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

CENTER FOR MEDICARE

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 2025

CMS will not be presenting the Spring 2025 ICD-10-PCS procedure code topics during a public meeting. Instead, CMS will be posting the meeting materials and soliciting public comments regarding any clinical questions or coding options consistent with the approach we 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, 2025 implementation is **April 18, 2025.**

Members of the public should send any questions or comments related to the procedure code topics that are under consideration for an October 1, 2025 implementation to the CMS mailbox at: ICDProcedureCodeRequest@cms.hhs.gov by the April 18, 2025 deadline.

All meeting 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 deadline.

Note: Questions regarding the Diagnosis code topics should be directed to the Centers for Disease Control and Prevention's National Center for Health Statistics at nchsicd10cm@cdc.gov.

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

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Topics Being Considered for ICD-10-PCS Procedure Codes[1]

Introductions & Overview	Mady Hue, CMS Co-Chair, ICD-10 Coordination and Maintenance Committee
ICD-10-PCS Topics:	
1. Transfer of Vascularized Nasal Tissue Pages 12-14	Andrea Hazeley, CMS Lynn Kuehn, MS, RHIA, CCS-P, FAHIMA President Kuehn Consulting, LLC
2. Introduction of Peptide Enhanced Bone Void Filler in Transforaminal Lumbar Interbody Fusion Procedures* Pages 15-17	Andrea Hazeley, CMS Alan French Senior Strategic Partner EQUITAS Life Sciences Mickey Brown Vice President Cerapedics Inc.
3. Dilation of Arteriovenous Fistula with Cell Impermeable Endoprosthesis* Pages 18-21	Andrea Hazeley, CMS Mahmood K. Razavi, MD, FSIR, FSVM Medical Director Dept. of Clinical Trials St. Joseph Heart & Vascular Center Leah Amir, MS, MHA Executive Director Institute for Quality Resource Management
4. Dilation of Carotid Artery with Integrated Embolic Protection* Pages 22-24	Jeanine DuVerney, CMS William A. Gray, MD, FACC Division of Cardiology Lankenau Heart Institute, Main Line Health

[1]*The slide presentations and recordings for these procedure code topics will be made available at:* https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials.

5. Computer-aided Triage and Notification Software for Measurement of Biomarkers** Pages 25-26	Jeanine DuVerney, CMS Jim Sianis, PharmD, MBA Executive Director Prenosis
6. Addenda and Key Updates Pages 27-39	Andrea Hazeley, CMS
7. Insertion of Volume Sensor Management Device** Pages 40-43	Mady Hue, CMS Mandeep Mehra, MD Professor of Medicine Harvard Medical School
8. Announcements Page 44	Mady Hue, CMS
9. Division of Aortic Valve Leaflets Using Radiofrequency Energy** Pages 45-47	Mady Hue, CMS Toby Rogers, MD Valvular & Structural Heart Disease Medstar Washington Hospital Center
10. Gene Expression Testing System for Whole Blood Samples* Pages 48-50	Andrea Hazeley, CMS Sam Ajizian Chief Medical Officer Inflammatix Tim Sweeney Chief Executive Officer Inflammatix
11. Dilation using Expandable Intraluminal Device with Growth Technology* Pages 51-54	Andrea Hazeley, CMS Evan Zahn Director, Division of Pediatric Cardiology & Guerin Family Congenital Heart Program, Cedars-Sinai; Chief Medical Officer, Renata Medical Dustin Armer Co-Founder & Chief Executive Officer Renata Medical

19. Stereotactic-aided Intraprocedural Neuronavigation System Pages 86-89	Mady Hue, CMS Daniel J. Curry, MD Director, Functional Neurosurgery and Epilepsy Surgery Texas Children's Hospital
20. Sacroiliac Joint Fusion/Pelvic Fracture Fixation with Threaded Implant System* Pages 90-93	Mady Hue, CMS W. Carlton Reckling Chief Medical Officer SI-Bone
21. Quantitative Analysis of Human Milk Macronutrient Content* Pages 94-95	Jeanine DuVerney, CMS Stephanie Canale, MD Physician CEO Lactation Lab Inc.
Closing Remarks	Mady Hue, CMS
22. Morphological Structure Analysis System Pages 96-97	Jeanine DuVerney, CMS Greg Shaw, MD Professor of Urology University College of London Hospital Leslie Stephens VP, Market Access and Marketing SamanTree Medical
23. Inspection of Upper GI Tract using Ingestible Wireless Capsule Pages 98-99	Jeanine DuVerney, CMS Andrew Storm, MD Director of Endoscopy Mayo Clinic
24. Insertion of Posterior Cervicothoracic Spinal Stabilization System* Pages 100-103	Mady Hue, CMS Ankit I. Mehta, MD Chief of Spine University of Illinois at Chicago
25. Cervical Spinal Fusion with Custom-Made Anatomically Designed Interbody Fusion Device* Pages 104-106	Mady Hue, CMS Christopher J. Salmen, M.B.S. Vice President, Health Economics & Patient Access Carlsmed, Inc

26. Radiofrequency Ablation of Cardiac Plexus** Pages 107-110	Mady Hue, CMS Giora Weisz, MD Director Cardiac Catheterization Laboratory New York-Presbyterian Hudson

Therapeutic Agent Topics Also Under Consideration for ICD-10-PCS Codes

27. Administration of fosfomycin anti-infective* Pages 111-114	Andrea Hazeley, CMS
28. Administration of xanomeline & trospium chloride* Pages 115-116	Jeanine DuVerney, CMS
29. Administration of iloprost* Pages 117-120	Mady Hue, CMS
30. Administration of fibrinogen (human) concentrate* Pages 121-122	Jeanine DuVerney, CMS
31. Administration of letetresgene autoleucel (lete-cel)** Pages 123-125	Andrea Hazeley, CMS
32. Administration of mozafancogene autotemcel (fanca-cel)** Pages 126-128	Mady Hue, CMS
33. Administration of aztreonam-avibactam* Pages 129-131	Andrea Hazeley, CMS
34. Administration of rozanolixizumab-noli* Pages 132-133	Jeanine DuVerney, CMS

** Requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2026.*
*** Requestor intends to submit a NTAP application for FY 2027 consideration.*

Continuing Education Credits:
Continuing education 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 either statement, please contact the respective organization, not CMS.

Contact Information
Comments on the Spring 2025 procedure code topics should be sent to the following email address: ICDProcedureCodeRequest@cms.hhs.gov

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Andrea Hazeley
Andrea.Hazeley@cms.hhs.gov

Jeanine DuVerney
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ICD-10 TIMELINE

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

March 2025	The Spring 2025 ICD-10 Coordination and Maintenance Committee Update will open the ICD-10-PCS topics for public comment.
March 2025	Recordings and slide presentations of the Spring 2025 ICD-10 Coordination and Maintenance Committee Update will be posted on the following web page: **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
April 1, 2025	Any new or revised ICD-10 codes will be implemented on April 1, 2025.
April 18, 2025	**Deadline for receipt of public comments on proposed new procedure codes and revisions displayed in association with the Spring 2025 ICD-10 Coordination and Maintenance Committee Update being considered for implementation on October 1, 2025**.
April 2025	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 2026 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/medicare-fee-for-service-payment/acuteinpatientpps
May/June 2025	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 6, 2025	**Deadline for requestors: Those members of the public requesting that topics be considered for the Fall 2025 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.**

	Requestors should indicate if they are submitting their code request for consideration for an April 1, 2026 implementation date or an October 1, 2026 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, 2026 implementation date or an October 1, 2026 implementation date.
August 2025	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, 2025. This rule can be accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html

Introductions and Overview

- The ICD-10 Coordination & Maintenance (C&M) Committee provides a public forum for ICD-10 code updates
- CMS has lead responsibility on procedure code issues
- Coding proposals requested by the public are provided and the public is given the opportunity to comment

Code Proposals and Public Comments

- ICD-10-PCS code proposals are being considered for implementation on October 1, 2025
- Submit written comments by April 18, 2025 to CMS at: ICDProcedureCodeRequest@cms.hhs.gov

Proposed and Final Rules

- April 2025 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to Spring 2025 C&M Committee Update

- August 2025 – Final rule with links to final codes to be implemented October 1, 2025
  - Includes any additional codes approved from Spring 2025
  - https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps

Addenda

- May/June 2025 – Final code updates and addenda posted
  - FY 2026 ICD-10-PCS (Procedures) https://www.cms.gov/medicare/coding-billing/icd-10-codes
  - FY 2026 ICD-10-CM (Diagnoses) https://www.cdc.gov/nchs/icd/icd-10-cm/files.html

Topic # 01 – Transfer of Vascularized Nasal Tissue

Issue: There are currently no unique ICD-10-PCS codes to describe the transfer of vascularized nasal tissue in procedures to reconstruct defects in the skull base. An October 1, 2025 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No.

Background: Skull base defects present a major challenge in head and neck reconstructive surgery. The main goal of skull base reconstruction is to create a watertight separation between the intracranial cavity and aerodigestive tract. Successful reconstruction aims to avoid complications, such as meningitis, intracranial abscesses, encephaloceles, cerebrospinal fluid (CSF) leaks, and tension pneumocephalus. Small skull base defects can be successfully repaired using a variety of free grafts and other techniques however, free tissue grafting is not as dependable when reconstructing larger, more complex skull base defects (>3 cm).[1] Currently, pedicled flaps provide the most reliable technique when used as a component of a multilayer reconstruction for the repair of large skull base defects. Pedicled flaps can be employed in the reconstruction of a variety of skull base defects. They do not require a wide base, have greater reach, and mobilize easier to the defects. Their mobility also helps in conforming well to irregular surfaces, which are common at the skull base. The nasoseptal flap remains the most widely used vascular pedicled flap for endoscopic repair of skull base defects.[2] The advantages of the NSF include an endoscopic graft harvest avoiding a second incision and the ability to cover most anterior skull base defects based on radioanatomic studies.[3] The nasoseptal flap is associated with minimal morbidity and low rates of CSF leaks (< 5%) compared to free grafts.[4]

Technology
The nasoseptal flap (NSF) is a mucosa-based flap that uses a vascular pedicle within the nasal cavity. The NSF receives vascularization from the posterior septal artery (PSA), a terminal branch of the sphenopalatine artery. Also known as the Hadad-Bassagasteguy flap, the NSF was first described in 2006 and was rapidly adopted as the primary reconstructive method for reconstruction in endoscopic endonasal surgery (EES) of the skull base.[5] Its ease of harvest, wide arch of rotation, and high success rates make it a popular choice among surgeons. Post-operative complications associated with these flaps can include nasal crusting/discharge, atrophic rhinitis, and olfactory changes but nasal life quality scores are usually not significantly impacted with these endoscopic techniques.[6]

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[1] Kim GG, Hang AX, Mitchell CA, Zanation AM. Pedicled extranasal flaps in skull base reconstruction. Adv Otorhinolaryngol. 2013;74:71-80. doi: 10.1159/000342282. Epub 2012 Dec 18. PMID: 23257554; PMCID: PMC3568756.
[2] Gutierrez WR, Bennion DM, Walsh JE, Owen SR. Vascular pedicled flaps for skull base defect reconstruction. Laryngoscope Investigative Otolaryngology. 2020;5:1029–1038. https://doi.org/10.1002/lio2.471.
[3] Pinheiro-Neto CD, Prevedello DM, Carrau RL, Snyderman CH, Mintz A, Gardner P, Kassam A. Improving the design of the pedicled nasoseptal flap for skull base reconstruction: a radioanatomic study. Laryngoscope. 2007 Sep;117(9):1560–9. doi: 10.1097/MLG.0b013e31806db514.
[4] Kwon D, Iloreta A, Miles B, Inman J. Open anterior skull base reconstruction: a contemporary review. Semin Plast Surg 2017;31:189-96.
[5] Hadad G, Bassagasteguy L, Carrau R L et al. A novel reconstructive technique after endoscopic expanded endonasal approaches: vascular pedicle nasoseptal flap. Laryngoscope. 2006;116(10):1882–1886. doi: 10.1097/01.mlg.0000234933.37779.e4.
[6] Reyes C, Mason E, Solares CA. Panorama of reconstruction of skull base defects: from traditional open to endonasal endoscopic approaches, from free grafts to microvascular flaps. Int Arch Otorhinolaryngol 2014;18:S179-86.

The nasoseptal flap (NSF) is classically described as harvesting septal mucosa 1.5cm inferior to the skull base to preserve olfactory nerve fibers. The NSF is pedicled on the posterior septal branch of the sphenopalatine artery and can be custom sized and shaped based on reconstructive needs. Olfactory epithelium is preserved during harvesting. Several variations of intranasal vascularized pedicled NSFs, including a "rescue" nasoseptal flap, have been developed. Unlike conventional NSFs, only the posterior superior incision is made at the beginning of an operation for NSF "rescue" flaps, which allows for reflection and protection of the vascular supply should an NSF be needed for the defect repair. Other less commonly used pedicled intranasal flaps include the middle turbinate flap, the posterior pedicled inferior turbinate flap (PPITF), and the anterior pedicle lateral nasal wall flap (Hadad-Bassagaisteguy 2 or HB2 flap).[7]

Procedure Description

Since its development in 2006 by Hadad et al, the vascularized pedicled NSF has become the "workhorse" of reconstructive techniques for large skull base defects with high-flow CSF leaks.[8] The paddle of the NSF incorporates the mucoperichondrium and mucoperiostium of the nasal septum, and it receives its vascular supply from the posterior septal branch of the sphenopalatine artery. The nasal mucosa is decongested by placement of Afrin pledgets and the neurovascular pedicled flap is harvested from the nasal septum. The incision lines for the flap are determined based on a branch of the sphenopalatine artery inside the nose. Incisions are made through the mucosa with electrocautery and the flap is elevated. The flap may be harvested at either the outset of the case, during the initial paranasal sinus exposure of the skull base (early harvest) and kept protected in the nasopharynx or maxillary sinus for later use, or it may be harvested at the end of the case after tumor resection (late harvest), when the full extent of the skull base defect can be appreciated. When needed, the flap is rotated to cover the skull base defect and held in place with bioglue and bioresorbable packing or a balloon catheter.

[7] Hadad G, Rivera-Serrano CM, Bassagaisteguy LH, Carrau RL, Fernandez-Miranda J, Prevedello DM, Kassam AB. Anterior pedicle lateral nasal wall flap: a novel technique for the reconstruction of anterior skull base defects. Laryngoscope. 2011 Aug;121(8):1606-10. doi: 10.1002/lary.21889. PMID: 21792948.

[8] Jean Anderson Eloy, Amit A. Patel, Pratik A. Shukla, Osamah J. Choudhry, James K. Liu. Early harvesting of the vascularized pedicled nasoseptal flap during endoscopic skull base surgery, American Journal of Otolaryngology, Volume 34, Issue 3,2013,Pages 188-194,ISSN 0196-0709. https://doi.org/10.1016/j.amjoto.2012.10.005.

Current Coding: There are no unique ICD-10-PCS codes to describe the transfer of vascularized nasal tissue. Code the procedure in table 0NQ Repair of Head and Facial Bones using the body part value C Sphenoid Bone or the applicable ethmoid bone body part value(s) and the approach value 0 Open.

Section	**0** Medical and Surgical
Body System	**N** Head and Facial Bones
Operation	**Q** Repair: Restoring, to the extent possible, a body part to its normal anatomic structure and function

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Skull **1** Frontal Bone **3** Parietal Bone, Right **4** Parietal Bone, Left **5** Temporal Bone, Right **6** Temporal Bone, Left **7** Occipital Bone **B** Nasal Bone **C** Sphenoid Bone **F** Ethmoid Bone, Right **G** Ethmoid Bone, Left **H** Lacrimal Bone, Right **J** Lacrimal Bone, Left **K** Palatine Bone, Right **L** Palatine Bone, Left **M** Zygomatic Bone, Right **N** Zygomatic Bone, Left **P** Orbit, Right **Q** Orbit, Left **R** Maxilla **T** Mandible, Right **V** Mandible, Left **X** Hyoid Bone	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the transfer of vascularized nasal tissue. Continue coding as described in current coding.

Option 2. In the Medical and Surgical section, create new table 09X Transfer of Ear, Nose, Sinus. Create new qualifier values 1 Frontal Bone, 2 Ethmoid Bone, 3 Sphenoid Bone and 4 Occipital Bone, applied to the body part values K Nasal Mucosa and Soft Tissue, L Nasal Turbinate and M Nasal Septum and the open approach, to identify the transfer of vascularized nasal tissue.

Section	**0** Medical and Surgical
Body System	**9** Ear, Nose, Sinus
Operation	**ADD X** Transfer: Moving, without taking out, all or a portion of a body part to another location to take over the function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
ADD K Nasal Mucosa and Soft Tissue **ADD L** Nasal Turbinate **ADD M** Nasal Septum	**0** Open	**Z** No Device	**ADD 1** Frontal Bone **ADD 2** Ethmoid Bone **ADD 3** Sphenoid Bone **ADD 4** Occipital Bone

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 02 – Introduction of Peptide Enhanced Bone Void Filler in Transforaminal Lumbar Interbody Fusion Procedures

Issue: There are currently no unique ICD-10-PCS codes to describe the introduction of peptide enhanced bone void filler in transforaminal lumbar interbody fusion procedures. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? No. The PearlMatrix P-15 Peptide Enhanced Bone Graft was granted Breakthrough Medical Device status by the FDA on March 15, 2021. The PearlMatrix P-15 Peptide Enhanced Bone Graft is indicated for intervertebral body fusion of the spine in skeletally mature patients. The PearlMatrix P-15 Peptide Enhanced Bone Graft is intended for use at one level in the lumbar spine (L2-S1) for the treatment of degenerative disc disease with up to Grade I spondylolisthesis in conjunction with transforaminal lumbar interbody fusion (TLIF) devices and posterior pedicle screw fixation systems that are cleared by the FDA for use in the lumbosacral spine. The system is to be used in patients who have had at least six months of non-operative treatment. According to the requestor, a Class III Premarket Approval (PMA) application was submitted to the FDA on December 29, 2023 and is currently under active FDA review.

Background: Degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. With the deterioration or breaking down of discs, the nerve roots in the spinal canal are compressed, leading to radiation of neurological back pain, neurological symptoms, and in severe cases, dysfunction of the nerve. Lumbar DDD is the most common cause of lower back pain. As lumbar DDD is a degenerative process that occurs concurrently with aging, its prevalence increases among senior populations. The yearly prevalence of DDD, which usually happens in the lumbar spine region, is estimated to be 12.2% in the US population aged 65 or older.[1]

Surgical intervention for lumbar DDD includes lumbar fusion and lumbar total disc replacement. In lumbar fusion surgeries, autograft is considered the established standard graft material. However, local autograft bone may be of insufficient volume or uncertain quality, which limits their usage as bone grafts. According to the requestor, though numerous bone graft replacement (BGR) options (e.g., allograft, demineralized bone matrix (DBM)) are currently available in the US market, most were cleared for use by the FDA solely based on animal studies through the 510(k) pathway. The lack of randomized controlled human clinical studies and long-term data for a majority of the current BGR options has posed a challenge for surgeons in making evidence-based decisions.

[1] Parenteau CS, Lau EC, Campbell IC, Courtney A. Prevalence of spine degeneration diagnosis by type, age, gender, and obesity using Medicare data. Sci Rep. 2021 Mar 8;11(1):5389. doi: 10.1038/s41598-021-84724-6. PMID: 33686128; PMCID: PMC7940625.

Technology
PearlMatrix P-15 Peptide Enhanced Bone Graft is a composite drug-device combination bone graft material consisting of synthetic P-15 peptide bound onto calcium phosphate particles, which are incorporated into a collagen matrix carrier. The synthetic collagen fragment (P-15), the active agent in PearlMatrix P-15 Peptide Enhanced Bone Graft, is a synthetically derived fifteen amino acid short chain peptide sequence that mimics a cell binding domain of Type I collagen, thus providing a favorable environment that facilitates attachment and activation of osteogenic cells to accelerate new bone formation. The calcium phosphate particles, also known as anorganic bone mineral (ABM) provide a scaffolding and source of calcium for new bone growth. The calcium phosphate particles are highly porous, irregularly shaped and sized at 106-1000 microns (average size = 481 microns). The ABM/P-15 particles are incorporated into a fibrous collagen matrix as a carrier. The ABM/P-15 particles are the functional component of the bone graft, whereas the collagen simply acts as a carrier, aiding in the placement and containment of the particles at the graft site. PearlMatrix P-15 Peptide Enhanced Bone Graft is composed of 80% ABM/P-15 particles and 20% collagen. After implantation, the collagen is metabolized, and the ABM/P-15 particles are concomitantly enveloped and stabilized by new bone tissue and are eventually remodeled into native bone via cell mediated (osteoclastic) resorption.

In clinical trials, 141 and 149 patients using PearlMatrix P-15 Peptide Enhanced Bone Graft and autograft, respectively, showed that at 24 months the serious device-related adverse event rate in the PearlMatrix group (5.7%) was non-inferior compared to the control autograft group (4.7%).[2] The device-related adverse event rate in the PearlMatrix group (15.6%) was also demonstrated to be non-inferior compared to the control autograft group (13.4%) at 24 months. Device-related adverse events most frequently resulted in musculoskeletal and connective tissue disorders for both groups, including back pain, radiculopathy, and pseudoarthrosis. The second most frequent device-related adverse events occurred in nervous system, including hypoesthesia, paresthesia, piriformis syndrome, radiculopathy, sciatica, and spinal claudication. The third most frequent device-related adverse events were associated with product issues, including device dislocation, device fastener issues, and implant subsidence.

Procedure Description
PearlMatrix P-15 Peptide Enhanced Bone Graft is a composite drug-device combination bone graft material in a "putty-like" form used as a bone graft material in conjunction with a polyetheretherketone (PEEK) TLIF device and posterior pedicle screw fixation to assist with TLIF surgery in the lumbosacral spine. PearlMatrix P-15 Peptide Enhanced Bone Graft is intended for use at one level in the lumbosacral spine (L2-S1). Based on the clinical trials data, the average number of units per procedure is 8.2 cc.[2]

Patients are placed in the prone position on the operating room table. Three surgical approaches are available depending on the surgeon's and/or patient's preference of procedure: open, percutaneous or percutaneous endoscopic. In all approaches, the appropriate disc level is identified radiographically, and vertebral body distraction is applied. A discectomy, and if necessary, an osteophytectomy, is performed to achieve neural decompression and to allow further preparation of the disc space. Next, the disc space is prepared for the graft and the endplates are shaped. Sizing tools are used to determine the appropriate interbody cage size for selection. Once the appropriate size interbody cage is determined, its central cavity is filled with PearlMatrix P-15 Peptide

[2] https://clinicaltrials.gov/study/NCT03438747

Enhanced Bone Graft. The filled static PEEK interbody cage is then tapped gently into the prepared disc space. Appropriate placement of the construct is then confirmed radiographically or endoscopically. The static PEEK interbody cage as well as the interdiscal space around the cage is filled to the greatest extent possible. Additional support is provided by the placement of posterior pedicle screw fixation bilaterally along the vertebral column. The screws are inserted through the pedicle bones of the vertebrae to be fused. Once the posterior pedicle screw fixation is implanted, the surgical site is closed.

Current Coding: There are no unique ICD-10-PCS codes to describe the introduction of peptide enhanced bone void filler in conjunction with TLIF procedures. Assign the appropriate interbody lumbar fusion code from table 0SG Fusion, Lower Joints. If desired, facilities can report the introduction of peptide enhanced bone void filler using one of the following codes:

3E0U0GC	Introduction of other therapeutic substance into joints, open approach
3E0U3GC	Introduction of other therapeutic substance into joints, percutaneous approach
3E0U4GC	Introduction of other therapeutic substance into joints, percutaneous endoscopic approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the introduction of peptide enhanced bone void filler in TLIF procedures. Continue coding as described in current coding.

Option 2. In section X table XW0, Anatomical Regions, create new substance value X Peptide Enhanced Bone Void Filler, applied to the body part value U Joints and the approaches shown, to identify the introduction of peptide enhanced bone void filler in TLIF procedures. Also, assign the appropriate interbody lumbar fusion code from table 0SG Fusion, Lower Joints.

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*
U Joints	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD X** Peptide Enhanced Bone Void Filler	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 03 – Dilation of Arteriovenous Fistula with Cell Impermeable Endoprosthesis

Issue: There are currently no unique ICD-10-PCS codes to describe dilation of an arteriovenous fistula with a cell impermeable endoprosthesis. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. Merit Wrapsody® Cell-Impermeable Endoprosthesis (CIE) was granted Premarket Approval (PMA) on December 19, 2024. The device is indicated for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis access outflow circuit, including stenosis or occlusion in the peripheral veins of individuals with an arteriovenous (AV) fistula or at the venous anastomosis of a synthetic AV graft. The Merit Wrapsody® CIE was granted Breakthrough Medical Device status by the FDA on March 20, 2020.

Background: Hemodialysis, a renal function replacement method, needs a regular entry into the bloodstream with sufficient blood flow (at least 500 mL/min). The insertion of a special central vein catheter, introduced into the superior or inferior vena cava, is an option, however, the long-term use of hemodialysis catheters is associated with a significantly increased risk of infection and mortality.[1] The preferred vascular access is an arteriovenous fistula (AVF), which is the direct connection of a patient's artery and vein, or an arteriovenous graft (AVG), which is when an artificial (polytetrafluoroethylene) vascular graft is used for punctures in cases of abandoned superficial veins.[2]

Although AVFs are considered the best currently available hemodialysis access (over AVGs and catheters), their lifespan is limited by several complications, of which stenoses are by far the most frequent.[3] Stenosis within the arteriovenous fistula (AVF), or arteriovenous graft (AVG) of patients undergoing hemodialysis refers to a narrowing of the blood vessel created surgically to connect an artery to a vein used for dialysis access, which can significantly impair blood flow and negatively impact the effectiveness of dialysis treatment for kidney failure patients. This narrowing is a common complication that often requires medical intervention to maintain proper dialysis access and contributes to a considerable economic burden for the U.S. healthcare system with an unabated increase of prevalence and the high cost of dialysis treatment. Maintaining long-term vascular access is critical for patients on hemodialysis as there is a direct correlation between mortality and access dysfunction. Percutaneous transluminal angioplasty (PTA) is the standard first line therapy to treat stenosis for 70% of patients on kidney hemodialysis.[4]

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[1] Soleymanian T., Sheikh V., Tareh F., Argani H., Ossareh S. Hemodialysis vascular access and clinical outcomes: An observational multicenter study. J. Vasc. Access. 2017;18:35–42. doi: 10.5301/jva.5000610.

[2] Haddad D.J., Jasty V.S., Mohan B., Hsu C.-H., Chong C.C., Zhou W., Tan T.-W. Comparing outcomes of upper extremity brachiobasilic arteriovenous fistulas and arteriovenous grafts: A systematic review and meta-analysis. J. Vasc. Access. 2022;23:32–41. doi: 10.1177/1129729820970789.

[3] Chytilova E., Jemcov T.A.-O., Malik J.A.-O., Pajek J.A.-O., Fila B., Kavan J. Role of Doppler ultrasonography in the evaluation of hemodialysis arteriovenous access maturation and influencing factors. J. Vasc. Access. 2021;22((Suppl. S1)):42–55. doi: 10.1177/1129729820965064.

[4] Bountouris I, Kritikou G, Degermetzoglou N, Avgerinos KI. A Review of Percutaneous Transluminal Angioplasty in Hemodialysis Fistula. Int J Vasc Med. 2018 Mar 27;2018:1420136. doi: 10.1155/2018/1420136. PMID: 29785307; PMCID: PMC5892221.

Technology
The Merit Wrapsody® CIE, a flexible, self-expanding endoprosthesis, integrates 3 functional layers: 1) spun polytetrafluoroethylene (PTFE) luminal surface providing a hemocompatible surface limiting thrombus formation and a microstructure enhancing tissue stabilization; 2) a cell-impermeable middle layer preventing transgraft cellular migration and luminal tissue accumulation leading to restenosis; and 3) an abluminal expanded PTFE layer aiding tissue ingrowth to prevent device migration, thus avoiding the need for flared or exposed end rows for device fixation. This multi-layer polymer construct encapsulates a self-expanding nitinol (NiTi) stent frame for compression resistance and outward radial force for use in areas of high flexion (e.g., cephalic arch). The NiTi frame design incorporates softer end rows (i.e., reduced radial force) for atraumatic transition to the adjacent healthy vessel.

According to the requestor, the Wrapsody® CIE device offers a unique cell-impermeable construct addressing challenging lesions in the hemodialysis venous outflow circuit. Precise and controlled endoprosthesis deployment is achieved with the use of a novel single-handed, ratchet-style mechanism allowing the physician to confirm location and reposition, as needed, during device delivery. Additionally, the delivery system incorporates a hydrophilic coating to enhance catheter pushability in challenging anatomy.

The target population for application of the Wrapsody® CIE are patients undergoing hemodialysis thought access via an AVF or AVG with an occlusion accompanied by clinical signs of dysfunctional dialysis access (e.g., variation in thrill/bruit, difficult cannulation, recirculation, edema, excessive bleeding from the venipuncture site, or thrombosis. Stenosis is diagnosed via doppler vascular ultrasound and confirmed on angiography. The Wrapsody® CIE is indicated for treatment of venous outflow circuit stenoses or occlusions in vessels ranging from 4.6 mm to 14.4 mm in diameter with up to 25% vessel oversizing. The device is available in diameters ranging from 6 to 16 mm and in lengths ranging from 30 to 125 mm, enabling the treatment of vessels ranging from 4.6 to 14.4 mm in diameter. The delivery catheter is available in lengths of 80 and 120 cm and is compatible with sheath sizes ranging from 8 to 14-French.

According to the requestor, in studies among patients with stenosis in their AVF, the Wrapsody® CIE was superior to percutaneous transluminal angioplasty (PTA) with respect to six-month target lesion primary patency (TLPP) and access circuit primary patency (ACPP). The primary safety endpoint was the proportion of patients with adverse events through 30-days following the index procedure affecting the access or venous outflow circuit resulting in reintervention, hospitalization, or death (not including stenosis or thrombosis). Results showed that the CIE is associated with superior efficacy versus PTA. Thirty days following the index procedure, there was no statistically significant difference in the primary safety rates for the CIE population versus PTA population (3.4 vs. 5.0%; p=0.54). No significant differences were observed in adverse events between either cohort. No serious adverse events were observed locally or systemically during the first 30 days post-procedure. In the PTA cohort, five patients experienced device-related adverse events and in the CIE cohort, one patient experienced a device-related event. Eight procedure-related events were recorded in the PTA cohort and two events were reported in the CIE cohort. No significant differences were observed in adverse event rates between cohorts.

Procedure Description
The Wrapsody® CIE procedure is typically performed after percutaneous transluminal angioplasty (PTA) to remove the lesion that is preventing the venous outflow stopping the patient from receiving their medically necessary hemodialysis treatment. The Wrapsody® CIE system is delivered complete in its sterile packaging. Typically, only one device is used to complete the procedure of placing the Wrapsody® CIE, into the intended vessel wall.

After angioplasty with a fully effacing PTA balloon, an angiogram is taken for vessel sizing and create a roadmap for stenting. With a diagnostic catheter still in place, the hydrophilic guidewire should be exchanged for a stiff 0.035" guidewire (i.e. Amplatz). The 5-7 French sheath is removed and replaced with the appropriately sized sheath for use with Wrapsody® (based on target lesion vessel size) and corresponding Wrapsody® catheter French size. Wrapsody® CIE is inserted over a stiff guidewire, through the sheath and up to the stenosis. The proximal and distal ends of Wrapsody® should be placed in healthy tissue approximately 1cm beyond the diseased vessel segment. The vessel sizing chart found in the instructions is used to determine CIE diameter and length with the appropriate 10-25% oversizing of Wrapsody® to ensure proper wall apposition is achieved.

Under fluoroscopic guidance, the Wrapsody® delivery catheter is advanced through the valved introducer sheath until the leading edge of the stent graft is past the lesion. Maintaining tip position, after verifying that delivery catheter is optimally positioned, that the selected stent graft length covers the entire lesion, and both ends of the stent graft extend at least 1 cm into a non-diseased vessel segment, the Wrapsody® CIE is deployed. An angiogram is taken through the Wrapsody® CIE delivery catheter to confirm proper placement of the CIE. The Wrapsody® CIE catheter is removed. A post Wrapsody® CIE balloon dilation is performed using a standard PTA balloon to ensure the covering is properly seated against the vessel wall.

The deployment of the Wrapsody® CIE and placement into the target vessel wall is intended to be permanent. If the target vessel with the Wrapsody® CIE placed re-occludes, then the Wrapsody® CIE procedure would be repeated to remove the occluded region and to attain patency to maintain the patient's hemodialysis.

