DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

Agenda

ICD-10 Coordination and Maintenance Committee Update
Department of Health and Human Services
Centers for Medicare & Medicaid Services
ICD-10-PCS Topics Open for Public Comment
Spring 2026

CMS will not be presenting the Spring 2026 ICD-10-PCS procedure code topics during a public meeting. Instead, CMS will be posting the procedure code topic materials and soliciting public comments regarding any clinical questions or coding options consistent with the approach we utilized for the Spring and Fall 2025 updates and have utilized as of March 2021 for the procedure code requests that involve a new technology add-on payment (NTAP) application for the administration of a therapeutic agent. The deadline to submit comments for procedure code topics being considered for an October 1, 2026 implementation is April 17, 2026.

Members of the public should send any questions or comments related to the procedure code topics that are under consideration for an October 1, 2026 implementation to the CMS mailbox at: ICDProcedureCodeRequest@cms.hhs.gov by the respective deadline.

All procedure code topic materials and related documents will be made available on the CMS web site at https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials. Additionally, CMS will post a question-and-answer document to address any clinical or coding questions that members of the public may have submitted by the designated April 17, 2026 deadline.

Note: Proposals for diagnosis code topics will be presented virtually by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and are scheduled for both days, March 17-18, 2026. Please visit the CDC's website for the diagnosis code topics agenda located at: https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html.

Instructions for Joining the ICD-10 Coordination and Maintenance Committee Meetings Govdelivery Subscriber List

To sign up go to CMS website:
https://public.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS_124 20

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2. A new subscriber screen will appear. Confirm your primary email address.
3. Select an Email delivery preference.
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5. Check privacy box confirming your consent to our data privacy. Additional information on our data privacy policy can be found at www.cms.gov/privacy.
6. You should receive a SUCCESS message that states (your email address) has been successfully subscribed to ICD-10 Coordination and Maintenance
7. Click on the Finish button at bottom of screen.
8. You should now be on the Welcome Quick subscribe page. You can subscribe to receive information from a list of topics of your choice from our partner organizations by checking the boxes; unsubscribe by unchecking the boxes.
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Topics Being Considered for ICD-10-PCS Procedure Codes

Overview	Mady Hue, CMS Co-Chair, ICD-10 Coordination and Maintenance Committee
ICD-10-PCS Topics:	
1. Insertion of Posterior Cervicothoracic Spinal Stabilization Device* Pages 14-16	Mady Hue, CMS C. Rory Goodwin, MD, PhD Associate Professor of Neurosurgery, Orthopedics, and Mechanical Engineering Duke University
2. Introduction of Recombinant Human Bone Morphogenetic Protein-2 with Collagen Scaffold* Pages 17-19	Mady Hue, CMS Scott Vickers, PhD Distinguished Engineer Medtronic
3. Endovascular Restriction of Thoracic Aorta* Pages 20-22	Andrea Hazeley, CMS
4. Transcatheter Mitral Valve Replacement with a Balloon-Expandable Device via Transseptal Access* Pages 23-25	Andrea Hazeley, CMS
5. Open Insertion of a Neurostimulator Generator onto the Vagus Nerve* Pages 26-28	Andrea Hazeley, CMS
6. Computer-aided Guidance for Intraprocedural Navigation Pages 29-31	Jeanine Du Verney, CMS Delphine Le Roux, Ph.D., PMP Sr. Director, Market Access & Strategic Partnerships Rivanna Medical
7. Computer-aided Detection and Notification Software for Assessment and Triage of Inflammatory Response* Pages 32-33	Jeanine Du Verney, CMS
8. Computer-aided Triage and Notification Software for Imaging Abnormalities in Computerized Tomography* Pages 34-36	Jeanine Du Verney, CMS
9. Percutaneous Epicardial Access for Diagnostic and Therapeutic Cardiac Interventions* Pages 37-38	Mady Hue, CMS

** Requestor has submitted an NTAP application for fiscal year (FY) 2027 consideration.*
***Requestor intends to submit an NTAP application for future consideration.*

Continuing Education Credits:
Continuing education (CEU) credits may be awarded by the American Academy of Professional Coders (AAPC) or the American Health Information Management Association (AHIMA) for participation in CMS ICD-10 Coordination and Maintenance (C&M) Committee Meeting Conference Calls, Meetings and Webcasts.

Continuing Education Information for American Academy of Professional Coders (AAPC)
If you have attended or are planning to attend a CMS ICD-10 Coordination and Maintenance (C&M) Committee Meeting Conference Call, you should be aware that CMS does not provide certificates of attendance for these calls. Instead, the AAPC will accept your e-mailed confirmation and call description as proof of participation. Please retain a copy of your e-mailed confirmation for these calls as the AAPC will request them for any conference call you entered into your CEU Tracker if you are chosen for CEU verification. Members are awarded one (1) CEU per hour of participation.

Continuing Education Information for American Health Information Management Association (AHIMA)
AHIMA credential-holders may claim 1 CEU per 60 minutes of attendance at an educational program. Maintain documentation about the program for verification purposes in the event of an audit. A program does not need to be pre-approved by AHIMA, nor does a CEU certificate need to be provided, in order to claim AHIMA CEU credit. For detailed information about AHIMA's CEU requirements, see the Recertification Guide on AHIMA's web site.

Please note: The statements above are standard language provided to CMS by the AAPC and the AHIMA. If you have any questions concerning CEUs or either statement, please contact the respective organization, not CMS.

Contact Information
Comments on the procedure code proposals should be sent to the following email address:
ICDProcedureCodeRequest@cms.hhs.gov

Mady Hue
Marilu.Hue@cms.hhs.gov

Andrea Hazeley
Andrea.Hazeley@cms.hhs.gov

Jeanine Du Verney
Jeanine.DuVerney@cms.hhs.gov

ICD-10 TIMELINE

A timeline of important dates in the ICD-10 process is described below:

March 17-18, 2026	The diagnosis code portion of the March 2026 ICD-10 Coordination and Maintenance Committee Meeting will be fully virtual by zoom and dial-in. Those who wish to attend must participate via Zoom Webinar or by dialing in. The procedure code topics will be open for public comment.
March 2026	Recordings and slide presentations of the diagnosis code topics and procedure code topic materials of the March 17-18, 2026 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html **Procedure code portion of the materials–** https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials
April 1, 2026	Any new or revised ICD-10 codes will be implemented on April 1, 2026.
April 17, 2026	**Deadline for receipt of public comments on proposed new codes and revisions presented at the March 17-18, 2026 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2026**.
April 2026	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by the Omnibus Budget Reconciliation Act of 1986, Public Law 99-509 (Pub. L. 99-509). This notice will include references to the FY 2027 ICD-10-CM diagnosis and ICD-10-PCS procedure codes finalized to date. It will also include proposed revisions to the MS-DRG system based on ICD-10-CM/PCS codes on which the public may comment. The proposed rule can be accessed at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps
May 15, 2026	**Deadline for receipt of public comments on proposed new codes and revisions presented at the March 17-18, 2026 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2027.**

	Deadline for receipt of public comments on proposed new diagnosis codes and revisions presented at the March 17-18, 2026 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2027.
May/June 2026	Final addenda posted on web pages as follows: **Diagnosis addendum -** https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **Procedure addendum -** https://www.cms.gov/medicare/coding-billing/icd-10-codes
June 5, 2026	**Deadline for requestors: Those members of the public requesting that topics be considered for the September 15-16, 2026 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.** **Procedure code requests should be directed to CMS at:** https://mearis.cms.gov **Diagnosis code requests should be directed to NCHS at:** nchsicd10cm@cdc.gov Requestors should indicate if they are submitting their code request for consideration for an April 1, 2027 implementation date or an October 1, 2027 implementation date. **The ICD-10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an April 1, 2027 implementation date or an October 1, 2027 implementation date.**
July 2026	Federal Register notice for the September 15-16, 2026 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
August 1, 2026	Hospital Inpatient Prospective Payment System final rule expected to be published in the Federal Register as mandated by Pub. L. 99-509. This rule will also include links to all the final codes to be implemented on October 1, 2026. This rule can be accessed at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps

August 2026	Tentative agenda for the procedure portion of the September 15, 2026 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the CMS webpage at – https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials Tentative agenda for the diagnosis portion of the September 16, 2026 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the NCHS webpage at – https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html
September 15-16, 2026	The September 2026 ICD-10 Coordination and Maintenance Committee Meeting is anticipated to be fully virtual by Teams and dial-in. Those who wish to attend must participate via Teams Webinar or by dialing in.
September 2026	Recordings and slide presentations of the September 15-16, 2026 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html **Procedure code portion of the recording and related materials–** https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials
October 1, 2026	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes. Final addendum available on web pages as follows: **Diagnosis addendum –** https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **Procedure addendum –** https://www.cms.gov/medicare/coding-billing/icd-10-codes
October 16, 2026	**Deadline for receipt of public comments on proposed new codes discussed at the September 15-16, 2026 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2027.**

November 2026	Any new ICD-10 codes that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2027 will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd-10-cm/files.html https://www.cms.gov/medicare/coding-billing/icd-10-codes
November 13, 2026	**Deadline for receipt of public comments on proposed new codes and revisions presented at the September 15-16, 2026 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2027.**
December 4, 2026	**Deadline for requestors: Those members of the public requesting that topics be considered for the March 16-17, 2027 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.** **Procedure code requests should be directed to CMS at:** https://mearis.cms.gov **Diagnosis code requests should be directed to NCHS at:** nchsicd10cm@cdc.gov Requestors should indicate if they are submitting their code request for consideration for an October 1, 2027 implementation date, an April 1, 2028 implementation date, or an October 1, 2028 implementation date. **The ICD-10 Coordination and Maintenance Committee may not be able to consider all requests received for the next Committee code update and will determine if it would be appropriate to postpone consideration of any code requests to a future time. The Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration at the March 16-17, 2027 meeting for an October 1, 2027 implementation date, an April 1, 2028 implementation date, or an October 1, 2028 implementation date.** **In addition, requestors indicate whether they have submitted or intend to submit a New Technology Add-on Payment (NTAP) policy application related to the ICD-10-PCS procedure code request. If it is not submitted as indicated or is withdrawn, the Committee will determine if it would be appropriate to postpone consideration of the code request to a future time.**

Overview

- The ICD-10 Coordination & Maintenance (C&M) Committee provides a public forum for proposed ICD-10-CM & ICD-10-PCS code updates
- CMS & CDC Co-chair the Committee
  - CMS has lead responsibility for procedure code issues
  - CDC has lead responsibility for diagnosis code issues
- Coding proposals requested by the public are made available and the public is given an opportunity to comment

Code Proposals

- ICD-10-PCS code proposals are being considered for implementation on October 1, 2026
- CMS will provide code options and recommendations
- The public can send comments
- No final decisions are made until public comments have been reviewed

Comments on Code Proposals

- Submit public comments by
  - April 17, 2026 for procedure codes being considered for October 1, 2026 implementation
  - May 15, 2026 for diagnosis codes being considered for October 1, 2027 implementation (FY 2028)
- Procedure topic comments to CMS: ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis topic comments to NCHS: nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2026 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to the Spring 2026 ICD-10 Coordination and Maintenance Committee Update

- August 2026 – Final rule with links to final codes to be implemented October 1, 2026
  - Includes any additional codes approved from the Spring 2026 ICD-10 Coordination and Maintenance Committee Update
  - https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps

Addenda

- June 2026 – Final code updates and addendum posted
  - FY 2027 ICD-10-PCS (Procedures)
    https://www.cms.gov/medicare/coding-billing/icd-10-codes
  - FY 2027 ICD-10-CM (Diagnoses)
    https://www.cdc.gov/nchs/icd/icd-10-cm/files.html

Public Participation

- For this procedure code update, the public may participate in the following ways:
  - Listen to proceedings through free conference lines
  - Listen to recordings and view slide presentations

ICD-10-PCS Codes Implementation

- ICD-10-PCS code proposals are under consideration for October 1, 2026 (FY 2027) implementation

September 15-16, 2026 C&M Code Requests

- June 5, 2026 – Deadline for submitting topics to be considered for the September 15-16, 2026 C&M meeting
  - Procedure requests to CMS: https://mearis.cms.gov
  - Diagnosis requests to NCHS: nchsicd10cm@cdc.gov

The ICD-10 Coordination and Maintenance Committee may not be able to consider all requests received for the next Committee code update and will determine if it would be appropriate to postpone consideration of any code requests to a future time. The Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration at the September 15-16, 2026 meeting for an April 1, 2027 implementation date or an October 1, 2027 implementation date.

In addition, requestors indicate whether they are submitting or intend to submit a New Technology Add-on Payment (NTAP) policy application related to the ICD-10-PCS procedure code request. If an NTAP application is not submitted as indicated or is withdrawn, the Committee will determine if it would be appropriate to postpone consideration of the code request or finalization of a code to a future time.

Topic # 01 – Insertion of Posterior Cervicothoracic Spinal Stabilization Device

Issue: There is no unique ICD-10-PCS code to describe the insertion of a posterior cervico-thoracic spinal stabilization device with BlackArmor® Carbon/Polyetheretherketone material. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-On Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? Yes. The icotec Ag CMORE® Cervicothoracic (CT) System is 510(K) approved as of November 12th, 2025 (K252327) and received Breakthrough Device designation on April 11, 2025 (Q251028).

Background: There are approximately 43,000 cases annually that require posterior surgical spine treatments. Of these 43,000 cases, the five largest indications are degenerative conditions, trauma, deformity, infection, and tumor. Current treatment includes non-surgical options such as anti-inflammatory medications, physical therapy, immobilization, and epidural steroid injections. Surgical interventions include anterior cervical discectomy and fusion, laminectomies, corpectomies and vertebral body replacements, and posterior decompressions that utilize screws and rods to stabilize the spine.

The CMORE® CT System is intended to provide immobilization and stabilization of spinal segments with anterior interbody support implanted at the same spinal level(s) with autogenous and/or allogenic bone graft as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3): Traumatic spinal fractures and/or traumatic dislocations, instability or deformity, failed previous fusions (e.g., pseudarthrosis), degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, degenerative disease of the facets with instability, spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.

Technology
The CMORE® CT System, made from BlackArmor® Carbon/Polyetheretherketone (PEEK) material, is comprised of a set of instruments and implants for posterior cervicothoracic fixation of the upper spinal column. The CMORE® CT screws, rods and connectors are made of BlackArmor® Carbon/PEEK material, a carbon-fiber-reinforced polyetheretherketone composite (Carbon/PEEK). The BlackArmor® material is a combination of continuous, high strength carbon-fiber-reinforced PEEK and a process developed by the manufacturer. The result is an implant component with an interwoven three-dimensional (3D) fiber architecture. According to the requestor, the implanted devices and system that are made from BlackArmor® Carbon/PEEK material produce fewer artifacts in magnetic resonance imaging (MRI) and other imaging modalities (e.g., x-ray, computed tomography (CT), etc.) as BlackArmor® is radiolucent in all diagnostic imaging modes. Per the requestor, this composite technology allows for optimal post-operative surveillance of fusion or healing of the affected spinal segment. As an example, in degenerative cervical myelopathy, the most common cause of spinal cord impairment, post-surgical follow-up typically relies on MRI to assess the neural structures.

Per FDA clearance, the CMORE® CT System is intended to be used with anterior interbody support implanted at the same spinal level/s with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The CMORE® CT System may be connected to the VADER® Pedicle System using connectors.

According to the requestor, there have been no reported adverse events or complications.

Procedure Description
The posterior cervicothoracic surgical stabilization procedure begins with the patient being placed under general anesthesia, followed by appropriate patient positioning. Open or minimally invasive surgical access to the posterior spine is prepared to expose the spinal structures to the extent required, and neural structures are decompressed. The entry points for screw placement are identified and the screw trajectories prepared using awl, drill, and tap subsequently. Based on the anatomical situation and surgeon's preference, bone screws are placed either in the pedicle or the lateral mass of the spinal segments to be stabilized. The screws are connected with longitudinal rods of the required length and curvature. These rods are fixed in every screw head with a nut screw. Correct positioning of the implants is intra-operatively guided and controlled by image intensifier or by using a navigation system.

Current Coding: There are no unique ICD-10-PCS codes to describe insertion of a carbon/PEEK posterior cervicothoracic spinal stabilization device. Code the procedure in table 0RH Insertion of Upper Joints, using the device value C Spinal Stabilization Device, Pedicle-Based applied to the appropriate cervical/thoracic joint body part value(s) and the applicable approach. Assign a separate code for the cervical fusion procedure with the applicable code from table 0RG Fusion, Upper Joints.

Section	**0** Medical and Surgical
Body System	**R** Upper Joints
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Occipital-cervical Joint **1** Cervical Vertebral Joint **4** Cervicothoracic Vertebral Joint **6** Thoracic Vertebral Joint **A** Thoracolumbar Vertebral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**3** Infusion Device **4** Internal Fixation Device **8** Spacer **B** Spinal Stabilization Device, Interspinous Process **C** Spinal Stabilization Device, Pedicle-Based **D** Spinal Stabilization Device, Facet Replacement	**Z** No Qualifier

Coding Options

Option 1. Do not create a new ICD-10-PCS code for insertion of a carbon/PEEK posterior cervicothoracic spinal stabilization device. Continue as described in current coding.

Option 2. In section X table XRH, Insertion of Joints, create new device value N Carbon/PEEK Spinal Stabilization Device, applied to the cervical and thoracic joint body part values and the approaches shown, to identify insertion of a carbon/PEEK posterior cervicothoracic spinal stabilization device. Assign a separate code for the cervical fusion procedure with the applicable code from table 0RG Fusion, Upper Joints.

Section **X** New Technology *Body System* **R** Joints *Operation* **H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
1 Cervical Vertebral Joint **2** Cervical Vertebral Joints, 2 or more **4** Cervicothoracic Vertebral Joint **6** Thoracic Vertebral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD N** Carbon/PEEK Spinal Stabilization Device	**C** New Technology Group 12
1 Cervical Vertebral Joint **2** Cervical Vertebral Joints, 2 or more **4** Cervicothoracic Vertebral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**G** Molybdenum Rhenium Alloy Spinal Stabilization Device	**B** New Technology Group 11
6 Thoracic Vertebral Joint **7** Thoracic Vertebral Joints, 2 to 7 **8** Thoracic Vertebral Joints, 8 or more **A** Thoracolumbar Vertebral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**F** Carbon/PEEK Spinal Stabilization Device, Pedicle Based	**A** New Technology Group 10
B Lumbar Vertebral Joint	**0** Open	**1** Posterior Spinal Motion Preservation Device	**8** New Technology Group 8
B Lumbar Vertebral Joint **C** Lumbar Vertebral Joints, 2 or more	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**F** Carbon/PEEK Spinal Stabilization Device, Pedicle Based	**A** New Technology Group 10
D Lumbosacral Joint	**0** Open	**1** Posterior Spinal Motion Preservation Device	**8** New Technology Group 8
D Lumbosacral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**F** Carbon/PEEK Spinal Stabilization Device, Pedicle Based	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 02 – Introduction of Recombinant Human Bone Morphogenetic Protein-2 with Collagen Scaffold

Issue: There is no unique ICD-10-PCS code to describe the introduction of recombinant human bone morphogenetic protein-2 with collagen scaffold in the context of lumbar spinal fusion. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-On Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? Yes. INFUSE™ Bone Graft for use in transforaminal lumbar interbody fusion (TLIF) procedures was granted PMA approval on February 13, 2026 and FDA Breakthrough Device designation was granted in TLIF procedures on April 6, 2024. INFUSE™ Bone Graft with an FDA cleared intervertebral body fusion device and metallic screw-and-rod system is indicated for use in a TLIF surgical approach at one or two adjacent levels from L2-S1 in the treatment of symptomatic degenerative disc disease confirmed by patient history and radiographic studies and having at least six months of nonoperative treatment attempted prior to treatment with INFUSE™ Bone Graft.

INFUSE™ Bone Graft also has FDA approval or clearance for three other indications: 1) Spinal fusion via anterior lumbar interbody fusion (ALIF) and oblique lateral interbody fusion (OLIF), 2) Acute open tibial shaft fractures, and 3) Sinus augmentation and localized alveolar ridge augmentations for defects related to extraction sockets.

Background: Degenerative disc disease (DDD) is a condition where the discs in the spine begin to wear over time and cause pain. As a disc wears due to age, injury, and daily activity, it may dry out, bulge, or herniate, reducing disc height and cushioning between vertebral bodies. In the United States and Canada, over 24 million people are affected by degenerative disc disease each year.[1]

In addition to pain, numbness or weakness in the back and legs, DDD of the lumbosacral spine commonly involves vertebral instability, such as spondylolisthesis/retrolisthesis, significant spinal canal or foramen stenosis, and/or recurrent disc herniation. A common approach to treatment of DDD is TLIF. The intent of spine fusion is to lessen the patient's pain. A successful fusion occurs in two phases; 1) initial anatomical correction and stabilization achieved by the fusion procedure itself where the spine is mechanically supported by hardware (e.g., screws and rods, plates, and interbody fusion devices) and 2) permanent biologic healing, facilitated by bone graft implanted during the surgical procedure, completes the fusion of bone between adjacent vertebrae over time so that the adjacent vertebrae can no longer swivel or bend.

Autologous iliac crest bone graft (ICBG) has historically been considered the gold standard graft material for spinal fusion procedures due to its osteogenic, osteoinductive, and osteoconductive properties. However, harvesting ICBG is associated with well-recognized disadvantages, including donor site pain, increased operative time, and donor site morbidity, which may adversely impact patient recovery. Local autograft obtained during the index procedure avoids

[1] Ravindra, V.M., Senglaub, S.S., Rattani, A., Dewan, M.C., Härtl, R., Bisson, E., et al. (2018). Degenerative lumbar spine disease: estimating global incidence and worldwide volume. Global Spine Journal, 8(8), 784-794.

donor site harvest but is frequently limited in both quantity and biological quality, particularly in revision cases or patients with compromised bone. Infuse® Bone Graft provides an alternative that eliminates donor site morbidity while offering a consistent and effective biologic option to support spinal fusion in TLIF procedures.

Technology
Per the requestor, INFUSE™ Bone Graft is a combination drug/device product. It has two components. The first is recombinant human bone morphogenetic protein-2 (rhBMP-2), a protein known to actively induce formation of new bone. The second is an absorbable collagen sponge which serves as a carrier for rhBMP-2 and a scaffold for bone growth. Among other approved indications, INFUSE™ Bone Graft is commonly used in spine fusion to promote creation of new bone as a means of fusing adjacent spinal levels. INFUSE™ Bone Graft is approved for anterior lumbar interbody fusion (ALIF) and oblique lateral interbody fusion (OLIF) procedures.

INFUSE™ Bone Graft is used in intervertebral body, i.e., anterior, spine fusion procedures. An interbody fusion device maintains the height of the disc space and stabilizes the spine while the INFUSE™ Bone Graft induces new bone growth. INFUSE™ Bone Graft is biologically active and designed to be gradually resorbed and replaced by newly formed bone.

According to the requestor, adverse events for use of INFUSE™ Bone Graft in TLIF include pseudoarthrosis, subsidence, osteolysis, ectopic bone formation, wound infection, and cyst formation. These same adverse events are also seen in other spine fusion procedures.

Procedure Description
As part of the transforaminal lumbar interbody spine fusion (TLIF) procedure, an angled incision is made to expose the interlaminar window and the medial aspect of the facet joint. Part of the facet joint is removed for access to the intervertebral disc space. A discectomy is performed to clear the space and prepare the vertebral bodies for fusion. The INFUSE™ Bone Graft is placed into the disc space anterior and contralateral to the intended location of the interbody fusion device and surrounded by autograft bone saved from the facetectomy and bony decompression. An interbody fusion device, packed with other bone graft material is then inserted through the opening and into the disc space. The remainder of the disc space is filled with additional autograft bone. If additional bone graft volume is required, autograft may be supplemented with mineralized cancellous allograft. Finally, pedicle screw-and-rod assemblies in the posterior spine are also placed to provide supplemental posterior fixation.

Per the requestor, for this new TLIF indication, it is anticipated that one INFUSE™ Bone Graft implant will be delivered per level treated. Over time, the implant is resorbed into the body as new bone is formed. In this particular context, INFUSE™ Bone Graft is always used in conjunction with transforaminal lumbar interbody fusion.

Current Coding: There are no unique ICD-10-PCS codes to describe introduction of recombinant human bone morphogenetic protein-2 with collagen scaffold. Facilities can report the introduction of rhBMP-2 with collagen scaffold using the following code:

3E0V0GB Introduction of recombinant bone morphogenetic protein into bones, open approach

Assign a separate code for the spinal fusion procedure performed from the applicable table.

Coding Options

Option 1. Do not create a new ICD-10-PCS code for introduction of recombinant human bone morphogenetic protein-2 with collagen scaffold. Continue as described in current coding.

Option 2. In section X table XW0, Introduction, Anatomical Regions, create new substance value C Recombinant Human Bone Morphogenetic Protein-2 with Collagen Scaffold, applied to the body part value V Bones and the open approach, to identify the introduction of rhBMP-2 with collagen scaffold. Assign a separate code for the spinal fusion procedure performed from the applicable table.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
V Bones	**0** Open	**ADD C** Recombinant Human Bone Morphogenetic Protein-2 with Collagen Scaffold	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 03 – Endovascular Restriction of Thoracic Aorta

Issue: There is no unique ICD-10-PCS code to describe the endovascular restriction of the thoracic aorta. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? No. The NEXUS® Aortic Arch Stent Graft System was granted Breakthrough Medical Device Status by the FDA in April 2020 and is indicated for a range of aortic arch pathologies including chronic dissection, aortic aneurysm, intramural hematoma and penetrating aortic ulcer.

Background: The treatment of complex multi-segment disease concomitantly affecting the aortic arch and descending thoracic aorta is technically challenging. Until the 1990s, such extensive pathology was addressed by median sternotomy for aortic arch replacement followed by a traumatic thoraco-abdominal incision for reconstruction of the descending aorta as a single- or two-stage procedure.[1] Thoracic Endovascular Aortic Repair (TEVAR) is a minimally invasive procedure to repair the major blood vessel in the body, the aorta. The development of TEVAR has allowed a minimally invasive approach for management of an array of thoracic aortic pathologies. Initially developed specifically for exclusion of thoracic aortic aneurysms, TEVAR is now used as an alternative to open surgery for a variety of disease pathologies due to the lower morbidity of this approach. Advances in endograft technology continue to broaden the applications of this technique. Initially utilized in the treatment of aortic aneurysmal disease, TEVAR indications have expanded to include treatment of type B aortic dissection with malperfusion or rupture, traumatic aortic transection, and penetrating aortic ulcer (PAU). Although there are no randomized controlled trials directly comparing TEVAR to open surgery, numerous studies suggest that TEVAR is associated with decreased morbidity compared with open repair.[2] Benefits of the endovascular approach include avoidance of thoracotomy or sternotomy incision, avoidance of aortic cross-clamping, decreased blood loss, and decreased end-organ ischemia.[3]

TEVAR approaches to address disease involving zone 0 (innominate), zone 1 (left carotid), or zone 2 (left subclavian) include debranching procedures or the use of specialized endografts (i.e., fenestrated grafts, branched grafts). The NEXUS® Aortic Arch Stent Graft System, an aortic arch branch device, was designed to treat aortic arch pathologies and address the morphology and hemodynamic challenges of the aortic arch.

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[1]Acharya M, Sherzad H, Bashir M, Mariscalco G. The frozen elephant trunk procedure: indications, outcomes and future directions. Cardiovasc Diagn Ther. 2022 Oct;12(5):708-721. doi: 10.21037/cdt-22-330. PMID: 36329958; PMCID: PMC9622409.

[2] Nation DA, Wang GJ. TEVAR: Endovascular Repair of the Thoracic Aorta. Semin Intervent Radiol. 2015 Sep;32(3):265-71. doi: 10.1055/s-0035-1558824. PMID: 26327745; PMCID: PMC4540616.

[3] Walsh S R, Tang T Y, Sadat U. et al. Endovascular stenting versus open surgery for thoracic aortic disease: systematic review and meta-analysis of perioperative results. J Vasc Surg. 2008;47(5):1094–1098. doi: 10.1016/j.jvs.2007.09.062.

Technology
The NEXUS® Aortic Arch Stent Graft System is comprised of two primary implantable stent grafts, and an optional extension. Each stent graft is introduced and implanted separately into the patient's vascular system. The three stent grafts that make up the NEXUS® Aortic Arch Stent Graft System are the Arch Stent Graft, the Ascending Curved Stent Graft, and the Optional Descending Extension. The cranial narrow end of the Arch Stent Graft is intended to be deployed into the brachiocephalic artery, and the distal end is to be deployed into the descending thoracic aorta. The Ascending Curved Stent Graft intended to be deployed in the ascending aorta. The Optional Descending Extension can be used in case the aortic lesion elongates further distally and out of the covered length offered by the arch stent graft. Multiple descending extensions can be used if needed to cover the entire length of the lesion. Disconnection of the modules is prevented by the proprietary locking system, where the locking latches engage the inner stent graft of the docking sleeve.

The NEXUS® Aortic Arch Stent Graft System is available in a range of sizes that can adapt to a wide range of anatomies. It can be introduced in vessels diameter as small as 7 mm reducing concerns for access complications. The device is considered permanent.

Procedure Description
The NEXUS® Aortic Arch Stent Graft System is used by a physician to repair complex aortic arch disease in patients who are high-risk for open surgery. The procedure is performed endovascularly through a femoral artery access point, where the physician deploys the modular graft using a lower profile 20 F system in two steps: first placing the main arch module with a branch to the brachiocephalic artery, then connecting it to the ascending module using the Dock & Lock™ mechanism to provide stable anatomical anchoring. This creates a continuous sealed pathway, excluding the diseased aortic segment while preserving blood flow to the brain and upper body.

Current Coding: There are no unique ICD-10-PCS codes to identify endovascular restriction of the thoracic aorta. Facilities can report the restriction of the ascending thoracic aorta using the appropriate code in table 02V, Restriction of Heart and Great Vessels. When applicable, also report the additional deployment of a descending extension using the body part value W Thoracic Aorta, Descending in table 02V.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
W Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **E** Intraluminal Device, Branched or Fenestrated, One or Two Arteries **F** Intraluminal Device, Branched or Fenestrated, Three or More Arteries **Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify endovascular restriction of the thoracic aorta. Continue as described in current coding.

Option 2. In section X New Technology table X2V, Restriction of the Cardiovascular System, create new device value H Branched Intraluminal Device, Integrated System with Brachiocephalic Trunk Branch, applied to the new body part value J Thoracic Aorta, Ascending and Arch and the percutaneous approach to describe endovascular restriction of the thoracic aorta. Also create new device value J Branched Intraluminal Device, Integrated System Extension, applied to the body part value W Thoracic Aorta, Descending and the percutaneous approach to describe the additional deployment of a descending extension in the endovascular restriction of the thoracic aorta, when applicable.

Section **X** New Technology *Body System* **2** Cardiovascular System *Operation* **V** Restriction: Partially closing an orifice or the lumen of a tubular body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
7 Coronary Sinus	**3** Percutaneous	**Q** Reduction Device	**7** New Technology Group 7
E Descending Thoracic Aorta and Abdominal Aorta	**3** Percutaneous	**S** Branched Intraluminal Device, Manufactured Integrated System, Four or More Arteries	**A** New Technology Group 10
ADD J Thoracic Aorta, Ascending and Arch	**3** Percutaneous	**ADD H** Branched Intraluminal Device, Integrated System with Brachiocephalic Trunk Branch	**C** New Technology Group 12
W Thoracic Aorta, Descending	**3** Percutaneous	**ADD J** Branched Intraluminal Device, Integrated System Extension	**C** New Technology Group 12
W Thoracic Aorta, Descending	**0** Open	**N** Branched Synthetic Substitute with Intraluminal Device	**7** New Technology Group 7
Y Thoracic Aortic Arch and Descending Thoracic Aorta	**0** Open	**6** Intraluminal Device, Uncovered with Support Cuff	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 04 – Transcatheter Mitral Valve Replacement with a Balloon-Expandable Device via Transseptal Access

Issue: There is no unique ICD-10-PCS code to describe transcatheter mitral valve replacement with a balloon-expandable device via transseptal access. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? Yes. The Edwards SAPIEN M3 Transcatheter Mitral Valve Replacement System received premarket approval (PMA) by the FDA on December 22, 2025. The device is indicated for the treatment of symptomatic moderate-to-severe or severe mitral regurgitation (MR) in patients who are deemed unsuitable for surgery or transcatheter edge-to-edge repair (TEER) therapy by a multidisciplinary heart team. It is also indicated for the treatment of symptomatic mitral valve dysfunction (moderate-to-severe or severe MR, severe mitral stenosis (MS), or moderate MR with moderate MS) associated with mitral annular calcification (MAC) in patients who are deemed unsuitable for surgery or TEER therapy by a multidisciplinary heart team.

Background: Mitral regurgitation (MR) is the most frequent valve disease in the United States, with moderate or severe MR estimated to be 1.7% of the population and increasing with age.[1] MR is defined as either primary or secondary. In primary MR, there is an abnormality in one or more components of the mitral apparatus (e.g., leaflets, annulus, chordae tendineae, papillary muscles), most commonly caused by mitral valve prolapse. In the more common secondary MR, the valve itself is usually normal, and mitral insufficiency arises from alterations in left ventricular geometry. In both primary and secondary chronic MR, the volume overload results in progressive cardiac remodeling and cyclical worsening of MR severity, which ultimately leads to heart failure and increased mortality.

Current treatment options for chronic MR include surgical valve repair or replacement, guideline-directed medical therapy, cardiac resynchronization therapy and transcatheter valve repair. The current standard of care (SOC) to treat patients with symptomatic mitral stenosis, according to current guidelines from the 2020 American College of Cardiology/American Heart Association Recommendations for Medical Therapy and Intervention for Chronic Mitral Regurgitation, is surgical repair and replacement, and percutaneous mitral balloon valvotomy (PMBV). Despite current practice guidelines, nearly 50% of patients with severe MR do not undergo surgery due to high surgical risk from advanced age, multiple comorbidities or a lack of familiarity with the guidelines. This has led to the development of minimally invasive cardiac surgery and less invasive transcatheter techniques for mitral valve repair/replacement.

Technology
The Edwards SAPIEN M3 system is comprised of the Edwards SAPIEN M3 valve and dock steerable catheter system. The Edwards SAPIEN M3 valve is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, tri-leaflet bovine pericardial tissue valve, polyethylene

[1] Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a population-based study. Lancet. 2006;368(9540):1005-1011.

terephthalate (PET) fabric inner skirt, and a PET outer cloth cover. The SAPIEN M3 dock steerable catheter system is used for delivery of the SAPIEN M3 dock to its intended location and consists of a dock and delivery system. The SAPIEN M3 dock is provided pre-attached to the SAPIEN M3 dock delivery system via suture. The dock encircles the native mitral leaflet applying an inward force to the mitral apparatus, pulling the leaflets and chordae to the dock center and approximating the papillary muscles creating a landing zone for implantation of the SAPIEN M3 valve. The dock has a nitinol core covered with expanded polytetrafluoroethylene (ePTFE) tubing, PET braid, and a PVL guard and is attached to the pusher of the delivery system with a suture.

