncddetails.aspx?NCDid=355&ncdver=1&NCAid=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+(TAVR)&bc=ACAAAAAACAAAAA%3D%3D&.%20

[2] Estimate based on AHRQ HCUP data www.hcupnet.ahrq.gov

Physician Coding and Payment

Based on CMS billing instructions, physician claims will need to have the following items to support the NCD for TAVR procedures. The following summaries physician and hospital claim submission requirements set forth by the NCD.

Codes and Modifiers:

- CPT® codes 33361-33366 listed in the chart below, include access, balloon valvuloplasty, insertion, placement, temporary pacing, intra-procedural contrast injection[s], fluoroscopic radiological supervision and interpretation, and imaging guidance when performed as part of TAVR procedure.
- Modifier 62: The NCD requires two surgeons (each in a different specialty) to perform TAVR procedures. Modifier 62 is required to be used by both the interventional cardiologist and surgeon when documenting the TAVR CPT codes.
- Surgeons: Applicable bypass add-on codes 33367-33369 do not require the use of modifier 62.
- Modifier Q0 (zero): Investigational clinical service provided in a clinical research study that is in an approved clinical research study. Modifier Q0 indicates participation per the NCD requirement for a qualified clinical study or registry.
- Z00.6 Diagnosis Code (placed as a secondary diagnosis code): Z00.6 Encounter for examination for normal comparison and control in a clinical research program to report qualified study or registry participation (e.g., REPRISE III Clinical Study, TVT Registry, etc.)
- Clinical Trial Number(s): Mandatory reporting of the applicable 8-digit clinical trial or registry number for study or registry participation because TAVR is covered only under CED.
- The clinical trial number should be preceded by the two alpha characters of “CT” and placed in Field 19 of the paper Form CMS-1500 or it should be entered WITHOUT the “CT” prefix in the electronic 837P in Loop 2300 REF02(REF01=P4).
    - TVT Registry: CT01737528
- Place of Service (POS)[2,3]: POS 21 Inpatient Only: TAVR procedures are currently on the inpatient only list.

[3] Source: OPPS Addendum E; https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending

2019 Physician Coding and Payment – TAVR Procedures

CPT® Codes	CPT® Code Description	Physician In-Hospital Payment*	*Work RVU* Total RVU
Endovascular or Transthoracic Valves			
33361 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	**$1,423**	*25.13* 39.48
33362 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	**$1,553**	*27.52* 43.10
33363 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	**$1,609**	*28.50* 44.64
33364 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	**$1,663**	*30.00* 46.14
33365 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)	**$1,868**	*33.12* 51.83
33366 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)	**$2,019**	*35.88* 56.03
+33367 *Aortic*	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)	**$659**	*11.88* 18.29
+33368 *Aortic*	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)	**$783**	*14.39* 21.72
+33369 *Aortic*	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)	**$1,033**	*19.00* 28.67
33477 *Pulmonary*	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed	*Carrier priced*	*0.00* 0.00
33999	Unlisted procedure, cardiac surgery	*Carrier priced*	0.00 0.00
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis	$1,888	*32.25* 52.39
+33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)	$446	*7.93* 12.36
Paravalvular Leak Repair			
93590	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve	$1124	*21.70* 31.20
93591	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve	$926	*17.97* 25.70
93592	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)	$410	*8.00* 11.39

Inpatient information effective through September 30, 2019 | Physician fee information effective through December 31, 2019
National average Medicare physician payment rates calculated using the 2019 conversion factor of $36.0391

Hospital Coding and Payment

Based on CMS billing instructions, hospital claims will need to have the following items to support the NCD for TAVR procedures, in addition to the appropriate ICD-10 PCS code[4]:

- Z00.6 Diagnosis Code (placed as a secondary diagnosis code): Z00.6 Encounter for examination for normal comparison and control in clinical research program to report qualified study or registry participation (e.g., REPRISE III Clinical Study, TVT Registry, etc.).
- Condition Code 30 Qualifying Clinical Trial: Report in UB-04 fields 18-28 to indicate participation per the NCD requirement for qualified clinical study or registry.
- Clinical Trial Number(s): Mandatory reporting of the applicable 8-digit clinical trial or registry number for study or registry participation since TAVR is covered only under CED.
- The 8-digit numeric clinical trial number should be placed in the value amount of value code D4 on the paper claim UB-40 (Form Locators 39-41) or in Loop 2300, HI – Value Information segment, qualifier BE on the 837I.
    - IDE Study Devices: report IDE# in revenue code 624
    - TVT Registry: CT01737528
- Place of Service (POS)[5]: POS 21 Inpatient Only (TAVR procedures are currently on the inpatient only list).

