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SENTINEL™ 2025 Hospital Reimbursement & Coding Guide

This comprehensive guide provides an overview of the coding, coverage and payment landscape for the SENTINEL™ Cerebral Protection System.

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.

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SENTINEL™
Cerebral Protection System

REIMBURSEMENT & CODING GUIDE

SH-939604-AF

SENTINEL™ CEREBRAL PROTECTION SYSTEM

INDICATIONS FOR USE

The SENTINEL Cerebral Protection System is indicated for use as an embolic protection device to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures. The diameters of the arteries at the site of filter placement should be between 9.0 mm – 15.0 mm for the brachiocephalic and 6.5 mm – 10.0 mm in the left common carotid.

CONTRAINDICATIONS

- Do not use in patients for whom anticoagulant and antiplatelet therapy is contraindicated.
- Do not use in patients with a known hypersensitivity to nickel-titanium.
- Do not use in vessels with excessive tortuosity.
- Do not use in patients with uncorrected bleeding disorders.
- Do not use in patients with compromised blood flow to the right upper extremity.
- Do not use in patients who have arterial stenosis >70% in either the left common carotid artery or the brachiocephalic artery.
- Do not use in patients whose brachiocephalic or left carotid artery reveals significant stenosis, ectasia, dissection, or aneurysm at the aortic ostium or within 3 cm of the aortic ostium.

WARNINGS

- The appropriate antiplatelet/anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice.
- It is recommended that the patency of the right radial or brachial artery be assessed prior to the introduction of the SENTINEL System.
- It is recommended that the patient be tested for occlusion of the radial or brachial artery prior to device introduction.
- Do not use the device in left radial or left brachial access.
- Do not use the SENTINEL System to deliver any type of fluid to the patient e.g. contrast media, heparinized saline, etc. due to risk of air embolization and comprise to device performance. Excessive movement of filters may lead to embolization of debris, vessel and/or device damage.
- Do not deploy the filters within a previously repaired artery, an artery that has been used for dialysis purposes, or an AV fistula.
- Indwell time of the SENTINEL System is not to exceed 90 minutes as occlusion could occur, resulting in slow or no flow.
- Do not undersize or oversize the filters in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the filters. (Refer to Sizing Guide, Table 1 in the DFU).

PRECAUTIONS

- Do not forcefully bend or reshape the Articulating Sheath of the SENTINEL System.
- Use of TAVR delivery systems other than those designed to cross the aortic arch with a valve frame in a sheathed or crimped configuration may result in device interference or entanglement.

ADVERSE EVENTS

Possible adverse events associated with SENTINEL System use and application procedure include, but are not limited to, the following:

• Access site complications • Angina • Aortic dissection • Arrhythmia • Arteriovenous fistula • Atelectasis • Bleeding, operative or post-operative • Cardiac Tamponade • Cardiogenic Shock • Conduction system injury • Congestive Heart Failure (CHF) • Death • Endocarditis • Embolism, including air • Gastrointestinal (GI) bleed • Hematoma • Ischemia (coronary, limb, arotid) • Infection (local or systemic) • Myocardial Infarction (MI) • Nerve injury • Pericardial effusion • Pneumonia • Pulmonary edema • Pulmonary embolism • Respiratory failure • Respiratory insufficiency • Stroke • Vessel injury (e.g., dissection, rupture, perforation, pseudoaneurysm).

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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IMPORTANT INFORMATION

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules, and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice.

Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered.

It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters.

Boston Scientific does not promote the use of its products outside their FDA-approved label.

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.

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. The Health Care Provider (HCP) is solely responsible for selecting the site of service and treatment modalities appropriate for the patient based on medically appropriate needs of that patient and the independent medical judgement of the HCP.

Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

SENTINEL™ 2025 REIMBURSEMENT & CODING GUIDE

This guide has been developed as a resource for individuals seeking a better understanding of hospital and physician reimbursement for services rendered to patients who receive SENTINEL in conjunction with a transcatheter aortic valve replacement (TAVR) procedure. We strongly suggest that you consult relevant payer organizations regarding local coverage, coding and reimbursement policies.