A single SAPIEN M3 valve is routinely implanted during mitral valve replacement procedures. Major adverse events associated with the SAPIEN M3 device observed in the ENCIRCLE trial (NCT04153292) up to 1 year included disabling stroke in 11 patients (Kaplan–Meier rate 3·9%), five of which occurred within 30 days, and clinically significant valve thrombosis in 19 (7%) of 283 patients (Guerrero, et al., 2025).

Procedure Description
The SAPIEN M3 TMVR system is implanted in a two-stage, transseptal procedure. During the first stage, the SAPIEN M3 dock, delivery system introduces the SAPIEN M3 dock which encircles the native mitral leaflet applying an inward force to the mitral apparatus, pulling the leaflets and chordae to the dock center and approximating the papillary muscles creating a landing zone for implantation of the SAPIEN M3 valve. The second stage of the procedure is transseptal delivery of the SAPIEN M3 valve into the SAPIEN M3 dock using the valve delivery system.

Current Coding: There is no unique ICD-10-PCS code to describe transcatheter mitral valve replacement with a balloon-expandable device via transseptal access. Facilities can report the procedure using the appropriate code in table 02R, Replacement of Heart and Great Vessels.

Section	**0** Medical and Surgical		
Body System	**2** Heart and Great Vessels		
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part		
Body Part	*Approach*	*Device*	*Qualifier*
G Mitral Valve **J** Tricuspid Valve	**3** Percutaneous	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**H** Transapical **Z** No Qualifier

Coding Options

Option 1. Do not create a new ICD-10-PCS code to describe transcatheter mitral valve replacement with a balloon-expandable device via transseptal access. Continue as described in current coding.

Option 2. In section X New Technology table X2R, Replacement of Cardiovascular System, create new device value F Bioprosthetic Valve, Balloon-expandable, applied to the new body part value shown and the percutaneous approach, to identify transcatheter mitral valve replacement with a balloon-expandable device via transseptal access.

Section *Body System* *Operation*	**X** New Technology **2** Cardiovascular System **R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Upper Extremity Artery, Right **6** Upper Extremity Artery, Left **7** Lower Extremity Artery, Right **8** Lower Extremity Artery, Left	**0** Open	**W** Bioengineered Human Acellular Vessel	**A** New Technology Group 10
ADD G Mitral Valve	**3** Percutaneous	**ADD F** Bioprosthetic Valve, Balloon-expandable	**C** New Technology Group 12
J Tricuspid Valve	**3** Percutaneous	**R** Multi-plane Flex Technology Bioprosthetic Valve	**A** New Technology Group 10
X Thoracic Aorta, Arch	**0** Open	**N** Branched Synthetic Substitute with Intraluminal Device	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 05 – Open Insertion of a Neurostimulator Generator onto the Vagus Nerve

Issue: There is no unique ICD-10-PCS code to describe the open insertion of a neurostimulator generator onto the vagus nerve. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? Yes. The SetPoint System was granted Premarket Approval (PMA) on July 30, 2025. The SetPoint System is indicated for use in the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response, loss of response, or intolerance to one or more biological or targeted synthetic disease modifying antirheumatic drugs. The SetPoint System was granted Breakthrough Device designation on March 15, 2024 (Q240179).

Background: Rheumatoid arthritis (RA) is a chronic autoimmune disease that primarily affects the joints. The total prevalence of RA in the U.S. is estimated to be about 1.3 million individuals.[1] RA is more common in women than men, with a female-to-male ratio of roughly 3:1. Despite the availability of multiple biologic disease-modifying antirheumatic drugs (bDMARDs) and targeted synthetic disease-modifying antirheumatic drugs (tsDMARDs) for treating the target patient population, around 50% of patients discontinue or change their medication within 24 months, primarily due to loss of efficacy. While the safety profile of b/tsDMARDs is generally accepted by rheumatologists and RA patients, RA drugs are not without potential side effects and serious adverse events, which has resulted in Black Box warnings (e.g., serious infections, gastrointestinal perforation, malignancy, venous thromboembolism, major adverse cardiac events, etc.). These safety risks are increased among individuals over age 50 with comorbidities. Women are disproportionately affected by RA and certain immunosuppressive drugs affect fertility or are contraindicated in women who are pregnant or breastfeeding. As a result, many individuals with RA are contraindicated, are intolerant, or experience a loss of efficacy of drug therapy.

Technology

The SetPoint System is a neuroimmune modulation therapy system with components that are implanted on the vagus nerve, using an open or minimally invasive technique. The SetPoint System is a complete system, which includes a fully integrated (leadless) implantable pulse generator, a flexible silicone pod, a charger with docking station and a patient programmer. The implantable components include the fully integrated (leadless) implantable pulse generator, which has integrated electrodes, circuit, and a rechargeable battery, hermetically sealed within a ceramic capsule with titanium endcaps. The pulse generator has a 10-year battery life, after which the device is removed or replaced. The device is about 2.5 cm in length, 2.6 grams in weight and delivers electrical stimulation to the vagus nerve. The flexible silicone pod is a flexible silicone clamshell used to position and hold the implant on the vagus nerve.

The SetPoint System is the first FDA approved, non-pharmacological treatment for RA. The requestor stated the fully integrated (e.g., leadless) design and small form factor of the SetPoint

[1] Xu Y, Wu Q. Prevalence Trend and Disparities in Rheumatoid Arthritis among US Adults, 2005-2018. J Clin Med. 2021 Jul 26;10(15):3289. doi: 10.3390/jcm10153289. PMID: 34362073; PMCID: PMC8348893.

System has advantages to lead-and-generator-based stimulation systems. The single-incision procedure reduces the risk of infection in the generator pocket, and the fully integrated (e.g., leadless) design avoids the risk of lead fracture, which is the leading long-term complication of other stimulation systems. According to the requestor, as a result, the SetPoint System avoids the risks and complications associated with b/tsDMARDs while providing drug-like efficacy.

The SetPoint System insertion procedure was studied in multiple controlled trials, the largest of which was a 242-patient, randomized, double blinded, sham controlled trial, the RESET-RA study (NCT 01552941). Results of the clinical study showed that 76% of the patients enrolled in the RESET-RA pivotal trial were drug free at one year and 70% were drug free at 18 months.
In the RESET-RA study, 4 of 242 patients (1.65%) experienced a related serious adverse event. All events were related to the implant procedure and all resolved with no significant sequalae. There were no reports of serious infections, malignancies or cardiovascular events attributed to the SetPoint System during the clinical study.

Procedure Description
The procedure to insert the SetPoint System is a 60-90 minute surgical procedure, typically performed in a hospital setting. The procedure involves accessing the left cervical vagus nerve and inserting the implantable components of the SetPoint System. The procedure steps include the following:

General anesthesia is administered, and the patient is placed in a supine position, and the head is turned to the contralateral (right) side, opposite the planned incision. A transverse incision (typically 3-5 cm) is made at the level of the mid-cervical region about halfway between the clavicle and mandible. The carotid sheath is identified, and the sternocleidomastoid is retracted laterally. The internal jugular vein is retracted laterally, and the carotid artery is retracted medially. The vagus nerve is exposed approximately 3cm. The flexible silicone pod is folded and compressed with forceps and slipped under the vagus nerve and released. Once the silicone pod has expanded and is wrapped around the vagus nerve, the fully integrated pulse generator is placed inside the pod, with the electrodes facing the vagus nerve. The silicone pod is closed and held closed with a suture. The incision is irrigated with saline and checked for homeostasis. The platysma and subcutaneous layers are closed with absorbable sutures, and the skin is closed with sutures or adhesive strips.

Current Coding: There are no unique ICD-10-PCS codes to describe the open insertion of a neurostimulator generator onto the vagus nerve. Facilities report the insertion of the neurostimulator generator using the following ICD-10-PCS code:

00HE3MZ Insertion of neurostimulator lead into cranial nerve, open approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe the open insertion of a neurostimulator generator onto the vagus nerve. Continue as described in current coding.

Option 2. In section X table X0H Insertion of Nervous System, create new device value 5 Leadless Neurostimulator Generator, applied to the body part value shown and the open approach, to identify the open insertion of a neurostimulator generator onto the vagus nerve.

Section	**X** New Technology
Body System	**0** Nervous System
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
K Sphenopalatine Ganglion	**3** Percutaneous	**Q** Neurostimulator Lead	**8** New Technology Group 8
Q Vagus Nerve	**ADD 0** Open	**ADD 5** Leadless Neurostimulator Generator	**C** New Technology Group 12
Q Vagus Nerve	**3** Percutaneous	**R** Neurostimulator Lead with Paired Stimulation	**8** New Technology Group 8

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 06 – Computer-aided Guidance for Intraprocedural Navigation

Issue: There are no unique ICD-10-PCS codes to identify the use of computer-aided guidance for intraprocedural navigation in the performance of neuraxial anesthesia. An October 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. Accuro 3S Epidural Navigation System was granted Class II 510(k) premarket approval by the FDA on May 23, 2025, and is indicated for use as an ultrasound imaging system by qualified and trained healthcare professionals. Accuro 3S is designed for use in a hospital or medical clinic environment at the point of care. Accuro 3S supports B-mode imaging and a SpineNav-AI™ image processing software. Accuro 3S clinical applications include musculoskeletal, conventional, and superficial, and guidance for needle or catheter placement. A typical examination using Accuro 3S is guidance of neuraxial anesthesia.

Background: According to the requestor, neuraxial anesthesia remains a cornerstone of obstetric and surgical pain management despite continuing to be performed primarily through tactile feedback. Notwithstanding decades of experience, landmark-based epidurals carry a measurable complication burden. Published data show accidental dural puncture rates ("wet tap") of 1–3 percent, post-dural-puncture headache rates of 0.5–0.9 percent, and catheter replacement rates of 6–13 percent, all contributing to patient morbidity and extended hospital stays. A 2016 meta-analysis confirmed that neuraxial ultrasound improves interspace identification accuracy, predicts epidural depth within 3 mm, reduces the number of needle passes, and lowers the risk of traumatic puncture.[1] These benefits, however, derive from static imaging performed before needle insertion. This workflow differs substantively from conventional epidural placement. Landmark-based methods rely on tactile resistance, offering no visualization of underlying anatomy. Pre-procedural ultrasound can identify an insertion point but cannot guide needle advancement once imaging ceases. Accuro 3S is intended to eliminate the blind interval by providing continuous navigation and needle-tip tracking, thereby extending ultrasound from being an adjunct to an active component of the procedure.

Per the requestor, clinical implementation is expected to reduce accidental dural puncture and post-dural-puncture headache by at least 50 percent, decrease procedure time, and improve first-pass success and patient satisfaction. According to the requestor, early evaluations confirm that the technology's learning curve is minimal and that Accuro 3S is particularly valuable in patients with obesity, spinal deformity, or other anatomical challenges where surface landmarks are unreliable. These gains in efficiency and safety correspond directly to national quality-improvement goals in obstetric anesthesia and perioperative care.

Technology
The Accuro 3S Epidural Navigation System is an FDA-regulated, non-significant-risk diagnostic ultrasound device incorporating artificial intelligence and dual-array imaging to enable real-time needle navigation for neuraxial anesthesia. The system's dual-array convex probe contains two

[1] Perlas, A., Chaparro, L. E., & Chin, K. J. (2016). Lumbar Neuraxial Ultrasound for Spinal and Epidural Anesthesia: A Systematic Review and Meta-Analysis. Regional anesthesia and pain medicine, 41(2), 251–260. https://doi.org/10.1097/AAP.0000000000000184

opposed transducer elements that project intersecting imaging planes through the midline of the lumbar spine. This geometry allows the device to visualize both the vertebral anatomy and the advancing needle tip along its true trajectory. The SpineNav-AI™ software continuously interprets ultrasound data to identify vertebral levels, the epidural and intrathecal spaces, and tissue boundaries. It overlays a dynamic trajectory map that updates as the needle advances, producing an image analogous to a "navigation display" rather than a static scan. A sterile suspension drape anchors the probe to the patient's back, so the image field remains fixed while the clinician manipulates the needle with both hands, supporting a single-operator workflow.

The console provides B-mode imaging augmented by artificial intelligence (AI) annotations and quantitative depth measurements, permitting the clinician to monitor the real-time position of the needle tip relative to the ligamentum flavum and dura. The Accuro 3S supplies continuous visualization throughout the insertion, combining the spatial awareness of fluoroscopic navigation with the portability and safety of ultrasound, which the requestor maintains differentiates the technology from conventional ultrasound devices used only for pre-procedure localization. The Accuro 3S provides continuous midline visualization and automated needle-tip tracking, transforming the process into a navigated intervention akin to computer-assisted surgery. Per the requestor, neuraxial anesthesia is performed at a specific intervertebral level. The Accuro 3S system displays vertebral level and depth in real time, with the target being the epidural or subarachnoid space of the spinal canal, rather than a defined number of vertebrae.

The Accuro 3S emits only diagnostic-level ultrasound energy, which is within long-established safety thresholds. According to the requestor, comprehensive bench testing and early clinical use demonstrate no device-related serious adverse events. Minor occurrences such as transient paresthesia or failed block have appeared only at background rates inherent to neuraxial anesthesia. The requestor maintains that the technology's planned studies include data-safety monitoring, adverse-event reporting, and compliance with institutional review board oversight.

Procedure Description

In an inpatient setting, during a standard epidural performed with the Accuro 3S, the patient is positioned in the sitting or lateral decubitus position and prepared using routine sterile technique. The Accuro 3S probe, enclosed in its sterile cover and suspension drape, is positioned over the intended interspace, most commonly L3-4. Once activated, the SpineNav-AI™ software automatically displays a live image of the vertebral column, identifies the midline, and marks the estimated depth to the epidural space. The clinician observes this navigation display as a continuous video stream while inserting a standard Tuohy or spinal needle. The needle's trajectory and tip location appear as a dynamic icon that moves in real time relative to the ligamentum flavum-dura mater complex. The clinician adjusts the angle and depth of insertion based on the system's feedback, allowing the needle to reach the epidural space precisely with minimal tissue passes. When the tip enters the epidural space, the catheter is advanced and secured according to institutional protocol.

The procedure is performed using a single, integrated neuraxial anesthesia technique. When Accuro 3S is used, the navigation and continuous needle-tracking functions are inherent to the placement of the neuraxial block and is not performed as a separate diagnostic or imaging procedure. The technology is not additive to another interventional technique; rather, it modifies how the neuraxial anesthetic is placed. The anesthetic administration remains the primary procedure, with Accuro 3S functioning as the embedded navigation method that defines the

technique. The navigation probe and drape are removed once placement is complete. The device is not permanent. Only one navigation probe is used per case; the system is reusable, and all disposable components are discarded.

Current Coding: The use of a diagnostic ultrasound imaging navigation system in the performance of neuraxial anesthesia is not reported separately for inpatient hospital coding. If desired, facilities can report the introduction of neuraxial anesthesia using the following code:

3E0R3BZ Introduction of anesthetic agent into spinal canal, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify the use of a diagnostic ultrasound imaging navigation system in the performance of neuraxial anesthesia. Continue as described in current coding.

Option 2. In section X New Technology create new table XEZ, Other Procedures on Physiological Systems and Anatomical Regions, add new technology value H Computer-aided Guidance for Intraprocedural Navigation using Ultrasound Imaging with Continuous Needle Tracking, applied to body part U Spinal Canal, and the percutaneous approach to identify the use of a diagnostic ultrasound imaging navigation system in the performance of neuraxial anesthesia. If desired, continue to report the neuraxial anesthesia as described in current coding.

Section	**X** New Technology		
Body System	**E** Physiological Systems and Anatomical Regions		
Operation	**Z** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Part	Approach	Device / Substance / Technology	Qualifier
ADD U Spinal Canal	**3** Percutaneous	**ADD H** Computer-aided Guidance for Intraprocedural Navigation using Ultrasound Imaging with Continuous Needle Tracking	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 07 – Computer-aided Detection and Notification Software for Assessment and Triage of Inflammatory Response

Issue: There are no unique ICD-10-PCS codes to describe the use of software with a high-dimensional Mixture-of-Experts computer model to aid in the assessment and triage of sepsis risk. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? No. The Bayesian Health Sepsis Flagging Device was granted Breakthrough Medical Device Status by the FDA on May 19, 2023. It is indicated as an artificial intelligence and machine learning-based software as a medical device intended for use in conjunction with clinical assessments and other laboratory findings to aid the early detection and/or risk prediction of sepsis within the next 24 hours, for adult individuals in emergency, observation, general ward, and intensive care units.

Background: Sepsis is a life-threatening condition that occurs when a person's immune response to an underlying infection causes dysfunction, damage, or even failure of the patient's tissues and organs. Various types of infections can trigger sepsis. According to the CDC, sepsis contributes to at least 1.7 million adult hospitalizations and at least 350,000 deaths annually in the United States, with 43,750 preventable sepsis deaths per year. According to the Journal of the American Medical Association (JAMA), prompt diagnosis and treatment of sepsis decreases sepsis-related mortality.[1]

Technology

The Bayesian Health Sepsis Flagging Device (formerly Targeted Real-time Early Warning System (TREWS)) is an artificial intelligence and machine learning-based software as a medical device (SaMD) that will be used to aid in identifying patients at risk for developing sepsis within one day of the assessment. According to the requestor, the Bayesian Health Sepsis Flagging Device uses a multimodal Mixture-of-Experts machine learning algorithm to continuously monitor and analyze comprehensive patient data from the electronic healthcare record (EHR), which includes a combination of patient demographic information, comorbidities, the chief complaint documented at presentation to the emergency department, laboratory measurements, vital signs, procedures, medications, and consultation orders. The technology calculates a risk score and categorizes the score as "Sepsis High Risk" if the score is associated with a high risk of developing sepsis. When the technology determines that there is a high risk of sepsis, the Bayesian Health Sepsis Device outputs a flag that is displayed within the EHR. The findings from the Bayesian Health Sepsis Flagging Device are interpreted in conjunction with other diagnostic and clinical information to inform treatment management decisions. Per the requestor, there have been no adverse outcomes or complications from the Bayesian Health Sepsis Flagging Device, as it is not yet commercially available.

[1] Reitz, K. M., Kennedy, J., Li, S. R., Handzel, R., Tonetti, D. A., Neal, M. D., Zuckerbraun, B. S., Hall, D. E., Sperry, J. L., Angus, D. C., Tzeng, E., & Seymour, C. W. (2022). Association Between Time to Source Control in Sepsis and 90-Day Mortality. *JAMA surgery*, *157*(9), 817–826. https://doi.org/10.1001/jamasurg.2022.2761

Procedure Description
In the inpatient setting, the requestor maintains that the Bayesian Health Sepsis Flagging Device uses multimodal high-dimensional clinical information (e.g., vitals, laboratory data, notes, problem lists, procedures, medications, and other structured/unstructured data) captured for the patient in the EHR to calculate the risk of developing or having sepsis each time a new input or event is logged in the medical record. The device receives data from the patient's EHR through Fast Healthcare Interoperability Resources®, Health Level 7®, and the electronic medical record's specific application programming interface. The software performs data validation and technical quality control checks on the inputs received before being passed to the model. If the patient's inputs are rejected due to technical reasons or software failure, an error message is returned to the healthcare system. Based on the inputs received, the technology calculates a risk score and categorizes the score as "Sepsis High Risk" if the score is associated with a high risk of developing sepsis. When the device calculates a high risk, a flag is added to the medical record, and the provider or other members of the care team can review the justification for the score, specifically the timing of the finding and the factors (e.g., vital signs or laboratory results) contributing to the high risk of sepsis.

Current Coding: The use of software with a high-dimensional Mixture-of-Experts computer model to aid in the assessment and triage of sepsis risk is not reported separately for inpatient hospital coding.

Option 1. Do not create new ICD-10-PCS codes to identify the use of software with a high-dimensional Mixture-of-Experts computer model to aid in the assessment and triage of sepsis risk. Continue as described in current coding.

Option 2. In section X New Technology, create new table XEZ, Other Procedures on Physiological Systems and Anatomical Regions, add new technology value J High Dimensional Mixture-of-Experts Computer-aided Assessment of Inflammatory Response and Organ Function for Notification and Triage, applied to the body part value Z None and the external approach, to identify the use of software with a high dimensional Mixture-of-Experts computer model to aid in the assessment and triage of sepsis risk.

Section	**X** New Technology		
Body System	**E** Physiological Systems and Anatomical Regions		
Operation	**Z** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD Z None	**X** External	**ADD J** High Dimensional Mixture-of-Experts Computer-aided Assessment of Inflammatory Response and Organ Function, for Notification and Triage	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 08 – Computer-aided Triage and Notification Software for Imaging Abnormalities in Computerized Tomography

Issue: There are currently no unique ICD-10-PCS codes to identify the use of single artificial intelligence (AI) foundation model software to analyze computerized tomography (CT) scans for suspected critically actionable imaging abnormalities. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? Yes. BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT Body was granted Breakthrough Device Status by the FDA on August 7, 2025 and 510(k) premarket notification (K252970) on January 7, 2026. BriefCase-Triage: CARE Multi-Triage CT Body is a radiological computer-aided triage and notification software indicated for use in the analysis of contrast and non-contrast CT images of the chest, abdomen, and/or pelvis, in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive findings, per study, of:

1. Diverticulitis;
2. Abdominal-pelvic abscess;
3. Appendicitis;
4. Intestinal ischemia and/or pneumatosis;
5. Obstructive renal stone;
6. Small bowel obstruction;
7. Large bowel obstruction;
8. Spleen injury;
9. Liver injury;
10. Kidney injury;
11. Pelvic fracture.

Background: According to the Open Access Emergency Medicine journal, abdominal pain is a common complaint in the emergency department, accounting for nearly 7% of emergency department visits and representing over 3 million patient encounters.[1] CT imaging is the most common modality for undifferentiated abdominal pain. CT scans of the abdomen and pelvis account for approximately 10 to 20% of emergency department CT examinations.[2] Triage of diagnostic imaging is important to ensure that life-threatening cases are prioritized in emergent settings.

CT scanning of the chest, abdomen and pelvis (CT-CAP) is a scan of the trunk used to diagnose trauma, infections, or cancers and is generally performed as one continuous, single-session scan that takes images from above the lungs down to the bottom of the pelvis. It uses special x-ray equipment and computers to produce images of multiple "slices" of the part of the body being

[1] Wolfe, J. M., Võ, M. L., Evans, K. K., & Greene, M. R. (2011). Visual search in scenes involves selective and nonselective pathways. *Trends in cognitive sciences*, *15*(2), 77–84. https://doi.org/10.1016/j.tics.2010.12.001

[2] Wang, D. C., Parry, C. R., Feldman, M., Tomlinson, G., Sarrazin, J., & Glanc, P. (2015). Acute Abdomen in the Emergency Department: Is CT a Time-Limiting Factor?. *AJR. American journal of roentgenology*, *205*(6), 1222–1229. https://doi.org/10.2214/AJR.14.14057

scanned without or with contrast (dye) to enhance different organs. These images of the inside of the body can then be examined on a computer monitor. BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT Body is software for analyzing CT images of the chest, abdomen, and pelvis that aids in triaging/prioritizing medical images using professional judgment alongside other patient information.

Technology
BriefCase-Triage: CARE Multi-Triage CT Body is a radiological computer-aided triage and notification software indicated for use in the analysis of contrast and non-contrast CT images of the chest, abdomen, and/or pelvis, in adults. According to the requestor, the device flags cases with at least one suspected finding to assist with triage/prioritization of medical images. The device will provide a flag for each suspected finding of diverticulitis, abdominal-pelvic abscess, appendicitis, intestinal ischemia, or pneumatosis, obstructive renal stone, small and large bowel obstructions, spleen injury, liver injury, kidney injury, and/or pelvic fracture within this study.

A preview image will be provided for each distinct suspected finding. BriefCase-Triage: CARE Multi-Triage CT Body uses a foundation model-based artificial intelligence (AI) system to analyze images and highlight cases with detected findings in parallel with the ongoing standard of care image interpretation. The device does not alter the original medical images. The user is presented with notifications for cases with suspected findings. The findings from BriefCare-Triage: CARE Multi-Triage CT Body are reviewed and considered by the clinical team in conjunction with other patient information (e.g., signs, symptoms, diagnostic test results) to determine the next appropriate steps in patient management. Notified clinicians are responsible for viewing full images per the standard of care. According to the requestor, adverse reactions have not been associated with the use of BriefCase-Triage: CARE Multi-Triage CT Body.

Procedure Description
In an inpatient setting, BriefCase-Triage: CARE Multi-Triage CT Body is integrated into the radiology standard workflow with applicable CT cases sent to the manufacturer's cloud-based platform. The software performs data validation and technical quality control checks on the CT images received before being passed to its AI model. The technology analyzes applicable contrast and non-contrast CT images for potential findings for any of the possible clinical indications. BriefCase-Triage: CARE Multi-Triage CT Body notifies end users for cases with suspected findings. Notifications include compressed preview images for each suspected finding that are meant for informational purposes only and not intended for diagnostic use beyond notification. The results of BriefCase-Triage: CARE Multi-Triage CT Body are intended to be used in conjunction with other patient information and based on the provider's professional judgment, to assist with triage/prioritization of medical images.

Current Coding: The use of single AI foundation model software to analyze for suspected critically actionable imaging abnormalities in CT scans is not reported separately for inpatient hospital coding. If desired, facilities can report the CT scan with the applicable code in section B Imaging.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify the use of single AI foundation model software to analyze CT scans. Continue as described in current coding.

Option 2.
In section X New Technology create new table XEZ, Other Procedures on Physiological Systems and Anatomical Regions, with new technology value K Computer-aided Triage and Notification for Imaging Abnormalities in Computed Tomography, applied to the new body part value as shown and the external approach, to identify the use of single AI foundation model software to analyze CT scans for suspected critically actionable imaging abnormalities. If desired, facilities can continue to report the CT scan as described in current coding.

Section *Body System* *Operation*	**X** New Technology **E** Physiological Systems and Anatomical Regions **Z** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 5 Chest, Abdomen, and Pelvis	**X** External	**ADD K** Computer-aided Triage and Notification for Imaging Abnormalities in Computed Tomography	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 09 – Percutaneous Epicardial Access for Diagnostic and Therapeutic Cardiac Interventions

Issue: There are no unique ICD-10-PCS codes to describe percutaneous epicardial access using a blunt-tip concealed needle with a mechanical gripping mechanism for diagnostic and therapeutic cardiac interventions. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-On Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? Yes. The ViaOne™ Epicardial Access System received 510(k) clearance on March 20, 2025 (K243928). It is intended to access the epicardial surface of the heart via a subxiphoid approach to deliver diagnostic and therapeutic interventions for ventricular tachycardia.

Background: Ventricular tachycardia (VT) is a type of abnormal heart rhythm (arrhythmia) that originates in the ventricles. It is characterized by a rapid heart rate, typically over 100 beats per minute, caused by abnormal electrical signals in the ventricles rather than the normal conduction pathway. This fast rhythm reduces the time for the heart to fill with blood between beats, which can significantly impair cardiac output and lead to symptoms such as palpitations, chest pain, shortness of breath, dizziness, or fainting. Cardiac arrhythmias are life-threatening disturbances in the heart's rhythm.

According to the requestor, current treatments often have limited efficacy, particularly for arrhythmias that originate on the heart's surface. Most clinicians avoid direct access to the epicardial surface because existing techniques require advancing a long needle toward the beating heart, a maneuver associated with significant risk. The requestor stated that the procedure carries an estimated one-in-three chance of cardiac perforation, making it a high-risk intervention and a major barrier to effective treatment.

Technology
ViaOne™ is a sterile, single use device, designed to allow safe pericardial access utilizing a non-advancing blunt-tip fixed concealed-needle system with mechanical tissue-responsive guidance and controlled tissue retraction, non-vacuum. It is designed for interventional cardiologists and electrophysiologists to access the heart's surface safely without the risk of perforation. The device consists of a blunt distal tip with integrated mechanical capture aperture, mechanical tissue-responsive sensing, a stainless-steel shaft, and a proximal handle that encases a 17.5 gauge fixed needle and has interfaces to facilitate guide wire delivery. The mechanical tissue-responsive engagement element gently lifts the pericardial "envelope" tissue surrounding the heart and retracts it into a protected channel. Once the tissue is secured within the device, it is punctured in a controlled manner, enabling bi-directional access for subsequent therapeutic interventions. The ViaOne™ device is available in two lumen sizes, compatible with up to 0.018" or up to 0.035" guide wires.

Per the requestor, across all procedures performed with ViaOne™, adverse events were limited and consisted with the expected profile of subxiphoid pericardial access, with no unforeseen safety concerns. All events resolved within the follow-up period, and there was no indication of any chronic effects, particularly regarding cardiac rhythm stability. Two device-related serious adverse

events (SAEs) (pericardial hemorrhage) occurred early in the learning curve and were fully resolved without sequela. After operator training optimization, no further device related SAEs occurred. One non-serious adverse event (a minor pericardial effusion) was reported.

Procedure Description
The procedure is started by creating a subxiphoid incision to access the pericardial space. Entry is established using a 17–18 gauge Touhy needle that remains fixed and concealed throughout the procedure, and a tunneling tool or an introducer sheath. The sheath is positioned within the anterior mediastinal cavity, approximately 2 cm from the heart silhouette. The ViaOne™ device is inserted through the pre-positioned sheath and, under fluoroscopic guidance, advanced towards the pericardium until the tip is approximately 2 cm away. The device is slowly advanced until it contacts the outer surface of the pericardium, with the mechanical tissue-responsive sensing being observed as it reflects cardiac motion and confirm correct positioning. The device's engagement element gently retracts pericardial tissue into the leading channel and the non-advancing concealed needle performs a protected puncture. A guidewire is then advanced under fluoroscopy, and the device is withdrawn over the wire.

Per the requestor, one ViaOne™ device is used once per patient per hospital stay and is designed to provide safe pericardial access to facilitate placement of devices into the pericardial space.

Current Coding: There is no unique ICD-10-PCS code to describe percutaneous epicardial access using a blunt-tip concealed needle with a mechanical gripping mechanism for diagnostic and therapeutic cardiac interventions. Code the diagnostic or therapeutic cardiac intervention performed from the applicable ICD-10-PCS table using the appropriate values.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe percutaneous epicardial access using a blunt-tip concealed needle with a mechanical gripping mechanism for diagnostic and therapeutic cardiac interventions. Continue as described in current coding.

Option 2. In section X New Technology table XEZ, Other Procedures in Physiological Systems and Anatomical Regions, create new technology value Q, Access using Blunt-tip Concealed Needle with Mechanical Gripping Mechanism, applied to the body part value D Pericardial Cavity, to identify pericardial cavity access using a blunt-tip concealed needle with a mechanical gripping mechanism. Separately report the diagnostic or therapeutic cardiac intervention performed from the applicable ICD-10-PCS table using the appropriate values.

Section	**X** New Technology		
Body System	**E** Physiological Systems and Anatomical Regions		
Operation	**Z** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
D Pericardial Cavity	**3** Percutaneous	**ADD Q** Access using Blunt-tip Concealed Needle with Mechanical Gripping Mechanism	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 10 – Introduction of Vancomycin-eluting Bone Void Filler into Bones

Issue: There are no unique ICD-10-PCS codes to describe the introduction of vancomycin-eluting bone void filler into bones. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-On Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? No. CERAMENT® V received Breakthrough Device designation on 10/15/2023 for the indication of bone infection. The De Novo application for the device is currently in process.

Background: Osteomyelitis is a bone infection most often caused by bacteria; however, it can also result from other germs that have spread to a bone from infected skin or underlying tissues next to a bone. Surgical management of osteomyelitis is commonly done as a two-stage procedure. Per the requestor, in the first stage, surgery is carried out to remove any infected or necrotic bone tissue (i.e., debridement) and most often, antibiotic-loaded bone cement such as polymethyl methacrylate (PMMA) or calcium sulfate mixed with antibiotics off-label is placed in the location of the excised bone, and the wound is closed. PMMA must be removed, as it prevents bone ingrowth that can hinder long-term healing of a fractured bone and can act as a focal point for infection. Furthermore, the calcium sulfate in the mix resorbs and does not remodel into bone. Approximately 6 to 12 weeks later, a second operation is carried out to manage the bone void, also known as 'dead-space.' The current options for dead-space management are limited to autografts, allografts, or other bone graft substitutes.

According to the requestor, CERAMENT® V eliminates the need to harvest autologous bone in patients diagnosed with bone infection, thereby avoiding donor site morbidity (e.g., pain, infection, etc.). Per the requestor, CERAMENT® V also benefits patients by reducing the recurrence of infection by delivering a precise and known quantity of vancomycin to prevent the colonization of vancomycin-sensitive microorganisms. The requestor asserted that CERAMENT® V is the sole bone void filler that elutes the antibiotic vancomycin, a glycopeptide antibiotic. It is particularly useful when bacteria in infected bone are vancomycin-sensitive or gram-positive microorganisms resistant to gentamicin and indicated one such bacteria that are especially problematic are methicillin-resistant staphylococcus aureus (MRSA).

Technology
CERAMENT® V is an implantable bone void filler (combination device/drug) consisting of hydroxyapatite, calcium sulfate, and vancomycin. CERAMENT® V remodels into bone and elutes vancomycin, which prevents colonization of vancomycin-sensitive microorganisms to protect bone healing. It is used for dead-space management as part of the surgical treatment of osteomyelitis.

According to the requestor, the properties of CERAMENT® V create an effective tool for dead-space management to restore healthy bone and reduce the rate of infection recurrence (in osteomyelitis) compared to other bone void fillers which do not have an antibiotic component. Once in the bone void, CERAMENT® V has two modes of action with the primary mode of action being to promote bone healing in gaps and voids in the skeleton system created when infected bone is debrided. The secondary mode of action is to prevent colonization of the bone void filler by vancomycin-sensitive microorganisms to protect bone healing.

Per the requestor, reported adverse events related to the use of CERAMENT® V include soft tissue complications (such as hematoma and drainage), recurrence of infection, pathological fracture, non-union, sinus formation, delayed wound healing and delayed bone healing. The most common adverse event is sterile soft tissue leakage/drainage.

CERAMENT® V is only available in 10 mL units and it is not recommended to implant more than 20 mL of CERAMENT® V for cases of bone infection.