2019 ICD 10 PCS Codes			
Character 1 – Section: 0 Medical and Surgical **Character 2 – Body System: 2 Heart** **Character 3 – Root Operation: R Replacement**			
Body Part **Character 4**	**Approach** **Character 5**	**Device** **Character 6**	**Qualifier** **Character 7**
Select Appropriate Options			
F Aortic Valve	**3 Percutaneous**	**7 Autologous Tissue Substitute** **8 Zooplastic Tissue** **J Synthetic Tissue** **K Nonautologous Tissue Substitute**	**H Transapical** **Z No Qualifier**
ICD-10-PCS	**Lotus Valve System: 02RF38Z**		

2019 Most Common MS - DRG Assignments for TAVR procedures		
MS-DRG	**Definition**	**MS-DRG National Base Rate Payment Amounts**
MS-DRG 266	Endovascular cardiac valve replacement with Major Complication or Comorbidity [MCC])	$43,935
MS-DRG 267	Endovascular cardiac valve replacement without Major Complication or Comorbidity [MCC])	$35,727

[4] Source: Section 290.2 CMS Manual System Transmittal 2827; https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2827CP.pdf

[5] Source: OPPS Addendum E; https://www.cms.gov/Medicare/Medicare-Fee-for-Service Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending

SENTINEL™ Cerebral Protection System Coding

The SENTINEL Cerebral Protection System is a percutaneously delivered embolic protection device, designed to protect the brain from injury caused by embolic debris dislodged during endovascular procedures.

There is currently a new technology add-on payment available for SENTINEL Cerebral Protection System. CMS approved a new technology add-on payment (NTAP) for SENTINEL systems as part of the FY 2019 Inpatient Prospective Payment System (IPPS) final rule. The NTAP payment became effective for discharges on October 1, 2018.

Based on CMS billing instructions, hospital claims will need to have the following items documented in order to be eligible for the NTAP payment:

- Hospitals must use the existing SENTINEL ICD-10-PCS code below (X2A5312) when SENTINEL is used in TAVR procedures. In addition:
- Potential diagnosis codes may include:
  - Primary ICD-10 diagnosis code:
    - 135.0 - Nonrheumatic aortic (valve) stenosis
    - 106.0 – Rheumatic aortic stenosis
  - Secondary diagnosis code:
    - Z00.6 - Encounter for examination for normal comparison and control in clinical research program

2019 Procedure Codes for TAVR Procedures Using SENTINEL Embolic Protection Device		
Code Type	**Code**	**Definition**
HCPCS**	C1884	Embolization Protective System
ICD-10-PCS	**X2A5312**	**Cerebral Embolic Filtration, Dual Filter in Innominate Artery and Left Common Carotid Artery, Percutaneous Approach, New Technology Group**
ICD-10-PCS	02RF38H	Replacement of Aortic Valve with Zooplastic Tissue, Transapical, Percutaneous Approach
ICD-10-PCS	02RF38Z	Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach
ICD-10-PCS	02RF3KH	Replacement of Aortic Valve with Nonautologous Tissue Substitute, Transapical, Percutaneous Approach
ICD-10-PCS	02RF3KZ	Replacement of Aortic Valve with Nonautologous Tissue Substitute, Percutaneous Approach

**There is not a unique CPT-code for the use of SENTINEL as embolic protection is seen as part of the procedure. HCPCS code C1884 (Embolization protective system) may be used when appropriate.

SENTINEL™ Cerebral Protection System NTAP Payment

SUMMARY

As stated above, CMS approved the SENTINEL Cerebral Protection System application for a new technology add-on payment (NTAP) as part of the FY 2019 Inpatient Prospective Payment System (IPPS) final rule. The NTAP is an additional payment that is added on top of MS-DRG payments to qualifying cases at institutions where the costs of using new technology exceed the reimbursement for the procedure. Hospitals may be eligible for incremental reimbursement up to $1400 per case.

CALCULATION

Medicare has created the NTAP to help hospitals ensure patients have access to care that may be more expensive due to the newness of a technology. CMS determines NTAP payments on a case by case basis. For each case where the new technology has been used and documented, CMS will determine if the total costs of the case are more than the MS-DRG payment. If they are, Medicare will provide an add-on payment (NTAP).