Current Coding: There are no unique ICD-10-PCS codes to describe dilation of an arteriovenous fistula with a cell impermeable endoprosthesis. Code the procedure in table 057 Dilation of Upper Veins, with the applicable body part value, the device value D Intraluminal Device and the percutaneous approach.

Section	**0** Medical and Surgical
Body System	**5** Upper Veins
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Azygos Vein **1** Hemiazygos Vein **G** Hand Vein, Right **H** Hand Vein, Left **L** Intracranial Vein **M** Internal Jugular Vein, Right **N** Internal Jugular Vein, Left **P** External Jugular Vein, Right **Q** External Jugular Vein, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**D** Intraluminal Device **Z** No Device	**Z** No Qualifier

R Vertebral Vein, Right **S** Vertebral Vein, Left **T** Face Vein, Right **V** Face Vein, Left **Y** Upper Vein			
3 Innominate Vein, Right **4** Innominate Vein, Left **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 **F** Cephalic Vein, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**D** Intraluminal Device **Z** No Device	**1** Drug-Coated Balloon **Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for dilation of an arteriovenous fistula with a cell impermeable endoprosthesis. Continue coding as described in current coding.

Option 2. In section X New Technology table X27, Dilation, Cardiovascular System, create new device value 5 Intraluminal Device, Cell Impermeable, applied to the new body part values shown and the percutaneous approach, to identify the dilation of an arteriovenous fistula with a cell impermeable endoprosthesis.

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*
ADD 5 Subclavian Vein, Right **ADD 6** Subclavian Vein, Left **ADD 7** Axillary Vein, Right **ADD 8** Axillary Vein, Left **ADD 9** Brachial Vein, Right **ADD A** Brachial Vein, Left **ADD B** Basilic Vein, Right **ADD C** Basilic Vein, Left **ADD D** Cephalic Vein, Right **ADD E** Cephalic Vein, Left	**3** Percutaneous	**ADD 5** Intraluminal Device, Cell Impermeable	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 04 – Dilation of Carotid Artery with Integrated Embolic Protection

Issue: There are currently no unique ICD-10-PCS codes to describe dilation of the carotid artery with integrated embolic protection using a single distal filter. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. Neuroguard IEP® 3-in-1 Carotid Stent, Post-Dilation Balloon System with Integrated Embolic Protection was granted premarket approval (PMA) by the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) for the indications of improving the carotid luminal diameter in subjects at high risk for adverse events from carotid endarterectomy who require carotid revascularization and post-dilation of the stent component with simultaneous capture and removal of embolic material, on October 11, 2024.

Background: Carotid artery disease (CAD) is a major risk factor for ischemic stroke, characterized by the narrowing or blockage of carotid arteries due to atherosclerosis. If untreated, CAD can lead to transient ischemic attacks (TIAs) or ischemic strokes, causing permanent neurological damage, disability, or death. In 2023, there were 446,000 US patients diagnosed with CAD, with the majority being treated with medical management. Currently, 30-40% of these patients (~170k) undergo procedural interventions, either carotid artery stenting or surgical carotid endarterectomy (CEA), with approximately 50k treated with carotid artery stenting and 120k with CEA. While carotid artery stenting (CAS) is a proven alternative to CEA, it has been associated with a higher stroke risk, primarily due to embolization during the procedure. Current embolic protection devices fail to capture all microemboli, particularly those smaller than 100 μm due to the large pore size of the filter, which can cause stroke and neurological dysfunction. According to the requestor, the Neuroguard IEP® 3-in-1 Carotid Stent and Post-Dilation Balloon System with Integrated Embolic Protection is indicated for improving the carotid luminal diameter addresses this issue for patients with carotid artery stenosis who require carotid revascularization. The Neuroguard IEP® System features a 40 μm integrated distal embolic protection filter, with pores 3-4 times smaller than traditional filters used in CAS (typically 100-250 μm). Per the requestor, this design can minimize the risk of stroke and cognitive impairment by capturing microemboli smaller than 100 μm, which pose a significant risk during critical phases of stent deployment and post-dilation. The Neuroguard IEP® filter is deployed during these phases, offering additional protection and reducing the likelihood of microemboli reaching the brain.

Technology

The Neuroguard IEP® 3-in-1 Carotid Stent, Post-Dilation Balloon System with Integrated Embolic Protection (Neuroguard IEP® System) is a novel, 3-in-1 device that integrates a nitinol self-expanding stent, a post-dilation balloon, and a 40 μm distal embolic protection filter. The system consists of a multi-lumen shaft with an inflatable semi-compliant angioplasty balloon at the distal end and a handle on the proximal end. Distal to the angioplasty balloon is an integrated filter in the baseline-collapsed state. A nitinol self-expanding stent is preloaded on top of the angioplasty balloon. The stent has a closed cell design with an asymmetrical hourglass configuration with flares on either end and is designed to balance flexibility and radial strength. Both the stent and filter are

covered by an outer sheath. The system's filter, with pores that are significantly smaller (40 μm) than those in traditional distal embolic protection devices (typically 100 to 250 μm), is designed to capture microemboli that would otherwise escape. According to the requestor, this provides greater protection during the riskiest phases of carotid stenting; stent deployment and post-dilation; reducing the risk of embolic particles reaching the brain and causing strokes. Conventional embolic protection devices cannot use smaller pores because they are open throughout the entire procedure and must permit sufficient flow to reduce the risk of thrombosis and complications. In contrast, the Neuroguard IEP® System integrated filter is open only during the critical phases; stent deployment and post-dilation; allowing the use of smaller pores, delivering enhanced protection while maintaining safety.

Procedure Description
The Neuroguard IEP® System is deployed via minimally invasive access of the carotid artery. The placement of the Neuroguard IEP® System involves the following key steps: First, the system is advanced over a guidewire to the site of carotid stenosis. Next, the integrated embolic protection filter is deployed distal to the lesion to capture any potential debris. The self-expanding stent is then deployed to restore vessel patency and the integrated post-dilation balloon is inflated to optimize stent apposition. Finally, the filter, potentially containing captured debris, is retrieved along with the delivery system. The stent component is permanent. Typically, one Neuroguard IEP® System is used per procedure although multiple devices may be used per procedure. The procedure is usually performed as a standalone intervention. In certain limited cases (estimated at <10% of the time), the stent could be placed in one location (e.g., the common carotid artery) and the filter placed at a different location (i.e., internal carotid artery), even though the stent is part of the same device.

Current Coding: There are no unique ICD-10-PCS codes to describe integrated embolic protection in the context of carotid artery dilation with stent placement. Facilities would report the appropriate code from table 037 Dilation, Upper Arteries for the carotid artery dilation and stent placement portion of the procedure.

Section	**0** Medical and Surgical
Body System	**3** Upper Arteries
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
D Hand Artery, Right **F** Hand Artery, Left **G** Intracranial Artery **H** Common Carotid Artery, Right **J** Common Carotid Artery, Left **K** Internal Carotid Artery, Right **L** Internal Carotid Artery, Left **M** External Carotid Artery, Right **N** External Carotid Artery, Left **P** Vertebral Artery, Right **Q** Vertebral Artery, Left **R** Face Artery **S** Temporal Artery, Right **T** Temporal Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Intraluminal Device, Drug-eluting **5** Intraluminal Device, Drug-eluting, Two **6** Intraluminal Device, Drug-eluting, Three **7** Intraluminal Device, Drug-eluting, Four or More **D** Intraluminal Device **E** Intraluminal Device, Two **F** Intraluminal Device, Three **G** Intraluminal Device, Four or More **Z** No Device	**Z** No Qualifier

U Thyroid Artery, Right **V** Thyroid Artery, Left **Y** Upper Artery			

Coding Options

Option 1. Do not create new ICD-10-PCS codes for dilation of the carotid artery with integrated embolic protection. Facilities would continue to report the appropriate code from table 037 Dilation of Upper Arteries for the carotid artery dilation and stent placement portion of the procedure, as described in current coding.

Option 2. In section X New Technology table X2A, Assistance, Cardiovascular System, create new technology value 4 Cerebral Embolic Filtration, Single Integrated Distal Filter, applied to the body part values H Common Carotid Artery, Right and J Common Carotid Artery, Left, the new body part values K Internal Carotid Artery, Right and L Internal Carotid Artery, Left and the percutaneous approach, to identify dilation of carotid artery with integrated embolic protection. Facilities would continue to separately report the appropriate code from table 037 Dilation of Upper Arteries for the carotid artery dilation and stent placement portion of the 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*
5 Innominate Artery and Left Common Carotid Artery	**3** Percutaneous	**1** Cerebral Embolic Filtration, Dual Filter	**2** New Technology Group 2
6 Aortic Arch	**3** Percutaneous	**2** Cerebral Embolic Filtration, Single Deflection Filter	**5** New Technology Group 5
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	**3** Percutaneous	**3** Cerebral Embolic Filtration, Extracorporeal Flow Reversal Circuit	**6** New Technology Group 6
H Common Carotid Artery, Right **J** Common Carotid Artery, Left **ADD** K Internal Carotid Artery, Right **ADD L** Internal Carotid Artery, Left	**3** Percutaneous	**ADD 4** Cerebral Embolic Filtration, Single Integrated Distal Filter	**B** New Technology Group 11

Note: As reflected in the Addenda on page 42, we are proposing to delete existing ICD-10-PCS codes describing cerebral embolic filtration in Table X2A and to create new codes in Table 5A0. If finalized, those changes would impact this table.

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 05 – Computer-aided Triage and Notification Software for Measurement of Biomarkers

Issue: There are currently no unique ICD-10-PCS codes to describe computer-aided triage and notification software for sepsis risk using measurement of biomarkers. An October 1, 2025 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? Yes. The Sepsis ImmunoScore was granted De Novo Class II approval by the FDA on April 02, 2024, for the indication of a software device to aid in the prediction or diagnosis of sepsis.

Background: Sepsis, a life-threatening condition resulting from a dysregulated host-response to infection, claims over 200,000 lives annually in the United States.[1] In 2021, although sepsis-related hospitalizations accounted for 0.04% to 1.09% of hospital stays, they consumed 5.1% to 12.8% of aggregate hospital resources.[2] According to the requestor, sepsis is notoriously difficult to diagnose due to its complex and variable presentation.

Technology
Per the requestor, Sepsis ImmunoScore is the first ever FDA-authorized AI-based software designed to identify patients at risk of sepsis. Sepsis ImmunoScore is a software device to aid in the early prediction or diagnosis of sepsis, and sepsis related deterioration such as in-hospital mortality, extended length of stay, use of vasopressors, ICU admission within 24 hours, and need for mechanical ventilation within 24 hours. Sepsis ImmunoScore uses individual patient biomarker and clinical data along with advanced algorithms to aid health care providers in the prediction and/or diagnosis of sepsis. The device is intended for adjunctive use and is not intended to be used as the sole determining factor in assessing a patient's sepsis status. The device may contain alarms that alert the care provider of the patient's status. According to the requestor, the intent is for the device to be utilized in inpatient facilities in patients for which sepsis is suspected, and a blood culture was ordered as part of the evaluation for sepsis. The device is not intended to monitor response to treatment in patients being treated for sepsis.

Procedure Description
The Sepsis ImmunoScore uses up to 22 predetermined inputs from the patient's electronic health record to generate a risk score and to assign the patient to one of four discrete risk stratification categories, based on the increasing risk of sepsis. When an ImmunoScore is ordered for a patient, the status of the score is displayed as pending. This time is used to collect any parameters needed for the algorithm. The software can inform the user of the orders that need to be placed and their status on the pending screen. While the necessary parameters are gathered, the risk score and category are displayed as "Result Pending". If after three hours and thirty minutes the necessary parameters are not obtained, a "No Result" will appear on the screen and a score will not be calculated for this order of an ImmunoScore.

[1] Kramarow E. Sepsis-related Mortality Among Adults Aged 65 and Over: United States, 2019. Published online 11/21.
[2] Roemer M, Zodet M, Esselman D, Sheng M. State Variation in Inpatient Stays Involving Sepsis, 2021. September 2024. Accessed September 26, 2024. https://hcup-us.ahrq.gov/reports/statbriefs/sb310-state-variation-sepsis-2021.pdf

Current Coding: The use of software using measurement of biomarkers to aid in the detection of sepsis is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for computer-aided triage and notification software for sepsis risk. Continue coding as described in current coding.

Option 2. In section X New Technology table XXE, Measurement, Physiological Systems, create new technology value C Infection, Computer-aided Triage and Notification, applied to the body part value Z None and the external approach, to identify computer-aided triage and notification software for sepsis risk.

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*
ADD Z None	**X** External	**ADD C** Infection, Computer-aided Triage and Notification	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 06 - ICD-10-PCS Index Addenda*

Lttr A
Main Ablation
Main Add see Stereotactic Radiosurgery

Main Add AUCATZYL(R) use Obecabtagene autoleucel

Lttr C
Main Add Clivus
Main Add use Occipital Bone

Lttr D
Main Add DIEP (Deep Inferior Epigastric Artery Perforator) flap
Add see Deep Inferior Epigastric Artery Perforator Flap

Lttr H
Main Delete Heterotopic Bioprosthetic Valve(s), Intraluminal Device, Supplement X2U93YA
Main Add Heterotopic Bioprosthetic Valve(s), Intraluminal Device, Supplement, Atrium, Right X2U93YA

Lttr K
Main Add KEBILIDI use Eladocagene exuparvovec

Lttr N
Main New Technology
Supplement
Delete Heterotopic Bioprosthetic Valve(s), Intraluminal Device X2U93YA
Add Atrium, Right, Heterotopic Bioprosthetic Valve(s), Intraluminal Device X2U93YA

Lttr S
Main Add Stereotactic Arrhythmia Radioablation (STAR) D228DZZ
Main Add Stereotactic Body Radiotherapy (SBRT), Cardiac D228DZZ
Main Supplement
Atrium
Right 02U6
Add Heterotopic Bioprosthetic Valve(s), Intraluminal Device X2U93YA
Delete Heterotopic Bioprosthetic Valve(s), Intraluminal Device X2U93YA

Lttr T
Main Add TECELRA(R) use Afamitresgene Autoleucel Immunotherapy

**All proposed addenda updates are being considered for implementation on October 1, 2025.*

Lttr	Z	
Main Add		ZEGALOGUE(R) use Dasiglucagon

ICD-10-PCS Body Part Key Addenda

Section 0		Medical and Surgical
Axis 4		Body Part
Term		Occipital Bone
Includes	Add	Clivus

ICD-10-PCS Substance Key Addenda

Section X		New Technology
Axis 6		Device / Substance / Technology
Row	Add	
Term	Add	Afamitresgene Autoleucel Immunotherapy
Includes	Add	TECELRA(R)
Row	Add	
Term	Add	Dasiglucagon
Includes	Add	ZEGALOGUE(R)
Row	Add	
Term	Add	Eladocagene exuparvovec
Includes	Add	KEBILIDI
Row	Add	
Term	Add	Obecabtagene autoleucel
Includes	Add	AUCATZYL(R)

ICD-10-PCS Table Addenda

Medical and Surgical Section

Axis 3 Root Operation
Cricothyroidotomy/Cricothyrotomy

Issue: At the September 2024 C&M meeting[1], in the Medical and Surgical section table 0B1, Bypass of Respiratory System, we proposed to add the device value H Other Airway Device, applied to the body part value 1 Trachea, approach values 0 Open and 3 Percutaneous, with qualifier value 4 Cutaneous to differentiate tracheostomy and cricothyroidotomy procedures in the

[1] September 10, 2024 ICD-10 Coordination and Maintenance Meeting Materials are available at https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials/2024-09-10-icd10-meeting-materials.

classification. Commenters did not support our proposal to add a new device value to table 0B1, stating that the existing code captures the intent of the procedure, which is to create an airway and there is no need to differentiate between tracheostomy and cricothyroidotomy procedures.

Procedure Description:
There are three main approaches to cricothyroidotomy: open cricothyrotomy, needle cricothyrotomy, and percutaneous cricothyrotomy using the Seldinger technique.[2] In the "traditional" (open) cricothyrotomy technique, a 2- to 3-cm vertical incision is made through the skin and subcutaneous tissue. The cricothyroid membrane is then palpated through the incision and a horizontal incision of less than 1.0 cm in length is made through the cricothyroid membrane into the trachea and a tracheostomy tube is placed through the incision to establish an airway. If a tracheostomy tube is not available or if there is difficulty placing the tracheostomy tube into the opening in the cricothyroid membrane, a 6-0 cuffed endotracheal (ET) tube cut to a shorter length can be placed as an alternative to a tracheostomy tube.

There are no absolute contraindications to open cricothyrotomy in adults, but it should not be performed in children <10 years old. Needle cricothyrotomy, a temporary method that uses a 12- to 14-gauge angiocatheter attached to a bag-valve-mask device (or a jet ventilator if available), is the preferred cricothyrotomy method for children <10 years old.

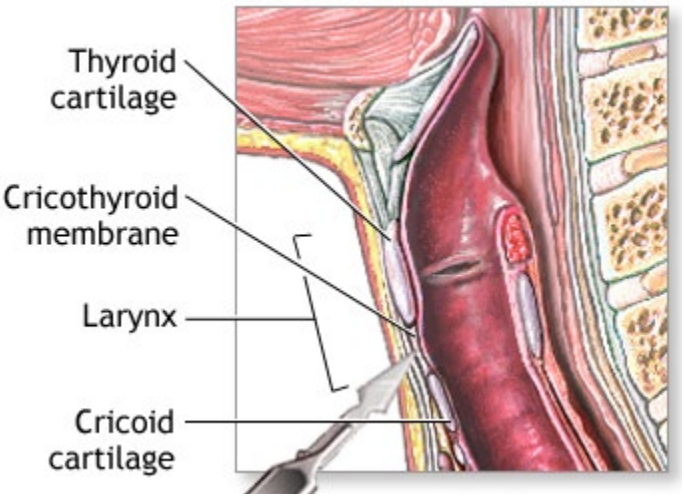
After cricothyrotomy, a permanent tracheostomy should be placed within 24 hours. Needle cricothyrotomy can be used for approximately 40 minutes, after which time carbon dioxide accumulates which can be particularly devastating in patients with head trauma.[3,4]

Coding:
CMS continues to believe that there is a need to differentiate cricothyroidotomy and tracheostomy procedures in the classification. Cricothyroidotomy and tracheostomy are clinically different procedures, typically performed under different circumstances and with different potential complications.

a) Clinicians may use cricothyrotomy in emergency situations where securing an airway quickly is paramount. In contrast, tracheostomy is a more stable long-term solution for airway management, allowing for comfort and more straightforward airway clearance. Although both procedures aim to provide airway access, they differ significantly in technique, intended indications, and duration of use. There are also times where the need exists to convert a cricothyroidotomy to a tracheotomy. These revisions are generally done because a cricothyroidotomy, if allowed to remain for too long, can increase the risk of subglottic stenosis, which can be a considerable problem.
b) Not all cricothyroidotomies are performed emergently—sometimes the anatomy is such that this is the more accessible location for a surgical airway (short neck), sometimes the higher location for the surgical airway is preferred such as with a laryngeal cancer when an eventual laryngectomy will need to be performed, and some surgeons may prefer the technically easier to perform cricothyroidotomy to the tracheotomy.

[2] McKenna P, Desai NM, Tariq A, et al. Cricothyrotomy. [Updated 2023 Feb 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537350/
[3] Roberts, J. R., & Hedges, J. R. (1998). Clinical procedures in emergency medicine. WB Saunders Company.
[4] Ali J (2014). Priorities in multisystem trauma. Hall J.B., & Schmidt G.A., & Kress J.P.(Eds.), Principles of Critical Care, 4e. McGraw-Hill Education. https://accessmedicine.mhmedical.com/content.aspx?bookid=1340&sectionid=80026930

Additional Clinical Considerations:
Cricothyrotomy (or cricothyroidotomy) refers to the surgical procedure in which an incision is made in the skin and the cricothyroid membrane to establish an airway in emergency (life or death) situations where there is airway blockage, such as oral or maxillofacial trauma, angioedema, or physical or anatomical blockages. The cricothyroid membrane is part of the larynx, not the trachea, as the larynx extends from the tip of the epiglottis to the bottom of the cricoid cartilage, where the trachea begins. Therefore, a cricothyroidotomy is technically a bypass of the larynx, not the trachea.



Accordingly, CMS has revised the coding proposal as follows:

Source	Description	Code specification
2024, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section, create new table 0C1, Bypass of Mouth and Throat. Add the device values E Intraluminal Device, Endotracheal Airway, F Tracheostomy Device, and Z No Device, applied to the body part value S Larynx, approach values 0 Open and 3 Percutaneous, and qualifier value 4 Cutaneous. This proposed change would enable the capture of procedures such as cricothyrotomy.	Add: 0C1S[03][FHZ]4 (6 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**C** Mouth and Throat
Operation	**ADD 1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
ADD S Larynx	**0** Open **3** Percutaneous	**ADD E** Intraluminal Device, Endotracheal Airway **ADD F** Tracheostomy Device **ADD Z** No Device	**4** Cutaneous

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr C

Main Revise from Cricoid cartilage use Trachea

	Revise to	Cricoid cartilage use Larynx
Main	Add	Cricothyroid membrane use Larynx
Main	Add	Cricothyroidotomy see Bypass, Mouth and Throat 0C1
Main	Add	Cricothyrotomy see Bypass, Mouth and Throat 0C1

Body Part Key entry to accompany this addenda proposal:

ICD-10-PCS Body Part Key Addenda

Section 0	Medical and Surgical	
Axis 4	Body Part	
Term	Larynx	
Includes	Add	Cricoid cartilage
Includes	Add	Cricothyroid membrane

Section 0	Medical and Surgical	
Axis 4	Body Part	
Term	Trachea	
Includes	Delete	Cricoid cartilage

Axis 4 Body Part

Removal or Revision of Devices in the Dura or Spinal Meninges

Source	Description	Code specification
2024, public request with CMS internal review	In the Central Nervous and Cranial Nerves body system of the Medical and Surgical section, add body part values 2 Dura Mater and T Spinal Meninges, applied to the device values 7 Autologous Tissue Substitute, J Synthetic Substitute and K Nonautologous Tissue Substitute and the open approach, to the root operation tables Removal 00P and Revision 00W, to enable the capture of procedures such as the removal or revision of devices used to supplement or replace the cranial dura and spinal meninges. Removal or revision of these devices can be required in situations of allergic response, infections, regrowth of tumors, cysts, meningoceles of the cranial dura or myelomeningoceles of the spinal meninges.	Add: 00P[2T]0[7JK]Z (6 codes) 00W[2T]0[7JK]Z (6 codes)

EXAMPLES

Section	**0** Medical and Surgical
Body System	**0** Central Nervous System and Cranial Nerves
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Brain **V** Spinal Cord	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier

0 Brain **V** Spinal Cord	**X** External	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **M** Neurostimulator Lead	**Z** No Qualifier
ADD 2 Dura Mater **ADD T** Spinal Meninges	**0** Open	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**0** Central Nervous System and Cranial Nerves
Operation	**W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	*Approach*	*Device*	*Qualifier*
0 Brain **V** Spinal Cord	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier
0 Brain **V** Spinal Cord	**X** External	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Neurostimulator Lead	**Z** No Qualifier
ADD 2 Dura Mater **ADD T** Spinal Meninges	**0** Open	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

Axis 5 Approach
Choledochoduodenostomy

Source	Description	Code specification
2024, Coding Clinic Editorial Advisory Board & CMS internal review	In Medical and Surgical section table 0F1, Bypass of Hepatobiliary System and Pancreas, add the approach value 8 Via Natural or Artificial Opening Endoscopic, applied to body part value 9 Common Bile Duct, device value D Intraluminal Device and Z No Device and qualifier value 3 Duodenum. This change will enable the capture of procedures such as endoscopic choledochoduodenostomy, which is a surgical procedure that creates a connection between the common bile duct and the duodenum to drain the biliary system.	Add: 0F198[DZ]3 (2 codes)

EXAMPLES

Section	**0** Medical and Surgical
Body System	**F** Hepatobiliary System and Pancreas
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
4 Gallbladder **5** Hepatic Duct, Right	**0** Open **4** Percutaneous Endoscopic	**D** Intraluminal Device **Z** No Device	**3** Duodenum **4** Stomach

6 Hepatic Duct, Left **7** Hepatic Duct, Common **8** Cystic Duct **9** Common Bile Duct			**5** Hepatic Duct, Right **6** Hepatic Duct, Left **7** Hepatic Duct, Caudate **8** Cystic Duct **9** Common Bile Duct **B** Small Intestine
9 Common Bile Duct	**ADD 8** Via Natural or Artificial Opening Endoscopic	**D** Intraluminal Device **Z** No Device	**3** Duodenum

Axis 7 Qualifier
Bypass from the Innominate Artery

Source	Description	Code specification
2024, public request with CMS internal review	In Medical and Surgical section table 031, Bypass of Upper Arteries, add the qualifier value Y Upper Artery, applied to body part value 2 Innominate Artery, the approach value 0 Open and all device values. This change will enable the capture of detail for bypass procedures from the innominate artery to a subclavian artery or an axillary artery. Thoracic endovascular aortic repair (TEVAR) performed to treat aneurysm or dissection of the aortic arch can involve one or more of the branch vessels of the arch by endovascular deployment of a thoracic branch endoprosthesis across zone zero of the aortic arch, with a single branched graft being placed into the innominate artery to preserve blood flow and perfusion to the head and arms. In the current landing zone classification system, any portion of the aorta proximal to the left common carotid artery is considered zone zero.[5]	Add: 03120[9AJKZ]Y (5 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**3** Upper Arteries
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
2 Innominate Artery	**0** Open	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**0** Upper Arm Artery, Right **1** Upper Arm Artery, Left **2** Upper Arm Artery, Bilateral **3** Lower Arm Artery, Right **4** Lower Arm Artery, Left **5** Lower Arm Artery, Bilateral **6** Upper Leg Artery, Right **7** Upper Leg Artery, Left **8** Upper Leg Artery, Bilateral **9** Lower Leg Artery, Right **B** Lower Leg Artery, Left **C** Lower Leg Artery, Bilateral

[5] Fillinger MF, Greenberg RK, McKinsey JF, Chaikof EL; Society for Vascular Surgery Ad Hoc Committee on TEVAR Reporting Standards. Reporting standards for thoracic endovascular aortic repair (TEVAR). J Vasc Surg. 2010 Oct;52(4):1022-33, 1033.e15. doi: 10.1016/j.jvs.2010.07.008. PMID: 20888533.

			D Upper Arm Vein **F** Lower Arm Vein **J** Extracranial Artery, Right **K** Extracranial Artery, Left **W** Lower Extremity Vein **ADD Y** Upper Artery

Medical and Surgical Section
Axis 7 Qualifier

Meniscus Replacement

Source	Description	Code specification
2024, public inquiry with CMS internal review	In Medical and Surgical section table 0SR, Replacement of Lower Joints, create new qualifier values D Medial Meniscus and E Lateral Meniscus, applied to the body part values C Knee Joint, Right, and D Knee Joint, Left, device values 7 Autologous Tissue Substitute, and K Nonautologous Tissue Substitute and to the approach value 0 Open. These changes will enable the capture of detail for replacement of the medial or lateral meniscus of the knee with an autologous or a nonautologous tissue substitute. The meniscus is a structure within the knee joint, located between the femur and the tibia on either the inside or outside of the knee, that acts as a shock absorber and helps distribute weight and stress across the joint. A meniscus replacement is a surgical procedure to replace a damaged or missing meniscus. Numerous materials including plastics and metals have been used to develop different types of meniscus implants.[6] Meniscal replacement using autografts is possible using the peroneus longus tendon, the patellar tendon or the semitendinosus muscle. In addition, there are four types of meniscal allografts: fresh, cryopreserved, deep-frozen and lyophilized, but deep-frozen and cryopreserved meniscal allografts are the most frequently used in the clinical practice. Currently in New Technology section table XRR, Replacement of Joints, there are procedure codes	Add: 0SR[CD]0[7K][DE] (8 codes)

[6] van Minnen, B.S., van Tienen, T.G. The Current State of Meniscus Replacements. Curr Rev Musculoskelet Med 17, 293–302 (2024). https://doi.org/10.1007/s12178-024-09902-1

	that describe the replacement of the medial or lateral meniscus of the knee with a synthetic substitute. Tracking of meniscal transplantation using autografts and allografts is important for studying the outcomes of surgery and providing evidence to guide appropriate care.	