Procedure Description
After the surgical site has been prepared and dead bone is debrided, the CERAMENT® V paste is prepared by the surgeon or surgical technician for injection. The paste can be injected using the tip extenders provided in the kit or by attaching a needle to the delivery syringe, or it can be placed into a bead mold to form beads.

Current Coding: There are no unique ICD-10-PCS codes to describe the introduction of vancomycin-eluting bone void filler into bones. Facilities can report the introduction of vancomycin-eluting bone void filler into bones using the following code:

XW0V0P7	Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the introduction of vancomycin-eluting bone void filler into bones. Continue as described in current coding.

Option 2. In section X table XW0, Introduction of Anatomical Regions, create new substance value B Vancomycin-eluting Bone Void Filler, applied to the body part value V Bones, and the open approach, to identify the introduction of vancomycin-eluting bone void filler into bones.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
V Bones	**0** Open	**ADD B** Vancomycin-eluting Bone Void Filler	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 11 – Insertion of a Venous Angle Decompression Device

Issue: There is no unique ICD-10-PCS code to describe the insertion of a venous angle decompression device. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for future consideration.

Food & Drug Administration (FDA) Approval? No. The WhiteSwell eLym™ System was granted Breakthrough Device designation by the FDA in October 2024 for use in the treatment of fluid overload or congestion in adult patients with acute decompensated heart failure with an unsatisfactory response to diuretics.

Background: Hospitalization for acute decompensated heart failure (ADHF) is associated with poor outcomes. Within six months of discharge, nearly half of patients are rehospitalized, a third require emergency care, and 15% die.[1, 2] Congestion is the primary driver of admissions and readmissions.[3, 4, 5] Despite guideline-directed intravenous diuretics, many patients leave the hospital with residual fluid overload, which is the strongest predictor of rehospitalization and death.[6, 7, 8] Standard therapy primarily targets intravascular fluid (25% of extracellular fluid), relying upon intravascular decongestion to set up conditions that eventually pull through interstitial fluid (75% of extracellular fluid).[9, 10] Past efforts to improve diuresis or protect renal function—

[1] Van Spall HGC, DeFilippis EM, Lee SF, Oz UE, et al. Sex-specific clinical outcomes of the PACT-HF randomized trial. Circ Heart Fail. 2021;14:e008548. doi: 10.1161/CIRCHEARTFAILURE.121.008548

[2] Felker, G. Michael, Lee, Kerry L., et al. Diuretic Strategies in Patients with Acute Decompensated Heart Failure N Engl J Med 2011; 364:797-805, doi: 10.1056/NEJMoa1005419.

[3] Gheorghiade M, Follath F, Ponikowski P, et al. Assessing and grading congestion in acute heart failure: a scientific statement from the acute heart failure committee of the heart failure association of the European Society of Cardiology and endorsed by the European Society of Intensive Care Medicine. Eur J Heart Fail. 2010; 12: 423-33.

[4] O'Connor CM, Stough WG, Gallup DS, Hasselblad V and Gheorghiade M. Demographics, clinical characteristics, and outcomes of patients hospitalized for decompensated heart failure: observations from the IMPACT-HF registry. J Card Fail. 2005; 11: 200-5.

[5] Goldsmith SR, Brandimarte F and Gheorghiade M. Congestion as a therapeutic target in acute heart failure syndromes. Prog Cardiovasc Dis. 2010; 52: 383-92.

[6] Lala A, McNulty SE, Mentz RJ, Dunlay SM, Vader JM, AbouEzzeddine OF, DeVore AD, Khazanie P, Redfield MM, Goldsmith SR, Bart BA, Anstrom KJ, Felker GM, Hernandez AF, Stevenson LW. Relief and Recurrence of Congestion During and After Hospitalization for Acute Heart Failure: Insights From Diuretic Optimization Strategy Evaluation in Acute Decompensated Heart Failure (DOSE-AHF) and Cardiorenal Rescue Study in Acute Decompensated Heart Failure (CARESS-HF). Circ Heart Fail. 2015 Jul;8(4):741-8. doi: 10.1161/CIRCHEARTFAILURE.114.001957. Epub 2015 Jun 3.

[7] Rubio-Gracia J, Demissei BG, Ter Maaten JM, Cleland JG, O'Connor CM, Metra M, Ponikowski P, Teerlink JR, Cotter G, Davison BA, Givertz MM, Bloomfield DM, Dittrich H, Damman K, Pérez-Calvo JI, Voors AA. Prevalence, predictors and clinical outcome of residual congestion in acute decompensated heart failure. Int J Cardiol. 2018 May 1;258:185-191. doi: 10.1016/j.ijcard.2018.01.067.

[8] Fudim M, Loungani R, Doerfler SM, Coles A, Greene SJ, Cooper LB, Fiuzat M, O'Connor CM, Rogers JG, Mentz RJ. Worsening renal function during decongestion among patients hospitalized for heart failure: Findings from the Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) trial. Am Heart J. 2018 Oct;204:163-173. doi: 10.1016/j.ahj.2018.07.019. Epub 2018 Jul 29.

[9] Aronson D. The interstitial compartment as a therapeutic target in heart failure. Front Cardiovasc Med. 2022 Aug 17;9:933384. doi: 10.3389/fcvm.2022.933384. PMID: 36061549; PMCID: PMC9428749.

[10] Cleland JGF, Pfeffer MA, Clark AL, Januzzi JL, McMurray JJV, Mueller C, Pellicori P, Richards M, Teerlink JR, Zannad F, Bauersachs J. The struggle towards a Universal Definition of Heart Failure – how to proceed? Eur Heart J. 2021 Jun 21; 42(24):2331-2343.

such as low-dose dopamine, nesiritide, rolofylline, or ultrafiltration—failed to improve outcomes.[11, 12]

Normally, the thoracic duct (a major lymphatic vessel) drains interstitial fluid back into the circulation at the venous angle. In ADHF, elevated central venous pressure (CVP) impedes lymphatic drainage, trapping fluid in organs and tissues. This CVP-impaired lymphatic drainage worsens edema, renal congestion, and symptoms.[13, 14]

Ninety percent of ADHF patients present with congestion.[15] Current therapies decongest only the intravascular space. No approved ADHF therapies directly target interstitial fluid or support lymphatic drainage.

The WhiteSwell eLym™ System was designed to address this therapeutic gap. By creating a lower pressure zone at the outflow of the thoracic duct, the eLym™ System creates favorable lymphatic drainage conditions and supports the return of excess lymph from the interstitial space into the vascular compartment. When used alongside loop diuretics, this approach enables simultaneous decongestion of both intravascular and interstitial compartments. This dual mechanism may improve the effectiveness and safety of diuretic therapy, maintain intravascular volume and so preserve renal function, relieve tissue and organ edema and intra-abdominal hypertension, and enhance symptom relief and reduce the risk of recurrent hospitalizations. According to the requestor, by re-establishing natural lymphatic drainage and supporting interstitial decongestion, the WhiteSwell eLym™ System has the potential to address residual congestion—the strongest predictor of poor outcomes in ADHF—and improve the trajectory of patient care.

Technology

The eLym™ System, developed by WhiteSwell, is designed to create a localized reduced pressure zone at the thoracic duct outflow located adjacent to the venous angle (junction of the left subclavian vein and left internal jugular vein which creates the innominate vein). This lower-pressure zone facilitates drainage of fluid (lymph) from the interstitial compartment through the lymphatic system into the intravascular space. Removal of fluid from the intravascular space is enabled using concurrent diuretic therapy.

The eLym™ System comprises two endovascular components, a Sheath and a Catheter used in combination with a Console. The system is configured by connecting the Sheath and Catheter cable connectors to the eLym™ Console controller. The Catheter includes a microaxial impeller

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[11] Massie BM, O'Connor CM, Metra M, et al. Rolofylline, an adenosine A1-receptor antagonist, in acute heart failure. N Engl J Med. 2010; 363: 1419-28.

[12] Chen HH, Anstrom KJ, Givertz ,MM, et al. Low-dose dopamine or low-dose nesiritide in acute heart failure with renal dysfunction: the ROSE acute heart failure randomized trial. JAMA. 2013; 310: 2533-43.

[13] Biegus J, Lindenfeld J, Felker GM, Bakris G, Jonas M, Lala A, Kereselidze Z, Khabeishvili G, Gogorishvili I, Núñez J, Bayés-Genís A, Ponikowski P, Abraham WT. Design and rationale of the eLym™ System for Decompensation of Excess Lymphatic Fluid via the Thoracic Duct in Acute Heart Failure (DELTA-HF). ESC Heart Fail. 2025 Jun;12(3):1719-1726. doi: 10.1002/ehf2.15192. Epub 2024 Dec 24. PMID: 39716986; PMCID: PMC12055369.

[14] Abraham WT, Jonas M, Dongaonkar RM, Geist B, Ueyama Y, Render K, Youngblood B, Muir W, Hamlin R, Del Rio CL. Direct Interstitial Decongestion in an Animal Model of Acute-on-Chronic Ischemic Heart Failure. JACC Basic Transl Sci. 2021 Nov 22;6(11):872-881. doi: 10.1016/j.jacbts.2021.09.008. PMID: 34869951; PMCID: PMC8617571.

[15] Chioncel O, Mebazaa A, Maggioni AP, Harjola VP, Rosano G, Laroche C, Piepoli MF, Crespo-Leiro MG, Lainscak M, Ponikowski P, Filippatos G, Ruschitzka F, Seferovic P, Coats AJS, Lund LH; ESC-EORP-HFA Heart Failure Long-Term Registry Investigators. Acute heart failure congestion and perfusion status - impact of the clinical classification on in-hospital and long-term outcomes; insights from the ESC-EORP-HFA Heart Failure Long-Term Registry. Eur J Heart Fail. 2019 Nov;21(11):1338-1352. doi: 10.1002/ejhf.1492. Epub 2019 May 24. PMID: 31127678.

pump, which is used to move flow out of the venous angle to create a reduced pressure zone and favorable lymph drainage conditions near the thoracic duct outflow. It also includes a compliant balloon to center the impeller pump in the innominate vein and to prevent innominate retrograde flow and thus enhance the pump's pressure reducing capacity at the thoracic duct outflow. The catheter also has an optical pressure sensor to monitor pressure in the lower-pressure zone, referred to as thoracic duct zone pressure.

The kink-resistant flexible Sheath is intended for delivery and removal of the Catheter, and it includes a pressure monitor and a flow-restricting balloon which can be inflated to reduce inflow into the venous angle, if necessary. The Sheath has a catheter-lock feature to ensure stability of the eLym™ System position during treatment. The Console controls the microaxial impeller pump and includes an algorithm that adjusts speed based on continuous pressure monitoring to attain a target pressure as selected by the clinician at the thoracic duct outflow zone. The system thus creates a lower pressure zone which draws lymph fluid from the interstitial space to the intravascular space and is expected to lead to more complete decongestion in conjunction with IV diuretic therapy. The treatment duration will be up to 60 hours. Complications may include the typical vascular complications associated with catheterization procedures via the jugular vein.

Procedure Description
Insertion of the eLym™ System is performed under local anesthesia using ultrasound and fluoroscopic guidance in the cardiac catheterization lab. Ultrasound-guided percutaneous access via the left jugular vein is obtained, and after access site dilation, the sheath is introduced over a guidewire and positioned above the venous angle. The catheter is advanced through the sheath using a guidewire and is positioned in the innominate vein beyond the venous angle but proximal to the superior vena cava. Fluoroscopy is used to confirm position of the catheter and sheath relative to the venous angle. The pump is activated, the catheter balloon inflated, and then, using the console, the impeller speed is optimized to reduce the monitored thoracic duct zone pressure. The system is secured in place at the neck. The patient is then transferred to a cardiac critical care unit, intensive care unit, or an intermediate critical care unit for up to 60 hours of treatment.

Removal of the eLym™ System can be performed bedside. The pump is stopped, the catheter balloon is fully deflated, and then it is removed through the sheath. The sheath balloon is deflated, if needed, and once the activated clotting time (ACT) / activated partial thromboplastin time (aPTT) levels have stabilized, the sheath is removed, and hemostasis is achieved by applying pressure.

Current Coding: There is no unique ICD-10-PCS code to describe the insertion of a venous angle decompression device. Code the procedure in table 05H Insertion of Upper Veins, with the body part value 4, Innominate Vein, Left, the device value D Intraluminal Device, and the percutaneous approach.

Section	**0** Medical and Surgical
Body System	**5** Upper Veins
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device*	*Qualifier*
3 Innominate Vein, Right **4** Innominate Vein, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**3** Infusion Device **D** Intraluminal Device M Neurostimulator Lead	**Z** No Qualifier

Coding Options

Option 1. Do not create a new ICD-10-PCS code to describe the insertion of a venous angle decompression device. Continue as described in current coding.

Option 2. In section X New Technology table X2H, Insertion of Cardiovascular System, create new device value M Temporary Intraluminal Device, Venous Angle Decompression using Impeller Pump, applied to the new body part value shown and the percutaneous approach, to describe the insertion of a venous angle decompression device.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 4 Innominate Vein, Left	**3** Percutaneous	**ADD M** Temporary Intraluminal Device, Venous Angle Decompression using Impeller Pump	**C** New Technology Group 12

In addition, in section 5, Extracorporeal or Systemic Assistance and Performance table 5A0, add the function value 7 Decompression and qualifier value D Impeller Pump, applied to body system value 5 Circulatory, and duration value 2 Continuous.

Section	**5** Extracorporeal or Systemic Assistance and Performance
Body System	**A** Physiological Systems
Operation	**0** Assistance: Taking over a portion of a physiological function by extracorporeal means

Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**1** Intermittent **2** Continuous	**2** Oxygenation	**1** Hyperbaric
5 Circulatory	**2** Continuous	**ADD 7** Decompression	**ADD D** Impeller Pump

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 12 – Division of Mitral Valve Leaflets during Transcatheter Mitral Valve Replacement

Issue: There is no unique ICD-10-PCS code to describe the division of mitral valve leaflets during transcatheter mitral valve replacement. An October 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. Investigational Device Exemption (IDE) for the Intentional Laceration of the Anterior Mitral Leaflet to Prevent Left Ventricular Outflow Tract Obstruction was issued on December 8, 2016 (IDE G1602390).

Background: Left Ventricular Outflow Tract (LVOT) obstruction is a life-threatening complication of transcatheter mitral valve replacement (TMVR). It occurs when the anterior leaflet of the mitral valve is displaced toward the interventricular septum by the newly implanted transcatheter device, severely narrowing or occluding the outflow tract. The incidence of LVOT obstruction in TMVR occurs in up to 10–40% of valve-in-MAC, 5% of valve-in-ring, and 0.7–2% of valve-in-valve cases (Guerrero and Yoon). LVOT obstruction leads to acute hemodynamic collapse, heart failure, and high mortality. Patients excluded from TMVR and device trials most commonly have predicted LVOT obstruction risk based on cardiac CT imaging (neo-LVOT area ≤ 200 mm^2).

For these high-risk patients, alternatives are limited: open-heart surgery (often contraindicated due to frailty/comorbidity), trans-coronary alcohol septal ablation (limited by artery anatomy and necessary waiting periods), or no intervention, which is invariably fatal. Laceration of the Anterior Mitral Leaflet to Prevent Outflow Obstruction (LAMPOON) is a minimally invasive heart technique that slices the anterior mitral leaflet to prevent a fatal blockage (LVOT obstruction) during TMVR for patients unable to have open-heart surgery, using catheters and an electrified wire guided by imaging. LAMPOON provides a fully percutaneous means of mitigating this catastrophic risk, enabling TMVR in otherwise ineligible patients. Adoption of this technique is expanding as an adjunct to TMVR in high-risk patients, particularly where LVOT obstruction is predicted.

Balloon valvuloplasty is optional with a TMVR, meaning that the valve may or may not be "rendered nonfunctional". Balloon valvuloplasty may be performed during TMVR when the mitral valve anatomy is stenotic or rigid, and pre-dilation is needed to prepare the valve annulus and leaflets for successful deployment of the transcatheter valve. It can be used to widen the mitral valve orifice, allowing better valve expansion, improve valve seating and function, and reduce the risk of complications such as paravalvular leak or valve malposition. This makes the valve "nonfunctional".

Balloon valvuloplasty may not be necessary when the patient has pliable, non-calcified mitral valve leaflets, such as in a child with a malformation. In this case, the mitral valve remains functional and is not made "nonfunctional" prior to the TMVR procedure.

Technology
LAMPOON is performed using standard cardiovascular catheterization equipment with specialized guidewires, microcatheters, and electrosurgery units. A guidewire insulated by a locking microcatheter and manipulated is used to form the "flying V" for targeted leaflet laceration. Radiofrequency electrosurgery (usually 50–70 W, pure cut mode) is used to facilitate transcatheter leaflet laceration.

There are no catheters engineered specifically for LAMPOON. Therefore, the technique is performed by adapting off-the-shelf devices that fulfill the required mechanical and insulation functions. Most physicians choose from multiple available brands based on reference and availability. Two common products used for this procedure are a Snare Catheter (Amplatz GooseNeck, Medtronic) used to help position and externalize the guidewire within the heart chambers to create the necessary loop and tension for successful laceration, and a Piggyback Wire Converter Microcatheter (Teleflex, USA), which is a polymer insulating jacket designed to fit over standard guidewires. It allows precise insulation, exposing only the segment of the wire used for electrocautery use during leaflet traversal and subsequent laceration.

Procedure Description
Access is obtained using percutaneous venous and arterial access, transseptal puncture is performed, and a guide sheath is placed into the left atrium under transesophageal echocardiogram (TEE) and fluoroscopic guidance. A guidewire traverses the mitral valve and is snared in the LVOT/aorta to establish a stable rail for leaflet manipulation. Leaflet traversal and laceration is performed using a guidewire that is electrified and maneuvered through the anterior mitral leaflet, creating a midline split (Flying “V”, "base-to-tip" or "tip-to-base" depending on anatomy), confirmed by imaging. After the leaflet is cut, TMVR is performed using standard delivery techniques (Edwards M3 or 3 Ultra bovine pericardial stented valves, or Abbott Tendyne TMVR valve), performed either with balloon mitral valvuloplasty or without a valvuloplasty. Final assessment includes hemodynamics, valve stability, and assessment for paravalvular leak (PVL).

The classic retrograde technique uses dual transfemoral catheters via the aorta. The antegrade version (now preferred) relies on a transseptal approach with improved stability and reduced procedure time. Both techniques produce precise midline leaflet division aligned with LVOT, minimizing post-procedure obstruction.

Current Coding: There are no unique ICD-10-PCS codes to describe the division of mitral valve leaflets during transcatheter mitral valve replacement. Code the procedure in table 02Q, Repair of Heart and Great Vessels, using the body part value G Mitral Valve, the approach value 3 Percutaneous and the qualifier value Z No Qualifier.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**Q** Repair: Restoring, to the extent possible, a body part to its normal anatomic structure and function

Body Part	*Approach*	*Device*	*Qualifier*
G Mitral Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**E** Atrioventricular Valve, Left **Z** No Qualifier

Separately code the TMVR procedure in table 02R, Replacement of Heart and Great Vessels, with the body part value G Mitral Valve, the applicable device value, and the percutaneous approach.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
G Mitral Valve **J** Tricuspid Valve	**3** Percutaneous	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**H** Transapical **Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe the division of mitral valve leaflets during transcatheter mitral valve replacement. Continue as described in current coding.

Option 2. In Medical and Surgical section table 028, Division of Heart and Great Vessels, add new body part value G Mitral Valve, applied to new qualifier value 0 Leaflet Laceration Technique and the percutaneous approach, to identify the division of mitral valve leaflets. Continue to separately report the appropriate code from table 02R, Replacement of Heart and Great Vessels, for the TMVR procedure as described in current coding.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**8** Division: Cutting into a body part, without draining fluids and/or gases from the body part, in order to separate or transect a body part

Body Part	*Approach*	*Device*	*Qualifier*
8 Conduction Mechanism **9** Chordae Tendineae **D** Papillary Muscle	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier
ADD G Mitral Valve	**3** Percutaneous	**Z** No Device	**ADD 0** Leaflet Laceration Technique

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 13 – Retinal Angiography using Fluorescing Agent

Issue: There are no unique ICD-10-PCS codes to describe retinal angiography using a fluorescing agent. An October 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. Fluorescein angiography is approved by the FDA. The approval covers both the injectable fluorescein (such as FLUORESCITE® and AK-FLUOR®) used in retinal and iris angiography, and the specific device indications in ophthalmic diagnostics.

Background: Both the retina and the choroid, the pigmented vascular layer of the eyeball between the retina and the sclera, receive their blood supply from the ophthalmic artery, which is the first branch of the internal carotid artery. Fluorescein angiography is an ophthalmic diagnostic procedure which uses fluorescent dye and rapid photography to visualize blood flow in the retina and choroid with special ophthalmic camera systems, such as the Sentinel Camera (AI Optics) and the CLARUS 700 (Zeiss Meditec). Fluorescein angiography helps to assess the anatomy, physiology, and pathology of retinal and choroidal circulation. It can aid in the diagnosis of various ocular pathologies and contribute to decision-making when planning the management of ocular pathology.[1] Fluorescein angiography relies on light stimulation, not X-rays, to make vessels glow for photos, making it a radiation free eye test.

Fluorescein angiography can be performed on one or both eyes as an outpatient procedure but is performed as an inpatient in the operating room for many pediatric patients. Indications for fluorescein angiography are diagnosing and assessing eye diseases such as diabetic retinopathy, macular degeneration, retinal vein occlusions, and other retinal vascular disorders. It is also used for evaluating areas of leakage, blockage, or neovascularization in retinal vasculature. This procedure is a vital diagnostic tool for retinal disease evaluation and management.

Technology
Fluorescein angiography technology integrates specialized fundus cameras equipped with excitation and barrier filters, allowing for detailed imaging of the retinal and choroidal vasculature during the procedure. The process utilizes a blue excitation filter (typically transmitting light between 465 and 490 nm) to illuminate the back of the eye after intravenous injection of fluorescein dye, which absorbs this light and then emits fluorescent light in the yellow-green spectrum (520 to 530 nm). A barrier filter on the camera blocks unwanted wavelengths while capturing only the emitted light from the fluorescein, producing high-contrast images of the dye as it passes through retinal blood vessels.

Procedure Description
The fluorescein angiography procedure begins with the administration of eye drops to dilate the patient's pupils. The patient is positioned with their chin and forehead stabilized against supports to keep the head steady throughout the imaging process. Initial baseline photographs of the retina are taken, after which fluorescein, an orange water-soluble fluorescent dye, is injected intravenously,

[1] Ruia S, Tripathy K. Fluorescein Angiography. [Updated 2023 Aug 25]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK576378/

typically into a vein in the arm. As the dye enters the bloodstream, it quickly reaches the blood vessels in the eye, often within seconds. Patients are informed about possible sensations (nausea, warmth, yellow discoloration of skin and urine) after injection. The healthcare team monitors for rare complications like allergic reactions or syncope.

Injection of the dye is timely coordinated with the process of taking photographs. Special cameras are used to capture the series of photographs; the dye fluoresces when exposed to blue light, and the emitted fluorescence is detected by the camera. Sequential images are then taken over several minutes, documenting the passage of the dye through the retinal and choroidal circulation, which allows for detailed visualization of both normal and abnormal retinal blood vessels. Depending on the specific pathology and imaging needs, the test can take anywhere from 10 to 30 minutes to complete.

The adult dose of fluorescein is 500 mg intravenously. For children, based on age and weight, 7.7 mg/kg of fluorescein can be injected up to a maximum dose of 500 mg. As an alternative to IV administration, oral administration can be used for children by mixing 2 ampules of 10% fluorescein dye with 30 mL of apple juice for the child to ingest. Using this method, the dye reaches in eye in approximately 5 minutes after ingested. The remainder of the procedure is the same (JAMA), with this method taking between 15 and 60 minutes.

Current Coding: There are no unique ICD-10-PCS codes to describe retinal angiography using a fluorescing agent. Facilities can report the retinal angiography in table 08J, Inspection of Eye.

Section	**0** Medical and Surgical
Body System	**8** Eye
Operation	**J** Inspection: Visually and/or manually exploring a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Eye, Right **1** Eye, Left **J** Lens, Right **K** Lens, Left	**X** External	**Z** No Device	**Z** No Qualifier
L Extraocular Muscle, Right **M** Extraocular Muscle, Left	**0** Open **X** External	**Z** No Device	**Z** No Qualifier

Facilities can report the administration of the fluorescein with the following ICD-10-PCS codes:

3E033KZ	Introduction of other diagnostic substance into peripheral vein, percutaneous approach
3E043KZ	Introduction of other diagnostic substance into central vein, percutaneous approach
3E0DXKZ	Introduction of other diagnostic substance into mouth and pharynx, external approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for retinal angiography using a fluorescing agent. Continue as described in current coding.

Option 2. In section B Imaging, create new table B85, Other Imaging of Eye, applied to the body part values as shown and the contrast agent 2 Fluorescing Agent, to identify retinal angiography using a fluorescing agent.

Section *Body System* *Type*	**B** Imaging **8** Eye **ADD 5** Other Imaging: Other specified modality for visualizing a body part		
Body Part	*Contrast*	*Qualifier*	*Qualifier*
A Choroid, Right **B** Choroid, Left **G** Retinal Vessel, Right **H** Retinal Vessel, Left	**2** Fluorescing Agent	**Z** None	**Z** None

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 14 – Insertion of a Temporary Intravascular Embolic Protection Device in Transcatheter Aortic Valve Replacement

Issue: There are currently no unique ICD-10-PCS codes to describe full aortic arch intravascular embolic protection with a cylindrical capture filter during transcatheter aortic valve replacement. An October 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The Emboliner® Embolic Protection Catheter (Emboliner®) received FDA Investigational Device Exemption (IDE) in December 2022 to begin clinical trials, with enrollment in a U.S. pivotal trial completed in October 2025. The requestor intends to submit a Premarket Notification (510(k)) application in 2026, aligned with completion of the pivotal IDE study and other preparatory regulatory activities.

Background: A cerebral embolism is a blood clot (thrombus) that starts from the heart or blood vessel where the clot originates and stops in an artery that leads to or rests within the brain.[1] Cerebral embolism is a known complication of cardiac surgery, cardiopulmonary bypass and catheter-based interventional cardiology and electrophysiology procedures. Embolic particles, which may include thrombus, valvular tissue, and foreign material, may become dislodged by surgical or catheter manipulations and enter the bloodstream. Cerebral embolism can lead to neurological and neurocognitive deficits, stroke or death. The accumulation of subclinical lesions is associated with increased risk of dementia and reduced resistance to future brain insult. Other organs downstream can also be damaged by embolism, resulting in diminished function or organ failure. These risks are especially critical in percutaneous heart valve therapies (PHVT), such as transcatheter aortic valve replacement (TAVR). New white matter brain lesions have been noted using magnetic resonance imaging (MRI) in about 70 to 95% of TAVR patients following the procedure, indicating high risks of long-term ischemic damage.[2] Furthermore, when TAVR is performed with a cerebral embolic protection device, debris is captured in up to 99% of the patients with captured particles as large as 2 mm in size. The use of embolic protection devices has been shown to significantly reduce the volume of new ischemic lesions and the incidence of peri-procedural strokes during TAVR.

Technology
The Emboliner® Embolic Protection Catheter (Emboliner®) is a cylindrical, 360-degree intraluminal filter that consists of the Emboliner® filter, which is attached to the end of the Emboliner® catheter, and its associated delivery system. The Emboliner® filter consists of a cylindrical heparin-coated Nitinol filter that expands to appose the aortic wall and simultaneously covers all three branch cerebral vessels (i.e. the brachiocephalic, left common carotid and left subclavian arteries) and the descending aorta. The filter is deployed as a single device spanning the entire aortic arch. The proximal/downstream end of the filter contains a radially expanding access port through which procedural devices such as the TAVR delivery system are passed. The access

[1] Roth, E.J. (2018). Cerebral Embolism. In: Kreutzer, J.S., DeLuca, J., Caplan, B. (eds) Encyclopedia of Clinical Neuropsychology. Springer, Cham. https://doi.org/10.1007/978-3-319-57111-9_2166
[2] Grubman, Daniel, "Implications Of Acute Brain Injury Following Transcatheter Aortic Valve Replacement" (2024). Yale Medicine Thesis Digital Library. 4228.

port conforms to each procedural device's outer diameter to maintain a debris seal and enable the filter to capture debris throughout the procedure.

The Emboliner® is placed using an integrated 9.5 Fr delivery sheath via the contralateral femoral artery access port that is typically used for the angiographic pigtail catheter during TAVR. The Emboliner®'s integrated sheath eliminates the need for a separate introducer sheath. The Emboliner® contains an integrated 6 Fr lumen that is initially used for an inflatable dilator catheter to facilitate arterial insertion and is later exchanged for the angiographic pigtail. Prior to Emboliner® insertion, the contralateral femoral artery access is slightly upsized from 5 or 6 Fr to 9.5 Fr. This approach eliminates the need for a third arterial puncture site.

Only one device is used routinely per patient. The Emboliner® filter is a temporary intravascular embolic protection device that is used intraoperatively and only in conjunction with another transcatheter cardiac intervention, most commonly TAVR. It is deployed and fully removed before the procedure concludes. According to the requestor, because the Emboliner® is not yet commercially available and is still under an FDA IDE, no commercial-use adverse event data exist at this time. The device has been used only within controlled clinical studies. Enrollment for the pivotal IDE trial has recently been completed, and final data—including adjudicated adverse events—will not be available until patient follow-up, monitoring, data cleaning, site closeout, and clinical events adjudication have concluded.

Procedure Description
Using the example of TAVR as the index procedure, the procedure begins with establishing arterial access in both femoral arteries. An extra-stiff j-tip exchange-length guide wire is inserted into the ipsilateral arteriotomy and advanced to the non-coronary cusp. The Emboliner® filter is loaded into the integrated delivery sheath, the balloon dilator tip is inflated with dilute contrast and is docked into the distal tip of the sheath. Under fluoroscopic imaging, the Emboliner® is inserted over the guidewire and advanced over the aortic arch, with the balloon tip near the sinotubular junction (STJ). The balloon tip is then deflated and removed over the wire through the integrated 6 Fr lumen. The cylindrical embolic filter is then unsheathed across the aortic arch, where it expands to appose the aortic wall, positioned to filter blood entering the brachiocephalic, left common carotid and left subclavian arteries. A 6 Fr angiographic pigtail is then advanced over the guidewire through the integrated 6 Fr lumen and placed in the non-coronary cusp, and the guidewire is removed. A separate guidewire is inserted in the ipsilateral femoral arteriotomy, is advanced through the access port in the Emboliner® filter, and advanced towards the native valve. As in a typical TAVR, native valve crossing proceeds via various exchanging of wires and catheters, and the TAVR delivery system is advanced over the guidewire for alignment in the native valve and deployment of the prosthetic valve. After valve deployment, the TAVR delivery system is removed from the patient, all wires and catheters are removed from the Emboliner® filter, and the Emboliner® filter containing the captured debris is retrieved back into the integrated sheath and removed from the patient.

Current Coding: Facilities may report the following ICD-10-PCS code to describe full aortic arch intravascular embolic protection with a cylindrical capture filter during TAVR:

5A05A6M Intraoperative cerebral embolic filtration, single capture filter

In addition, facilities would report the appropriate code from table 02R Replacement of Heart and Great Vessels for the aortic valve replacement procedure.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for full aortic arch intravascular embolic protection with a cylindrical capture filter during TAVR. Continue as described in current coding.

Option 2. In section X New Technology table X2A, Assistance of Cardiovascular System, create new technology value R Embolic Filtration, Cylindrical Capture Filter, applied to the body part value X Thoracic Aorta, Arch and the percutaneous approach, to identify full aortic arch intravascular embolic protection with a cylindrical capture filter during TAVR. Continue to separately report the appropriate code from table 02R, Replacement of Heart and Great Vessels, for the TAVR procedure as described in current coding.

Section	**X** New Technology		
Body System	**2** Cardiovascular System		
Operation	**A** Assistance: Taking over a portion of a physiological function by extracorporeal means		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
7 Coronary Sinus	**3** Percutaneous	**5** Intermittent Coronary Sinus Occlusion	**8** New Technology Group 8
H Common Carotid Artery, Right **J** Common Carotid Artery, Left **K** Internal Carotid Artery, Right **L** Internal Carotid Artery, Left	**3** Percutaneous	**4** Cerebral Embolic Filtration, Single Integrated Distal Filter	**B** New Technology Group 11
X Thoracic Aorta, Arch	**3** Percutaneous	**ADD R** Embolic Filtration, Cylindrical Capture Filter	**C** New Technology Group 12

CMS Recommendation: Option 1, as described above.

Rationale: CMS notes that the Emboliner® filter is a single filter that covers the three branches of the aortic arch. As such, we believe existing code 5A05A6M (Intraoperative cerebral embolic filtration, single capture filter) accurately describes the Emboliner® filter, and the Emboliner® filter aligns with other single capture filter devices that are also described by the code. Under the ICD-10-PCS procedure classification, within Table 5A0, Assistance of Physiological Systems, the 7th character qualifier value does not reflect the number of vessels; it reflects the type of device (i.e., filter) being used. As also reflected in Table 5A0, the body system is specified as the circulatory system.

Interim Coding Advice: Continue as described in current coding.

Topic # 15 – Computer-aided Detection of Cardiac Amyloidosis in Echocardiography

Issue: There are currently no unique ICD-10-PCS codes that identify the use of software that analyzes echocardiography to aid in the detection of cardiac amyloidosis. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-On Payment (NTAP) application for FY 2027.

Food & Drug Administration (FDA) Approval? Yes. InVision Precision Cardiac Amyloidosis Screening Software was granted class II 510(k) premarket approval by the FDA on May 21, 2025, and is indicated as a screening tool for adult patients aged 65 years and over undergoing cardiovascular assessment using echocardiography.

Background: Cardiac amyloidosis is a condition where an abnormal amyloid protein builds up in the heart muscle. Over time, these deposits make the heart walls stiff and thick, which makes cardiac contractility difficult. This can lead to symptoms such as shortness of breath, swelling in the legs or belly, fatigue, and irregular heartbeats. There are different types of cardiac amyloidosis, some related to changes in a protein made by the liver and others linked to bone marrow disorders. Clinically, patients often present with unexplained heart failure, low-voltage ECG despite increased wall thickness, and systemic features such as neuropathy or carpal tunnel syndrome.

Diagnosis of cardiac amyloidosis requires a multimodal approach, including echocardiography with strain imaging, nuclear medicine testing, or cardiac magnetic resonance imaging (MRI), blood work, and sometimes a biopsy to confirm the presence of amyloid. According to the requestor, multiple clinical studies and registries show that patients identified before advanced heart failure benefit significantly from newer disease-modifying therapies, have fewer hospitalizations, and live longer compared to those diagnosed late. Current imaging techniques like echocardiography and cardiac MRI provide valuable structural and tissue insights but lack specificity and cannot distinguish amyloid subtypes without additional tests. Definitive diagnosis still relies on invasive endomyocardial biopsy, which carries procedural risks, or nuclear medicine imaging, which carries radiation risk. Per the requestor, both are impractical for routine screening.

