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

CENTER FOR MEDICARE

Agenda

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

CMS is posting the procedure code topic materials and soliciting public comments regarding any clinical questions or coding options consistent with the approach we utilized since the Spring 2025 update and have utilized as of March 2021 for the procedure code requests that involve a new technology add-on payment (NTAP) application for the administration of a therapeutic agent. The deadline to submit comments for procedure code topics being considered for an April 1, 2027 implementation is October 16, 2026, and the deadline to submit comments for procedure code topics being considered for an October 1, 2027 implementation is November 13, 2026.

Members of the public should send any questions or comments related to the procedure code topics that are under consideration for an April 1, 2027 implementation or an October 1, 2027 implementation to the CMS mailbox at: ICDProcedureCodeRequest@cms.hhs.gov by the respective deadline.

All procedure code topic materials and related documents are 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 October 16, 2026 or November 13, 2026 deadline.

Note: Proposals for diagnosis code topics will be presented virtually by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and are scheduled for both days, September 15-16, 2026. Please visit the CDC's website for the diagnosis code topics agenda located at: https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html.

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

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Topics Being Considered for ICD-10-PCS Procedure Codes

Overview	Mady Hue, CMS Co-Chair, ICD-10 Coordination and Maintenance Committee
ICD-10-PCS Topics:	
1. Extracorporeal Interstitial Fluid Removal** Pages 15-17	Mady Hue, CMS William Abraham, MD Professor of Medicine Ohio State University
2. Transcutaneous Spinal Cord Stimulation** Pages 18-22	Andrea Hazeley, CMS Katie Velez Senior Vice President of Global Marketing and Strategy ANEUVO Nicole Coustier Expert Advisor PRIA Healthcare
3. Visualization Guidance for Pressure Offloading during Patient Repositioning*** Pages 23-26	Andrea Hazeley, CMS Ron Ferber President & CTO Wellsense, Inc.
4. Intracranial Introduction of Ultrasound Imaging Fluid*** Pages 27-29	Mady Hue, CMS Josh Aronson, MD, FAANS Neurosurgeon Beth Israel Deaconess Medical Center
5. Measurement of Volumetric Blood Flow in Peripheral Vessels**** Pages 30-32	Mady Hue, CMS S. Eric Ryan, MD President and CEO Provisio Medical Technologies Corp.
6. Intraoperative Control of Coronary Artery Hemorrhage using Rapid Exchange Catheter with Helical Perfusion Balloon**** Pages 33-35	Mady Hue, CMS Christopher E. Buller, MD, FRCPC, FACC Global Medical Director Teleflex, Inc.
7. Monitoring of Peritoneal Cavity using Electrode Sensors**** Pages 36-37	Mady Hue, CMS Eileen Ke VP Business Development Exero Medical

16. Section X Updates — Andrea Hazeley, CMS
    Pages 66-78

17. Addenda and Reference Key Updates — Andrea Hazeley, CMS
    Pages 79-93

18. Administration of cefepime-zidebactam** — Andrea Hazeley, CMS
    Pages 94-95

19. Administration of tanruprubart** — Mady Hue, CMS
    Pages 96-98

20. Administration of ristoglogene autogetemcel** — Andrea Hazeley, CMS
    Pages 99-101

21. Administration of mivocabtagene autoleucel** — Mady Hue, CMS
    Pages 102-103

22. Administration of anzutresgene autoleucel**** — Andrea Hazeley, CMS
    Pages 104-106

23. Administration of imlifidase** — Andrea Hazeley, CMS
    Pages 107-109

**Request is for an April 1, 2027 implementation date.*
***Request is for an April 1, 2027 implementation date and the requestor intends to submit a New Technology Add-on Payment (NTAP) application for future consideration.*
****Request is for an October 1, 2027 implementation date.*
*****Request is for an October 1, 2027 implementation date and the requestor intends to submit an NTAP application for future consideration.*

Continuing Education Credits:
If you have any questions concerning CEUs, please contact the respective credentialing organization, not CMS.

Continuing education (CEU) credits may be awarded by the American Academy of Professional Coders (AAPC) or the American Health Information Management Association (AHIMA) for participation in CMS ICD-10 Coordination and Maintenance (C&M) Committee Updates.

Continuing Education Information for American Academy of Professional Coders (AAPC)
Please see the AAPC website at: https://www.aapc.com/medical-coding-education/.

Continuing Education Information for American Health Information Management Association (AHIMA)
AHIMA credential-holders may claim 1 CEU per 60 minutes for participating in 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 at: https://www.ahima.org/certification-careers/recertify/.

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

Mady Hue
Marilu.Hue@cms.hhs.gov

Andrea Hazeley
Andrea.Hazeley@cms.hhs.gov

ICD-10 TIMELINE

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

September 15-16, 2026	The diagnosis code portion of the September 2026 ICD-10 Coordination and Maintenance Committee Meeting will be fully virtual by Zoom and dial-in. Those who wish to attend must participate via Zoom Webinar or by dialing in. The procedure code topics will be open for public comment. **Procedure code topics and related materials–** https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials
September 2026	Recordings and slide presentations of the diagnosis code portion of the September 15-16, 2026 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web page: **Diagnosis code topics and related materials–** https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html
October 1, 2026	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes. Final addendum available on web pages as follows: **Diagnosis addendum –** https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **Procedure addendum –** https://www.cms.gov/medicare/coding-billing/icd-10-codes
October 16, 2026	**Deadline for receipt of public comments on proposed new codes discussed at the September 15-16, 2026 ICD-10 Coordination and Maintenance Committee Update being considered for implementation on April 1, 2027.**
November 2026	Any new ICD-10 codes that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2027 will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd-10-cm/files.html https://www.cms.gov/medicare/coding-billing/icd-10-codes
November 13, 2026	**Deadline for receipt of public comments on proposed new codes and revisions presented at the September 15-16, 2026 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2027.**

December 4, 2026	**Deadline for requestors: Those members of the public requesting that topics be considered for the March 16-17, 2027 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.** **Procedure code requests should be directed to CMS at:** https://mearis.cms.gov **Diagnosis code requests should be directed to NCHS at:** nchsicd10cm@cdc.gov Requestors should indicate if they are submitting their code request for consideration for an October 1, 2027 implementation date, an April 1, 2028 implementation date, or an October 1, 2028 implementation date. **The ICD-10 Coordination and Maintenance Committee may not be able to consider all requests received for the next Committee code update and will determine if it would be appropriate to postpone consideration of any code requests to a future time. The Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration at the March 16-17, 2027 meeting for an October 1, 2027 implementation date, an April 1, 2028 implementation date, or an October 1, 2028 implementation date.** **In addition, requestors indicate whether they have submitted or intend to submit a New Technology Add-on Payment (NTAP) policy application related to the ICD-10-CM diagnosis code request or the ICD-10-PCS procedure code request. If an NTAP application is not submitted as indicated, is deemed ineligible, or is withdrawn, the Committee will determine if it would be appropriate to postpone consideration of the code request to a future time.**
January 2027	Federal Register notice for the March 16-17, 2027 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative list of code topics.
February 2027	Tentative list of topics for the procedure code portion of the Spring 2027 ICD-10 Coordination and Maintenance Committee Code Update posted on CMS webpage at: https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials

	Tentative agenda for the diagnosis portion of the March 16-17, 2027 ICD-10 Coordination and Maintenance Committee Meeting posted on NCHS homepage at: https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html
February 1, 2027	ICD-10 MS-DRG Grouper software and related materials posted on CMS webpage at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software
February 1, 2027	Any updates to the ICD-10-CM and ICD-10-PCS Coding Guidelines will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd-10-cm/files.html https://www.cms.gov/medicare/coding-billing/icd-10-codes
February 1, 2027	All ICD-10-CM and ICD-10-PCS code update files (includes April 1 update and full files from prior October 1) will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd-10-cm/files.html https://www.cms.gov/medicare/coding-billing/icd-10-codes
March 16-17, 2027	The diagnosis code portion of the March 2027 ICD-10 Coordination and Maintenance Committee Meeting will be fully virtual by Zoom and dial-in. Those who wish to attend must participate via Zoom Webinar or by dialing in. The procedure code topics will be open for public comment. **Procedure code topics and related materials–** https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials
March 2027	Recordings and slide presentations of the diagnosis code portion of the March 16-17, 2027 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web page: **Diagnosis code topics and related materials–** https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html
April 1, 2027	Any new or revised ICD-10 codes will be implemented on April 1, 2027.
April 16, 2027	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 16-17, 2027 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2027**.

April 2027	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 2028 ICD-10-CM diagnosis and ICD-10-PCS procedure codes finalized to date. It will also include proposed revisions to the MS-DRG system based on ICD-10-CM/PCS codes on which the public may comment. The proposed rule can be accessed at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.
May 14, 2027	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 16-17, 2027 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2028.** **Deadline for receipt of public comments on proposed new diagnosis codes and revisions discussed at the March 16-17, 2027 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2028**.
June 2027	Final addenda posted on web pages as follows: **Diagnosis addendum -** https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **Procedure addendum -** https://www.cms.gov/medicare/coding-billing/icd-10-codes
June 5, 2027	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September7-8, 2027 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.** **Procedure code requests should be directed to CMS at:** https://mearis.cms.gov **Diagnosis code requests should be directed to NCHS at:** nchsicd10cm@cdc.gov Requestors should indicate if they are submitting their code request for consideration for an April 1, 2028 implementation date or an October 1, 2028 implementation date. **The ICD-10 Coordination and Maintenance Committee may not be able to consider all requests received for the next Committee code update and will determine if it would be appropriate to postpone consideration of any code requests to a future time. The**

	Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration at the September 7-8, 2027 meeting for an April 1, 2028 implementation date, or an October 1, 2028 implementation date. **In addition, requestors indicate whether they have submitted or intend to submit a New Technology Add-on Payment (NTAP) policy application related to the ICD-10-CM diagnosis code request or the ICD-10-PCS procedure code request. If an NTAP application is not submitted as indicated, is deemed ineligible, or is withdrawn, the Committee will determine if it would be appropriate to postpone consideration of the code request to a future time.**
July 2027	Federal Register notice for the September 7-8, 2027 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative list of topics.
August 1, 2027	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, 2027. This rule can be accessed at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps
August 2027	Tentative list of topics for the procedure portion of the Fall 2027 ICD-10 Coordination and Maintenance Committee Code Update will be posted on the CMS webpage at – https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials Tentative agenda for the diagnosis portion of the September 7-8, 2027 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the NCHS webpage at – https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html
September 7-8, 2027	The diagnosis code portion of the September 2027 ICD-10 Coordination and Maintenance Committee Meeting will be fully virtual by Zoom and dial-in. Those who wish to attend must participate via Zoom Webinar or by dialing in. The procedure code topics will be open for public comment.

	Procedure code topics and related materials– https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials
September 2027	Recordings and slide presentations of the diagnosis code portion of the September 7-8, 2027 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web page: **Diagnosis code topics and related materials–** https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html
October 1, 2027	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes. Final addendum available on web pages as follows: **Diagnosis addendum –** https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **Procedure addendum –** https://www.cms.gov/medicare/coding-billing/icd-10-codes

Overview

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

Code Proposals

- ICD-10-PCS code proposals are being considered for implementation on April 1, 2027 and October 1, 2027
- CMS will provide code options and recommendations
- The public can send comments
- No final decisions are made until public comments have been reviewed

Comments on Code Proposals

- Submit public comments by
  - October 16, 2026 for codes being considered for April 1, 2027 implementation
  - November 13, 2026 for codes being considered for October 1, 2027 implementation
- Procedure topic comments to CMS: ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis topic comments to NCHS: nchsicd10cm@cdc.gov

Proposed and Final Rules

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

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

Addenda and Errata

- June 2026 – Final code updates and addendum posted
  - FY 2027 ICD-10-PCS (Procedures)
    https://www.cms.gov/medicare/coding-billing/icd-10-codes
  - FY 2027 ICD-10-CM (Diagnoses)
    https://www.cdc.gov/nchs/icd/icd-10-cm/files.html
- August 2026 – Errata for 2 new procedure codes posted
    https://www.cms.gov/medicare/coding-billing/icd-10-codes

Public Participation

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

ICD-10-PCS Codes Implementation

- ICD-10-PCS code proposals are under consideration for April 1, 2027 (FY 2027) or October 1, 2027 (FY 2028) implementation

March 17-18, 2027 C&M Code Requests

- December 4, 2026 – Deadline for submitting topics for the March 16-17, 2027 C&M meeting
  - Procedure requests to CMS: https://mearis.cms.gov
  - Diagnosis requests to NCHS: nchsicd10cm@cdc.gov

The ICD-10 Coordination and Maintenance Committee may not be able to consider all requests received for the next Committee code update and will determine if it would be appropriate to postpone consideration of any code requests to a future time. The Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be included for consideration in the Spring 2027 procedure code update materials for an October 1, 2027 implementation date or an April 1, 2028 implementation date.

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

Topic # 01 – Extracorporeal Interstitial Fluid Removal

Issue: There is no unique ICD-10-PCS code to describe hyperthermia using a wearable garment with integrated control system for extracorporeal interstitial fluid removal. An April 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. AQUAPASS received Breakthrough Device designation from the FDA in 2022 for reducing fluid overload in patients with congestive heart failure (CHF) or chronic kidney disease (CKD) stages 2-3 and in 2024 for removal of fluids in end-stage renal disease (ESRD) patients.

Background: In the United States, approximately 35.5 million individuals have kidney disease, with over 808,000 living with kidney failure and more than 557,000 requiring dialysis. CHF affects an estimated 6.5 million Americans and is the leading cause of hospitalization in individuals over 65, resulting in over one million hospital admissions annually. Fluid overload is among the most common and dangerous clinical complications in these populations. Currently, fluid overload is treated with diuretics, ultrafiltration, and dialysis. Per the requestor, these existing therapies have poor efficacy, require significant resources, or are invasive. The requestor stated AQUAPASS therapy provides non-invasive extracorporeal (regional) thermal treatment to support volume management in patients with fluid overload when conventional therapies are insufficient and can be particularly beneficial for patients with diuretic resistance, which can lead to repeated hospitalizations for volume overload. Additionally, sweating is a natural heat-dissipation mechanism triggered at skin temperatures as low as 33°C, with sweat gland activity increasing steadily between 33–40°C without risk of thermal injury. Within this range, individuals can excrete more than 100 mL/hour of sweat, which is especially advantageous for patients experiencing fluid overload because the expelled fluid originates from the interstitial compartment, where most excess fluid resides. According to the requestor, by safely elevating skin temperature of the torso and lower body into this therapeutic range, AQUAPASS enables clinically meaningful fluid removal while providing uniform heat distribution and continuous monitoring to sustain this physiologic response. Because diuretics frequently cause hypokalemia, hyponatremia, magnesium loss, and rapid volume shifts that can destabilize blood pressure, a sweat-based approach offers an important advantage: sweat contains far lower concentrations of electrolytes than urine. As a result, the requestor stated that AQUAPASS-induced fluid loss can help reduce edema and congestion without the same degree of electrolyte depletion, and in some cases may allow clinicians to reduce diuretic dosing. This non-pharmacological method of fluid reduction decreases strain on the kidneys, minimizes diuretic-related side effects, and enhances overall comfort and symptom control for patients managing fluid overload, according to the requestor.

Technology
AQUAPASS is a non-invasive extracorporeal hyperthermia-based therapy that uses controlled external warming to induce physiologic sweating for fluid management in patients with heart failure and kidney disease who are experiencing volume overload. Per the requestor, functionally, AQUAPASS takes over a portion of renal physiological activity by facilitating controlled removal of interstitial fluid through an external mechanism. The system functions by safely activating the body's natural sweating mechanism to remove excess fluid from the interstitial compartment. This

is achieved by creating a regulated microclimate at the skin surface, elevating regional skin temperature while maintaining core temperature within physiological norms.

The AQUAPASS system includes two main components: (1) a control station and (2) a single-patient wearable garment. The system delivers regulated warm air across the body surface to achieve therapeutic skin-temperature elevation consistent with extracorporeal regional hyperthermia. The wearable garment serves as the method of applying external heat and is intended to provide consistent thermal exposure. These components are connected via an air passage tube that incorporates multiple sensors for real time monitoring. The attending physician programs individualized treatment parameters, including target temperature and duration, based on the patient's fluid removal needs.

The control station is a portable unit containing a heat pump, integrated control system, and airflow delivery tube. The heat pump circulates warmed air at 1.4–1.8 m^3/min [±0.2] into the wearable garment, maintaining the treatment microclimate between 44–48°C [±0.5°C], sufficient to stimulate eccrine sweat gland activation while protecting the skin from thermal injury. The air passage tube incorporates two types of sensors: temperature and humidity sensors located at (1) the outlet of the hose toward the wearable garment and (2) the skin-facing region where evaporated sweat mixes with the airflow. These measurements allow the system to calculate patient sweat rate in real time, which is a key indicator of treatment effectiveness because it directly reflects the volume of fluid being mobilized from the interstitial compartment. Temperature sensors also serve as a safety mechanism by ensuring the delivered air remains within the physician-prescribed temperature range. Although clinical staff independently monitor patient vital signs as part of routine care, the AQUAPASS system itself does not contain embedded sensors for blood pressure, heart rate, or core temperature. Instead, the system continuously monitors airflow, humidity, and temperature to verify that treatment conditions remain within the programmed therapeutic limits. The wearable garment covers the patient's torso through the lower extremities and is designed to evenly distribute heated air across the body surface. It maintains close contact with the patient's skin to ensure efficient thermal transfer and uniform sweating. No serious adverse events have been reported in any of the clinical trials. As with all extracorporeal hyperthermia procedures, theoretical risks include skin irritation or discomfort, which may be mitigated through continuous monitoring.

Procedure Description

AQUAPASS therapy begins with a physician determining the necessary fluid removal target and prescribing treatment parameters. The patient is appropriately sized for the wearable garment and assisted by the clinician in securing the device directly against the skin. After a baseline weight is documented, the wearable garment is attached to the control station via the air passage tube, and the clinician programs patient specific temperature and treatment duration settings.