The SENTINEL™ Cerebral Protection System is a percutaneously delivered dual-filter protection device designed to capture and remove debris dislodged during TAVR procedures. Through right radial access, SENTINEL delivers a Proximal Filter to the brachiocephalic artery, and a Distal Filter to the left common carotid artery. At procedure completion, the filters and debris are recaptured into the catheter and removed from the patient.

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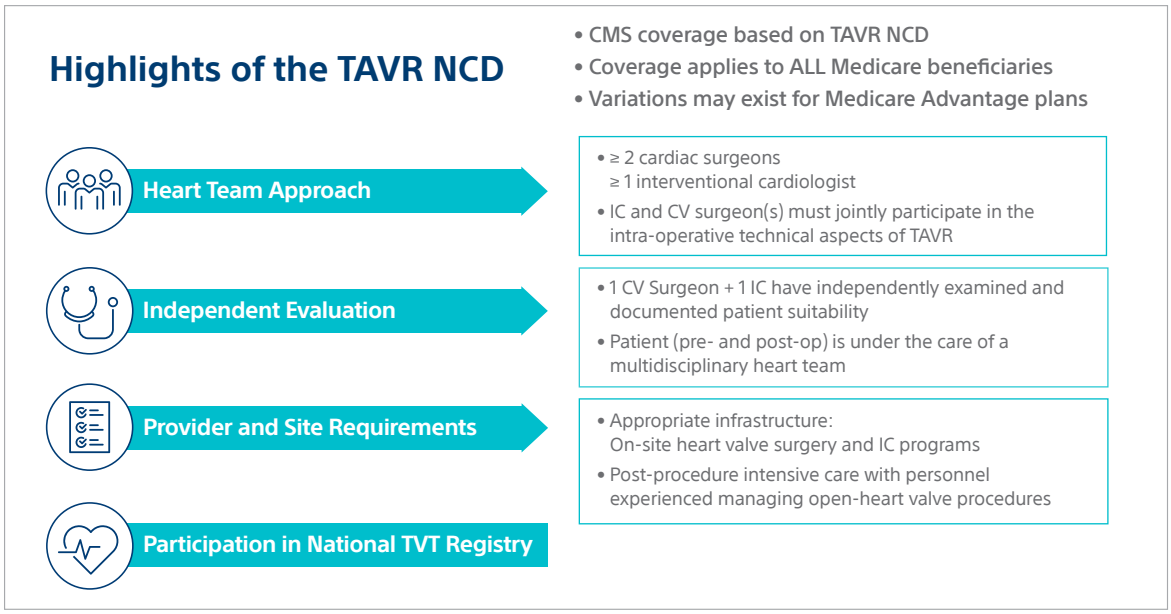
TAVR MEDICARE COVERAGE: NATIONAL COVERAGE DETERMINATION (NCD)

Transcatheter aortic valve replacement (TAVR), also known as TAVI or transcatheter aortic valve implantation, is used in the treatment of aortic stenosis (AS). 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] The graphic below provides highlights of the National Coverage Determination (NCD).



For full coverage description in the NCD visit:
https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=293

Original Medicare – CMS National Coverage Determination (NCD CED 20.32, updated final memo on June 21, 2019, CAG-00430R) establishes uniform coverage criteria

Medicare Advantage – Medicare Advantage plans must cover all the services that Original Medicare covers. The NCD CED coverage criteria for Original Medicare also provides coverage to Medicare Advantage Patients*

Private Payers – Coverage dependent on individual payer policy

* https://www.medicare.gov/what-medicare-covers/what-medicare-health-plans-cover/medicare-advantage-plans-cover-all-medicare-services

CODING

Based on CMS billing instructions, hospital claims will need to have the following items to support the NCD for TAVR procedures including SENTINEL™.

Diagnosis and Procedure Codes

Medicare has determined that the TAVR procedure is most appropriately performed in the inpatient hospital site of service. Inpatient hospital procedures will be reported using ICD-10 procedure codes (ICD-10-PCS) and ICD-10 diagnosis codes (ICD-10-CM). The most commonly reported ICD-10-PCS procedure code for TAVR procedures is 02RF38Z. Due to the NCD requirement to participate in the STS/ACC TVT Registry, the ICD-10-CM code, Z00.6 designating participation in a clinical trial should be used in all Medicare claims in addition to the other relevant diagnoses of the patient.