EXAMPLE

Section	**0** Medical and Surgical
Body System	**S** Lower Joints
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*
C Knee Joint, Right **D** Knee Joint, Left	**0** Open	**6** Synthetic Substitute, Oxidized Zirconium on Polyethylene **J** Synthetic Substitute **L** Synthetic Substitute, Unicondylar Medial **M** Synthetic Substitute, Unicondylar Lateral **N** Synthetic Substitute, Patellofemoral	**9** Cemented **A** Uncemented **Z** No Qualifier
C Knee Joint, Right **D** Knee Joint, Left	**0** Open	**E** Articulating Spacer	**Z** No Qualifier
C Knee Joint, Right **D** Knee Joint, Left	**0** Open	**7** Autologous Tissue Substitute **K** Nonautologous Tissue Substitute	**ADD D** Medial Meniscus **ADD E** Lateral Meniscus **Z** No Qualifier

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr R

Main Replacement, knee

Delete Meniscus implant only see New Technology, Joints XRR

Add Meniscus only

Add see Replacement, Lower Joints 0SR

Add see New Technology, Joints XRR

New Technology Section
Axis 6 Device / Substance / Technology

Sonodynamic therapy (SDT)

Source	Description	Code specification
2024, Coding Clinic Editorial Advisory Board & CMS internal review	In the New Technology section, add the axis 6 device/substance/technology value 4 Focused Ultrasound Therapy, body part value 2 Brain, and approach value X External, to table X05, Destruction of Nervous System, to enable the capture of investigational focused ultrasound brain tumor ablation procedures such as sonodynamic therapy. Assign an additional code(s) as appropriate to describe the administration of any blood brain barrier disruption substances or therapeutics provided in the performance of the procedure.	Add: X052X4B (1 code)

	Sonodynamic therapy (SDT) is an investigational minimally invasive anti-cancer therapy involving a chemical sonosensitizer and focused ultrasound. A high-intensity focused ultrasound (HIFU) beam is used to destroy or denature targeted cancer tissues. In some SDTs, HIFU is combined with a drug, known as a chemical sonosensitizer, to amplify the drug's ability to damage cancer cells preferentially. Combining multiple chemical sonosensitizers with ultrasound creates a substantial synergistic effect that could effectively disrupt tumorigenic growth, induce cell death, and elicit an immune response. [7] The safety and tolerability of SDT using MR-Guided Focused Ultrasound (MRgFUS) energy in combination with SONALA-001 in subjects with diffuse intrinsic pontine glioma is currently being studied.[8]	

EXAMPLE

Section	**X** New Technology
Body System	**0** Nervous System
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 2 Brain	**ADD X** External	**ADD 4** Focused Ultrasound Therapy	**B** New Technology Group 11
1 Renal Sympathetic Nerve(s)	**3** Percutaneous	**2** Ultrasound Ablation	**9** New Technology Group 9
1 Renal Sympathetic Nerve(s)	**3** Percutaneous	**3** Radiofrequency Ablation	**A** New Technology Group 10

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr D
Main Destruction
Brain 0050
Add Focused Ultrasound Therapy X052X4B

Lttr F
Main Add Focused Ultrasound Therapy, Destruction, Brain X052X4B

Lttr N
Main New Technology
Destruction
Add Brain, Focused Ultrasound Therapy X052X4B

[7] Yamaguchi T, Kitahara S, Kusuda K, Okamoto J, Horise Y, Masamune K, Muragaki Y. Current Landscape of Sonodynamic Therapy for Treating Cancer. Cancers (Basel). 2021 Dec 8;13(24):6184. doi: 10.3390/cancers13246184. PMID: 34944804; PMCID: PMC8699567.
[8] https://clinicaltrials.gov/study/NCT05123534

Temporary Intraoperative Embolic Protection

Source	Description	Code specification
2024, public request with CMS internal review	In the Extracorporeal or Systemic Assistance and Performance section table 5A0, Assistance of Physiological Systems, add the axis 6 function value 6 Cerebral Embolic Filtration, applied to body system value 5 Circulatory, duration value A Intraoperative, and qualifier values M Single Capture Filter, N Dual Capture Filter, P Single Deflection Filter, and Q Extracorporeal Flow Reversal Circuit to describe the utilization of temporary intraoperative embolic protection devices to capture and remove debris that may dislodge during an interventional procedure with the intent to reduce the incidence of adverse events. The following ICD-10-PCS procedure codes currently exist to describe embolic protection and would be deleted: • X2A5312 (Cerebral embolic filtration, dual filter in innominate artery and left common carotid artery, percutaneous approach, new technology group 2) • X2A6325 (Cerebral embolic filtration, single deflection filter in aortic arch, percutaneous approach, new technology group 5) • X2AH336 (Cerebral embolic filtration, extracorporeal flow reversal circuit from right common carotid artery, percutaneous approach, new technology group 6) • X2AJ336 (Cerebral embolic filtration, extracorporeal flow reversal circuit from left common carotid artery, percutaneous approach, new technology group 6)	Delete: X2A5312 X2A6325 X2A[HJ]336 (4 codes) Add: 5A05A6[MNPQ] (4 codes)

EXAMPLE

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*
DELETE 5 Innominate Artery and Left Common Carotid Artery	**3** Percutaneous	**DELETE 1** Cerebral Embolic Filtration, Dual Filter	**DELETE 2** New Technology Group 2
DELETE 6 Aortic Arch	**3** Percutaneous	**DELETE 2** Cerebral Embolic Filtration, Single Deflection Filter	**DELETE 5** New Technology Group 5
7 Coronary Sinus	**3** Percutaneous	**5** Intermittent Coronary Sinus Occlusion	**8** New Technology Group 8
DELETE H Common Carotid Artery, Right **DELETE J** Common Carotid Artery, Left		**DELETE 3** Cerebral Embolic Filtration, Extracorporeal Flow Reversal Circuit	**DELETE 6** New Technology Group 6

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*
2 Cardiac	**1** Intermittent	**1** Output	**0** Balloon Pump **5** Pulsatile Compression **6** Other Pump **D** Impeller Pump
2 Cardiac	**2** Continuous	**1** Output	**0** Balloon Pump **5** Pulsatile Compression **6** Other Pump **D** Impeller Pump
2 Cardiac	**2** Continuous	**2** Oxygenation	**C** Supersaturated
5 Circulatory	**1** Intermittent **2** Continuous	**2** Oxygenation	**1** Hyperbaric
5 Circulatory	**A** Intraoperative	**0** Filtration	**L** Peripheral Veno-venous
5 Circulatory	**A** Intraoperative	**ADD 6** Cerebral Embolic Filtration	**ADD M** Single Capture Filter **ADD N** Dual Capture Filter **ADD P** Single Deflection Filter **ADD Q** Extracorporeal Flow Reversal Circuit
9 Respiratory	**2** Continuous	**0** Filtration	**Z** No Qualifier
9 Respiratory	**3** Less than 24 Consecutive Hours **4** 24-96 Consecutive Hours **5** Greater than 96 Consecutive Hours	**5** Ventilation	**7** Continuous Positive Airway Pressure **8** Intermittent Positive Airway Pressure **9** Continuous Negative Airway Pressure **A** High Flow/Velocity Cannula **B** Intermittent Negative Airway Pressure **Z** No Qualifier
9 Respiratory	**B** Less than 8 Consecutive Hours **C** 8-24 Consecutive Hours **D** Greater than 24 Consecutive Hours	**5** Ventilation	**K** Intubated Prone Positioning
2 Cardiac	**1** Intermittent	**1** Output	**0** Balloon Pump **5** Pulsatile Compression **6** Other Pump **D** Impeller Pump
2 Cardiac	**2** Continuous	**1** Output	**0** Balloon Pump **5** Pulsatile Compression **6** Other Pump **D** Impeller Pump
2 Cardiac	**2** Continuous	**2** Oxygenation	**C** Supersaturated

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr A

Main Assistance

Circulatory

Delete Intraoperative, Filtration, Peripheral Veno-venous 5A05A0L

Add Intraoperative

Add Cerebral Embolic Filtration

Add Dual Capture Filter 5A05A6N

Add Extracorporeal Flow Reversal Circuit 5A05A6Q

Add Single Capture Filter 5A05A6M

	Add	Single Deflection Filter 5A05A6P
	Add	Filtration, Peripheral Veno-venous 5A05A0L

Lttr	C	
Main	Cerebral Embolic Filtration	
	Delete	Dual Filter X2A5312
	Add	Dual Capture Filter 5A05A6N
	Revise from	Extracorporeal Flow Reversal Circuit X2A
	Revise to	Extracorporeal Flow Reversal Circuit 5A05A6Q
	Add	Single Capture Filter 5A05A6M
	Revise from	Single Deflection Filter X2A6325
	Revise to	Single Deflection Filter 5A05A6P

Lttr	E	
Main	Revise from	ENROUTE(R) Transcarotid Neuroprotection System see New Technology, Cardiovascular System X2A
	Revise to	ENROUTE(R) Transcarotid Neuroprotection System see Assistance, Physiological Systems 5A0
Main	Add	Extracorporeal Flow Reversal Circuit, Assistance, Circulatory, Intraoperative, Cerebral Embolic Filtration 5A05A6Q

Lttr	K	
Main	Revise from	Keystone Heart TriGuard 3(tm) CEPD (cerebral embolic protection device) X2A6325
	Revise to	Keystone Heart TriGuard 3(tm) CEPD (cerebral embolic protection device) 5A05A6P

Lttr	N	
Main	New Technology	
	Delete	Cerebral Embolic Filtration
	Delete	Dual Filter X2A5312
	Delete	Extracorporeal Flow Reversal Circuit X2A
	Delete	Single Deflection Filter X2A6325

Lttr	S	
Main	Revise from	Sentinel (tm) Cerebral Protection System (CPS) X2A5312
	Revise to	Sentinel (tm) Cerebral Protection System (CPS) 5A05A6N

Lttr	T	
Main	Revise from	TriGuard 3(tm) CEPD (cerebral embolic protection device) X2A6325
	Revise to	TriGuard 3(tm) CEPD (cerebral embolic protection device) 5A05A6P

Topic # 07 – Insertion of a Volume Sensor Management Device

Issue: There are currently no unique ICD-10-PCS codes to describe the insertion of a volume sensor management device for heart failure. An October 1, 2025 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. The FIRE1 NORM™ Heart Failure Management Device received FDA Breakthrough Device designation In January 2025 and has been accepted into the FDA's Total Product Life Cycle Advisory Program (TAP), a voluntary program to help spur more rapid development of high-quality, safe, effective, and innovative medical devices that are considered critical to public health.

Background: Heart failure (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. Acute decompensated heart failure (ADHF) affects over one million Americans annually and is the most common hospital discharge diagnosis among Medicare beneficiaries. Notably, ADHF is thought to account for more than half of all heart failure related expenditures. Following discharge, readmission rates remain remarkably high with nearly 50% of patients rehospitalized within 6 months.

On a population level, ADHF is overwhelmingly a disease of congestion rather than low cardiac output. As a compensatory mechanism to a failing pump, the kidney retains excessive salt and water to restore adequate cardiac output. This maladaptive response of the kidney leads to fluid overload and the classic signs and symptoms of heart failure such as dyspnea on exertion, orthopnea, and edema. Given the primacy of fluid overload in precipitating HF symptoms and hospitalizations, early detection and treatment of fluid overload is paramount.

According to the requestor, there is currently no optimal method by which to measure a chronic heart failure patient's fluid status. In most patients, the current standard of care relies on signs and symptoms of fluid accumulation, such as weight gain and breathlessness, to identify possible worsening of a patient's heart failure. However, by the time a patient has developed symptoms, it is often too late to prevent a heart failure hospitalization with outpatient therapy. The requestor states that despite progress with implantable technologies, heart failure mortality across the U.S. continues to climb with a rise in heart failure deaths. In the U.S., the heart failure-related mortality rate of approximately 82 deaths per 100,000 people started to increase, reaching 106 per 100,000 by 2012, a spike that has not been seen since 1999 when heart failure-related mortality rate stood at 105 per 100,000 people.

The NORM™ volume sensor management device is indicated for use in NYHA Class II heart failure patients with HF hospitalization <12 months ago and for NYHA Class III patients who have elevated levels of natriuretic peptides or have had a HF hospitalization <12 months ago.

Technology
The NORM™ volume sensor management device consists of the sensor, which is a crown-shaped implant that is deployed in the inferior vena cava (IVC). The sensor will be available in one size, which will cover the range of IVC diameters currently indicated for use of the device [14 – 28mm IVC diameter].

The implantable sensor consists of an electromagnetic resonator with an electrical circuit using multiple parallel strands of 0.0016" gold wire. The gold wires are individually coated in polyurethane/nylon, wrapped around a "crown" shape-set nitinol wire frame, and then covered in an outer layer of PET shrink sleeve, leaving a short portion exposed at either end for further processing. A capacitor is then attached to the two open ends of the gold Litz subassembly, so that the gold wire forms the inductor of a resonant circuit. The capacitor and its solder bond to the gold terminals is encapsulated using a polyethylene terephthalate (PET) shrink sleeve. A separate laser-cut electropolished nitinol "anchor frame" featuring eight alternating cranial and caudal facing barbs is attached cranially to the "sensor frame" at the four crowns, also using PET shrink sleeve ('Reflow'), to prevent migration from the site of deployment. The sensor has been designed to provide a low radial force within the vessel, which allows it to react to changes in the geometry of the IVC and prevent vessel damage and remodeling of the vessel.

The delivery system comprises a loader tube that holds the crimped sensor and a radiopaque pusher that is used to deploy the crimped sensor through a commercially available introducer sheath (Cook Medical, 70 cm 16F Performer™ Introducer Sheath) during a percutaneous procedure via femoral vein access.

The external system is composed of a belt system with a power supply and carrying case, as well as a mobile application running on a compatible mobile device such as a smartphone.

The function of the sensor is that it conforms to, and tracks, the geometry of the IVC through the patient's respiratory cycle, and the system tracks the longitudinal fluctuation of the IVC area. Per the requestor, this fluctuation is the critical index that correlates with fluid volume status and is monitored by the NORM™ system, which enables more refined management of HF. According to the requestor, these data can provide an earlier, more sensitive indication of fluid overload which can be managed more effectively than if the patient and physician were to wait for more traditional signs and symptoms of a deterioration in HF status. The requestor asserts use of this early signal offers the potential to avoid critical acute decompensation episodes leading to a better quality of life and a reduction in hear failure related events, including hospitalizations; and as a result, also has the potential to slow down the progression of the disease.

Procedure Description
The volume sensor management device is deployed through the delivery system during a percutaneous procedure via femoral vein access. After the patient is prepared by attaching the wearable sensor-reading belt covered in plastic prior to creating a sterile field, the patient is prepared for the femoral venous access, which is performed using an appropriately sized introducer sheath (e.g., 5-9 Fr.) If necessary, a right heart catheterization is performed to gain Pulmonary Artery Pressure (PAP), Right Atrial Pressure (RAP) and Pulmonary Capillary Wedge Pressure (PCWP) readings. An atomical evaluation of the Inferior Vena Cava (IVC) is performed via cavogram using a calibrated pigtail catheter with powered contrast injector and the location length of the implantation is identified. The diameter of the IVC is then confirmed using AP and lateral cavograms. The femoral access is upsized to 16 Fr. And the sensor is deployed by advancing the

sensor to the tip of the sheath, then unsheathing the Sensor at the intended deployment site. A baseline signal recording from the sensor is taken, after which the Sensor deployment is assessed using fluoroscopy. The sheath is withdrawn and the wound is closed as per standard of care.

Only one device is routinely implanted in the patient and is considered a permanent device. There would be no circumstance when multiple devices would be implanted in a single patient.

Per the requestor, there have been no device-related adverse events, complications, or sequela with implantation of the volume sensor management device in ~65 implants performed as of February 2025.

Current Coding: There are no unique ICD-10-PCS codes to describe the insertion of a volume sensor management device in the inferior vena cava for heart failure. Code the procedure in table 06H, Insertion in Lower Veins, using the body part value 0 Inferior Vena Cava, the device value D Intraluminal Device and the percutaneous approach.

Section **0** Medical and Surgical *Body System* **6** Lower 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*
0 Inferior Vena Cava	**0** Open **3** Percutaneous	**3** Infusion Device	**T** Via Umbilical Vein **Z** No Qualifier
0 Inferior Vena Cava	**0** Open **3** Percutaneous	**D** Intraluminal Device	**Z** No Qualifier
0 Inferior Vena Cava	**4** Percutaneous Endoscopic	**3** Infusion Device **D** Intraluminal Device	**Z** No Qualifier
1 Splenic Vein **2** Gastric Vein **3** Esophageal Vein **4** Hepatic Vein **5** Superior Mesenteric Vein **6** Inferior Mesenteric Vein **7** Colic Vein **8** Portal Vein **9** Renal Vein, Right **B** Renal Vein, Left **C** Common Iliac Vein, Right **D** Common Iliac Vein, Left **F** External Iliac Vein, Right **G** External Iliac Vein, Left **H** Hypogastric Vein, Right **J** Hypogastric Vein, Left **M** Femoral Vein, Right **N** Femoral Vein, Left **P** Saphenous Vein, Right **Q** Saphenous Vein, Left **T** Foot Vein, Right **V** Foot Vein, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**3** Infusion Device **D** Intraluminal Device	**Z** No Qualifier
Y Lower Vein	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **Y** Other Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the insertion of a volume sensor management device in the inferior vena cava for heart failure. Continue coding as described in current coding.

Option 2. In section X New Technology table X2H, Insertion, Cardiovascular System, create new device value B Volume Sensor Management Device, applied to the body part value 0 Inferior Vena Cava and the percutaneous approach, to identify insertion of a volume sensor management 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*
0 Inferior Vena Cava	**3** Percutaneous	**ADD B** Volume Sensor Management Device	**B** New Technology Group 11
0 Inferior Vena Cava **1** Superior Vena Cava	**3** Percutaneous	**R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9
2 Femoral Vein, Right **3** Femoral Vein, Left	**0** Open	**R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9
6 Atrium, Right **K** Ventricle, Right	**3** Percutaneous	**V** Intracardiac Pacemaker, Dual-Chamber	**9** New Technology Group 9
L Axillary Artery, Right **M** Axillary Artery, Left **X** Thoracic Aorta, Ascending	**0** Open	**F** Conduit to Short-term External Heart Assist System	**9** New Technology Group 9

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

MS-DRG Classifications and Software

Notice Regarding Upcoming Releases of the MS-DRG Grouper and Medicare Code Editor (MCE)

The current versions of the MS-DRG Grouper and MCE use Java software and are currently based on Java version 8. Support for Java version 8 will end by November 2026. Hospitals and their software vendors who implement these programs in a mainframe environment will be impacted by this change. CMS is preparing now to convert the programs to Java version 17.

The Fiscal Year 2025 releases of these programs, effective October 2024, included two Common Business-Oriented Language (COBOL) Java bridge modules instead of the one that was previously delivered. CMS continues to provide the existing bridge module that utilizes the 31-bit, Java 8 Java Virtual Machine (JVM) environment. We also provided a new bridge module that utilizes the 64-bit, Java 17 JVM. The Java jar file for each continues to be compiled using Java 8. This preserves backwards compatibility with all existing mainframe deployments (both batch and Customer Information Control System (CICS)). The installation guides for the programs provided notice of the changes. This allows users to test upgrades to their systems to prepare to move to Java 17.

The release of the Fiscal Year 2026 release of these programs, effective October 2025, will be compiled with Java 17 and only the Java 17, 64-bit COBOL calling module will be delivered. Providers and their software vendors should continue planning this year to ensure they are prepared for this conversion in the fall.

Questions about the Java 17 conversion can be sent at any time to the resource mailbox GrouperBetaTesting@cms.hhs.gov.

Topic # 09 – Division of Aortic Valve Leaflets Using Radiofrequency Energy

Issue: There are currently no unique ICD-10-PCS codes to describe division of aortic valve leaflets using radiofrequency energy during transcatheter aortic valve replacement (TAVR). An October 1, 2025 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. The TELLTALE Electrosurgical Guidewire System was granted Breakthrough Device designation by the FDA on April 12, 2024. An Investigational Device Exemption (IDE) was approved by the FDA on November 2, 2022.

Background: Coronary artery obstruction is a devastating complication of TAVR, with a reported mortality of greater than 50%. TAVR is an effective alternative to surgical aortic valve replacement in low, intermediate, and high-risk patients with native aortic stenosis. TAVR is also an effective treatment for failure of bioprosthetic surgical or transcatheter aortic valves, a treatment known as valve-in-valve TAVR. Based on the current TAVR market (~100K implants per year), coronary obstruction occurs in approximately 2% of native aortic stenosis procedures but the incidence could be as high as 25% of redo TAVR procedures (TAVR to treat a failing transcatheter heart valve). Coronary obstruction occurs when the newly deployed transcatheter heart valve displaces the degenerated bioprosthetic or native aortic valve leaflets outwards and towards the coronary artery ostia. Obstruction to coronary perfusion occurs either by sequestration of the entire sinus of Valsalva at the sinotubular junction or by the leaflet directly covering a coronary ostium due to low lying coronary ostium and inadequate sinus of Valsalva width. Per the requestor, coronary obstruction during TAVR can lead to an irreversibly debilitating condition for the patient such as an acute heart attack, reduced ejection fraction and chronic heart failure or unplanned high-risk surgery.

According to the requestor, if a patient's pre-TAVR CT scan predicts risk of coronary obstruction then there are limited treatment options: they may undergo surgery, but many such patients are high risk for open heart surgery due to advanced age, comorbidity and/or frailty; they may choose not to undergo aortic valve replacement, but untreated severe symptomatic aortic stenosis is invariably fatal. Per the requestor, for these patients, the TELLTALE Electrosurgical Guidewire System allows for a TAVR procedure to be performed and avoids the life-threatening complication of coronary obstruction.

The requestor maintains that the TELLTALE Electrosurgical Guidewire System differs from a recently approved similar technology described as a mechanical leaflet splitting device and indicated for patients with bioprosthetic valves (valve-in-valve procedures) because the TELLTALE Electrosurgical Guidewire System is an electrosurgical device using radiofrequency energy for leaflet modification. The requestor asserts that electrosurgical laceration does not rely on force to cut the leaflet and thereby reduces the risk of mechanical leaflet avulsion that may be associated with serious hemodynamic deterioration caused by acute iatrogenic valve regurgitation.

Technology
The TELLTALE Electrosurgical Guidewire System is intended for transcatheter electrosurgical traversal and laceration of native and bioprosthetic tissue in patients at risk of coronary obstruction during TAVR. It is used to traverse and lacerate an aortic valve leaflet prior to TAVR implantation. The system is comprised of
1) A 0.014"OD x 310cm electrically insulated stainless steel Guidewire
2) electrically insulated Pachyderm Guide Catheters (7 curve types available, specifically designed for left and right cusp engagement and for guidewire ensnarement). Pachyderm guides are made of traditional medical materials such as high density polyethylene (HDPE), Pebax, Vestimid, polycarbonate, and stainless steel braid.
3) and an Accessories kit which includes:
a. a connector between the electrosurgical generator and the guidewire,
b. a denuder/kinker for creating a reproducible kink and denuded area at the mid-shaft location of the guidewire for laceration and
c. two guidewire grippers to provide traction during laceration.

Procedure Description
A leaflet laceration procedure also known as BASILICA (Bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction) is planned using ECG-gated contrast-enhanced computed tomography (CT), performed under general anesthesia, and guided by fluoroscopy and transesophageal echocardiography. Pre-procedure, the leaflet(s) at risk of obstruction are identified. Catheter access is typically the same as for TAVR (two arterial sheaths and one venous introducer sheath for temporary transvenous pacing).

A Pachyderm guide catheter is positioned on the aortic side of the target aortic leaflet near the hinge point. The guidewire is aimed at a snare delivered through a second Pachyderm guide catheter and positioned immediately below the target leaflet in the left ventricular outflow tract (LVOT). Using fluoroscopy and echocardiography, the position of the traversal guide catheter and the tip of the guidewire is confirmed and the guidewire is connected to the radiofrequency (RF) generator. With 15-20W of monopolar RF energy in pure cut mode, the guidewire is advanced through the base of the leaflet. The tip of the guidewire is snared in the LVOT using the snare and captured into the snare guide catheter. The 1cm gold mid-shaft section of the guidewire is denuded and kinked using the provided denuder/kinker tool and the newly created mid-shaft laceration section (Flying-V) is advanced to the aortic cusp by externalizing the snared tip of the guidewire. The tips of the Pachyderm guide catheters are positioned at the radiopaque ends of the Flying-V and locked in placed using the guidewire grippers. The proximal end of the guidewire is re-attached to the RF generator and electrified at 30-40W under gentle traction to lacerate the leaflet down the centerline. The split leaflet typically splays in systole and coapts in diastole, and per the requestor, typically maintains hemodynamic stability in the interval between leaflet splitting and TAVR implantation. The TELLTALE system is disconnected from the generator and removed from the body. TAVR is then performed using standard technique. Coronary artery patency is assessed using aortography and/or selective coronary angiography.

The TELLTALE System is a single-use disposable non-implant device. One TELLTALE System is intended for one laceration of an aortic leaflet. Multiple guide catheter shapes may be tried by physicians to obtain an optimal fit for varying patient anatomy. To date 77 of 90 subjects have undergone successful leaflet laceration (BASILICA) using the TELLTALE System at 11 clinical sites. Among treated subjects, 29 had native aortic stenosis and 48 bioprosthetic aortic valve failure.

Current Coding: There are no unique ICD-10-PCS codes to describe division of aortic valve leaflets using radiofrequency energy. Code the procedure in table 02Q, Repair of Heart and Great Vessels, using the body part value F Aortic 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*
F Aortic Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**J** Truncal Valve **Z** No Qualifier

Separately code the TAVR procedure in table 02R Replacement of Heart and Great Vessels, with the body part value F Aortic Valve, the device value 8 Zooplastic Tissue 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*
F Aortic Valve	**3** Percutaneous	**8** Zooplastic Tissue	**H** Transapical **N** Rapid Deployment Technique **Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for division of aortic valve leaflets using radiofrequency energy. Continue coding as described in current coding.

Option 2. In section X New Technology table X28, Division, Cardiovascular System, create new technology value W Leaflet Laceration, Radiofrequency Energy, applied to the body part value F Aortic Valve and the percutaneous approach, to identify division of aortic valve leaflets using radiofrequency energy.

Section	**X** New Technology
Body System	**2** Cardiovascular System
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 / Substance / Technology*	*Qualifier*
F Aortic Valve	**3** Percutaneous	**V** Intraluminal Bioprosthetic Valve Leaflet Splitting Technology in Existing Valve	**A** New Technology Group 10
F Aortic Valve	**3** Percutaneous	**ADD W** Leaflet Laceration, Radiofrequency Energy	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 10 – Gene Expression Testing System for Whole Blood Samples

Issue: There are currently no unique ICD-10-PCS codes to describe a gene expression testing system for whole blood samples. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. The TriVerity™ test received 510(k) clearance on January 10, 2025. The TriVerity test is indicated for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial infections, viral infections, and non-infectious illness, as well as to determine the likelihood of 7day need for mechanical ventilation, vasopressors, and/or renal replacement therapy in adult patients with suspected acute infection or suspected sepsis presenting to the emergency department. The TriVerity™ test was granted Breakthrough Medical Device status by the FDA on November 20, 2023, and Investigational Device Exemption was granted on August 8, 2024.

Background: When making decisions regarding infectious diseases, physicians must carefully consider the patient's symptoms, medical history, exposure history, local epidemiology, and laboratory findings to accurately diagnose the infection and choose the most appropriate treatment, often involving a nuanced balance between selecting the right antibiotic or antiviral while considering potential resistance and minimizing unnecessary medication use. Diagnosing infections is also challenging because signs and symptoms are usually non-specific for a particular infection. In addition, the choice of treatment, or the decision not to treat, can be difficult. Also, determining the level of care (i.e. discharge, observe, ward, ICU) for a patient suspected with infection or sepsis can be challenging given that symptoms of often similar in patients that recover or decompensate. As a result, some patients are discharged only to see their symptoms worsen and reappear at hospital emergency departments and many patients are admitted who could have possibly been safely discharged. These decisions often require consultation with an infectious disease specialist, especially in complex cases involving immunocompromised or co-morbid patients.

The TriVerity™ test was developed to potentially be an improvement to current technology across multiple dimensions. According to the requestor, the features of the TriVerity™ test, specifically informing on the likelihood of a bacterial infection, a viral infection and illness severity, can help emergency physicians make important clinical decisions such as whether antibiotics should be prescribed, whether additional downstream testing is necessary and deciding on the appropriate level of care (i.e. discharge vs admit).

Technology
The TriVerity™ Test is an automated, semi-quantitative in vitro diagnostic test that measures the relative expression levels of 29 host response genes (and three housekeeping genes) in ribonucleic acid (RNA) isolated from whole blood collected in a PAXgene® Blood RNA tube using the amplification technique reverse transcription loop-mediated isothermal amplification (RT-LAMP). The TriVerity™ test fits into routine clinical workflows easily and an operator can perform a test using less than a minute of hands-on time, and test results are available in around 30 minutes.

Machine learning-derived classifiers generate three results: (1) the likelihood of a bacterial infection, (2) the likelihood of a viral infection, and (3) the likelihood of severe illness, as defined

by the need for mechanical ventilation, vasopressors, and/or renal replacement therapy (RRT) within seven days. The three scores each are shown as a number between 0 and 50 and fall into one of five interpretation bands ranging from Very low to Very high.

The test is executed completely (RNA extraction and RNA amplification) within the TriVerity™ Cartridge with manipulation by the Myrna Instrument where valves and pressure push blood and reagents throughout the cartridge's fluidic paths, the gene expression levels are measured, and the scores are calculated by on-instrument TriVerity™ software. The TriVerity™ Test has not been associated with any complications, sequela, or adverse events. On rare occasions, tests return a "No Result" which may be due to a TriVerity™ Cartridge manufacturing issue, lack of measurable RNA (i.e. truly neutropenic immunocompromised patient), or Myrna Instrument error.

Procedure Description
The TriVerity™ test is a single use test. 2.5 ml of whole blood is collected via routine phlebotomy from an adult patient suspected of an acute infection or sepsis into a PAXgene® Blood RNA tube. The PAXgene® tube is inverted 10 times to mix the blood with the RNA stabilizing reagent within the tube. The tube is placed into a TriVerity™ Cartridge and the Cartridge is inserted into the Myrna Instrument for testing to commence.

According to the requestor, this test initiation process, including interacting with the Myrna Instrument through a few simple prompts, should take an operator less than a minute. Once testing is complete (in approximately 30 minutes), results can be viewed on the Myrna Instrument screen, printed or transmitted to the laboratory information system or electronic medical record. The treating physician can use the results as an aid in treatment decisions such as whether antibiotics should be prescribed, downstream diagnostic tests should be ordered, whether the severe sepsis and septic shock management (SEP-1) bundle should be started, and the level of care necessary for the patient (e.g. discharge, observe, ward, ICU).

Current Coding: Gene expression testing for whole blood samples is not reported separately for inpatient hospital coding. If desired, facilities can report the collection of a patient's specimen from an indwelling vascular catheter using the following code:

8C02X6K Collection of blood from indwelling device in circulatory system

Coding Options

Option 1. Do not create new ICD-10-PCS codes for a gene expression testing system for whole blood samples. Continue coding as described in current coding.

Option 2. In section X New Technology table XXE, Measurement, Physiological Systems, create new technology value B Infection and Immune Response, Gene Expression Testing System, applied to the body part value 5 Circulatory and the external approach, to identify gene expression testing system for whole blood samples.

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*
5 Circulatory	**X** External	**ADD B** Infection and Immune Response, Gene Expression Testing System	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 11 – Dilation using Expandable Intraluminal Device with Growth Technology

Issue: There are currently no unique ICD-10-PCS codes to describe an expandable intraluminal device with growth technology. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. The Minima Stent System was granted Breakthrough Medical Device status by the FDA on February 7, 2022, and Premarket Approval (PMA) was granted on August 28, 2024. The Minima Stent is indicated for use in the treatment of native or acquired pulmonary artery stenoses or coarctation of the aorta in neonates, infants, and children at least 1.5 kg in weight.

Background: Congenital vascular stenosis occurs when the outflow of arterial blood from the right (pulmonary arteries) or left ventricle (aorta) is blocked by a narrowing or stenosis within that vessel. These lesions can occur in isolation, but more often are associated with complex congenital heart disease involving other abnormalities of the heart (e.g. Tetralogy of Fallot, single ventricle, etc.). Obstruction to arterial blood flow can result increased pressure load placed upon the ventricles which can result in myocardial hypertrophy and dysfunction as well as under perfusion of organs distal to the obstruction such as the kidney (in the case of aortic coarctation) or pulmonary vascular bed (in the case of branch pulmonary artery stenosis). The most common location for congenital vascular obstruction to occur in infants and small children are the branch pulmonary arteries and the aorta. Stenoses of these vessels may be "native" (i.e., a child is born with them) or "acquired" (i.e., a recurrent obstruction following cardiac surgery).

Pulmonary artery stenosis (PAS) is a vascular narrowing seen most commonly in the central right and left branch pulmonary but may occur anywhere along the pulmonary arterial tree. Branch PAS may be unilateral or bilateral and may be single or multiple. While PAS may occur in isolation it is much more commonly associated with a variety of cardiac malformations such as Tetralogy of Fallot, transposition of the great arteries, or a variety of forms of single ventricle. The clinical presentation of these infants is often dictated by these associated lesions. In general terms, if a single lung is affected, typically right ventricular pressure will be normal or only minimally elevated, however in this scenario, an infant may still present as cyanotic, and the affected pulmonary vascular bed will almost certainly not develop normally if left untreated. In the setting of bilateral branch pulmonary artery obstruction, the right ventricle is under significant strain manifested by elevated right ventricular pressure and ultimately dysfunction. One relatively common scenario is the presentation of unilateral or bilateral PAS after complex neonatal or infant cardiac surgery. These children are often critically ill, requiring significant ICU support including extracorporeal membrane oxygenation (ECMO). Urgent repair of this PAS in this setting may be lifesaving.

Coarctation of the aorta is a localized obstruction occurring in the thoracic aorta caused by a combination of a protruding shelf of tissue and an infolding of the vessel wall. In newborns, the obstructive lesion often coexists with tubular hypoplasia (diffuse narrowing) of the aortic isthmus, the segment of the aorta which lies between the left subclavian artery and the ductus arteriosus. This is a common lesion and ranks 6th in frequency of all congenital heart lesions, accounting for 4-8% of all congenital heart defects. Other left-sided heart lesions are commonly associated with coarctation including bicuspid aortic valve, subaortic stenosis, and hypoplastic left heart syndrome.

Currently, the preferred method of therapy for newborn coarctation is surgical repair, however, despite a long evolution and a variety of surgical techniques, recurrent obstruction is still quite common, on the order of 5-25%. Currently, balloon angioplasty (for children < 20 kg) and stent implantation (for children > 20kg) are the preferred treatment options for recurrent coarctation despite the fact that stent implantation has been shown in numerous reports to be superior to angioplasty in terms of better acute and long-term results and lower rates of complications. The primary reason for this is the lack of availability of a stent that can safely be implanted in an infant (i.e., small enough delivery system to prevent damage to the peripheral arterial vasculature) that can ultimately be dilated to an adult diameter. Current results with angioplasty used to treat recurrent coarctation in infants suggest a recurrence rate of 44% at an average of 2.4 months after the procedure. Despite this obvious unmet need, there is currently not an endovascular stent that was designed specifically to treat infant vascular stenoses nor approved for use in infants.

Technology

The Minima Stent System is an expandable metal (cobalt-chromium) mesh tube that can be used to reopen a narrowed pulmonary artery (blood vessel that carries blood from the heart to the lungs) or narrowed aorta (major artery carrying blood from the heart to the rest of the body). Particularly for patients that have already undergone one surgical intervention in the early years of life, the Minima Stent is built to provide minimally invasive, percutaneous stenosis relief today and in the years ahead. The stent restores healthy blood flow in the aorta and/or pulmonary arteries. Its re-expansion capabilities ensure the vessel can stay open as the patient grows, which may prevent future surgical intervention or purposeful fracturing of off-label adult stents. Unlike stents being used off-label today, the Minima Stent comes pre-mounted, and front loaded on an integrated delivery system, with an implantable range between 5.1-8.5 mm, suitable for neonate and infant vasculature. Minima is also designed to be re-expanded over the course of the patient's somatic growth period to accommodate adult size vasculature. Only one device is routinely placed, however there may be rare occasions when multiple lesions or longer lesions would require multiple devices. Additionally, the Minima Stent is permanent. While there may be re-expansion procedures following the initial procedure, it is not expected that there will be an occasion where the Minima Stent is removed.

Procedure Description

To place the Minima Stent System, the operator will prepare the patient for a standard transcatheter procedure. Typically, the procedure will be performed under general anesthesia. Once vascular access is achieved, anticoagulation is administered to achieve an activated clotting time (ACT) of greater than 250 seconds prior to device placement, unless the patient has a significant risk for bleeding and is unable to be anticoagulated. Prophylactic antibiotics will be administered. The operator will then perform a right and/or a left heart catheterization as indicated, obtaining access using conventional methods. The covered system allows for sheathless delivery, with the entire system having an outer diameter equivalent to a 4 Fr sheath, making it suitable for use in neonates, infants, and young children. If a physician elects to use a sheath, a 6 Fr sheath is required. Hemodynamic measurements are taken, as indicated. The operator will then perform selective angiography of the target lesion to measure stenosis diameter as well as the adjacent non-stenotic vessel diameter both proximal and distal to the target lesion. They will also measure the target lesion length to ensure it is suitable for the 16 mm Minima Stent. Based on these measurements, the Minima Stent System (either 6 mm or 8 mm) is chosen.