During the approximately four-hour treatment session, the patient may sit, recline, or ambulate short distances while the system continuously monitors the treatment environment. Controlled regional warming elevates skin temperature into the therapeutic hyperthermia range, triggering physiologic sweating and evaporation to remove fluid from the interstitial compartment. The temperature and humidity sensors within the air circuit provide real-time data that allow the system to calculate sweat rate and ensure that air temperature and airflow remain within the physician-prescribed limits throughout treatment. Continuous evaporation cools the skin surface, stabilizes core temperature, and maintains patient comfort. Clinical staff monitor vital signs as part of standard clinical practice; these measurements are not performed by the AQUAPASS system itself.

The AQUAPASS System is a standalone extracorporeal hyperthermia procedure using external thermal application.

Current Coding: There are no unique ICD-10-PCS codes to describe hyperthermia using a wearable garment with integrated control system for extracorporeal interstitial fluid removal. Facilities can report hyperthermia for extracorporeal interstitial fluid removal using one of the following codes:

6A3Z0ZZ Hyperthermia, Single
6A3Z1ZZ Hyperthermia, Multiple

Coding Options

Option 1. Do not create new ICD-10-PCS codes for hyperthermia using a wearable garment with integrated control system for extracorporeal interstitial fluid removal. Continue as described in current coding.

Option 2. In section 6 Extracorporeal or System Therapies table 6A3, Hyperthermia, Physiological Systems, create new qualifier value 0 Wearable Garment with Integrated Control System for Interstitial Fluid Removal, applied to the body part value Z None and the continuous duration value, to identify hyperthermia using a wearable garment with integrated control system for extracorporeal interstitial fluid removal.

Section	**6** Extracorporeal or Systemic Therapies		
Body System	**A** Physiological Systems		
Operation	**3** Hyperthermia: Extracorporeal raising of body temperature		
Body System	*Duration*	*Qualifier*	*Qualifier*
Z None	**2** Continuous	**Z** No Qualifier	**Z** No Qualifier **ADD 0** Wearable Garment with Integrated Control System for Interstitial Fluid Removal

Option 3. In section X New Technology table XXA, Assistance, Physiological Systems, create new technology value J Hyperthermia using Wearable Device for Interstitial Fluid Removal, applied to the body part value 5 Circulatory and the external approach, to identify hyperthermia using a wearable garment with integrated control system for extracorporeal interstitial fluid removal.

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	**X** External	**ADD J** Hyperthermia using Wearable Garment with Integrated Control System for Interstitial Fluid Removal	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 02 – Transcutaneous Spinal Cord Stimulation

Issue: There are currently no unique ICD-10-PCS codes to describe transcutaneous spinal cord stimulation for restoration of voluntary motor function following spinal cord injury. An April 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? Yes. The ExaStim® Stimulation System was granted class II 510(k) premarket approval (K252893) by the FDA on February 23, 2026 and is indicated for the improvement of hand sensation and strength in individuals between 18 and 75 years old who present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury, when used in conjunction with functional task practice.

Background: Approximately 300,000 individuals in the United States live with spinal cord injury (SCI), with roughly 18,000 new cases reported annually.[1] The majority of these injuries are traumatic and result in partial or complete loss of voluntary motor function below the level of injury. Despite advances in acute management, long-term recovery remains limited because existing rehabilitation approaches primarily focus on compensatory strategies rather than reactivation of impaired neural pathways. Most patients experience chronic motor deficits, spasticity, and loss of independence in mobility and activities of daily living, leading to significant healthcare utilization and reduced quality of life.

Current rehabilitation strategies for motor recovery after SCI rely on conventional physical and occupational therapy, supported by functional electrical stimulation (FES) devices that activate individual muscles or muscle groups. While FES can aid muscle conditioning and prevent atrophy, it does not directly modulate the spinal circuits responsible for coordinated movement. Epidural spinal cord stimulation (eSCS) has shown potential for re-engaging motor networks through implanted electrodes, but it is invasive, costly, off-label, and available only at a limited number of specialized centers. The surgical nature of eSCS also restricts access for patients with incomplete injuries or those not eligible for implantation.

Technology
The ExaStim® Stimulation System ("ExaStim®") is a non-invasive, portable spinal neuromodulation system designed to deliver transcutaneous electrical spinal stimulation for therapeutic use in individuals with incomplete SCI to activate spinal motor networks and restore voluntary motor function by targeting spinal segments associated with motor control. By optimizing stimulation parameters—amplitude, frequency, and pulse width— ExaStim® re-engages dormant neural pathways and promotes coordinated muscle activation without surgery or anesthesia. Unlike traditional FES, which is designed to peripherally elicit involuntary motor response for muscle strengthening and the reduction of spasticity, ExaStim® acts at the level of the spinal cord rather than the peripheral musculature, facilitating recovery of complex motor patterns such as standing, stepping, and grasping.

[1] Margetis K, Munakomi S, Gillis CC. Central Cord Syndrome. 2026 Apr 20. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan–. PMID: 28722961.

The ExaStim® system is primarily composed of the ReCure® Electrode Pad, a proprietary external multi-electrode pad with up to 16 channels that can be independently configured, the ExaStim® Portable Stimulator, and the ExaStim® Programmer, a mobile digital device with proprietary medical device programming software. Additional components and accessories are also included as part of the system (e.g., cables, and ground electrodes).

The ReCure® Electrode Pad is a non-invasive 16-channel multi-electrode array comprised of hydrogel, adhesives, and silver ink traces. The electrode pad can be placed cutaneously along the midline of the cervical, thoracic, or lumbar spine, typically spanning two to three vertebral levels. Additionally, two neurostimulation return electrodes are placed on the left and right iliac crests to complete the electrical circuit. The specific placement of the electrode pad depends on the patient's neurological injury and functional objectives. The goal of this targeting is to activate spinal networks involved in locomotor and postural control without direct contact with neural tissue.

The ExaStim® Portable Stimulator is a portable, battery-operated, rechargeable generator that delivers multiple-independent-current-controlled (MICC) stimulation to the spinal cord and dorsal roots according to parameters configured by the ExaStim® Programmer by a clinician. The treatment uses low-level, current-regulated electrical stimulation to modulate spinal excitability and enable motor pattern activation. The portable stimulator application-specific integrated circuit (ASIC) enables each of the 16 electrodes on ReCure® Electrode Pad to be programmed independently (i.e., amplitude, frequency, pulse width, and polarity), enabling selective mapping and precise activation of targeted spinal segments, allowing the clinician to map and activate specific spinal regions relevant to the patient's rehabilitation needs. Integrated impedance sensing maintains safety and therapeutic precision. The stimulator is connected to the multi-electrode pad via a custom stimulation cable that delivers electricity from the stimulator to the electrodes on the array via silver ink traces.

The ExaStim® Programmer is controlled by a Bluetooth-connected mobile digital device preloaded with proprietary ExaStim® Programming Software. The clinician interface allows the clinician to create and control patient-specific stimulation parameters and procedures as well as monitor the patient's therapy and therapy utilization. The patient interface allows the patient to select from therapy programs that have been previously established by their clinician as well as view their therapy progress and utilization.

According to the requestor, in the ANEUVO ASPIRE™ Study, a 128-subject, multi-center, randomized, controlled, double-blinded trial, evaluating the safety and performance of ExaStim®, preliminary assessment of the summary of adverse events indicates there were 46 device-related adverse events out of 1,800 active therapy sessions. There were no serious device-related adverse events in active subjects. The device-related adverse events were primarily due to device-related pain (n=5), elevated blood pressure (n=2), fatigue related to the procedure (n=2), and headache (n=2).

Procedure Description
During inpatient rehabilitation, a qualified clinician applies ExaStim® to facilitate volitional motor re-engagement after SCI. Although the ExaStim® system interacts functionally with the spinal cord, the technology is entirely external and non-invasive. The spinal neuromodulation is performed with the patient in a sitting, standing, or supine position. The ReCure® multi-electrode

pad is placed externally over 2–3 vertebral levels of the cervical or thoracolumbar spine, depending on the level of injury, while two ground electrodes are placed on the left and right iliac crests.

Using the ExaStim® Programmer, the provider performs real-time spinal mapping by selecting desired electrode configurations and adjusting stimulation parameters—amplitude (3 –150 mA), frequency (1-100 Hz), and pulse width (0.3–1.0 ms)—to identify optimal volitional motor responses. The spinal mapping phase is an integral component of the procedure, not a preparatory activity, because it determines patient-specific electrode configuration and stimulation parameters required for therapeutic activation. Once individualized settings are defined, stimulation is delivered during guided functional activities (e.g., massed task practice, high intensity interval training) or passive sessions lasting 60-90 minutes. During mapping and stimulation sessions, patients may engage in guided motor tasks (e.g., assisted standing, stepping, or reaching) to reinforce voluntary control while stimulation is delivered. These concurrent activities are therapeutic complements, not procedural dependencies.

The multi-electrode pad, ground electrode, and stimulator unit are applied to the skin surface and removed after each session. One ExaStim® System, including the ReCure® Electrode Pad is used per treatment session; however, the system, not including the electrode pads, can be used across multiple patients in a day, as the battery life is up to 8 hours. Sessions occur under qualified clinician (e.g., physical medicine and rehabilitation physician, physical or occupational therapist, or trained technician) supervision, typically 5 to 7 days per week during inpatient rehabilitation and may continue post-discharge in outpatient settings or home-based care settings.

ExaStim® spinal neuromodulation is performed as a standalone therapy, though it may be performed in coordination with standard rehabilitative activities such as physical or occupational therapy. There is no incision, implantation, or imaging guidance required.

Current Coding: There are no unique ICD-10-PCS codes to describe transcutaneous spinal cord stimulation for restoration of voluntary motor function following SCI. Facilities can report the transcutaneous spinal cord stimulation using the applicable neurological body system value in section F table F07 Rehabilitation of Motor Treatment with the type qualifier value 3 Motor Function and the equipment value Y Other Equipment.

Section	**F** Physical Rehabilitation and Diagnostic Audiology		
Section Qualifier	**0** Rehabilitation		
Type	**7** Motor Treatment: Exercise or activities to increase or facilitate motor function		
Body System / Region	*Type Qualifier*	*Equipment*	*Qualifier*
0 Neurological System - Head and Neck **1** Neurological System - Upper Back / Upper Extremity **2** Neurological System - Lower Back / Lower Extremity **3** Neurological System - Whole Body **J** Musculoskeletal System - Head and Neck **K** Musculoskeletal System - Upper Back / Upper Extremity **L** Musculoskeletal System - Lower Back / Lower Extremity **M** Musculoskeletal System - Whole Body	**0** Range of Motion and Joint Mobility **1** Muscle Performance **2** Coordination/Dexterity **3** Motor Function	**E** Orthosis **F** Assistive, Adaptive, Supportive or Protective **U** Prosthesis **Y** Other Equipment **Z** None	**Z** None

Coding Options

Option 1. Do not create new ICD-10-PCS codes for transcutaneous spinal cord stimulation for restoration of voluntary motor function following spinal cord injury. Continue as described in current coding.

Option 2. In section F table F07 Rehabilitation, Motor Treatment, create new qualifier value 1 Transcutaneous Spinal Cord Stimulation, applied to the body system values shown, the type qualifier value Y Other Therapy Techniques and the equipment value D Electrotherapeutic, to identify transcutaneous spinal cord stimulation for restoration of voluntary motor function following spinal cord injury.

Section	**F** Physical Rehabilitation and Diagnostic Audiology		
Section Qualifier	**0** Rehabilitation		
Type	**7** Motor Treatment: Exercise or activities to increase or facilitate motor function		
Body System / Region	*Type Qualifier*	*Equipment*	*Qualifier*
0 Neurological System - Head and Neck **1** Neurological System - Upper Back / Upper Extremity **2** Neurological System - Lower Back / Lower Extremity **3** Neurological System - Whole Body **J** Musculoskeletal System - Head and Neck **K** Musculoskeletal System - Upper Back / Upper Extremity **L** Musculoskeletal System - Lower Back / Lower Extremity **M** Musculoskeletal System - Whole Body	**0** Range of Motion and Joint Mobility **1** Muscle Performance **2** Coordination/Dexterity **3** Motor Function	**E** Orthosis **F** Assistive, Adaptive, Supportive or Protective **U** Prosthesis **Y** Other Equipment **Z** None	**Z** None
0 Neurological System - Head and Neck **1** Neurological System - Upper Back / Upper Extremity **2** Neurological System - Lower Back / Lower Extremity	**ADD Y** Other Therapy Techniques	**ADD D** Electrotherapeutic	**ADD 1** Transcutaneous Spinal Cord Stimulation

Option 3. In section X table X0Z Other Procedures, Nervous System, create new technology value 7 Transcutaneous Spinal Cord Stimulation with Multi-channel Targeted Neuromodulation System, applied to the body part value V Spinal Cord and the external approach, to identify transcutaneous spinal cord stimulation for restoration of voluntary motor function following spinal cord injury.

Section	**X** New Technology		
Body System	**0** Nervous System		
Operation	**Z** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD V Spinal Cord	**X** External	**ADD 7** Transcutaneous Spinal Cord Stimulation with Multi-channel Targeted Neuromodulation System	**C** New Technology Group 12

CMS Recommendation: Option 3, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 03 – Visualization Guidance for Pressure Offloading during Patient Repositioning

Issue: There are currently no unique ICD-10-PCS codes to identify the use of visualization guidance for pressure offloading during patient repositioning. An October 1, 2027 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? The hardware components of the Wellsense VŪ® Visually Guided Pressure Offloading (VGPO) system — a sensor mat and color display — are both registered with the FDA as Class I medical devices, compliant with FDA unique device identifier (UDI) requirements, and are exempt from 510(k) premarket notification requirements.

Background: 60,000 Americans die annually from pressure injuries, with pressure injury accounting for 34.2% of all adverse events among Medicare hospitalizations and an estimated 43.5% of all adverse-event-related deaths. Pressure injuries are the only major adverse event category whose share has continued to rise — increasing 14% from 2021 to 2023 (from 30.0% to 34.2%) — even as the overall rate of adverse events among Medicare hospitalizations declined.[1] Pressure injuries can and do develop in any hospitalized patient regardless of admitting condition, age, or mobility status, including those admitted for elective procedures who are otherwise healthy. The greatest concentration of risk for pressure injury exists in the intensive care unit, where patient acuity and immobility are highest and where the majority of hospital-acquired pressure injuries (HAPIs) occur; however, risk is applicable across all inpatient care settings, including the operating room, emergency room, step-down, post-surgical, neurological, and general medical units.

Pressure offloading is the strategic reduction or redistribution of mechanical stress and weight-bearing forces on a specific body area. The current standard of care for pressure injury prevention is manual turning every two hours, which typically requires two nurses, twelve times a day, throughout the entire inpatient stay. However, this protocol has proven ineffective as turning a patient does not guarantee adequate pressure offloading. Published evidence demonstrates that 95% of routine turns leaves pressure on some area of the sacral and pelvic region, including the sacrum, coccyx, ischial tuberosities, and greater trochanters where 70–75% of all pressure injuries occur, above clinically established pressure thresholds.[2]

According to the requestor, visually guided pressure offloading transforms pressure injury prevention by giving nurses the ability to see pressure in real time, to act on what they see, and to confirm that offloading has actually been achieved before leaving the bedside. Published studies have found meaningful reductions in pressure injury incidence across clinical settings — including

[1] AHRQ, Adverse Events Among Medicare Hospitalizations 2021–2023, September 2025; AHRQ National Scorecard on Hospital-Acquired Conditions, January 2019

[2] Peterson MJ, Gravenstein N, Schwab WK, van Oostrom JH, Caruso LJ. Patient repositioning and pressure ulcer risk--monitoring interface pressures of at-risk patients. J Rehabil Res Dev. 2013;50(4):477-88. doi: 10.1682/jrrd.2012.03.0040. PMID: 23934869.

a 95% reduction in hospital acquired pressure injuries in the seven months following the implementation of the Wellsense VŪ® in an individual institutional study.[3]

Technology
Visually Guided Pressure Offloading (VGPO) involves a nurse actively directing and confirming therapeutic repositioning using real-time visual feedback. The Wellsense VŪ®, an advanced pressure visualization (APV) system, gives nurses visibility into patient pressure using real-time interface pressure data shown on a color display, enabling accurate assessment, precise intervention, and confirmation that pressure has been effectively offloaded from at-risk body areas in immobile or mobility-impaired patients. The Wellsense VŪ® consists of two hardware components: a thin, flexible, proprietary sensor mat installed beneath the patient on virtually any standard hospital bed, and a display affixed to a universal armature at the foot of the hospital bed that converts pressure measurements into a real-time color map.

The sensor mat measures interface pressure twice per second across the full patient contact surface, transmitting readings continuously to the foot-of-bed display, which renders them as a real-time color-coded pressure map. Interface pressure is measured in millimeters of mercury (mmHg) and displayed as a graduated color spectrum — cool colors such as blue and green reflecting lower mmHg readings indicating adequately offloaded zones, progressing through yellow and orange to red and white at the highest pressure levels — giving the nurse immediate visual confirmation of pressure distribution across the entire contact surface at any moment.

The display serves as a real-time clinical decision support tool enabling the nurse to act. The display is positioned facing inward toward the patient during the procedure, ensuring direct nurse line of sight. In this position, the patient and family may also participate by taking simple actions such as adjusting the head of the bed or removing a foreign object the patient may be lying on. When unattended, the display rotates outward toward the corridor, allowing any passing clinician to assess the patient's real-time pressure status without entering the room.

The nurse performs the pressure offloading by observing the display, actively repositioning the patient, and confirming that pressure has been reduced below clinically established risk thresholds before leaving the bedside. Per the requestor, there are no known adverse events associated with the performance of VGPO across in excess of 20 million recorded clinical hours in over 20 academic medical centers and health systems across the United States.

Procedure Description
Prior to use, the patient is registered in the Wellsense VŪ® system with their name, medical record number, weight, existing pressure injury locations, and repositioning interval — typically every two hours, though clinicians may manage select patients without a fixed interval based on acuity.

In an inpatient setting, VGPO begins the moment the nurse enters the room. The live pressure image on the foot-of-bed display immediately presents the patient’s full pressure distribution in real time, allowing the nurse to assess the current clinical situation before touching the patient. The nurse then reviews the existing injury record shown on the display, identifying any active pressure

[3] Parks, J & Northrop, Kunthida & Bhavsar, D & Korentager, Richard & Harris, N. (2018). 317 Patient Engagement through Advanced Pressure Visualization as a Component of Pressure Injury Prevention. Journal of Burn Care & Research. 39. S128-S128. 10.1093/jbcr/iry006.239.

injuries and their precise anatomical locations. This step is critical: failure to actively offload pressure from an existing wound accelerates tissue damage toward further injury.