Technology
The InVision Precision Cardiac Amyloid (InVision PCA) is a Software as a Medical Device (SaMD) machine-learning disease detection clinical decision support tool that utilizes an algorithm and operates in conjunction with an institution's picture archiving and communication system (PACS) to identify high suspicion of cardiac amyloidosis from routinely obtained echocardiogram videos. The device assists clinicians in the diagnosis of cardiac amyloidosis by providing information that alerts the physician to refer the patient for confirmatory investigations. According to the requestor, there have been no adverse events reported to date with the use of the InVision Precision Cardiac Amyloid Screening Software.

Procedure Description
The InVision Precision Cardiac Amyloid algorithm software-based clinical decision support tool operates within the hospital's PACS to analyze echocardiographic studies in the inpatient setting.

Echocardiogram images and video loops are uploaded into the PACS, and the algorithm applies a machine learning process that is trained to recognize structural and functional patterns associated with cardiac amyloidosis. After processing, the algorithm generates a report indicating whether the findings are suggestive or not suggestive of cardiac amyloidosis. This report is then reviewed by the physician, who integrates the algorithm's output with clinical judgment to decide whether the patient should be referred for confirmatory diagnostic investigations such as cardiac MRI or nuclear medicine testing. The technology is used once per patient during a hospital admission.

Current Coding: The use of software that analyzes echocardiography to aid in detection of cardiac amyloidosis is not reported separately for inpatient hospital coding. If desired, facilities can report the echocardiogram with the applicable code in section B Imaging.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify the use of software that analyzes echocardiography to aid in detection of cardiac amyloidosis. Continue as described in current coding.

Option 2. In section X New Technology create new table XEZ, Other Procedures on Physiological Systems and Anatomical Regions, create new technology value L Computer-aided Detection and Notification for Imaging Abnormalities in Echocardiography, applied to the body part value Z None and the external approach, to identify the use of software that analyzes echocardiography to aid in detection of cardiac amyloidosis. If desired, facilities can continue to report the echocardiogram as described in current coding.

Section	**X** New Technology		
Body System	**E** Physiological Systems and Anatomical Regions		
Operation	**Z** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD Z None	**X** External	**ADD L** Computer-aided Detection and Notification for Imaging Abnormalities in Echocardiography	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 16 – Dilation of Lower Leg Arteries with Small-diameter Peripheral Vascular Intraluminal Device

Issue: There is no unique ICD-10-PCS code to describe dilation of lower leg arteries with a small-diameter peripheral vascular intraluminal device. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-On Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? No. The MicroStent Peripheral Vascular Stent System was granted Breakthrough Device designation by the FDA on April 28, 2021. It is indicated to improve luminal diameter in the treatment of ischemia in the lower leg with reference vessel diameters ranging from 2.5 mm - 4.5 mm.

Background: Chronic limb-threatening ischemia (CLTI) is associated with a high risk for cardiovascular events and mortality and accounts for approximately 90% of major amputations performed worldwide. Historically, CLTI in lesions below the knee (BTK) has been treated with autologous vein grafts, however many patients are precluded from having the procedure due to the absence of suitable venous conduits or the presence of significant underlying comorbidities. Over the last decade, various catheter-based endovascular techniques, including angioplasty, atherectomy, and stenting, have been developed, offering perfusion restoration alternatives to open bypass surgery. Restenosis and recoil of the artery remain the major drawbacks of infrapopliteal revascularization in CLTI patients. According to the requestor, the MicroStent Peripheral Stent System offers a solution to improve luminal diameter in the treatment of ischemia in the lower leg.

Technology
The Micro Medical Solutions MicroStent and the MicroStent XL Peripheral Vascular Stent System are self-expanding nitinol stent systems for permanent implantation. The MicroStent is made of a nickel-titanium alloy (nitinol) and comes pre-loaded in a 3.5F, 0.014" over-the-wire delivery system. The stent is formed from nitinol wires woven in a braided configuration. The delivery system includes a 3.5F sheath catheter with a coaxial inner assembly (stent stabilizer). A proximally located rotational hemostasis valve on the sheath catheter provides hemostasis and a safety lock to prevent premature deployment of the stent and is used to irrigate the catheter. The stent stabilizer terminates distally through the pre-loaded stent and out the distal end of the sheath catheter. The distal portion of the sheath catheter contains a radiopaque marker band. A second radiopaque marker band located on the stabilizer marks the proximal portion of the self-expanding stent when it is positioned within the space between the stent stabilizer and the sheath catheter. The MicroStent Peripheral Vascular Stent is implanted into any of the tibial or peroneal vessels, with patients receiving an average of 2 stents.

According to the requestor, no unanticipated adverse device effects (UADE) were reported in the MicroStent arm during the STAND trial, which was designed to evaluate the safety and effectiveness of the MicroStent compared to percutaneous transluminal angioplasty (PTA) in treating subjects with CLTI and infrapopliteal artery lesions. Serious adverse events (SAE) were reported in 69.0% of subjects in both treatment arms, with the most frequent SAEs being vascular disorders (147 total events), cardiac disorders (46 total events), and infections and infestations (37 total events). Nonserious adverse events were reported in 56.6% of subjects in the MicroStent arm

and 48.3% in the PTA arm. The most frequent nonserious adverse event classifications were vascular disorders (57 total events), injury, poisoning, and procedural complications (45 total events), and musculoskeletal and connective tissue disorders (38 total events).

Procedure Description
The MicroStent Peripheral Vascular Stent is implanted into any of the tibial or peroneal vessels. The procedure is performed in conjunction with balloon angioplasty for pre-dilation of the vessel and may be performed with other revascularization procedures, including atherectomy and intravascular lithotripsy. The lesion is first prepared using standard balloon dilation techniques. The MicroStent delivery system is then advanced over a guidewire and through an introducer sheath, passing beyond the target lesion. The system is then carefully retracted until the radiopaque marker bands are positioned appropriately, one distal and one proximal to the lesion, indicating correct alignment. Under fluoroscopic guidance, the stent is deployed by pulling back on the hemostasis valve until it reaches the point where the MicroStent stabilizer is held in place. Post-deployment, conventional PTA balloon catheter methods are employed to ensure optimal apposition of the MicroStent. Final confirmation of MicroStent placement and improved distal flow is achieved through angiographic imaging. The typical patient will receive an average of 2.0 stents per procedure. The MicroStent Peripheral Vascular Stent is designed to be a permanent implant, and revision and removal are not performed.

Current Coding: There is no unique ICD-10-PCS code to describe dilation of lower leg arteries with a small-diameter peripheral vascular intraluminal device. Facilities can report the procedure using the appropriate code in table 047, Dilation of Lower Arteries.

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
K Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left	**0** Open **4** Percutaneous Endoscopic	**4** Intraluminal Device, Drug-eluting **D** Intraluminal Device **Z** No Device	**1** Drug-Coated Balloon **Z** No Qualifier
K Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left	**0** Open **4** Percutaneous Endoscopic	**5** Intraluminal Device, Drug-eluting, Two **6** Intraluminal Device, Drug-eluting, Three **7** Intraluminal Device, Drug-eluting, Four or More **E** Intraluminal Device, Two **F** Intraluminal Device, Three **G** Intraluminal Device, Four or More	**Z** No Qualifier

T Peroneal Artery, Right **U** Peroneal Artery, Left			
K Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left	**3** Percutaneous	**4** Intraluminal Device, Drug-eluting	**1** Drug-Coated Balloon **2** Sustained Release **Z** No Qualifier
K Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left	**3** Percutaneous	**5** Intraluminal Device, Drug-eluting, Two **6** Intraluminal Device, Drug-eluting, Three **7** Intraluminal Device, Drug-eluting, Four or More	**2** Sustained Release **Z** No Qualifier
K Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left	**3** Percutaneous	**D** Intraluminal Device **Z** No Device	**1** Drug-Coated Balloon **Z** No Qualifier
K Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left	**3** Percutaneous	**E** Intraluminal Device, Two **F** Intraluminal Device, Three **G** Intraluminal Device, Four or More	**Z** No Qualifier

Coding Options

Option 1. Do not create a new ICD-10-PCS code to describe dilation of lower leg arteries with a small-diameter peripheral vascular intraluminal device. Continue as described in current coding.

Option 2. In section X New Technology table X27, Dilation of Cardiovascular System, create new device value N Intraluminal Device(s), Small-diameter applied to the body part values shown and the percutaneous approach, to identify dilation of lower leg arteries with a small-diameter peripheral vascular intraluminal device.

Section	**X** New Technology		
Body System	**2** Cardiovascular System		
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
2 Inferior Vena Cava and Iliocaval Confluence	**3** Percutaneous	**C** Intraluminal Device, Open-structure Polymer Lattice	**B** New Technology Group 11
3 Pulmonary Artery, Right **4** Pulmonary Artery, Left	**3** Percutaneous	**9** Intraluminal Device, Expandable	**B** New Technology Group 11
5 Subclavian Vein, Right **6** Subclavian Vein, Left **7** Axillary Vein, Right **8** Axillary Vein, Left **9** Brachial Vein, Right **A** Brachial Vein, Left **B** Basilic Vein, Right **C** Basilic Vein, Left **D** Cephalic Vein, Right **E** Cephalic Vein, Left	**3** Percutaneous	**5** Intraluminal Device, Cell Impermeable	**B** New Technology Group 11
P Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left	**3** Percutaneous	**T** Intraluminal Device, Everolimus-eluting Resorbable Scaffold(s)	**A** New Technology Group 10
W Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch	**3** Percutaneous	**9** Intraluminal Device, Expandable	**B** New Technology Group 11
P Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left	**3** Percutaneous	**ADD N** Intraluminal Device(s), Small-diameter	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 17 – Restriction of Thoracic Aortic Arch using a Branched Intraluminal Device with Conical Collar

Issue: There are no unique ICD-10-PCS codes to describe restriction of the thoracic aortic arch using a branched intraluminal device with a conical collar. An October 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The Arcevo™ Left Subclavian Artery (LSA) Hybrid Stent Graft System (Arcevo™ LSA) is currently being studied as part of the ARTIZEN IDE clinical trial (NCT07089576), which is a prospective, multi-center clinical study to evaluate the safety and effectiveness of the Arcevo™ LSA in the open repair of aortic arch aneurysms and dissections in patients that have an acute or chronic aortic dissection and/or aneurysm that involves the aortic arch and the descending thoracic aorta, with or without the involvement of the ascending aorta, with the first enrollment occurring on October 4th, 2025.

Background: The aorta is the major arterial conduit conveying blood from the heart to the systemic circulation. It originates immediately beyond the aortic valve and ascends initially, then curves, forming the aortic arch, and descends caudally adjacent to the spine. The ascending thoracic aorta gives off the coronary arteries, and the aortic arch branches are typically the brachiocephalic trunk (i.e., innominate artery, which provides branches to the right carotid and right subclavian arteries), left carotid, and left subclavian arteries; however, aortic arch anatomy can vary.

A thoracic aortic aneurysm (TAA) is defined as a permanent localized dilation of the thoracic aorta having at least a 50 percent increase in diameter compared with the expected normal diameter for that aortic segment. Aneurysms of the thoracic aorta are classified by the segment of the aorta that is involved. Patients with thoracic aneurysms are often asymptomatic at the time of presentation. The aneurysm may be discovered incidentally on echocardiography performed to evaluate an aortic murmur (ascending aneurysm), computed tomography (CT) scan for an unrelated condition (e.g., lung nodule or pulmonary embolus), or as a result of screening for TAA in a patient at risk for disease.

When present, symptoms are usually due to compression of adjacent structures, which may lead to chest, back, flank, or abdominal pain. Aneurysms that produce symptoms are typically very large and are at an increased risk for rupture, which is associated with high mortality rates. Depending upon the aneurysm location, pulmonary symptoms or signs of nerve compression (e.g., hoarseness, diaphragm paralysis) can also occur. Other symptoms may be due to arterial compression causing ischemia or thromboembolism. The most serious complications of thoracic aortic aneurysm are aortic dissection and rupture, which is most often into the left intrapleural space or intrapericardial space. Rupture is associated with severe pain and hypotension or shock. TAA represents approximately one-third of aortic aneurysm admissions, and complications of aortic aneurysmal

disease are a leading cause of death in the United States, particularly in individuals aged >55 years. [1]

Replacement of the aortic arch is technically challenging and is associated with a high risk of perioperative death and stroke. When disease involving the arch extends into the descending thoracic aorta, a repair is commonly necessary. The standard surgical treatment for patients with acute, subacute, or chronic dissection and/or aneurysm of the aortic arch and the descending thoracic aorta, with or without involvement of the ascending aorta, includes a total aortic arch replacement (TAR) procedure, using a conventional elephant trunk (cET) or frozen elephant trunk (FET) approach.

Technology

The Arcevo™ LSA Hybrid Stent Graft System (Arcevo™ LSA) is indicated for use in patients with dissection and/or aneurysm involving the aortic arch and the descending thoracic aorta, with or without involvement of the ascending aorta. According to the requestor, the incorporation of the stented LSA branch in the Arcevo™ LSA eliminates the need for a surgical anastomosis of the LSA, thereby enabling a potentially safer and faster procedure with less bleeding and fewer post-op complications.

The Arcevo™ LSA is comprised of an aortic arch portion with a left subclavian artery branch. The implant is made of self-expanding nitinol stent springs attached to polyethylene terephthalate (PET) or polyester graft material using ultra-high molecular weight polyethylene sutures, which are sewn to the aortic main body and LSA branch polyester tubular grafts. The proximal end of the stent graft has a conical-shaped collar for anastomosis to the native aorta and a proximal aortic arch surgical graft. There are platinum-iridium radiopaque markers within the aortic body and the LSA branch. The LSA branch is offered in two diameters (11 mm and 15 mm), both with an approximate length of 40 mm.

The Arcevo™ LSA delivery system has atraumatic aortic and LSA tips that are designed to guide the delivery system into the thoracic aorta and LSA. The Arcevo™ LSA delivery system with implant is designed to be introduced antegrade into the transected aorta, with or without the use of an aortic guidewire. The Arcevo™ LSA Hybrid Stent Graft System is intended for attachment to a proximal aortic arch surgical graft (not supplied) and may require a distal graft extension after the initial index procedure depending on disease extent, as determined by a physician. If a thoracic endovascular aortic repair (TEVAR) device is required as an extension to the Arcevo™ LSA, surgeons are required to use the commercially available Medtronic Valiant™ thoracic stent graft with the Captivia™ delivery system.

Procedure Description

Typical procedures using the Arcevo™ LSA Hybrid Stent Graft System involve the following steps:

Step 1: Transect the Aorta - Transect the aorta perpendicularly in Zone 2 by leaving at least 10 mm of aortic tissue proximal to the LSA.

[1] Isselbacher EM, Preventza O, Hamilton Black J 3rd, et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. Circulation 2022; 146:e334.

Step 2: Aortic Guidewire Use - Optional

- If no aortic guidewire is used, pre-shape the delivery system, with the shaping wire still in place, to approximate the aortic curvature.
- If using an aortic guidewire, remove the shaping wire and insert a 0.035" guidewire through the aortic tip, using antegrade or retrograde (femoral) approach.

Step 3: LSA Guidewire Use - Strongly Recommended

- For antegrade access, insert an 0.035" guidewire through the LSA guidewire lumen located at the base of the LSA Tab until it exits the LSA tip.
- For retrograde (arm) access, navigate the guidewire through the LSA until it exits the transected aorta, then feed the soft-tip guidewire through the LSA Tip until it exits the LSA guidewire lumen at the LSA Pull Tab.

Step 4: Insert Arcevo™ LSA into the Aorta

- Align the Arcevo™ LSA branch with the location of the LSA vessel and advance the device into the transected aorta and LSA vessel, respectively. Advance the delivery system until the collar aligns with the transected aorta and slowly push the handle to the outer aortic curve to fully insert the LSA branch into the LSA vessel.

Step 5: Deploy Aortic Segment

- While holding the handle steady to maintain position, deploy the aortic stent graft by pulling the trigger and retracting the handle until the delivery system locks.
(TIP: Secure the implant by gently holding the device and aortic wall in place at the transection)

Step 6: Deploy LSA Branch Segment

- Pull the LSA Pull Tab to unlace the LSA Wrap and expand the LSA stented branch. Continue to retract the LSA deployment wire via the LSA Pull Tab until resistance is felt and the LSA Tip retracts toward the handle.

Step 7: Remove the Delivery System

- Remove the shaping wire and/or any guidewires. Carefully withdraw the delivery system using slight rotational movements, if needed.

Step 8: Complete the Anastomoses

- First Anastomosis - Anastomose the Arcevo™ LSA collar to the transected aorta using standard surgical techniques.
- Second Anastomosis - Perform the desired arch repair with the proximal aortic arch surgical graft of choice (not supplied) using institutional protocol. Anastomose the surgical graft to the Arcevo™ LSA/Aorta construct at Zone 2 using standard surgical techniques.

Step 9: Optional Placement of Distal Thoracic Extension

- Should the patient require a distal extension to complete the treatment, the Medtronic Valiant™ thoracic stent graft with the Captivia™ delivery system should be used.

Current Coding: There are no unique ICD-10-PCS codes to describe restriction of the thoracic aortic arch using a branched intraluminal device with conical collar. Facilities can report the thoracic aortic arch restriction using the appropriate code in table 02V, Restriction of Heart and Great Vessels. Code separately the replacement of the proximal portion of the aortic arch with surgical graft using the appropriate code in table 02R, Replacement of Heart and Great Vessels, and, if performed, the restriction of the descending thoracic aorta using the appropriate code in table 02V, Restriction of Heart and Great Vessels.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
W Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **E** Intraluminal Device, Branched or Fenestrated, One or Two Arteries **F** Intraluminal Device, Branched or Fenestrated, Three or More Arteries **Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
5 Atrial Septum **6** Atrium, Right **7** Atrium, Left **9** Chordae Tendineae **D** Papillary Muscle **K** Ventricle, Right **L** Ventricle, Left **M** Ventricular Septum **N** Pericardium **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava **W** Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch	**0** Open **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe restriction of the thoracic aortic arch using a branched intraluminal device with conical collar. Continue as described in current coding.

Option 2. In section X New Technology table X2V, Restriction of Cardiovascular System, create new device value K Branched Intraluminal Device with Conical Collar, applied to the body part value shown and the open approach, to describe restriction of the thoracic aortic arch using a branched intraluminal device with conical collar. Continue to report the proximal thoracic aortic arch replacement and restriction of the descending thoracic aorta as described in current coding.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
W Thoracic Aorta, Descending	**0** Open	**P** Intraluminal Device with Branched Synthetic Substitute	**7** New Technology Group 7
ADD X Thoracic Aorta, Arch	**0** Open	**ADD K** Branched Intraluminal Device with Conical Collar	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 18 – Computer-assisted Cardiac Conduction Mapping using Computed Tomography Angiography

Issue: There is no unique ICD-10-PCS code to describe computer-assisted cardiac conduction mapping using computed tomography angiography. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? No. CARA System received FDA Breakthrough Device designation on February 27th, 2025. A 510(k) application was accepted by the FDA on August 8, 2025, and is currently under review. According to the indication for use, "the CARA System is intended for preplanning and guidance of medical interventions in an area known to contain or be adjacent to the cardiac conduction system, such as percutaneous or surgical structural heart (SHD) procedures, including transcatheter aortic valve replacement (TAVR), transcatheter mitral valve replacement (TMVR), and transcatheter tricuspid valve replacement (TTVR), or in medical procedures where the physician desires to deliver therapy to the patient's cardiac conduction system or to a targeted location within it."

Background: Mapping is the term used to describe the process of creating a three-dimensional (3D) model of a cardiac chamber. The initial model is anatomical, outlining the endocardial surface of the cardiac chamber, and overlaid on this anatomical model are additional data points describing the electrical conduction characteristics of the myocardial tissue at a particular location in the cardiac chamber, including the voltage, velocity and direction of the electrical signal passing through the tissue. When used intraoperatively, conduction mapping can effectively localize the conduction system during surgery to enable the surgeon to avoid its injury.[1] and allows for a patient-specific approach to conduction localization as surgical repair or pacemaker implantation is being performed.

The CARA Medical CARA System is a noninvasive cardiac conduction mapping system designed to simulate the personalized path of the conduction system in patients. The CARA System simulates the conduction system path from manually annotated computed tomography angiography (CTA) landmarks to enable conduction guided intervention (CGI) procedures. It generates patient specific 3D conduction pathway digital models that can be used for procedure planning and can be overlaid onto fluoroscopy during therapies, enabling both pre-planning and real-time guidance for providers.

Technology
The CARA system enables operators to non-invasively visualize conduction systems for preprocedural planning and/or real time guidance during conduction system pacing (CSP) and structural heart interventions (e.g., TAVR/TTVR) by generating a patient's specific 3D conduction pathways digital model that can be used for procedure planning and can be overlaid onto fluoroscopy during therapy. The system simulates the path of manually identified key anatomical

[1]Feins EN, O'Leary ET, Hoganson DM, Schulz N, Eickoff E, Davee J, Triedman JK, Baird CW, Del Nido PJ, Emani S, DeWitt ES. Intraoperative conduction mapping in complex congenital heart surgery. JTCVS Tech. 2022 Feb 1;12:159-163. doi: 10.1016/j.xjtc.2021.11.017. PMID: 35403044; PMCID: PMC8987603.

landmarks to highlight the atrioventricular (AV) node, His bundle and bundle branches, and the Bachmann bundle. According to the requestor, overlaying the 3D map onto live fluoroscopy while integrating electroanatomic data and tracking tools demonstrates improved procedural safety, precision, and outcomes as supported by translational and clinical evidence.

The CARA System is a software and device combination and is comprised of two integrated modules:

- CARA Metis™ Simulator - planning software that builds a patient specific 3D conduction pathways digital model from a physician manually annotated CTA. It identifies the personalized anatomical location of the cardiac conduction system derived from the patient's computed tomographic angiography.
- CARA Atlas™ Navigator - intraoperative guidance that overlays the personalized anatomical location of the cardiac conduction system (generated by the CARA Metis™ Simulator) onto real-time, intra-procedural, fluoroscopic imaging to assist in fluoroscopic-guided interventional heart procedures and tracks catheters and tools in real time.

The CARA System is designed to guide the physician through the review of a patient's CTA. The CARA Metis™ Simulator software enables the physician to manually annotate each of the conduction landmarks that are indicated clinically. The physician must perform the annotation with a submillimeter accuracy to later feed it into the Metis™ 3D digital conduction simulator that can draw the path of the personalized conduction system with respect to the heart's 3D anatomy. The physician edits the 3D conduction system digital model and generates a procedure pre plan that is presented as a report and in digital form to support its use for conduction guided intervention. Using the CARA Atlas™ Navigator the physician can potentially protect the native conduction system from injury or target it accurately for delivering therapy to it.

Procedure Description

Before an intervention, the physician orders a high-resolution CTA scan for the patient with a protocol optimized to visualize cardiac anatomy relevant to the cardiac conduction system. The physician uploads the CTA dataset into the CARA Metis™ Simulator planning software, the data is reformatted and presented to the physician who then performs a series of planning tasks including: (1) reviewing and manually and annotating the AV node and His bundle locations; (2) running a 3D simulation of the patient's conduction pathway; (3) reviewing and editing the 3D conduction digital model the simulation generated and (4) formulating a tailored procedural plan using the conduction pathways 3D digital model. A formal report of this plan is generated to document the strategy.

During conduction guided interventions, the physician uploads the patient CARA Metis™ Simulator pre plan conduction pathways digital model to the CARA Atlas™ Navigator and performs a detailed accurate registration of the fluoroscopy or ultrasound visualization with the overlayed CTA generated heart anatomy. Throughout the procedure the physician needs to control the accuracy of the registration and adjusts it when they decide it is incorrect.

In interventional cardiac applications, the physician uploads the preoperative personal conduction pathways digital model (generated by the CARA Metis™ Simulator) into the CARA Atlas™ Navigator. The physician must perform a series of tasks that are distinct from typical fluoroscopic guidance. These include initiating and validating the 2D/3D CT–fluoroscopic registration, selecting optimal working projections, and performing real-time three-dimensional navigation using the

patient-specific conduction pathways digital model projected by the Atlas™ Navigator. The physician is also responsible for continuously verifying registration accuracy throughout the procedure and documenting how the overlay informed clinical decisions such as device trajectory, depth, and risk avoidance.

In surgical applications, the CARA Metis™ Simulator conduction pathways digital model is used in visualization-only mode. The physician aligns the map projected by the CARA Atlas™ Navigator to the operative field using surgical anatomical landmarks and uses the visualization of the then aligned 3D personalized conduction system digital model to guide surgical planning and execution. The physician may refer to the conduction anatomy to avoid, protect, or engage conduction tissue as clinically indicated. At key decision points, the physician documents how the visualization informed surgical margins, implant depth, or trajectory relative to conduction anatomy. Representative images may be archived to support the final alignment and intraoperative decision-making.

Current Coding: There is no unique ICD-10-PCS code to describe computer-assisted cardiac conduction mapping using CTA. If desired, facilities can report the CTA with the applicable code in section B Imaging. If desired, facilities can also report the use of the intraprocedural navigation software using the following code:

8E0WXBF Computer assisted procedure of trunk region, with fluoroscopy

Coding Options

Option 1. Do not create a new ICD-10-PCS code to describe computer-assisted cardiac conduction mapping using computed tomography angiography. Continue as described in current coding.

Option 2. In section X New Technology table XXE, Measurement of Physiological Systems, create new technology value H Cardiac Conduction Mechanism, Computer-aided Mapping for Planning, applied to the body part value shown and the external approach, to identify the use of planning software to build a digital model of the conduction pathways. If desired, facilities can continue to report the CTA as described in current coding.

Section **X** New Technology *Body System* **X** Physiological Systems *Operation* **E** Measurement: Determining the level of a physiological or physical function at a point in time			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
2 Cardiac	**X** External	**ADD H** Cardiac Conduction Mechanism, Computer-aided Mapping for Planning	**C** New Technology Group 12

In section X New Technology, new table XEZ, Other Procedures of Physiological Systems and Anatomical Regions, create new technology value P Cardiac Conduction Mechanism, Computer-aided Guidance for Intraprocedural Navigation using Fluoroscopic Imaging, applied to the body part value shown and the external approach, to identify guidance for intraprocedural navigation using fluoroscopic imaging in interventional cardiac applications. A separate code for the interventional cardiac procedure performed would be reported from the applicable ICD-10-PCS table using the appropriate values.

Additionally, in section X New Technology, new table XEZ, Other Procedures of Physiological Systems and Anatomical Regions, create new technology value S Cardiac Conduction Mechanism,

Computer-aided Intraprocedural Visualization for Guidance, applied to the body part value shown and the external approach, to identify intraprocedural visualization for guidance in surgical cardiac procedures. A separate code for the surgical cardiac procedure performed would be reported from the applicable ICD-10-PCS table using the appropriate values.

Section *Body System* *Operation*	**X** New Technology **E** Physiological Systems and Anatomical Regions **ADD Z** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD Z None	**X** External	**ADD P** Cardiac Conduction Mechanism, Computer-aided Guidance for Three Dimensional Intraprocedural Navigation using Fluoroscopic Imaging	**C** New Technology Group 12
ADD Z None	**X** External	**ADD S** Cardiac Conduction Mechanism, Computer-aided Intraprocedural Visualization for Guidance	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 19 – Percutaneous Coronary Intervention using an Image-Guided Crossing and Re-Entry Catheter System

Issue: There are no unique ICD-10-PCS codes to describe percutaneous coronary intervention using a simultaneous image-guided crossing and re-entry catheter system. An October 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The Acolyte™ Image Guided Crossing and Re-Entry Catheter System received Breakthrough Device designation and has been granted Investigational Device Exemption (IDE) for its clinical trial. It has also been accepted into the Total Product Life Cycle Advisory Program Pilot (TAP Pilot) by the Center for Devices and Radiological Health (CDRH) of the FDA.

Background: Chronic total occlusion (CTO) is a coronary artery blockage that has been completely obstructed for an extended period of time (typically defined as at least three months) resulting in little to no antegrade blood flow through the vessel. Over time, the occlusion becomes composed of dense fibrotic and often calcified tissue, making it technically challenging or impossible to cross with standard guidewires and catheters in the performance of standard coronary intervention techniques. CTOs can limit myocardial perfusion and contribute to angina, ischemia, and reduced quality of life.

The Acolyte™ system is intended for use in patients undergoing percutaneous coronary intervention (PCI) for CTO, where operators must determine vessel architecture while attempting to cross a CTO. At the discretion of the operator, the Acolyte™ system can be utilized to cross a CTO either directly through the CTO (a true-lumen-to-true-lumen approach) or around the CTO utilizing the subintimal space of the artery to bypass the CTO and re-enter the coronary artery distal to the CTO (a re-entry approach). CTO-PCI is a technically challenging procedure characterized by prolonged case times, high radiation and contrast burden, and the frequent need for multiple complex tools. Conventional techniques rely on tactile feedback and 2D angiographic imaging, which cannot visualize vascular morphology, plaque distribution or the lumen boundary within the lesion or at the crossing/re-entry site. According to the requestor, the Acolyte™ system addresses this unmet need by providing real-time intravascular optical coherence tomography (OCT) imaging directly from within the occlusion, enabling a more predictable, controlled, and anatomically informed crossing or re-entry process.

Technology
Per the requestor, the Acolyte™ Image Guided Crossing and Re-Entry Catheter System is a first-in-class, single-use catheter designed to assist operators in navigating, crossing, and re-entering the true lumen of a coronary artery affected by a coronary CTO using real-time OCT visualization. The system integrates an image-guided interventional catheter, a console containing a swept-source OCT engine, a GPU-based processing system, a sled that links the catheter to the console's optical and electrical components, a touchscreen interface, and a display monitor that provides live intravascular OCT imaging. This integrated design allows operators to determine whether the device is intraplaque, intraluminal, or in the subintimal space. With integrated wire ports, the device further allows, when subintimal, to perform controlled/directional, image-guided re-entry at the appropriate site and when intraluminal, to perform a controlled true-to-true crossing. Unlike

traditional CTO tools that operate solely by fluoroscopy and tactile feedback, Acolyte™ provides simultaneous imaging and guidewire control and delivery, representing a new therapeutic approach to CTO-PCI.

The Acolyte™ is designed to be used in the coronary vasculature as part of a PCI procedure for the revascularization of CTO lesions, such as in the right coronary artery, the left anterior descending coronary artery and the left circumflex. The device is to be deployed to traverse a coronary CTO in advance of coronary artery balloon angioplasty and stenting.

A total of 11 adverse events have been reported during the study period. No deaths have occurred in this clinical study to date. No unanticipated adverse device effects (UADE) have been reported during the reporting period.

Procedure Description
During PCI for a CTO, the operator utilizes the Acolyte™ catheter over a standard 0.014" coronary guidewire to the occlusion segment. The catheter is connected to the Acolyte™ console via a proprietary sled that houses the optical interconnects, enabling the console to utilize OCT imaging and process real-time intravascular images with signals retrieved from the distal end of the catheter. The touchscreen interface allows operators to activate imaging and recording, review frames, freeze images, rotate views, and optimize contrast and brightness as needed.

Once imaging is activated, the operator uses OCT to assess the vessel micro-structure and confirm whether the guidewire and catheter are in the intraluminal space, within plaque, or within the subintimal space. At the discretion of the operator, the Acolyte™ catheter can be utilized to cross a CTO either directly through the CTO (a true-lumen-to-true-lumen approach) or around the CTO utilizing the subintimal space of the artery to bypass the CTO and re-enter the coronary artery past the CTO (a re-entry approach). If utilizing the true-lumen-to-true-lumen approach, the operator will confirm intraluminal positioning, utilizing OCT imaging, prior to advancing the guidewire (and the device) along the CTO plane. If utilizing the re-entry approach, the operator will confirm subintimal positioning, utilizing OCT imaging, prior to using the Acolyte™ catheter's directional re-entry capability by orienting the re-entry port toward the lumen and advancing the guidewire under image guidance to achieve precise re-entry into the distal true lumen, past the CTO.

Per the requestor, a key distinction from conventional CTO PCI is that crossing and re-entry decisions with the Acolyte™ catheter are made based on intravascular OCT images acquired at the location where the wire is deployed, rather than relying solely on fluoroscopic landmarks or tactile wire feedback. The combination of OCT imaging, directional control, guidewire navigation, and a dedicated re-entry mechanism within a single device creates a fundamentally different CTO revascularization procedure than traditional wire escalation, knuckling, or use of mechanical re-entry tools. After successful crossing or re-entry, the operator can then deliver balloons, stents, or other adjunctive devices over the established guidewire, consistent with standard PCI workflow.

It is anticipated that each procedure will require one Acolyte™ catheter. The Acolyte™ catheter is compatible with standard 0.014" guidewires and may be used along with other ancillary tools such as a guide catheter and trapper or the TrapLiner™ catheter. The Acolyte™ catheter is a single-use temporary device used to facilitate guidewire crossing and re-entry of a coronary CTO lesion. It is removed at the end of the procedure.

Current Coding: There are currently no codes to report a PCI procedure using an image-guided crossing and re-entry catheter system. Facilities would report the PCI procedure from the applicable ICD-10-PCS table using the appropriate coronary artery body part value.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for percutaneous coronary intervention using an image-guided crossing and re-entry catheter system. Continue as described in current coding.

Option 2. In section X New Technology create new table XEZ, Other Procedures in Physiological Systems and Anatomical Regions, create new technology value N Coronary Artery Access using Image-Guided Crossing and Re-entry System, applied to the body part value J Coronary Artery/Arteries, to identify coronary artery access using an image-guided crossing and re-entry catheter system. Continue to separately report the PCI procedure performed from the applicable ICD-10-PCS table using the appropriate coronary artery body part value.

Section	**X** New Technology
Body System	**E** Physiological Systems and Anatomical Regions
Operation	**Z** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD J Coronary Artery/Arteries	**3** Percutaneous	**ADD N** Coronary Artery Access using Image-Guided Crossing and Re-entry System	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 20 – Single-Use Cholangioscope During Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures

Issue: There are no unique ICD-10-PCS codes to describe the use of a single-use cholangioscope during endoscopic retrograde cholangiopancreatography (ERCP) procedures. An October 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The SpyGlass™ DS II Direct Visualization System is a single-operator cholangioscope platform designed for use in the pancreaticobiliary system, including the hepatic ducts. The system is comprised of the SpyGlass™ DS Digital Controller and the SpyScope™ DS Access and Delivery Catheter or the 3rd generation SpyScope™ DS II Access and Delivery Catheter, which received 510(k) clearance on January 22, 2019 (K183636).