The operator will then prepare the device, starting by ensuring the lock is engaged with the hypotube. Then the operator will flush the guidewire lumen of the balloon catheter and the

injection port of the outer shaft using saline until saline visibly exits the distal end of the guidewire lumen and outer shaft. A balloon inflation device is attached to the y-connector and the air is removed from the balloon using a saline and contrast mixture. Either a .014 or .018 guidewire is introduced into the vasculature and advanced across the target lesion. The Minima Stent delivery system is tracked over the guidewire to the target lesion. Once at the intended deployment position, the outer shaft is unlocked, and the Minima Stent is unsheathed by pulling the outer shaft back while holding the balloon shaft stationary. Ensuring the outer shaft is fully retracted with the balloon y-connector flush with the handle, the system is then re-locked in this position. An angiogram with the unsheathed stent is then taken to confirm "final" positioning. Small adjustments in the stent position are made, and then the Minima Stent is deployed by slowly inflating the balloon to the pressure needed to achieve the desired stent diameter as listed on the sterile insert card provided in the packaging. When the desired Minima Stent expansion is obtained, the balloon is deflated. The operator will confirm proper stent deployment using a contrast injection through the outer sheath injection port. After confirmation, the balloon catheter is retracted and removed through the system. The operator will perform a post-deployment angiogram and hemodynamic measurements to evaluate that the Minima Stent is properly positioned, the stenosis has been adequately expanded, and there is no vascular damage. Should further expansion of the stent be desired, a ballon that is larger than the implant balloon can be advanced across the stent and inflated. Upon completion of the procedure, the system is removed from the vasculature and hemostasis is obtained with manual pressure.

Current Coding: There are no unique ICD-10-PCS codes to describe transcatheter dilation of the thoracic aorta or pulmonary artery with the placement of an expandable intraluminal device. Code the procedure in table 027 Dilation of Heart and Great Vessels, with the applicable thoracic aorta or pulmonary artery body part value, the device value D Intraluminal Device and the percutaneous approach.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Coronary Artery, One Artery **1** Coronary Artery, Two Arteries **2** Coronary Artery, Three Arteries **3** Coronary Artery, Four or More Arteries	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Intraluminal Device, Drug-eluting **5** Intraluminal Device, Drug-eluting, Two **6** Intraluminal Device, Drug-eluting, Three **7** Intraluminal Device, Drug-eluting, Four or More **D** Intraluminal Device **E** Intraluminal Device, Two **F** Intraluminal Device, Three **G** Intraluminal Device, Four or More **T** Intraluminal Device, Radioactive **Z** No Device	**6** Bifurcation **Z** No Qualifier
F Aortic Valve **G** Mitral Valve **H** Pulmonary Valve **J** Tricuspid Valve **K** Ventricle, Right **L** Ventricle, Left **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Intraluminal Device, Drug-eluting **D** Intraluminal Device **Z** No Device	**Z** No Qualifier

W Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch			
R Pulmonary Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Intraluminal Device, Drug-eluting **D** Intraluminal Device **Z** No Device	**T** Ductus Arteriosus **Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for dilation of the thoracic aorta or pulmonary artery with placement of an expandable intraluminal device. Continue coding as described in current coding.

Option 2. In section X New Technology table X27, Dilation, Cardiovascular System, create new device value 9 Intraluminal Device, Expandable, applied to the thoracic aorta and pulmonary artery body part values shown and the percutaneous approach, to identify dilation of the thoracic aorta or pulmonary artery with placement of an expandable 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*
ADD 3 Pulmonary Artery, Right **ADD 4** Pulmonary Artery, Left **ADD W** Thoracic Aorta, Descending **ADD X** Thoracic Aorta, Ascending/Arch	**3** Percutaneous	**ADD 9** Intraluminal Device, Expandable	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 12 – Extracorporeal Pheresis of Ticagrelor

Issue: There are currently no unique ICD-10-PCS codes to describe the extracorporeal pheresis of ticagrelor. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? No. The DrugSorb™-ATR device received Breakthrough Device Designation from the FDA on April 20, 2020. According to the requestor, a De Novo classification request was submitted on September 27, 2024.

Background: Ticagrelor (Brilinta®) is indicated to 1) reduce the risk of cardiovascular death, myocardial infarction (MI) and stroke in patients with acute coronary syndrome (ACS) or a history of MI, 2) to reduce the risk of a first MI or stroke in patients with coronary artery disease at high risk for such events, and 3) to reduce the risk of stroke in patients with acute ischemic stroke. Treatment with ticagrelor in patients with ACS has been increasingly used since it has been shown to reduce the rate of death from vascular causes, MI, and stroke. Ticagrelor possesses a more potent and consistent platelet inhibition with faster onset and offset of action compared with clopidogrel. While the clinical benefit of ticagrelor is well established, there is a trade-off to clinical benefits, as antiplatelet therapy also increases risk and severity of major bleeding and of bleeding associated with surgery or invasive procedures.[1,2] There are no currently approved agents to reverse the antiplatelet effects of ticagrelor and ticagrelor is also not expected to be dialyzable. Further, the antiplatelet effects of ticagrelor cannot be reliably reversed with platelet transfusion.[1,3]

Patients with ACS who receive dual-antiplatelet therapy and urgently need coronary artery bypass grafting (CABG) have a high risk for severe perioperative bleeding complications. Surgeons are faced with a difficult dilemma in patients on ticagrelor requiring CABG of either proceeding with the indicated surgery at an increased bleeding risk, or postponing the procedure for several days while accepting the incrementally but steadily increasing thrombotic risks associated with delaying a clinically indicated procedure without antiplatelet protection.[2] To reduce the risk of bleeding complications, it is recommended that CABG should be postponed at least 3 days after discontinuation of ticagrelor and 5 days after clopidogrel.

Technology
The DrugSorb™-ATR antithrombotic removal system is an investigational device developed to be used to intraoperatively remove ticagrelor from the blood of patients undergoing CABG within two days of ticagrelor discontinuation to significantly reduce perioperative bleeding complications. The DrugSorb™-ATR device is a sorbent-filled hemoperfusion cartridge effective at binding small molecules with molecular moieties contained in ticagrelor. According to the requestor, ticagrelor in whole blood easily passes into the pores of the polymer where it adsorbs onto the internal polymer surface. The surface adsorption is governed by the hydrophobic nature of the polymer, through a combination of non-polar interactions, hydrogen bonding, and Van der Waals forces. These drug-

[1] Bhatt DL, et al. Bentracimab for ticagrelor reversal in patients undergoing urgent surgery. *NEJM Evidence;* DOI:10.1056/EVIDoa2100047, December 2021.
[2] Bhatt DL, et al. Antibody-based ticagrelor reversal agent in healthy volunteers. *N Engl J Med* 2019;380:1825-33. DOI:10.1056/NEJMoa1901778, March 2019.
[3] Teng J, et al. Effects of autologous platelet transfusion on platelet inhibition in ticagrelor-treated and clopidogrel-treated subjects. *J Thromb Haemost.* 2016;14:2342-2352.

polymer interactions favor removal of hydrophobic molecules over hydrophilic ones. In clinical trials, no device-related serious adverse effects occurred in either the DrugSorb™-ATR treatment arm or the control group.

Procedure Description
The DrugSorb™-ATR device is designed for use in extracorporeal circuits and is used once per patient. The device can easily be incorporated as a component in a shunt of a standard cardiopulmonary bypass (CPB) circuit. The DrugSorb™-ATR device is a sorbent-filled hemoperfusion cartridge which consists of a cylinder and end-cap assembly filled with biocompatible porous polymer beads. At either end of the cylinder, a fine mesh screen is placed to retain the polymer beads within the device. Each end cap has a standard blood tubing connector, which is compatible with standard CPB blood tubing lines. The polymer beads are composed of a divinylbenzene/polyvinyl pyrrolidone co-polymer, where each bead has hundreds of thousands of tightly controlled pores and channels that are generated via suspension polymerization. These pores and channels, in turn, enable the porous polymer beads to remove hydrophobic substances based on pore capture (size) and surface adsorption (hydrophobicity). Blood flow is controlled via an adjustable roller clamp distal to the cartridge. Upon completion of the procedure, the entire circuit containing the device is flushed with saline, which is consistent practice with all CPB circuits, and the blood in the circuit is delivered back to the patient.

Current Coding: There are no unique ICD-10-PCS codes to describe the extracorporeal pheresis of ticagrelor.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the extracorporeal pheresis of ticagrelor. Continue coding as described in current coding.

Option 2. In section X New Technology table X2A, Assistance, Cardiovascular System, create new technology value 9 Filtration, Ticagrelor, applied to the existing body part value 5 Circulatory and the percutaneous approach, to identify the extracorporeal pheresis of ticagrelor.

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**A** Assistance: Taking over a portion of a physiological function by extracorporeal means		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Circulatory	**3** Percutaneous	**6** Filtration, Blood Pathogens	**A** New Technology Group 10
5 Circulatory	**3** Percutaneous	**ADD 9** Filtration, Ticagrelor	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 13 – Shoulder Arthroplasty using the Subscapularis-Sparing Technique

Issue: There are currently no unique ICD-10-PCS codes to describe total shoulder arthroplasty using the subscapularis-sparing technique. An October 1, 2025 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The INHANCE INTACT™ specialized surgical instruments utilized in the performance of the subscapularis-sparing procedural technique received FDA 510(k) clearance in December 2024 (K243248). The INHANCE INTACT™ instruments are intended to be used during orthopedic surgery with the INHANCE™ Anatomic Stemless Shoulder System. The INHANCE™ Shoulder System with humeral stemless anchor is intended for use in anatomic total shoulder replacement procedures to address osteoarthritis, post-traumatic arthrosis, focal avascular necrosis of the humeral head, and prior surgeries of the shoulder that do not compromise the fixation.

Background: Subscapularis-sparing total shoulder arthroplasty is typically performed for individuals with severe osteoarthritis, rheumatoid arthritis, posttraumatic arthritis, and osteonecrosis. In the U.S., more than 100,000 individuals undergo total shoulder arthroplasty each year, including both anatomic and reverse arthroplasty.

The subscapularis is the largest and most powerful muscle of the rotator cuff, which stabilizes and moves the shoulder. Detaching and reattaching it, as in a conventional total shoulder arthroplasty, requires immobilizing the shoulder via sling by 4 to 6 weeks postoperatively with range of motion and lifting limitations for 6 to 12 weeks. Full strength often does not return to normal. Subscapularis dysfunction is estimated to occur in up to 47% of conventional shoulder arthroplasty cases, with fatty infiltration of the subscapularis muscle and increased risk of subscapularis failure.

Technology
Subscapularis-sparing total shoulder arthroplasty is a shoulder replacement procedure. The humeral head is removed and replaced with a metal implant, which may be stemmed or stemless, and the glenoid surface is prepared and replaced with a shallow plastic implant.

The humeral and glenoid implants are the same as those used with conventional shoulder arthroplasty. Of necessity, subscapularis-sparing arthroplasty is currently performed with conventional shoulder arthroplasty instruments. However, new instruments specific to subscapularis-sparing arthroplasty, which reflect the different and distinctive technique, are now approved by the FDA.

In conventional total shoulder arthroplasty, the glenohumeral joint is exposed by detaching the subscapularis tendon from the humerus, either by tenotomy, tendon peel, or osteotomy of the lesser tuberosity of the humerus where the subscapularis inserts. Detaching and removing the subscapularis provides the surgeon with unobstructed visualization and direct access to the joint. Following placement of the implants, the subscapularis is then repaired or reattached.

The subscapularis is part of the rotator cuff. Detaching and repairing this key muscle leads to a lengthy postoperative recovery period. Non-healing or tendon injury may lead to long term complications and shoulder dysfunction. The subscapularis-sparing technique for shoulder arthroplasty was developed to address these issues.

Procedure Description
The subscapularis-sparing technique is performed via a modified open approach in which, rather than being detached, the subscapularis is partially or fully preserved. According to the requestor, this greatly limits exposure and requires working through intervals, the surgeon must use significantly modified, specialized techniques to access the glenohumeral joint, advance and deploy instruments and tools, and place the implants. Intervals, which could also be referred to as windows, are anatomic spaces between muscles, tendons, and bones. In shoulder arthroplasty, the deltopectoral interval is between the deltoid and pectoralis muscles. The inferior window is the space beneath and under the lower edge of the subscapularis. The rotator interval (superior window) is the area between the subscapularis and supraspinatus.

Two general subscapularis-sparing techniques are in use at this time:

* In the partial subscapularis-sparing technique, the inferior part of the subscapularis is incised and reflected while the superior part, which accounts for about 70% of strength and function, remains intact. After incision at the shoulder and dissection to the subscapularis tendon via the deltopectoral interval, the inferior part of the subscapularis is incised and released from its humeral insertion as a flap. The flap is “flipped” and the humeral head is reached through the inferior interval, enabling osteophyte removal. The humeral head is removed and the implant sized. The intact upper part of the subscapularis is then retracted and the humerus distracted to sufficiently expose the glenoid. The glenoid surface is prepared and, after sizing, the implant is placed. Returning to the humeral head, the implant is placed. The flap of the inferior subscapularis is returned to its place and reattached.

* In the full subscapularis-sparing technique, the subscapularis is not incised or released and remains completely intact. The entire procedure is performed through intervals. After incision at the shoulder and accessing the subscapularis via the deltopectoral interval, the inferior window is accessed by lifting and retracting the subscapularis to visualize the humeral head. Osteophytes are removed through the inferior window. The rotator interval is then entered to create a superior window, through which most of the procedure is performed. A saw is used to remove the articular surface of the humeral head, allowing the glenoid to be visualized and accessed. After measurements are taken to ensure proper sizing, the glenoid is reamed and the glenoid implant is cemented and impacted into place. Continuing through the rotator interval, attention is returned to the humeral implant. After the subscapularis is retracted and the arm rotated for visualization, proper sizing of the humeral implant is identified and the surface is prepared. The implant stem or base is then impacted into the humerus and the humeral head is attached. Intraoperative imaging confirms properly sized and placed implants.

Like conventional total shoulder arthroplasty, component implants are typically used at the humerus (a stem or base plus the ball of the humeral head) and one implant is used at the glenoid surface (socket). The implants are permanent, and as with any shoulder arthroplasty, they may need to be removed or revised. However, per the requestor, the subscapularis-sparing technique is

designed and intended for use in initial shoulder arthroplasty procedures, both anatomic and reverse, and is not used in removal or revision procedures.

According to the requestor, the subscapularis-sparing technique utilized in the performance of a total shoulder arthroplasty is a stand-alone procedure, however, the procedure typically includes several integral components, such as tenodesis of the biceps tendon.

Complications of the procedure have included incomplete removal of humeral osteophytes, tendon rupture, loosening of implants, and infection.

Current Coding: There are no unique ICD-10-PCS codes to describe total shoulder arthroplasty using the subscapularis-sparing technique. Code the procedure in table 0RR Replacement of Upper Joints, with the qualifier value Z No Qualifier, the applicable device value, the applicable shoulder joint body part value and the open approach.

Section	**0** Medical and Surgical
Body System	**R** Upper Joints
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*
J Shoulder Joint, Right **K** Shoulder Joint, Left	**0** Open	**0** Synthetic Substitute, Reverse Ball and Socket **7** Autologous Tissue Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier
J Shoulder Joint, Right **K** Shoulder Joint, Left	**0** Open	**J** Synthetic Substitute	**6** Humeral Surface **7** Glenoid Surface **Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for total shoulder arthroplasty using the subscapularis-sparing technique. Continue coding as described in current coding.

Option 2. In table 0RR Replacement of Upper Joints, create new qualifier value 8 Subscapularis-sparing Technique, applied to the device values 0 Synthetic Substitute, Reverse Ball and Socket and J Synthetic Substitute, the shoulder joint body part values and the open approach, to identify total shoulder arthroplasty using the subscapularis-sparing technique.

Section	**0** Medical and Surgical
Body System	**R** Upper Joints
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*
J Shoulder Joint, Right **K** Shoulder Joint, Left	**0** Open	**0** Synthetic Substitute, Reverse Ball and Socket **J** Synthetic Substitute	**ADD 8** Subscapularis-sparing Technique **Z** No Qualifier

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 14 – Section X Update
Spring 2025 ICD-10 Coordination and Maintenance Committee Meeting

During the September 2024 meeting we shared our analysis results for the Group 6 section X codes from FY 2021, 2022, and 2023. Therefore, we are now sharing our updated analysis that includes the results for the Group 6 section X codes for FY 2024, along with the CMS recommendation.

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

- Was the procedure code related to a new technology add-on payment application (NTAP)?
- 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. Updates are shown as underlined below.
    1. Leave the code in Section X (e.g., procedure codes related to the administration of a specific medication)
    2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code in the Medical/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 main Medical/Surgical section)
    3. Delete the Section X code, corresponding Index entries, and any Reference Key entries from the classification (e.g., the procedure is not 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 Med/Surg 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/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 created to reflect the newly established code(s).

Section X – Spring 2025 Update
Group 6

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
X2AH336	Cerebral embolic filtration, extracorporeal flow reversal circuit from right common carotid artery, percutaneous approach, new technology group 6	854	NO	856	NO	2530	NO	2982	NO	7222	Option 4. Create new codes in Extracorporeal or Systemic Assistance and Performance section table 5A0. See ICD-10-PCS Table Addenda proposal on page 42.	Enroute® NPS (Neuroprotection System)
X2AJ336	Cerebral embolic filtration, extracorporeal flow reversal circuit from left common carotid artery, percutaneous approach, new technology group 6	821	NO	821	NO	2468	NO	2767	NO	6877		Enroute® NPS (Neuroprotection System)
XNU0356	Supplement lumbar vertebra with mechanically expandable (paired) synthetic substitute, percutaneous approach, new technology group 6	199	YES	200	YES	344	NO	354	NO	1097	Option 4. Create new codes in Tables 0PU and 0QU with new device value "mechanically expandable paired synthetic substitute" to identify supplement lumbar vertebra with mechanically expandable (paired) synthetic substitute.	SpineJack® Expansion Kit
XNU4356	Supplement thoracic vertebra with mechanically expandable (paired) synthetic substitute, percutaneous approach, new technology group 6	155	YES	158	YES	227	NO	216	NO	756		SpineJack® Expansion Kit
XW013G6	Introduction of REGN-COV2 monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6	0	NO	0	NO	0	NO	0	NO	0	Option 1. Leave the code in Section X. Indicated for the treatment of COVID-19.	Casirivimab (REGN10933) and Imdevimab (REGN10987)
XW013H6	Introduction of other new technology monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6	6	NO	6	NO	10	NO	1	NO	23	Option 1. Leave the code in Section X. Implemented to describe new monoclonal antibodies	

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
											indicated for the treatment of COVID-19.	
XW013K6	Introduction of leronlimab monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6	17	NO	19	NO	0	NO	0	NO	36	Option 1. Leave the code in Section X. Indicated in the treatment of HIV; and is used in clinical trials for COVID-19 and colorectal cancer.	
XW013S6	Introduction of COVID-19 vaccine dose 1 into subcutaneous tissue, percutaneous approach, new technology group 6	102	NO	102	NO	11	NO	3	NO	218	Option 1. Leave the codes in Section X. Indicated for COVID-19 prevention.	COMIRNATY® SPIKEVAX®
XW013T6	Introduction of COVID-19 vaccine dose 2 into subcutaneous tissue, percutaneous approach, new technology group 6	28	NO	28	NO	1	NO	0	NO	57		COMIRNATY® SPIKEVAX®
XW013U6	Introduction of COVID-19 vaccine into subcutaneous tissue, percutaneous approach, new technology group 6	46	NO	46	NO	13	NO	4	NO	109		COMIRNATY® SPIKEVAX®
XW023S6	Introduction of COVID-19 vaccine dose 1 into muscle, percutaneous approach, new technology group 6	2505	NO	2507	NO	321	NO	41	NO	5374		COMIRNATY® SPIKEVAX®
XW023T6	Introduction of COVID-19 vaccine dose 2 into muscle, percutaneous approach, new technology group 6	799	NO	800	NO	99	NO	9	NO	1707		COMIRNATY® SPIKEVAX®
XW023U6	Introduction of COVID-19 vaccine into muscle, percutaneous approach, new technology group 6	2336	NO	2339	NO	575	NO	209	NO	5459		COMIRNATY® SPIKEVAX®
XW03306	Introduction of brexanolone into peripheral vein, percutaneous approach, new technology group 6	1	NO	1	NO	5	NO	1	NO	8	Option 3. Delete the Section X code, corresponding Index entries, and any Reference Key entries from the classification.	ZULRESSO™

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
											This product is no longer commercially available in the U.S. as of January 1, 2025.	
XW03326	Introduction of nerinitide into peripheral vein, percutaneous approach, new technology group 6	2	NO	2	NO	0	NO	0	NO	4	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of other therapeutic substance in Table 3E0.	NA-1
XW03336	Introduction of durvalumab antineoplastic into peripheral vein, percutaneous approach, new technology group 6	23	YES	23	YES	25	NO	24	NO	95	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of an antineoplastic in Table 3E0.	IMFINZI®
XW03366	Introduction of lefamulin anti-infective into peripheral vein, percutaneous approach, new technology group 6	3	YES	3	YES	2	NO	0	NO	8	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of an anti-infective in Table 3E0.	XENLETA®
XW03396	Introduction of ceftolozane/tazobactam anti-infective into peripheral vein, percutaneous approach, new technology group 6	416	YES	499	YES	1458	NO	1006	NO	3379	Option 1. Leave the code in Section X. Indicated for the treatment of complicated intra-abdominal infections, complicated urinary tract infections,	ZERBAXA®

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
											including pyelonephritis, and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP).	
XW033A6	Introduction of cefiderocol anti-infective into peripheral vein, percutaneous approach, new technology group 6	106	YES	144	YES	501	YES (HABP/VABP only[1])	501	NO	1252	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of an anti-infective in Table 3E0.	FETROJA®
XW033B6	Introduction of omadacycline anti-infective into peripheral vein, percutaneous approach, new technology group 6	5	YES	5	YES	18	NO	14	NO	42	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of an anti-infective in Table 3E0.	NUZYRA™
XW033C6	Introduction of eculizumab into peripheral vein, percutaneous approach, new technology group 6	89	YES	91	YES	100	NO	88	NO	368	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of recombinant humanized	Soliris®

[1] HABP/VABP – Approved for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia only.

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
											monoclonal antibody in Table 3E0.	
XW033D6	Introduction of atezolizumab antineoplastic into peripheral vein, percutaneous approach, new technology group 6	67	YES	70	YES	48	NO	31	NO	216	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of an antineoplastic in Table 3E0.	TECENTRIQ®
XW033E6	Introduction of etesevimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	131	NO	131	NO	6	NO	3	NO	271	Option 3. Delete the Section X code, corresponding Index entries, and any Reference Key entries from the classification. In June 2021, the US Office of the Assistant Secretary for Preparedness and Response (ASPR) paused distribution of bamlanivimab and etesevimab together, and etesevimab alone (to pair with existing supply of bamlanivimab), due to the increase of circulating variants.	
XW033F6	Introduction of bamlanivimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	1289	NO	1291	NO	40	NO	0	NO	2680	Option 3. Delete the Section X code, corresponding Index entries, and any Reference Key entries from the classification.	

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
											bamlanivimab is no longer authorized for emergency use in the U.S.	
XW033G6	Introduction of REGN-COV2 monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	1240	NO	1242	NO	7	NO	1	NO	2490	Option 1. Leave the code in Section X. Indicated for the treatment of COVID-19.	Casirivimab (REGN10933) and Imdevimab (REGN10987)
XW033H6	Introduction of other new technology monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	485	NO	485	NO	892	NO	29	NO	1891	Option 1. Leave the code in Section X. Implemented to describe new monoclonal antibodies indicated for the treatment of COVID-19.	
XW033L6	Introduction of CD24Fc immunomodulator into peripheral vein, percutaneous approach, new technology group 6	0	NO	0	NO	1	NO	0	NO	1	Option 1. Leave the code in Section X. Indicated for the treatment of COVID-19.	
XW04306	Introduction of brexanolone into central vein, percutaneous approach, new technology group 6	0	NO	0	NO	1	NO	0	NO	1	Option 3. Delete the Section X code, corresponding Index entries, and any Reference Key entries from the classification. This product is no longer commercially available in the U.S. as of January 1, 2025.	ZULRESSO™
XW04326	Introduction of nerinitide into central vein, percutaneous approach, new technology group 6	1	NO	1	NO	0	NO	1	NO	3	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing	NA-1

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
											administration of other therapeutic substance in Table 3E0.	
XW04336	Introduction of durvalumab antineoplastic into central vein, percutaneous approach, new technology group 6	6	YES	6	YES	11	NO	9	NO	32	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of an antineoplastic in Table 3E0.	IMFINZI®
XW04366	Introduction of lefamulin anti-infective into central vein, percutaneous approach, new technology group 6	2	YES	2	YES	0	NO	0	NO	4	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of an anti-infective in Table 3E0.	XENLETA®
XW04396	Introduction of ceftolozane/tazobactam anti-infective into central vein, percutaneous approach, new technology group 6	66	YES	66	YES	281	NO	155	NO	568	Option 1. Leave the code in Section X. Indicated for the treatment of complicated intra-abdominal infections, complicated urinary tract infections, including pyelonephritis, and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP indication).	ZERBAXA®

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW043A6	Introduction of cefiderocol anti-infective into central vein, percutaneous approach, new technology group 6	27	YES	42	YES	87	YES (HABP/ VABP only)	84	NO	240	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of an anti-infective in Table 3E0.	FETROJA®
XW043B6	Introduction of omadacycline anti-infective into central vein, percutaneous approach, new technology group 6	2	YES	2	YES	6	NO	2	NO	12	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of an anti-infective in Table 3E0.	NUZYRA™
XW043C6	Introduction of eculizumab into central vein, percutaneous approach, new technology group 6	33	YES	33	YES	31	NO	28	NO	125	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of recombinant humanized monoclonal antibody in Table 3E0.	Soliris®
XW043D6	Introduction of atezolizumab antineoplastic into central vein, percutaneous approach, new technology group 6	46	NO	46	NO	0	NO	27	NO	119	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of an antineoplastic in Table 3E0.	TECENTRIQ®

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW043E6	Introduction of etesevimab monoclonal antibody into central vein, percutaneous approach, new technology group 6	4	NO	4	NO	0	NO	0	NO	8	Option 3. Delete the Section X code, corresponding Index entries, and any Reference Key entries from the classification. In June 2021, the US Office of the Assistant Secretary for Preparedness and Response (ASPR) paused distribution of bamlanivimab and etesevimab together, and etesevimab alone (to pair with existing supply of bamlanivimab), due to the increase of circulating variants.	
XW043F6	Introduction of bamlanivimab monoclonal antibody into central vein, percutaneous approach, new technology group 6	20	NO	20	NO	1	NO	0	NO	41	Option 3. Delete the Section X code, corresponding Index entries, and any Reference Key entries from the classification. bamlanivimab is no longer authorized for emergency use in the U.S.	
XW043G6	Introduction of REGN-COV2 monoclonal antibody into central vein, percutaneous approach, new technology group 6	23	NO	23	NO	0	NO	0	NO	46	Option 1. Leave the code in Section X. Indicated for the treatment of COVID-19.	Casirivimab (REGN10933) and Imdevimab (REGN10987)
XW043H6	Introduction of other new technology monoclonal antibody into central vein, percutaneous approach, new technology group 6	19	NO	19	NO	20	NO	4	NO	62	Option 1. Leave the code in Section X. Indicated for the	

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
											treatment of COVID-19.	
XW043L6	Introduction of CD24Fc immunomodulator into central vein, percutaneous approach, new technology group 6	1	NO	1	NO	0	NO	0	NO	2	Option 1. Leave the code in Section X. Indicated for the treatment of COVID-19.	
XW0DX66	Introduction of lefamulin anti-infective into mouth and pharynx, external approach, new technology group 6	0	YES	0	YES	1	NO	0	NO	1	Option 2. Delete the Section X code. Revise Index and/or Reference key entries to direct the user to an existing code describing administration of an anti-infective in Table 3E0.	XENLETA®
XW0DXM6	Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6	4,547	NO	4676	NCTAP [2]	3088	NCTAP	1583	NO	13894	Option 1. Leave the code in Section X. Indicated for the treatment of COVID-19.	Olumiant®
XW0G7M6	Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6	164	NO	164	NCTAP	97	NCTAP	50	NO	475		Olumiant®
XW0G886	Introduction of mineral-based topical hemostatic agent into upper GI, via natural or artificial opening endoscopic, new technology group 6	1,741	YES	1806	YES	2936	NO	3803	NO	10286	Option 4. Create new codes in Table 3E0 with new qualifier "mineral-based topical hemostatic agent" to identify the introduction of mineral-based topical hemostatic agent into upper GI.	Hemospray® Endoscopic Hemostat

[2] NCTAP – New COVID-19 Treatments Add-on Payment. Through NCTAP, Medicare provided an enhanced payment from November 2, 2020 through September 30, 2023, for eligible inpatient cases that use certain new products with current FDA approval or emergency use authorization (EUA) to treat COVID-19.

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW0H7M6	Introduction of baricitinib into lower GI, via natural or artificial opening, new technology group 6	17	NO	17	NCTAP	7	NCTAP	7	NO	48	Option 1. Leave the code in Section X. Indicated for the treatment of COVID-19.	Olumiant®
XW0H886	Introduction of mineral-based topical hemostatic agent into lower GI, via natural or artificial opening endoscopic, new technology group 6	271	YES	276	YES	413	NO	677	NO	1637	Option 4. Create new codes in Table 3E0 with new qualifier "mineral-based topical hemostatic agent" to identify the introduction of mineral-based topical hemostatic agent into upper GI.	Hemospray® Endoscopic Hemostat
XW0Q316	Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6	1	NO	1	NO	0	NO	0	NO	2	Option 1. Leave the code in Section X. Indicated for aromatic L-amino acid decarboxylase (AADC) deficiency in pediatric populations.	Upstaza™
XXE5XN6	Measurement of infection, positive blood culture fluorescence hybridization for organism identification, concentration and susceptibility, new technology group 6	0	NO	0	NO	1	NO	1	NO	2	Option 3. Delete the Section X code, corresponding Index entries, and any Reference Key entries from the classification.	Accelerate PhenoTest™ BC kit
XXEBXQ6	Measurement of infection, lower respiratory fluid nucleic acid-base microbial detection, new technology group 6	368	NO	399	NO	2318	NO	3144	NO	6229	Option 3. Delete the Section X code, corresponding Index entries, and any Reference Key entries from the classification.	The BioFire Pneumonia Panel

Topic # 15 – Dilation using Temporary Retrievable Intraluminal Device

Issue: There are currently no unique ICD-10-PCS codes to describe insertion of a temporary retrievable intraluminal device used during percutaneous angioplasty. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? No. Breakthrough Device Designation was granted by the FDA on August 23, 2021, to Spur™ Peripheral Retrievable Stent System indicated the treatment of de novo or stenosed lesions of the infrapopliteal arteries to increase luminal gain.

Background: Atherosclerosis is a systemic disease process of plaque build-up within arterial vessels that may lead to hardening, narrowing and blockage of vessels, resulting in a loss of oxygenated blood flow to the area of the body. Peripheral arterial disease (PAD) occurs because of atherosclerosis in the lower limbs which can lead to numbness, pain and ischemia. PAD is estimated to affect more than one in five people over the age of 70. Therefore, treatment is critical to restoring adequate blood flow in this patient population. Bypass surgery was long considered first-line therapy for the management of PAD. However, recently there has been more momentum in development of interventions to treat infrapopliteal disease. Treatment methods that are available have been adapted from coronary applications and include percutaneous transluminal angioplasty (PTA), cutting/scoring balloon angioplasty, bare metal stents (BMS), drug eluting stents (DES), atherectomy and intravascular lithotripsy (IVL). According to the requestor, the Spur™ Peripheral Retrievable Stent was developed to directly address many of the pitfalls of infrapopliteal disease, including calcification, vessel recoil, dissections and vessel tortuosity. It is designed to create temporary mechanical scaffolding by remodeling of the arterial wall through channels in the endothelium created by the deployed temporary stent.