If the patient is not in the expected position, the nurse accesses the pressure history replay function, which renders the previous two hours of pressure data as a condensed visual timeline, which provides an immediate, objective picture of how the patient arrived at their current position and the cumulative pressure burden that has accumulated and enables clinically informed repositioning decisions.

The nurse then repositions the patient, guided in real time by the live pressure image, and confirms success only when all at-risk anatomical regions — including the sacrum, coccyx, ischial tuberosities, and greater trochanters — show visually confirmed pressure offloading below clinically established thresholds.

Upon completion, the nurse presses the confirmation tab, responding to the prompt "Intervention Completed?" The response — yes or no — is automatically timestamped and permanently recorded. If yes is selected, and a repositioning interval has been assigned, the timer resets. In either case, a record is created, capturing every intervention, its timing, and its outcome. This audit trail provides a basis for root cause analysis if a pressure injury develops and a record of care when one does not. The Wellsense VŪ® system is designed to integrate with any electronic medical record (EMR), enabling seamless incorporation of VGPO documentation into the patient's permanent clinical record.

Current Coding: The use of visualization guidance for pressure offloading during patient repositioning is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify the use of visualization guidance for pressure offloading during patient repositioning. Continue as described in current coding.

Option 2. In section X New Technology table XX2, Monitoring of Physiological Systems, create new technology value T Visualization Guidance for Patient Repositioning, applied to the body part value K Whole Body and the external approach, to identify the use of visualization guidance for pressure offloading during patient repositioning.

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*
ADD K Whole Body	**X** External	**ADD T** Visualization Guidance for Patient Repositioning	**D** New Technology Group 13

CMS Recommendation: Option 1, as described above.

Rationale: CMS notes that standard routine bed repositioning or turning of patients is a general nursing care activity and is not separately reported using ICD-10-PCS procedure codes. As a result,

the use of visualization guidance for pressure offloading during patient repositioning is not currently reported separately for inpatient hospital coding.

Interim Coding Advice: Continue as described in current coding.

Topic # 04 – Intracranial Introduction of Ultrasound Imaging Fluid

Issue: There is no unique ICD-10-PCS code to describe the intracranial introduction of ultrasound imaging fluid. An October 1, 2027 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The SonoClear® System received Breakthrough Device designation on June 18, 2025. The proposed indication for use reflects that the SonoClear® System is a biocompatible, bioexcretable, sterile, unit dose packaged, ultrasound acoustic coupling fluid for intracranial ultrasound procedures. The SonoClear® System is intended to provide tissue-like attenuation that leads to minimization of cavity signal enhancement and hyperechogenicity. The SonoClear® System is intended for use intracranially in the brain parenchyma during surgical resection of brain tumors. It is intended to assist in the intraoperative, ultrasound-guided surgical resection of brain tumors.

Background: Brain tumors, both primary and metastatic, affect more than 400,000 patients annually in the United States and require complex neurosurgical management to optimize survival and neurological outcomes. Surgical resection remains a central component of treatment for a wide range of intracranial tumors, including gliomas, meningiomas, metastatic lesions, pediatric brain tumors, and other central nervous system neoplasms. Achieving the greatest possible extent of resection (EOR) is strongly associated with improved progression-free and overall survival; however, safely maximizing EOR is challenging because tumor margins can be difficult to visualize in real time, especially in infiltrative or irregularly shaped lesions.

Intraoperative ultrasound (ioUS) is widely used during brain tumor surgery because it provides real-time imaging without radiation, supports surgical navigation, and helps identify residual tumor. According to the requestor, despite its clinical value, standard ioUS imaging is frequently limited by poor acoustic coupling, air artifacts, signal attenuation, and cavity collapse after tumor debulking. These issues degrade image quality and reduce the ability of surgeons to accurately detect tumor boundaries or confirm complete resection. Per the requestor, currently, surgeons rely primarily on irrigation fluid (normal saline or Ringer's solution) as a coupling medium, but irrigation fluids are suboptimal as an ultrasound coupling medium, distorting the ultrasound image during a significant proportion of the cases. According to the requestor, the SonoClear® System, is a novel sterile imaging adjunct specifically designed to enhance ultrasound performance within the resection cavity during open brain tumor surgery.

Technology
The SonoClear® System is a specialized fat emulsion for use in intracranial ioUS procedures. It is biocompatible, bio-excretable, sterile, and unit-dose packaged. The system was engineered to match the acoustic properties of brain tissue. The SonoClear® System is comprised of one 100 ml bag of SonoClear® fluid, nine (9) 20ml BBraun Luer lock Piston syringes, one SonoClear® bag spike as well as the instructions for use. Per the requestor, by stabilizing the acoustic window, reducing air–tissue interface artifacts, and improving signal transmission, the couplant provides clearer differentiation between tumor and normal tissue and more reliable identification of residual disease, representing a meaningful improvement over the existing standard of care. The requestor indicated it directly addresses known limitations of ioUS and supports surgeons in achieving safer and more complete tumor resections. The technology is intended for use in all

open intracranial tumor surgeries and the requestor stated it has the potential to benefit a high proportion of the neurosurgical oncology population.

Procedure Description
The SonoClear® System is used in intracranial procedures where ioUS guidance is required to surgically resect malignant or benign brain tumors. It is used intracranially in the brain parenchyma. Intraoperative ultrasound currently utilizes standard irrigation fluids of normal saline (0.9%) / Ringer's solution as an interface between the ultrasound probe and the tissue to obtain images. The SonoClear® Acoustic Coupling Fluid is utilized as a replacement for irrigation fluids as an ultrasound couplant, when used in conjunction with intra-operative ultrasound imaging. SonoClear® is not used as an irrigation fluid during the resection procedure. Per the requestor, SonoClear® removes the acoustic noise/image artifacts typically seen with the use of irrigation fluids in conjunction with intra-operative ultrasound. By removing the acoustic noise/image artifacts, the requestor stated SonoClear® can deliver improved image quality and better tissue differentiation during the resection of brain tumors.

During tumor resection, the cavity is filled with SonoClear® (fluid) prior to ultrasound imaging to provide acoustic coupling between the ultrasound transducer and tissue. The intended function of SonoClear® is to transmit the energy emitted by the ultrasound transducer and the signals echoed from the surface of the surrounding tissues by conducting the sound in a manner that emulates biological tissue. SonoClear® attenuates sound in a similar magnitude as biological tissue. This ensures that surgically induced ultrasound image artifacts are reduced when using SonoClear® compared to using conventional irrigation fluid such as normal saline or Ringer´s solution. The BBraun Luer lock Piston syringe(s) and SonoClear® Spike set are utilized to aspirate the SonoClear® (fluid) from the bag. SonoClear® fluid is removed from the cavity immediately after ultrasound imaging by standard suction and discarded as fluid waste.

Current Coding: There are no unique ICD-10-PCS codes to describe the intracranial introduction of ultrasound imaging fluid. Facilities can report the intracranial introduction of ultrasound imaging fluid using the following code:

3E0Q0KZ	Introduction of other diagnostic substance into cranial cavity and brain, open approach

If desired, facilities can also report the intraoperative ultrasound using the following code:

B040ZZZ	Ultrasonography of brain

Coding Options

Option 1. Do not create a new ICD-10-PCS code to describe the intracranial introduction of ultrasound imaging fluid. Continue as described in current coding.

Option 2. In section X table XW0, Introduction, Anatomical Regions, create new substance value L Acoustic Coupling Fluid, Ultrasound Imaging Adjunct, applied to the body part value Q Cranial Cavity and Brain and the open approach, to identify the intracranial introduction of ultrasound imaging fluid. Continue to report the intraoperative ultrasound as described in current coding.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
Q Cranial Cavity and Brain	**0** Open	**ADD L** Acoustic Coupling Fluid, Ultrasound Imaging Adjunct	**D** New Technology Group 13

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 05 – Measurement of Volumetric Blood Flow in Peripheral Vessels

Issue: There is no unique ICD-10-PCS code to describe measurement of volumetric blood flow in peripheral vessels. An October 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. The Provisio® Sonic Lumen Tomography Intravascular Ultrasound (SLT IVUS®) FLOW™ System application is currently under review by the FDA. The Provisio® SLT IVUS FLOW™ System is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature and as an adjunct to conventional angiographic procedures to evaluate the vessel lumen and provide dimensional measurements. The Provisio® SLT IVUS FLOW™ System with volumetric flow software is intended for use in adult patients during endovascular procedures to measure volumetric blood flow (mL/min) in peripheral arteries. It is intended to provide real-time quantitative hemodynamic information to assist in diagnosing and evaluating the effectiveness of vascular interventions. The SLT IVUS FLOW™ Support Crossing Catheter also guides and supports a guidewire during access of the vasculature and provides a conduit for the delivery of saline solutions or radiopaque contrast agents. The Provisio® SLT IVUS FLOW™ System technology is based on the Provisio® Sonic Lumen Tomography Intravascular Ultrasound (SLT IVUS®) System.

On April 23, 2024, the Provisio® Sonic Lumen Tomography Intravascular Ultrasound (SLT IVUS®) System received 510(k) premarket authorization (PMA) (K233948). The Provisio® SLT IVUS® System is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature. The Provisio® SLT IVUS® System is designed for use as an adjunct to conventional angiographic procedures to evaluate the vessel lumen and provide dimensional measurements. The SLT IVUS® Support Crossing Catheter also guides and supports a guidewire during access of the vasculature and provides a conduit for the delivery of saline solutions or radiopaque contrast agents.

Background: Chronic limb-threatening ischemia (CLTI), a severe form of peripheral artery disease (PAD), represents a significant public health challenge, affecting millions worldwide and contributing to substantial morbidity and mortality through complications such as amputation and cardiovascular events. Characterized by atherosclerotic narrowing or occlusion of arteries in the lower extremities, PAD impairs blood flow, leading to symptoms ranging from intermittent claudication to tissue loss. Current interventional treatments, including balloon angioplasty, atherectomy, stenting, and bypass grafting, aim to restore adequate perfusion. However, the success of these procedures is often evaluated using indirect metrics such as angiographic imaging or ankle-brachial index (ABI), which provide anatomical insights but fall short in quantifying actual blood flow dynamics. According to the requestor, this limitation highlights a need for real-time, objective assessment during endovascular interventions, where measurement of volumetric blood flow may inform procedural decisions and potentially impact patient outcomes. Volumetric blood flow measurement, defined as the volume of blood passing through a vessel per unit time (typically in mL/min), may be useful for evaluating the hemodynamic impact of PAD treatments. Unlike pressure-based assessments or qualitative Doppler signals, volumetric flow provides a direct indicator of tissue perfusion, enabling clinicians to detect subtle changes in flow resistance, collateral circulation, or post-intervention improvements. In

PAD, where multifocal lesions and variable collateralization complicate treatment, inaccurate flow assessment can lead to under- or over-treatment, recurrent stenosis, or unnecessary adjunctive therapies. Per the requestor, the Provisio® SLT IVUS FLOW™ System is designed to offer the potential for intra-arterial quantification without relying on external devices, addressing the need for integration into these minimally invasive procedures. Up to 10% of the approximately 750,000 PAD interventions done annually in the United States would be classified as CLTI and would be the initial target of this technology.

Technology
The Provisio® SLT IVUS FLOW™ System consists of the SLT IVUS® P1 system (which includes the Pulser Receiver Unit, the Display Unit, and a cart) and the SLT IVUS FLOW™ Support Crossing Catheter, which is a single-patient-use disposable catheter designed for use with the SLT IVUS® P1 System. The Provisio® SLT IVUS FLOW™ System is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature, to evaluate the vessel lumen and provide dimensional measurements, and, uniquely, to measure volumetric blood flow (mL/min) in peripheral vessels to assist in diagnosing and evaluating the effectiveness of vascular interventions. The SLT IVUS FLOW™ Support Crossing Catheter also guides and supports a guidewire during access of the vasculature and provides a conduit for the delivery of saline solutions or radiopaque contrast agents.

Procedure Description
To perform a flow measurement, the catheter distal tip is positioned 20-30cm from the distal tip of a guide catheter or introducer that contains the catheter. The catheter is then retracted over that length at a consistent rate of approximately 1cm per second while sequential lumen measurements are captured, facilitating a volume measurement over that length of vessel. The catheter tip is then repositioned to the same distal length and 3-5 injections of 1-2cc of saline or contrast media are injected, when instructed by the Provisio® SLT IVUS® P1 System, through the guide catheter or introducer. Volumetric blood flow is then calculated from the measured lumen volume and flow velocity and displayed on the Provisio® SLT IVUS® P1 System.

Current Coding: There are no unique ICD-10-PCS codes to describe measurement of volumetric blood flow in peripheral vessels. Facilities can report measurement of volumetric blood flow in peripheral vessels using one of the following codes:

4A03351	Measurement of arterial flow, peripheral, percutaneous approach
4A04351	Measurement of venous flow, peripheral, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe the measurement of volumetric blood flow in peripheral vessels. Continue as described in current coding.

Option 2. In section X New Technology table XXE, Measurement, Physiological Systems, create new technology value L Peripheral Vessel Flow, Volumetric, applied to the body part value 3 Arterial and add body part value 4 Venous and the external approach, to identify measurement of volumetric blood flow in peripheral vessels.

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*
3 Arterial **ADD 4** Venous	**X** External	**ADD L** Peripheral Vessel Flow, Volumetric	**D** New Technology Group 13

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 06 – Intraoperative Control of Coronary Artery Hemorrhage using Rapid Exchange Catheter with Helical Perfusion Balloon

Issue: There are no unique ICD-10-PCS codes to describe intraoperative control of coronary artery hemorrhage using a rapid exchange catheter with a helical perfusion balloon. An October 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. The Ringer™ Perfusion Balloon Catheter received Breakthrough Device designation on August 19, 2019 for the proposed indication of managing hemorrhage due to coronary vessel perforations while facilitating distal perfusion and interventional device delivery until definitive treatment is determined. Premarket Approval (PMA) is pending in alignment with the Breakthrough Device designation.

The Ringer™ Perfusion Balloon Catheter received FDA 510(k) clearance on May 31, 2024 for the indication of balloon dilatation of coronary artery or coronary artery bypass graft stenoses where the physician desires distal blood perfusion during balloon inflation for the purpose of improving myocardial perfusion.

Background: Coronary artery perforation (CAP) is an uncommon but life-threatening complication of percutaneous coronary intervention (PCI) procedures that requires urgent or emergent treatment. Treatment begins with control of hemorrhage to avoid pericardial tamponade and hemodynamic collapse. Current management of CAP ranges from prolonged balloon inflation, covered stent placement, therapeutic embolization, and reversal of anticoagulation after intracoronary equipment is removed. However, according to the requestor, existing treatments are not reliably successful due in part to complex anatomy that both predisposes patients to CAP and interferes with the delivery of specific CAP therapies, in addition to a lack of readily available solutions. Despite being the most common and readily available maneuver, prolonged balloon inflation compromises myocardial perfusion distal to the perforation site, introducing ischemic injury and shortening tolerable inflation times.

Technology
The Ringer™ Perfusion Balloon Catheter (PBC) is a rapid-exchange catheter with a helical-shaped inflatable balloon that approximates a hollow cylinder when inflated. Specifically for CAP, the catheter is designed to act as a physical barrier, sealing perforated or ruptured coronary arteries to prevent hemorrhage into the pericardial space, while simultaneously maintaining continuous distal blood flow to enable myocardial perfusion. Because of the design characteristics with cylindrical balloon expansion, the device also permits the delivery of guide wires and catheters through its lumen if needed.

A Pebax balloon tube is configured in a helix that when inflated approximates a hollow cylinder that apposes the vessel wall but allows distal perfusion through its central lumen. Radiopaque markers at the proximal and distal end of the balloon facilitate visualization and intravascular placement of the catheter prior to inflation. The catheter shaft has positioning marks located at 95cm (single mark) and 105cm (double mark) from the distal tip. The Ringer™ PBC is available in eleven configurations.

Procedure Description
The Ringer™ PBC is used during PCI procedures in which systemic anticoagulation, typically with intravenous unfractionated heparin, is already administered. Use of the Ringer™ PBC involves a coronary guidewire that is generally already in place. The Ringer™ PBC is advanced over that preexisting guidewire under fluoroscopy using the radiopaque markers to position the balloon portion of the device across the site of coronary perforation. Once the balloon is positioned in the desired location, the balloon is inflated to the desired pressure (not to exceed rated burst pressure of 8 atm). Confirmation of a fully inflated balloon with control of hemorrhage and continued antegrade blood flow are confirmed using standard angiographic techniques. The Ringer™ BPC may remain inflated for up to 60 minutes while definitive treatment of the perforation is determined and planned. The Ringer™ PBC may be removed by deflation and withdrawal.

A single Ringer™ PBC is generally sufficient for perforation management. Multiple Ringer™ perfusion balloon catheters may be required when adjustments to balloon diameter or length are necessary to effect complete control of hemorrhage.

Current Coding: There are no unique ICD-10-PCS codes to describe intraoperative control of coronary artery hemorrhage using a rapid exchange catheter with a helical perfusion balloon. Facilities can report the procedure using the following code:

0W3C3ZZ Control bleeding in mediastinum, percutaneous approach

Separately, assign a code for the PCI procedure using the applicable code in table 027, Dilation of Heart and Great Vessels.

Coding Options
Option 1. Do not create new ICD-10-PCS codes to describe intraoperative control of coronary artery hemorrhage using a rapid exchange catheter with a helical perfusion balloon. Continue as described in current coding.

Option 2. In section X New Technology create new table X23, Control of Cardiovascular System, with new technology value P Rapid Exchange Catheter with Helical Perfusion Balloon, applied to the coronary body part values shown and the percutaneous approach, to identify intraoperative control of coronary artery hemorrhage using a rapid exchange catheter with a helical perfusion balloon. Separately assign a code for the PCI procedure using the applicable code in table 027, Dilation of Heart and Great Vessels.

