

SENTINEL™ 2021 HOSPITAL REIMBURSEMENT 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. For questions regarding SENTINEL reimbursement, please contact:

Email: IC.Reimbursement@bsci.com

Voicemail: (877) 786-1050 – select option 2 for Reimbursement
Support Messages are monitored M-F, 8am-4pm CT and responses are typically on the same or following business day.

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 compromise 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, carotid) • 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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SENTINEL™ 2021 REIMBURSEMENT GUIDE

This guide has been developed as a resource for individuals seeking a better understanding of hospital reimbursement for services rendered to patients who receive SENTINEL in conjunction with a transcatheter aortic valve replacement (TAVR). 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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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.

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).

Highlights of the TAVR NCD

- CMS coverage based on TAVR NCD
- Coverage applies to ALL Medicare beneficiaries
- Variations may exist for Medicare Advantage plans



Heart Team Approach

- ≥ 2 cardiac surgeons
≥ 1 interventional cardiologist
- IC and CV surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR



Independent Evaluation

- 1 CV Surgeon + 1 IC have independently examined and documented patient suitability
- Patient (pre- and post-op) is under the care of a multidisciplinary heart team



Provider and Site Requirements

- Appropriate infrastructure:
On-site heart valve surgery and IC programs
- Post-procedure intensive care with personnel experienced managing open-heart valve procedures



Participation in National TVT Registry

For full coverage description in the NCD visit:

<https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=293>

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.

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.

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 Zooplasic Tissue, Percutaneous Approach
02RF38H	Replacement of Aortic Valve with Zooplasic Tissue, Transapical, Percutaneous Approach

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 Code
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.

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 clinical trial or registry number for study or registry participation.²

For a list of approved clinical trials, visit Medicare's "Coverage with Evidence Development" page.

<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR>. Boston Scientific-specific trials are included in the list below:

Boston Scientific Trial Name	Trial Number
STS/ACC Transcatheter Valve Therapy (TVT) Registry	CT01737528*
PROTECTED TAVR [IDE: NCT04149535]	Report through the STS/ACC Registry (see above)
ACURATE IDE [IDE: G190051]	CT03735667*

**Each trial number begins with a "CT" for the physician claim (CMS Form 1500) but is listed without "CT" on the hospital claim (CMS Form UB-04).*

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.

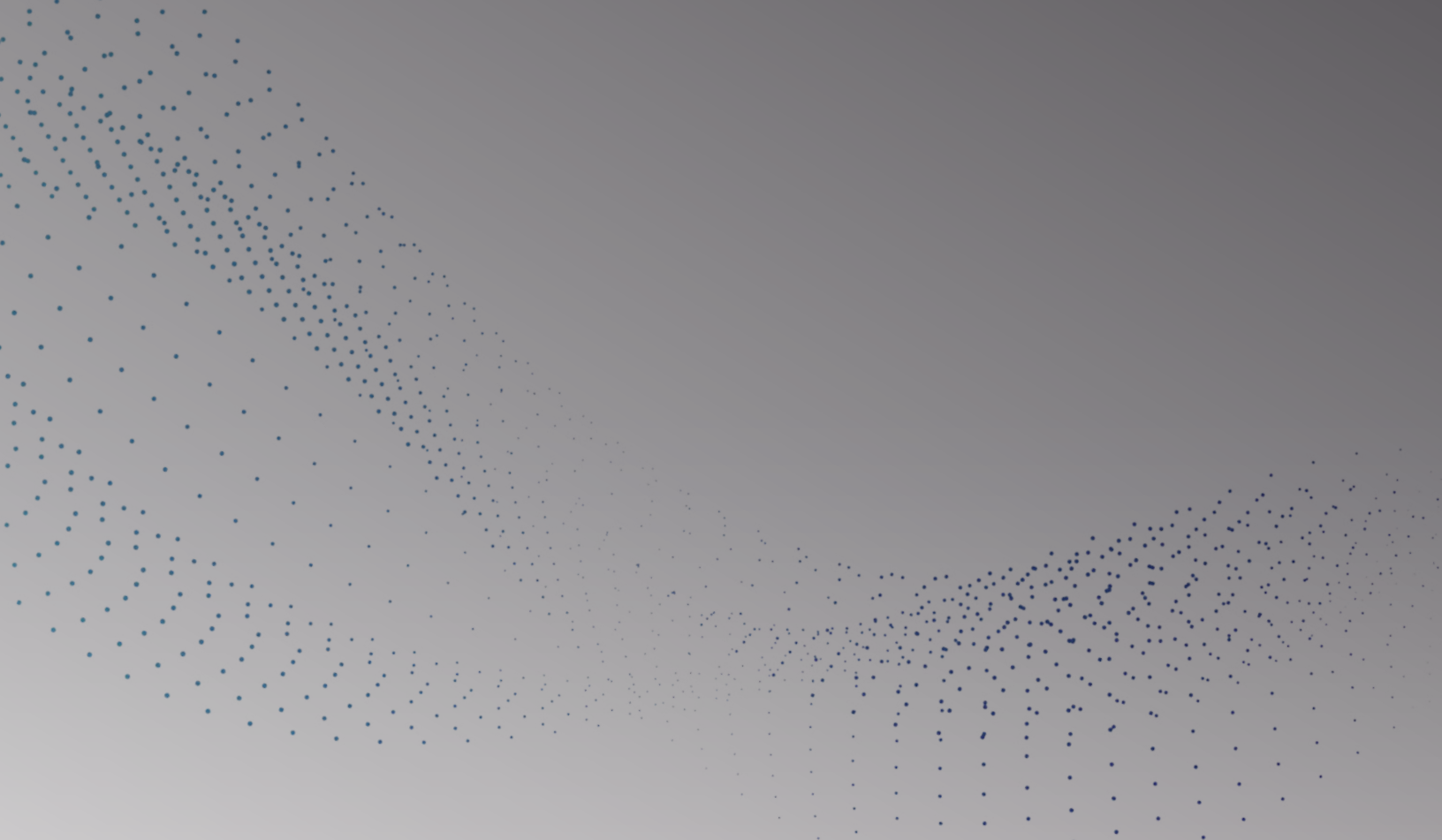
There is not a unique CPT-code for the use of SENTINEL CPS at this time. HCPCS code C1884 (Embolization Protective System) may be used when appropriate.

HCPCS CODE	
C1884	Embolization Protective System

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.

FY2020 MS-DRG Assignments for TAVR Procedures		
MS-DRG	Definition	MS-DRG National Base Rate Payment Amounts
MS-DRG 266	Endovascular Cardiac Valve Replacement and Supplement Procedures with Major Complication or Co-morbidity (w MCC)	\$45,617
MS-DRG 267	Endovascular Cardiac Valve Replacement and Supplement Procedures without Major Complication or Co-morbidity (w/o MCC)	\$35,999

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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: FY2021 Hospital Inpatient Prospective Payment System, Final Rule; September 2, 2020. <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipp-pps-final-rule-home-page>.

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

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Interventional Cardiology
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

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