Payment is determined separately for each eligible discharge claim, depending on the estimated hospital cost and hospital-specific DRG payment for that specific patient discharge, and will be between $0-$1400 for each claim.

CMS will pay 50% of the excess between estimated hospital costs and payments for that claim, up to a maximum of $1400.

NTAP Calculation Examples	Example A	Example B	Example C
Hospital costs for the individual patient claim[1] (Including SENTINEL)	$43,000	$47,000	$49,000
Hospital-specific DRG payment for that claim[2]	$45,000	$45,000	$45,000
Difference between DRG payment and cost (before NTAP payment)	+$2,000	-$2,000	-$4,000
Resulting NTAP payment for SENTINEL for that claim (50% of difference above, if costs with SENTINEL exceed DRG payment, up to max of $1400)	$0	$1,000	$1,400
Difference between payment and cost (after NTAP payment)	+$2,000	-$1,000	-$2,600

[1]Hospital charges reduced to estimated costs by applying hospital-specific cost-to-charge ratio

[2]Including adjustments for indirect medical education and disproportionate share but excluding outlier payments

DOCUMENTATION

Hospitals should continue to capture all charges and resources reported with TAVR procedures. For reimbursement purposes, all work that is done should be documented. When a procedure includes the use of SENTINEL, it would be appropriate to document its use with the ICD-10-PCS section X procedure code, X2A5312, Cerebral Embolic Filtration, Dual Filter in Innominate Artery and Left Common Carotid Artery, Percutaneous Approach, New Technology Group 2. However, documentation is no guarantee of payment.

Documenting usage is important because CMS uses hospital charges and cost report data to determine payment rates under the Inpatient Prospective Payment System (IPPS). For example, claims data from October 1, 2016 through September 30, 2017 were used to determine payment rates for discharges that took place from October 1, 2017 through September 30, 2018. Therefore, it is important to appropriately capture all charges associated with TAVR procedures for CMS to set payment rates that most accurately reflect procedure costs, including the cost of the devices utilized. The cost parameters and resources reflected may vary based on clinical practice so it is important that hospitals' documentation and charges accurately reflect what is occurring in their institution. (Medicare claims reflect data that predate the year for which rates are being set usually by two years.)

Coding & Reimbursement Support

Boston Scientific is dedicated to providing physicians, allied health professionals and hospitals with world-class programs and services to help advance the standard of patient care and appropriate access to life-enhancing technologies.

For questions regarding TAVR procedures and SENTINEL™ reimbursement, please contact:

Email: IC.Reimbursement@bsci.com
Voicemail: 1(800) CARDIAC, and request extension 24114 to leave a message.
Messages are monitored M-F, 8am-4pm CT and responses are typically on the same or following business day.

Uses and Limitations

IMPORTANT—Please Note:

This Billing and Coding Guide for transcatheter aortic valve repair (TAVR) procedures provides coding and reimbursement information for physicians and healthcare facilities.

The codes included in this guide are intended to represent typical TAVR procedures where there is: 1) at least one product approved by the U.S. Food and Drug Administration (FDA) for use in the listed procedure; and 2) specific procedural coding guidance provided by a recognized coding or reimbursement authority such as the American Medical Association (AMA) or the Centers for Medicare and Medicaid Services (CMS). This guide is in no way intended to promote the off-label use of medical devices.

Please note that while these materials are intended to provide coding information for TAVR procedures, the FDA-approved/cleared labeling for all products may not be consistent with all uses described in these materials. Some payers, including some Medicare contractors, may treat a procedure which is not specifically covered by a product's FDA-approved labeling as a non-covered service.

The Medicare reimbursement amounts shown are currently published national average payments. Actual reimbursement will vary for each provider and institution for a variety of reasons including geographic differences in labor and non-labor costs, hospital teaching status, proportion of low-income patients, coverage, and/or payment rules. Please feel free to contact the Boston Scientific reimbursement department at 1-800-CARDIAC if you have any questions about the information in these materials. You can also find reimbursement updates on our website: www.bostonscientific.com/reimbursement

Disclaimer

Please note: this coding information may include codes for procedures for which Boston Scientific currently offers no cleared or approved products. In those instances, such codes have been included solely in the interest of providing users with comprehensive coding information and are not intended to promote the use of any Boston Scientific products for which they are not cleared or approved.

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Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

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