Section **X** New Technology *Body System* **2** Cardiovascular System *Operation* **ADD** **3** Control: Stopping, or attempting to stop, postprocedural or other acute bleeding			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 0 Coronary Artery, One Artery **ADD 1** Coronary Artery, Two Arteries **ADD 2** Coronary Artery, Three Arteries **ADD 3** Coronary Artery, Four or More Arteries	**3** Percutaneous	**ADD P** Rapid Exchange Catheter with Helical Perfusion Balloon	**D** New Technology Group 13

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 07 – Monitoring of Peritoneal Cavity using Electrode Sensors

Issue: There are no unique ICD-10-PCS codes to describe post-operative monitoring of the peritoneal cavity using a drainage system embedded with electrode sensors. An October 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. The xBar System received Breakthrough Device designation by the FDA and is currently under review with a De Novo Classification.

Background: Anastomotic leak after colorectal resection is a major cause of morbidity and mortality. Per the requestor, current postoperative surveillance relies on clinical changes, labs, and imaging, none of which provide direct physiologic monitoring at the anastomotic site. No existing drains incorporate sensors or electrodes capable of real-time direct assessment of tissue healing.

Technology
The xBar System is a diagnostic monitoring device that integrates an electrode array directly into a surgical drain to measure electrical tissue characteristics at the anastomotic site. The system includes a sterile surgical drain containing multiple embedded electrodes, an external recording pod connected by a dedicated cable, a cloud-based processing platform, and a clinician-facing dashboard. According to the requestor, its defining feature is the incorporation of electrodes into the drain itself, which enables direct physiological monitoring during the postoperative period that cannot be achieved with standard passive surgical drains. That requestor stated that this embedded configuration is fundamental to the system's clinical purpose and distinguishes it from existing devices.

Per the requestor, the safety profile of the xBar system was confirmed in two multi-center clinical trials including >270 patients. In both studies, no unanticipated serious adverse device effects (USADEs) were observed or reported, indicating that use of the xBar system does not introduce additional safety concerns beyond those inherent to standard colorectal surgery.

Procedure Description
Following completion of the anastomosis during colorectal surgery (open or laparoscopic), the surgeon inserts the xBar drain into the pelvic or abdominal cavity using the same approach used for the primary surgical procedure. The surgeon positions the electrode-embedded segment adjacent to the anastomosis site, routes the proximal tubing and cable through the incision or trocar site, and secures it externally. The external cable is connected to the monitoring pod postoperatively. No additional operative steps beyond drain placement and cable routing are required.

Current Coding: Post-operative drainage system placement is not reported separately for inpatient hospital coding.

Option 1. Do not create new ICD-10-PCS codes to describe post-operative monitoring of the peritoneal cavity using a drainage system embedded with electrode sensors. Continue as described in current coding.

Option 2. In section X New Technology table XX2, Monitoring, Physiological Systems, create new technology value N Peritoneal Fluid Volume, Drainage System with Integrated Electrode Sensors, applied to the body part value G Peritoneal Cavity and the open and percutaneous endoscopic approaches, to identify post-operative monitoring of the peritoneal cavity using a drainage system embedded with electrode sensors.

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*
ADD G Peritoneal Cavity	**0** Open **4** Percutaneous Endoscopic	**ADD N** Peritoneal Fluid Volume, Drainage System with Integrated Electrode Sensors	**D** New Technology Group 13

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 08 – Transfusion of Cryopreserved Organ Donor-derived Bone Marrow

Issue: There are no unique ICD-10-PCS codes to describe the transfusion of cryopreserved organ donor-derived bone marrow. An April 1, 2027 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Not required.

Background: The conventional medical uses of hematopoietic progenitor cell (HPC) transplants are to treat blood cancers, blood disorders, and bone marrow failure by providing hematologic and immunologic reconstitution. Allogeneic hematopoietic stem cell transplant (alloHCT) remains the only potentially curative therapy for various high-risk hematologic malignancies, including acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), high-risk myelodysplastic syndrome (MDS), and aplastic anemia. However, according to the requestor, despite the readily available graft sources for alloHCT, a significant unmet need remains in the timely provision of suitable unrelated donor grafts. This shortage is related to the rarity of human leukocyte antigen (HLA) alleles in the donor pool, nonclearance of donors owing to infectious disease or general health status, and prolonged graft procurement and processing times. Other complicating factors include the rate of graft failure and acute graft versus host disease (aGVHD) and/or chronic graft versus host disease (cGVHD), pre-engraftment infections, and post-transplant relapse rates.

Per the requestor, recovery of functional bone marrow from deceased donors is conceptually similar to the procurement of organs and tissues, which is robust and well established in the United States. Organ Donor HPC, Marrow has been developed to directly address the unmet needs for patients who may benefit from potentially curative alloHCT. Extensive Organ Donor HPC, Marrow cryopreservation validation and proprietary good manufacturing practice (GMP) discipline provide a high-quality bone marrow source that eliminates the variability associated with center-specific, operator-dependent procedures that have historically plagued cryopreserved allografts. According to the requestor, with up to 3x higher doses, Organ Donor HPC, Marrow achieves robust engraftment and platelet recovery, a lower risk of relapse and cGVHD, with manageable aGVHD risk, even in the presence of significant HLA disparities (with post-transplant cyclophosphamide (PTCy) used for the prevention of GVHD). Finally, the requestor stated that cryopreserved off-the-shelf availability and rapid delivery of Organ Donor HPC, Marrow decouples transplantation from donor scheduling, transportation delays, and attrition, enabling faster, more predictable access to life-saving therapy, including in urgent situations when a living donor becomes unavailable, as well as the potential to prevent further advancement of disease. Per the requestor, cryopreserved, off-the-shelf Organ Donor HPC, Marrow will expand access to life saving alloHCT to individuals in the United States.

Technology:
According to the requestor, Organ Donor HPC, Marrow is the first-of-its-kind cryopreserved organ donor-derived and banked bone marrow alloHCT graft source, derived from the hematopoietic cell rich cancellous bone within vertebral bodies recovered from organ donors. Organ Donor HPC, Marrow changes the current paradigm by offering a high-quality, banked bone marrow graft source that can be delivered within days rather than months. All donations require opt-in consent from the donor (if possible) and from their family.

Every donor is exhaustively screened and tested to ensure the high quality and safety of Organ Donor HPC, Marrow. Donor inclusion criteria: 1) those who donated after brain death or after circulatory death, 2) male and female donors aged 7-55 years old who have authorization or authorized for organ and tissue procurement, 3) maximum warm ischemia time: 8 hours, 4) maximum cold ischemia time: 84 hours, and 5) donor undergoes eligibility screening procedures, including an evaluation of medical history and relevant social behavior, per the FDA's Guidance for Industry. After evaluation of donor demographics and uniform donor risk assessment interviews, serology testing is performed to extensively screen for infectious diseases. Product testing is then conducted to determine the count and characterization of cells.

The stepwise production process for Organ Donor HPC, Marrow: Step 1) donor screening and recovery performed at the contracted organ procurement organizations (OPOs), then Steps 2-4) proprietary good manufacturing practice (GMP) methods for tissue processing, automated cell processing, cryopreserving, and packaging bone marrow performed at the manufacturing site. Per the requestor, Organ Donor HPC, Marrow is stored in the first-of-its-kind off-the-shelf bone marrow banking platform, providing access to immediate graft availability in urgent situations. In response to donor search requests initiated by transplant centers (TC), Organ Donor HPC, Marrow is selected from banked inventory across 4/8-8/8 human leukocyte antigen (HLA)-matched grafts.

Interim data from the PRESERVE I national clinical trial (NCT05589896) and the HOPE Expanded Access Program presented at Tandem[1] 2026 demonstrate the safety and feasibility of transplanting cryopreserved organ donor-derived bone marrow, including up to 3x higher CD34+ doses, enabling swift neutrophil engraftment and rapid platelet recovery, with 70% fewer naïve T cells, reducing the risk of graft-versus-host disease (GVHD). Importantly, "on demand" availability (within 72 hours after donor search request) reduces the interval between remission and time to transplant, which is a critical factor for post-transplant outcomes, and facilitates access in urgent situations (primary or secondary graft failure, chemotherapy cycle limitations, donor fall-through, and rare HLA types, among others).

Per the requestor, clinical experience with the 25 patients treated with Organ Donor HPC, Marrow as of April 30, 2026 demonstrates robust (100%) neutrophil engraftment, with no adverse events or deaths attributed to Organ Donor HPC, Marrow. Grade 3 or higher aGVHD was reported in 4 patients (3 Grade 3; 1 Grade 4). cGVHD requiring systemic steroids was reported in 2 patients and all cases were classified as mild. Infection (CTCAE grade 3 or higher for cytomegalovirus (CMV) or BK cystitis or Epstein-Barr virus (EBV) or Adenovirus) was reported in 2 patients treated in the PRESERVE I study and was not considered related to the product; data are pending for patients treated in the HOPE expanded access program. No infusion reactions have been reported to date in patients transplanted with Organ Donor HPC, Marrow in PRESERVE I or HOPE. Enrolled patients in PRESERVE I will be followed for 36 months after infusion of Organ Donor HPC, Marrow.

Procedure Description: Organ Donor HPC, Marrow isolated from organ donors is phenotypically and functionally similar to living donor bone marrow sources. Cryopreserved, off-the-shelf Organ Donor HPC, Marrow is supplied to the transplant centers in units suitable for transplantation by infusion, the same procedure used for transplantation of other sources of HPCs, such as live donor

[1] https://www.tandemmeetings.com/

bone marrow aspirates, live donor apheresis products, or cord blood. Thus, no changes to existing HPC transplantation protocols are required to use Organ Donor HPC, Marrow in adult and pediatric populations. As with all alloHCTs, patients first receive either myeloablative conditioning (MAC) or reduced intensity conditioning (RIC). Each participating institution is to thaw and infuse Organ Donor HPC, Marrow following the instructions for use. The target cell dose of cryopreserved, off-the-shelf Organ Donor HPC, Marrow is 3 to 6x10^6 CD34+ per kilogram (kg) patient weight, with a minimum cell dose of 2.5x10^6 CD34+ per kg and maximum cell dose of 6x10^6 CD34+ per kg patient weight. Organ Donor HPC, Marrow is infused intravenously as a single dose. The standard post-transplant GVHD prophylaxis regimen includes cyclophosphamide, sodium 2-mercaptoethanesulfonate (MESNA), tacrolimus or sirolimus, and mycophenolate mofetil (MMF).

Current Coding: There are no unique ICD-10-PCS codes to describe the transfusion of cryopreserved organ donor-derived bone marrow. Facilities can report the intravenous transfusion of cryopreserved organ donor-derived bone marrow using one of the following codes:

30233G3	Transfusion of allogeneic unrelated bone marrow into peripheral vein, percutaneous approach
30243G3	Transfusion of allogeneic unrelated bone marrow into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the transfusion of cryopreserved organ donor-derived bone marrow. Continue as described in current coding.

Option 2. In section X New Technology table XW1, Transfusion, Anatomical Regions, create new substance value E Bone Marrow, Cryopreserved Organ Donor-derived, applied to the body part values 3 Peripheral Vein and 4 Central Vein and the percutaneous approach, to identify the transfusion of cryopreserved organ donor-derived bone marrow.

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 E** Bone Marrow, Cryopreserved Organ Donor-derived	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 09 – Sirolimus-Eluting Balloon Catheter for Percutaneous Coronary Intervention

Issue: There are no unique ICD-10-PCS codes to describe the use of a sirolimus-eluting balloon catheter in percutaneous coronary intervention procedures. An April 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. The SELUTION Sustained Limus Release™ (SLR™) Percutaneous Transluminal Coronary Angioplasty (PTCA) Drug-Eluting Balloon (DEB) received IDE approval for the SELUTION4 In-stent Restenosis Trial on April 11, 2024. It is intended to be used after appropriate vessel preparation in patients undergoing percutaneous coronary intervention (PCI) in coronary arteries that are 2.25 mm to 4.50 mm in diameter and lesions ≤ 26 mm in length for the purpose of improving myocardial perfusion when treating in-stent restenosis (ISR).

Background: Per the Diagnostic Catheterization and Percutaneous Coronary Intervention (CathPCI) registry of the National Cardiovascular Data Registry (NCDR), ISR represents approximately 10% of PCIs with approximately 25% of patients presenting with acute myocardial infarction. Existing treatments for coronary ISR include percutaneous coronary interventions such as repeat stenting with either a drug-eluting or bare-metal stent, repeated balloon dilation and coronary brachytherapy. Coronary artery bypass grafting is a surgical procedure for the treatment of coronary ISR, however, the majority of ISR procedures in the United States are currently treated by implantation of an additional stent. Repeated drug-eluting stent implantation has historically shown superior results for treating ISR compared with balloon dilation alone. However, use of a metallic scaffold further narrows the luminal diameter, and multiple stent layers are associated with a progressively higher risk of recurrent ISR and negative clinical outcomes. According to the requestor, the SELUTION SLR™ PTCA DEB provides superior outcomes for ISR treatment as compared to balloon dilation with a non-drug treated balloon alone, providing sustained therapeutic drug delivery without requiring the implant of a metallic stent.

Technology
The SELUTION SLR™ PTCA DEB is a semi-compliant percutaneous transluminal coronary angioplasty (PTCA) catheter composed of an expandable balloon at the distal end and a shaft with a port at the proximal end. The catheter has a rapid exchange construction where the distal end has a coaxial dual lumen design. The outer lumen is used for inflation of the balloon to conform to the vessel wall, and the inner lumen permits the use of a 0.014” guidewire to facilitate advancement of the catheter. The semi-compliant balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The SELUTION SLR™ drug coating is applied to the surface of the angioplasty balloon and consists of a proprietary formulation of the active pharmaceutical ingredient sirolimus, poly (lactic-co-glycolic acid) or PLGA, and a proprietary blend of lipid-based excipients. The balloon has two radiopaque markers that indicate the balloon's working length and aid in the positioning of the balloon relative to the stenosis. The catheter tip is tapered to facilitate advancement of the catheter to the treatment area and through the stenosis. The proximal shaft consists of a stainless steel hypotube and is marked with exit markers, and 18-21 cm of the distal shaft is coated with a hydrophilic coating for lubricity.

Procedure Description
PCI procedures involving the SELUTION SLR™ PTCA DEB begin with the physician gaining arterial access (arm or groin) using standard interventional techniques. A guide catheter is advanced through the vasculature and positioned in the coronary artery (left main or right). Under fluoroscopic guidance, a guidewire is advanced into the targeted coronary vessel, across the stenotic lesion. To prepare the lesion for treatment, a non-drug coated balloon angioplasty catheter is advanced and used to dilate the target vessel. Following lesion preparation, precise measurement of the area to be treated is calculated and a SELUTION SLR™ PTCA DEB is selected based on the lesion treatment size. The DEB is delivered to the prepared lesion and positioned using the balloon's radiopaque markers for reference. The balloon is inflated to the reference vessel diameter using the appropriate pressure. Balloon inflation is maintained for a minimum of 30 seconds and to an optimal target of one minute as tolerated. Once vessel patency is confirmed, the hemostasis valve is opened, and negative pressure is applied to the DEB to withdraw the device. To complete the procedure, the catheters and sheath are removed, the arterial access site is closed and the patient is sent to recovery.

A single SELUTION SLR™ PTCA DEB is routinely used during percutaneous coronary interventions. However, a second DEB may be used when the lesion length to be treated is greater than the DEB balloon size to ensure complete coverage of the lesion.

Current Coding: There are no unique ICD-10-PCS codes to describe the use of a sirolimus-eluting balloon catheter in PCI procedures. Facilities can report the delivery of sirolimus using a percutaneous balloon delivery system with the following code:

> 3E073GC Introduction of other therapeutic substance into coronary artery, percutaneous approach

Code the non-drug coated balloon angioplasty procedure performed to dilate the target vessel and prepare the lesion for balloon delivery of sirolimus using device value Z No Device and the appropriate body part value in table 027, Dilation of Heart and Great Vessels. Separately, code the placement of any stents using the applicable code in table 027, Dilation of Heart and Great Vessels.

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe use of a sirolimus-eluting balloon catheter in PCI procedures. Continue as described in current coding.

Option 2. In section X New Technology table XW0, Introduction, Anatomical Regions, create new technology value M Sirolimus-Eluting Balloon Technology, applied to the coronary artery body part values and the percutaneous approach, to identify use of a sirolimus-eluting balloon catheter in PCI procedures.

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*
J Coronary Artery, One Artery **K** Coronary Artery, Two Arteries **L** Coronary Artery, Three Arteries **M** Coronary Artery, Four or More Arteries	**3** Percutaneous	**ADD M** Sirolimus-Eluting Balloon Technology	**C** New Technology Group 12

Code the non-coated balloon angioplasty procedure performed to dilate the target vessel and prepare the lesion for balloon delivery of sirolimus using device value Z No Device and the appropriate body part value in table 027, Dilation of Heart and Great Vessels. Separately, code the placement of any stents using the applicable code in table 027, Dilation of Heart and Great Vessels.

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 10 – Computer-aided Assessment of Acute Abdominopelvic Pathology

Issue: There are currently no unique ICD-10-PCS codes to describe computer-aided assessment of acute abdominopelvic pathology using artificial intelligence (AI) analysis of computed tomography (CT) imaging of the abdomen/pelvis. An October 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? Yes. The a2z-Unified-Triage system was granted class II 510(k) premarket approval (K252366) by the FDA on November 3, 2025, and is indicated for use in the analysis of abdominal/pelvic CT images in adults aged 22 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive cases of the following seven specified abdominopelvic findings:

1. Acute cholecystitis;
2. Acute pancreatitis;
3. Unruptured abdominal aortic aneurysm;
4. Acute diverticulitis;
5. Free air;
6. Hydronephrosis; and
7. Small bowel obstruction.

Background: Acute abdominal and pelvic conditions represent a significant and growing clinical burden in the United States. Abdominal pain is one of the most common reasons for emergency department (ED) visits, accounting for approximately 8–10% of all adult ED presentations. Many acute abdominopelvic conditions are time-sensitive, meaning that delays in diagnosis and treatment directly impact patient outcomes. For conditions such as bowel obstruction and free air, delays of even a few hours can substantially increase mortality. Similarly, delayed identification of unruptured abdominal aortic aneurysm can result in preventable morbidity and death if progression to rupture is not identified in time.