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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HOSPITAL CODING

ICD-10-PCS Procedure Codes

ICD-10-PCS Procedure Code	Procedure Description
X2A5312	Cerebral Embolic Filtration, Dual Filter in Innominate Artery and Left Common Carotid Artery, Percutaneous Approach, New Technology Group
02RF38Z	Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach
02RF38H	Replacement of Aortic Valve with Zooplastic Tissue, Transapical, Percutaneous Approach

The SENTINEL™ ICD-10-PCS code X2A5312 should continue to be used to allow tracking of usage, costs and outcomes.

ICD-10-CM Diagnosis Codes

There are many ICD-10-CM diagnosis codes that may be appropriate for TAVR procedures. Some of the more common ones include:

	ICD-10-CM Diagnosis Codes
Primary	I35.0 - Nonrheumatic aortic (valve) stenosis
Secondary	Z00.6 - Encounter for examination for normal comparison and control in clinical research program Other diagnosis codes that document complications and comorbidities that are actively managed during an admission will be relevant to document.

Because TAVR is designated as an inpatient-only procedure, there are no C-codes assigned. C-codes are reported for device-intensive procedures performed in the outpatient hospital site of service. However, C-codes are sometimes used in other hospital departments. Therefore, HCPCS code C1884 (Embolization protective system) may be used when appropriate.

HCPCS Code	
C1884	Embolization protective system

PHYSICIAN CODING

CPT® code for Percutaneous Cerebral Embolic Protection

The American Medical Association (AMA) established a CPT "add-on" code for use of SENTINEL cerebral embolic protection during TAVR procedures: +33370 Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (list separately in addition to code for primary procedure). It was created as add-on code to report percutaneous transcatheter placement and subsequent removal of cerebral embolic protection (CEP) device(s).

CEP devices used in transcatheter aortic valve replacement (TAVR) and transcatheter aortic valve implantation (TAVI) procedures:

- Captures embolic material (eg, calcification fragments) that may be loosened during the TAVR/TAVI procedure to prevent a potential cerebrovascular accident (CVA).
- Add-on code +33370 is reported in conjunction with codes 33361 - 33366.

This is a physician code to report billing and payments representing the work and effort associated with the use of cerebral embolic protection during TAVR/TAVI procedures. The physician that is doing the work to place the SENTINEL device, is the only physician that should report the CPT code +33370 for billing and payment.

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PHYSICIAN CODING CONTINUED

Instructions on appropriate reporting of code +33370:

- Add-on code +33370 may be reported for cerebral embolic protection in conjunction with TAVR/TAVI codes 33361, 33362, 33363, 33364, 33365, 33366.
- Code +33370 includes percutaneous arterial (eg, right radial or femoral) access, placement of a guiding catheter, and delivery of the embolic protection filters(s) prior to the procedure.
- Placement of additional/multiple filters is not separately reportable. Code +33370 includes removal of the filter(s) and debris, removal of the arterial sheath, and closure of the arteriotomy by pressure and application of an arterial closure device or standard closure of the puncture by suture. Extensive repair or replacement of an artery may be additionally reported.
- Code +33370 includes all imaging guidance and radiological supervision and interpretation associated with performing cerebral embolic protection (eg, 75600, 75710, 76937).
- Use +33370 in conjunction with 33361, 33362, 33363, 33364, 33365, 33366.

CPT® Code for SENTINEL	
Potential CPT® Code*	**Description**
+33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure)

CPT® codes for TAVR

Physicians use Current Procedural Terminology (CPT) codes to bill for procedures and services. The most commonly reported CPT code for TAVR procedures is 33361.

Physician Codes for TAVR Procedures	
Potential CPT® 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 artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
33365	Transcatheter aortic valve replacement aortic approach (e.g., median sternotomy, (TAVR/TAVI) with prosthetic valve; transmediastinotomy)
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)

CLINICAL TRIAL NUMBERS

Because TAVR is covered under NCD CED 20.32, Coverage with Evidence Development, there is mandatory Medicare claims reporting of the applicable 8-digit national clinical trial (NCT) for clinical study or registry participation.