Background: Approximately 650,000 ERCP procedures are performed annually in the U.S. for the diagnosis and treatment of pancreaticobiliary conditions. ERCP provides fluoroscopic visualization of the biliary and pancreatic ducts and is used to evaluate abnormalities identified on imaging studies such as computed tomography (CT), magnetic resonance imaging (MRI), abdominal ultrasound, or endoscopic ultrasound (EUS).

Per the requestor, in certain situations, such as indeterminate biliary strictures or large or difficult stones, fluoroscopic imaging alone may be insufficient for definitive diagnosis or therapy. In these cases, peroral cholangioscopy or pancreatoscopy may be used as adjunct procedures to provide direct intraductal visualization and enable targeted diagnostic or therapeutic interventions.

Direct visualization during ERCP has been shown to improve characterization of ductal lesions, support targeted biopsy sampling, and enhance stone management. The SpyGlass™ DS II Direct Visualization System is indicated for diagnostic and therapeutic procedures during ERCP when conventional methods are inadequate. Clinical indications may include but are not limited to the following:

- Biliary system cancer
- Biliary duct cancer
- Pancreatic cancer
- Intraductal pancreatic mucinous tumor
- Choledocholithiasis
- Primary sclerosing cholangitis
- Indeterminant pancreatic strictures/masses
- Pancreatic stones/debris
- Pancreatic leaks or fistulas
- Biliary strictures/masses
- Biliary papillomatosis
- Post-liver transplant strictures

Technology
The SpyGlass™ DS II Direct Visualization System is a single-operator cholangioscope platform designed for use in the pancreaticobiliary system, including the hepatic ducts. It consists of two main components, the SpyGlass™ DS Digital Controller and the SpyScope™ DS or SpyScope™ DS II Access and Delivery Catheter, a sterile, single-use cholangioscope that provides direct visualization and guides both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts. The SpyGlass™ DS Digital Controller is a reusable unit that provides illumination and processes images from the SpyScope DS II.

The system enables physicians to diagnose and treat conditions of the bile and pancreatic ducts by providing high-resolution imaging, four-way steerable navigation, and a working channel for accessories such as biopsy forceps, lithotripsy probes, snares, or retrieval baskets, using a single-use cholangioscope. Cholangioscopy is typically performed as an adjunct to endoscopic retrograde cholangiopancreatography (ERCP), enhancing it by providing direct, high-resolution visualization of the pancreaticobiliary system. During the ERCP, the SpyScope™ DS II catheter is advanced through the duodenoscope to permit intraductal inspection and therapeutic intervention under direct visualization. At the end of the procedure, the single-use cholangioscope is disposed of, eliminating the need for reprocessing and the risk of patient-to-patient cross-contamination.

Possible adverse events are consistent with ERCP, including pancreatitis, cholangitis, infection, perforation, hemorrhage, allergic reaction, and mucosal trauma. Device malfunctions are rare, with no serious sequelae reported across more than 196,000 catheter uses.

Procedure Description
Cholangioscopy is an adjunct to ERCP, providing direct visualization of the pancreaticobiliary system using a thinner cholangioscope (reusable or single-use) that is advanced through the duodenoscope and into the bile ducts. The camera transmits live video to a monitor, and the working channel allows delivery of diagnostic and therapeutic tools. Below are the specific steps involved in a cholangioscopy procedure using a single-use cholangioscope.

1. The physician introduces a duodenoscope through the patient's mouth into the duodenum.
2. The single-use cholangioscope is advanced through the duodenoscope's working channel into the bile or pancreatic ducts.
3. The single-use cholangioscope provides direct digital visualization of the ducts, enabling the physician to identify stones, strictures, or tumors in real time.
4. Through the working channel, the physician can pass accessories such as biopsy forceps, retrieval baskets, snares, or lithotripsy probes to perform targeted therapy.
5. Irrigation through the scope maintains a clear view, and any retrieved materials are removed through the same catheter.
6. Once the inspection or therapy is complete, the single-use cholangioscope is withdrawn and disposed of.

The single-use cholangioscope is intended for one patient and only one single-use cholangioscope is routinely used per case and disposed of after the procedure is completed. Per the requestor, in the absence of a specific code, the use of single-use cholangioscopes cannot be tracked for purposes of supporting evidence development.

Current Coding: There are currently no codes to report the use of a single-use cholangioscope during ERCP procedures. Facilities may report the applicable ICD-10-PCS pancreaticobiliary system code(s) using the approach value 8 Via Natural or Artificial Opening Endoscopic. Facilities may also choose to report the radiologic portion of the ERCP procedure with a code from Imaging section table BF1, Fluoroscopy of Hepatobiliary System and Pancreas.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe the use of a single-use cholangioscope during ERCP procedures. Continue as described in current coding.

Option 2. In section X New Technology table XFJ, Inspection of Hepatobiliary System and Pancreas, create new technology value B Single-use Cholangioscope, applied to the body part values B Hepatobiliary Duct and D Pancreatic Duct and the via natural or artificial opening endoscopic approach, to identify the use of a single-use cholangioscope during ERCP procedures. Facilities may report the radiologic portion of the ERCP procedure with a code from Imaging section table BF1, Fluoroscopy of Hepatobiliary System and Pancreas.

Section	**X** New Technology		
Body System	**F** Hepatobiliary System and Pancreas		
Operation	**J** Inspection: Visually and/or manually exploring a body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
B Hepatobiliary Duct **D** Pancreatic Duct	**8** Via Natural or Artificial Opening Endoscopic	**A** Single-use Duodenoscope	**9** New Technology Group 9
B Hepatobiliary Duct **D** Pancreatic Duct	**8** Via Natural or Artificial Opening Endoscopic	**ADD B** Single-use Cholangioscope	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 21 – Single-Use Choledochoscope During Pancreaticobiliary System and Hepatic Duct Procedures

Issue: There are no unique ICD-10-PCS codes to describe the use of a single-use choledochoscope during pancreaticobiliary system and hepatic duct procedures. An October 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The SpyGlass™ Discover Digital Catheter and SpyGlass™ Discover Digital Controller received 510(k) clearance on May 21, 2020 (K200483).

Background: Approximately 700,000 cholecystectomy procedures are performed annually in the U.S. for the treatment of gallbladder diseases including but not limited to inflammation (cholecystitis), gallbladder stones (cholelithiasis), retained common bile duct stones (choledocholithiasis), etc. Of these procedures, approximately 10-20% of patients are diagnosed with retained stones in the biliary system including the hepatic ducts.

In addition, percutaneous transhepatic cholangioscopy (PTC) via choledochoscopy allows direct visualization of the pancreaticobiliary system enabling targeted diagnostic and therapeutic interventions for patients where endoscopic retrograde cholangiopancreatography (ERCP) may not be an option due to altered anatomy (e.g., Whipple or Roux-en-Y gastric bypass procedures) or other reasons.

The SpyGlass™ Discover Digital System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts via laparoscopic or percutaneous methods of access in individuals with common bile duct stones, biliary lesions, or strictures irrespective of age and weight. Per the requestor, it can offer an alternative approach via laparoscopic common bile duct exploration (LCBDE) and PTC that allows access to the biliary tree with direct visualization and sampling of the bile duct via choledochoscopy. This approach also facilitates optically guided intraductal fragmentation and clearance of biliary calculi. Direct visualization by choledochoscopy permits the identification of mucosal features suspicious for malignancy and targeted biopsies.

Clinical indications may include:
- Choledocholithiasis and pancreatic duct stones
- Biliary and pancreatic duct strictures (benign or malignant)
- Pancreatic leaks or fistulas
- Pancreatitis
- Primary sclerosing cholangitis
- Post-liver transplant strictures

Technology
The SpyGlass™ Discover Digital System is comprised of two components: the access and delivery catheter and the controller. The SpyGlass™ Discover Digital Catheter is a sterile, single-use choledochoscope intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the

pancreaticobiliary system, including the hepatic ducts. It can be used to access targeted pancreaticobiliary anatomy via laparoscopic port, percutaneous access, or other endoscope channel with or without a guidewire.

The catheter directly contacts the patient's body and is composed of plastic optical fiber. Other components making direct contact such as the camera assembly, distal cap, tubing, and steering wire are constructed of acrylic polymer, inorganic glass, 316L stainless steel, PEBAX, and stainless steel 304, respectively. The SpyGlass™ Discover Digital Controller is intended to provide illumination and receive, process, and output images from the SpyGlass™ Discover Digital Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system, including the hepatic ducts. None of the components of the SpyGlass™ Discover Digital Controller directly or indirectly contact the patient.

The system enables physicians to diagnose and treat conditions of the pancreaticobiliary and hepatic duct systems by providing high-resolution imaging, four-way steerable navigation, and a working channel for accessories such as lithotripsy probes, retrieval baskets, or balloon dilation catheters using a single-use choledochoscope. Choledochoscopy is most frequently performed as an adjunct to laparoscopic bile duct exploration, or percutaneous biliary interventions, enhancing them by providing direct visualization of the pancreaticobiliary system, including the hepatic ducts. During the procedure, the SpyGlass™ Discover Digital Catheter is advanced through the pancreaticobiliary system or hepatics ducts to permit intraductal inspection and therapeutic intervention under direct visualization. At the end of the procedure, the single-use choledochoscope is disposed of, eliminating the need for reprocessing and the risk of patient-to-patient cross-contamination.

Possible complications include allergic reaction, cholangitis, hematoma, hemorrhage, infection/septicemia, mucous membrane damage/ tissue damage, pain/discomfort, pancreatitis, and perforation.

Procedure Description
Diagnostic and therapeutic procedures utilizing single-use choledochoscopes may include laparoscopic cholecystectomy with common bile duct exploration (LCBDE), or percutaneous procedures such as percutaneous transhepatic cholangioscopy (PTCS), percutaneous biliary endoscopy, or intraoperative pancreatoscopy (IPMN). Below are the specific steps involved in a choledochoscopy procedure using a single-use choledochoscope.

1. The physician introduces the single-use choledochoscope directly into the duct via laparoscopic port, percutaneous access, or other endoscope channel with or without a guidewire used through the working channel.
2. The single-use choledochoscope is advanced through the pancreaticobiliary system towards the targeted site.
3. The single-use choledochoscope provides direct visualization of the ducts, enabling the physician to identify stones, strictures, or tumors in real time.
4. Through the working channel, the physician may introduce accessories such as balloon dilation catheters, stone retrieval baskets, lithotripsy probes or biopsy forceps to perform targeted therapy.
5. Irrigation through the scope maintains a clear view, and any retrieved materials are removed with the accessory.

6. Once the inspection or therapy is complete, the single-use choledochoscope is withdrawn and disposed of.

The single-use choledochoscope is intended for one patient and only one single-use choledochoscope is routinely used per case and disposed of after the procedure is completed. Per the requestor, in the absence of a specific code, the use of single-use choledochoscope cannot be tracked for purposes of supporting evidence development.

Current Coding: There are currently no codes to report the use of a single-use choledochoscope during pancreaticobiliary system and hepatic duct procedures. Facilities may report the applicable ICD-10-PCS pancreaticobiliary system and hepatic duct procedure code(s) using the approach values 3 Percutaneous or 4 Percutaneous Endoscopic.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe the use of a single-use choledochoscope during pancreaticobiliary system and hepatic duct procedures. Continue as described in current coding.

Option 2. In section X New Technology table XFJ, Inspection of Hepatobiliary and Pancreas, create new technology value C Single-use Choledochoscope, applied to the body part values B Hepatobiliary Duct and D Pancreatic Duct with the percutaneous and percutaneous endoscopic approaches, to identify the use of a single-use choledochoscope during pancreaticobiliary system and hepatic duct procedures.

Section	**X** New Technology		
Body System	**F** Hepatobiliary System and Pancreas		
Operation	**J** Inspection: Visually and/or manually exploring a body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
B Hepatobiliary Duct **D** Pancreatic Duct	**8** Via Natural or Artificial Opening Endoscopic	**A** Single-use Duodenoscope	**9** New Technology Group 9
B Hepatobiliary Duct **D** Pancreatic Duct	**3** Percutaneous **4** Percutaneous Endoscopic	**ADD C** Single-use Choledochoscope	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 22 – Transcatheter Aortic Valve Replacement with Integrated Native Leaflet Clipping Locators

Issue: There is no unique ICD-10-PCS code to describe transcatheter aortic valve replacement with integrated native leaflet clipping locators. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? No. The Trilogy® Transcatheter Aortic Valve Regurgitation System received Breakthrough Device Designation by the FDA on January 9, 2020, and is intended to help treat symptomatic severe native aortic regurgitation.

Background: Severe native aortic regurgitation (AR) is a progressive, life-limiting valvular disorder in which the aortic valve fails to close properly, allowing retrograde diastolic blood flow into the left ventricle. This leads to chronic volume overload, ventricular dilation, declining ejection fraction, heart failure symptoms, and increased mortality. In the United States, approximately 500,000–650,000 individuals are estimated to have moderate-to-severe AR, with ~65,000–80,000 new diagnoses annually. Up to 25–30% of patients with symptomatic severe AR are considered high-surgical-risk or inoperable due to advanced age, frailty, comorbidities, or prior cardiac surgery, leaving a substantial population without safe access to definitive therapy.

The current standard of care for severe AR is surgical aortic valve replacement (SAVR); however, many patients cannot tolerate open-heart surgery. No FDA-approved transcatheter valve currently exists for the treatment of native AR. Off-label use of transcatheter valves designed for aortic stenosis has historically been associated with poor outcomes—including high rates of valve embolization, migration, paravalvular leak, and mortality—due to inadequate anchoring in the non-calcified anatomy typical of AR.

Currently available transcatheter aortic valves designed for aortic stenosis rely on calcific annular support for anchoring. Because AR typically involves non-calcified, pliable annuli, off-label use of stenosis-based transcatheter aortic valve replacement (TAVR) valves has been associated with malpositioning, valve embolization, suboptimal sealing, and increased procedural risk- including high rates of valve embolization (up to 24% in historical series), need for second valve implantation, and moderate/severe paravalvular regurgitation (up to 19%).

The Trilogy® Transcatheter Heart Valve System is the first transcatheter valve specifically engineered for the non-calcified anatomy of native AR, using an integrated leaflet-clipping mechanism rather than radial force or reliance on annular calcium. According to the requestor, this approach enables stable fixation, predictable positioning, and low rates of embolization and paravalvular leak, addressing the fundamental mechanical limitation that renders contemporary TAVR devices unsuitable for AR.

Technology
The Trilogy® Transcatheter Heart Valve System is a transcatheter aortic valve replacement technology specifically engineered for the treatment of symptomatic, severe native aortic

regurgitation. Trilogy® consists of a porcine pericardial tissue valve mounted on a self-expanding nitinol frame with a novel, integrated frame-mounted leaflet-clipping mechanism. Unlike conventional TAVR valves that require native calcium and radial force for stability, Trilogy®'s frame incorporates nitinol "locator" elements that are built directly into the valve frame structure. After valve deployment, these locators clip directly onto the native aortic valve leaflets, pinning them against an integrated sealing ring to achieve secure, calcium-independent fixation. The Trilogy® delivery system features an integrated rotation mechanism enabling precise commissural alignment during deployment, facilitating future coronary access.

The valve is delivered transfemorally via a low-profile, percutaneous delivery system that facilitates repositionability during deployment. The system is designed to restore physiologic unidirectional blood flow, reduce regurgitant volume, and improve hemodynamics in patients who are poor candidates for surgical aortic valve replacement. This procedure is technically distinct from TAVR AS devices that use two-step sequential deployment with external anchor rings. Only the Trilogy® valve incorporates the combination of integrated frame-mounted leaflet-clipping locators with single-action deployment.

In the ALIGN-AR trial (NCT04415047), Trilogy® demonstrated high device success (95%), very low valve embolization (~1%), and <1% moderate/severe paravalvular regurgitation-outcomes significantly improved compared with historical off-label TAVR attempts in AR.[1] Across the ALIGN-AR clinical trial, reported device- or procedure-related events included vascular complications, conduction disturbances requiring permanent pacemaker, valve malposition, and rare cases of valve embolization, consistent with other TAVR technologies. Minor instances of paravalvular regurgitation, access-site bleeding, and temporary hemodynamic instability were also reported. Rates of serious device-specific complications such as dislodgement, frame failure, or leaflet dysfunction were low.

Procedure Description

Trilogy® TAVR-AR is a percutaneous transfemoral valve replacement procedure performed under fluoroscopic and echocardiographic guidance. Native valve assessment via angiography with TEE is performed as appropriate to confirm native root anatomy and leaflet morphology.

Key procedural steps include:

1. After femoral arterial access is obtained and a vascular sheath is introduced, the Trilogy® delivery catheter is advanced retrograde to the sinotubular junction.
2. The Trilogy® Transcatheter Heart Valve (THV) is positioned using catheter deflection to center the valve above the leaflets.
3. Through a unified mechanism on the delivery system, the Trilogy® valve is positioned and then deployed via a single-actuation motion (Deployer advancement). During positioning, the three integrated locators:
    (a) are lowered into each aortic sinus and positioned within the native valve cusps,
    (b) leaflet capture, coaxiality, and valve depth are confirmed via TEE and/or fluoroscopy, and

[1] Vahl TP, Thourani VH, Makkar RR, Hamid N, Khalique OK, Daniels D, McCabe JM, Satler L, Russo M, Cheng W, George I, Aldea G, Sheridan B, Kereiakes D, Golwala H, Zahr F, Chetcuti S, Yadav P, Kodali SK, Treede H, Baldus S, Amoroso N, Ranard LS, Pinto DS, Leon MB. Transcatheter aortic valve implantation in patients with high-risk symptomatic native aortic regurgitation (ALIGN-AR): a prospective, multicentre, single-arm study. Lancet. 2024 Apr 13;403(10435):1451-1459. doi: 10.1016/S0140-6736(23)02806-4. Epub 2024 Mar 26. PMID: 38552656.

(c) as the nitinol frame expands during valve release, the sealing ring seals against the LVOT and annulus, followed by release of the THV locator eyelets, whereby the native leaflets are clipped between the middle of the valve and the locator arms. This single action deployment technique contrasts with two-step sequential deployment systems that require first deploying anchor structures, then separately expanding the valve within them.

4. Final confirmation of stable positioning, coronary patency, absence of paravalvular leak, and hemodynamic improvement after catheter withdrawal.

Current Coding: There is no unique ICD-10-PCS code to describe transcatheter aortic valve replacement with integrated native leaflet clipping locators. Code the procedure using the following code:

02RF38Z Replacement of aortic valve with zooplastic tissue, percutaneous approach

Coding Options

Option 1. Do not create a new ICD-10-PCS code to describe transcatheter aortic valve replacement with integrated native leaflet clipping locators. Continue as described in current coding.

Option 2. In section X New Technology table X2R, Replacement of Cardiovascular System, create new device value L Zooplastic Tissue, with Integrated Native Leaflet Clipping Locators, applied to the body part value shown and the percutaneous approach, to describe transcatheter aortic valve replacement with integrated leaflet clipping locators.

Section	**X** New Technology		
Body System	**2** Cardiovascular System		
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD F Aortic Valve	**3** Percutaneous	**ADD L** Zooplastic Tissue, with Integrated Native Leaflet Clipping Locators	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 23 – Replacement of Pulmonary Valve with Size Adjustable Device

Issue: There is no unique ICD-10-PCS code to describe the replacement of the pulmonary valve with a size adjustable device. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for future consideration.

Food & Drug Administration (FDA) Approval? No. The Autus Size-Adjustable Valve ("Autus Valve"), a size-adjustable surgical pulmonary valve replacement device, received Breakthrough Device Designation by the FDA on August 25, 2023. The Autus Valve is indicated for use in pediatric patients with congenital pulmonary valve disease aged 18 months to 16 years.

Background: Congenital heart disease is the most common major birth defect; each year more than 1.35 million individuals worldwide are born with a congenital heart defect, with 40,000 livebirths per year in the U.S.[1] An estimated 2.4 million pediatric patients (newborn to 21 years of age) and adults are currently living with congenital heart disease in the U.S. Heart valve defects account for over 25% of all congenital heart disease. Of the four native heart valves, the pulmonary valve is most commonly affected by congenital valve disease. In the U.S. alone, approximately 6,500 babies are born each year with congenital pulmonary valve disease. This figure includes the following anatomic diagnoses: congenital pulmonary stenosis, tetralogy of Fallot, pulmonary atresia, double outlet right ventricle. Today, more than 110,000 pediatric patients aged 18 months to 16 years are living with congenital pulmonary valve disease in the U.S.

The Autus Valve is indicated for use in the management of pediatric patients with congenital pulmonary valve disease aged 18 months to 16 years with severe pulmonary stenosis (defined as right ventricle (RV) to pulmonary artery (PA) peak instantaneous gradient ≥ 60 mmHg), at least moderate pulmonary regurgitation, or at least moderate pulmonary stenosis (defined as right ventricle (RV) to pulmonary artery (PA) peak instantaneous gradient ≥ 40 mmHg) plus at least moderate pulmonary regurgitation, as determined by echocardiography, who have a native or surgically-repaired right ventricular outflow tract (RVOT) and are clinically indicated for surgical pulmonary valve replacement.

Technology
The Autus Valve is a surgically implanted balloon-expandable synthetic pulmonary heart valve replacement device that is specifically designed for pediatric patients. Inspired by the geometric profile of the human venous valve, the Autus Valve features a biomimetic bileaflet design with a balloon-expandable stent-frame. The biomimetic valve design enables the valve to function optimally across a wide range of diameters to customize the valve diameter to match the patient's body size (calculated body surface area), thereby meeting the needs of pediatric patients. The Autus Valve offers a paradigm shift in the treatment of congenital pulmonary valve disease. According to the requestor, the availability of a dimensionally optimized, size-adjustable pulmonary valve prosthesis would enable pediatric patients to be successfully bridged through childhood with a functional pulmonary valve.

[1] https://www.cdc.gov/heart-defects/data/index.html

The Autus Valve is constructed from two identical valve leaflets of 0.1 mm thickness expanded polytetrafluoroethylene (ePTFE) membrane and an outer sleeve made of stretch ePTFE material. The leaflets and sleeve are hand-sewn to a laser cut 316L stainless steel stent-frame. According to the requestor, the 0.1 mm thickness ePTFE membrane has several material properties that are particularly well-suited for use as a pulmonary valve leaflet in the pediatric patient population: the material is chemically inert, has proven biocompatibility and is non-thrombogenic. In addition, the low-mass and flexibility of the ePTFE membrane enables optimal leaflet function in the low-pressure, low-flow velocity hemodynamic environment that exists in the right heart of pediatric patients.

The Autus Valve is manufactured at a single size of 12.7 mm internal diameter (ID). While the Autus Valve has a maximal functional expansion diameter of 22 mm ID, the ability to further expand the Autus Valve frame beyond the functional diameter range could facilitate future implantation, of an adult-sized valve via a transcatheter valve-in-valve replacement procedure. Depending on an individual patient's age and body size, the diameter of the Autus Valve at implant may be sufficient to bridge the patient through childhood without requiring further size-adjustment or another valve replacement. As the patient grows, the Autus Valve may undergo post-implant size-adjustment via percutaneous transcatheter balloon dilation to optimize valve hemodynamic performance as the patient grows. It is expected that post-implant Autus Valve balloon dilation procedures will take place in the cardiac catheterization lab in the hospital outpatient setting.

To date, no device-related serious adverse events or unanticipated adverse device effects have been reported in the Autus Valve IDE study (NCT05006404).

Procedure Description
The Autus pulmonary valve replacement procedure is performed through an open surgical approach, using standard surgical technique. The Autus Valve implant diameter is determined based on the patient's body surface area, with the device internal diameter corresponding to a pulmonary valve annulus z-score ranging between -1 to +1.

If the treating surgeon determines an Autus Valve size-adjustment is indicated prior to implantation, a separate sterile field is set up in the operating room. An appropriate diameter non-compliant balloon dilation catheter is opened onto the sterile field, and the uninflated balloon (minimum 4cm length) is passed through the valve opening, with the device positioned across the mid-portion of the balloon. A hand insufflator is used to inflate the balloon to its specified nominal pressure, then the balloon is deflated, and the Autus Valve is passed over the distal balloon tip. Next, the treating surgeon may trim the proximal end of the outer sleeve to the solid black line, per the instructions for use. The Autus Valve is then placed in a sterile basin, covered, dry, and ready for implantation.

Surgical implantation is performed through a median sternotomy to access the thoracic cavity. Arterial and venous cannulation is performed, and cardiopulmonary bypass is initiated under mild to moderate hypothermia. Concomitant intracardiac procedures (e.g., tricuspid valve repair, proximal branch pulmonary patch augmentation etc.) are performed prior to device implantation. The right ventricular outflow tract is exposed, and an incision is made in the proximal main pulmonary artery to expose the pulmonary valve annulus region. Remnants of the native pulmonary valve leaflets or other leaflet material are excised, if present. The device is positioned in

the right ventricular outflow tract with the stent-frame in an anterior-posterior orientation in relation to the main pulmonary artery. Interrupted or continuous sutures are passed circumferentially through the inferior aspect of the outer ePTFE sleeve and sutured to the native tissue, using conventional surgical techniques. Depending on the dimensions of the right ventricular tract, the valve may be sewn circumferentially at or near the level of the native pulmonary valve annulus with primary closure of the main pulmonary artery or sewn posteriorly and covered with an anterior hood of patch material (patch material used is surgeon discretion). Valve performance, cardiac function, and hemostasis are confirmed prior to chest closure.

Current Coding: There is no unique ICD-10-PCS code to describe the replacement of the pulmonary valve with a size adjustable device. Code the procedure in table 02R Replacement of Heart and Great Vessels, with the body part value H Pulmonary Valve, the device value J Synthetic Substitute, and the open approach.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
H Pulmonary Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

Coding Options

Option 1. Do not create a new ICD-10-PCS code to describe the replacement of the pulmonary valve with a size adjustable device. Continue as described in current coding.

Option 2. In section X New Technology table X2R, Replacement of Cardiovascular System, create new device value G Intraluminal Device, Size-adjustable, applied to the new body part value shown and the open approach, to describe the replacement of the pulmonary valve with a size adjustable device.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD H Pulmonary Valve	**0** Open	**ADD G** Intraluminal Device, Size-adjustable	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 24 – Insertion of a Cardiac Contractility Modulation Device with Defibrillator

Issue: There is no unique ICD-10-PCS code to describe the insertion of a cardiac contractility modulation device with defibrillator. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for future consideration.

Food & Drug Administration (FDA) Approval? No. The Impulse Dynamics CCM-D System (CCM-D) received Breakthrough Device Designation by the FDA on February 3, 2020 and is indicated for patients with Stage C or D heart failure who remain symptomatic despite being on guideline-directed medical therapy (GDMT), are not indicated for cardiac resynchronization therapy (CRT), and have heart failure with reduced left ventricular ejection fraction (LVEF ≤40%).

Background: Heart failure (HF) is a common clinical syndrome in which symptoms result from a structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood. HF may be caused by disease of the myocardium, pericardium, endocardium, heart valves, vessels, or by metabolic disorders.[1] HF is characterized by the inability of the heart to pump sufficient blood to meet metabolic needs at normal cardiac filling pressure. It is a debilitating condition and the most common cause of hospitalization in people aged 65 and over. Heart failure incidence is rising, driven by deteriorating lifestyle, increased survival after myocardial infarction and the aging population. Estimates show that up to 6 million Americans suffer from HF. Roughly half of those patients have reduced ejection fraction (rEF), putting them at risk for dying suddenly from a ventricular arrhythmia. These patients need both relief from their HF symptoms, as well protection from sudden cardiac death (SCD).

Cardiac contractility modulation (CCM) is an FDA-approved device-based therapy for patients with heart failure. The system delivers biphasic electric stimulation to the ventricular myocardium during the absolute refractory period to augment left ventricular contraction.[2] CCM devices alleviate symptoms associated with heart failure and improve both quality of life and functional capacity. An implantable cardioverter defibrillator (ICD) is a device used to continuously monitor and help regulate fast heart rates. When an ICD senses arrhythmia, it delivers a shock to the heart to reestablish a normal rhythm. Defibrillators protect against SCD and provide mortality benefit; however, they do not address symptoms or quality of life. Currently, to receive both therapies, a patient must receive bilateral procedures, typically an ICD in the left pectoral region and a CCM in the right pectoral region. CCM-D systems combine both CCM and ICD functions into a single device and, hence, a single procedure.

Technology
CCM-D systems are investigational implantable cardiovascular devices intended to combine insertion of both CCM and ICD implants into a single procedure while offering the same therapy

[1] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation 2022; 145:e895.
[2] Cardiac Contractility Modulation for Heart Failure: Current and Future Directions. Pipilas, Daniel C. et al. Journal of the Society for Cardiovascular Angiography & Interventions, Volume 2, Issue 6, 101176

benefits to the patient as bilateral implants. CCM-D systems contain two batteries. The first battery is rechargeable. It performs primary functions of the device. The second battery serves only as a back-up in the event a patient fails to re-charge the primary battery. In addition to the device itself, a CCM-D implant requires two transvenous leads. One lead is a standard pacemaker lead. The other is a standard defibrillation lead. A majority of commercially available pacemaker and ICD leads may be utilized with a CCM-D system. Once the CCM-D system is inserted, patients receive an external transcutaneous charging unit that they use to re-charge the device on a roughly weekly basis. Charging takes approximately one hour or less.

The CCM-D System is currently being studied in the INTEGRA-D clinical trial (NCT05855135) for the assessment of the safety and efficacy of a combined cardiac contractility modulation and implantable cardioverter defibrillator device for subjects with heart failure and reduced ejection fraction. The INTEGRA-D trial is fully enrolled. According to the requestor, based on both clinical trial enrollment and real-world evidence, approximately 75% of patients who are indicated for a CCM are also indicated for an ICD. The anticipated risk profile of the CCM-D system is consistent with other transvenous cardiac devices, most notably pacemakers or ICDs. Expected risks include infection, lead dislodgement, hematoma and inappropriate shock, all of which are considered anticipated adverse events for this device class. To date, no unanticipated adverse device effects (UADEs) have been identified. The rate of infection risk with CCM-D procedures is expected to be in line with the rate of infection for other Cardiovascular Implantable Electronic Devices (CIEDs), approximately 1 – 2 %. To date, no CCM-D device has malfunctioned or been recalled. Observed safety rates remain consistent with anticipated rates.

Procedure Description
The method to implant a CCM-D system closely mirrors that of an ICD and uses the same components, primarily two leads placed in the right ventricular myocardium, specifically in a mid-septal position. One lead is a standard, active-fixation pacing lead. The other is a standard, active-fixation defibrillator lead. Several manufacturers produce both pacing and defibrillation leads that are compatible with a CCM-D generator. Operators can choose the leads they prefer.

The actual procedure involves bringing the patient into the electrophysiology lab or operating suite in a fasting state and prepping the patient in a sterile fashion. Vital signs are continuously monitored. Conscious sedation is used throughout the surgery, as the patient should be rousable but not be able to feel pain associated with the procedure. The two leads are advanced through the venous system, secured into the heart muscle and tested for appropriate electrical performance using an analyzer. A subcutaneous pocket is then fashioned, typically in the left pectoral region. The leads are attached to the CCM-D generator. After attaching the leads, they are retested for appropriate electrical parameters through a programmer. Assuming no changes in lead performance, the pocket is closed using sutures. The wound is dressed, and the patient moves to the recovery area.

Current Coding: There are no unique ICD-10-PCS codes to describe the insertion of a cardiac contractility modulation device with defibrillator. Code the procedure with four codes: in table 02H Insertion of Heart and Great Vessels, use the body part value K Ventricle, Right, the device values J Cardiac Lead, Pacemaker and K Cardiac Lead, Defibrillator and the percutaneous approach; in table 0JH Insertion of Subcutaneous Tissue and Fascia, two codes are reported using the body part value 6 Subcutaneous Tissue and Fascia, Chest, the device values 8 Defibrillator Generator and A Contractility Modulation Device with the open approach to describe the insertion of the generator of the system.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device*	*Qualifier*
4 Coronary Vein **6** Atrium, Right **7** Atrium, Left **K** Ventricle, Right **L** Ventricle, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Monitoring Device, Pressure Sensor **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **J** Cardiac Lead, Pacemaker **K** Cardiac Lead, Defibrillator **M** Cardiac Lead **N** Intracardiac Pacemaker **Y** Other Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**J** Subcutaneous Tissue and Fascia
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device*	*Qualifier*
6 Subcutaneous Tissue and Fascia, Chest	**0** Open **3** Percutaneous	**0** Monitoring Device, Hemodynamic **2** Monitoring Device **4** Pacemaker, Single Chamber **5** Pacemaker, Single Chamber Rate Responsive **6** Pacemaker, Dual Chamber **7** Cardiac Resynchronization Pacemaker Pulse Generator **8** Defibrillator Generator **9** Cardiac Resynchronization Defibrillator Pulse Generator **A** Contractility Modulation Device **B** Stimulator Generator, Single Array **C** Stimulator Generator, Single Array Rechargeable **D** Stimulator Generator, Multiple Array **E** Stimulator Generator, Multiple Array Rechargeable **F** Subcutaneous Defibrillator Lead **H** Contraceptive Device **M** Stimulator Generator **N** Tissue Expander **P** Cardiac Rhythm Related Device **V** Infusion Device, Pump **W** Vascular Access Device, Totally Implantable **X** Vascular Access Device, Tunneled **Y** Other Device	**Z** No Qualifier

Coding Options

Option 1. Do not create a new ICD-10-PCS code to describe the insertion of a cardiac contractility modulation device with defibrillator. Continue as described in current coding.

Option 2. In section X New Technology table XHH, Insertion of Skin, Subcutaneous Tissue, Fascia and Breast, create new device value J Contractility Modulation Device with Defibrillator Generator, applied to the body part value shown and the open approach, to describe the insertion of a cardiac contractility modulation device with defibrillator. Continue to code the insertion of the two transvenous leads as described in current coding.

Section	**X** New Technology
Body System	**H** Skin, Subcutaneous Tissue, Fascia and Breast
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
8 Subcutaneous Tissue and Fascia, Chest	**0** Open	**ADD J** Contractility Modulation Device with Defibrillator Generator	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 25 – Computer-aided Detection and Notification Software for Electrocardiograms

Issue: There are currently no unique ICD-10-PCS codes that identify the use of software that analyzes electrocardiograms for the detection and notification of cardiac abnormalities. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-On Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? No. The STEMI AI ECG Model was granted Breakthrough Device designation by the FDA on March 21, 2025. The STEMI AI ECG Model is a stand-alone software device (SaMD) intended for the analysis of resting 12-lead ECGs of adult patients presenting with symptoms suspicious of acute coronary syndrome (chest pain or perceived anginal equivalent such as shortness of breath and epigastric pain) in the triage setting. The device is intended to be used in conjunction with the standard of care in emergency department and emergency medical services settings to improve the prioritization of patients with ST-elevation myocardial infarction (STEMI) or STEMI- equivalents with an automated timely notification to a cardiologist for a full patient evaluation.