CT scanning of the abdomen and pelvis (CT-AP) is the primary diagnostic imaging modality for evaluating these patients, with over 90 million CT scans performed annually in the United States. It is a scan that is used to assess the abdomen and pelvis for tumors and other lesions, injuries, intra-abdominal bleeding, infections, unexplained abdominal pain, obstructions, or other conditions. CT-AP uses special x-ray equipment and computers to produce images of multiple "slices" of the part of the body being scanned without or with contrast (dye) to enhance different organs. These images of the inside of the body can then be examined on a computer monitor.

The current standard of care relies on radiologists manually reviewing CT-AP studies in the order they appear in the reading worklist, typically on a first-in, first-out basis. During periods of high imaging volume — particularly overnight, on weekends, and in hospitals with limited radiology staffing — critical findings may remain unread for extended periods. This creates a potential clinical gap: time-sensitive findings may not be communicated to providers promptly enough to optimize patient outcomes. The a2z-Unified-Triage system is a radiological computer-assisted triage and notification software device that automatically analyzes CT-AP images of the

abdomen and pelvis in parallel with the standard radiologist interpretation to identify time-sensitive pathology and facilitate worklist prioritization for providers.

Technology
The a2z-Unified-Triage system is a Software as a Medical Device (SaMD) AI software platform that integrates with hospital PACS (picture archiving and communication system) infrastructure to provide automated, real-time analysis of CT-AP imaging studies. The software consists of an algorithmic component that supports both cloud-based and on-premises deployment on standard server hardware. The system uses deep learning neural network algorithms trained on an extensive and diverse dataset of abdomen/pelvis CT studies from multiple clinical sites, encompassing multiple CT scanner manufacturers (GE, Siemens, Canon, Toshiba, and others), both contrast-enhanced and non-contrast studies, and variable slice thicknesses to identify findings consistent with acute abdominopelvic pathology, completing its assessment in a mean of 58.39 seconds.

Upon detecting a suspected positive finding, studies are flagged for priority review, enabling providers to attend to the most urgent cases first rather than relying on chronological worklist order. The results from the a2z-Unified-Triage system can include digital imaging and communication in medicine (DICOM) instance unique identifiers (UIDs) for key images, which are meant for informational purposes only and are not intended for primary diagnosis beyond notification. The technology is intended as a clinical support tool to assist providers in prioritizing patients; it does not replace physician judgment or provide a final diagnosis. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The system operates as both a cloud-based and on-premises deployment on standard server hardware and integrates with existing hospital IT infrastructure via standard DICOM protocols. Integration with clinical imaging systems can be either directly with healthcare facility systems or through third-party healthcare technology platforms. No additional hardware is required beyond the existing CT scanner and PACS infrastructure.

As a software-only technology that does not involve direct patient contact, invasive procedures, or administration of therapeutic agents, the a2z-Unified-Triage system does not introduce direct procedural complications. According to the requestor, there have been no device-related adverse events reported. The primary risk associated with the technology is the potential for false positive or false negative classifications. False positive results may lead to unnecessary prioritization of non-urgent cases. False negative results may result in continued reliance on standard worklist prioritization for a study that contains a critical finding. In both cases, the radiologist's standard interpretation of the CT study remains the definitive diagnostic step; the AI assessment function supplements but does not replace the standard of care. The device does not alter the original medical image, does not remove cases from standard care reading queues, and does not de-prioritize cases.

Procedure Description
In an inpatient setting, the computer-aided assessment using the a2z-Unified-Triage system is performed as follows. First, a CT scan of the abdomen and/or pelvis is acquired using standard clinical protocols. The CT-AP study may be performed with or without intravenous contrast. Upon completion of the CT-AP acquisition, the images are automatically routed to the a2z-Unified-Triage platform via DICOM. No manual intervention is required to initiate the AI analysis. The transfer occurs in parallel with normal PACS routing and does not delay standard image

availability. The a2z-Unified-Triage algorithms then automatically analyze the CT images to identify findings consistent with acute abdominopelvic pathology. The analysis is completed with a mean turnaround time of 58.39 seconds (95% CI: 56.11–60.68 seconds), median 55.02 seconds, and 95th percentile of 90.36 seconds. The AI implements deep learning models that analyze CT studies and return binary outputs indicating the presence or absence of each of the seven target abdominopelvic findings. When a finding is detected, the algorithm identifies a key image slice most likely to show the condition.

Based on the analysis, the system classifies the study as suspected positive for one or more of the seven target findings, or negative. The device provides a JavaScript object notation (JSON) object with binary classification for each of the seven findings and DICOM instance UIDs for positive cases. Studies classified as suspected positive are flagged for priority review. For studies flagged as suspected positive, the analysis results are returned to the client system for worklist prioritization. The software provides analysis results that enable the client system to generate appropriate notifications to providers. The provider reviews the flagged study and the underlying CT images, incorporates the AI assessment into their clinical workflow, and takes appropriate action. The technology supplements but does not replace the radiologist's interpretation of the CT study. The device does not remove cases from standard care reading queues or de-prioritize cases. It operates in parallel to standard care as the default option.

Current Coding: Computer-aided assessment of acute abdominopelvic pathology using AI analysis of CT imaging of the abdomen/pelvis is not reported separately for inpatient hospital coding. If desired, facilities can report the CT scan with the applicable code in section B Imaging.

Coding Options

Option 1. Do not create a new ICD-10-PCS code to describe computer-aided assessment of acute abdominopelvic pathology using AI analysis of CT imaging of the abdomen/pelvis. Continue as described in current coding.

Option 2. In section X New Technology table XEZ, Other Procedures on Physiological Systems and Anatomical Regions, create new body part value 6 Abdomen, and Pelvis, applied to technology value K Computer-aided Triage and Notification for Imaging Abnormalities in Computed Tomography, and the external approach, to describe computer-aided assessment of acute abdominopelvic pathology using AI analysis of CT imaging of the abdomen/pelvis. If desired, facilities can continue to report the CT scan as described in current coding.

Section **X** New Technology *Body System* **E** Physiological Systems and Anatomical Regions *Operation* **Z** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Chest, Abdomen, and Pelvis	**X** External	**K** Computer-aided Triage and Notification for Imaging Abnormalities in Computed Tomography	**C** New Technology Group 12
ADD 6 Abdomen and Pelvis	**X** External	**K** Computer-aided Triage and Notification for Imaging Abnormalities in Computed Tomography	**D** New Technology Group 13

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 11 – Computer-aided Monitoring of Urine Output with Diuretic and Saline Administration

Issue: There is no unique ICD-10-PCS code to describe computer-aided monitoring of urine output with diuretic and saline administration. An October 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. The Reprieve System technology received Breakthrough Device designation and an Investigational Device Exemption (IDE) approval for the Fluid Management of Acute Decompensated Heart Failure Subjects Treated with Reprieve Decongestion Management System (DMS) (FASTR) Trial on December 3, 2021. Following completion of the FASTR Trial, the Reprieve System technology received approval of a pivotal IDE for Fluid Management of Acute Decompensated Heart Failure Subjects Treated with Reprieve System FASTR II Trial on January 27, 2025, and the trial is ongoing.

Background: Heart failure (HF) is the leading cause of hospital admissions in patients over 65 and the primary diagnosis for hospital discharges in approximately 1 million patients annually, with another 2 million patients receiving HF as a secondary diagnosis upon discharge. Current estimates suggest 6.8 million individuals are affected by HF in the United States, a number expected to rise to 8.5 million by 2030. Loop diuretics are the cornerstone of decongestive therapies for HF patients. Per the requestor, multiple previous large randomized clinical studies of new heart failure therapeutics have failed to show clinical improvements over loop diuretics, thus decongestive therapy with loop diuretics continue to be the primary treatment for acute decompensated heart failure (ADHF).

The administration of loop diuretics is typically started in the emergency department (ED) or in settings where patients are monitored by care teams including nursing staff and attending physicians. However, the requestor stated it can often take several days to find a therapeutic loop diuretic dose when there is significant diuretic resistance, and despite the fact that over 90% of ADHF patients admitted to the hospital are given a diuretic, approximately 20% of patients do not lose any weight and greater than 50% lose less than 5 lbs./2.2kg with this current therapy.

Diuretic resistance is a common complication impairing decongestion during hospitalized treatment for ADHF with IV diuretics. The literature reports up to 20% to 50% of hospitalized patients with ADHF have a poor response to IV loop diuretics, and the vast majority have some degree of reduced diuretic responsiveness. Additionally, per the requestor, diuretic dosing is inherently unique to each patient based on their individual cardio-renal physiology. Dosing at too low a rate can fail to decongest the patient while dosing at too high a rate risks exposing the patient to the adverse events that can occur from excess diuretics infusion.

It is also known that most patients admitted with ADHF have significant renal impairment, which can influence treatment protocols and outcomes. Avoiding further harm to long-term kidney function is an important consideration for both the physicians and patients. Lastly, sodium excretion is strongly associated with 6-month mortality, whereas traditional fluid-based metrics are not. Poor sodium excretion, even in the context of fluid loss, portends a worse prognosis.

According to the requestor, Reprieve Therapy overcomes these limitations by precisely dosing diuretics to efficiently remove fluid and sodium, while replenishing saline to support kidney function. Real-time physiological monitoring guides escalation or termination of therapy, enabling physicians to tailor treatment to each patient. The Reprieve System technology is designed to achieve more complete decongestion much more rapidly than standard therapy.

Technology
The Reprieve System Console consists of a roller pump for normal saline infusion, a syringe pump for IV furosemide infusion, a urine collection system and a touchscreen display, all integrated into a mobile unit. The Reprieve Therapy Console is AC-powered with a backup battery that is designed to enable patient transport and ambulation. During an infusion using the Reprieve Therapy, the rate at which saline and furosemide are infused are controlled based on the urine output from the patient.

Procedure Description
A urinary catheter and intravenous (IV) catheter are inserted into the patient and connected to the Reprieve System Console. Before initiating infusion therapy, the physician must enter an estimated excess fluid volume. This value must be updated every 24 hours. During an infusion using the Reprieve System technology, a dose finding phase is initiated which automatically ramps up diuretic infusion to find the optimum dose needed to reach a target rate of urine output. Once this phase is complete, the technology delivers a personalized continuous dose of the diuretic based on the dose identified during the dose finding phase. Additionally, the patient's urine output is measured by the Reprieve System Console and normal saline is infused to replace a portion of the patient’s sodium output. The infusion therapy using the Reprieve System concludes when the patient's urine output becomes low despite receiving the maximum continuous diuretic infusion rate and a large percentage of the estimated excess fluid remaining has been removed, or 72 hours, whichever comes first.

Current Coding: The monitoring of urine output with diuretic and saline administration is not reported separately for inpatient hospital coding. If desired, facilities can report the diuretic administration using the following code:

3E0337Z	Introduction of electrolytic and water balance substance into peripheral vein, percutaneous approach

Coding Options

Option 1. Do not create a new ICD-10-PCS code to describe computer-aided monitoring of urine output with diuretic and saline administration. Continue as described in current coding.

Option 2. In section X New Technology table XX2, Monitoring, Physiological Systems, create new technology value K Fluid Volume, Computer-Aided Urine Output with Diuretic and Saline Administration System, applied to the body part value 5 Circulatory and the percutaneous approach, to identify computer-aided monitoring of urine output with diuretic and saline administration.

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*
5 Circulatory	**3** Percutaneous	**ADD K** Fluid Volume, Computer-Aided Urine Output with Diuretic and Saline Administration System	**D** New Technology Group 13

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 12 – Insertion of Brain Computer Interface Device

Issue: There is no unique ICD-10-PCS code to describe the insertion of a brain computer interface device. An April 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. On July 23, 2020, the Neuralink N1 Implant received FDA Breakthrough Device designation for the indication to provide individuals with paralysis the ability to control computing devices (computers/smartphones) without physical movement. The Neuralink N1 Implant received an additional FDA breakthrough device designation on April 30, 2025 with the proposed indications for use that includes providing the ability to communicate to individuals with severe and irreversible speech production impairment. It is indicated for adults with neurological conditions of the central speech pathways who have impaired upper limb function.

Background: Patients with amyotrophic lateral sclerosis (ALS) and cervical spinal cord injury (SCI) can experience severe speech and physical impairments. ALS is a progressive neurological disorder that affects the upper and lower motor neuron cells of the brain and spinal cord. In 2024, ALS affected an estimated 33,859 people in the United States. ALS is most prevalent in individuals over 50 years of age. As motor neurons degenerate and die, they are unable to send messages to the muscles, causing the muscles to weaken. In patients with ALS, although the brain retains its ability to generate motor intent commands, the rest of the nervous system loses its ability to relay and control voluntary movements. Almost all individuals (80 to 95%) become unable to meet daily communication needs using natural speech, and most will become unable to speak. For most patients, there are no existing treatments that stop or reverse the progression of ALS. As such, there remains a significant unmet clinical need to improve management of the debilitating symptoms of ALS, such as loss of communication.

Approximately 311,560 people live with a SCI in the United States. SCI to the upper cervical region can result in severe and often irreversible paralysis affecting both upper and lower extremities. Paralysis of all four limbs, commonly referred to as quadriplegia or tetraplegia, severely limits an individual's ability to perform basic activities of daily living such as walking, eating, and operating digital devices (e.g., a personal smart phone or computer). Among individuals with SCI, approximately 12% are diagnosed with complete tetraplegia. For permanent paralysis due to severe SCI, there is no widely available treatment that fully restores voluntary movement and there are limited assistive technology options.

The technology is intended to provide individuals with paralysis the ability to control computing devices without physical movement. In individuals with severe and irreversible speech and physical impairment, the technology is intended to provide the ability to communicate. The BCI implant records neural activity from the brain and translates it to actions that reflect the user's intention. The information encoded in the recorded neural activity and the intended actions predicted from this neural activity depend on the cortical area of implantation. Clinical trials[1] are

[1] https://neuralink.com/trials/

underway studying the effectiveness of the BCI implant in enabling those with tetraplegia or tetraparesis to control digital devices.

Technology
The N1 Implant consists of two principal components: a skull mounted, hermetically-sealed enclosure (the BCI unit) and a polyimide thin-film array (the electrode array). The enclosure contains the battery and other electronics for signal processing and relay. The electrode array currently features 100+ highly-flexible, ultra-thin threads (similar to leads) and 1,000+ electrodes. Implantation of each thread in the electrode array into the brain is performed with the assistance of the R1 Robot, a high-precision neurosurgical platform that inserts individual electrode array threads rapidly and in a minimally invasive manner overseen by the neurosurgeon. The electrode array captures neural signals that are processed and sent wirelessly to an external device, where software interprets the signals to achieve control of software applications (e.g., computer cursor or virtual keyboard).

Procedure Description
Prior to surgery, pre-operative imaging is taken to support surgical planning and intraoperative neuronavigation. Under general anesthesia, the neurosurgeon establishes intraoperative neuronavigation. After patient positioning is finalized, the patient's head is pinned in a head fixation device and placed orthogonally to the operating table. The incision site is marked, a final sterile prep and drape is completed, sterile navigation and surgical tools are connected, and a surgical time out is performed. The neurosurgeon reconfirms registration and makes the planned incision and then marks the craniectomy site. The surgeon drills a craniectomy and performs fit checks and additional drilling until proper fit is obtained. A durectomy may be performed, hemostasis obtained, and the patient is oriented toward the surgical robot. The neurosurgeon plans placement of the intracortical electrode array leads via imaging obtained by the surgical robot, confirms targeting within the desired regions of interest, and identifies surface targets to avoid cortical vessels. The neurosurgeon monitors the electrode array implantation during robotic implantation, adjusting electrode array lead position as needed, and directing re-registration after any adjustments. The neurosurgeon places the dural substitute, if necessary, and lowers the implant into the surgical opening, securing it to the skull with cranial screws tightened in a star pattern. The site may be irrigated, antibiotic powder may be applied, and a long-acting local anesthetic may be injected into the incision edges. The scalp is closed with sutures and/or staples, a bandage is applied and the head is removed from the clamp without rotation.

Where clinically indicated, if a patient receives an additional implant, the procedure for the implantation of the additional unit will be similar to the implantation of the original unit detailed above. Clinical circumstances may also warrant removal of the complete BCI implant (electrode array and BCI unit) and implantation of a new electrode array and BCI unit.

Current Coding: There are no unique ICD-10-PCS codes to describe insertion of a brain computer interface implant. Facilities can report the procedure using the codes below.

For insertion of the electrode array component in the brain with surgical robot assistance, assign two codes:

00H00YZ	Insertion of other device into brain, open approach
8E090CZ	Robotic assisted procedure of head and neck region, open approach

For attachment of the brain computer interface unit component to the skull, assign:

0WH00YZ Insertion of other device into head, open approach

Report the applicable insertion codes more than once if additional electrodes or brain computer interface units are inserted.

For removal of the electrode array component, assign:

00P00YZ Removal of other device from brain, open approach

For removal of the brain computer interface unit component of the implant, assign:

0NP00JZ Removal of synthetic substitute from skull, open approach

Report the applicable removal codes more than once if additional electrodes or brain computer interface units are removed.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for insertion of a brain computer interface implant. Continue coding as described in current coding.

Option 2. In section X New Technology table X0H, Insertion of Nervous System, create new device value 8 Electrode Array, Single and new device value 9 Electrode Array, Multiple applied to the body part value 0 Brain and the open approach, to identify insertion of the electrode array component of the brain computer interface implant.

Section **X** New Technology *Body System* **0** Nervous System *Operation* **H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 0 Brain	**0** Open	**ADD 8** Electrode Array, Single **ADD 9** Electrode Array, Multiple	**C** New Technology Group 12

In section X New Technology table XNH, Insertion of Bones, create new device value J Brain Computer Interface Device, applied to the body part value 1 Skull and the open approach, to identify insertion of the brain computer interface unit component of the implant that is comprised of the battery and other electronics for signal processing and relay.

Section **X** New Technology *Body System* **N** Bones *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 Skull	**0** Open	**ADD J** Brain Computer Interface Device	**C** New Technology Group 12

Continue to report 8E090CZ Robotic assisted procedure of head and neck region, open approach for the robotic assistance as described in current coding.

For removal of the electrode array component, assign code 00P00YZ Removal of other device from brain, open approach as described in current coding.

For removal of the brain computer interface unit component of the implant, assign code 0NP00JZ Removal of synthetic substitute from skull, open approach as described in current coding.