Technology

The Spur™ Peripheral Retrievable Stent System (Spur™ stent) is an over the wire catheter system, compatible with 0.014" guidewires. The device is available with an effective catheter length of 135 cm and 150 cm. The Spur™ Peripheral Retrievable Stent System consists of a delivery system that can deliver (deploy, expand) and re-capture the Spur™ stent and balloon. The Spur™ stent has radial structures ("spikes") to allow for controlled penetration into the arterial wall in its expanded state. The structures extend approximately 1.8 mm from the outer surface of the stent's outer diameter. The delivery system maintains the Spur™ stent and balloon in the collapsed position, tracks over a guidewire to the intended site, deploys and then re-captures the device for removal from the vasculature. Per the requestor, the Spur™ Peripheral Retrievable Stent System is intended to mitigate the acute adverse effects of intra-arterial expansion, including dissections, vessel recoil, and failure to achieve acute luminal gain that can be seen in percutaneous balloon-based interventions, while leaving no device behind within the body. It also allows for blood flow while the mechanical scaffold is temporarily expanded within the artery.

Procedure Description
The Spur™ Peripheral Retrievable stent resides within the delivery catheter's outer shaft in a collapsed state over an integral inner balloon catheter. After successful pre-dilation, the Spur™ Peripheral Retrievable stent is tracked over a guidewire to the intended site. After transcatheter vascular access under fluoroscopic guidance to the stenotic lesion, the Spur™ Peripheral Retrievable stent is then deployed within the target lesion through retraction of the outer delivery catheter shaft. After deployment, the balloon catheter is inflated to fully expand the Spur™ Peripheral Retrievable stent. The balloon is deflated allowing for restoration of circulation at the target site while facilitating a dwell of the Spur™ Peripheral Retrievable stent within the target lesion for a period of time (approximately 2-5 minutes). After the desired dwell time, the Spur™ Peripheral Retrievable stent is collapsed and re-captured into the outer shaft for removal from the vasculature.

- A single Spur™ Peripheral Retrievable stent is typically used during the revascularization procedure. However, if required due to lesion length and/or vessel diameter sizing, multiple devices may be used.
- The Spur™ Peripheral Retrievable Stent is temporarily deployed within the target lesion and retracted after adequate dwell time to allow for restoration of the circulation.
- The Spur™ Peripheral Retrievable Stent is designed to be used in the infrapopliteal (i.e., tibial, peroneal) arteries, but is not appropriate for the inframalleolar or cardiac vasculature. It is considered a standalone technology in that one device will treat a single lesion (vessel). There may be circumstances when it could be combined with other revascularization therapies to treat multi-vessel disease, or in cases with severely calcified lesions.

Current Coding: There are no unique ICD-10-PCS codes to describe insertion of a temporary retrievable intraluminal device during a percutaneous angioplasty procedure. Code the angioplasty procedure using the applicable code(s) 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 **T** Peroneal Artery, Right **U** Peroneal 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

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 new ICD-10-PCS codes for insertion of a temporary retrievable intraluminal device. Continue coding as described in current coding.

Option 2. In section X New Technology table X2H, Insertion, Cardiovascular System, create new device value 8 Intraluminal Device, Temporary, applied to the infrapopliteal artery body part values shown and the percutaneous approach, to identify insertion of a temporary retrievable intraluminal device. Continue to separately report the appropriate code from table 047 Dilation of Lower Arteries for the angioplasty procedure, as described in current coding.

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*

0 Inferior Vena Cava **1** Superior Vena Cava	**3** Percutaneous	**R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9
2 Femoral Vein, Right **3** Femoral Vein, Left	**0** Open	**R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9
6 Atrium, Right **K** Ventricle, Right	**3** Percutaneous	**V** Intracardiac Pacemaker, Dual-Chamber	**9** New Technology Group 9
L Axillary Artery, Right **M** Axillary Artery, Left **X** Thoracic Aorta, Ascending	**0** Open	**F** Conduit to Short-term External Heart Assist System	**9** New Technology Group 9
ADD P Anterior Tibial Artery, Right **ADD Q** Anterior Tibial Artery, Left **ADD R** Posterior Tibial Artery, Right **ADD S** Posterior Tibial Artery, Left **ADD T** Peroneal Artery, Right **ADD U** Peroneal Artery, Left	**3** Percutaneous	**ADD 8** Intraluminal Device, Temporary	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 16 – Continuous Glucose Monitoring

Issue: There are currently no unique ICD-10-PCS codes to describe continuous monitoring of interstitial glucose. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? No. Per the requestor, the Dexcom Hospital Continuous Glucose Monitoring System received an initial Breakthrough Device Designation from the FDA in February 2022.

Background: Hyperglycemia affects 32% of hospitalized patients and hypoglycemia approximately affects 6%. According to the requestor, the current standard of care for glucose monitoring in the hospital is point-of-care testing (POCT), which has been shown to miss 33% of hyperglycemic and up to 90% of hypoglycemic events[1]. The 2025 American Diabetes Association Standards of Care in Diabetes recommends POCT before meals for hospitalized individuals who are eating, every four to six hours for those who are not eating, and every 30 minutes to two hours for those on intravenous insulin therapy.

Technology
The Dexcom Hospital CGM System is a real-time continuous glucose monitoring (CGM) device. If approved, it will be indicated for use by healthcare professionals to monitor and manage glucose levels of patients ages 18 years and older in a hospital environment. The Dexcom Hospital CGM System is comprised of three main components: the glucose-sensing wearable, the applicator, and the smartphone-based bedside display app. The CGM device is not an implant and is not permanent. The Dexcom Hospital CGM System provides real-time CGM monitoring as a standalone service. According to the requestor, continuous glucose monitoring measures interstitial glucose every five minutes and provides additional information, such as glucose direction and rate of change, to give health care professionals access to more data for glucose management decisions.

Procedure Description
Per to the requestor, the Dexcom Hospital CGM System provides real-time monitoring of hospitalized patients, which can provide more glucose information than episodic point-of-care measurements. A sensor insertion site is selected on the back of the patient's arm and cleaned with alcohol. To apply the CGM, the healthcare provider opens the single-use applicator and presses it against the patient's skin until the safety guard is pushed in. A button is pushed to insert the CGM's sensor under the skin into the subcutaneous tissue. The applicator is removed from the skin and the healthcare provider secures the sensor and patch by rubbing a finger around the patch three times. An overlay patch is then applied over the CGM for protection. Customized target ranges can be set for each patient along with hypo- and hyperglycemic alerts. Finally, the CGM is paired via Bluetooth to a patient-specific display device. The CGM measures interstitial glucose every five minutes, sending patient readings to the display device. The display device shows the current sensor glucose, a trend arrow that indicates the direction and rate of glucose change, a historical trend graph, and the date and time for the sensor start and end session. The CGM sensor can be

[1] https://diabetesjournals.org/care/article/48/Supplement_1/S6/157564/Summary-of-Revisions-Standards-of-Care-in-Diabetes

worn up to five days before expiring. The number of CGM sensors needed for each patient will be based on the length of the hospital stay.

Current Coding: Continuous monitoring of interstitial glucose is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for continuous monitoring of interstitial glucose. Continue coding as described in current coding.

Option 2. In section X New Technology table XX2, Monitoring, Physiological Systems, create new technology value D Interstitial Glucose, Wearable Sensor, applied to the body part value K Subcutaneous Tissue and the external approach, to identify continuous monitoring of interstitial glucose.

Section	**X** New Technology
Body System	**X** Physiological Systems
Operation	**2** Monitoring: Determining the level of a physiological or physical function repetitively over a period of time

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Central Nervous	**X** External	**8** Brain Electrical Activity, Computer-aided Detection and Notification	**9** New Technology Group 9
5 Circulatory	**X** External	**0** Blood Flow, Adhesive Ultrasound Patch Technology	**A** New Technology Group 10
F Musculoskeletal	**3** Percutaneous	**W** Muscle Compartment Pressure, Micro-Electro-Mechanical System	**9** New Technology Group 9
K Subcutaneous Tissue	**X** External	**P** Interstitial Fluid Volume, Sub-Epidermal Moisture using Electrical Biocapacitance	**9** New Technology Group 9
K Subcutaneous Tissue	**X** External	**ADD D** Interstitial Glucose, Wearable Sensor	B New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 17 – Insertion of Implantable Endocardial Pacing System

Issue: There are currently no unique ICD-10-PCS codes to describe the insertion of an implantable endocardial pacing system. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? No. The WiSE CRT System was granted Breakthrough Device Designation by the FDA on July 18, 2019.

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 due to left ventricular (LV) dysfunction is categorized according to LV ejection fraction (LVEF) into HF with reduced ejection fraction (with LVEF ≤40 percent, known as HFrEF; also referred to as systolic HF), HF with preserved ejection fraction (with LVEF ≥50 percent; known as HFpEF; also referred to as diastolic HF), and HF with mid-range ejection fraction (with LVEF 41 to 49 percent; known as HFmrEF).

A key component of the management of patients with HFrEF in addition to pharmacologic therapy and other device-based therapies is cardiac resynchronization therapy (CRT). CRT is a modality of cardiac pacing that provides simultaneous or nearly simultaneous electrical activation of the LV and right ventricle (RV) via stimulation of the LV and RV (biventricular pacing) or LV alone. CRT devices pace the LV via a lead placed in a branch of the coronary sinus or, less commonly, via either an epicardial LV lead or a right-sided lead placed near or in the left bundle branch block or His bundle. Many of the indications for CRT overlap with those for implantable cardioverter-defibrillators (ICDs). As a treatment for heart failure, CRT has demonstrated benefits in clinical status, reduced heart failure hospitalizations, and improved mortality. Unfortunately, the coronary sinus (CS) lead has long been recognized as a primary shortcoming and point of failure of CRT. Prior studies have reported a 2.4% to 5.4% failure rate for placement of coronary sinus (CS) lead during cardiac resynchronization therapy (CRT) device implantation.[2] In addition, conventional lead-based systems persistently experience lead failures, infection, or are challenged by venous occlusion and perforation. As a result, there is a significant unmet clinical need to provide an alternative approach to stimulating the left ventricle for CRT.

Technology
The WiSE System is an implantable cardiac pacing system that delivers left ventricular endocardial pacing (LVEP) specifically for CRT without the use of wires or leads (also known as leadless) going into the heart. To address unmet clinical needs, the WiSE CRT System was designed to provide leadless LVEP with the ability to select an LV pacing location specific to the individual

[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] Gamble J.H.P., Herring N., Ginks M., Rajappan K., Bashir Y., Betts T.R. Procedural success of left ventricular lead placement for cardiac resynchronization therapy: a meta-analysis. J Am Coll Cardiol EP. 2016;2:69–77. doi: 10.1016/j.jacep.2015.08.009.

patient. It is used in conjunction with a previously implanted RV stimulation system. According to the requestor, it is the only leadless left ventricular pacing device in clinical development and is engineered to benefit patients with heart failure who were previously untreatable with conventional CRT or who are considered at high risk for placement of a coronary sinus (CS) lead for CRT upgrades. The WiSE CRT System applies the leadless technology to stimulate the endocardial surface of the left ventricle. Working in conjunction with previously implanted standard, commercially available pacemakers or defibrillators, the WiSE System replaces the pacing function of a coronary sinus lead to achieve cardiac resynchronization therapy (CRT).

The WiSE CRT System is not intended to be a life-sustaining device and only one WiSE CRT System is implanted per patient. The WiSE CRT System consists of four single-patient use components: an electrode (implanted via catheter), delivery sheath, battery and transmitter. The receiver, also known as the receiver electrode or electrode, converts ultrasonic energy into electrical energy to stimulate cardiac tissue. An external programmer is used to adjust parameters of the battery. In the SOLVE-CRT (Stimulation of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy) study, 14.6% of patients experienced adverse events which included cardiac perforations, pocket events, and device system events.[3] Two additional vascular events were not caused by the closure device.

Procedure Description
The patient is brought to the electrophysiology laboratory and anesthetized to achieve deep sedation. Physician performs transthoracic echocardiography (TTE) imaging to verify the appropriate intercostal location to implant the transmitter. The skin is prepared and draped. Skin incisions are made for the transmitter and battery. Two pockets are then created using sharp and blunt techniques. Using a tunneling tool, a routing tube is placed from the battery pocket to the medial incision. The transmitter's cable is inserted into the routing tube and pulled through the tunnel to the battery pocket. The transmitter is positioned medially in the channel and secured. The physician connects the device battery to the cable and then secures in the battery pocket. The two pocket are filled with saline and wound closure is performed with layered suturing.

For implant of the electrode into the left ventricle (LV), the left groin is then prepped and draped in the usual sterile manner. Heparin is administered to attain an activated clotting time (ACT) >200 seconds. Two 8F Perclose vascular closure devices are inserted into the femoral artery and a 12F introducer is positioned into the artery. A 12F sheath assembled with a pigtail dilator is inserted into the introducer. The sheath’s distal balloon is inflated with imaging contrast. The sheath is advanced in the aorta and the dilator advanced across the aortic valve to the apex of the LV followed by the sheath. The pigtail dilator is exchanged for the catheter containing the electrode at the distal tip with the electrode advanced to the distal end of the sheath. The sheath is positioned within the LV. Intracardiac electrograms and pacing thresholds through the electrode are evaluated at two different LV locations. An acceptable pacing threshold of 1.5V and a Q-LV interval of 105ms are found at the second location. The electrode is advanced under fluoroscopic imaging and contrast injection until it appears attached to the ventricular wall. After attachment the pacing threshold is 2.0V. The

[3] Jagmeet P. Singh, Christopher A. Rinaldi, Prashanthan Sanders, Spencer H. Kubo, Simon James, Imran K. Niazi, Timothy R. Betts, Christian Butter, Toshimasa Okabe, Matthew P. Latacha, Ryan Cunnane, Emad F. Aziz, Mauro Biffi, Amir M. Zaidi, Jeffrey F. Alison, Angelo Auricchio, Michael R. Gold, JoAnn Lindenfeld, Mary N. Walsh, LB-456088-4 Safety and efficacy of a leadless ultrasound-based cardiac resynchronization pacing system in heart failure – Results from the SOLVE-CRT study, Heart Rhythm, Volume 20, Issue 7, 2023, Pages 1096-1097, ISSN 1547-5271, https://doi.org/10.1016/j.hrthm.2023.04.047.

electrode is disconnected from the system and the electrode is released from the sheath. The sheath is withdrawn, and the vascular closure device is used to seal the arterial access.

Current Coding: There are no unique ICD-10-PCS codes to describe the insertion of an implantable endocardial pacing system. Code the procedure with three codes: in table 02H Insertion of Heart and Great Vessels, use the body part value L Ventricle, Left, the device value M Cardiac Lead 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 value Y Other Device and the approach value 0 Open to describe the insertion of the transmitter component and the battery component 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	**Z** No Qualifier

		Y Other Device	

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the insertion of an implantable endocardial pacing system. Continue coding as described in current coding.

Option 2. In section X New Technology table X2H, Insertion, Cardiovascular System, create new device value 7 Intracardiac Pacing Electrode, applied to the body part value N Ventricle, Left and the percutaneous approach. In addition, in section X New Technology, create new table XHH, Insertion, Skin, Subcutaneous Tissue, Fascia and Breast, with new device value H Ultrasound Transmitter and Battery for Intracardiac Pacing Electrode, applied to the body part value 8 Subcutaneous Tissue and Fascia, Chest and the open approach. Both codes are needed to identify the insertion of an implantable endocardial pacing system.

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*
0 Inferior Vena Cava **1** Superior Vena Cava	**3** Percutaneous	**R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9
2 Femoral Vein, Right **3** Femoral Vein, Left	**0** Open	**R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9
6 Atrium, Right **K** Ventricle, Right	**3** Percutaneous	**V** Intracardiac Pacemaker, Dual-Chamber	**9** New Technology Group 9
L Axillary Artery, Right **M** Axillary Artery, Left **X** Thoracic Aorta, Ascending	**0** Open	**F** Conduit to Short-term External Heart Assist System	**9** New Technology Group 9
ADD N Ventricle, Left	**3** Percutaneous	**ADD 7** Intracardiac Pacing Electrode	**B** New Technology Group 11

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*
ADD 8 Subcutaneous Tissue and Fascia, Chest	**0** Open	**ADD H** Ultrasound Transmitter and Battery for Intracardiac Pacing Electrode	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 18 – Restriction of the Thoracic Aorta with Hybrid Intraluminal Device

Issue: There are currently no unique ICD-10-PCS codes to describe restriction of the thoracic aorta with a hybrid intraluminal device. An October 1, 2025 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? Yes. The AMDS™ Hybrid Prosthesis was granted Humanitarian Use Device (HUD) Designation on December 11, 2017, for the treatment of acute DeBakey Type I aortic dissections. Breakthrough Device Designation was granted by the FDA on November 9, 2020, and Humanitarian Device Exemption (HDE) approval was granted on December 4, 2024.

Background: Aortic dissection follows an intimal tear occurring in the wall of the aorta leading to a dissection plane within the media that separates the intima from the overlying adventitia of the aorta.[1] Consequently, blood flow in the aorta passes through the aortic (true) lumen and the dissection plane within the media (false lumen). The site of intimal disruption is termed the primary (intimal) tear. Sudden severe chest pain is the most frequent symptom, often described as ripping or tearing in the intrascapular area but the topography varies according to the part of the aorta affected and may change as the dissection evolves. The DeBakey system, an anatomic classification used to classify the type of aortic dissection according to location and extent of the dissection, is based upon the site of origin, with Type I dissection involving the ascending aorta, arch, and descending aorta; Type II is limited to the ascending aorta and Type III is limited to the descending aorta distal to the left subclavian artery.[2]

Acute DeBakey Type I aortic dissection is a medical and surgical emergency and is the most common life-threatening pathology of the aorta. Left untreated, an acute DeBakey Type I dissection may result in rupture of the aorta and death, with an early mortality of 1-2% per hour after symptom onset, with increased risk in patients presenting with cardiac tamponade, acute myocardial infarction, stroke or other malperfusion.[3] Once a patient presents to the hospital (typically within 12 hours after symptom onset) and a dissection involving the ascending aorta is diagnosed, emergent surgery is recommended within the first 48 hours in patients without significant risk factors (e.g., advanced age, reoperation, frailty) or prohibitive risk factors (e.g., dementia, stroke, or severe malperfusion). Approximately 50% of patients with an acute DeBakey Type I aortic dissection who do not undergo immediate surgical treatment do not

[1] Svensson LG, Labib SB, Eisenhauer AC, Butterly JR. Intimal tear without hematoma: an important variant of aortic dissection that can elude current imaging techniques. Circulation 1999; 99:1331.
[2] Pape LA, Awais M, Woznicki EM, et al. Presentation, Diagnosis, and Outcomes of Acute Aortic Dissection: 17-Year Trends From the International Registry of Acute Aortic Dissection. J Am Coll Cardiol 2015; 66:350.
[3] Isselbacher EM, Preventza O, Hamilton Black J 3rd, Augoustides JG, Beck AW, Bolen MA, Braverman AC, Bray BE, Brown-Zimmerman MM, Chen EP, Collins TJ, DeAnda A Jr, Fanola CL, Girardi LN, Hicks CW, Hui DS, Schuyler Jones W, Kalahasti V, Kim KM, Milewicz DM, Oderich GS, Ogbechie L, Promes SB, Gyang Ross E, Schermerhorn ML, Singleton Times S, Tseng EE, Wang GJ, Woo YJ; Peer Review Committee Members. 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 Dec 13;146(24):e334-e482. doi: 10.1161/CIR.0000000000001106. Epub 2022 Nov 2. PMID: 36322642; PMCID: PMC9876736.

survive beyond three days.[4]

Rapid diagnosis followed by immediate referral to a cardiac surgical center are crucial for survival. High clinical suspicion should be confirmed with either CT scanning or transesophageal echocardiogram (TEE). The latter can be undertaken in the operating room to allow for more immediate surgical management. The goal of surgical management is to prevent rupture of the aorta and to avoid extension of the dissection to the coronary ostia or aortic valve which is achieved by resecting the ascending aorta and arch if affected by the intimal tear and replacing it with a prosthetic graft. Several techniques can be employed to replace the ascending aorta with or without reimplantation of the coronary ostia and replacement of the aortic valve or aortic arch.

Technology

The AMDS™ Hybrid Prosthesis is indicated for use in patients with acute DeBakey Type I aortic dissections with malperfusion (including cerebral, visceral, renal, and peripheral malperfusion) and a primary entry tear within the ascending aorta proximal to the innominate artery, who are undergoing open surgical repair within 0-14 days of diagnosis. It is intended for aortic repair, aortic remodeling and re-expansion of the intimal flap within the ascending aorta, aortic arch, and into the descending aorta. According to the requestor, there is no other comparable device or alternative forms of treatment approved or marketed in the United States for this indication for use.

The AMDS™ Hybrid Prosthesis is comprised of a radiopaque, self-expanding, nitinol stent, which is attached proximally to a polytetrafluoroethylene (PTFE) felt cuff with polyester (PET) suture and secured to the single-use Delivery System with an expanded polytetrafluoroethylene (ePTFE) deployment suture. The stent is compressed to the diameter of the catheter shaft, and the proximal end of the stent is constrained by a protective sheath, which keeps the stent collar compressed during transport and implantation until final deployment and anastomosis to a surgical ascending aortic graft. The delivery system consists of a catheter shaft with a pigtail tip that can accommodate insertion of a 0.035" guidewire through the port at the proximal handle. The AMDS™ Delivery System is not placed directly in circulating blood (as blood flow is stopped during transection of the aorta while undergoing hemiarch repair) but is considered an external communicating device which comes in contact with residual blood in the aorta for a limited contact duration (< 24 hours).

The AMDS™ Hybrid Prosthesis is a non-covered nitinol open stent graft with a sewing cuff which is directly attached/anchored to the surgical graft replacing the patients' aorta. The AMDS™ Hybrid Prosthesis uses the implantable uncovered stent component of the device, which is implanted distal to the aortic anastomosis, to expand the true lumen and support the intimal flap, with the goal of promoting remodeling in the aortic arch. In addition, the stent is intended to expand the true lumen and improve the blood flow through the aorta and its tributaries. The primary function of the stent is to expand within the true lumen to restore patency and perfusion to the distal aorta and associated organs. The stent is constructed from electropolished nitinol wire braided into open cells approximately 6mm x 10mm in size. The proximal end of the stent contains the wire ends formed into loops for attachment of the collar using surgical suture; the distal end of the stent is designed with atraumatic continuous wires which point away from the aortic wall to avoid distal stent-induced new-entry (dSINE) tears. The cuff is used to strengthen the distal aortic

[4] Criado FJ. Aortic dissection: a 250-year perspective. Tex Heart Inst J. 2011;38(6):694-700. PMID: 22199439; PMCID: PMC3233335.

anastomosis created between a conventional polyester graft and the transected aorta. The main function of the cuff is to assist in closing the false lumen at the site of the conventional graft to the aorta anastomosis.

The procedure to implant the AMDS™ Hybrid Prosthesis is performed as an adjunct to ascending aorta replacement or standard hemiarch repair by trained cardiothoracic surgeons in a surgical suite or the operating room. The AMDS™ Hybrid Prosthesis is offered in eight (8) models, including two collar sizes in both straight and tapered stent configurations for each stent diameter, to fit a range of native proximal and distal aortic diameters. The stent length is driven by the patient aortic diameter through the aortic arch. According to the requestor, the AMDS™ Hybrid Prosthesis is commercially available in many countries around the world and has not been withdrawn from marketing for any reason relating to the safety and probable benefit of the device.

Procedure Description
The AMDS™ Hybrid Prosthesis is an implantable hybrid stent graft used in combination with surgical replacement of the ascending aorta and requires only one device per patient and procedure. The implantation procedure is performed by a qualified physician trained and skilled in cardiothoracic surgery in the operating room under direct vision via an open chest procedure while on cardiopulmonary bypass. Once the chest is opened through a sternotomy, the patient is placed on cardiopulmonary bypass (CPB) utilizing the cannulation technique that the surgeon prefers. Hypothermic circulatory arrest (HCA) is induced by cooling the patient's core temperature. Cardiopulmonary bypass is stopped, the ascending aorta is transected and removed, and the distal ascending aorta is trimmed so that at least 1 cm of aortic tissue proximal to the innominate artery (IA) remains. The true lumen and false lumen of the aorta are identified, and the anastomotic edge is prepared as done in a standard hemiarch repair procedure. The AMDS™ stent is deployed. The stent is compressed to the diameter of the catheter shaft and constrained by a clear, protective sheath located on the proximal end of the stent, which constrains the collar and proximal stent profile for atraumatic insertion of the AMDS™ system into the transected aorta. The proximal sheath is removed immediately upon stent insertion; an ePTFE suture is circumferentially wrapped to secure the stent to the catheter with slip knots around the entire length of the stent. The ePTFE suture is passed through a skive in the catheter lumen and connected to the green cap (deployment mechanism). To deploy the AMDS™ stent, the green cap attached to the ePTFE suture is pulled to unravel the slip knots which compress the braided stent first proximally, then distally, at the time of implantation. The proximal sheath is then withdrawn to release the stent proximally at the location of the anastomosis.

Current Coding: There are no unique ICD-10-PCS codes to describe the restriction of the thoracic aorta with a hybrid intraluminal device. Code the procedure with two codes: in table 02V Restriction of Heart and Great Vessels, assign the device value D Intraluminal Device applied to the body part value W Thoracic Aorta, Descending, and the approach value 0 Open; also in table 02V Restriction of Heart and Great Vessels, assign the device value D Intraluminal Device applied to the body part value X Thoracic Aorta, Ascending/Arch, and the approach value 0 Open. Separately assign the applicable ICD-10-PCS code(s) from Table 02R for the replacement of the ascending aorta or hemiarch repair.

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 for restriction of the thoracic aorta with a hybrid intraluminal device. Continue coding as described in current coding.

Option 2. In section X New Technology table X2V, Restriction, Cardiovascular System, create new device value 6 Intraluminal Device, Uncovered with Support Cuff, applied to the body part value Y Thoracic Aortic Arch and Descending Thoracic Aorta and the open approach, to identify restriction of the thoracic aorta with hybrid intraluminal device. Separately assign the applicable ICD-10-PCS code(s) from Table 02R for the replacement of the ascending aorta or hemiarch repair.

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
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	**ADD 6** Intraluminal Device, Uncovered with Support Cuff	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 19 – Stereotactic-aided Intraprocedural Neuronavigation System

Issue: There are currently no unique ICD-10-PCS codes to describe the use of a stereotactic-aided intraprocedural neuronavigation system to insert a temporary infusion device for the delivery of eladocagene exuparvovec-tneq.[1] An October 1, 2025 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The SmartFlow® Neuro Cannula received FDA De Novo clearance on November 13, 2024 and is indicated for use with compatible stereotactic and therapeutic delivery devices for the intraputaminal administration of eladocagene exuparvovec-tneq for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency.

Background: AADC deficiency is a rare genetic disorder that impairs the production of certain neurotransmitters, primarily dopamine and serotonin and is caused by mutations in the Dopa Decarboxylase (DDC) gene. The DDC gene provides instructions for making the enzyme aromatic L-amino acid decarboxylase. This enzyme is crucial for the conversion of precursor molecules (like L-dopa and 5-HTP) into dopamine and serotonin, essential neurotransmitters for proper brain function. According to the requestor, estimates suggest that AADC deficiency affects fewer than 200 individuals in the U.S., although the exact number is uncertain due to underdiagnosis and limited awareness among healthcare providers. Many cases in the U.S. remain undiagnosed or misdiagnosed due to the disease's nonspecific and overlapping symptoms with other neurological disorders. Increased access to genetic testing and biochemical assays in recent years has improved the likelihood of accurate diagnosis.

Technology
The SmartFlow® Neuro Cannula is a magnetic resonance imaging (MRI) compatible device that features a rigid ceramic body that safeguards the fluid lumen and provides added rigidity to the distal end of the device. The center section and proximal end are protected by soft tubing, with the proximal end terminating in a female luer fitting. The cannula comes in two tubing lengths: 4 ft and 10 ft. The rigid ceramic section measures 26.8 mm in length with a 16-gauge diameter. The inner silica lumen has a diameter of 200 µm, running the entire length of the device, allowing for low-volume priming and preventing leaks. The SmartFlow® cannula is intended for single patient use and is designed to deliver gene therapy to specific regions of the brain using stereotactic guidance. The ClearPoint® Neuro navigation system has been used as the stereotactic approach to insert the SmartFlow® Neuro cannula. The neuro navigation system consists of an MRI conditional SmartFrame® and the ClearPoint® Neuro Navigation Software which provides intraprocedural guidance during the SmartFlow® Cannula insertion and delivery of the drug. The procedure can be performed in a standard diagnostic MRI room or intraoperative MRI suite. The SmartFlow® Neuro Cannula can also be used with other stereotactic navigation systems in an operating room setting.

[1] Eladocagene exuparvovec-tneq is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with aromatic L-amino decarboxylase (AADC) deficiency.

Procedure Description
The patient is induced under general endotracheal anesthesia and their head is then fixated in a ClearPoint® head fixation frame. The surgeon preps the patient's head, and places ClearPoint® SmartGrids over the desired entry points. A whole-head scan is taken, and the ClearPoint® software instructs the surgeon where to mark the entry points to reach the desired target based on the preoperative plan determined by the surgeon using preoperative MR imaging. Incision lines are marked (unilateral or bilaterally, if appropriate) centered on the entry point. Burr holes are drilled on either side at the selected entry points and the dura is opened . ClearPoint® SmartFrames are fixated above each burr hole. Targeting MR imaging is then performed to align the SmartFrame(s) to the first trajectory(s). The SmartFlow® Neuro Cannula is then prepped by connecting a syringe containing eladocagene exuparvovec-tneq via a luer lock connector at the proximal end of the SmartFlow® Neuro Cannula. The syringe is then loaded into an infusion pump and the SmartFlow® cannula is primed. Once priming is complete, the cannula is inserted into the brain using the SmartFrame® to guide its trajectory to the putamen which are bilateral (paired) structures located on each side of the brain in the basal ganglia. The ClearPoint® Neuro Navigation Software is used to enable near real-time, accurate guidance of the cannula to the putamen. The eladocagene exuparvovec-tneq is infused according to the manufacturer's instructions. After the desired infusion is completed, the cannula is removed. The above steps are repeated for any remaining targets. Following the above, the SmartFrame®(s) is/are removed, and the surgical site(s) is/are closed per standard neurosurgical procedure and the patients is cared for according to the institution's standard of care.

Per the requestor, a single SmartFlow® cannula was used for all infusions for each patient for procedures performed as a part of clinical studies to date. This may not be the case for all procedures in the future as bilateral cannula placement is an option and would require at least two cannulas.

Current Coding: There are no unique ICD-10-PCS codes to describe the use of a stereotactic-aided intraprocedural neuronavigation system to insert a temporary infusion device for the delivery of eladocagene exuparvovec-tneq.[1] Code the procedure in table 00H Insertion, Central Nervous System and Cranial Nerves, using the device value 3 Infusion Device applied to the body part value 0 Brain and the approach value 3 Percutaneous. Code the procedure for removal of the intraprocedural neuronavigation system table in 00P Removal, Central Nervous System and Cranial Nerves, using the device value 3 Infusion Device applied to the body part value 0 Brain and the approach value 3 Percutaneous.

Code the administration of eladocagene exuparvovec with the following code:

XW0Q316 Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6

If desired, facilities can report the use of the intraprocedural neuronavigation system using the following code:

8E09XBH Computer assisted procedure of head and neck region, with magnetic resonance imaging

Section	**0** Medical and Surgical
Body System	**0** Central Nervous System and Cranial Nerves
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 Brain	**0** Open	**1** Radioactive Element **2** Monitoring Device **3** Infusion Device **4** Radioactive Element, Cesium-131 Collagen Implant **5** Radioactive Element, Palladium-103 Collagen Implant **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier
0 Brain	**3** Percutaneous **4** Percutaneous Endoscopic	**1** Radioactive Element **2** Monitoring Device **3** Infusion Device **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier
6 Cerebral Ventricle **E** Cranial Nerve **U** Spinal Canal **V** Spinal Cord	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**1** Radioactive Element **2** Monitoring Device **3** Infusion Device **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**0** Central Nervous System and Cranial Nerves
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Brain **V** Spinal Cord	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe the use of a stereotactic-aided intraprocedural neuronavigation system to insert a temporary infusion device for the delivery of eladocagene exuparvovec-tneq. Continue coding as described in current coding.

Option 2. In table 00H Insertion**,** Central Nervous System and Cranial Nerves, add qualifier value J Temporary applied to the device value 3 Infusion Device, the body part value 0 Brain and the approach value 3 Percutaneous, to identify the insertion of a temporary infusion device. Facilities would also assign code XW0Q316 Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6 for the administration of the gene therapy. If desired, facilities may assign code 8E09XBH, Computer assisted procedure of head and neck region, with magnetic resonance imaging, to report the use of the intraprocedural neuronavigation system.