Background: Heart attacks are the acute events of coronary artery disease and ischemic heart disease due to atherosclerotic plaque, which are the leading causes of death in the United States. In the United States, there are at least 800,000 heart attacks per year, affecting patients with an average age of 69 years old, and accounting for more than half of all cardiovascular events in men and women over age 75. An acute STEMI occurs due to a rupture of plaque covering the inside wall of a coronary artery, leading to acute blockage of the artery. The immediate consequence is reduced vital blood flow to the heart muscle, resulting in rapid death of the heart cells and increased morbidity and mortality rate for patients if not recognized and treated immediately. STEMI diagnosis is traditionally achieved by diagnostic testing such as electrocardiogram (EKG or ECG), echocardiogram (Echo), cardiac computerized tomography (CT), magnetic resonance imaging (MRI) or elevated troponin levels. According to the requestor, the STEMI AI ECG model software module integrates with existing medical systems (e.g., hospital electronic health record system or ECG Management System) and is an adjunctive indicator of STEMI that aids healthcare professionals in prioritizing patients presenting with a clinical suspicion for acute coronary syndromes needing to be assessed by a cardiologist. By performing unique artificial intelligence (AI)-based evaluations, the requestor maintains that the device offers significant clinical and operational benefits, including faster intervention, improved accuracy, better resource management, reduced false positives, greater inter-rater reliability, and enhanced health equity, leading to improved patient outcomes and reduced disparities in the management of acute coronary syndromes.

Technology

The STEMI AI ECG Model is a stand-alone software module that integrates with existing medical systems and is an adjunctive indicator of STEMI intended for healthcare professionals to help triage and prioritize patients presenting with a clinical suspicion for acute coronary syndromes for review by a cardiologist. The STEMI AI ECG Model analyzes 12-lead resting ECG data from adult patients using an AI-based algorithm to detect ST-segment elevation myocardial infarction (STEMI) and STEMI-equivalent ECG patterns in patients presenting with a clinical suspicion of acute coronary syndrome. The STEMI AI ECG Model is a SaMD and is not implanted.

Procedure Description
In an inpatient setting, the STEMI AI ECG Model receives and analyzes 12-lead resting ECG recordings of patients presenting with a clinical suspicion of acute coronary syndrome using an AI algorithm and provides an output indicating the presence of STEMI, including both STEMI and STEMI-equivalents. Upon detection of a suspected STEMI, the software can send a notification to a specialist clinician. The software provides an adjunctive accelerated pathway for ECG analysis that will identify and prioritize STEMI patients more accurately for immediate referral to a cardiologist for full evaluation, diagnosis confirmation, and intervention.

Current Coding: The use of software that analyzes electrocardiograms to aid in detection and notification of cardiac abnormalities is not reported separately for inpatient hospital coding. If desired, facilities can report the electrocardiogram with the applicable code in table 4A0, Measurement of Physiological Systems.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify the use of software that analyzes electrocardiograms to aid in detection and notification of cardiac abnormalities. Continue as described in current coding.

Option 2. In section X New Technology create new table XEZ, Other Procedures on Physiological Systems and Anatomical Regions, create new technology value M Computer-aided Detection and Notification for Abnormalities in Electrocardiogram, applied to the body part value Z None and the external approach, to identify the use of software that analyzes electrocardiograms to aid in detection and notification of cardiac abnormalities. If desired, facilities can continue to report the electrocardiogram as described in current coding.

Section	**X** New Technology		
Body System	**E** Physiological Systems and Anatomical Regions		
Operation	**Z** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD Z None	**X** External	**ADD M** Computer-aided Detection and Notification for Abnormalities in Electrocardiogram	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 26 – Computer-aided Detection and Notification of Cardiac Function

Issue: There are currently no unique ICD-10-PCS codes to identify the use of software that uses vital signs to aid in detection and notification of cardiac abnormalities. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-On Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? No. VUNO Med-DeepCARS® was granted Breakthrough designation by the FDA on June 6, 2023. It is indicated to utilize common and routinely recorded vital signs (blood pressure, heart rate, respiratory rate, and body temperature), along with the corresponding time of measurement and patient age, extracted from the electronic medical records of general ward patients to compute the DeepCARS® Score. The DeepCARS® Score is intended to diagnose an elevated risk of impending cardiac arrest within a 24-hour period.

Background: Cardiac arrest is defined as the abrupt loss of heart function in a person who may or may not have been diagnosed with heart disease. According to a 2023 article in the Journal of the American Medical Association (JAMA), in-hospital cardiac arrest (IHCA) affects approximately 290,000 patients per year in the U.S.[1] It is associated with a poor survival rate, and where patients do survive, a high incidence of neurological disability or deficit post-IHCA. As noted in the article, cardiac arrest is rarely sudden and often may be the result, in part, due to delays in patients with deteriorating conditions. According to the requestor, DeepCARS® is an artificial intelligence (AI)-based technology that monitors and assesses a patient's risk of impending cardiac arrest within 24 hours, which in turn demonstrates higher predictive accuracy and fewer false alarms than the existing early warning systems.

Technology
DeepCARS® is an artificial intelligence-based technology that monitors and assesses a patient's risk of impending cardiac arrest within 24 hours in medical and surgical hospital units. It is not intended for use in intensive care units or emergency departments. Using imported data from the patient's electronic medical records, the technology analyzes vital signs with a risk determination model. More specifically, using the patient's current and previous physiological data (systolic pressure, diastolic pressure, pulse rate, respiratory rate, body temperature) and other patient characteristics, a pre-trained risk determination model developed based on Long Short-Term Memory Unit (LSTM) and Recurrent Neural Network (RNN) technologies provides a number between 0 to 100, representing the patient's risk of experiencing cardiac arrest within the next 24 hours. The findings from the DeepCARS® Score are interpreted in conjunction with other clinical information to inform treatment management decisions. According to the requestor, ongoing monitoring of the patient's risk score and demonstrating trends in their risk of cardiac arrest allows for timely intervention, ensuring prompt actions are taken when necessary to improve patient safety and clinical outcomes. DeepCARS® is intended for use in adult patient populations.

[1] Rasmussen TP, Riley DJ, Sarazin MV, Chan PS, Girotra S. Variation Across Hospitals in In-Hospital Cardiac Arrest Incidence Among Medicare Beneficiaries. JAMA Netw Open. 2022;5(2):e2148485. doi:10.1001/jamanetworkopen.2021.48485

Procedure Description
During an inpatient admission on a medical or surgical unit, DeepCARS® receives data via Hypertext Transfer Protocol communication, including patient vital signs (systolic and diastolic pressure, heart rate, body temperature, and respiratory rate) and other patient characteristics (e.g., age, gender). The DeepCARS® software performs data validation and technical quality control checks on the inputs received prior to being passed to the DeepCARS® model. The device then generates a risk score and calculates the net change in risk score since the previous calculation, if applicable. The results are displayed through the DeepCARS® software user interface. If the patient data (e.g., vitals) are rejected due to technical reasons or software failure, an error message is returned to the healthcare system. The software allows the clinical team to flag the patient's status and the clinical team's response to any deterioration in the DeepCARS® score.

Current Coding: The use of software that uses vital signs to aid in detection and notification of cardiac abnormalities is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify the use of software that uses vital signs to aid in detection and notification of cardiac abnormalities. Continue as described in current coding.

Option 2. In section X New Technology create new table XEZ, Other Procedures on Physiological Systems and Anatomical Regions, create new technology value R Computer-aided Detection and Notification of Cardiac Abnormalities using Vital Signs, applied to the body part value Z None and the external approach, to identify the use of software that uses vital signs to aid in detection and notification of cardiac abnormalities.

Section	**X** New Technology		
Body System	**E** Physiological Systems and Anatomical Regions		
Operation	**Z** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD Z None	**X** External	**ADD R** Computer-aided Detection and Notification of Cardiac Abnormalities using Vital Signs	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 27 - Section X Updates
Spring 2026 ICD-10 Coordination and Maintenance Committee Update

For the Fall 2025 code update we shared our analysis results for the Group 7 section X Codes, using frequency data and new technology add-on payment (NTAP) status from FYs 2022, 2023, and 2024. Therefore, for this Spring 2026 update, we are now sharing our analysis that also includes the results for the Group 7 section X codes for FY 2025, along with the CMS recommendation.

For the proposed disposition of section X code(s), we consider the following during our review:

- Was the procedure code related to an NTAP application?
- If yes, was the technology approved for the NTAP?
- What is the frequency (total number of cases) of this procedure code as reported in the Medicare Provider Analysis and Review (MedPAR) data for the relevant FYs?

Based on review of the data and the clinical aspects of each procedure code, we will propose one of the options below.

1. Leave the code in section X (e.g., procedure codes related to the administration of a specific medication, **the description of the code in section X better identifies the device/substance/technology or other aspect of the procedure than could otherwise be reflected in the Medical and Surgical or other section of ICD-10-PCS based on the conventions of the classification)**.
2. Delete the section X code. Revise the Index and/or Reference key entries to direct the user to an existing code in the Medical and Surgical or other section of ICD-10-PCS (e.g., NTAP has expired, data analysis and clinical review justifies incorporating this technology/procedure into the Medical and Surgical or other section of ICD-10-PCS).
3. Delete the section X code, corresponding Index entries, and any Reference Key entries from the classification (e.g., the procedure has not been reported as anticipated in the data, therefore the absence of a unique code for this technology/procedure in the classification has minimal impact).
4. Create a new code(s) in the Medical and Surgical or other section of ICD-10-PCS and delete the code from section X. (e.g., NTAP has expired, data analysis and clinical review justifies uniquely identifying the technology in the Medical and Surgical section). The corresponding Index entries for the section X code(s) will also be deleted, and new Index entries, along with any Reference Key entries will be added to reflect the newly created code(s).

Section X – Spring 2026 Update*
Group 7

CMS Recommendations:
Option 1 - Leave the code(s) in section X

1) ABECMA® (idecabtagene vicleucel) is a BCMA-directed CAR T-cell immunotherapy for adults with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW033K7	Introduction of idecabtagene vicleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	27	YES	35	YES	14	NO	20	NO	96
XW043K7	Introduction of idecabtagene vicleucel immunotherapy into central vein, percutaneous approach, new technology group 7	174	YES	271	YES	111	NO	150	NO	706

2) Aidoc Briefcase for PE – Indicated for the use in the diagnosis of pulmonary embolism.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XXE3X27	Measurement of pulmonary artery flow, computer-aided triage and notification, new technology group 7	69	NO	97	NO	34	NO	19	NO	219

3) Allogeneic engineered chimeric antigen receptor t-cell immunotherapy

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW033G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	10	NO	8	NO	7	NO	11	NO	36
XW043G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	26	NO	66	NO	64	NO	52	NO	208

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 1 - Leave the code(s) in section X

4) AMTAGVI™ (lifileucel) is an FDA-approved, one-time Tumor-Infiltrating Lymphocyte (TIL) therapy for adults with unresectable or metastatic melanoma previously treated with a PD-1 inhibitor (and BRAF inhibitor if applicable).

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW033L7	Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	0	NO	0	NO	0	NO	10	NO	10
XW043L7	Introduction of lifileucel immunotherapy into central vein, percutaneous approach, new technology group 7	1	NO	3	NO	8	NO	56	NO	68

5) Anti-SARS-CoV-2 hyperimmune globulin; IGIV-C – Implemented to describe new monoclonal antibodies indicated for the treatment of COVID-19.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW133E7	Transfusion of hyperimmune globulin into peripheral vein, percutaneous approach, new technology group 7	15	NO	14	NO	16	NO	12	NO	57
XW143E7	Transfusion of hyperimmune globulin into central vein, percutaneous approach, new technology group 7	2	NO	3	NO	1	NO	1	NO	7

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 1 - Leave the code(s) in section X

6) ApiFix Minimally Invasive Deformity Correction (MID-C) System is indicated for use in patients with adolescent idiopathic scoliosis (AIS) for treatment of single curves classified as Lenke 1 (thoracic major curve) or Lenke 5 (thoracolumbar/lumbar major curve), having a Cobb angle of 40 to 60 degrees which reduces to less than or equal to 30 degrees on lateral side-bending radiographs, and thoracic kyphosis less than 55 degrees as measured from T5 toT12. Humanitarian Device Exemption (HDE) was approved in 2019. The low usage in MedPAR is expected because this device is indicated for adolescent patients.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XNS00C7	Reposition of lumbar vertebra using posterior (dynamic) distraction device, open approach, new technology group 7	5	NO	6	NO	6	NO	5	NO	22
XNS03C7	Reposition of lumbar vertebra using posterior (dynamic) distraction device, percutaneous approach, new technology group 7	0	NO	0	NO	1	NO	1	NO	2
XNS40C7	Reposition of thoracic vertebra using posterior (dynamic) distraction device, open approach, new technology group 7	4	NO	3	NO	2	NO	1	NO	10
XNS43C7	Reposition of thoracic vertebra using posterior (dynamic) distraction device, percutaneous approach, new technology group 7	0	NO	0	NO	0	NO	1	NO	1

7) aScope™ Duodeno & EXALT Model D Single-Use Duodenoscope* - Note - Exalt D not approved for NTAP for FY 2023. We received a request to maintain these codes for tracking the use of the single-use duodenoscopes. We agree that the numbers support continuing to capture the use of technology.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XFJB8A7	Inspection of hepatobiliary duct using single-use duodenoscope, new technology group 7	692	YES	824	YES	789	NO	833	NO	3138
XFJD8A7	Inspection of pancreatic duct using single-use duodenoscope, new technology group 7	175	YES	151	YES	145	NO	155	NO	626

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 1 - Leave the code(s) in section X

8) Autologous engineered chimeric antigen receptor t-cell immunotherapy

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW033C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	20	NO	30	NO	14	NO	12	NO	76
XW043C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	94	NO	105	NO	97	NO	120	NO	416

9) Breyanzi® (lisocabtagene maraleucel) is a CD19-directed, autologous CAR T-cell therapy approved by the FDA to treat various relapsed/refractory B-cell non-Hodgkin lymphomas, including DLBCL, high-grade B-cell lymphoma, FL, CLL/SLL, MCL, and MZL. It is a one-time, personalized infusion treatment manufactured from a patient's own white blood cells.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW033N7	Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	14	NO	19	NO	30	NO	64	NO	127
XW043N7	Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7	87	NO	133	NO	193	NO	349	NO	762

10) Caption Guidance is an artificial-intelligence (AI) driven, FDA-cleared software that assists clinicians in acquiring diagnostic-quality cardiac ultrasound images (2D-TTE) in real-time.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
X2JAX47	Inspection of heart using transthoracic echocardiography, computer-aided guidance, new technology group 7	398	YES	1127	YES	693	NO	683	NO	2901

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 1 - Leave the code(s) in section X

11) CARVYKTI™ (ciltacabtagene autoleucel) is a BCMA-targeted, genetically modified autologous T-cell immunotherapy (CAR-T) for adults with relapsed or refractory multiple myeloma who have received at least one prior line of therapy and are lenalidomide-refractory.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW033A7	Introduction of ciltacabtagene autoleucel into peripheral vein, percutaneous approach, new technology group 7	1	NO	23	YES	29	NO	49	NO	102
XW043A7	Introduction of ciltacabtagene autoleucel into central vein, percutaneous approach, new technology group 7	36	NO	159	YES	289	NO	452	NO	936

12) CERAMENT® G – See revision proposal on page 132 in Topic#28 – Addenda and Key Updates.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW0V0P7	Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7	269	NO	541	YES	859	YES	1236	YES	2905

13) COMIRNATY®/ SPIKEVAX™ - Indicated for COVID-19 prevention.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW013V7	Introduction of covid-19 vaccine dose 3 into subcutaneous tissue, percutaneous approach, new technology group 7	7	NO	2	NO	1	NO	1	NO	11
XW013W7	Introduction of covid-19 vaccine booster into subcutaneous tissue, percutaneous approach, new technology group 7	90	NO	38	NO	1	NO	1	NO	130
XW023V7	Introduction of covid-19 vaccine dose 3 into muscle, percutaneous approach, new technology group 7	502	NO	61	NO	12	NO	9	NO	584
XW023W7	Introduction of covid-19 vaccine booster into muscle, percutaneous approach, new technology group 7	4518	NO	3016	NO	178	NO	98	NO	7810

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

CMS Recommendation:
Option 1 - Leave the code(s) in section X

14) ISC-REST kit -

The ISC-REST kit reports three test results to provide information related to cause of ischemic stroke and COVID-19 status:

i. ISCDx, (ICD-10-PCS code XXE5XT7) a test result based upon a whole blood sample as a source of mRNA, to aid in the diagnosis of cardioembolic and large artery atherosclerotic stroke (two major leading stroke causes and affecting treatment decisions). The testing results indicate whether the gene expression in the sample was consistent with cardioembolic stroke or large artery atherosclerosis stroke. *See page 115 for CMS recommended disposition of ICD-10-PCS code XXE5XT7.*

ii. Second, the QIAstat-Dx Respiratory SARS-CoV-2 Panel (ICD-10-PCS code XXE97U7) is a multiplexed nucleic acid real-time PCR test intended for the qualitative detection and differentiation of nucleic acid from multiple respiratory viral and bacterial organisms, including the SARS-CoV-2 virus, in nasopharyngeal swabs (NPS) eluted in universal transport media collected from patients suspected of COVID-19 by their healthcare provider.

iii. Third, the QIAGEN Access Anti-SARS-CoV-2 Total Test (ICD-10-PCS code XXE5XV7) is a rapid, digital lateral flow serological test, using nanoparticle fluorescence, intended for qualitative detection of total antibodies to SARS-CoV-2 in human serum and plasma (heparin, EDTA). The Access Anti-SARS-CoV-2 Total Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XXE97U7	Measurement of infection, nasopharyngeal fluid sars-cov-2 polymerase chain reaction, new technology group 7	711	NO	1664	NO	2391	NO	6832	NO	11,598
XXE5XV7	Measurement of infection, serum/plasma nanoparticle fluorescence sars-cov-2 antibody detection, new technology group 7	1	NO	94	NO	1	NO	7	NO	103

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 1 - Leave the code(s) in section X

15) KYMRIAH® (tisagenlecleucel) is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse; adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, and adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW033J7	Introduction of tisagenlecleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	9	NO	9	NO	6	NO	1	NO	25
XW043J7	Introduction of tisagenlecleucel immunotherapy into central vein, percutaneous approach, new technology group 7	43	NO	44	NO	21	NO	10	NO	118

16) Neovasc Reducer System is a minimally invasive, hourglass-shaped stainless steel mesh device designed to treat refractory angina. It is currently undergoing Phase III clinical trials as of October 9, 2025.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
X2V73Q7	Restriction of coronary sinus with reduction device, percutaneous approach, new technology group 7	3	NO	2	NO	0	NO	0	NO	5

17) Niyad™ (nafamostat) is intended as an anticoagulant in the extracorporeal circuit for patients undergoing continuous renal replacement therapy (CRRT) who cannot tolerate heparin. It holds Breakthrough Device Designation, and as of early 2026, the company is conducting the NEPHRO CRRT registrational study to support a Premarket Approval (PMA) submission.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XY0YX37	Extracorporeal introduction of nafamostat anticoagulant, new technology group 7	4	NO	0	NO	1	NO	1	NO	6

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

CMS Recommendation:
Option 1 - Leave the code(s) in section X

18) Other new technology monoclonal antibodies - Implemented to describe new monoclonal antibodies indicated for the treatment of COVID-19.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW023Y7	Introduction of other new technology monoclonal antibody into muscle, percutaneous approach, new technology group 7	112	NO	27	NO	6	NO	0	NO	145

19) Penumbra Indigo® Aspiration System with Lightning™ Aspiration Tubing is indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism. The Indigo® System uses a mechanical pump (the Penumbra Engine®) to generate a vacuum for aspiration. Additionally, the Lightning™ tubing is the technology aspect of the Indigo® System that detects when the catheter is in patent flow (and therefore removing blood) or in thrombus (and removing clot). This technology automatically stops and starts the Penumbra Engine® to reduce blood loss (e.g., stopping the pump when the catheter is in patent flow, and starting when the physician moves the catheter back into thrombus).

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
X2CP3T7	Extirpation of matter from abdominal aorta using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	37	NO	31	NO	41	NO	59	NO	168
X2CQ3T7	Extirpation of matter from right upper extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	59	NO	50	NO	55	NO	63	NO	227
X2CR3T7	Extirpation of matter from left upper extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	115	NO	61	NO	107	NO	118	NO	401
X2CS3T7	Extirpation of matter from right lower extremity artery using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	390	NO	342	NO	361	NO	472	NO	1565
X2CT3T7	Extirpation of matter from left lower extremity artery using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	416	NO	285	NO	377	NO	494	NO	1572

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

CMS Recommendation:
Option 1 - Leave the code(s) in section X

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
X2CU3T7	Extirpation of matter from right lower extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	101	NO	142	NO	231	NO	247	NO	721
X2CV3T7	Extirpation of matter from left lower extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	179	NO	230	NO	370	NO	446	NO	1225
X2CY3T7	Extirpation of matter from great vessel using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	583	NO	575	NO	683	NO	934	NO	2775

20) Phagenyx® System is a neurostimulation device delivering electrical stimulation to the oropharynx. It continues to receive NTAP in FY 2026.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XWHD7Q7	Insertion of neurostimulator lead into mouth and pharynx, via natural or artificial opening, new technology group 7	3	NO	1	NO	8	YES	15	YES	27

21) The Pure-Vu® System is a single-use device that easily fits on standard and slim colonoscopes and gastroscopes to facilitate intra-procedural cleansing of the GI tract to improve visualization. It provides physicians support in addressing emergent or challenging endoscopies especially in GI bleeding and in therapeutic procedures where debris, including blood, blood clot, and other matter in the GI tract can impede visualization.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XDPH8K7	Irrigation of lower GI using intraoperative single-use oversleeve, via natural or artificial opening endoscopic, new technology group 7	115	NO	125	NO	114	NO	116	NO	470

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 1 - Leave the code(s) in section X

22) Rapid ASPECTS. Indicated for use in the diagnosis of strokes, aneurysm and pulmonary embolism.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XXE0X07	Measurement of intracranial vascular activity, computer-aided assessment, new technology group 7	433	NO	428	NO	419	NO	508	NO	1788

23) StrataGraft is an FDA-approved bioengineered, allogeneic cellularized scaffold (human keratinocytes and dermal fibroblasts in a collagen matrix) used for treating adults with deep partial thickness burns. It is applied topically to the burn site, promoting the growth of the patient's own skin cells to aid healing, often eliminating the need for autografting.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XHRPXF7	Replacement of skin with bioengineered allogeneic construct, external approach, new technology group 7	353	YES	344	YES	479	YES	492	NO	1668

24) Tecartus™ (brexucabtagene autoleucel) is a CD19-directed genetically modified autologous (self-directed) T-cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory (r/r) B-cell precursor acute lymphoblastic leukemia (B-ALL).

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW033M7	Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	6	YES	11	YES	13	NO	3	NO	33
XW043M7	Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7	83	YES	94	YES	86	NO	55	NO	318

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 1 - Leave the code(s) in section X

25) Thoraflex™ Hybrid Device - Designed for the open surgical repair of aneurysms and/or dissections in the aortic arch and descending aorta.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
X2RX0N7	Replacement of thoracic aorta, arch using branched synthetic substitute with intraluminal device, open approach, new technology group 7	103	NO	76	YES	123	YES	152	YES	454
X2VW0N7	Restriction of thoracic aorta, descending using branched synthetic substitute with intraluminal device, open approach, new technology group 7	91	NO	79	YES	119	YES	145	YES	434

26) YARTEMLEA® (narsoplimab) - Approved by the FDA in December 2025 and is indicated for the treatment of adult and pediatric patients two years of age and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA). The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2027 consideration. See Index and Substance Key proposal on page 127 in Topic#28 – Addenda and Key Updates.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW03357	Introduction of narsoplimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 7	2	NO	0	NO	0	NO	0	NO	2
XW04357	Introduction of narsoplimab monoclonal antibody into central vein, percutaneous approach, new technology group 7	0	NO	0	NO	2	NO	0	NO	2

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 1 - Leave the code(s) in section X

27) Yescarta® (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy; adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy; and adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW033H7	Introduction of axicabtagene ciloleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	27	NO	41	NO	33	NO	28	NO	129
XW043H7	Introduction of axicabtagene ciloleucel immunotherapy into central vein, percutaneous approach, new technology group 7	177	NO	250	NO	226	NO	148	NO	801

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 2 - Delete the section X code. Revise Index and/or Reference key entries to direct the user to an existing code in the Medical and Surgical or other section of ICD-10-PCS

1) COSELA™ (trilaciclib) is indicated to decrease the incidence of chemotherapy-induced myelosuppression in patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen in adults with extensive-stage small cell lung cancer.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW03377	Introduction of trilaciclib into peripheral vein, percutaneous approach, new technology group 7	6	YES	1	YES	2	NO	1	NO	10
XW04377	Introduction of trilaciclib into central vein, percutaneous approach, new technology group 7	1	YES	1	YES	0	NO	1	NO	3

Code Specification:
Delete: XW0[34]377 (2 codes)

Index entries to accompany this proposal:
ICD-10-PCS Index Addenda
Lttr C
Main Delete COSELA(tm) use Trilaciclib
Main Add COSELA(tm) (Trilaciclib) use Other Therapeutic Substance

Lttr N
Main New Technology
Main Delete Trilaciclib XW0

Lttr T
Main Delete Trilaciclib XW0
Main Add Trilaciclib use Other Therapeutic Substance

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

CMS Recommendation:
Option 2 - Delete the section X code. Revise Index and/or Reference key entries to direct the user to an existing code in the Medical and Surgical or other section of ICD-10-PCS

Substance Key entries to accompany this proposal:
ICD-10-PCS Substance Key Addenda

Section 3	Administration	
Axis 6	Substance	
Term		Other Therapeutic Substance
Includes	Add	Trilaciclib
Includes	Add	COSELA(tm)

Section X	New Technology	
Axis 6	Device / Substance / Technology	
Term	Delete	Trilaciclib
Includes	Delete	COSELA(tm)

2) ENSPRYNG™ (satralizumab-mwge) is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD), a rare relapsing autoimmune disease, in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW01397	Introduction of satralizumab-mwge into subcutaneous tissue, percutaneous approach, new technology group 7	2	NO	0	NO	0	NO	5	NO	7

Code Specification:
Delete: XW01397 (1 code)

Index entries to accompany this proposal:
ICD-10-PCS Index Addenda

Lttr		E
Main	Delete	ENSPRYNG(tm) use Satralizumab-mwge
Main	Add	ENSPRYNG(tm) (Satralizumab-mwge) use Other Therapeutic Substance
Lttr		N

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

CMS Recommendation:
Option 2 - Delete the section X code. Revise Index and/or Reference key entries to direct the user to an existing code in the Medical and Surgical or other section of ICD-10-PCS

Main New Technology
Main Delete Satralizumab-mwge XW01397

Lttr S
Main Delete Satralizumab-mwge XW01397
Main Add Satralizumab-mwge use Other Therapeutic Substance

Substance Key entries to accompany this proposal:
ICD-10-PCS Substance Key Addenda
Section 3 Administration
Axis 6 Substance
Term Other Therapeutic Substance
Includes Add Satralizumab-mwge
Includes Add ENSPRYNG(tm)

Section X New Technology
Axis 6 Device / Substance / Technology
Term Delete Satralizumab-mwge
Includes Delete ENSPRYNG(tm)

3) TERLIVAZ® (terlipressin) is an FDA-approved vasopressin receptor agonist used in adults with hepatorenal syndrome (HRS) involving rapid, acute reduction in kidney function. It causes constriction of blood vessels to increase blood pressure and improve kidney function. New technology add-on payments were discontinued effective FY 2026.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW03367	Introduction of terlipressin into peripheral vein, percutaneous approach, new technology group 7	1	NO	6	NO	104	YES	132	YES	243
XW04367	Introduction of terlipressin into central vein, percutaneous approach, new technology group 7	0	NO	1	NO	16	YES	13	YES	30

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 2 - Delete the section X code. Revise Index and/or Reference key entries to direct the user to an existing code in the Medical and Surgical or other section of ICD-10-PCS

Code Specification:

Delete:	XW0[34]367 (2 codes)	

Index entries to accompany this proposal:

ICD-10-PCS Index Addenda

Lttr	T	
Main	Delete	Terlipressin XW0
Main	Add	Terlipressin use Vasopressor
Main	Delete	TERLIVAZ(R) use Terlipressin
Main	Add	TERLIVAZ(R) (Terlipressin) use Vasopressor
Lttr	N	
Main	New Technology	
Main	Delete	Terlipressin XW0

Substance Key entries to accompany this proposal:

ICD-10-PCS Substance Key Addenda

Section 3	Administration	
Axis 6	Substance	
Term		Vasopressor
Includes	Add	Terlipressin
Includes	Add	TERLIVAZ(R) (Terlipressin)
Section X	New Technology	
Axis 6	Device / Substance / Technology	
Term	Delete	Lurbinectedin
Includes	Delete	ZEPZELCA(tm)

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

CMS Recommendation:
Option 2 - Delete the section X code. Revise Index and/or Reference key entries to direct the user to an existing code in the Medical and Surgical or other section of ICD-10-PCS

4) RYBREVANT™ (amivantamab) is a targeted antibody treatment for adults with advanced or metastatic non-small cell lung cancer (NSCLC) possessing specific EGFR exon 19 deletions or L858R substitutions.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW033B7	Introduction of amivantamab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 7	7	YES	6	YES	8	YES	8	NO	29
XW043B7	Introduction of amivantamab monoclonal antibody into central vein, percutaneous approach, new technology group 7	0	YES	0	YES	2	YES	4	NO	6

Code Specification:
Delete: XW0[34]3B7 (2 codes)

Index entries to accompany this proposal:
ICD-10-PCS Index Addenda
Lttr A
Main Delete Amivantamab Monoclonal Antibody XW0
Main Add Amivantamab Monoclonal Antibody see Introduction with qualifier Monoclonal Antibody

Lttr N
Main New Technology
Main Delete Amivantamab Monoclonal Antibody XW0

Lttr R
Main Delete RYBREVANT (tm) use Amivantamab Monoclonal Antibody
Main Add RYBREVANT (tm) (Amivantamab Monoclonal Antibody) see Introduction with qualifier Monoclonal Antibody

Section X New Technology
Axis 6 Device / Substance / Technology
Term Delete Amivantamab Monoclonal Antibody

CMS Recommendation:
Option 2 - Delete the section X code. Revise Index and/or Reference key entries to direct the user to an existing code in the Medical and Surgical or other section of ICD-10-PCS

Includes Delete RYBREVANT (tm)

5) TAVALISSE® (fostamatinib) is a kinase inhibitor used to treat low platelet counts (thrombocytopenia) in adults with chronic immune thrombocytopenia (ITP) who have not responded to previous treatments.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW0DXR7	Introduction of fostamatinib into mouth and pharynx, external approach, new technology group 7	10	NO	19	NO	18	NO	25	NO	72
XW0G7R7	Introduction of fostamatinib into upper GI, via natural or artificial opening, new technology group 7	0	NO	0	NO	1	NO	0	NO	1
XW0H7R7	Introduction of fostamatinib into lower GI, via natural or artificial opening, new technology group 7	0	NO	0	NO	0	NO	0	NO	0

Code Specification:
Delete: XW0DXR7 (1 code); XW0[GH]7R7 (2 codes)

Index entries to accompany this proposal:
ICD-10-PCS Index Addenda
Lttr F
Main Delete Fostamatinib XW0
Main Add Fostamatinib use Other Therapeutic Substance
Lttr N
Main New Technology
Main Delete Fostamatinib XW0

Lttr T
Main Add TAVALISSE(R) (Fostamatinib) use Other Therapeutic Substance

CMS Recommendation:
Option 2 - Delete the section X code. Revise Index and/or Reference key entries to direct the user to an existing code in the Medical and Surgical or other section of ICD-10-PCS

Substance Key entries to accompany this proposal:
ICD-10-PCS Substance Key Addenda

Section 3	Administration	
Axis 6	Substance	
Term		Other Therapeutic Substance
Includes	Add	Fostamatinib
Includes	Add	TAVALISSE(R)

6) ZEPZELCA™ (lurbinectedin) is an alkylating drug indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW03387	Introduction of lurbinectedin into peripheral vein, percutaneous approach, new technology group 7	7	YES	12	YES	7	NO	7	NO	22
XW04387	Introduction of lurbinectedin into central vein, percutaneous approach, new technology group 7	6	YES	8	YES	3	NO	8	NO	25

Code Specification:
Delete: XW0[34]387 (2 codes)

Index entries to accompany this proposal:
ICD-10-PCS Index Addenda

Lttr		L
Main	Delete	Lurbinectedin XW0
Main	Add	Lurbinectedin use Other Antineoplastic
Lttr		N
Main		New Technology
Main	Delete	Lurbinectedin XW0

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 2 - Delete the section X code. Revise Index and/or Reference key entries to direct the user to an existing code in the Medical and Surgical or other section of ICD-10-PCS

Lttr		Z
Main	Delete	ZEPZELCA(tm) use Lurbinectedin
Main	Add	ZEPZELCA(tm) (Lurbinectedin) use Other Antineoplastic

Substance Key entries to accompany this proposal:

ICD-10-PCS Substance Key Addenda

Section 3	Administration	
Axis 6	Substance	
Term		Other Antineoplastic
Includes	Add	Lurbinectedin
Includes	Add	ZEPZELCA(tm) Lurbinectedin
Section X	New Technology	
Axis 6	Device / Substance / Technology	
Term	Delete	Lurbinectedin
Includes	Delete	ZEPZELCA(tm)

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 3 - Delete the section X code, corresponding Index entries, and any Reference Key entries from the classification

1) Ellipsys® Vascular Access System was intended for use to create an arteriovenous (AV) fistula via percutaneous access. The manufacturer discontinued production in early 2025.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
X2KB317	Bypass right radial artery using thermal resistance energy, percutaneous approach, new technology group 7	3	NO	1	NO	2	NO	0	NO	6
X2KC317	Bypass left radial artery using thermal resistance energy, percutaneous approach, new technology group 7	5	NO	2	NO	5	NO	0	NO	12

Code Specification:
Delete: X2K[BC]317 (2 codes)

Index entries to accompany this proposal:
ICD-10-PCS Index Addenda
Lttr E
Main Delete Ellipsys(R) vascular access system see New Technology, Cardiovascular System X2K
Main Delete Endovascular fistula creation, using thermal resistance energy *see* New Technology, Cardiovascular System X2K

Lttr N
Main New Technology
Main Delete Radial artery arteriovenous fistula, using Thermal Resistance Energy X2K

Lttr P
Main Delete pAVF (percutaneous arteriovenous fistula), using thermal resistance energy see New Technology, CardiovascularSystem X2K

Lttr R
Main Delete Radial artery arteriovenous fistula, using Thermal Resistance Energy X2K

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 3 - Delete the section X code, corresponding Index entries, and any Reference Key entries from the classification

2) EVUSHELD™ (tixagevimab and cilgavimab) was a combination of two monoclonal antibodies formerly authorized for pre-exposure prophylaxis (prevention) of COVID-19 in immunocompromised individuals. It is no longer authorized in the U.S. as of January 26, 2023.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW023X7	Introduction of tixagevimab and cilgavimab monoclonal antibody into muscle, percutaneous approach, new technology group 7	438	NO	363	NO	0	NO	0	NO	801

Code Specification:
Delete: XW023X7 (1 code)

Index entries to accompany this proposal:
ICD-10-PCS Index Addenda
Lttr E
Main Delete EVUSHELD(tm) use Tixagevimab and Cilgavimab Monoclonal Antibody

Substance Key entries to accompany this proposal:
ICD-10-PCS Substance Key Addenda
Section X New Technology
Axis 6 Device / Substance / Technology
Term Delete Tixagevimab and Cilgavimab Monoclonal Antibody
Includes Delete EVUSHELD(tm)

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 3 - Delete the section X code, corresponding Index entries, and any Reference Key entries from the classification

3) FUJIFILM EP-7000X System is a high-definition endoscopic imaging platform introduced for enhanced visualization in GI procedures. New technology add-on payments for the FUJIFILM EP-7000X System were not approved for FY 2022 (86 FR 45140 through 45146).