Report the applicable removal codes more than once if additional electrodes or brain computer interface units are removed as described in current coding.

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 13 – Fragmentation of Carotid Arteries

Issue: There are no unique ICD-10-PCS codes to describe intravascular lithotripsy of the carotid arteries. An April 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. The Shockwave Medical SkyRunner Carotid Intravascular Lithotripsy (IVL) System received Investigational Device Exemption (IDE) approval for the SKYWARD Trans-Femoral Study on March 27, 2026, and for the SKYWARD Trans-Carotid Study on April 10, 2026. Shockwave Medical intends to submit for Premarket Approval (PMA) following submission of the IDE.

Background: Carotid arterial disease is a common form of atherosclerotic disease that impacts over 3% of people over the age of 65 and is responsible for up to 30% of all strokes. It is caused by the accumulation of plaque in the carotid arteries, which supply blood to the brain. This plaque buildup can narrow the vessel lumen, reduce cerebral blood flow, and lead to neurologic complications including changes in cognitive function, stroke, or death. Over time, plaque may harden through calcification, increasing vessel wall stiffness and fixed stenosis; studies have shown that some degree of calcification is present in 65-89% of clinically significant carotid stenosis. Risk factors for carotid arterial disease include advanced age, smoking, hypertension, diabetes, and concomitant cardiovascular disease.

Carotid revascularization can reduce morbidity and mortality in patients with carotid arterial disease. While surgical interventions have traditionally been the standard approach, percutaneous endovascular therapies are increasingly used as less invasive revascularization options and may offer faster recovery in appropriately selected patients, including elderly, frail, or comorbid individuals. These therapies include carotid artery stenting, which can be placed through either a transfemoral or transcarotid approach. However, carotid lesions are often technically challenging to treat because of anatomic complexity, plaque characteristics, and patient-specific factors such as age. In cases of severe calcification, treatment options are further limited, as calcium can prevent adequate stent expansion and increase the risk of dissection, embolization, restenosis, or recoil. As a result, patient comorbidities, advanced atherosclerosis, and lesion calcification continue to constrain the applicability and effectiveness of both surgical and endovascular treatment approaches.

IVL has become commonly used in other vascular territories (e.g., coronary and lower limb) for the treatment of calcified atherosclerotic lesions. Per the requestor, the SkyRunner IVL catheter is designed for use in the carotid arteries to fracture calcified lesions and facilitate subsequent carotid stenting, thereby expanding access to a safe and effective endovascular treatment option for patients who previously had limited or no such alternatives.

Technology
The Shockwave Medical SkyRunner Carotid IVL System is comprised of an array of five integrated lithotripsy emitters for the localized delivery of acoustic pressure pulses within a 30 mm integrated balloon. The catheter is filled with fluid and connected to a power source that energizes the lithotripsy device to generate acoustic pressure waves at the target treatment site, disrupting

calcium within the lesion and allowing subsequent dilation of a calcified carotid artery stenosis at low balloon pressures. According to the requestor, the design of the Shockwave SkyRunner Carotid IVL Catheter is based on the same technical characteristics and principles of operations for delivery as commercially available coronary and peripheral IVL catheters.

As of June 2, 2026, there have not been any adverse events reported in the SKYWARD clinical studies which have recently started enrolling patients. The SkyRunner IVL Catheter will not be used outside of clinical studies until it is commercially approved. Adverse events are expected to be similar in nature to adverse events with carotid stenting in general. The SkyRunner IVL Catheter is designed to enable treatment of calcified carotid artery lesions with a lower risk of adverse events compared to stenting without IVL.

Procedure Description
Access to the target lesion is gained either by a transfemoral or transcarotid approach. In a transfemoral approach where distal protection is used, the lesion is crossed with a 0.014" guidewire, embolic protection is deployed, and the filter wire is used as the working wire for delivery of IVL and other devices during the procedure. In a transcarotid approach, neuroprotection is placed, flow reversal is initiated, and then the lesion is crossed with a standard 0.014" guidewire. With either the transfemoral or transcarotid approach, the operator may choose to pre-dilate the lesion with a standard percutaneous transluminal angioplasty (PTA) balloon prior to delivery of the SkyRunner catheter in heavily stenosed lesions. The IVL catheter is then loaded onto the 0.014" guidewire, inserted through the sheath, and the balloon is advanced to the treatment site. The balloon is positioned at the treatment site using the marker bands to aid in positioning. Once the IVL catheter is placed across the target lesion, the IVL balloon is inflated to 2.0 atm - 4.0 atm to ensure there is full apposition to the vessel wall. Treatment cycles are performed until the operator determines that the lesion is sufficiently modified. Up to 10 treatment cycles (each cycle is 30 pulses) can be performed if deemed necessary. If the balloon is repositioned due to a lesion length greater than the IVL balloon length, the recommended balloon overlap is at least 1 cm to prevent any gaps in the treated lesion. Stent placement is performed according to the utilized stent system's instructions for use (IFU). Following either IVL therapy or stent placement, balloon post-dilatation may also be performed per physician discretion.

Per the requestor, the treatment of calcified carotid arteries requires preparation of the vessel using intravascular lithotripsy performed in conjunction with permanent stenting of the target vessel. IVL is not typically performed as a standalone procedure.

Current Coding: There are no unique ICD-10-PCS codes to describe intravascular lithotripsy of carotid arteries. Facilities can report the procedure using the following code:

03FY3ZZ Fragmentation of upper artery, percutaneous approach

Facilities should also continue to report the applicable procedure code from table 5A0 for any cerebral embolic filtration performed and the applicable procedure code from table 037 Dilation of Upper Arteries, for any PTA performed to prepare the vessel for IVL and the subsequent carotid artery stent placement. Also noting the Neuroguard IEP™ System, a 3-in-1 carotid stent and post-dilation balloon system with integrated embolic protection (IEP) (table X2A) may be used following IVL performed with the Shockwave Medical SkyRunner Carotid IVL System.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe intravascular lithotripsy of the carotid arteries. Continue as described in current coding.

Option 2. In the Medical and Surgical section table 03F, Fragmentation of Upper Arteries, add the carotid artery body part values shown for the common, internal and external carotid arteries, applied to the percutaneous approach, to identify intravascular lithotripsy of carotid arteries.

Section	**0** Medical and Surgical
Body System	**3** Upper Arteries
Operation	**F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device*	*Qualifier*
2 Innominate Artery **3** Subclavian Artery, Right **4** Subclavian Artery, Left **5** Axillary Artery, Right **6** Axillary Artery, Left **7** Brachial Artery, Right **8** Brachial Artery, Left **9** Ulnar Artery, Right **A** Ulnar Artery, Left **B** Radial Artery, Right **C** Radial Artery, Left **G** Intracranial Artery **Y** Upper Artery	**3** Percutaneous	**Z** No Device	**0** Ultrasonic **Z** No Qualifier
ADD H Common Carotid Artery, Right **ADD J** Common Carotid Artery, Left **ADD K** Internal Carotid Artery, Right **ADD L** Internal Carotid Artery, Left **ADD M** External Carotid Artery, Right **ADD N** External Carotid Artery, Left	**3** Percutaneous	**Z** No Device	**Z** No Qualifier

Facilities should also continue to report the applicable procedure code from table 5A0 for any cerebral embolic filtration performed and the applicable procedure codes from table 037 Dilation of Upper Arteries, for any PTA performed to prepare the vessel for IVL and the subsequent carotid artery stent placement. Also noting the Neuroguard IEP™ System, a 3-in-1 carotid stent and post-dilation balloon system with integrated embolic protection (IEP) (table X2A) may be used following IVL performed with the Shockwave Medical SkyRunner Carotid IVL System.

Option 3. In section X New Technology table X2F, Fragmentation of Cardiovascular System, create new technology value Q Intravascular Lithotripsy, applied to the body part values shown for the common, internal and external carotid arteries, and the percutaneous approach, to identify intravascular lithotripsy of carotid arteries.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 6 Common Carotid Artery, Right **ADD 7** Common Carotid Artery, Left **ADD 8** Internal Carotid Artery, Right **ADD 9** Internal Carotid Artery, Left **ADD A** External Carotid Artery, Right **ADD B** External Carotid Artery, Left	**3** Percutaneous	**ADD Q** Intravascular Lithotripsy	**C** New Technology Group 12

Facilities should also continue to report the applicable procedure code from table 5A0 for any cerebral embolic filtration performed and the applicable procedure codes from table 037 Dilation of Upper Arteries, for any PTA performed to prepare the vessel for IVL and the subsequent carotid artery stent placement. Also noting the Neuroguard IEP™ System, a 3-in-1 carotid stent and post-dilation balloon system with integrated embolic protection (IEP) (table X2A) may be used following IVL performed with the Shockwave Medical SkyRunner Carotid IVL System.

CMS Recommendation: Option 3, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 14 – Computer-aided Detection and Notification of Whole-Body Positioning Status using Wireless Sensor

Issue: There are currently no unique ICD-10-PCS codes to describe computer-aided detection and notification of whole-body positioning status using a wireless sensor. An April 1, 2027 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The LEAF Patient Monitoring System was granted 510(k) premarket approval (K141877) by the FDA on October 14, 2014.

Background: While pressure injuries (PIs) stem from multifaceted causes, they require mechanical loading on tissue. Prolonged pressure from sustained lying or sitting causes tissue deformation and damage. Repositioning and mobilization are key prevention strategies. Hospital-acquired pressure injuries (HAPIs) are common, with over 50 percent being stage two or higher.[1] PIs diminish patients' quality of life, causing pain, odor, and loss of mobility, with elderly patients facing a 3.6-fold increase in mortality within 21 months.[2] Proper turning reduces PI risk, but adherence is low due to competing priorities and manual tracking delays.[3,4,5,6,7,8]

Traditional prevention of PIs relies on scheduled turning, skin assessment, moisture management, nutrition, support surfaces, and documentation. In the Hospital Inpatient Quality Reporting Program, Hospital Harm-Pressure Injury is one of seven electronic clinical quality measures (eCQMs) that have been adopted that are aimed at addressing different types of and various aspects of preventable hospital harms.[9] As hospitals must report on this eCQM, timely and appropriate patient turning are integral to success in preventing these injuries. According to the requestor, the LEAF Patient Monitoring System enhances workflows with real-time patient monitoring, helping clinicians prioritize care, identify missed or overdue turns, and ensure protocol compliance. Per the requestor, LEAF Patient Monitoring Systems help maintain 95 percent turn protocol adherence over six months without hiring additional staff to turn patients.

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[1] Li Z, Lin F, Thalib L, Chaboyer W. Global prevalence and incidence of pressure injuries in hospitalised adult patients: A systematic review and meta-analysis.Int J Nurs Stud. 2020;105:103546. doi:10.1016/j.ijnurstu.2020.103546
[2] Song et al. IntWound J. 2019;16(6):1533-44.
[3] Winkelman, C., & Ling-Chun, C. (2010). Manual Turning in Patients Receiving Mechanical Ventilation. Critical Care Nurse, 30(4), 36–44.
[4] Schallom L, Metheny NA, Stewart J, et al. Effect of frequency of manual turning on pneumonia. Am J Crit Care. 2005;14(6):476-478.
[5] Schutt SC, Tarver C, Pezzani M. Pilot study: Assessing the effect of continual position monitoring technology on compliance with patient turning protocols. Nurs Open. 2018;5(1):21-28.
[6] Pickham D, Berte N, Pihulic M, et al. Effect of a wearable patient sensor on care delivery for preventing pressure injuries in acutely ill adults: A pragmatic randomized clinical trial (LS-HAPI study). Int J Nurs Stud. 2018;80:12-19.
[7] Yap, T. L., Kennerly, S. M., & Ly, K. (2019). Pressure injury prevention: outcomes and challenges to use of resident monitoring technology in a nursing home. Journal of Wound, Ostomy, and Continence Nursing, 46(3), 207–213.
[8] Voz, A., Williams, C., & Wilson, M. (2011). Who is turning the patients?: A survey study. Journal of Wound Ostomy Continence Nursing, 38(4), 413–418.
[9] https://ecqi.healthit.gov/mcw/ecqm/hospital-harm-%E2%80%93-pressure-injury

Technology
The LEAF Patient Monitoring System is a medical device designed to continuously monitor the orientation and activity of patients susceptible to pressure ulcers. It allows healthcare providers to implement individualized turn management plans and easily identify patients that are in need of caregiver-assisted turns according to the institution's guidelines or protocols. The LEAF Patient Monitoring System provides visual and electronic medical record (EMR) notifications when patient orientation or activity deviates from parameters set by healthcare providers. The components of the LEAF Patient Monitoring System include wearable patient sensor, wireless mesh network (antennae and cellular bridge), and a user interface.

The LEAF Patient sensor is a single-use, disposable, wireless device that is adhesively affixed to the skin on a patient's chest to enable repositioning. The sensor itself is comprised of several key components: a tri-axel accelerometer to measure patient orientation and activity; a photo transistor that measures ambient light levels and turns on the device when the packaging is removed; a capacitive sensor that enables the device to sense when it is attached to skin and sense when it is removed from skin; light emitting diode (LED) indicators to visually communicate information to staff; a micro controller for automated data collection, analysis, and storage; a radio frequency (RF) radio for transmitting and receiving messages; and a coin-cell battery for providing electrical power. The three-axis accelerometer of the sensor is a semiconductor sensitive to acceleration and gravity and detects the direction of gravitational pull to determine the patient's position. The component that contacts the patient's skin is a polyurethane dressing with a silicone adhesive. The sensor will light up to indicate the proper orientation of the device with respect to the patient once the liner is removed and the circuit detects ambient light. Generally, one wearable sensor per patient is used for their length of stay. The LEAF sensor will show an indication to replace the battery. The battery life of one sensor is up to 21 days.

The LEAF repositioning algorithm is built directly into the sensor and is grounded in studies showing that it takes about 15 minutes for compressed tissue to fully reperfuse. The algorithm incorporates the 15-minute reperfusion window into how it tracks and credits offload time. It is designed to ensure that tissue has sufficient time to reperfuse based on how long it has already been offloaded.

The LEAF monitoring system is installed in each inpatient unit utilizing wireless mesh network (WMN) technology. Upon activation, a LEAF Patient sensor automatically attempts to join the LEAF WMN by communicating with the nearest LEAF Relay Antenna with the strongest RF signal. The sensor can wirelessly connect from distances of 75 feet or more to an available LEAF Relay Antenna. This enables patients to wear their LEAF sensor when transferred to a different unit that also employs the LEAF monitoring system. The system uses a proprietary wireless local area network (WLAN) to transmit messages between LEAF Patient sensors and LEAF Bridges. Healthcare providers can easily view patient turning information through the LEAF user interface, which displays current turning status along with a digital timer and a color-coded indicator.

According to the requestor, there have been no adverse events associated with the Leaf Patient Monitoring System. The LEAF Patient sensor can be removed by peeling off the adhesive if a patient experiences skin sensitivity. All patients should be evaluated for silicone sensitivity prior to attachment of a LEAF Patient sensor.

Procedure Description
In an inpatient setting, there are four procedural steps:

(1) Apply the LEAF Patient Sensor: The wearable sensor is removed from packaging, and the adhesive backing is peeled off. The sensor is activated when the adhesive backing is removed and the sensor is exposed to light. The sensor is placed anywhere on the upper anterior torso below the clavicles on the sternum or as close to midline as possible on a flat area with intact, clean, and dry skin, and quality contact is ensured. The same sensor can be reapplied if the sensor is removed so that the patient can undergo a procedure or a scan.

(2) Register the patient: On the LEAF desktop application, the patient is matched with the sensor by using the patient's medical number and the sensor serial number. Other adjustments, such as turn period, restricting a side, and adding documentation if there is already a pressure injury, can be made here.

(3) Interpret the display screen: The user interface displays the current turning status, specific position details, and relevant messages. Room and bed numbers are populated on the screen. The digital timer counts down to the next turn. There is also a color-coded turning status for each patient. If any patients are overdue, the digital clock begins counting up to help with prioritization. The position column also shows if a patient is ambulating. The system will alert staff whenever the patient turns to a restricted side. Turning status and turn quality can be ascertained additionally at patient bedside by tapping the sensor. Turn alerts can be paused for patients who cannot be turned temporarily, so the system will continue to monitor but will not alert. The user interface includes a turn score which calculates the unit's two hour running average term protocol adherence. The turn score updates in real time and is represented as a percentage. The LEAF Patient Monitoring System generates reports, including daily and monthly reports, that provide actionable insights based on unit and facility repositioning trends.

(4) Turn the patient: Staff will turn the patient based on the facility's turn protocol. Once the turn is complete, staff can tap the sensor to ensure the turn is sufficient (sensor will blink green light to depict a quality turn).

Current Coding: Computer-aided detection and notification of whole-body positioning status using a wireless sensor is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for computer-aided detection and notification of whole-body positioning status using a wireless sensor. Continue as described in current coding.

Option 2. In section X New Technology table XX2, Monitoring of Physiological Systems, create new technology value M Computer-aided Detection and Notification of Positioning Status using Wireless Sensor, applied to the body part value K Whole Body and the external approach, to identify computer-aided detection and notification of whole-body positioning status using a wireless sensor.

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*
ADD K Whole Body	**X** External	**ADD M** Computer-aided Detection and Notification of Positioning Status using Wireless Sensor	**C** New Technology Group 12

CMS Recommendation: Option 1, as described above.

Rationale: CMS notes that standard routine bed repositioning or turning of patients is a general nursing care activity and is not separately reported using ICD-10-PCS procedure codes. As a result, computer-aided detection and notification of whole-body positioning status using a wireless sensor is not currently reported separately for inpatient hospital coding.

Interim Coding Advice: Continue as described in current coding.

Topic # 15 – Bypass using Endovascular Transvenous Cerebrospinal Fluid Shunt

Issue: There are currently no unique ICD-10-PCS codes to describe bypass using an endovascular transvenous cerebrospinal fluid (CSF) shunt. An October 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. The CereVasc® eShunt® implant received Breakthrough Device designation for adult normal-pressure hydrocephalus in August 2024, as well as for pediatric hydrocephalus in April 2025. The requestor anticipates Premarket Approval (PMA) CereVasc® eShunt® implant in 2028.