Section	**0** Medical and Surgical
Body System	**0** Central Nervous System and Cranial Nerves
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 Brain	**0** Open	**1** Radioactive Element **2** Monitoring Device **3** Infusion Device **4** Radioactive Element, Cesium-131 Collagen Implant **5** Radioactive Element, Palladium-103 Collagen Implant **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier
0 Brain	**3** Percutaneous	**3** Infusion Device	**ADD J** Temporary **Z** No Qualifier
0 Brain	**3** Percutaneous **4** Percutaneous Endoscopic	**1** Radioactive Element **2** Monitoring Device **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 20 – Sacroiliac Joint Fusion/Pelvic Fracture Fixation with Threaded Implant System

Issue: There are currently no unique ICD-10-PCS codes to describe the use of a bone density-specific threaded implant for sacroiliac joint fusion or pelvic fracture fixation. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. The iFuse TORQ TNT™ Implant System received 510(k) clearance (K241504) and Breakthrough Device designation from the FDA in August 2024. The technology is indicated for fracture fixation of the pelvis, including acute, nonacute and non-traumatic fractures. The iFuse TNT™ Implant System is also indicated for sacroiliac joint fusion for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis. The iFuse TNT™ Navigation instruments are intended to be used with the iFuse TNT™ Implant System to assist the surgeon in precisely locating anatomical structures in iFuse TNT™ Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.

Background: Acute fractures, also called traumatic fractures, are caused by a direct blow or impact. In low-energy trauma, fracture implies existence of poor bone quality (osteoporosis). Low-energy fracture is a synonym of fragility fracture. A non-traumatic fracture is a break of a weakened bone without any identifiable trauma or following a minor injury that would not ordinarily break a healthy bone. A non-traumatic fracture is a synonym of insufficiency fracture. Sacroiliac (SI) joint dysfunction is pain that occurs in the lower back, buttocks, hips, and legs that may be caused by trauma/injury, arthritis, pregnancy and childbirth, or malalignment in the spine or hips. Left untreated, fractures or SI joint dysfunction can greatly impact quality of life.

Technology
The iFuse TORQ TNT™ Implant System is a porous, 3D-printed, titanium (Ti-6Al-4V ELI) implant with a bone density-specific thread pattern designed for placement in the transiliac transsacral or "through and through" (TNT) configuration across the pelvis, extending from one ilium to the contralateral ilium. The purpose of iFuse TORQ TNT™ Implant System is to provide superior fixation compared with currently available transiliac transsacral screws, or for fusion of the sacroiliac joint when performed. Key features include a tapered proximal end that provides additional "press-fit" integration with the bone, bone density-specific thread design and pattern, and a 3D-printed porous surface which mimics natural cancellous bone. According to the requestor, these features provide advantages in both the early and late postoperative periods, with the goal of minimizing the risk of screw back-out and fixation failure, to allow earlier weight-bearing (i.e., early ambulation). Early mobilization is likely to reduce the severe negative consequences of prolonged bedrest in the elderly. Ensuring secure screw fixation in the early postoperative period is important since underlying poor bone quality increases the risk for delayed fracture healing and implant failure.

Procedure Description
The iFuse TORQ TNT™ implant is placed in a manner that spans the osseous pelvis, traversing varying bone structures and densities. The implant is placed with a starting position on the lateral aspect of the ipsilateral ilium. The implant is then advanced across the ipsilateral ilium, across the sacrum and across the contralateral ilium, terminating in the lateral cortex of the contralateral ilium. The implant is placed in a trajectory that is perpendicular to the long axis of the sacrum and traverses the sacrum either through the S1 body, above the S1 neuroforamina, or through the S2 body, between the S1 and S2 neuroforamina. The starting point on the lateral ilium is established under multiplanar fluoroscopy. A small incision is made in the skin. A guide wire is then placed through the skin and advanced to the lateral aspect of the ipsilateral ilium at the level of the S1 or S2 body. The guide wire is then advanced across the ipsilateral ilium, through the sacrum, and across the contralateral ilium under fluoroscopic guidance utilizing a power wire driver. Multiplanar fluoroscopic imaging is used to confirm acceptable position and trajectory of the guide wire. After successful placement of the guide wire, the surgeon measures the depth of the guide wire that is within bone to determine desired implant length. The surgeon then drills over the guide wire to the level of the mid sacral body. The surgeon subsequently places a transiliac transsacral ("through and through") iFuse TORQ TNT™ implant with a washer. After placement of this implant, fluoroscopic imaging is used to confirm acceptable position of the iFuse TORQ TNT™ implant. A second transiliac transsacral implant may on occasion be placed at the same or at the adjacent level.

The average number of implants placed per case is 1.8 when only pelvic fixation for treatment of fracture is required. For cases involving both pelvic fixation for treatment of fracture and sacroiliac joint fusion, the average number of implants placed per case increases to 2.4 implants. Placement of a single iFuse TORQ TNT™ implant or multiple implants is specific to the pelvis. The iFuse TORQ TNT™ implant placement will often be performed without additional concomitant procedures or implants. However, per the requestor, the iFuse TORQ TNT™ will be used in conjunction with spinal instrumentation and will also be used in conjunction with other iliosacral instrumentation. If a patient has a complex sacral fracture or has fractures of both the lower lumbar spine and sacrum, a surgeon will typically utilize pedicle screw instrumentation with pelvic fixation in addition to placing the iFuse TORQ TNT™ implant(s). In cases where the surgeon is treating a sacral fracture that extends into the sacroiliac joint, the surgeon may place one or more iliosacral implants in addition to the iFuse TORQ TNT™ implant(s) placed in a through and through trajectory. Per the requestor, there have been no adverse events to date.

Current Coding: There are no unique ICD-10-PCS codes to describe sacroiliac joint fusion or pelvic fracture fixation with a threaded implant system. If joint fusion is performed, code the procedure in table 0SG Fusion of Lower Joints, using the device value 4 Internal Fixation Device applied to the appropriate sacroiliac joint body part value(s) and the applicable approach. If pelvic bone fracture fixation is performed, code the procedure in table 0QS Reposition of Lower Bones, using the device value 4 Internal Fixation Device applied to the appropriate pelvic bone body part value(s) and the applicable approach.

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*
5 Sacrococcygeal Joint **7** Sacroiliac Joint, Right **8** Sacroiliac Joint, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**Q** Lower Bones
Operation	**S** Reposition: Moving to its normal location, or other suitable location, all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
2 Pelvic Bone, Right **3** Pelvic Bone, Left **D** Patella, Right **F** Patella, Left **L** Tarsal, Right **M** Tarsal, Left **Q** Toe Phalanx, Right **R** Toe Phalanx, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **5** External Fixation Device **Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for sacroiliac joint fusion or pelvic fracture fixation with a threaded implant system. Continue coding as described in current coding.

Option 2. In section X New Technology table XRG, Fusion of Joints, create new device value H Internal Fixation Device, Bone-Density-Specific Thread and Porosity Pattern, applied to the body part values E Sacroiliac Joint, Right and F Sacroiliac Joint, Left and the approaches shown, to identify sacroiliac joint fusion with a threaded implant system.

In section X New Technology table XNS, Reposition of Bones, create new device value H Internal Fixation Device, Bone-Density-Specific Thread and Porosity Pattern, applied to the body part values N Pelvic Bone, Right and P Pelvic Bone, Left and the approaches shown, to identify pelvic fracture fixation with a threaded implant system.

Section	**X** New Technology
Body System	**R** Joints
Operation	**G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
E Sacroiliac Joint, Right **F** Sacroiliac Joint, Left	**0** Open **3** Percutaneous	**5** Internal Fixation Device with Tulip Connector	**8** New Technology Group 8
E Sacroiliac Joint, Right **F** Sacroiliac Joint, Left	**0** Open **3** Percutaneous	**ADD H** Internal Fixation Device, Bone Density-Specific Thread and Porosity Pattern	**B** New Technology Group 11

Section	**X** New Technology
Body System	**N** Bones
Operation	**S** Reposition: Moving to its normal location, or other suitable location, all or a portion of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD N Pelvic Bone, Right **ADD P** Pelvic Bone, Left	**0** Open **3** Percutaneous	**ADD H** Internal Fixation Device, Bone Density-Specific Thread and Porosity Pattern	B New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 21 – Quantitative Analysis of Human Milk Macronutrient Content

Issue: There are currently no unique ICD-10-PCS codes to describe quantitative analysis of human milk macronutrient content. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. Emily's Care Nourish Test System was granted 510 (k) premarket notification as a class II device by the FDA on May 3, 2024, with the indication to quantitatively measure the concentration of protein, fat (triglycerides), and carbohydrates (lactose) in human milk, provide calculated values for calories (energy). These measurements, in conjunction with other clinical assessments, may be used to aid in the nutritional management of newborns, including preterm, and infants. This device is intended for use in healthcare by trained healthcare personnel at point of care or clinical laboratory settings.

Background: Each year, approximately 1.4% of all live births in the United States (about 56,000 infants) fall into the very low birth weight (VLBW) category. These infants require precise, individualized nutritional management during their NICU stay to support optimal growth, neurodevelopment, and overall health outcomes. Per the requestor, within the current standard of care the nutritional needs of VLBW and preterm infants are typically met through human milk fortification. However, standard fortification practices rely on assumed macronutrient compositions, which often fail to meet the American Academy of Pediatrics (AAP) and European Society for Pediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) guidelines. Existing methods, such as the MIRIS Human Milk Analyzer, provide macronutrient data but are costly, require large sample volumes (3 mL), and involve complex laboratory setups, making them impractical for frequent use in NICUs. According to the requestor, Emily's Care Nourish Test System is a breakthrough solution that addresses these limitations. It provides accurate, real-time macronutrient analysis of human milk at the point of care using an enzyme-based test strip and smartphone application. The device's specifications include improvements such as the requirement of minimal milk volume, enhanced speed, accessibility, and measurement accuracy, and family-integrated care.

Technology

The Emily's Care Nourish Test System is an innovative system that revolutionizes the analysis of human milk by combining colorimetric/enzymatic assay technology with a user-friendly mobile application, allowing precise measurement of protein, fat, and lactose concentrations within three minutes. Designed for use in NICU settings, the system delivers immediate results, facilitating rapid adjustments to infant nutrition plans without the need for external lab analysis. Per the requestor, utilizing validated iPhone models, the Emily's Care mobile app ensures seamless operation. The app guides users step-by-step, scans test strips via built-in spectrometry and displays detailed nutritional data directly under the patient's profile. By quantifying macronutrient levels and calculating caloric content, the system provides actionable insights that enable healthcare providers to customize human milk fortification to meet individual feeding protocol guidelines.

Procedure Description

Emily's Care Nourish Test System is a diagnostic tool for measuring the macronutrient composition of human milk. This device provides precise concentrations of protein, fat, and

lactose, and calculates total caloric content to optimize nutrition for neonates and infants via the following steps described below (refer to Emily's Care Nourish Test System Manual).

1. Milk Collection and Preparation:
   Freshly expressed or thawed human milk is collected in a provided sterile vial (minimum 0.03 mL). The sample is gently mixed to prevent separation and ensure homogeneity.
2. Macronutrient Analysis:
   A test strip containing three reagent pads is dipped into the milk sample for 2-3 seconds. The test strip is then placed on a reference card inside a lightbox with controlled lighting. Using the Emily's Care mobile application on a validated iPhone, the test strip is scanned after a 3-minute incubation period. The app's integrated spectrometry analyzes the colorimetric changes in the pads to determine the concentrations of macronutrients.
3. Data Interpretation:
   The results are displayed within the app as protein (g/dL), fat (g/dL), lactose (g/dL), and total calories (kcal/dL and kcal/oz). The results are saved under the patient's profile for easy access.
4. Fortification Protocol Implementation:
   Based on the measured macronutrient composition, healthcare professionals use the data to customize human milk fortification to meet feeding protocol guidelines.

Current Coding: Quantitative analysis of human milk macronutrient content is not reported separately for inpatient hospital coding. If desired, facilities can report the collection of human milk using the following code:

8E0HX62 Breast milk collection

Coding Options

Option 1. Do not create new ICD-10-PCS codes for quantitative analysis of human milk macronutrient content for nutrition management. Continue coding as described in current coding.

Option 2. In section X New Technology table XXE, Measurement, Physiological Systems, create new technology value A Macronutrient Content, Computer-aided Assessment for Nutrition Management, applied to the body part value Z None and the external approach, to identify quantitative analysis of human milk macronutrient content for nutrition management.

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*
Z None	**X** External	**ADD A** Macronutrient Content, Computer-aided Assessment for Nutrition Management	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 22 – Morphological Structure Analysis System

Issue: There are currently no unique ICD-10-PCS codes to describe a point of care morphological structure analysis system. An October 1, 2025 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The Histolog® Scanner was granted 510 (k) premarket notification as a Class II device on August 19, 2024, for the indication as a confocal laser system intended to allow imaging of the internal microstructure of tissues including, but not limited to, the identification of cells, vessels and their organization or architecture.

Background: The Histolog® Scanner is intended to provide real-time imaging for intraoperative evaluation of excised fresh tissue. The device is expected to be used on approximately 28,776 patients in the fiscal year 2026, the first full fiscal year the Scanner is available. Current options for "immediate" margin analysis include transport of tissue to a pathology lab on-site or off-site for frozen tissue analysis, and this process lasts at least 45-60 minutes. The requestor maintains that the Histolog® Scanner is a significant improvement over existing options due to rapid, nondestructive image processing at the point of care within the existing surgical suite. Easy-to-interpret images are available immediately, providing decision-making support at the point of care. Per the requestor, the use of the Histolog® Scanner will improve physician and patient confidence in tumor assessment.

Technology
The Histolog® Scanner is a digital laser confocal microscopy scanner for use on excised human tissue. The device uses confocal fluorescence and non-ionizing, low-power optical radiation. It integrates seamlessly into existing processes within the operating room or pathology laboratory. The Histolog® Scanner has a hardware component in the form of a rolling cart with a touchscreen monitor for viewing the cellular images of the patient tissue specimen in real-time. The Histolog® Scanner Software Application is used with the hardware device to allow the physician to quickly analyze the surface of the excised tissue for abnormal cells. Through the Histolog® Scanner Software Application, the user operates the Histolog® Scanner device to view and analyze the digital images generated using the device. The software allows the user to save the images and organize them into "sessions" for each of the patients. Once the specimen has been scanned, the Histolog® Digital Solution allows for immediate sharing of the images with pathologists or doctors remotely.

The Histolog® Scanner is intended to be used in combination with the following accessory devices: The Histolog® Dish (single-use disposable), a single-use high optical grade protection preventing direct contact of the tissue specimen with the Histolog® Scanner during imaging and the Histolog® Dip fluorescent histological stain (supply to be used with each scan). After staining the specimen with the Histolog® Dip and rinsing, the Histolog® Dish is placed over the imaging window of the Histolog® Scanner. The specimen is then placed in the correct position on the Histolog® Dish, and the image is captured. Use of the Histolog® Scanner is non-destructive, which allows for future pathological analysis if needed. The scanner is then cleaned before the next use.

Procedure Description
Using the Histolog® Scanner involves four steps: excision, preparation, imaging, and evaluation. First, the surgeon will excise the tumor from the patient as is normally performed. Secondly, the surgeon or pathologist will immerse the fresh tissue that has been excised from the patient into the Histolog® Dip, a proprietary histological stain, and rinse the specimen with water to remove the excess stain. The Histolog® Dip is compatible with downstream histopathology assessment and molecular testing. Next, the specimen is placed on the imaging surface and each surface is scanned. The evaluation is performed by a physician using the Histolog® Scanner Software Application to assess the surface of the specimen. The physician annotates the image using the touchscreen on the device. Lastly, the specimen is sent to pathology for a standard post-surgical assessment.

Current Coding: There are no unique ICD-10-PCS codes to describe use of a point of care morphological structure analysis system for the intraoperative analysis of tissue. Facilities would report the appropriate code for the procedure performed to obtain the tissue specimen.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for a point of care morphological structure analysis system. Facilities would continue to separately report the appropriate code for the procedure to obtain the tissue specimen, as described in current coding.

Option 2. In section 8 Other Procedures, create new method value G Confocal Microscopy, and new qualifier value P Intraoperative Specimen Analysis, applied to the body region value Z None and the external approach, to identify a point of care morphological structure analysis system.

Section	**8** Other Procedures		
Body System	**E** Physiological Systems and Anatomical Regions		
Operation	**0** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Region	*Approach*	*Method*	*Qualifier*
Z None	**X** External	**ADD G** Confocal Microscopy	**ADD P** Intraoperative Specimen Analysis

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 23 – Inspection of Upper GI Tract using Ingestible Wireless Capsule

Issue: There are currently no unique ICD-10-PCS codes to describe an ingestible wireless capsule for inspection of the upper gastrointestinal tract. An October 1, 2025 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. PillSense System was granted De Novo Class II device approval by the FDA on September 29, 2022, for the indication of gastrointestinal blood detection. The PillSense capsule is an ingestible prescription device that uses spectrophotometry (light absorption technology) to detect the presence or absence of blood in the gastrointestinal tract.

Background: Acute gastrointestinal (GI) bleeding is a potentially life-threatening abdominal emergency that remains one of the most common causes of both emergency department visits and hospital admissions, accounting for over half a million admissions annually.[1] Common signs and symptoms at presentation include hematemesis (73%), melena (21%), and coffee-ground emesis (6%); however, patients may also experience vague symptoms such as epigastric pain, abdominal tenderness, or dizziness.[2] According to the requestor, PillSense's innovative optical sensor, housed in the ingestible wireless capsule, is capable of detecting upper gastrointestinal bleeds (UGIB). Unlike traditional methods that rely on endoscopic imaging, this device is sensor-based.

Technology
The manufacturer materials describe PillSense as a novel technology developed to accurately detect UGIB in real-time using an optical sensor contained in an ingestible wireless capsule. The overall system consists of an atraumatic, ingestible, and disposable capsule that detects blood and wirelessly transmits data to an external real-time receiver. The capsule features an optical sensor that is designed to detect the presence of liquid blood and/or hematin by analyzing the absorption of multiple wavelengths of light in the environment in which it is immersed. The blood presents a characteristic and unique absorption behavior along the visible light range and therefore; by analyzing the absorption behavior or selected lights, it is possible to discriminate the presence of blood from other liquids and foods. The system does not require any special patient preparation and provides results almost immediately. Per the requestor, the rapid and accurate detection of active upper GI bleeds by the sensor capsule provides important additional clinical data to the physicians for more effective and efficient triage of patients, use of hospital resources, and decreased hospital stay.

Procedure Description
The standalone procedure is initiated by turning on the receiver and removing the wireless optical sensor capsule from its packaging. The capsule is paired with the receiver. The provider administers the capsule to the patient with a full glass of water to swallow. Then the patient is

[1] Peery AF, Crockett SD, Murphy CC, et al. Burden and cost of gastrointestinal, liver, and pancreatic diseases in the United States: Update 2018. Gastroenterology 2019;156:254–72.e11.
[2] Owensby, S., Taylor, K., & Wilkins, T. (2015). Diagnosis and Management of Upper Gastrointestinal Bleeding in Children. The Journal of the American Board of Family Medicine, 28, 134 LP – 145. 3

placed in the left lateral position. Data is then acquired using the receiver. The ingestion of water and left-side lateral positioning allows the blood coming from esophageal or gastric sources or regurgitating from a proximal duodenal source to mix with the water and gastric content and accumulate in the fundus of the stomach. The capsule then gravitates toward the fundus where it is fully immersed in the gastric content, analyzing the content for the presence of blood. The receiver must remain in close proximity to the patient until data acquisition is completed. Data acquisition is complete when the message "Blood Detected" or "No Blood Detected" is displayed, which is usually 10 minutes unless the physician wishes to monitor for a prolonged amount of time. After the study is completed, results are recorded in the patient chart, which may be used for subsequent patient management. After ingestion, the capsule makes its way through the GI tract and is then passed naturally from the body.

Current Coding: There are no unique ICD-10-PCS codes to describe an ingestible wireless capsule for inspection of the upper GI tract. Code the procedure in table 0DJ Inspection of Gastrointestinal System, with the body part value 0 Upper Intestinal Tract and the via natural or artificial opening approach.

Section	**0** Medical and Surgical		
Body System	**D** Gastrointestinal System		
Operation	**J** Inspection: Visually and/or manually exploring a body part		
Body Part	*Approach*	*Device*	*Qualifier*
0 Upper Intestinal Tract **6** Stomach **D** Lower Intestinal Tract	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic **X** External	**Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for an ingestible wireless capsule for inspection of the upper GI tract. Continue coding as described in current coding.

Option 2. In section X New Technology create new table XDJ, Inspection of Gastrointestinal System, with technology value L Ingestible Capsule with Light Absorption Sensor, applied to the body part value 0 Upper Intestinal Tract and the via natural or artificial opening approach, to identify ingestible wireless capsule for inspection of the upper GI tract.

Section	**X** New Technology		
Body System	**D** Gastrointestinal System		
Operation	**J** Inspection: Visually and/or manually exploring a body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Upper Intestinal Tract	**7** Via Natural or Artificial Opening	**ADD L** Ingestible Capsule with Light Absorption Sensor	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 24 – Insertion of Posterior Cervicothoracic Spinal Stabilization System

Issue: There are currently no unique ICD-10-PCS codes to describe a posterior cervicothoracic spinal stabilization device as an adjunct to cervical fusion. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a new technology add-on payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. The EUROPA™ Posterior Cervical Fusion System received Breakthrough Device designation on July 30, 2024 and 510(k) clearance on November 19, 2024 (K242516). The EUROPA™ Posterior Cervical Fusion System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (Cl 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)
- Tumors involving the cervical/thoracic spine
- 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

The EUROPA™ Posterior Cervical Fusion System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the EUROPA™ Posterior Cervical Fusion System may be connected to the EUROPA™ Pedicle Screw System via the rod to rod connectors.

Background: There is a range of acute and chronic spinal conditions that can significantly impact a patient's quality of life, causing severe pain, neurological deficits, and progressive disability. Cervical and thoracic spinal conditions requiring surgical intervention may include but are not limited to traumatic spinal fractures and dislocations, instability or deformity, pseudarthrosis, spinal tumors, and degenerative diseases. Implantation of a pedicle screw based posterior fixation system in the spine as an adjunct to fusion can stabilize and immobilize the cervical and upper thoracic spine, aiding in the restoration of spinal function. It can help alleviate symptoms by improving mobility and reducing pain and discomfort for the patient.

According to the requestor, with the rising prevalence of cervical spine disease, the number of patients needing posterior cervical fusion (PCF) surgery is expected to increase. Annual PCF procedures are projected to grow from 29,620 in 2020 to 35,335 in 2040, a 19.3% increase, impacting the elderly population the most, as the prevalence of cervical and thoracic spinal diseases rises with age.

Per the requestor, current posterior fixation technologies present several challenges, including implant failures (e.g., fractures and hardware pullout), fusion failure, large implant volumes, and

material sensitivity. These complications often necessitate revision surgeries, increasing the amount of implanted hardware and extending patient recovery time and costs. According to the requestor, the EUROPA™ Posterior Cervical Fusion System incorporates a proprietary Molybdenum-47.5 Rhenium (MoRe®) alloy which provides superior strength, durability, and biocompatibility while being nickel-free compared to commonly used alloys such as titanium (Ti) and cobalt-chromium (CoCr) and allows for a lower-profile system. The requestor stated that in posterior cervical-thoracic fusion surgery, space for implant and biologics is limited, hence reducing the implant profile ~40% allows the surgeon to apply additional biologics that is critical to achieve the goal of fusion in PCF surgery. Per the requestor, a MoRe® alloy-based pedicle screw posterior fixation system may also help reduce the need for revision surgeries and additional hardware while enhancing patient comfort and satisfaction.

Technology

The EUROPA™ Posterior Cervical Fusion System is a posterior cervical screw system intended to provide structural stability and mechanical support to the cervical spine through posterior cervical fusion. The EUROPA™ Posterior Cervical Fusion System consists of rods, manufactured from Molybdenum-47.5 Rhenium Alloy (MoRe) per ASTM F3273, pedicle screws, set screws, and connectors manufactured from Titanium-6 Aluminum-4 Vanadium ELI per ASTM F136, and instrumentation manufactured from Stainless Steel per ASTM F899. The implants offered in this system are offered in multiple configurations and different sizes to accommodate various patient anatomical requirements. Procuring and heat treatment of the MoRe® Superalloy™ to attain its desired material characteristics has significant resource consumption and challenges in the metallurgy. According to the requestor, the MoRe® alloy is processed to the desired rod diameter and is superior in performance characteristics to titanium (Ti) or cobalt-chromium (CoCr). A cervical to thoracic transition rod requires further metallurgy. Current pedicle screw tulips in the market use a 3.5 or 4.0 mm Ti or CoCr rod diameter. The requestor stated a 2.9 mm MoRe® alloy rod allows the reduction of tulip volume by ~40% compared to competitive products.

Procedure Description

The posterior cervical fusion procedure begins with the patient being placed under general anesthesia. Following that, appropriate patient positioning is conducted. The patient is placed in the prone position with the head and neck held securely in proper alignment. The use of a pinion head holder or halo will be used to securely hold the occiput and cervical spine in position. Use of an image intensifier or radiograph (e.g., X-ray), as well as direct visualization prior to draping to confirm proper alignment also occurs.

Once proper positioning is confirmed, the incision site is marked on the skin. Access to the operative site is initiated by creating an incision to expose required levels (e.g., C1-T3). To continue accessing the operative site, all soft tissue is removed, and the facets and laminae are decorticated. Once required exposure is achieved, the anatomy is evaluated and assessed if it can accept preoperative construct strategy. All system components (the number and sizes of rods, screws, set screws, and connectors) for the final construct are then determined.

Following the exposure of the operative site, decompression of the spine is conducted to relieve pressure. Using a variety of instruments (e.g., awls, drill guides, probes, tabs, inserters, etc.), pedicle screws are placed in the pedicles above and below the vertebrae to be fused. Once screws have been placed and their positions confirmed via radiography, the appropriate rod length and lordosis (i.e., curvature) are determined. The rod can be bent to the desired degree of lordosis. The

rod is then reduced in the pedicle screw and secured in place with a set screw. Final tightening of the set screw is done to secure the rod in place. If the anatomy allows and extra stability is required, one or more connectors can be secured to the rods.

Radiography is used to confirm proper placement of the hardware and final lordosis. For supplemental aid in fusion, bone graft may be added on the affected vertebrae. The procedure concludes with wound closure, suturing of the incision, and the application of a sterile bandage.

According to the requestor, the implant is generally considered a permanent implant, but there may be occasions for removal or revision based on the performance of the construct and the bone healing in a patient. It will also vary depending on thoracolumbar complications due to prior surgery which might lead to cervical complications (like chin on chest, degenerative conditions or sagittal or coronal deformity arising due to loss of lordosis) and the need for multiple hardware additions to correct that deformity. The ultimate goal of spine surgery is to correct for deformity, provide stability, and/or provide an environment for fusion and creating a balance in the cervico-thoracic-lumbar spine.

The number and type of devices within the system to be used in one operative episode will vary depending on the number of vertebrae/levels of fusion required for a specific patient. It is a patient specific decision based on the surgeon's assessment of how many implants are needed to stabilize the spine in complicated cervico-thoracic surgeries.

The EUROPA™ Posterior Cervical Fusion System may be extended or connected to the thoraco-lumbar EUROPA™ Pedicle Screw System via the rod to rod or lateral offset connectors using various MoRe® Superalloy™ rod diameter options (2.9 mm, 4.0 mm, 4.5 mm, 5.0 mm and 5.5 mm) to create an effective environment for fusion and stabilization on the entire spine.

When there is a non-union (due to a multitude of factors), then a surgeon would have to consider a revision. In some cases, they may choose to revise the construct by adding hardware or extending the construct to occiput or further below into the thoraco-lumbar region. In some complicated clinical cases involving malignant cancer or tumors, the surgeon may decide to remove hardware previously implanted and strengthen it with bigger diameter screws, additional rods, and connectors.

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

Current Coding: There are no unique ICD-10-PCS codes to describe insertion of a molybdenum rhenium 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	**0** Open	**3** Infusion Device	**Z** No Qualifier

1 Cervical Vertebral Joint **4** Cervicothoracic Vertebral Joint **6** Thoracic Vertebral Joint **A** Thoracolumbar Vertebral Joint	**3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **8** Spacer **B** Spinal Stabilization Device, Interspinous Process **C** Spinal Stabilization Device, Pedicle-Based **D** Spinal Stabilization Device, Facet Replacement	

Coding Options

Option 1. Do not create new ICD-10-PCS codes for insertion of a molybdenum rhenium posterior cervicothoracic spinal stabilization device. Continue coding as described in current coding.

Option 2. In section X table XRH, Insertion, Joints, create new device value G Molybdenum Rhenium Alloy Spinal Stabilization Device, applied to the cervical and thoracic joint body part values and the approaches shown, to identify insertion of a molybdenum-rhenium 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*
ADD 1 Cervical Vertebral Joint **ADD 2** Cervical Vertebral Joints, 2 or more **ADD 4** Cervicothoracic Vertebral Joint **6** Thoracic Vertebral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD 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 using codes as described in current coding.

Topic # 25 – Cervical Spinal Fusion with Custom-Made Anatomically Designed Interbody Fusion Device

Issue: There are currently no unique ICD-10-PCS codes to describe cervical spinal fusion using a custom-made anatomically designed cervical interbody fusion device. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. The aprevo® Cervical Anterior Cervical Discectomy and Fusion (ACDF) Interbody Fusion System received 510(k) clearance (K242260) on November 15, 2024. Breakthrough Device designation was previously obtained on September 15, 2023 for use in skeletally mature patients with degenerative cervical conditions including cervical disc degeneration, stenosis, deformity, and/or instability of the cervical spine (C2-T1) at one or more levels.

Background:
The aprevo®-C custom-made anatomically designed interbody fusion devices are surgically implanted in one or more levels of the cervical spine (C2-T1) during an anterior cervical discectomy and fusion (ACDF) procedure to treat a range of conditions that do not improve with conservative treatment. While these conditions may be caused by trauma, cancer, infection or other health conditions, the pathogenesis is typically from natural degeneration (spondylosis) of the disc and cervical bones. Patients typically present with symptoms of pain (radicular) or motor-function loss (myelopathy) and are diagnosed with radiographic evidence of cervical disc disease, spinal canal narrowing (stenosis), structural malalignment (adult cervical spinal deformity (ACSD)), nerve root compression or spinal cord injury. While 25% of individuals under the age of 40, 50% of individuals over the age of 40, and 85% of individuals over the age of 60 show some radiographic evidence of degenerative changes of the cervical spine, the vast majority are asymptomatic or successfully treated with conservative care.[1]

Degenerative spinal conditions are associated with pain, physical disabilities and mental disabilities, as well as decreases in health-related patient quality of life. For example, cervical spondylotic myelopathy's (CSM) detrimental impact on sensory and motor functions affects quality of life to an extent greater than diabetes or cancer.[2] ACSD has health related quality of life impact comparable to the bottom 25th percentile values for blindness/low vision, emphysema, renal failure, and stroke.[3]

During the ACDF procedure, the surgeon removes the degenerated disc between two cervical vertebral bodies and inserts an interbody fusion device into the disc space. The interbody device provides stability while the bone graft forms a fusion between the vertebral bodies. Optimal ACDF clinical outcomes are achieved by establishing appropriate cervical curvature (lordosis) during surgery. Optimized lordosis is important because poor alignment causes higher stress on other levels of the spine and contributes to a cascade effect where the stress is moved to adjacent levels causing further disc degeneration. Because the uneven bony anatomy of the vertebral endplate is different in every patient, the use of existing flat off-the-shelf devices does not fit the contours of the endplate and causes unpredictable lordotic angles. Suboptimal cervical lordosis leads to poor outcomes. In attempts to improve the fit of these flat off-the-shelf devices, surgeons frequently burr away surface irregularities on the bony endplate. However, removing just 1mm

of bone significantly weakens the endplate, which can allow a sinking of the interbody device into the bony surface (subsidence) causing pain and loss of alignment. According to the requestor, the aprevo®-C custom-made anatomically designed cervical interbody devices are created to match the precise personalized alignment plan for each patient and to fit the irregular surface contours of their bone.

Technology
The aprevo®-C cervical interbody fusion devices are custom-made and anatomically designed based on a patient's anatomy using imaging studies and surgeon feedback. The devices are intended to support a surgeon's treatment and alignment goals for the patient, including changes to intervertebral lordosis, improving overall cervical lordosis, increasing foraminal height, and correcting coronal alignment. The proprietary software uses an artificial intelligence (AI) based algorithm to render a 3D model of the cervical spine and the topography of each vertebral endplate. The inferior and superior device surfaces are matched to the topography of the upper and lower vertebral endplates of the patient, thereby creating a lock and key fit when the device is placed into the intervertebral space.