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XD2G4V7	Monitoring of upper GI oxygen saturation, percutaneous endoscopic approach, new technology group 7	0	NO	1	NO	2	NO	1	NO	4
XD2G8V7	Monitoring of upper GI oxygen saturation, via natural or artificial opening endoscopic, new technology group 7	1	NO	2	NO	3	NO	2	NO	8
XD2H4V7	Monitoring of lower GI oxygen saturation, percutaneous endoscopic approach, new technology group 7	0	NO	0	NO	0	NO	0	NO	0
XD2H8V7	Monitoring of lower GI oxygen saturation, via natural or artificial opening endoscopic, new technology group 7	1	NO	0	NO	2	NO	1	NO	4

Code Specification:
Delete: XD2[GH][48]V7 (4 codes)

Index entries to accompany this proposal:
ICD-10-PCS Index Addenda
Lttr F
Main Delete FUJIFILM EP-7000X System for Oxygen Saturation Endoscopic Imaging (OXEI)
see New Technology, Gastrointestinal System XD2

Lttr M
Main Monitoring
Main Delete Oxygen Saturation Endoscopic Imaging (OXEI) XD2

Lttr N
Main New Technology
Main Delete Oxygen Saturation Endoscopic Imaging (OXEI) XD2

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

CMS Recommendation:
Option 3 - Delete the section X code, corresponding Index entries, and any Reference Key entries from the classification

Lttr O
Main Delete Oxygen Saturation Endoscopic Imaging (OXEI) XD2

4) ISC-REST kit – ISC-REST kit -
The ISC-REST kit reports three test results to provide information related to cause of ischemic stroke and COVID-19 status:
   i. ISCDx, (ICD-10-PCS code XXE5XT7) a test result based upon a whole blood sample as a source of mRNA, to aid in the diagnosis of cardioembolic and large artery atherosclerotic stroke (two major leading stroke causes and affecting treatment decisions). The testing results indicate whether the gene expression in the sample was consistent with cardioembolic stroke or large artery atherosclerosis stroke.
   ii. Second, the QIAstat-Dx Respiratory SARS-CoV-2 Panel (ICD-10-PCS code XXE97U7) is a multiplexed nucleic acid real-time PCR test intended for the qualitative detection and differentiation of nucleic acid from multiple respiratory viral and bacterial organisms, including the SARS-CoV-2 virus, in nasopharyngeal swabs (NPS) eluted in universal transport media collected from patients suspected of COVID-19 by their healthcare provider.
   iii. Third, the QIAGEN Access Anti-SARS-CoV-2 Total Test (ICD-10-PCS code XXE5XV7) is a rapid, digital lateral flow serological test, using nanoparticle fluorescence, intended for qualitative detection of total antibodies to SARS-CoV-2 in human serum and plasma (heparin, EDTA). The Access Anti-SARS-CoV-2 Total Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2. *See page 97 for CMS recommended disposition of ICD-10-PCS codes XXE97U7 and XXE5XV7.*

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XXE5XT7	Measurement of intracranial arterial flow, whole blood mrna, new technology group 7	0	NO	5	NO	2	NO	7	NO	14

Code Specification:
Delete: XXE5XT7 (1 code)

Index entries to accompany this proposal:
ICD-10-PCS Index Addenda
Lttr I

CMS Recommendation:
Option 3 - Delete the section X code, corresponding Index entries, and any Reference Key entries from the classification

Main Delete Intracranial Arterial Flow, Whole Blood mRNA XXE5XT7
Main ISC-REST kit
Main Delete ISCDx XXE5XT7

Lttr N
Main New Technology
Main Delete Intracranial Arterial Flow, Whole Blood mRNA XXE5XT7

5) Steripath® Initial Specimen Diversion Device® is indicated to reduce blood culture contamination. New technology add-on payments for the Steripath® Initial Specimen Diversion Device® were not approved for FY 2022 (86 FR 45070 through 45079).

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XXE5XR7	Measurement of infection, mechanical initial specimen diversion technique using active negative pressure, new technology group 7	0	NO	0	NO	0	NO	0	NO	0

Code Specification:
Delete: XXE5XR7 (1 code)

Index entries to accompany this proposal:
ICD-10-PCS Index Addenda
Lttr M
Main Delete Mechanical Initial Specimen Diversion Technique Using Active Negative Pressure (blood collection) XXE5XR7

Lttr N
Main New Technology
Main Delete Mechanical Initial Specimen Diversion Technique Using Active Negative Pressure (blood collection) XXE5XR7
Lttr S
Main Delete Steripath(R) Micro(tm) Blood Collection System XXE5XR7

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:

Option 4 - Create a new code(s) in the Medical and Surgical or other section of ICD-10-PCS and delete the code from section X. The corresponding Index entries for the section X code(s) will also be deleted, and new Index entries, along with any Reference Key entries will be created to reflect the newly established code(s).

1) Aprevo™ Intervertebral Body Fusion Device

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XRGA0R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7[1]	4	YES	5	YES	7	YES	8	NO	24
XRGA3R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7[1]	0	YES	2	YES	0	YES	1	NO	3
XRGA4R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7[1]	0	YES	0	YES	0	YES	0	NO	0
XRGB0R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7[1]	126	YES	176	YES	131	YES	240	NO	673
XRGB3R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7[1]	2	YES	2	YES	2	YES	8	NO	14
XRGB4R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7[1]	1	YES	1	YES	0	YES	1	NO	3
XRGC0R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, open approach, new technology group 7[1]	67	YES	82	YES	101	YES	117	NO	367
XRGC3R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7[1]	0	YES	4	YES	1	YES	1	NO	6
XRGC4R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7[1]	0	YES	0	YES	0	YES	0	NO	0

[1] *Code Description revised effective FY 2024 - October 1, 2023*

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XRGD0R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7[1]	53	YES	132	YES	121	YES	218	NO	524
XRGD3R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7[1]	1	YES	1	YES	3	YES	2	NO	7
XRGD4R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7[1]	0	YES	0	YES	0	YES	0	NO	0

Code Specification:

Delete: XRG[ABCD][034]R7 (12 codes)
Add: 0RGA[034]E[0J] (6 codes); 0SG[013][034]E[0J] (18 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**R** Upper Joints
Operation	**G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile

Body Part	*Approach*	*Device*	*Qualifier*
A Thoracolumbar Vertebral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**A** Interbody Fusion Device **ADD E** Interbody Fusion Device, Custom-Made Anatomically and Virtually Designed	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:

Option 4 - Create a new code(s) in the Medical and Surgical or other section of ICD-10-PCS and delete the code from section X. The corresponding Index entries for the section X code(s) will also be deleted, and new Index entries, along with any Reference Key entries will be created to reflect the newly established code(s).

Section	**0** Medical and Surgical
Body System	**S** Lower Joints
Operation	**G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile

Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebral Joint **1** Lumbar Vertebral Joints, 2 or more **3** Lumbosacral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**A** Interbody Fusion Device **ADD E** Interbody Fusion Device, Custom-Made Anatomically and Virtually Designed	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

Index entries to accompany this proposal:

ICD-10-PCS Index Addenda

Lttr A
Main Delete aprevo(tm) use Interbody Fusion Device, Custom-Made Anatomically Designed in New Technology
Main Add aprevo(tm)
Main Add use Interbody Fusion Device, Custom-Made Anatomically Designed in New Technology
Main Add use Interbody Fusion Device, Custom-Made Anatomically and Virtually Designed in Upper Joints
Main Add use Interbody Fusion Device, Custom-Made Anatomically and Virtually Designed in Lower Joints

Lttr F
Main Fusion
Main Lumbar Vertebral 0SG0
Main 2 or more 0SG1
Main Delete Interbody Fusion Device, Custom-Made Anatomically Designed XRGC
Main Delete Interbody Fusion Device, Custom-Made Anatomically Designed XRGB
Main Lumbosacral 0SG3
Main Delete Interbody Fusion Device, Custom-Made Anatomically Designed XRGD
Main Thoracolumbar Vertebral 0RGA
Main Delete Interbody Fusion Device, Custom-Made Anatomically Designed XRGA

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

CMS Recommendation:

Option 4 - Create a new code(s) in the Medical and Surgical or other section of ICD-10-PCS and delete the code from section X. The corresponding Index entries for the section X code(s) will also be deleted, and new Index entries, along with any Reference Key entries will be created to reflect the newly established code(s).

Lttr		I
Main		Interbody Fusion Device, Custom-Made Anatomically Designed
Main	Delete	Lumbar Vertebral XRGB
Main	Delete	2 or more XRGC
Main	Delete	Lumbosacral XRGD
Main	Delete	Thoracolumbar Vertebral XRGA
Main	Add	Interbody Fusion Device, Custom-Made Anatomically and Virtually Designed
Main	Add	Lumbar Vertebral 0SG0
Main	Add	2 or more 0SG1
Main	Add	Lumbosacral 0SG3
Main	Add	Thoracolumbar Vertebral 0RGA
Lttr		N
Main		New Technology
Main		Fusion
Main		Lumbar Vertebral
Main		2 or more
Main	Delete	Interbody Fusion Device, Custom-Made Anatomically Designed XRGC
Main	Delete	Interbody Fusion Device, Custom-Made Anatomically Designed XRGB
Main		Lumbosacral
Main	Delete	Interbody Fusion Device, Custom-Made Anatomically Designed XRGD
Main		Thoracolumbar Vertebral
Main	Delete	Interbody Fusion Device, Custom-Made Anatomically Designed XRGA

Device Key entries to accompany this proposal:

Axis 6	Device	
Row		
Term	Add	Interbody Fusion Device, Custom-Made Anatomically and Virtually Designed
Includes	Add	aprevo(tm)

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:
Option 4 - Create a new code(s) in the Medical and Surgical or other section of ICD-10-PCS and delete the code from section X. The corresponding Index entries for the section X code(s) will also be deleted, and new Index entries, along with any Reference Key entries will be created to reflect the newly established code(s).

2) GAMUNEX-C and Octagam 10% -
   a. Gamunex-C is FDA-approved for treating primary humoral immunodeficiency, idiopathic thrombocytopenic purpura (ITP), and chronic inflammatory demyelinating polyneuropathy (CIDP). Gamunex-C is being used in research settings for potential applications in long COVID, specifically in trials investigating its effect on autonomic nervous system dysfunction (e.g., postural orthostatic tachycardia syndrome (POTS)).
   b. Octagam 10% (Immune Globulin Intravenous [Human], 10% liquid) remains available and is an FDA-approved treatment for dermatomyositis and chronic immune thrombocytopenia (cITP) in adults. It has not received broad, formal approval as a standard COVID-19 therapy.

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW133D7	Transfusion of high-dose intravenous immune globulin into peripheral vein, percutaneous approach, new technology group 7	64	NO	94	NO	145	NO	184	NO	487
XW143D7	Transfusion of high-dose intravenous immune globulin into central vein, percutaneous approach, new technology group 7	8	NO	13	NO	11	NO	22	NO	54

Code Specification:

Delete: XW1[34]3D7 (2 codes)
Add: 302[34]3S5 (2 codes)

EXAMPLE

Section	**3** Administration
Body System	**0** Circulatory
Operation	**2** Transfusion: Putting in blood or blood products

Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**S** Globulin	**0** Autologous **1** Nonautologous **ADD 5** Immune Globulin, High-Dose
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**H** Whole Blood **J** Serum Albumin **K** Frozen Plasma	**0** Autologous **1** Nonautologous

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

CMS Recommendation:

Option 4 - Create a new code(s) in the Medical and Surgical or other section of ICD-10-PCS and delete the code from section X. The corresponding Index entries for the section X code(s) will also be deleted, and new Index entries, along with any Reference Key entries will be created to reflect the newly established code(s).

		L Fresh Plasma **M** Plasma Cryoprecipitate **N** Red Blood Cells **P** Frozen Red Cells **Q** White Cells **R** Platelets **T** Fibrinogen **V** Antihemophilic Factors **W** Factor IX	

Index entries to accompany this proposal:

ICD-10-PCS Index Addenda

Lttr G
Main Delete GAMUNEX-C, for COVID-19 treatment use High-Dose Intravenous Immune Globulin
Main Add GAMUNEX-C see Transfusion with qualifier Immune Globulin, High-Dose

Lttr H
Main Delete hdIVIG (high-dose intravenous immunoglobulin), for COVID-19 treatment use High-Dose Intravenous Immune Globulin
Main Add hdIVIG (high-dose intravenous immunoglobulin) see Transfusion with qualifier Immune Globulin, High-Dose
Main Delete High-Dose Intravenous Immune Globulin XW1
Main Add High-Dose Intravenous Immune Globulin 302
Main Delete High-dose intravenous immunoglobulin (hdIVIG), for COVID-19 treatment use High-Dose Intravenous Immune Globulin
Main Add High-dose intravenous immunoglobulin (hdIVIG) see Transfusion with qualifier Immune Globulin, High-Dose

Lttr N
Main New Technology
Main Delete High-Dose Intravenous Immune Globulin XW1

Lttr O
Main Delete Octagam 10%, for COVID-19 treatment use High-Dose Intravenous Immune Globulin
Main Add Octagam 10% see Transfusion with qualifier Immune Globulin, High-Dose

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

CMS Recommendation:

Option 4 - Create a new code(s) in the Medical and Surgical or other section of ICD-10-PCS and delete the code from section X. The corresponding Index entries for the section X code(s) will also be deleted, and new Index entries, along with any Reference Key entries will be created to reflect the newly established code(s).

Substance Key entries to accompany this proposal:

ICD-10-PCS Substance Key Addenda

Section 3		Administration
Axis 6		Substance
Term		Globulin
Includes	Add	GAMUNEX-C
Includes	Add	hdIVIG (high-dose intravenous immunoglobulin)
Includes	Add	High-dose intravenous immunoglobulin (hdIVIG)
Includes	Add	Octagam 10%
Section X		New Technology
Axis 6		Device / Substance / Technology
Term	Delete	High-Dose Intravenous Immune Globulin
Includes	Delete	GAMUNEX-C, for COVID-19 treatment
Includes	Delete	hdIVIG (high-dose intravenous immunoglobulin), for COVID-19 treatment
Includes	Delete	High-dose intravenous immunoglobulin (hdIVIG), for COVID-19 treatment
Includes	Delete	Octagam 10%, for COVID-19 treatment

3) NexoBrid (anacaulase-bcdb) is a topical enzymatic agent for eschar removal in adults and pediatric patients with deep partial thickness and/or full thickness thermal burns. Chemical enzymatic debridement uses targeted proteolytic agents to selectively dissolve nonviable necrotic tissue in wounds while sparing healthy, granulated tissue. The FDA-approved topical enzymatic agents in the U.S. include collagenase (Santyl), which acts over days to weeks, and other, faster-acting agents such as bromelain-based gels (i.e. NexoBrid).

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW00X27	Introduction of anacaulase-bcdb into skin, external approach, new technology group 7[1]	29	NO	41	NO	45	NO	47	NO	162

[1] *Code Description revised effective FY 2024 - October 1, 2023*

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:

Option 4 - Create a new code(s) in the Medical and Surgical or other section of ICD-10-PCS and delete the code from section X. The corresponding Index entries for the section X code(s) will also be deleted, and new Index entries, along with any Reference Key entries will be created to reflect the newly established code(s).

ICD-10-PCS Code	Description	FY 2022		FY 2023		FY 2024		FY 2025		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW01X27	Introduction of anacaulase-bcdb into subcutaneous tissue, external approach, new technology group 7[2]	0	NO	0	NO	0	NO	22	NO	22

Code Specification:

Delete: XW0[01]X27 (2 codes)
Add: 3E0[01]XGF (2 codes)

EXAMPLE

Section	**3** Administration
Body System	**E** Physiological Systems and Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body System / Region	*Approach*	*Substance*	*Qualifier*
0 Skin and Mucous Membranes	**X** External	**G** Other Therapeutic Substance	**C** Other Substance **ADD F** Other Enzymatic/Chemical Agent
1 Subcutaneous Tissue	**ADD X** External	**G** Other Therapeutic Substance	**C** Other Substance **ADD F** Other Enzymatic/Chemical Agent

Index entries to accompany this proposal:

ICD-10-PCS Index Addenda

Lttr A
Main Delete Anacaulase-bcdb XW0
Main Add Anacaulase-bcdb see Introduction with qualifier Other Enzymatic/Chemical Agent

Lttr B
Main Delete Bromelain-enriched Proteolytic Enzyme use Anacaulase-bcdb
Main Add Bromelain-enriched Proteolytic Enzyme see Introduction with qualifier Other Enzymatic/Chemical Agent

Lttr C
Main Add Collagenase SANTYL Ointment see Introduction with qualifier Other Enzymatic/Chemical Agent

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Section X – Spring 2026 Update*
Group 7

CMS Recommendation:

Option 4 - Create a new code(s) in the Medical and Surgical or other section of ICD-10-PCS and delete the code from section X. The corresponding Index entries for the section X code(s) will also be deleted, and new Index entries, along with any Reference Key entries will be created to reflect the newly established code(s).

Lttr		N
Main		New Technology
Main	Delete	Anacaulase-bcdb XW0
Main	Delete	NexoBrid(tm) use Anacaulase-bcdb
Main	Add	NexoBrid(tm) see Introduction with qualifier Other Enzymatic/Chemical Agent
Lttr		S
Main	Add	SANTYL Ointment see Introduction with qualifier Other Enzymatic/Chemical Agent

Substance Key entries to accompany this proposal:

ICD-10-PCS Substance Key Addenda

Section 3	Administration	
Axis 6	Substance	
Term		Other Therapeutic Substance
Includes	Add	Anacaulase-bcdb
Includes	Add	Bromelain-enriched Proteolytic Enzyme
Includes	Add	Collagenase SANTYL Ointment
Includes	Add	NexoBrid(tm)
Includes	Add	SANTYL Ointment
Section X	New Technology	
Axis 6	Device / Substance / Technology	
Term	Delete	Anacaulase-bcdb
Includes	Delete	Bromelain-enriched Proteolytic Enzyme
Includes	Delete	NexoBrid(tm)

**All proposed Section X updates are being considered for implementation on October 1, 2026.*

Topic # 28 - Addenda and Reference Key Updates*

ICD-10-PCS Index Addenda

Lttr	C	
Main	Add	Cisterna Magna
Main	Add	use Subarachnoid Space, Intracranial

Lttr	Y	
Main	Add	YARTEMLEA(R) use Narsoplimab Monoclonal Antibody

ICD-10-PCS Body Part Key Addenda

Section 0		Medical and Surgical
Axis 4		Body Part
Term		Subarachnoid Space, Intracranial
Includes	Add	Cisterna Magna

ICD-10-PCS Substance Key Addenda

Section X		New Technology
Axis 6		Device / Substance / Technology

Row	Add	
Term	Add	Narsoplimab Monoclonal Antibody
Includes	Add	YARTEMLEA(R)

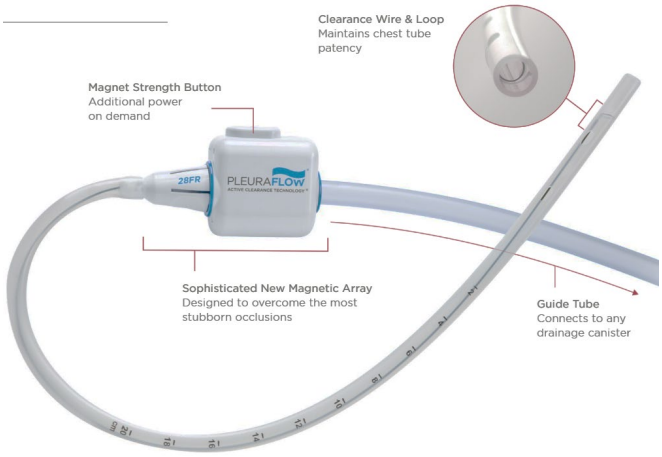
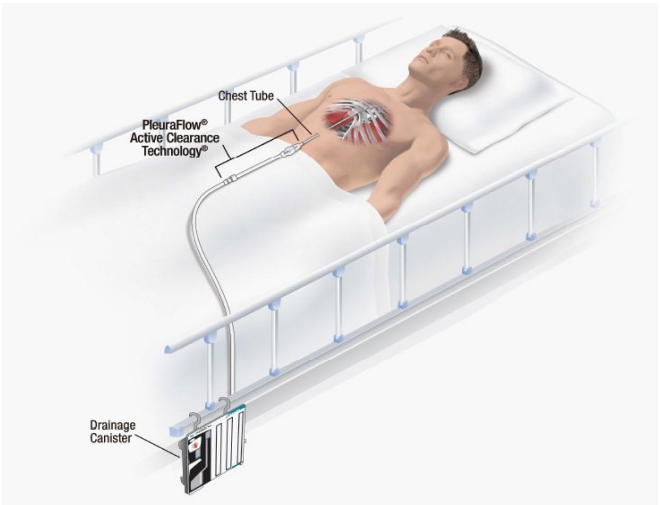
ICD-10-PCS Table Addenda

Medical and Surgical Section

Axis 7 Qualifier
Drainage Device using Active Clearance Technology

Source	Description	Code specification
2025, public request with CMS internal review	In the Medical and Surgical section table 0W9, Drainage of General Anatomical Regions, add the qualifier value 3 Active Mechanical Clearance, applied to body part values 9 Pleural Cavity, Right, B Pleural Cavity, Left and C Mediastinum, device value 0 Drainage Device, and all available approach values. This change will enable the reporting of a separate procedure to put in a drainage device that uses active clearance technology in the mediastinum or pleural cavity. The PleuraFlow® Active Clearance Technology® (ACT®) System is a Food & Drug Administration	Add: 0W9[9BC][034]03 (9 codes)

**All proposed addenda updates are being considered for implementation on October 1, 2026.*

	(FDA) approved chest drainage system used during and after cardiothoracic surgery. It connects to any drainage canister and features a proprietary active clearance mechanism that allows for the mechanical removal of intraluminal clots from within the chest tube, proactively maintaining chest tube patency. This function addresses a major failure mode of traditional passive drainage systems, chest tube occlusion. The PleuraFlow® ACT® System mitigates these risks by proactively preserving chest tube patency, enabling complete drainage and avoiding secondary interventions.   	

EXAMPLE

Section	**0** Medical and Surgical
Body System	**W** Anatomical Regions, General
Operation	**9** Drainage: Taking or letting out fluids and/or gases from a body part

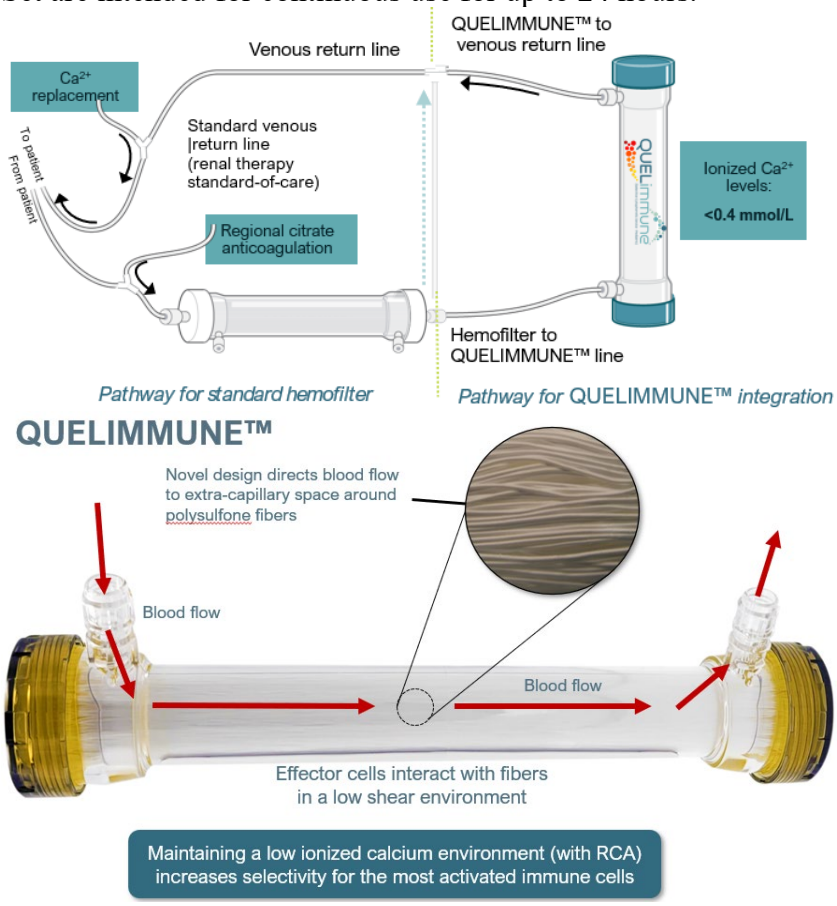
Body Part	*Approach*	*Device*	*Qualifier*

0 Head **1** Cranial Cavity **2** Face **3** Oral Cavity and Throat **4** Upper Jaw **5** Lower Jaw **8** Chest Wall **D** Pericardial Cavity **F** Abdominal Wall **G** Peritoneal Cavity **H** Retroperitoneum **K** Upper Back **L** Lower Back **M** Perineum, Male **N** Perineum, Female	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Drainage Device	**Z** No Qualifier
9 Pleural Cavity, Right **B** Pleural Cavity, Left **C** Mediastinum	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Drainage Device	**ADD 3** Active Mechanical Clearance **Z** No Qualifier

Extracorporeal or Systemic Assistance and Performance Section

Axis 7 Qualifier
Renal Replacement Therapy with Selective Cytopheresis

Source	Description	Code specification
2025, public request with CMS internal review	In the Extracorporeal or Systemic Assistance and Performance section table 5A1, add the qualifier value 1 Selective Cytopheresis, applied to body system value D Urinary, function value 0 Filtration, and all available duration values to describe renal replacement therapy with selective cytopheresis. The SeaStar Medical Selective Cytopheretic Device for Pediatrics, QUELIMMUNE™ (SCD-PED), was granted Food & Drug Administration (FDA) approval under a Humanitarian Device Exemption (HDE) on February 21, 2024. The QUELIMMUNE™ SCD is intended to treat pediatric patients (weight ≥ 10 kg and age ≤ 22 years) with acute kidney injury (AKI) due to sepsis or a septic condition on antibiotic therapy and requiring renal replacement therapy (RRT) and is currently being investigated for use in adult patients with AKI. The patented cell-directed extracorporeal therapy of the QUELIMMUNE™ SCD conveniently connects with existing RRT systems that are widely available in intensive care units (ICUs) to selectively target the most highly activated neutrophils and monocytes responsible for the destructive hyperinflammatory response. According to the requestor, the SCD therapy will not just stop the storm but could potentially reverse the damage.	Add: 5A1D[789]01 (3 codes)

	The QUELIMMUNE™ SCD consists of an SCD-PED Cartridge and an SCD Blood Tubing Set connected in-line to the extracorporeal RRT circuit of an existing hemodialysis delivery system with regional citrate infusion to maintain a circuit post- SCD ionized calcium level of less than 0.40 mmol/L. The SCD-PED Cartridge is a single-use, hollow-fiber synthetic membrane cartridge. The SCD Blood Tubing Set is an ethylene oxide-sterilized, single-use tubing set designed to connect the SCD-PED Cartridge to the post-RRT filter segment of the RRT. Each SCD-PED Cartridge and SCD Blood Tubing Set are intended for continuous use for up to 24 hours.  	

EXAMPLE

Section	**5** Extracorporeal or Systemic Assistance and Performance		
Body System	**A** Physiological Systems		
Operation	**1** Performance: Completely taking over a physiological function by extracorporeal means		
Body System	*Duration*	*Function*	*Qualifier*
D Urinary	**7** Intermittent, Less than 6 Hours Per Day **8** Prolonged Intermittent, 6-18 hours Per Day **9** Continuous, Greater than 18 hours Per Day	**0** Filtration	**ADD 1** Selective Cytopheresis **Z** No Qualifier

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr C
Main Delete Continuous renal replacement therapy (CRRT) 5A1D90Z
Add Continuous renal replacement therapy (CRRT)
see Performance, Urinary 5A1D9

Main Delete CRRT (Continuous renal replacement therapy) 5A1D90Z
Add CRRT (Continuous renal replacement therapy)
see Performance, Urinary 5A1D9

Lttr I
Main Delete IHD (Intermittent hemodialysis) 5A1D70Z
Add IHD (Intermittent hemodialysis) see Performance, Urinary 5A1D7

Main Delete Intermittent hemodialysis (IHD) 5A1D70Z
Add Intermittent hemodialysis (IHD) see Performance, Urinary 5A1D7

Lttr P
Main Performance
Urinary
Delete Continuous, Greater than 18 hours per day, Filtration 5A1D90Z
Add Continuous, Greater than 18 hours per day, Filtration 5A1D9
Delete Intermittent, Less than 6 Hours Per Day, Filtration 5A1D70Z
Add Intermittent, Less than 6 Hours Per Day, Filtration 5A1D7
Delete Prolonged Intermittent, 6-18 hours per day, Filtration 5A1D80Z
Add Prolonged Intermittent, 6-18 hours per day, Filtration 5A1D8

Main Delete PIRRT (Prolonged intermittent renal replacement therapy) 5A1D80Z
Add PIRRT (Prolonged intermittent renal replacement therapy)
see Performance, Urinary 5A1D8

Main Delete Prolonged intermittent renal replacement therapy (PIRRT) 5A1D80Z
Add Prolonged intermittent renal replacement therapy (PIRRT)
see Performance, Urinary 5A1D8

Lttr Q
Main Add QUELIMMUNE™ Selective Cytopheretic Device (SCD)
see Performance, Urinary 5A1D
Lttr S
Main Add Selective Cytopheretic Device (SCD)
see Performance, Urinary 5A1D

New Technology Section
Axis 6 Device / Substance / Technology

Antibiotic-eluting Bone Void Filler

Source	Description	Code specification
2023, public request with CMS internal review	In the New Technology section table XW0, revise the axis 6 device/substance/technology value P from Antibiotic-eluting Bone Void Filler to Gentamicin-eluting Bone Void Filler. This change is requested to distinguish the introduction of a gentamicin-eluting bone void filler from the introduction of bone void fillers that elute other antimicrobials. CERAMENT® G is an implantable bone void filler (combination device/drug) consisting of hydroxyapatite, calcium sulfate, and gentamicin sulfate. An ICD-10-PCS code is being requested to describe the introduction of CERAMENT® V, an implantable bone void filler (combination device/drug) consisting of hydroxyapatite, calcium sulfate and the antibiotic vancomycin hydrochloride. (Topic # 10 – page 39)	Revise: XW0V0P7 (1 code)

EXAMPLE

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
V Bones	0 Open	**REVISE from** P Antibiotic-eluting Bone Void Filler **REVISE to** P Gentamicin-eluting Bone Void Filler	**7** New Technology Group 7

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr A
Main Delete Antibiotic-eluting Bone Void Filler XW0V0P7

Lttr C
Main Delete CERAMENT(R) G use Antibiotic-eluting Bone Void Filler
Main Add CERAMENT(R) G use Gentamicin-eluting Bone Void Filler

Lttr G
Main Add Gentamicin-eluting Bone Void Filler XW0V0P7

Lttr N
Main New Technology
Delete Antibiotic-eluting Bone Void Filler XW0V0P7

Add Gentamicin-eluting Bone Void Filler XW0V0P7

Substance Key entries to accompany this addenda proposal:

ICD-10-PCS Substance Key Addenda

Section X New Technology
Axis 6 Device / Substance / Technology
Term Delete Antibiotic-eluting Bone Void Filler
Term Add Gentamicin-eluting Bone Void Filler
Includes CERAMENT(R) G

OTL-103 Name Revised

Source	Description	Code specification
2025, public request with CMS internal review	In New Technology section table XW1 Transfusion, delete the axis 6 device/substance/technology value F OTL-103 applied to the body part 3 Peripheral Vein and the percutaneous approach. Additionally, revise the axis 6 device/substance/technology value F from OTL-103 to Etuvetidigene Autotemcel applied to the body part 4 Central Vein and the percutaneous approach. This change request is from the manufacturer and reflects the final name of the drug. According to the requestor, etuvetidigene autotemcel is only transfused using a central venous catheter, therefore code XW133F8 (Transfusion of OTL-103 into peripheral vein, percutaneous approach, new technology group 8) is not clinically valid. WASKYRA™ (etuvetidigene autotemcel), formerly known as OTL-103, received FDA approval on December 9, 2025. It is an ex vivo autologous hematopoietic stem cell-based gene therapy designed to correct the underlying genetic defect responsible for Wiskott–Aldrich Syndrome (WAS). The therapy uses the patient's own $CD34^+$ hematopoietic stem and progenitor cells (HSPCs), which are collected from mobilized peripheral blood and transduced with a self-inactivating lentiviral vector (LVV) encoding a functional copy of the human WAS complementary DNA (cDNA). Etuvetidigene autotemcel is indicated for pediatric patients aged six months and older and adults with WAS who have a mutation in the WAS gene and for whom hematopoietic stem cell transplantation (HSCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available. The requestor has submitted a New Technology Add-On Payment (NTAP) application for FY 2027 consideration.	Delete: XW133F8 (1 code) Revise: XW143F8 (1 code)

**All proposed addenda updates are being considered for implementation on October 1, 2026.*

EXAMPLE

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**1** Transfusion: Putting in blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein	**3** Percutaneous	**DELETE F** OTL-103 **G** Atidarsagene Autotemcel	**8** New Technology Group 8
4 Central Vein	**3** Percutaneous	**REVISE from F** OTL-103 **REVISE to F** Etuvetidigene Autotemcel **G** Atidarsagene Autotemcel	**8** New Technology Group 8

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr E
Main Add Etuvetidigene Autotemcel XW1

Lttr N
Main New Technology
Delete OTL-103 XW1
Add Etuvetidigene Autotemcel XW1

Lttr O
Main Delete OTL-103 XW1

Lttr W
Main Add WASKYRA(tm) use Etuvetidigene Autotemcel

Substance Key entries to accompany this addenda proposal:

ICD-10-PCS Substance Key Addenda

Section X New Technology
Axis 6 Device / Substance / Technology
Term Add Etuvetidigene Autotemcel
Includes Add WASKYRA(tm)

Topic # 29 – Restriction using Thoracoabdominal Branch Endoprosthesis

Issue: Should the ICD-10-PCS code that describes the insertion of a thoracoabdominal branch endoprosthesis be revised? An October 1, 2026 implementation date is being requested.