Background: Hydrocephalus is a neurological condition caused by an excessive accumulation of CSF within the brain's ventricles. This excess fluid can increase intracranial pressure, resulting in symptoms such as persistent headaches, vision problems, and cognitive impairments. Communicating hydrocephalus (CH), one prevalent form of the disease, often arises from impaired CSF absorption rather than obstruction. Communicating hydrocephalus occurs when CSF remains able to circulate between the ventricular system and subarachnoid spaces, but impaired CSF absorption or obstruction outside the ventricular system results in progressive ventricular enlargement and increased intracranial pressure, potentially causing neurologic injury. CH can develop from trauma, perimesencephalic subarachnoid hemorrhage, or idiopathic conditions, including normal pressure hydrocephalus (NPH), which affects primarily older adults. For the communicating hydrocephalus patient population, the current standard treatment for hydrocephalus is the placement of a ventriculoperitoneal (VP) shunt. This is accomplished by diverting excess CSF from the brain to the peritoneal cavity. To place the shunt a cranial incision is made, and a burr hole is created in the skull. A ventricular catheter is inserted into the lateral ventricle under anatomic guidance and connected to a valve mechanism designed to regulate cerebrospinal fluid drainage. The exiting distal catheter is then tunneled subcutaneously from the scalp, down the neck and chest, into the peritoneal cavity through a separate abdominal incision. The distal catheter is positioned intraperitoneally to allow absorption of cerebrospinal fluid within the abdomen. The system is secured, irrigated, and tested for patency prior to wound closure. According to the requestor, while effective, VP shunts have high complication rates, including infection, obstruction, and over-drainage, leading to a significant proportion of patients requiring revision surgeries within two years of initial implantation. These complications create substantial physical and psychological burdens on patients. The transvenous endovascular procedure that utilizes the eShunt® System to treat CH is a minimally invasive, endovenous alternative to the traditional transdural shunt placement and the additional tunneled drainage catheter. Per the requestor, the eShunt® System has the potential to expand the use of CSF shunts in patients with co-morbidities in whom invasive surgery is currently contra-indicated.

Technology
The eShunt® System redirects cerebrospinal fluid from the subarachnoid space directly into the venous system. The system is comprised of an implantable CSF shunt and a delivery catheter that is designed to avoid the need for invasive surgery, including general anesthesia, extended hospitalization, and postoperative pain management. When the delivery catheter (which contains a distal needle and houses the diversion or shunting implant device) is positioned within the inferior

petrosal sinus, the delivery catheter is advanced through the dura mater and arachnoid mater into the subarachnoid space. The delivery catheter (needle) is used to pierce the dural layers, followed by deployment of the implant device which regulates and allows for CSF flow based on physiological pressure differentials.

Procedure Description
Under sterile conditions, establish percutaneous, femoral venous access with a standard introducer sheath inserted using the Seldinger technique. Perform diagnostic angiographic evaluation to define the venous anatomy and confirm suitability for treatment (including catheter-based venography/angiography of the relevant venous structures, supplemented by 3D rotational angiography). Following the diagnostic portion, under fluoroscopic guidance insert a 0.035" guide wire, 7F guide catheter, and shuttle sheath(s) into the femoral vein. Track the guide catheter through the venous vasculature into the internal jugular vein (IJV) with the assistance of the guide wire. Exchange the 0.035" guide wire for a 0.014" microwire and a 0.017" microcatheter coupled with the Delivery Catheter. Advance the micro wire and microcatheter into distal or cavernous sinus, distal to the target implantation site in the inferior petrosal sinus. Aim the eShunt® Delivery Catheter through venous vasculature to the target implantation site within the inferior petrosal sinus (IPS). Using image guidance, confirm needle positioning, orientation, and penetration trajectory by visualizing the Needle Spine radiopaque marker located on the needle on the Delivery Catheter. Retract needle guard completely to expose needle. Advance the Delivery Catheter distally to penetrate dura and arachnoid tissues to access the cerebellopontine angle cistern. Confirm cerebellopontine angle cistern access with image guidance. Advance the eShunt® Implant through the needle via Shroud with the Pusher Wire until the implant's Malecot expands within the subarachnoid space.

Current Coding: There are no unique ICD-10-PCS codes to describe bypass from the subarachnoid space to the inferior petrosal sinus (to redirect fluid from the inferior petrosal sinus to the internal jugular vein) using an endovascular transvenous CSF shunt. Facilities can report the procedure using the following codes:

To capture the drainage tip of the shunt deployed in the subarachnoid space:

009530Z	Drainage of intracranial subarachnoid space with drainage device, percutaneous approach

For the intraluminal portion of the shunt that functions to redirect the cerebrospinal fluid from the inferior petrosal sinus to the internal jugular vein, assign one of the following codes:

05HM3DZ	Insertion of intraluminal device into right internal jugular vein, percutaneous approach
05HN3DZ	Insertion of intraluminal device into left internal jugular vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe bypass using an endovascular transvenous CSF shunt. Continue as described in current coding.

Option 2. In section X New Technology, create new table X0K, Bypass of Nervous System, with new device value 6 Intraluminal Device to Inferior Petrosal Sinus, applied to the body part value 5

Subarachnoid Space, Intracranial and the percutaneous approach, to identify bypass using endovascular transvenous CSF shunt.

Section **X** New Technology *Body System* **0** Nervous System *Operation* **ADD** **K** Bypass: Altering the route of passage of the contents of a tubular body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 5 Subarachnoid Space, Intracranial	**3** Percutaneous	**ADD 6** Intraluminal Device to Inferior Petrosal Sinus	**D** New Technology Group 13

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 16 - Section X Updates
Fall 2026 ICD-10 Coordination and Maintenance Committee Update

For this Fall 2026 code update, we are sharing our analysis results for the Group 8 section X Codes, using frequency data and new technology add-on payment (NTAP) status from FYs 2023, 2024, and 2025. For the Spring 2027 code update, we will share an updated analysis to include the results for the Group 8 section X codes for FY 2026, along with the CMS recommendation.

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

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

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

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

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1) CASGEVY™ (exagamglogene autotemcel) is an FDA approved one-time autologous genome edited hematopoietic stem cell-based gene therapy indicated for the treatment of sickle cell disease (SCD) in patients 12 years and older with recurrent vaso-occlusive crises (VOCs). It is also indicated for the treatment of transfusion-dependent β-thalassemia (TDT) in patients 12 years of age or older.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XW133J8	Transfusion of exagamglogene autotemcel into peripheral vein, percutaneous approach, new technology group 8	0	NO	0	NO	0	YES (Sickle Cell Indication)		YES (Sickle Cell Indication)	0
XW143J8	Transfusion of exagamglogene autotemcel into central vein, percutaneous approach, new technology group 8	0	NO	0	NO	0	YES (Sickle Cell Indication)		YES (Sickle Cell Indication)	0

2) Darzalex Faspro®, an FDA approved antineoplastic monoclonal antibody therapy, is a combination of daratumumab, a CD38-directed cytolytic antibody, and hyaluronidase, an endoglycosidase, for the treatment of adult patients with multiple myeloma.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XW01318	Introduction of daratumumab and hyaluronidase-fihj into subcutaneous tissue, percutaneous approach, new technology group 8	148	YES	104	NO	135	NO		NO	387

3) DefenCath™ is an FDA approved combination of taurolidine, a thiadiazinane antimicrobial, and heparin, an anti-coagulant, indicated to reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC).

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XY0YX28	Extracorporeal introduction of taurolidine anti-infective and heparin anticoagulant, new technology group 8	10	YES (conditional)	11	YES (conditional)/ NTAP Effective January 1, 2024	173	YES		YES	194

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4) GRAFAPEX™ (treosulfan) is an FDA approved alkylating drug indicated for: 1) use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) in adult and pediatric patients 1 year of age and older with acute myeloid leukemia (AML) and 2) use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients 1 year of age and older with myelodysplastic syndrome (MDS).

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XW03388	Introduction of treosulfan into peripheral vein, percutaneous approach, new technology group 8	1	NO	0	NO	6	NO		YES	7
XW04388	Introduction of treosulfan into central vein, percutaneous approach, new technology group 8	1	NO	0	NO	0	NO		YES	1

5) HistoSonics System, an FDA cleared focused ultrasound system for non-thermal, mechanical tissue ablation, is indicated for the non-invasive destruction of liver tumors, including unresectable liver tumors. The ICD-10-PCS code request was not related to an NTAP application.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XF50X08	Destruction of liver using ultrasound-guided cavitation, external approach, new technology group 8	5	NO	10	NO	16	NO		NO	31
XF51X08	Destruction of right lobe liver using ultrasound-guided cavitation, external approach, new technology group 8	1	NO	1	NO	12	NO		NO	14
XF52X08	Destruction of left lobe liver using ultrasound-guided cavitation, external approach, new technology group 8	2	NO	5	NO	7	NO		NO	14

6) iFuse Bedrock™ Granite Implant System is an FDA approved device intended for sacroiliac joint fusion in skeletally mature patients for the following conditions: 1) sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis; 2) to augment immobilization and stabilization of the sacroiliac joint in patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion; and 3) acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

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ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XNH6058	Insertion of internal fixation device with tulip connector into right pelvic bone, open approach, new technology group 8	75	YES	176	YES	305	YES		NO	556
XNH6358	Insertion of internal fixation device with tulip connector into right pelvic bone, percutaneous approach, new technology group 8	5	YES	6	YES	12	YES		NO	23
XNH7058	Insertion of internal fixation device with tulip connector into left pelvic bone, open approach, new technology group 8	74	YES	174	YES	296	YES		NO	544
XNH7358	Insertion of internal fixation device with tulip connector into left pelvic bone, percutaneous approach, new technology group 8	5	YES	6	YES	11	YES		NO	22
XRGE058	Fusion of right sacroiliac joint using internal fixation device with tulip connector, open approach, new technology group 8	578	YES	958	YES	1478	YES		NO	3,014
XRGE358	Fusion of right sacroiliac joint using internal fixation device with tulip connector, percutaneous approach, new technology group 8	0	YES	51	YES	87	YES		NO	138
XRGF058	Fusion of left sacroiliac joint using internal fixation device with tulip connector, open approach, new technology group 8	575	YES	954	YES	1492	YES		NO	3,021
XRGF358	Fusion of left sacroiliac joint using internal fixation device with tulip connector, percutaneous approach, new technology group 8	0	YES	49	YES	77	YES		NO	126

7) Ischemic Stroke System (ISS500) is an investigational sphenopalatine ganglion stimulator proposed to be indicated to increase cerebral blood flow and reduce disability in adult patients with acute ischemic stroke with confirmed cortical involvement in the anterior circulation who are ineligible or have no access to intravenous tissue plasminogen activator (IV-tPA) and endovascular thrombectomy. Treatment is to be initiated between 8 and 24 hours from stroke onset. The FDA's Neurological Devices Advisory Committee voted against approving the ISS500 on December 10, 2021.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
X0HK3Q8	Insertion of neurostimulator lead into sphenopalatine ganglion, percutaneous approach, new technology group 8	2	NO	1	NO	2	NO		NO	5

8) LENMELDY™ (atidarsagene autotemcel) is an FDA approved autologous hematopoietic stem cell-based gene therapy indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). The ICD-10-PCS code request was not related to an NTAP application.

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ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW133G8	Transfusion of atidarsagene autotemcel into peripheral vein, percutaneous approach, new technology group 8[1]	0	NO	0	NO	0	NO		NO	0
XW143G8	Transfusion of atidarsagene autotemcel into central vein, percutaneous approach, new technology group 8[1]	0	NO	0	NO	0	NO		NO	0

9) LigaPASS 2.0™ PJK Prevention System is a FDA-cleared device specifically indicated for ligament augmentation in spine surgery to prevent proximal junctional kyphosis (PJK). The system uses polyester bands to support spinal ligaments.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XKUC068	Supplement upper spine bursa and ligament with posterior vertebral tether, open approach, new technology group 8	51	NO	77	NO	86	NO		NO	214
XKUD068	Supplement lower spine bursa and ligament with posterior vertebral tether, open approach, new technology group 8	24	NO	27	NO	26	NO		NO	77

10) LIVTENCITY™ (maribavir) is an FDA approved cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW0DX38	Introduction of maribavir anti-infective into mouth and pharynx, external approach, new technology group 8	93	YES	166	YES	88	NO		NO	347
XW0G738	Introduction of maribavir anti-infective into upper GI, via natural or artificial opening, new technology group 8	4	YES	3	YES	1	NO		NO	8
XW0H738	Introduction of maribavir anti-infective into lower GI, via natural or artificial opening, new technology group 8	0	YES	1	YES	0	NO		NO	1

[1] *Description revised effective April 1, 2025 - FY 2025*

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11) Lunsumio™ (mosunetuzumab) is an FDA-approved prescription, immunotherapy (bispecific CD20-directed CD3 T-cell engager) used to treat adults with relapsed or refractory follicular lymphoma who have received at least two prior systemic therapies.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW03358	Introduction of mosunetuzumab antineoplastic into peripheral vein, percutaneous approach, new technology group 8	13	NO	9	YES	16	YES		NO	38
XW04358	Introduction of mosunetuzumab antineoplastic into central vein, percutaneous approach, new technology group 8	10	NO	9	YES	16	YES		NO	35

12) Nelli® Seizure Monitoring System is a non-contact, artificial intelligence driven video and audio system for identifying and reviewing seizure events. The requestor submitted an NTAP application for FY 2027 consideration.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XXE0X48	Measurement of brain electrical activity, computer-aided semiologic analysis, new technology group 8	8	NO	2	NO	6	NO		NO	16

13) NUsurface® Meniscus Implant is an investigational device proposed to be indicated for: 1) mild or greater symptomatic medial compartment knee pain caused by a dysfunctional medial meniscus either related to a previous medial meniscus surgery and/or a clinically significant medial meniscal tear, as determined by patient history, diagnostic imaging, and/or validated knee pain measurement tool and 2) revision of symptomatic previous medial meniscus surgery, including an exchange of a previously implanted NUsurface device. It was evaluated in the SUN Clinical Trial, a multi-center, single-arm, prospective, open label, non-randomized, observational clinical trial to gather safety and probable clinical benefit data on the NUsurface® Meniscus Implant (NCT02483988). The study ended in December 2023.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XRRG0L8	Replacement of right knee joint with synthetic substitute, lateral meniscus, open approach, new technology group 8	2	NO	0	NO	1	NO		NO	3
XRRG0M8	Replacement of right knee joint with synthetic substitute, medial meniscus, open approach, new technology group 8	2	NO	0	NO	0	NO		NO	2
XRRH0L8	Replacement of left knee joint with synthetic substitute, lateral meniscus, open approach, new technology group 8	0	NO	1	NO	2	NO		NO	3

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ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XRRH0M8	Replacement of left knee joint with synthetic substitute, medial meniscus, open approach, new technology group 8	0	NO	2	NO	1	NO		NO	3

14) Omisirge® (omidubicel) is an FDA approved nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for the treatment of: 1) adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infections; and 2) adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW133C8	Transfusion of omidubicel into peripheral vein, percutaneous approach, new technology group 8	0	NO	0	NO	0	NO		NO	0
XW143C8	Transfusion of omidubicel into central vein, percutaneous approach, new technology group 8	1	NO	0	NO	0	NO		NO	1

15) PiCSO® (Pressured-controlled Intermittent Coronary Sinus Occlusion) Impulse System is an investigational catheter-based device used during percutaneous coronary intervention (PCI) to treat severe heart attacks (i.e. ST-segment elevation myocardial infarctions (STEMI)). It intermittently occludes the coronary sinus to increase cardiac venous pressure, improving microvascular perfusion, reducing heart muscle infarct size, and improving recovery. The device is being evaluated in a randomized controlled study to evaluate the safety and efficacy of PiCSO in anterior STEMI patients with TIMI 0-2 at presentation (NCT05497011).

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
X2A7358	Intermittent coronary sinus occlusion, percutaneous approach, new technology group 8	0	NO	3	NO	1	NO		NO	4

16) Precision TAVI™ Coronary Obstruction Module is simulation software that enables the visualization of transcatheter aortic valve placement and deployment for preoperative planning, coronary obstruction risk biomarker, and implant valve sizing for transcatheter aortic valve replacement (TAVR) procedures.

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ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XXE3X68	Measurement of coronary artery flow, computer-aided valve modeling and notification, new technology group 8	24	NO	0	NO	44	NO		NO	68

17) QAngio XA® 3D is an FDA cleared analytical software that enables accurate anatomical quantifications of one or more lesions in the analyzed coronary vessel segment, to determine the functional significance of the lesions, and to assess the best viewing angles, which can be helpful for optimal visualization of lesions during percutaneous coronary intervention (PCI) treatment. QAngio XA® 3D is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the assessment of coronary vessels in X-ray angiographic images, for use on individual patients with coronary artery disease. The ICD-10-PCS code request was not related to an NTAP application.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XXE3X58	Measurement of coronary artery flow, quantitative flow ratio analysis, new technology group 8	46	NO	42	NO	50	NO		NO	138

18) REBYOTA® (fecal microbiota, live-jslm) is an FDA-approved, single-dose, rectally administered liquid suspension designed to prevent the recurrence of *Clostridioides difficile* infection (CDI) in adults 18 and older following antibiotic treatment. The ICD-10-PCS code request was not related to an NTAP application.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW0H7X8	Introduction of broad consortium microbiota-based live biotherapeutic suspension into lower GI, via natural or artificial opening, new technology group 8	207	NO	173	YES	82	YES		NO	462

19) RETHYMIC® (allogeneic processed thymus tissue-agdc) is an FDA-approved, one-time regenerative therapy designed to treat pediatric patients with congenital athymia, a fatal condition where children are born without a thymus. It works by implanting processed donor-derived, thymus tissue to enable T-cell development.