The implants are made using titanium alloy or other materials such as polyetheretherketone (PEEK) and are available with and without integrated screw fixation. When used with the integrated fixation screws, the device may be used as a standalone implant, however, when used without the integrated screw fixation, supplemental fixation (such as an anterior plate with screws) is required. The creation of the custom surgical plan and the patient-specific devices take approximately four weeks.

Procedure Description
The surgeon enters the cervical disc space from the front (anterior) of the spine through an incision in the throat area. By moving aside the neck muscles, trachea, and esophagus, the disc and bony vertebrae are exposed. After the disc is removed from each affected level, the spaces between the bony vertebrae are carefully prepared and the aprevo®-C custom-made anatomically designed cervical interbody fusion devices are placed into the disc spaces. The devices will be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or cortico-cancellous bone to facilitate bone fusion. Per the requestor, each aprevo®-C device may be fixed in place with supplemental fixation, such as an anterior plate and screws, or may be used as a standalone construct with integrated bone screw fixation.

One or more devices can be used during an operative episode. If the patient has a spinal deformity, the average number of cervical interbody fusion devices implanted per procedure is 4.42 and the average number of devices implanted if the patient has a degenerative condition is 1.7. The average number of aprevo®-C devices implanted per procedure is expected to be 3.25.

The aprevo®-C cervical interbody fusion device is considered permanent once it is implanted. There could be rare situations where a removal or revision is needed due to surgical complications.

Current Coding: There are no unique ICD-10-PCS codes to describe cervical interbody fusion using a custom-made anatomically designed device. Code the procedure in table 0RG Fusion of Upper Joints, using the device value A Interbody Fusion Device applied to the appropriate cervical joint body part value, and the applicable approach and qualifier.

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*
0 Occipital-cervical Joint **1** Cervical Vertebral Joint **2** Cervical Vertebral Joints, 2 or more **4** Cervicothoracic Vertebral Joint **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	**A** Interbody Fusion Device	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

Coding Options

Option 1. Do not create new ICD-10-PCS codes for cervical interbody fusion using a custom-made anatomically designed device. Continue coding as described in current coding.

Option 2. In section X New Technology table XRG, Fusion of Joints, add body part values 1 Cervical Vertebral Joint, 2 Cervical Vertebral Joints, 2 or more, and 4 Cervicothoracic Vertebral Joint, applied to the device value R Interbody Fusion Device, Custom-Made Anatomically Designed and the approaches as shown, to identify cervical interbody fusion using a custom-made anatomically designed device.

Section	**X** New Technology
Body System	**R** Joints
Operation	**G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 1 Cervical Vertebral Joint **ADD 2** Cervical Vertebral Joints, 2 or more **ADD 4** Cervicothoracic Vertebral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**R** Interbody Fusion Device, Custom-Made Anatomically Designed	**B** New Technology Group 11
A Thoracolumbar Vertebral Joint	**0** Open	**E** Facet Joint Fusion Device, Paired Titanium Cages	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 26 – Radiofrequency Ablation of the Cardiac Plexus

Issue: There are currently no unique ICD-10-PCS codes to describe radiofrequency ablation of the cardiac plexus for the treatment of pulmonary hypertension. An October 1, 2025 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. Breakthrough device designation was received from the FDA on February 9, 2021. The PADN catheter is indicated for use with the PADN3000 multi-pole Synchronous pulmonary artery radio-frequency ablation generator for the treatment of drug resistant Group I, Group II, and Group IV pulmonary hypertension (PH) in patients aged ≥18 and＜70 years, who remain symptomatic after guideline directed therapy.

Background: Pulmonary hypertension (PH) is characterized by progressive pulmonary vascular arteriopathy with an elevation in pulmonary vascular resistance (PVR) and pulmonary arterial pressure (PAP). PH ultimately causes right heart enlargement, heart failure and death. The sympathetic nervous system has been shown to be hyperactive in patients with PH.[1] Current therapies for World Health Organization (WHO) Group 1 PH include optimal medical therapy (OMT) for PAH or lung transplantation.[2] For WHO Group 2 PH, treatment of left heart disease is recommended.[2] For WHO Group 3 PH, treatment of the underlying lung disease is paramount including bronchodilators, immunosuppression and antifibrotics as well as OMT.[3] For WHO Group 4 PH, treatment options include pulmonary thromboendarterectomy (PTE), ballon pulmonary angioplasty (BPA) and OMT.[4] For WHO Group 5 PH, given that it encompasses a variety of other disorders such as hematologic, systemic, metabolic, and additional conditions (e.g., chronic renal failure, HIV), it is essential to address both the underlying conditions and the PH itself.

Technology

The Pulnovo® Medical Multi-pole Pulmonary Artery RF Ablation Catheter (PADN® RF Catheter and Enhancor™ RF Catheter), in combination with the Pulnovo® Medical PHD360 RF Generator are intended for WHO Group 1-5 pulmonary hypertension (PH) treatment by ablating/denervating the cardiac plexus of sympathetic nerves of the pulmonary artery (PA). The PADN® RF Catheter as well as the Enhancor™ RF Catheter are both single-use, sterile, temporary invasive devices. Both catheters are composed of the following parts: one RF Segment, one Connection Segment, one Flex Segment, Main Sheathing Tubing, Color Code, one Control Handle and one Socket. The RF Segment, Flex Segment and the Main Sheathing Tubing are made of thermoplastic polyurethane (TPU). The RF Segment is in the form of a ring that incorporates electrodes made of platinum-iridium alloy (Pt/Ir10%), with a built-in T-shape thermocouple; the Connection Segment is made of

[1] Liu RX, Luo Q, Qiao H et al. Clinical Significance of the Sympathetic Nervous System in the Development and Progression of Pulmonary Arterial Hypertension. Curr Neurovasc Res 2017;14(2):190-198

[2] Humbert M, Kovacs G, Hoeper MM, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. Eur Respir J. 2023;61(1):2200879

[3] Singh N, Dorfmuller P, Shlobin OA, et al. Group 3 pulmonary hypertension: From bench to bedside. Circ Res. 2022;130:1404-1422

[4] Mahmud E, Madani MM, Kim NH, et al. Chronic thromboembolic pulmonary hypertension. JACC. 2018;71(3):2468-2486

polyether-ether-ketone (PEEK); the Color Code is made of polyolefin materials; the Control Handle is made of acrylonitrile butadiene styrene plastic (ABS) materials, functioning to adjust the curvature of the Flex Segment by rotating the Control Handle via manipulating a steel wire buried in the catheter. The RF connection cable has one end which is designed to insert into the Socket of the RF Catheter and the other end is connected to the PHD360 RF Generator through a Connection Cable.

The PHD360 RF Generator is an active therapeutic device that generates high frequency energy for use with the PADN® RF Catheter or the Enhancor™ RF Catheter. The RF Generator adopts single-electrode discharge method. The RF Generator is connected to a patient via the RF catheter electrode and the neutral electrode. The RF catheter is inserted into the patient's body until the position to be ablated, and the neutral electrode is in contact with the skin surface of the patient.

During ablation, the thermocouple temperature sensor feeds back temperature information from the electrode that contact the PA tissue at the ablation point to the RF generator for ablation temperature monitoring, and the RF Generator will automatically stop working once the ablation temperature reaches 60°C during ablation. The RF Generator can control distinct single electrode discharge of the catheter by switching channels. In the ablation process, the radiofrequency current passes through the RF catheter, patient tissues, and the neutral electrode to form a circuit. Due to a small cross-sectional area of the RF catheter electrode and a high intensity of the surrounding electric field, RF current has obvious thermal effects on adjacent tissues. And as the neutral electrode has a larger area, it has no significant thermal effects on the patient's skin. According to the requestor, the thermal effect of the ablation on the adjacent tissues (indicating the symptomatic nerves in the adventitia of the PA) results in tissue dehydration, protein degeneration and coagulation, leading to a profound reduction of catecholamine secretion with subsequent decrease of vasoconstriction, smooth muscle proliferation, and PA remodeling, the hallmarks of PH.

Procedure Description
An interventional physician performs a right heart catheterization (RHC) via the right internal jugular vein or the right median cubital vein, which include measuring hemodynamic parameters as well as conducting blood gas analysis of the right atrium, right ventricle and pulmonary artery before pulmonary artery denervation (PADN). Pulmonary angiography is performed to determine the anatomic relationships of the main, right and left pulmonary arteries, the inner diameter of main pulmonary artery and the three ablation targets. A RF Catheter with appropriate diameter of RF Segment is selected, inserted and pushed along the long sheath with inner diameter at least 8.5 French into the main pulmonary artery. The interventional physician gently and slowly retracts and rotates the RF Catheter to ensure that appropriate electrodes on the RF segment align with the designated three ablation targets. The following ablation parameters, including a minimum ablation temperature of 45°C (maximum temperature is 55°C) and a minimum ablation time of 120 seconds will be programmed beforehand at each target. After the ablation is complete, the RF catheter should be slowly retracted with the long sheath slowly advanced simultaneously. Once the RF catheter is completely retracted into the long sheath, it should be withdrawn uniformly. The hemodynamic parameters and the blood gas analysis of the right atrium, right ventricle and pulmonary artery are subsequently performed via RHC.

The procedure involves the denervation/ablation of the sympathetic nerves to the main trunk of the pulmonary artery which emanate from the cardiac nervous plexus. The PADN procedure is

performed in conjunction with other procedures. Typically, one RF catheter is used per procedure; the RF catheter is designed for single-patient use and should be subsequently disposed of.

Current Coding: There are no unique ICD-10-PCS codes to describe radiofrequency ablation of the cardiac plexus. Code the procedure in table 015 Destruction of Peripheral Nervous System, with the body part value L Thoracic Sympathetic Nerve and the percutaneous approach.

Section	**0** Medical and Surgical
Body System	**1** Peripheral Nervous System
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent

Body Part	*Approach*	*Device*	*Qualifier*
0 Cervical Plexus **1** Cervical Nerve **2** Phrenic Nerve **3** Brachial Plexus **4** Ulnar Nerve **5** Median Nerve **6** Radial Nerve **8** Thoracic Nerve **9** Lumbar Plexus **A** Lumbosacral Plexus **B** Lumbar Nerve **C** Pudendal Nerve **D** Femoral Nerve **F** Sciatic Nerve **G** Tibial Nerve **H** Peroneal Nerve **K** Head and Neck Sympathetic Nerve **L** Thoracic Sympathetic Nerve **M** Abdominal Sympathetic Nerve **N** Lumbar Sympathetic Nerve **P** Sacral Sympathetic Nerve **Q** Sacral Plexus **R** Sacral Nerve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for radiofrequency ablation of the cardiac plexus. Continue coding as described in current coding.

Option 2. In section X New Technology table X05, Destruction, Nervous System, create new body part value 2 Thoracic Sympathetic Nerve, Cardiac Plexus, applied to the new technology value 3 Radiofrequency Ablation and the percutaneous approach, to identify radiofrequency ablation of the cardiac plexus.

Section	**X** New Technology
Body System	**0** Nervous System
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
1 Renal Sympathetic Nerve(s)	**3** Percutaneous	**2** Ultrasound Ablation	**9** New Technology Group 9

1 Renal Sympathetic Nerve(s)	**3** Percutaneous	**3** Radiofrequency Ablation	**A** New Technology Group 10
ADD 2 Thoracic Sympathetic Nerve, Cardiac Plexus	**3** Percutaneous	**3** Radiofrequency Ablation	B New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using code as described in current coding.

Topic # 27 – Administration of fosfomycin anti-infective

Issue: After presentation at the March 5, 2019 ICD-10 Coordination and Maintenance (C&M) Committee Meeting[1], review of public comments, and internal discussion, the following two ICD-10-PCS codes were implemented to describe the intravenous administration of fosfomycin anti-infective with an effective date of October 1, 2019.

XW033K5	Introduction of fosfomycin anti-infective into peripheral vein, percutaneous approach, new technology group 5
XW043K5	Introduction of fosfomycin anti-infective into central vein, percutaneous approach, new technology group 5

At the March 19, 2024 ICD-10 C&M Committee Meeting[2], in the Section X Update discussion, CMS shared our data analysis results for the Group 5 Section X codes. Specifically, we shared the total frequency that procedure codes XW033K5 and XW043K5 were reported in the data from FY 2020, 2021, 2022, and 2023 was 277. For the proposed disposition of codes XW033K5 and XW043K5, CMS recommended Option 3, which was to delete the Section X code (e.g., the procedure is not reported as anticipated in the data, therefore the absence of a unique code for this technology/procedure in the classification has minimal impact), stating that existing codes in Table 3E0 can be reported to describe the intravenous administration of an anti-infective. After review of public comments in support of the disposition and internal discussion, codes XW033K5 and XW043K5 were deleted, effective October 1, 2024.

In the 4th quarter of calendar year 2024, the manufacturer of fosfomycin (CONTEPO™) submitted a new technology add-on payment application for fiscal year (FY) 2026 consideration. Consequently, CMS is proposing to create new codes as there are currently no unique ICD-10-PCS codes to describe the administration of fosfomycin. CMS is seeking an October 1, 2025 implementation date.

New Technology Application? Yes. The manufacturer has submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approved? No. Fosfomycin (CONTEPO™) was granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the following indications: complicated urinary tract infections (cUTI); complicated intra-abdominal infections (cIAI); hospital-acquired bacterial pneumonia (HABP)/ventilator-associated bacterial pneumonia (VABP); and acute bacterial skin and skin structure infections (ABSSSI).

According to the manufacturer, the new drug application (NDA) for fosfomycin (CONTEPO™) was first submitted to the FDA on October 31, 2018. Due to the COVID-19 pandemic, the FDA was unable to conduct site inspections which delayed full review of the NDA. A resubmission of the NDA for fosfomycin is currently under review by the FDA for the treatment of patients 18

[1] March 5, 2019 ICD-10 Coordination and Maintenance Committee Meeting Materials are available at https://www.cms.gov/medicarecodingicd10c-and-m-meeting-materials/2019-03-05-icd-10. Topic - Administration of CONTEPO™ (fosfomycin) pages 33-35.
[2] March 19, 2024 ICD-10 Coordination and Maintenance Meeting Materials are available at https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials/2024-03-19-icd10-meeting-materials.

years of age and older with complicated urinary tract infections (cUTI), including acute pyelonephritis caused by *Escherichia coli (E. coli)* and *Klebsiella pneumoniae* (*K. pneumoniae*).

Background[3]: Antibiotic resistance is a growing global crisis, described by the World Health Organization as "one of the biggest threats to global health, food security, and development today." According to the CDC, more than two million hospital infections caused by bacteria resistant to greater than one antibiotic class occur every year in the US, and over 23,000 patients with an antibiotic-resistant pathogen die each year.[4] The prevalence of multi-drug resistant (MDR) pathogens is increasing and is considered a significant threat to global health.[5] In particular, the CDC and the World Health Organization consider antibiotic resistance to be an urgent and critical threat to human health.[6] ESBL-producing Enterobacteriaceae, carbapenem-resistant Enterobacteriaceae (CRE), and MDR *Pseudomonas aeruginosa* (*P. aeruginosa)* account for ~26,000, ~9,000, and ~6,700 health care-associated infections, respectively, in the US each year.[7]

The Enterobacteriaceae, including *E. coli* and *K. pneumoniae*, may acquire plasmids that encode ESBLs and confer resistance to third-generation cephalosporins and other broad-spectrum antibiotics.[8] Third-generation cephalosporins and β-lactam inhibitors (BLIs) are also commonly ineffective against Enterobacteriaceae that generate AmpC enzymes.[9] Increasing rates of Enterobacteriaceae resistance to fluoroquinolones and beta-lactam antibiotics have limited both classes use as first-line therapies among inpatients with infections caused by suspected or confirmed MDR pathogens. Studies have examined The Surveillance Network Database to estimate the prevalence of drug resistance among uropathogens isolated from hospitalized patients in the US. The study demonstrated more than a two-fold increase in ESBL-producing *E. coli* (from 3.3% to 8%), ESBL-producing *K. pneumoniae* (from 9.1% to 18.6%), and CRE (from 0% to 2.3%) causing UTIs in the period 2000–2009.[10] Additionally, among catheter-associated UTIs reported to the National Healthcare Safety Network in 2009–2010, 12.3% and 2.3% of *E. coli* isolates, 26.9% and 12.5% of *Klebsiella* isolates, and 25.2% and 21.3% of *P. aeruginosa* isolates were resistant to extended-resistant to extended-spectrum cephalosporins and carbapenems, respectively.

Mechanism of Action
Fosfomycin (CONTEPO™) is an investigational, first-in-class intravenous (IV) epoxide antibiotic with a broad spectrum of bactericidal gram-negative and gram-positive activity,

[3] Taken from the March 5, 2019 ICD-10 Coordination and Maintenance Committee Final Agenda. Topic - Administration of CONTEPO™ (fosfomycin) pages 33-35.
[4] CDC. Antibiotic Use in the United States, 2017: Progress and Opportunities. Atlanta, GA: US Department of Health and Human Services, CDC; 2017. Can be found at https://www.cdc.gov/antibiotic-use/stewardship-report/outpatient.html
[5] O'Neill, The Review on Antimicrobial Resistance 2018. Can be found at: https://amrreview.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf
[6] CDC. Antibiotic Resistance Threats in the United States, 2013. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Can be found at https://www.cdc.gov/drugresistance/biggest_threats.html
[7] Id
[8] Rozwandowicz M, Brouwer M S M, Fischer J. Plasmids carrying antimicrobial resistance genes in Enterobacteriaceae. J Antimicrob Chemother. 2018 May 1;73(5):1121-1137.
[9] Jacoby GA. AmpC beta-lactamases. Clin Microbiol Rev. 2009 Jan;22(1):161-82
[10] Shorr AF, Zilberberg MD, Micek ST, Kollef MH. Prediction of Infection Due to Antibiotic-Resistant Bacteria by Select Risk Factors for Health Care-Associated Pneumonia. *Arch Intern Med.* 2008; 168(20): 2205-10.

including activity against most contemporary MDR strains that threaten hospitalized patients. Fosfomycin (CONTEPO™) inhibits the ability of the bacteria to form a cell wall, which is critical for cell survival and growth. According to the manufacturer, the inhibition of cell wall formation, which occurs at an early stage in cell wall synthesis, differentiates the mechanism of action of fosfomycin (CONTEPO™) from all other injectable antibiotics. The manufacturer further states the unique mechanism of action of fosfomycin (CONTEPO™) will result the following:

- broad spectrum microbiologic activity, including activity against most contemporary MDR pathogens with limited treatment options;
- no cross-resistance with other antibiotic classes; and
- in vitro synergy or additive effect in combination with other antimicrobial classes.

Inpatient Administration of fosfomycin
Upon approval, fosfomycin (CONTEPO™) will be indicated for adult patients (18 years of age and older) with complicated urinary tract infections (cUTI), including acute pyelonephritis (AP) caused by *E. coli* and *K. pneumoniae*, who are hospitalized and at increased risk for resistant infections. The recommended dose is 6 grams administered 3 times daily every 8 hours over a one-hour intravenous infusion, for a recommended duration of treatment of up to 14 days in patients with an estimated creatinine clearance (CrCl) greater than 50 mL/min. Dosage adjustments will be required for patients whose CrCl is 50mL/min or less.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of fosfomycin. Facilities can report the administration of fosfomycin with the following ICD-10-PCS codes:

3E03329 Introduction of other anti-infective into peripheral vein, percutaneous approach
3E04329 Introduction of other anti-infective into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of fosfomycin. Continue coding as described in current coding.

Option 2. In section X table XW0, Introduction, Anatomical Regions, create new substance value W Fosfomycin Anti-infective, applied to the body part values 3 Peripheral Vein and 4 Central Vein and the percutaneous approach, to identify the intravenous administration of fosfomycin.

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 W** Fosfomycin Anti-infective	**ADD B** New Technology Group 11

Index entries to accompany Option 2:

ICD-10-PCS Index Addenda

Lttr	C	
Main	Delete	CONTEPO(tm) (Fosfomycin Anti-infective) use Other Anti-infective
Main	Add	CONTEPO(tm) use Fosfomycin Anti-infective
Lttr	F	
Main	Revise from	Fosfomycin Anti-infective use Other Anti-infective
	Revise to	Fosfomycin Anti-infective XW0
	Add	Fosfomycin injection use Fosfomycin Anti-infective
Lttr	N	
Main		New Technology
	Add	Fosfomycin Anti-infective XW0

Substance Key entries to accompany Option 2:

ICD-10-PCS Substance Key Addenda

Section 3		Administration
Axis 6		Substance
Row		
Term		Other Anti-infective
Includes	Delete	CONTEPO(tm) (Fosfomycin Anti-infective)
Includes	Delete	Fosfomycin Anti-infective
Section X		New Technology
Axis 6		Device / Substance / Technology
Row	Add	
Term	Add	Fosfomycin Anti-infective
Includes	Add	CONTEPO(tm)
Includes	Add	Fosfomycin injection

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 28 – Administration of xanomeline & trospium chloride

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of xanomeline and trospium chloride. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes, COBENFY™ (xanomeline and trospium chloride) was granted FDA approval under a new drug application (NDA) on September 26, 2024, for the treatment of schizophrenia in adults.

Background: Schizophrenia is a chronic mental illness affecting approximately 24 million people worldwide, including 2.8 million in the United States, where about 1.6 million receive treatment. It manifests through three core symptom domains: positive (e.g., hallucinations, delusions), negative (e.g., lack of motivation, emotional expression), and cognitive (e.g., impaired attention, memory deficits). Symptoms usually begin in late adolescence or early adulthood, presenting uniquely in each patient, complicating treatment. Schizophrenia is among the causes of disability globally, significantly impacting employment, independent living, and relationships. Approximately 40 percent of people with schizophrenia qualify for Medicare due to disability, and over 80 percent are also eligible for Medicaid, highlighting the overlap between schizophrenia, disability, and eligibility for federal benefits programs. The illness is associated with a severely reduced life expectancy, with patients losing an estimated 30 years compared to the general population. The more than 20 FDA-approved therapies indicated for schizophrenia are antipsychotics that primarily target the management of "positive symptoms" (e.g., hallucination, delusions). However, patients living with schizophrenia also endure "negative symptoms" such as blunted affect, alogia, avolition, and anhedonia, which are often inadequately addressed by current treatments. In addition, current therapies have a side-effect profile that leads about 60 to 70 percent of patients to discontinue treatment.

According to the requestor, COBENFY™ is a first-in-class muscarinic agonist offering a new approach to treating schizophrenia by selectively targeting muscarinic receptors in the brain without targeting dopamine. It has the potential to improve outcomes by addressing both positive and negative symptoms, often inadequately managed by current drugs. Per the requestor, its unique mechanism of action reduces the risk of dopamine-related side effects, such as tardive dyskinesia, making it a valuable option for patients who may respond inadequately to current treatments.

Mechanism of Action
COBENFY™ (xanomeline and trospium chloride) is a fixed-dose combination oral antipsychotic medication used for the treatment of schizophrenia in adults. Per the requestor, it is the first antipsychotic drug approved to treat schizophrenia that targets muscarinic receptors as opposed to dopamine receptors, which has long been the standard of care. The efficacy of COBENFY™ is thought to be due to xanomeline's agonist activity at M1 and M4 muscarinic acetylcholine receptors in the central nervous system. Meanwhile, trospium chloride antagonizes the muscarinic receptors primarily in the peripheral tissues and does not measurably cross the blood-brain barrier.

According to the requestor, COBENFY™ specifically differs from typical and atypical antipsychotics by targeting M1 and M4 muscarinic acetylcholine receptors instead of dopamine receptors, which helps reduce psychotic symptoms without the common side effects such as weight gain and metabolic disturbances and movement disorders. Additionally, COBENFY™ has shown promising results in clinical trials, significantly improving both positive and negative symptoms of schizophrenia with a favorable safety profile.

Inpatient Administration of xanomeline and trospium chloride
The recommended starting dose for COBENFY™ is one 50 mg/20 mg capsule orally twice daily for at least two days. The dosage is then increased to one 100 mg/20 mg capsule orally twice daily for at least five days. It may be increased thereafter to one 125 mg/30 mg capsule orally twice daily based on patient tolerability and response. The oral dose should be administered at least one hour before or at least two hours after a meal. Per the requestor, the patient's average length of stay in the inpatient setting is 6 to 9 days.

The most common adverse reactions (incidence ≥ 5 percent and at least twice placebo) reported by the requestor were nausea, dyspepsia, constipation, vomiting, hypertension, abdominal pain, diarrhea, tachycardia, dizziness, and gastrointestinal reflux disease.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of xanomeline and trospium chloride. Facilities can report the oral administration of xanomeline and trospium chloride using the following code:

> 3E0DXGC Introduction of other therapeutic substance into mouth and pharynx, external approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the oral administration of xanomeline and trospium chloride. Continue coding as described in current coding.

Option 2. In section X table XW0, Introduction, Anatomical Regions, create new substance value V Xanomeline and Trospium Chloride, applied to the body part value D Mouth and Pharynx and the external approach, to identify the oral administration of xanomeline and trospium chloride.

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*
D Mouth and Pharynx	**X** External	**ADD V** Xanomeline and Trospium Chloride	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 29 – Administration of iloprost

Issue: There are currently no unique ICD-10-PCS codes to describe the intravenous administration of iloprost (AURLUMYN™). An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. The New Drug Application (NDA 217933) for iloprost (AURLUMYN™) was approved by the FDA on February 13, 2024, under Priority Review, and is indicated for the treatment of severe frostbite in adults to reduce the risk of digit amputations. Orphan Drug designation was previously granted for the treatment of frostbite. The iloprost (AURLUMYN™) NDA was submitted by the NDA sponsor, EICOS Sciences. SERB Pharmaceuticals acquired iloprost (AURLUMYN™) globally on October 18, 2024 and is the applicant for NTAP and the requestor for new ICD-10-PCS procedure codes.

Background: Frostbite is a thermal injury caused when tissue is exposed to freezing temperatures long enough for ice crystals to form in the affected tissue. Frostbite most commonly affects upper and lower limbs and digits, with high rates of amputation, up to 67% (grade 3) and 100% (grade 4), resulting in significant, debilitating, lifelong consequences, including long-term disability, reduced ability to perform activities of daily living, and the inability to work. The overall incidence of frostbite injury in the U.S. is extremely low at 0.83 cases per year per 100,000 people. The majority of cases are for superficial frostbite (64.8%) compared to severe frostbite injury (35.2%), a very rare condition estimated at <3,000 cases annually in the U.S. The underlying causes of frostbite are due to exposure to cold in the urban setting, in conjunction with the elderly/geriatric, trauma, hypothermia, physical disability, psychosocial issues, vehicular-related incident, work-related and recreational activities, smoking, unstable housing, or no/inadequate home heating. Certain medical comorbidities and conditions may also heighten the risk of frostbite, including peripheral vascular disease and routine medication use (e.g., beta-blockers).

According to the requestor, prior to the FDA-approval of iloprost (AURLUMYN™), there were no drugs approved in the U.S. for any grade of frostbite; medical treatment was limited to agents not specifically studied or approved for frostbite. Case study and anecdotal reports cite nonsteroidal anti-inflammatory drugs, heparin, antibiotics, dextran, tetanus toxoid, immune globulin, antiplatelet agents, anticoagulant therapy, among others. Outside the U.S., an intravenous formulation of iloprost is available, with published use in frostbite dating back to 1994. Since 2019, the Wilderness Medical Society Clinical Practice Guidelines include intravenous iloprost as the first-line treatment for severe frostbite (Strong Recommendation). Per the requestor, intravenous iloprost (AURLUMYN™) fulfills the clear unmet medical need for an acute therapy to reduce the risk of amputation for patients with severe frostbite in the U.S. The eligible population for iloprost (AURLUMYN™) therapy will be adults with severe frostbite that present at hospitals and treatment centers and are at risk of amputation of fingers and/or toes.

Mechanism of Action
Iloprost (AURLUMYN™) is a stable synthetic analog of prostaglandin 12 (PG12) and is a potent prostacyclin receptor agonist. Upon binding to the prostacyclin receptor, prostacyclin inhibits platelet activation and acts as a vasodilator. Iloprost infusion is associated with immediate generalized vasodilation, with the ratio of antiaggregatory:vasodilatory potency in vivo on the order of 2–7:1. As an anti-inflammatory and immunomodulatory agent, iloprost has been associated with reductions in neutrophil adhesion and chemotaxis and has been shown to down-regulate the intracellular expression of interleukin-6 (IL-6) and tumor necrosis factor (TNF) alpha in human monocytes. In addition, it has been shown to enhance fibrinolysis, increase red cell deformability, and reduce white cell adhesion to endothelial cells. Iloprost has also demonstrated activity with respect to increasing cyclic adenosine monophosphate (cAMP) levels in human platelets via stimulation of adenylate cyclase, with resultant inhibition of platelet aggregation. These properties are of relevance to frostbite treatment as iloprost may mitigate vasoconstriction and microthrombosis to limit frostbite injury. Iloprost inhibits arachidonic acid-induced vasoconstriction, which may be explained by its ability to counteract thromboxane.

Inpatient Administration of iloprost (AURLUMYN™)
Iloprost (AURLUMYN™) is an acute treatment for severe frostbite and is administered as a continuous intravenous infusion over 6 hours each day, starting at a rate of 0.5 ng/kg/minute and increased in increments of 0.5 ng/kg/minute every 30 minutes according to tolerability up to a maximum dose of 2 ng/kg/minute, for up to a maximum of 8 consecutive days. Iloprost (AURLUMYN™) is supplied in a carton containing one 100 mcg per mL single-dose glass vial (NDC 83226-2001-1). Dosage is based on actual patient body weight (kg). Dose titration is repeated on day 2 and day 3. From day 4 onward, the infusion is started at the highest tolerated dose from the previous day, and the rate is adjusted as needed, based on tolerability. The prescribing information includes instructions for stepwise dose decrease in the event of dose-limiting adverse reactions. Per the requestor, consistent with the inpatient dosing in the pivotal published open-label, randomized, controlled study, it is expected that iloprost (AURLUMYN™) will be dosed in the inpatient setting for 8 consecutive days using a total of 8 single-use vials (one per day).

Iloprost (AURLUMYN™) should only be diluted using 0.9% Sodium Chloride Injection, USP. Do not dilute or mix with any other parenteral medications or solutions prior to or during administration. Withdraw 1 mL (100 mcg) of iloprost (AURLUMYN™) solution from the vial and transfer into 100 mL of 0.9% Sodium Chloride Injection, USP polyvinyl chloride (PVC) infusion bag to make a final concentration of 1 mcg/mL (1,000 ng/mL). Iloprost (AURLUMYN™) can be added to commercially available infusion bags labeled to contain 100 mL of 0.9% Sodium Chloride Injection, USP. Immediately use diluted iloprost (AURLUMYN™) infusion solution. If not used immediately, the diluted solution can be stored at room temperature (20°C to 25°C [68°F to 77°F]) for up to 4 hours. Administer iloprost (AURLUMYN™) as an intravenous infusion through a peripheral line or peripherally inserted central catheter using an infusion pump. Use an infusion set with an in-line 0.22- or 0.2-micron filter. Once diluted, iloprost (AURLUMYN™) should be administered with an infusion pump that can support the minimum and maximum flow rates. The infusion pump used to administer iloprost (AURLUMYN™) should: (1) be able to deliver rates 0.1 to 99.9 mL per hour, (2) adjust infusions rates with increments of 0.1 mL per hour, (3) be accurate to within 5% of programmed rate, and (4) be positive pressure-driven (continuous or pulsatile). The reservoir and infusion line set should be made of polyvinyl chloride. Infusion rates may be calculated using the following formula: Infusion Rate (mL/hr) = [Dose (ng/kg/min) x Weight (kg)

x 60 min/hr] / Final Concentration (1,000 ng/mL). Avoid inadvertent administration of a bolus of the drug. Do not flush the catheter without withdrawing residual drug from the catheter system. Discard any unused portion.

According to the requestor, adverse events reported with the use of intravenous iloprost in patients with frostbite from the published literature include headache, flushing, palpitations/tachycardia, nausea vomiting, dizziness, and hypotension. The prescribing information states that adverse reactions such as headache, flushing, jaw pain, myalgia, nausea, and vomiting may be dose-limiting. If dose-limiting adverse reactions occur that cannot be tolerated by the patient, then decrease the dose in a stepwise manner by 0.5 ng/kg/min every 30 minutes, until a tolerated dose is reached. If a dose-limiting adverse reaction occurs during administration of iloprost (AURLUMYN™) at the starting dose, the infusion should be discontinued, and re-initiation of the infusion can be attempted after the event has resolved or been treated. If infusion is stopped at any point for a dose-limiting adverse event, infusion can be reinitiated at a previously tolerated dose/infusion rate once the event has resolved. The maximum tolerated dose should be maintained for the remaining 6-hour daily infusion.