New Technology Add-On Payment? Yes. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) was approved for new technology add-on payment for FY 2025 (89 FR 69213 through 62915) and FY 2026 (90 FR 36669).

Food & Drug Administration (FDA) Approval? Yes. The GORE® TAMBE received FDA approval on January 12, 2024 under the Premarket Approval (PMA) process for the endovascular repair of thoracoabdominal aortic aneurysms and in high-surgical risk patients with pararenal aortic aneurysms who have the indicated anatomy.

Background: Thoracoabdominal aortic aneurysm **(**TAAA) and pararenal aortic aneurysm (PAAA) are life-threatening conditions for which limited treatment options exist. Open surgical repair is considered the gold standard of treatment; however, it is a technically challenging, invasive procedure that carries a significant risk of mortality and post-procedural complications. Alternatively, the requestor stated that some clinicians are treating these conditions with off-label options by using physician-modified endografts (PMEGs) that are custom-made and modified for each patient at the time of surgery. According to the requestor, these PMEGs have not been studied in a clinical trial or FDA-approved for use in the treatment of TAAA or PAAA.

A proposal to create a procedure code that identifies and describes the insertion of a thoracoabdominal branch endoprosthesis using the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) was presented and discussed at the March 19-20, 2024 ICD-10 Coordination and Maintenance Committee meeting. Subsequently ICD-10-PCS code X2VE3SA (Restriction of descending thoracic aorta and abdominal aorta using branched intraluminal device, manufactured integrated system, four or more arteries, percutaneous approach, new technology group 10) was finalized effective October 1, 2024 (FY 2025).

In the last few years great progress has been noted in device technology and operator experience in treating complex aortic aneurysms. The Zenith® t-Branch® (Cook Medical), Artivion E-nside™, and GORE® TAMBE are "off-the-shelf" (OTS) multibranched stent grafts, however the TAMBE is the only FDA approved commercially available device indicated for endovascular repair of Type IV TAAAs and high risk PAAAs. Other branched stent grafts are currently being trialed in the US or are part of PS-IDE studies; these same devices are available commercially outside of the United States (OUS) and some utilized as off label. The primary differences between the TAMBE and other branched devices lie in the branch design, the bridging stents from a sole sourced manufacturer (GORE®), and the specific anatomical applicability of the OTS design based on the diameter of the patient's aorta.

The requestor, the manufacturer of the TAMBE, performed their own analysis and stated they found that ICD-10-PCS code X2VE3SA has at times been used for procedures where the TAMBE was not supplied. According to the requestor, other available OTS stent grafts and PMEGs differ substantially from the TAMBE in that the fully integrated TAMBE is sole sourced from the manufacturer (GORE®) with the four visceral artery component bridging stents and all of the parts integral to TAMBE's modular design. Other available OTS multibranched stent

grafts and PMEGs combine a mixture of components from various manufacturers for the main body component and bridging stents that go through the portals into the superior mesenteric artery (SMA), the celiac artery, and the bilateral renal arteries. Therefore, the requestor requested a revision to the description of ICD-10-PCS code X2VE3SA to emphasize the fully integrated nature of the TAMBE and to distinguish it from pieced devices without manufactured branches, PMEGs, and other devices that do not come with the four sole-sourced visceral artery bridging stents integral to the TAMBE.

Technology

The TAMBE is an endoprosthesis that is used for endovascular repair in patients with type IV thoracoabdominal aortic aneurysms (TAAA) and high-surgical risk patients with pararenal aortic aneurysms (PAAA) who have appropriate anatomy. The TAMBE is comprised of multiple required sole source GORE® components including: 1) an Aortic Component, 2) Branch Components, 3) a Distal Bifurcated Component (DBC), and a 4) Contralateral Leg Component. The Aortic Component is designed to provide proximal (supra celiac) sealing and anchoring within the aorta and is placed proximal to the Distal Bifurcated Component. The SMA, celiac artery, and renal arteries are perfused via four antegrade portals in the Aortic Component. For some patients a DBC Extender Component may be used to reinforce the seal between the Aortic Component and the Distal Bifurcated Component. Also, the anatomy of some patients requires the use of an Iliac Extender endoprosthesis added distal to the contralateral leg component. Together, these components comprise the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE). The proximal end is placed in the thoracic aorta and the distal end in the iliac arteries.

Procedure Description

1. A brief overview of the procedural steps for endovascular placement of the TAMBE Device are described below (refer to the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis Instructions for Use for full details):
    a. Following standard clinical practice, arterial access is gained via bi-lateral iliac/femoral and brachial/axillary vascular access with five through-and-through guidewires.
    b. The TAMBE Device Aortic Component (AC) has four removable guidewire tubes to facilitate pre-cannulation of guidewires through the portals.
    c. The TAMBE Device AC on the delivery catheter is tracked via femoral / iliac access through a 22 Fr sheath and positioned with portals in proximity to the target branch vessels (celiac, superior mesenteric, and renal arteries). With the AC positioned in the aorta at a level where the outlet of the proximal portals is 1 to 3 cm above the origin of the most proximal visceral artery, deployment initiates from the leading end and proceeds toward the trailing end of the delivery system.
    d. Removing the white outer knob of the delivery system deploys the AC to approximately 50% of the final diameter while the proximal fixation anchors remain constrained. At this time the position can be adjusted. Once the desired position is confirmed, the gray nut on the delivery system is rotated counterclockwise to unconstrain the proximal end to engage the anchors into the aortic wall. From the upper extremity access, target branch vessels are sequentially cannulated from their respective pre-cannulated portal guidewires. Once all branch vessels are cannulated with appropriate wires exchanged and final positioning confirmed, the constraining system, which includes the secondary sleeve, can be removed. This is done by

sliding the red safety lock on the delivery system back with rotating the secondary deployment knob counterclockwise and pulling back.

e. The Branch Components are introduced through each AC portal into its target branch vessel and deployed.
f. Once three of the four branches are deployed, the distal sleeve of the AC can be deployed to fully deploy the distal end of the TAMBE Device AC. This is accomplished by rotating the gray deployment knob counterclockwise and pulling back.
g. Once the final stage of the TAMBE Device AC is deployed, the delivery catheter may be removed, and the final branch may be deployed.
h. The Distal Bifurcated Component, which bifurcates the TAMBE Device, is introduced into the distal portion of the TAMBE Device AC and deployed.
i. Deployment of the Contralateral Leg Components and any necessary limb extensions complete the TAMBE Device by mating with the Distal Bifurcated Component and sealing in the common iliac arteries. To complete the procedure, all component seal zones and junctions are ballooned with appropriate balloon catheters. A final angiogram may be performed to confirm exclusion of the aneurysm and device seal integrity.

Current Coding: In section X New Technology table X2V, Restriction, Cardiovascular System, use the device value S Branched Intraluminal Device, Manufactured Integrated System, Four or More Arteries, applied to the body part value E Descending Thoracic Aorta and Abdominal Aorta and the percutaneous approach, to identify restriction using thoracoabdominal branched endoprosthesis.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
E Descending Thoracic Aorta and Abdominal Aorta	**3** Percutaneous	**S** Branched Intraluminal Device, Manufactured Integrated System, Four or More Arteries	**A** New Technology Group 10

Coding Options

Option 1. Do not revise the ICD-10-PCS code for restriction using a thoracoabdominal branched endoprosthesis. Continue as described in current coding.

Option 2. In the New Technology section table X2V, revise the axis 6 device/substance/technology value S from Branched Intraluminal Device, Manufactured Integrated System, Four or More Arteries to Branched Intraluminal Device, Non-Modified, Manufactured Fully Integrated System, Four or More Arteries, to identify restriction using a thoracoabdominal branched endoprosthesis.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**V** Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
E Descending Thoracic Aorta and Abdominal Aorta	**3** Percutaneous	**REVISE from S** Branched Intraluminal Device, Manufactured Integrated System, Four or More Arteries	**A** New Technology Group 10

		REVISE to S Branched Intraluminal Device, Non-Modified, Manufactured Fully Integrated System, Four or More Arteries	

Index entries to accompany this option:

ICD-10-PCS Index Addenda

Lttr B
Main Revise from Branched Intraluminal Device, Manufactured Integrated System, Four or More Arteries, Aorta, Thoracoabdominal X2VE3SA
Main Revise to Branched Intraluminal Device, Non-Modified, Manufactured Fully Integrated System, Four or More Arteries, Aorta, Thoracoabdominal X2VE3SA

Lttr G
Main Revise from GORE(R) EXCLUDER(R) TAMBE Device (Thoracoabdominal Branch Endoprosthesis)
use Branched Intraluminal Device, Manufactured Integrated System, Four or More Arteries in New Technology
Main Revise to GORE(R) EXCLUDER(R) TAMBE Device (Thoracoabdominal Branch Endoprosthesis)
use Branched Intraluminal Device, Non-Modified, Manufactured Fully Integrated System, Four or More Arteries in New Technology

Lttr N
Main New Technology
Aorta
Delete Thoracoabdominal, Branched Intraluminal Device, Manufactured Integrated System, Four or More Arteries X2VE3SA
Add Thoracoabdominal, Branched Intraluminal Device, Non-Modified, Manufactured Fully Integrated System, Four or More Arteries X2VE3SA

Lttr T
Main Revise from TAMBE Device (Thoracoabdominal Branch Endoprosthesis), GORE(R) EXCLUDER(R)
use Branched Intraluminal Device, Manufactured Integrated System, Four or More Arteries in New Technology
Main Revise to TAMBE Device (Thoracoabdominal Branch Endoprosthesis), GORE(R) EXCLUDER(R)
use Branched Intraluminal Device, Non-Modified, Manufactured Fully Integrated System, Four or More Arteries in New Technology

Device Key entries to accompany this option:

ICD-10-PCS Device Key Addenda

Axis 6	Device	
Row		
Term	Delete	Branched Intraluminal Device, Manufactured Integrated System, Four or More Arteries in New Technology
Term	Add	Branched Intraluminal Device, Non-Modified, Manufactured Fully Integrated System, Four or More Arteries in New Technology
Includes		GORE(R) EXCLUDER(R) TAMBE Device (Thoracoabdominal Branch Endoprosthesis) TAMBE Device (Thoracoabdominal Branch Endoprosthesis), GORE(R) EXCLUDER(R)

CMS Recommendation: Option 1, as described above.

Rationale: CMS notes that while a newly established ICD-10 code may be associated with an application for new technology add-on payment, such codes are generally not created to be product specific. At the time code proposals are presented in association with ICD-10 Coordination and Maintenance Committee updates, all efforts are made to provide code title descriptions in accordance with the conventions of the classification. Accordingly, under our established process, we have previously presented and discussed proposals to revise the code title for procedure codes that identify and describe specific procedures, services, or technologies in rare and limited circumstances.

Interim Coding Advice: Continue as described in current coding.

Topic # 30 – Administration of ifezuntirgene inilparvovec

Issue: There are no unique ICD-10-PCS codes to describe the administration of ifezuntirgene inilparvovec, an investigational gene therapy candidate for Huntington's disease. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-On Payment (NTAP) application for future consideration.

Food & Drug Administration (FDA) Approval? No. Ifezuntirgene inilparvovec received Orphan Drug Designation (September 27, 2017), Fast Track Designation (February 14, 2019), Regenerative Medicine Advanced Therapy (RMAT) Designation (May 29, 2024), and Breakthrough Therapy Designation (April 11, 2025) from the FDA for the treatment of Huntington's disease. The requestor intends to seek approval under a Biologics License Application.

Background: Huntington's disease (HD) is a rare, fatal, inherited neurodegenerative disorder that leads to motor symptoms, behavioral abnormalities and cognitive decline resulting in progressive physical and mental deterioration and early mortality. The disease is an autosomal dominant condition with a disease-causing expanded cytosine-adenine-guanine (CAG) repeat in exon 1 of the huntingtin gene that leads to the production and aggregation of toxic protein in the brain. In the United States, approximately 40,000 people have HD and over 1,000 people die from the disease each year. According to the requestor, despite the clear etiology of HD, there are currently no approved disease-modifying therapies to slow the disease's progression; as such, there is an urgent unmet need for a disease-modifying therapy.

Mechanism of Action
Ifezuntirgene inilparvovec is an investigational gene therapy candidate that uses an adeno-associated virus type 5 (AAV5) vector to deliver a microRNA (miRNA) that targets the huntingtin (HTT) messenger RNA (mRNA). The miRNA is processed by the cell's own machinery, and the mature miRNA binds to the HTT mRNA, causing it to be cleaved and degraded. This process is expected to lower the production of HTT protein, including the mutant version that causes Huntington's disease, and is designed to be a one-time treatment approach. Ifezuntirgene inilparvovec is infused directly into the brain's deep structures (striatum). The AAV5 vector then enters the cell and is transported to the nucleus, where its genetic material is released. The gene for the miRNA is expressed, and the cell's own RNA interference machinery processes it into a mature, active miRNA. The mature miRNA binds to the HTT mRNA instructions. The binding marks the HTT mRNA for destruction, effectively stopping the cell from making the HTT protein. By lowering the HTT mRNA, the overall production of HTT protein, both the normal and the mutant versions, is reduced, which is expected to prevent the formation of toxic protein aggregates.

According to the requestor, the most common adverse events in the clinical studies, as of June 2025, occurred early after the administration of ifezuntirgene inilparvovec and were mainly related to study procedures. The minimally invasive treatment procedure involved with the intraparenchymal administration of ifezuntirgene inilparvovec entails risks comparable to that involved in similar procedures, such as implantation of an electrode for deep brain stimulation.

Inpatient Administration of ifezuntirgene inilparvovec
Ifezuntirgene inilparvovec is infused via magnetic resonance imaging (MRI)-guided, convection-enhanced stereotactic neurosurgical delivery bilaterally directly into the brain's striatum (caudate and putamen). The single administration procedure consists of three infusions per hemisphere (two in the putamen and one in the caudate), for a total of six infusions. The target volume of each infusion is up to the maximal dose of 500 μL. Each patient will receive up to a target maximum dose of 3 mL of ifezuntirgene inilparvovec. The surgery is performed under general anesthesia. Trajectories for intrastriatal infusion of ifezuntirgene inilparvovec are assessed in real time using MRI guidance. Per the requestor, the administration of ifezuntirgene inilparvovec will be a single inpatient procedure, allowing time for the infusions and a minimum of one day to monitor patients.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of ifezuntirgene inilparvovec. Facilities can report the neurosurgical administration of ifezuntirgene inilparvovec using the following codes:

00H033J	Insertion of infusion device into brain, temporary, percutaneous approach
3E0Q3GC	Introduction of other therapeutic substance into cranial cavity and brain, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe the neurosurgical administration of ifezuntirgene inilparvovec. Continue as described in current coding.

Option 2. In section X table XW0, Introduction of Anatomical Regions, create new substance value 5 Ifezuntirgene Inilparvovec, applied to the body part value Q Cranial Cavity and Brain, and the percutaneous approach, to identify the neurosurgical administration of ifezuntirgene inilparvovec. Facilities would separately report insertion of the temporary infusion device.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
Q Cranial Cavity and Brain	**3** Percutaneous	**ADD 5** Ifezuntirgene Inilparvovec	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 31 – Allogeneic Stem Cell-derived, Insulin-producing Islet cell Therapy for Hepatic Portal Vein Infusion

Issue: There are no unique ICD-10-PCS codes to describe the administration of zimislecel. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-On Payment (NTAP) application for future consideration.

Food & Drug Administration (FDA) Approval? No. Zimislecel has been granted Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations from the FDA. Zimislecel is being evaluated for patients who have type 1 Diabetes (T1D) with impaired hypoglycemic awareness and severe hypoglycemia. An additional study will evaluate zimislecel in individuals with T1D who have had a prior kidney transplant and are already on immunosuppression.

Background: Pancreatic islets regulate blood glucose levels through secretion of hormones in response to increases and decreases in blood glucose. Beta cells within pancreatic islets release insulin in a highly regulated manner that stimulates glucose uptake by peripheral tissues providing physiological control of blood glucose. T1D results from the autoimmune destruction of insulin-producing beta cells in pancreatic islets and results in the complete deficiency of insulin. Insulin deficiency results in hyperglycemia and can lead to acute life-threatening complications such as ketoacidosis and dehydration.

Approximately 1.4 million Americans suffer from T1D.[1] Patients with T1D are reliant on lifelong treatment with exogenous insulin that requires careful monitoring of blood glucose levels. Even with the availability of advanced exogenous insulin delivery and glucose monitoring systems, people with T1D can have periods of very low and very high blood sugar levels. Exogenous insulin has a narrow therapeutic range and carries an inherent risk of causing low blood sugar levels or hypoglycemic events, which can potentially result in severe events requiring assistance of another person due to severity of symptoms. Untreated, severe hypoglycemia can cause cardiac arrhythmias, seizures, coma, accidents, and even death. Exposure to prolonged periods of high blood glucose levels, or hyperglycemia, can lead to long-term complications such as nerve damage, kidney disease/failure, eye disease (including vision loss), cardiovascular disease, stroke and even death.

Despite advances in the standard of care and due to the limitations and complexities of exogenous insulin treatment, it can be difficult for people with T1D to achieve and maintain good glucose control safely, in other words, without the risks of severe hypoglycemia. Restoring the function of islets can lead to physiologic glycemic control without an increased risk of hypoglycemia.[2,3] Beta-cell replacement with the use of islet or pancreas transplantation reduces or eliminates the need for insulin therapy, which decreases the risk of severe hypoglycemia

[1] Centers for Disease Control and Prevention: National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States., Atlanta, GA, USA (2020)
[2] Holt RIG, DeVries JH, Hess-Fischl A, et al. The management of type 1 diabetes in adults: a consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2021;44:2589-2625.
[3] Choudhary P, Rickels MR, Senior PA, et al. Evidence-informed clinical practice recommendations for treatment of type 1 diabetes complicated by problematic hypoglycemia. Diabetes Care 2015;38:1016-1029.

caused by insulin. However, beta-cell replacement is limited by organ availability and variable islet quality.[2,4] The need for multiple transplants from multiple donors in order to achieve acceptable clinical outcomes further limits the usefulness of islet transplantation.[5,6,7] Directed differentiation of pluripotent (capable of giving rise to several different cell types) stem cells into specialized cell types can potentially provide an inexhaustible supply of replacement tissues for serious diseases. Studies have shown that pluripotent stem cells can be differentiated into insulin-expressing beta cells and glucagon-expressing alpha cells and have shown to be capable of reversing diabetes in preclinical models.[8,9]

Mechanism of Action
Zimislecel, formerly known as VX-880, is an investigational allogeneic stem cell-derived, fully differentiated, insulin-producing islet cell therapy manufactured using proprietary technology, aimed at restoring physiological insulin production in select people with T1D.[10] Human pluripotent stem cells are directed with growth factors and small molecules to differentiate into the islet cells that comprise zimislecel. These islets resemble native human islets that are responsible for glucose regulation. According to the requestor, zimislecel has the potential to restore the body's ability to regulate glucose levels by restoring pancreatic islet cell function, including glucose-responsive insulin production. Zimislecel is delivered by an infusion into the hepatic portal vein and requires chronic immunosuppressive therapy to protect the islet cells from immune rejection.

Zimislecel is being evaluated in a phase 1/2/3 study in people with T1D with impaired hypoglycemic awareness and severe hypoglycemic events (SHEs) (FORWARD-101; NCT04786262) and in a phase 3 study of patients who have received a prior kidney transplant (FORWARD-102; NCT06832410). In the phase 1/2 FORWARD study (Reichman et al 2025 NEJM), following a single infusion of the full dose of zimislecel participants demonstrated engraftment of islets with glucose responsive endogenous insulin production, elimination of SHEs, improvement in glycemic control to American Diabetes Association (ADA) target levels (HbA1c <7% and TIR >70%), and reduction in exogenous insulin use. Additionally, 10 of 12 participants were able to eliminate insulin use. No serious adverse events were considered related to zimislecel. In the phase 1/2 data published in June 2025, the majority of adverse events (AEs) were mild or moderate in severity. There were no serious AEs considered related to zimislecel treatment. Two patient deaths were reported, both unrelated to treatment with zimislecel. The safety profile of zimislecel is consistent with the immunosuppressive regimen and the infusion procedure.

Inpatient Administration of zimislecel
Zimislecel is administered by means of a single gravity-assisted infusion through a catheter in the hepatic portal vein. All recipients require an induction and maintenance immunosuppressive

[4] Vantyghem M-C, Chetboun M, Gmyr V, et al. Ten-year outcome of islet alone or islet after kidney transplantation in type 1 diabetes: a prospective parallel-arm cohort study. Diabetes Care 2019;42:2042-2049.
[5] Gamble A, Pepper AR, Bruni A, Shapiro AMJ. The journey of islet cell transplantation and future development. Islets 2018;10:80-94.
[6] Bellin MD, Barton FB, Heitman A, et al. Potent induction immunotherapy promotes long-term insulin independence after islet transplantation in type 1 diabetes. Am J Transplant 2012;12:1576-1583.
[7] Shapiro AMJ. State of the art of clinical islet transplantation and novel protocols of immunosuppression. Curr Diab Rep 2011;11:345-354.
[8] Pagliuca FW, Millman JR, Gürtler M, et al. Generation of functional human pancreatic β cells in vitro. Cell 2014;159:428-439.
[9] Veres A, Faust AL, Bushnell HL, et al. Charting cellular identity during human in vitro β-cell differentiation. Nature 2019;569:368-373.
[10] Reichman TW, et al. N Engl J Med. 2025;393(9):858-868.

regimen before and after zimislecel infusion to protect the allogeneic islet cells from the recipient's immune system.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of zimislecel. Facilities can report the intravenous portal vein administration of zimislecel using the following code:

3E033U1	Introduction of nonautologous pancreatic islet cells into peripheral vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes the intravenous administration of zimislecel. Continue as described in current coding.

Option 2. In section X table XW0, Introduction of Anatomical Regions, create new substance value 7 Zimislecel Allogeneic Stem Cell-derived Islet Cell Therapy, applied to the body part value 3 Peripheral Vein, and the percutaneous approach, to identify the intravenous administration of zimislecel.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein	**3** Percutaneous	**ADD 7** Zimislecel Allogeneic Stem Cell-derived Islet Cell Therapy	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 32 – Administration of landiolol

Issue: There are no unique ICD-10-PCS codes to describe the administration of landiolol. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? Yes. RAPIBLYK® (landiolol) was approved by the FDA on November 22, 2024, and is indicated for the short-term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter.

Background: Supraventricular arrhythmia (SVA) is a broad term for a very fast or erratic heartbeat caused by abnormal electrical activity in the heart that affects the atria, or upper chambers. When the heart beats too fast, it cannot effectively pump blood through the body. As a result, the organs and tissues may not get enough oxygen. There are several different types of supraventricular arrhythmias, including supraventricular tachycardia (SVT), atrial fibrillation (AF) and atrial flutter.

Supraventricular tachycardia (SVT) is a type of irregular heartbeat that begins in the atria due to abnormal electrical connections in the heart . Symptoms of SVT include heart palpitations, dizziness or lightheadedness, shortness of breath, chest pain, tightness in the throat, sweating, or fainting. Sometimes, SVT can lead to cardiac arrest, in which the heart stops beating. AF is a heart rhythm problem where the heart's upper chambers (the atria) beat irregularly. AF is the most commonly treated cardiac arrhythmia and its incidence is increasing globally.[1] Additionally, AF and heart failure (HF) predispose one another and often occur in combination, leading to poor disease prognosis, and sepsis is strongly associated with the development of AF. Nonselective beta-blockers are not recommended for use in clinically fragile patient populations, such as patients with chronic HF experiencing supraventricular arrhythmia.

RAPIBLYK® (landiolol) is an intravenous beta-adrenergic blocker indicated for the short-term reduction of ventricular rate in adults with SVT, including AF and atrial flutter. It is used under continuous cardiac monitoring, typically for short durations (less than 24 hours), and is discontinued as soon as stable rhythm control is achieved or when transitioning to longer-acting therapies. RAPIBLYK® is the only injectable beta-blocker with an FDA-recognized dosing regimen for patients with cardiac impairment.

According to the requestor, compared to older beta-blockers, RAPIBLYK® offers superior heart rate control with lower hypotension risk and minimal beta-2–related side effects. RAPIBLYK® has rapid onset and offset of action, achieved through fast metabolism by plasma esterases, and its pharmacokinetics minimize accumulation and reduce the risk of prolonged bradycardia or hypotension. This allows clinicians to titrate the dose minute-to-minute and quickly reverse effects if needed. Because of its short half-life (about 4 minutes, which is the shortest for any available beta blocker) and rapid metabolism, RAPIBLYK® can be valuable in critical care, perioperative

[1] Joglar JA, Chung MK, Armbruster AL, et al. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation 2024; 149:e1.

care, or emergency situations where immediate rate control is needed but prolonged beta-blockade could increase the risk of harm.

Mechanism of Action
RAPIBLYK® directly blocks β_1-adrenergic receptors on cardiac myocytes, thereby preventing catecholamine-induced increases in heart rate and conduction velocity. This results in immediate negative chronotropic effects that are independent of parasympathetic pathways, thereby allowing RAPIBLYK® to rapidly reduce heart rate even during heightened sympathetic activity, such acute stress or perioperative settings.

β1 receptors are predominant in the heart myocardium (75%), but β2 receptors are also present (25%). As a short-acting, highly selective β1 adrenergic blocker, RAPIBLYK® specifically targets cardiac β1 receptors to slow the heart rate without significantly affecting β2 receptors in the lungs and blood vessels. According to the requestor, RAPIBLYK® is 100 times more selective for β1 receptors compared to intravenous (IV) metoprolol, a nonselective beta blocker, and 7-8 times more selective than esmolol. This selectivity reduces the risk of hypotension caused by β2 blocking. By inhibiting the effects of adrenaline and noradrenaline on the heart, RAPIBLYK® reduces heart rate, decreases spontaneous firing, slows conduction, and increases the refractory period of the atrioventricular node of the heart.

According to the requestor, RAPIBLYK® provides an effective tool for achieving rapid rate control with a high safety margin, especially in patients with chronic heart failure experiencing tachyarrhythmia, patients with post-operative atrial fibrillation (POAF) or at high risk of POAF, and patients in septic shock experiencing tachycardia. RAPIBLYK® was studied in 19 placebo-controlled clinical trials involving 1,761 patients (in a variety of clinical inpatient settings) with SVT or at high risk for SVT. The most common adverse reaction was hypotension, which occurred in 9.9% of patients receiving RAPIBLYK® vs. 1% in those receiving placebo.

Inpatient Administration of landiolol
RAPIBLYK® is administered via continuous IV infusion and titrated according to ventricular rate and effect to achieve rapid heart rate control in patients, including those with serious comorbidities, such as impaired cardiac function.

In the inpatient setting for patients with normal cardiac function, dosing is started at 9 mcg/kg/min, adjusted in 10-minute intervals as needed in increments of 9 mcg/kg/min, to a maximum of 36 mcg/kg/min. For patients with impaired cardiac function, dosing is started at 1 mcg/kg/min, adjusted in 15- minute intervals as needed in increments of 1 mcg/kg/min, to a maximum of 36 mcg/kg/min. The average patient will require 5 vials of RAPIBLYK®, with up to 8 vials needed for patients in septic shock.

RAPIBLYK® will be administered based on the clinical indication to patients primarily within the Intensive Care Unit and Coronary Intensive Care Unit (ICU/CICU) settings in the inpatient hospital. Continuous monitoring is required throughout the administration to ensure patient safety. While the ICU and CICU remain the primary care settings where landiolol will be administered, RAPIBLYK® may also be given in emergency rooms or post-surgical observational settings, provided the necessary monitoring infrastructure is in place. Currently, RAPIBLYK® is anticipated to have 100% inpatient use. However, there may be potential for outpatient use in the future (in selected facilities with the appropriate monitoring and tools for administration).

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of landiolol. Facilities can report the intravenous administration of landiolol using one of the following codes:

3E033RZ	Introduction of antiarrhythmic into peripheral vein, percutaneous approach
3E043RZ	Introduction of antiarrhythmic into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of landiolol. Continue as described in current coding.

Option 2. In section X table XW0, Introduction, Anatomical Regions, create new substance value 6 Landiolol Antiarrythmic, applied to the body part values 3 Peripheral Vein and 4 Central Vein and the percutaneous approach, to identify the intravenous administration of landiolol.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 6** Landiolol Antiarrhythmic	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 33 – Administration of elamipretide

Issue: There is no unique ICD-10-PCS code to identify the administration of elamipretide to improve muscle strength in adult and pediatric patients with Barth syndrome. An October 1, 2026 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-On Payment (NTAP) application for future consideration.

Food & Drug Administration (FDA) Approval? Yes. Elamipretide was granted Accelerated Approval and Orphan Drug designation under the new drug application (NDA) for the indication of improving muscle strength in adult and pediatric individuals with Barth syndrome who weigh at least 30 kg, as of September 19, 2025.

Background: Barth syndrome is a rare, serious, and life-threatening disorder caused by mutations in an X-linked gene (*TAZ*) that encodes the mitochondrial protein tafazzin**.** characterized by the triad of cardiomyopathy, skeletal muscle weakness, and growth delay. Genetic defects in the tafazzin, phospholipid-lysophospholipid transacylase or TAZ gene, responsible for protein coding, result in inadequate cardiolipin biosynthesis and remodeling. Cardiolipin is a complex glycerophospholipid with 4 acyl groups that is an integral component of mitochondrial structure and function. Although Barth syndrome has variable penetrance, it primarily affects male individuals, and cardiomyopathy is the most frequent clinical manifestation responsible for the high risk of death during infancy in this population. Individuals with Barth Syndrome who survive into adolescence and adulthood often have fatigue, poor stamina, and exercise intolerance. Barth syndrome occurs in 1:300,000–400,000 live births, with less than 150 patients in the United States (US), and as such, has been designated as a "rare pediatric disease." Per the requestor, elamipretide therapy is a mitochondria-targeting tetrapeptide that readily penetrates and localizes to the inner mitochondrial membrane, where it associates with cardiolipin, targeting the mitochondrial dysfunction seen in Barth syndrome and facilitating cell health by improving energy production in affected tissues. During clinical trials, elamipretide has been shown to enhance mitochondrial adenosine triphosphate (ATP) synthesis in multiple organs and tissues, including the heart, kidney, neurons, and skeletal muscle. According to the requestor, other therapeutic compounds such as beta 1-receptor agonists, benefit dissipates rapidly after withdrawal of therapy, while elamipretide appears to have a durable effect, which during chronic use, actively elicits structural, functional, and biochemical benefits.

Mechanism of Action
Elamipretide is a water-soluble, aromatic-cationic, mitochondria-targeting tetrapeptide and cardiolipin binder that readily penetrates and transiently localizes to the inner mitochondrial membrane. Cardiolipin plays an integral role in mitochondrial function by facilitating cristae formation, mitochondrial fusion, and mitochondrial DNA (deoxyribonucleic acid) stability, leading to appropriate segregation and organization of the mitochondrial respiratory complexes into super complexes that are used for cellular energy production through oxidative phosphorylation. Per the requestor, elamipretide improves inner mitochondrial membrane stability, protein–protein interactions and reduces pathogenic formation of reactive oxygen

species. By improving cardiolipin biosynthesis and remodeling, elamipretide targets the key deficits in Barth syndrome, improving heart and skeletal muscle functioning.

According to the requestor, in a randomized, double-blind, placebo-controlled clinical trial followed by a 168-week open-label extension in individuals with Barth syndrome, evaluating approximately 25% of the US Barth syndrome population, hypersensitivity reactions, including serious allergic reactions requiring emergency medical intervention, have been reported. The reactions included skin manifestations such as rash, papular lesions, and eczematous dermatitis, as well as respiratory symptoms, such as cough. Reactions may occur within minutes to months after treatment initiation. Overall, the requestor maintains that elamipretide is well tolerated both acutely and in the long term, with the most common adverse events being injection-site reactions (80%), including erythema and pruritus, and injection-site pain (70%).

Inpatient Administration of elamipretide
Elamipretide is administered daily as a subcutaneous injection in the abdomen or outer thigh and should be administered at the same time each day, rotating injection sites. Dosing for adults and children greater than 30 kg is 40 mg subcutaneously once daily. Dosing for individuals with kidney impairment (eGFR less than 30 mL/min, not on dialysis) is 20 mg daily. The unopened multi-dose vial should be stored refrigerated at 36-46°F (do not freeze). Before administering, the vial should be allowed to reach room temperature (10+ minutes) and can then be stored at room temperature for 8 days after opening. If a dose is missed, skip the dose and take the next dose of elamipretide at the scheduled time. Do not take a double dose of elamipretide. Continuation therapy for chronically ill individuals discharged from the hospital will occur at home.

Current Coding: There is no unique ICD-10-PCS code to describe the administration of elamipretide. Facilities can report the subcutaneous administration of elamipretide using the following code:

3E013GC	Introduction of other therapeutic substance into subcutaneous tissue, percutaneous approach

Coding Options

Option 1. Do not create a new ICD-10-PCS code for the subcutaneous administration of elamipretide. Continue as described in current coding.

Option 2. In section X table XW0, Introduction, Anatomical Regions, create new substance value 4 Elamipretide, applied to the body part value 1 Subcutaneous Tissue, and the percutaneous approach, to identify the subcutaneous administration of elamipretide.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
1 Subcutaneous Tissue	**3** Percutaneous	**ADD 4** Elamipretide	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.