For a list of CMS approved TAVR NCD clinical studies and registries, visit Medicare's "Coverage with Evidence Development" page. **www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR.** Boston Scientific-specific trials are included in the list below:

Boston Scientific Trial Name / IDs	National Clinical Trial (NCT) Numbers *(For Mandatory Medicare Claims Reporting*)*
STS/ACC Transcatheter Valve Therapy (TVT) Registry [NCT01737528]	Report NCT# for TVT Registry [NCT01737528]
PROTECTED TAVR Post-Approval Trial [NCT04149535]	Reported through NCT# for the TVT Registry (see above)
ACURATE IDE Study [IDE G190051 I NCT03735667]	Report NCT# for IDE Study NCT03735667

**Effective for claims with dates of service on or after January 1, 2014. It is mandatory to report a clinical trial number on claims for items/services provided under coverage with evidence development (CED) without "CT" on the hospital claim (CMS Form UB-04).*

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HOSPITAL REIMBURSEMENT

FY2025 MS-DRG Assignments for TAVR Procedures

MS-DRG assignment is based on a combination of diagnoses and procedure codes reported. While MS-DRGs listed in this guide represent likely assignments. Boston Scientific cannot guarantee assignment to any one specific MS-DRG.

FY2025 MS-DRG Assignments for TAVR Procedures		
MS-DRG	MS-DRG Description	MS-DRG National Base Rate Payment Amounts*
MS-DRG 266	Endovascular cardiac valve replacement with Major Complication or Comorbidity (MCC)	$42,754
MS-DRG 267	Endovascular cardiac valve replacement without Major Complication or Comorbidity (MCC)	$33,575

Source: Inpatient Prospective Payment System (IPPS FY 2025 Final Rule Home Page I CMS)

PHYSICIAN REIMBURSEMENT

CPT® code for SENTINEL

Use the following CPT code for the use of SENTINEL cerebral embolic protection during TAVR procedures: +33370 Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure).

The add on code +33370 was created to report the transcatheter placement and subsequent removal of cerebral embolic protection devices. CMS adopted the RUC recommendation for valuation of this code at 2.5 work RVUs. With a total facility RVUs of 3.93 and a conversion factor of $32.35, the national base payment rate for facility physician services will be **$127** when use of Sentinel is reported. The exact payment amount will vary regionally.

CPT® code for SENTINEL			
CPT® Code*	Description	CY2025 Medicare National Avg. Physician Payment**	CY2025 Facility RVUs
+33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure)	$127	3.93

CPT® codes for TAVR

CPT codes 33361-33366 listed in the table below describe the TAVR procedure. Each code include a variety of services when performed as part of TAVR procedure, also listed in the table. The most commonly reported CPT code for TAVR procedures is 33361. Please note that 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.

Physician Codes for TAVR Procedures				
Potential CPT® Code*	Description	CY2025 Medicare National Avg. Physician Payment**	Each Physician Payment (Modifier-62)***	CY2025 Facility RVUs
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	$1,149	$718	35.51
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	$1,253	$783	38.75
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	$1,298	$811	40.13
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	$1,295	$809	40.03
33365	Transcatheter aortic valve replacement aortic approach (e.g., median sternotomy, (TAVR/TAVI) with prosthetic valve; transmediastinotomy)	$1,352	$845	41.80
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)	$1,491	$932	46.11

***Commercial payment will vary and will be at discretion of the payer.*

****Because the NCD for TAVR requires two physician operators to perform the TAVR procedure, each physician receives a portion of the full payment for conducting the procedure.*

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1. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR (20.32) Accessed 08/28/2020. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=293.

2. CMS MLN Matters MM11660: www.cms.gov/files/document/mm11660.pdf

3. Centers for Medicare and Medicaid Services (CMS). Medicare Program: FY2025 Hospital Inpatient Prospective Payment System, Final Rule; August 1, 2024. IPPS FY 2025 Final Rule Home Page | CMS

4. Medicare Claims Processing Manual: Chapter 32 - Billing Requirements for Special Services, Section 69-Qualifying Clinical Trials. www.cms.gov/manuals/downloads/clm104c32.pdf

FOR MORE INFORMATION ON PROTECTED TAVR™ VISIT **bostonscientific.com/SENTINEL**

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