A pivotal, open-label, randomized controlled trial enrolled patients (N=47) with severe frostbite that were randomized to one of three treatment regimens over a 12-year period. In the intravenous iloprost arm (n=16) and the intravenous iloprost + rtPA arm (n=16), the only adverse reactions observed were minor (hot flushes in 55% of the patients, nausea in 25%, palpitation in 15%, and vomiting in 5%). None of these reactions led to discontinuation of the study medication.

A multicenter retrospective cohort study conducted at urban emergency departments (N=90) provided supportive clinical evidence for intravenous iloprost (n=26) used to treat severe frostbite patients in the urban setting compared to standard care (n=64). There were no predefined serious adverse events (AEs). Minor AEs occurred in 6 (23%) patients. A single patient with headache requested cessation of therapy after 2 days of infusions. The remaining two patients with headache and three patients with tachycardia required lower doses. Two patients were discontinued iloprost therapy at day 3 and 4, respectively at the request of the plastic surgery team deeming injury severity was too low.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of iloprost. Facilities can report the intravenous administration of iloprost using one of the following codes:

3E033GC Introduction of other therapeutic substance into peripheral vein, percutaneous approach
3E043GC Introduction of other therapeutic substance into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of iloprost. Continue coding as described in current coding.

Option 2. In section X table XW0, Introduction, Anatomical Regions, create new substance value Q Iloprost, applied to the body part values 3 Peripheral Vein and 4 Central Vein and the percutaneous approach, to identify the intravenous administration of iloprost.

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 Q** Iloprost	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 30 – Administration of fibrinogen (human) concentrate

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of fibrinogen (human) concentrate. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. The requestor, Octapharma submitted a supplemental Biologics License Application (sBLA) for FIBRYGA (fibrinogen human concentrate), and received FDA approval on July 31, 2024, for the indication of fibrinogen supplementation in bleeding adult and pediatric patients with acquired fibrinogen deficiency.

Background: FIBRYGA is a human fibrinogen concentrate indicated for fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency and for treating acute bleeding episodes in patients with congenital fibrinogen deficiencies, including afibrinogenemia and hypofibrinogenemia. According to the requestor, FIBRYGA addresses well-recognized issues associated with cryoprecipitate, the current standard of care for fibrinogen supplementation. Unlike cryoprecipitate, FIBRYGA undergoes pathogen inactivation, which the requestor maintains significantly reduces the potential risks of blood-borne infections. FIBRYGA is extracted from large, multi-donor, pathogen-inactivated pools of human plasma through fractionation. Additionally, this process dilutes agents that could cause transfusion-related allergic reactions and lung injuries when compared to cryoprecipitate, further minimizing clinical risks. Each vial of FIBRYGA contains a precise amount of fibrinogen, allowing healthcare providers to confidently administer the necessary dose for treatment.

Per the requestor, cryoprecipitate must be stored in a blood bank, requires approximately 30 minutes to thaw, and be transported to the point of care, leading to treatment delays for critically ill bleeding patients. In contrast, FIBRYGA is a pharmaceutical-grade, dried-powder form of fibrinogen, and shelf-stable at room temperature, allowing it to be stored at the point of care and reconstituted in just 5-10 minutes, facilitating rapid treatment of fibrinogen deficiency during emergency bleeding situations. Fibrinogen Replacement in Cardiac Surgery clinical trials (FIBRES) have shown that FIBRYGA is clinically non-inferior to cryoprecipitate and can be delivered in half the time. According to the requestor, FIBRYGA is a crucial factor in the final steps of blood clot formation, that meets the need for an FDA-approved readily available, shelf-stable, precise, and pathogen-inactivated form of fibrinogen for treating acquired fibrinogen deficiency caused by bleeding.

Mechanism of Action
Fibrinogen (Factor I) is a soluble plasma protein that is transformed into fibrin during coagulation one of the key components of blood clots. Fibrinogen is a heterohexamer with a molecular weight of 340 kDa, composed of two alpha, beta, and gamma polypeptide chains. When coagulation is activated and thrombin is generated, fibrinogen is cleaved by thrombin at specific sites on the alpha and beta chains, removing fibrinopeptide A (FPA) and fibrinopeptide B (FPB). This removal exposes binding sites on the fibrinogen molecule, leading to the formation of fibrin monomers that subsequently undergo polymerization. The resulting fibrin is then stabilized by activated factor XIII. Factor XIIIa acts on fibrin to create cross-links between fibrin polymers, making the fibrin

clot more resistant to fibrinolysis. The ultimate product of the coagulation cascade is cross-linked fibrin, which stabilizes the primary platelet plug and achieves secondary hemostasis.

Inpatient Administration of fibrinogen (human) concentrate
The initial recommended dose for adults is 4 g administered by a health care professional via intravenous infusion at a rate < 20 ml/min. Dosing adjustments are guided by standard Clauss serum fibrinogen assays, viscoelastic testing, and/or the clinician's discretion based on the patient's condition. The concentrate is provided in a vial as a dry powder containing 1 g of human fibrinogen that can be stored at room temperature for up to 48 months. The vial is reconstituted in 50 ml of sterile water using the provided transfer device.

Per the requestor, serious adverse reactions that may be observed with FIBRYGA are thromboembolic episodes and anaphylactic-type reactions. The most common adverse reactions observed in clinical studies with FIBRYGA when treating acquired fibrinogen deficiency (> 5% of patients) experienced abnormal hepatic function, acute kidney injury, anemia, atrial fibrillation, delirium, and renal failure. The most common adverse reactions observed in clinical studies with FIBRYGA when treating congenital fibrinogen deficiency (> 5% of patients) experienced nausea, vomiting, pyrexia (fever), and thrombocytosis.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of fibrinogen concentrate. Facilities can report the intravenous administration of fibrinogen concentrate using one of the following codes:

30233T1	Transfusion of nonautologous fibrinogen into peripheral vein, percutaneous approach
30243T1	Transfusion of nonautologous fibrinogen into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of fibrinogen concentrate. Continue coding as described in current coding.

Option 2. In section X table XW1, Transfusion, Anatomical Regions, create new substance value Y Nonautologous (Human) Fibrinogen Concentrate, Shelf-stable, applied to the body part values 3 Peripheral Vein and 4 Central Vein and the percutaneous approach, to identify the intravenous administration of fibrinogen concentrate.

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 **4** Central Vein	**3** Percutaneous	**ADD Y** Nonautologous (Human) Fibrinogen Concentrate, Shelf-stable	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 31 – Administration of letetresgene autoleucel (lete-cel)

Issue: There are no unique ICD-10-PCS codes to describe the administration of letetresgene autoleucel (lete-cel). An October 1, 2025 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. Letetresgene autoleucel (lete-cel) was granted Breakthrough Therapy Designation in February 2016 for the treatment of HLA-A*02:01, HLA-A*02:05, or HLA-A*02:06 allele-positive patients with unresectable or metastatic synovial sarcoma (SyS) who have received prior anthracycline-based chemotherapy and whose tumor expresses the NY-ESO-1 tumor antigen. Lete-cel was granted Breakthrough Therapy Designation in January 2025 for the treatment of patients with unresectable or metastatic myxoid/round cell liposarcoma (MRCLS) who have received prior anthracycline-based chemotherapy, are positive for HLA-A*02:01, HLA-A*02:05, or HLA-A*02:06, and whose tumor expresses the NY-ESO-1 tumor antigen. U.S. Orphan Drug Designation was granted in March 2016 for the treatment of soft tissue sarcoma.

Background: Synovial sarcoma (SyS) and myxoid/round cell liposarcoma (MRCLS) are sub-types of soft tissue sarcomas (STS), a rare and heterogeneous group of connective tissue cancers originating from mesenchymal cells and their precursors.[1] SyS accounts for approximately 5-10% of all STS[2], with an estimated U.S. annual incidence of 1,340 cases. The etiological driver of SyS is the t(X;18) reciprocal translocation leading to formation of the SYT-SSX fusion oncogene.[3] SyS affects young individuals with a peak incidence of first clinical presentation in the third decade of life.[4] Metastatic spread is observed in 50% to 70% of patients with SyS, even though the majority are initially diagnosed with localized disease. The most common sites of metastasis in SyS are lung (~80%), lymph nodes (11%), and bone (9.9%). Survival outcomes for metastatic SyS are particularly poor, with a 5-year overall survival (OS) rate of 20% after the date of diagnosis of metastatic disease.

MRCLS is a subtype of liposarcoma that frequently presents in the lower limbs and represents about 30-35% of liposarcomas and 5-10% of all adult STS.[5] MRCLS is caused by chromosomal translocations that result in the fusion of the DDIT3 and FUS genes on chromosome regions 12q13 and 16p11 or DDIT3 and EWSR1 genes on 22q12.[6] MRCLS commonly presents at an

[1] Blay JY, Sleijfer S, Schöffski P, Kawai A, Brodowicz T, Demetri GD, Maki RG. International expert opinion on patient-tailored management of soft tissue sarcomas. Eur J Cancer. 2014 Mar;50(4):679-89. doi: 10.1016/j.ejca.2013.11.011. Epub 2013 Nov 29. PMID: 24295638.
[2] Riedel RF, Jones RL, Italiano A, Bohac C, Thompson JC, Mueller K, Khan Z, Pollack SM, Van Tine BA. Systemic Anti-Cancer Therapy in Synovial Sarcoma: A Systematic Review. Cancers (Basel). 2018 Nov 1;10(11):417. doi: 10.3390/cancers10110417. PMID: 30388821; PMCID: PMC6267101.
[3] Nielsen TO, Poulin NM, Ladanyi M. Synovial sarcoma: recent discoveries as a roadmap to new avenues for therapy. Cancer Discov. 2015 Feb;5(2):124-34. doi: 10.1158/2159-8290.CD-14-1246. Epub 2015 Jan 22. PMID: 25614489; PMCID: PMC4320664.
[4] Aytekin MN, Öztürk R, Amer K, Yapar A. Epidemiology, incidence, and survival of synovial sarcoma subtypes: SEER database analysis. J Orthop Surg (Hong Kong). 2020 Jan-Apr;28(2):2309499020936009. doi: 10.1177/2309499020936009. PMID: 32618221.
[5] Fletcher, C.D.M., Unni, K.K. and Mertens, F. (2002) World Health Organization Classification of Tumors. Pathology and Genetics of Tumors of Soft Tissue and Bone. IARC Press, Lyon, 83-84.
[6] Antonescu CR, Elahi A, Healey JH, Brennan MF, Lui MY, Lewis J, Jhanwar SC, Woodruff JM, Ladanyi M. Monoclonality of multifocal myxoid liposarcoma: confirmation by analysis of TLS-CHOP or EWS-CHOP rearrangements. Clin Cancer Res. 2000 Jul;6(7):2788-93. PMID: 10914725.

age ranging from 35-55 years with a median time to first metastatic relapse of 35 months. Myxoid tumors with a round-cell component >5% have a poor prognosis with a 5-year survival rate of ~50-75% because they recur locally and tend to metastasize quickly and widely.[7] Median overall survival of MRCLS after first documented metastasis is around 2 years.[8]

Currently, NCCN guidelines recommend systemic therapies for patients with unresectable recurrent or metastatic SyS or MRCLS; however, they state that the benefits of systemic therapy are very limited.[9] According to the requestor, lete-cel once approved, will be a new treatment option for a patient population with very limited treatment options.

Mechanism of Action
Lete-cel is an NY-ESO-1-directed genetically modified autologous T-cell immunotherapy for the treatment of patients with metastatic synovial sarcoma (SyS) and advanced myxoid/round cell liposarcoma (MRCLS) who are HLA-A*02 subtype positive, and whose tumor expresses the NY-ESO-1 antigen. Lete-cel is genetically engineered to recognize and eliminate cells expressing the NY-ESO-1 antigen. Specifically, lete-cel is comprised of T-cells that express affinity-enhanced TCRs that recognize a specific HLA-A*02 restricted NY-ESO-1 peptide. By recognizing the cancer cell's HLA-peptide complex, lete-cel can target SyS and MRCLS cancer cells expressing NY-ESO-1/HLA-A*02 and eliminate them.

According to the requestor, lete-cel has demonstrated an adverse event (AE) profile that has generally been manageable and acceptable in the context of benefit-risk assessment to date. During the lymphodepletion phase, 98% of subjects experienced at least one adverse event, with common events being neutropenia, thrombocytopenia, anemia, leukopenia, and febrile neutropenia. 97% of subjects who received lete-cel experienced at least one treatment-emergent adverse event (TEAE), with the most common being cytokine release syndrome (CRS) and rash. There was one grade 5 T-cell related AE of cardiac arrest, attributed to primary pulmonary etiology.

Inpatient Administration of Letetresgene autoleucel (lete-cel)
Lete-cel is a genetically modified autologous T-cell product, administered similar to chimeric antigen receptor (CAR) T-cell, T-cell receptor-engineered T-cell (TCR-T), and tumor-infiltrating lymphocyte (TIL) therapies. Lete-cel is cryopreserved and provided in multiple bags, all intended to be infused sequentially on the same day unless specified otherwise. Each bag must be thawed immediately prior to infusion, using a water bath or equivalent device at 37°C, and the infusion, including a saline wash, should be completed within 45 minutes of thawing to maintain maximum product viability.

Once admitted to the hospital, patients will receive a dose ranging from 1 × 10^9 to 15 × 10^9 total transduced T-cells as a single intravenous infusion administered through either a central or peripheral vein. After infusion, the bags and lines should be flushed with approximately 50 mL

[7] Smith TA, Easley KA, Goldblum JR. Myxoid/round cell liposarcoma of the extremities. A clinicopathologic study of 29 cases with particular attention to extent of round cell liposarcoma. Am J Surg Pathol. 1996 Feb;20(2):171-80. doi: 10.1097/00000478-199602000-00005. PMID: 8554106.
[8] Pollack SM, Somaiah N, Araujo DM, Druta M, Van Tine BA, Burgess MA, Chawla SP, Seetharam M, Okuno SH, Bohac C, Chen M, Yurasov S, Attia S. Clinical outcomes of patients with advanced synovial sarcoma or myxoid/round cell liposarcoma treated at major cancer centers in the United States. Cancer Med. 2020 Jul;9(13):4593-4602. doi: 10.1002/cam4.3039. Epub 2020 May 6. PMID: 32374488; PMCID: PMC7333839.
[9] National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology (NCCN Guidelines®)
Soft Tissue Sarcoma, Version 2.2024 - July 31, 2024, available at https://www.nccn.org/patientresources/patient-resources

saline to minimize cell loss. Patients will receive premedication and be monitored for acute infusion reactions, with treatments administered according to protocol guidance.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of letetresgene autoleucel (lete-cel). Facilities can report the intravenous administration of letetresgene autoleucel (lete-cel) using one of the following codes:

XW033FA	Introduction of non-chimeric antigen receptor t-cell immune effector cell therapy into peripheral vein, percutaneous approach, new technology group 10
XW043FA	Introduction of non-chimeric antigen receptor t-cell immune effector cell therapy into central vein, percutaneous approach, new technology group 10

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of letetresgene autoleucel (lete-cel). Continue coding as described in current coding.

Option 2. In section X table XW0, Introduction, Anatomical Regions, create new substance value R Letetresgene Autoleucel, applied to the body part values 3 Peripheral Vein and 4 Central Vein and the percutaneous approach, to identify the intravenous administration of letetresgene autoleucel.

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 R** Letetresgene Autoleucel	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 32 – Administration of mozafancogene autotemcel (fanca-cel)

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of mozafancogene autotemcel (fanca-cel). An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit an NTAP application for FY 2027 consideration.

Food & Drug Administration (FDA) Approval? No. Mozafancogene autotemcel (fanca-cel) was granted U.S. Orphan Drug designation in May 2016, Rare Pediatric Disease designation in July 2018, Fast Track designation in November 2018, and Regenerative Medicine Advanced Therapy (RMAT) designation in November 2018 for the treatment of Fanconi anemia complementation group A.

Background: Fanconi anemia (FA) is a rare genetic disorder (estimated incidence of 1:136,000 live births) of defective deoxyribonucleic acid (DNA) repair characterized by congenital malformations, progressive bone marrow failure (BMF), and increased risk for solid and hematologic malignancies. In most cases, FA is an autosomal recessive disease resulting from biallelic mutations in a particular FA gene. To date, at least 23 FA genes have been identified, all of which are involved in the DNA repair pathway. FA-A (i.e., mutations in FANCA gene) is the most common (60-70%) and is what fanca-cel will be indicated to treat. Other common FA genes include FA-C (FANCC gene) (14%), and FA-G (FANCG gene) (10%). The inability to repair detrimental DNA damage results in chromosomal instability and increased risk of congenital malformations and malignancies.

A hallmark of the FA phenotype is severe BMF which develops in 80% of patients during the initial decade of life. The majority (60-70%) of FA patients have at least one major congenital malformation which may vary in severity across multiple major organ systems, and which may result in spontaneous abortion or perinatal death. Additionally, endocrinopathies such as glucose/insulin abnormalities, growth hormone insufficiency, and hypothyroidism are common.

Per the requestor, to date, allogeneic hematopoietic stem cell transplant (HSCT) is the only curative treatment option for the hematologic manifestations of FA. At transplant centers with experience treating FA patients, survival in patients with human leukocyte antigen (HLA) matched donors can exceed 80-90%; however, the efficacy of allogeneic transplant is limited by the availability of a suitable donor and risks of mortality and complications, such as infections, graft failure, graft-vs-host disease (GvHD) (acute and chronic) and organ damage. As such, there remains an unmet need for a sustained, curative treatment for FA-A associated bone marrow failure.

Mozafancogene autotemcel (fanca-cel) has successfully conferred engraftment by progressively increasing and sustaining genetic correction in both peripheral blood and bone marrow cells in 8 of 12 clinical trial patients with at least 1 year of follow up. All trial patients were required to not have an available and eligible HLA-identical sibling donor to qualify for the trial.

Mechanism of Action
Mozafancogene autotemcel (fanca-cel) is composed of autologous CD34+ cells that are transduced ex vivo with PGK-FANCA-WPRE LV, a replication-incompetent, self-inactivating third-generation lentiviral vector (LVV) carrying the FANCA complementary deoxyribonucleic acid DNA (cDNA), which inserts functional copies of the FANCA gene into patients' HSCs. The enriched CD34+ cells are washed, formulated into a suspension, and supplied in a single-dose, patient-specific infusion bag based on body weight, and infused back into the patient.

Following mozafancogene autotemcel (fanca-cel) administration without antecedent conditioning, the genetically corrected HSCs engraft in the bone marrow and have a selective advantage over uncorrected cells due to the restored FA DNA repair complex. The corrected FANCA gene cells, capable of repairing DNA damage, repopulate the bone marrow (and peripheral blood) over time.

Per the requestor, gene therapy using mozafancogene autotemcel (fanca-cel) is similar in overall approach to the current standard of care, allogeneic hematopoietic stem cell transplant (allo-HSCT), in that it involves transferring healthy hematopoietic cells into the patient to cure bone marrow failure. It is novel in that it employs genetic correction of a patient's own cells and does not rely on a related or unrelated donor. A suitable hematopoietic cell donor may not always be available and the allo-HSCT utilizing donor cells is associated with risk of mortality, infections, GvHD, and cytotoxic conditioning. Mozafancogene autotemcel (fanca-cel), by utilizing a patient's own cells, avoids these issues.

Inpatient Administration of mozafancogene autotemcel (fanca-cel)
Prior to initiating treatment with mozafancogene autotemcel (fanca-cel), patients are evaluated for evidence of hematologic malignancies including myelodysplastic syndromes (MDS), acute myeloid leukemia (AML), and progressive cytogenetic or molecular abnormalities known to be associated with MDS or AML. Clinical trials of mozafancogene autotemcel (fanca-cel) have enrolled pediatric patients without an available and medically eligible HLA-identical sibling donor.

Patients are required to undergo CD34+ HSC mobilization followed by apheresis to obtain the CD34+ cells needed for fanca-cel manufacturing. Treatment with fanca-cel will only be considered in patients who have a baseline bone marrow CD34+ cell concentration of at least 30 CD34+ cells/μL (assessed within approximately 3 months prior to initiation of apheresis) and whose bone marrow failure has not yet progressed to severe levels.

The timing of mozafancogene autotemcel (fanca-cel) infusion is coordinated so that administration begins as soon as possible after delivery to a qualified treatment center and within the expiration date and time indicated on the labels. Mozafancogene autotemcel (fanca-cel) cell viability is maintained for up to 42 hours when stored at 2°C to 8°C (36°F to 46°F). Once mozafancogene autotemcel (fanca-cel) is removed from refrigeration, the infusion must be completed within 1 hour at room temperature.

All patients are infused with fanca-cel through the central vein in the inpatient setting after appropriate mobilization and apheresis. Mozafancogene autotemcel (fanca-cel) is composed of one infusion bag containing 1 × 10e5 to 5 × 10e6 cells/mL suspended in a solution. The infusion bag contains approximately 200 mL of mozafancogene autotemcel (fanca-cel). The minimum recommended dose of mozafancogene autotemcel (fanca-cel) is 4 × 10e5 CD34+ cells per kilogram of body weight.

According to the requestor, the safety data reflect the experience of 23 patients with FA-A treated with mozafancogene autotemcel (fanca-cel) in 4 single-arm open-label studies. The most common treatment emergent adverse events (reported in ≥20% of patients treated with mozafancogene autotemcel (fanca-cel) were pyrexia (61%), anemia (44%), thrombocytopenia (44%), upper respiratory tract infection (39%), neutropenia (35%), vomiting (30%), COVID-19 infection (26%), nasopharyngitis (26%), and diarrhea (22%) neutrophil count decrease (22%). The majority of these events were non-serious and assessed as not related to (fanca-cel).

Eleven (48%) patients who received mozafancogene autotemcel (fanca-cel) experienced at least one serious adverse event (SAE). The only serious treatment-emergent adverse event occurring in more than one patient was pyrexia (13%). Most SAEs were assessed as not related to receiving mozafancogene autotemcel (fanca-cel). Serious adverse events assessed as possibly related include a Grade 2 infusion-related reaction that occurred in one patient on the day of mozafancogene autotemcel (fanca-cel) infusion and resolved with supportive care and without clinical sequela. Symptoms included pyrexia, transient hypotension, and tachycardia.

No cases of malignancies associated with mozafancogene autotemcel (fanca-cel) have been reported. Consistent with standard of care for patients with FA, monitoring for blood-based malignancies including myelodysplasia and leukemia, as well as evidence of other solid tumors should continue following treatment with mozafancogene autotemcel (fanca-cel).

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of mozafancogene autotemcel (fanca-cel). Facilities can report the intravenous administration of mozafancogene autotemcel (fanca-cel) using one of the following codes:

30233C0 Transfusion of autologous hematopoietic stem/progenitor cells, genetically modified into peripheral vein, percutaneous approach
30243C0 Transfusion of autologous hematopoietic stem/progenitor cells, genetically modified into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of mozafancogene autotemcel (fanca-cel). Continue coding as described in current coding.

Option 2. In section X table XW1, Transfusion, Anatomical Regions, create new substance value S Mozafancogene Autotemcel, applied to the body part values 3 Peripheral Vein and 4 Central Vein and the percutaneous approach, to identify the intravenous administration of mozafancogene autotemcel (fanca-cel).

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 **4** Central Vein	**3** Percutaneous	**ADD S** Mozafancogene Autotemcel	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 33 – Administration of aztreonam-avibactam

Issue: There are no unique ICD-10-PCS codes to describe the administration of aztreonam-avibactam. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? No. On November 8, 2019, ATM-AVI was granted Qualified Infectious Disease Product (QIDP) designation for the treatment of complicated intra-abdominal infections (cIAI), complicated urinary tract infections (cUTI), and hospital-acquired bacterial pneumonia (HABP)/ventilator-associated bacterial pneumonia (VABP). Pending FDA approval, aztreonam-avibactam (ATM-AVI), in combination with metronidazole, will be indicated in patients 18 years and older for the treatment of complicated intra-abdominal infections (cIAI) caused by susceptible gram-negative pathogens in patients with limited or no other treatment options. According to the requestor, a new drug application (NDA) was submitted to the FDA in August 2024 and is under priority review.

Background: Intra-abdominal infections are one of the main causes of post operative infection, the second most common cause of sepsis, leading to ICU admission, and are often life-threatening, affecting millions of patients annually. A complicated intra-abdominal infection (cIAI) is an infection that spreads from a hollow organ into the abdominal cavity, affecting multiple organs and causing peritonitis or abscesses. A wide variety of bacterial pathogens are responsible for cIAIs, including Gram-negative aerobic bacteria, Gram-positive aerobic bacteria, and anaerobic bacteria. Intra-abdominal infections can be complicated due to the wide range of pathogens, increasing antibiotic resistance, and difficulty in the microbiological diagnosis, with antimicrobial resistance equally common in community and hospital acquired infections and can affect all patients.

Antimicrobial resistance (AMR) is a major threat to human health worldwide, and in 2019 an estimated 1.27 million deaths globally were attributed to AMR.[1] *Enterobacterales*, including *Escherichia coli, Klebsiella pneumoniae* and *Enterobacter* species, pose a particular public health threat due to their high prevalence and propensity to develop resistance to antibiotics. These pathogens often produce β-lactamases that hydrolyze many β-lactam antibiotics, including penicillins, advanced generation cephalosporins, and carbapenems. The emergence and spread of carbapenem-resistant *Enterobacterales* (CRE) have left limited therapeutic options for severe infections. Patients with CRE have mortality rates two to three times higher than those with infections caused by carbapenem-susceptible *Enterobacterales*.[2] Although several β-lactam/β-lactamase inhibitor combinations have been approved recently by the FDA to address CRE, none of the current, clinically available compounds are active against MBL-producing *Enterobacterales*. As a result, there remains an urgent need for new antibiotics addressing these resistant Gram-negative pathogens.

[1] Antimicrobial Resistance Collaborators. (2022). Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. The Lancet; 399(10325): P629-655. DOI: https://doi.org/10.1016/S0140-6736(21)02724-0

[2] Baek, M.S., Kim, J.H., Park, J.H. et al. Comparison of mortality rates in patients with carbapenem-resistant Enterobacterales bacteremia according to carbapenemase production: a multicenter propensity-score matched study. Sci Rep 14, 597 (2024). https://doi.org/10.1038/s41598-023-51118-9

Mechanism of Action
Aztreonam-avibactam (ATM-AVI) is an investigational combination of the injectable β-lactam antibiotic aztreonam and the non-β-lactam, β-lactamase inhibitor avibactam. Aztreonam has a unique monocyclic β-lactam nucleus that makes it structurally different from other β-lactam antibiotics and resistant to degradation by metallo β-lactamases (MBLs; Ambler Class B), an increasing source of antibiotic resistance among multi-drug resistant (MDR) bacteria worldwide. However, aztreonam remains susceptible to inactivation by serine β-lactamases of Class A, C, or D. In order to counter aztreonam resistance among bacteria possessing serine β-lactamases, a combination product has been developed in which aztreonam is combined with avibactam. Although avibactam itself possesses no intrinsic antibacterial activity at clinically relevant concentrations, it has been shown to restore activity of aztreonam against pathogens that produce Class A and Class C β-lactamases, including extended spectrum β-lactamases (ESBLs), Klebsiella pneumoniae carbapenemases (KPCs), and AmpC producing strains, as well as some Class D β-lactamases (eg, OXA-48 type).

ATM-AVI provides activity against resistant Gram-negative pathogens including those that produce MBLs (e.g. New Delhi metallo- β -lactamases [NDM], Verona integron-encoded metallo-β -lactamase [VIM], and imipenemases [IMP]), AmpC, ESBLs, and KPCs. According to the requestor, ATM-AVI is the only monobactam/β-lactamase inhibitor combination and has a unique spectrum targeting resistant Gram-negative bacteria.

ATM-AVI was evaluated in one Phase 2 clinical trial in patients with cIAI and two Phase 3 clinical trials, one in patients with cIAI or hospital acquired bacterial pneumonia/ ventilator associated bacterial pneumonia (HABP/VABP), and one in patients with serious infections (cIAI, complicated urinary tract infections, HABP/VABP, or blood stream infections) due to multi-drug resistant Gram-negative MBL producing pathogens. The clinical trials included a total of 305 patients treated with ATM-AVI and 139 patients treated with comparator. Common adverse reactions occurring in greater than 5% of patients included: anemia, diarrhea, increased alanine aminotransferase (ALT), and increased aspartate aminotransferase (AST). Overall ATM-AVI was well tolerated, and the side effect profile was similar to the comparator arm.

Inpatient Administration of Aztreonam-avibactam
ATM-AVI 2.0-gram lyophilized powder for injection is supplied as a white to slightly yellow sterile powder for reconstitution in a single-dose, sterile, clear glass vial containing 1.5 grams of aztreonam and 0.5 grams of avibactam (equivalent to 0.542 grams of avibactam sodium). Following reconstitution and dilution, ATM-AVI will be administered by a healthcare professional via intravenous infusion. Upon completion of a loading dose (Aztreonam 2g / Avibactam 0.67g infused intravenously for 3 hours), the recommended dose is anticipated to be Aztreonam 1.5g / Avibactam 0.5g administered intravenously over 3 hours, every 6 hours. Adjustments to the dosing regimen for ATM-AVI are recommended for patients with estimated creatinine clearance less than or equal to 50 mL/min. The recommended duration of treatment with ATM-AVI is anticipated to be 5-14 days.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of aztreonam-avibactam. Facilities can report the intravenous administration of aztreonam-avibactam using one of the following codes:

3E03329 Introduction of other anti-infective into peripheral vein, percutaneous approach
3E04329 Introduction of other anti-infective into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of aztreonam-avibactam. Continue coding as described in current coding.

Option 2. In section X table XW0, Anatomical Regions, create new substance value P Aztreonam-avibactam Anti-infective, applied to the body part values 3 Peripheral Vein and 4 Central Vein and the percutaneous approach, to identify the intravenous administration of aztreonam-avibactam.

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 P** Aztreonam-avibactam Anti-infective	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 34 – Administration of rozanolixizumab-noli

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of rozanolixizumab-noli. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor submitted a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. The requestor was granted FDA approval for biologics license application (BLA) 761286 on June 26, 2023, for RYSTIGGO (rozanolixizumab-noli) injection indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK ab+) antibody positive.

Background: Generalized myasthenia gravis (gMG) is a rare chronic autoimmune disorder in which antibodies destroy the communication between nerves and muscles, resulting in weakness of the skeletal muscles, particularly the eyes, mouth, throat, and limbs. There are approximately 70,000 adult patients in the U.S. diagnosed with gMG, and approximately 4,100 to 6,600 of these gMG patients are MuSK ab+. According to the requestor, approximately 40% of these patients will experience an exacerbation that will require an inpatient stay. Several treatments have been approved by the FDA for gMG with varied success. This could be attributed to some gMG patients having anti-muscle-specific tyrosine kinase antibodies, which have limited treatment options. While other treatments are available for gMG, about 40% of patients continue to experience gMG exacerbation, suggesting an inadequate response to existing treatment. Per the requestor, RYSTIGGO is the first and only treatment approved by the FDA specifically for patients with either AChR or MuSK ab+ gMG.

Mechanism of Action
RYSTIGGO is a subcutaneously infused, monoclonal antibody (mAB) that specifically targets FcRn with high affinity, permitting the accelerated removal of all subclasses of IgG. Binding to the neonatal Fc receptor (FcRn), results in the reduction of circulating IgG. According to the requestor, there are specific differences in FcRn affinities between RYSTIGGO and other FcRn inhibitors. RYSTIGGO is the only FcRn inhibitor that is FDA-approved for muscle-specific kinase antibody-positive gMG in adults.

Inpatient Administration of rozanolixizumab-noli
The recommended dosing for rozanolixizumab-noli is based on the patient's body weight. For body weight less than 50 kg, each dose is 420 mg, for body weight between 50 kg to less than 100 kg, each dose is 560 mg, and for body weight 100 kg and above, each dose is 840 mg. Each dose is administered as a subcutaneous infusion in the lower abdomen using an infusion pump at a rate of up to 20 mL/hour once weekly for six weeks. by a health care professional via intravenous infusion over 30 minutes.

Per the requestor, the most common adverse reactions experienced (≥10%) in patients with gMG are headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of rozanolixizumab-noli. Facilities can report the subcutaneous administration of rozanolixizumab-noli using the following code:

3E013GC	Introduction of other therapeutic substance into subcutaneous tissue, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the subcutaneous administration of rozanolixizumab-noli. Continue coding as described in current coding.

Option 2. In section X table XW0, Introduction, Anatomical Regions, create new substance value T Rozanolixizumab-noli Monoclonal Antibody, applied to the body part value 1 Subcutaneous Tissue and the percutaneous approach, to identify the subcutaneous administration of rozanolixizumab-noli.

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 T** Rozanolixizumab-noli Monoclonal Antibody	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.