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ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW020D8	Introduction of engineered allogeneic thymus tissue into muscle, open approach, new technology group 8	1	NO	0	NO	1	NO		NO	2

20) Sabizabulin is an investigational oral microtubule disruptor that has dual antiviral and anti-inflammatory activities in preclinical models. It was studied extensively for COVID-19 and is now being evaluated in the treatment of castration-resistant prostate cancer.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW0DXK8	Introduction of sabizabulin into mouth and pharynx, external approach, new technology group 8	0	NO	2	NO	0	NO		NO	2
XW0G7K8	Introduction of sabizabulin into upper GI, via natural or artificial opening, new technology group 8	0	NO	0	NO	0	NO		NO	0
XW0H7K8	Introduction of sabizabulin into lower GI, via natural or artificial opening, new technology group 8	0	NO	0	NO	0	NO		NO	0

21) SAINT Neuromodulation System/ Magnus Neuromodulation System (MNS) with SAINT technology is an FDA approved non-invasive repetitive transcranial magnetic stimulation (rTMS) system that delivers individualized and navigationally directed repetitive magnetic pulses to the left dorsolateral prefrontal cortex (LDLPFC). It is indicated for the treatment of major depressive disorder (MDD) in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
X0Z0X18	Computer-assisted transcranial magnetic stimulation of prefrontal cortex, new technology group 8	1	NO	9	YES	0	YES		YES	10

22) SeptiCyte® RAPID is an FDA cleared gene expression assay that uses a reverse transcription polymerase chain reaction to quantify the relative expression levels of host response genes isolated from whole blood collected in the PAXgene Blood RNA Tube. The SeptiCyte RAPID test is used in conjunction with clinical assessments and other laboratory findings as an aid to differentiate infection-positive (sepsis) from infection-negative systemic inflammation in patients suspected of sepsis on their first day of intensive care unit (ICU) admission. New technology add-on payments for SeptiCyte® RAPID were not approved for FY 2024 (88 FR 58868 through 58879).

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ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XXE5X38	Measurement of infection, whole blood reverse transcription and quantitative real-time polymerase chain reaction, new technology group 8	1	NO	359	NO	528	NO		NO	888

23) Spevigo® (spesolimab) is an FDA approved humanized IgG1 antibody that acts as an interleukin-36 receptor (IL-36R) antagonist to treat generalized pustular psoriasis (GPP) flares in adults.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XW03308	Introduction of spesolimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 8	1	NO	1	YES	4	YES		NO	6
XW04308	Introduction of spesolimab monoclonal antibody into central vein, percutaneous approach, new technology group 8	1	NO	0	YES	0	YES		NO	1

24) Tabelecleucel (tab-cel) is an investigational allogeneic, off-the-shelf, T-cell immunotherapy. The immunotherapy is being evaluated in the ALLELE trial (NCT03394365), a multicenter, open-label, phase 3 study to assess the efficacy and safety of tabelecleucel for the treatment of Epstein-Barr virus (EBV)–positive post-transplant lymphoproliferative disease (EBV+ PTLD) in the setting of (1) solid organ transplant (SOT) after failure of rituximab (SOT-R) and rituximab plus chemotherapy (SOT-R+C) or (2) allogeneic hematopoietic cell transplant (HCT) after failure of rituximab. Tabelecleucel is also being evaluated in a phase 2 multicohort label-expansion study (NCT04554914) across patients with multiple EBV-associated diseases.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XW03378	Introduction of tabelecleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 8	0	NO	0	NO	0	NO		NO	0
XW04378	Introduction of tabelecleucel immunotherapy into central vein, percutaneous approach, new technology group 8	0	NO	0	NO	0	NO		NO	0

25) Tecelra® (afamitresgene autoleucel) is an FDA approved melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy, for adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen.

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ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XW03368	Introduction of afamitresgene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 8	0	NO	0	NO	0	NO		YES	0
XW04368	Introduction of afamitresgene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 8	0	NO	0	NO	1	NO		YES	1

26) TECVAYLI™ (teclistamab) is an FDA approved human bispecific monoclonal antibody (BsAb) with antineoplastic activity. It acts as a BCMA-directed CD3 T-cell engager, binding to both BCMA on multiple myeloma cells and CD3 on T-cells to induce a cytotoxic immune response. TECVAYLI™ is approved for adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XW01348	Introduction of teclistamab antineoplastic into subcutaneous tissue, percutaneous approach, new technology group 8	649	NO	849	YES	793	YES		NO	2,291

27) Premia Spine TOPS™ System is an FDA-approved, posterior lumbar implant designed as an alternative to spinal fusion for treating lumbar spinal stenosis, spondylolisthesis, and facet arthrosis. It stabilizes the spine, maintains motion in all directions (flexion, extension, rotation, bending), and is implanted at levels L2-L5 following decompression.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		Total Freq
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	
XRHB018	Insertion of posterior spinal motion preservation device into lumbar vertebral joint, open approach, new technology group 8	7	NO	96	YES	228	YES		YES	331
XRHD018	Insertion of posterior spinal motion preservation device into lumbosacral joint, open approach, new technology group 8	1	NO	4	YES	5	YES		NO	10

28) UPLIZNA® (inebilizumab-cdon) is an FDA-approved, a humanized IgG1 monoclonal antibody (mAb). It acts as a CD19-directed cytolytic antibody that binds to the CD19 antigen on B cells, causing their depletion to treat autoimmune diseases, specifically anti-aquaporin-4 (AQP4) antibody-positive neuromyelitis optica spectrum disorder (NMOSD), immunoglobulin G4-related disease (IgG4-RD), and anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody-positive generalized myasthenia gravis (gMG). New technology add-on payments for UPLIZNA® were not approved for FY 2023 (87 FR 48954 through 48960).

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ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW03398	Introduction of inebilizumab-cdon into peripheral vein, percutaneous approach, new technology group 8	0	NO	1	NO	0	NO		NO	1
XW04398	Introduction of inebilizumab-cdon into central vein, percutaneous approach, new technology group 8	0	NO	0	NO	3	NO		NO	3

29) Vivistim® Paired VNS System is an FDA-approved technology that uses vagus nerve stimulation during rehabilitation therapy and daily activities to help improve upper limb function for stroke survivors. This pairing helps strengthen the brain connections needed to improve hand and arm function, providing a boost during rehabilitation therapy and daily activities.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
X0HQ3R8	Insertion of neurostimulator lead with paired stimulation system into vagus nerve, percutaneous approach, new technology group 8	10	YES	5	YES	4	YES		NO	19

30) Waskyra™ (etuvetidigene autotemcel) is an FDA-approved cell-based gene therapy for the treatment of Wiskott-Aldrich syndrome (WAS). Waskyra™ is indicated for pediatric patients six months and older and adults with WAS who have a mutation in the WAS gene and for whom hematopoietic stem cell transplantation (HSCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available.

ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW143F8	Transfusion of etuvetidigene autotemcel into central vein, percutaneous approach, new technology group 8[2]	0	NO	0	NO	0	NO		NO	0

31) ZYNTEGLO® (betibeglogene autotemcel) is an FDA-approved gene therapy for adults and children with transfusion-dependent β-thalassemia, designed to eliminate the need for regular red blood cell transfusions. The ICD-10-PCS code request was not related to an NTAP application.

[2] *Description revised effective October 1, 2026 - FY 2027*

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ICD-10-PCS Code	Description	FY 2023		FY 2024		FY 2025		FY 2026		
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq
XW133B8	Transfusion of betibeglogene autotemcel into peripheral vein, percutaneous approach, new technology group 8	2	NO	1	NO	3	NO		NO	6
XW143B8	Transfusion of betibeglogene autotemcel into central vein, percutaneous approach, new technology group 8	0	NO	0	NO	0	NO		NO	0

Topic # 17 - Addenda and Reference Key Updates*

ICD-10-PCS Index Addenda

Lttr		C	
Main			Cauterization
Main	Add		see Control
Lttr		F	
Main			Fulguration
Main	Add		see Control
Lttr		G	
Main	Add		GORE(R) TAG(R) Thoracic Branched Endograft (TBE) use Intraluminal Device use Intraluminal Device, Branched or Fenestrated, One or Two Arteries in 02V
Lttr		M	
Main			Marsupialization
Main			see Drainage
Main	Delete		see Excision
Lttr		T	
Main	Add		TREGZI (tm) use Orca-T Allogeneic T-cell Immunotherapy

ICD-10-PCS Device Key Addenda

Axis 6	Device	
Row		
Term		Intraluminal Device
Includes	Add	GORE(R) TAG(R) Thoracic Branched Endograft (TBE)
Axis 6	Device	
Row		
Term	Add	Intraluminal Device, Branched or Fenestrated, One or Two Arteries for Restriction in Heart and Great Vessels
Includes	Add	GORE(R) TAG(R) Thoracic Branched Endograft (TBE)

**All proposed addenda updates are being considered for implementation on April 1, 2027.*

ICD-10-PCS Substance Key Addenda

Section X		New Technology
Axis 6		Device / Substance / Technology
Row	Add	
Term	Add	Orca-T Allogeneic T-cell Immunotherapy
Includes	Add	TREGZI (tm)

ICD-10-PCS Table Addenda

Medical and Surgical Section

Axis 3 Root Operation
Non-Excisional Debridement of Lower Joints

Source	Description	Code specification
2026, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section, create new table 0SD, Extraction of Lower Joints. Add the body part values 9 Hip Joint, Right, B Hip Joint, Left, C Knee Joint, Right, D Knee Joint, Left, applied to approach values 0 Open and 4 Percutaneous Endoscopic, device value Z No Device, and qualifier value Z No Qualifier. This proposed change would enable the identification of procedures such as the non-excisional debridement of lower joints. Non-excisional joint debridement is a procedure to remove devitalized tissue, loose cartilage, or debris from an affected hip or knee joint. More commonly performed arthroscopically, the procedure can effectively relieve pain, minimize inflammation, slow the progression of joint damage or arthritis, and improve mobility without physically cutting away tissue.	Add: 0SD[9BCD][04]ZZ (8 codes)

EXAMPLE

Section **0** Medical and Surgical *Body System* **S** Lower Joints *Operation* **ADD** **D** Extraction: Pulling or stripping out or off all or a portion of a body part by the use of force			
Body Part	*Approach*	*Device*	*Qualifier*
ADD 9 Hip Joint, Right **ADD B** Hip Joint, Left **ADD C** Knee Joint, Right **ADD D** Knee Joint, Left	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

**All proposed addenda updates are being considered for implementation on April 1, 2027.*

Axis 6 Device
Submuscular Implantation of Pacemaker or Defibrillator Generators

Source	Description	Code specification
2026, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0KH, Insertion of Muscles, add the device values 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, applied to body part value X Upper Muscle, and the open approach. This change will enable the reporting of submuscular implantation of pacemaker or defibrillator generators. The standard implantation technique for pacemaker or defibrillator generators involves inserting the device in an appropriately sized subcutaneous pocket in the subclavian area. In recent years, alternative implantation techniques have been explored to offer both operative and cosmetic advantages. [1,2] Submuscular implantation refers to positioning the generator underneath the pectoralis major muscle or serratus anterior muscle. The objective of this deeper position is to cover the generator with muscle tissue to prevent pocket complications, such as erosion because of excessive mechanical stress, and to improve the cosmetic result in patients with a lower body mass index.	Add: 0KHX0[456789]Z (6 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**K** Muscles
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*
X Upper Muscle	**0** Open	**ADD 4** Pacemaker, Single Chamber **ADD 5** Pacemaker, Single Chamber Rate Responsive **ADD 6** Pacemaker, Dual Chamber **ADD 7** Cardiac Resynchronization Pacemaker Pulse Generator **ADD 8** Defibrillator Generator	**Z** No Qualifier

[1] Asamura S, Kurita T, Motoki K, Yasuoka R, Hashimoto T, Isogai N. Efficacy and feasibility of the submuscular implantation technique for an implantable cardiac electrical device. Eplasty. 2014 Oct 30;14:e40. PMID: 25525479; PMCID: PMC4216570.
[2] Brouwer TF, Miller MA, Quast AB, Palaniswamy C, Dukkipati SR, Reddy V, Wilde AA, Willner JM, Knops RE. Implantation of the Subcutaneous Implantable Cardioverter-Defibrillator: An Evaluation of 4 Implantation Techniques. Circ Arrhythm Electrophysiol. 2017 Jan;10(1):e004663. doi: 10.1161/CIRCEP.116.004663. PMID: 28073910.

		ADD 9 Cardiac Resynchronization Defibrillator Pulse Generator **M** Stimulator Lead **Y** Other Device	
X Upper Muscle **Y** Lower Muscle	**3** Percutaneous **4** Percutaneous Endoscopic	**M** Stimulator Lead **Y** Other Device	**Z** No Qualifier

Axis 7 Qualifier

Coronary Vessel Plaque Modification during Percutaneous Coronary Intervention (PCI)

Source	Description	Code specification
2026, public request with CMS internal review	In Medical and Surgical section table 027, Dilation of Heart and Great Vessels, create new qualifier values 7 Cutting Balloon, 8 Scoring Balloon, 9 Super High-Pressure Balloon, A Cutting Balloon, Bifurcation, B Scoring Balloon, Bifurcation, and C Super High-Pressure Balloon, Bifurcation applied to the body part values 0 Coronary Artery, One Artery, 1 Coronary Artery, Two Arteries, 2 Coronary Artery, Three Arteries and 3 Coronary Artery, Four or More Arteries, the percutaneous approach and the device value Z No Device. These changes will enable the ability to report coronary vessel plaque modification for lesion preparation in percutaneous coronary intervention (PCI) procedures using specialty balloons. While conventional balloon angioplasty performed to prepare lesions prior to stent delivery or delivering a drug-coated balloon is not coded separately per ICD-10-PCS Guideline B3.1.b, which states "components of a procedure specified in the root operation definition or explanation as integral to that root operation are not coded separately," CMS believes that coronary vessel plaque modification for lesion preparation using cutting, scoring, or super high-pressure balloons has a distinct surgical objective. In general, calcified coronary lesions are prepared for PCI by inflating a standard non-compliant (NC) balloon to high pressures before stenting. However, for certain lesions, such as those with severe calcifications, high-pressure NC balloon inflation is insufficient to achieve adequate vessel preparation before stent implantation.[3] Severe calcium can make the delivery of equipment during PCI challenging, and if not adequately addressed,	Add: 027[0123]3Z[789ABC] (24 codes)* **When appropriate, assign a separate code for any atherectomy and/or intravascular lithotripsy also performed using the applicable root operation Extirpation or Fragmentation as needed to identify the procedure. Additionally, separately assign a code for the placement of any stents using the applicable code in table 027, Dilation of Heart and Great Vessels.*

[3] Scalamogna M, Kuna C, Voll F, Aytekin A, Lahu S, Kessler T, Kufner S, Rheude T, Sager HB, Xhepa E, Wiebe J, Joner M, Ndrepepa G, Kastrati A, Cassese S. Modified balloons to prepare severely calcified coronary lesions before stent implantation: a systematic review and meta-analysis of randomized trials. Clin Res Cardiol. 2024 Jul;113(7):995-1005. doi: 10.1007/s00392-023-02324-y. Epub 2023 Nov 6. PMID: 37930402; PMCID: PMC11219378.

	can lead to stent under-expansion, which is associated with stent thrombosis and in-stent restenosis.[4] Furthermore, patients with severe coronary artery calcification more frequently experience adverse outcomes after PCI, including death and stent failure.[5,6] For this reason, alternative balloon-based lesion preparation strategies, including specialty balloons, have been tested in patients with calcific coronary artery disease.[7] The decision relating to which modification technique to use is based on numerous anatomic and technical factors, including the location of the lesion, the concentricity of the calcium pool, operator familiarity/expertise, and local device availability (*Figure 1)*.[8] The "concentricity of the calcium pool" refers to the distribution and symmetry of calcified plaque deposits within an artery. Specialty balloons for coronary vessel plaque modification are specialized catheters designed to reshape, fracture, or modify hard, fibrotic, or calcified plaque in coronary arteries prior to stent placement. They overcome the limitations of standard balloons by focusing the inflation force and minimizing vessel trauma. Once the plaque is modified and the artery is prepared, these specialty balloons are completely deflated and withdrawn from the body, leaving the fractured plaque and widened vessel behind. The following specialty balloons are used in PCI.[9] 1. Cutting Balloons, such as the Wolverine™ (Boston Scientific), feature three or four tiny, longitudinally mounted atherotomes (micro-blades) made of surgical stainless steel. As the balloon inflates, the blades create precise, microscopic incisions in the	

[4] Butala NM, Shah B. Cracking Eccentric Calcium. Circ Cardiovasc Interv. 2023 Oct;16(10):e013538. doi: 10.1161/CIRCINTERVENTIONS.123.013538. Epub 2023 Oct 17. PMID: 37847767; PMCID: PMC10593499.
[5] Bourantas CV, Zhang YJ, Garg S, et al. Prognostic implications of coronary calcification in patients with obstructive coronary artery disease treated by percutaneous coronary intervention: a patient-level pooled analysis of 7 contemporary stent trials. Heart. 2014;100:1158-1164. doi: 10.1136/heartjnl-2013-305180
[6] Konigstein M, Madhavan MV, Ben-Yehuda O, et al. Incidence and predictors of target lesion failure in patients undergoing contemporary DES implantation-individual patient data pooled analysis from 6 randomized controlled trials. Am Heart J. 2019;213:105-111. doi: 10.1016/j.ahj.2019.03.011
[7] De Maria GL, Scarsini R, Banning AP. Management of calcific coronary artery lesions: is it time to change our interventional therapeutic approach? JACC Cardiovasc Interv. 2019;12:1465–1478. doi: 10.1016/j.jcin.2019.03.038.
[8] Max W Maffey, Rodrigo Bagur, Dedicated Balloon Techniques for Coronary Calcium Modification, *Interventional Cardiology 2024;19:e13.* https://doi.org/10.15420/icr.2024.06
[9] Shah M, Najam O, Bhindi R, De Silva K. Calcium Modification Techniques in Complex Percutaneous Coronary Intervention. Circ Cardiovasc Interv. 2021 May;14(5):e009870. doi: 10.1161/CIRCINTERVENTIONS.120.009870. Epub 2021 Jan 14. PMID: 33441017.

	plaque, reducing the pressure needed to dilate the vessel and preventing irregular tearing. 2. Scoring Balloons, such as the AngioSculpt Evo (Philips), Scoreflex Scoring PTCA Catheter (Abbott) or Lacrosse NSE Alpha™(Braun), utilize thin external nitinol struts or metallic wires wrapped around the balloon surface. The wires create concentrated points of stress that score the plaque and allow the balloon to expand evenly without slipping. 3. Super High-Pressure NC Balloons, such as the OPN NC (SIS Medical), are double-layered balloons constructed from robust materials like polyethylene terephthalate (PET) and are designed to withstand extraordinarily high inflation pressures (up to 35 to 40+ atmospheres). They exert massive radial forces to physically crack thick, concentric calcium deposits. 	

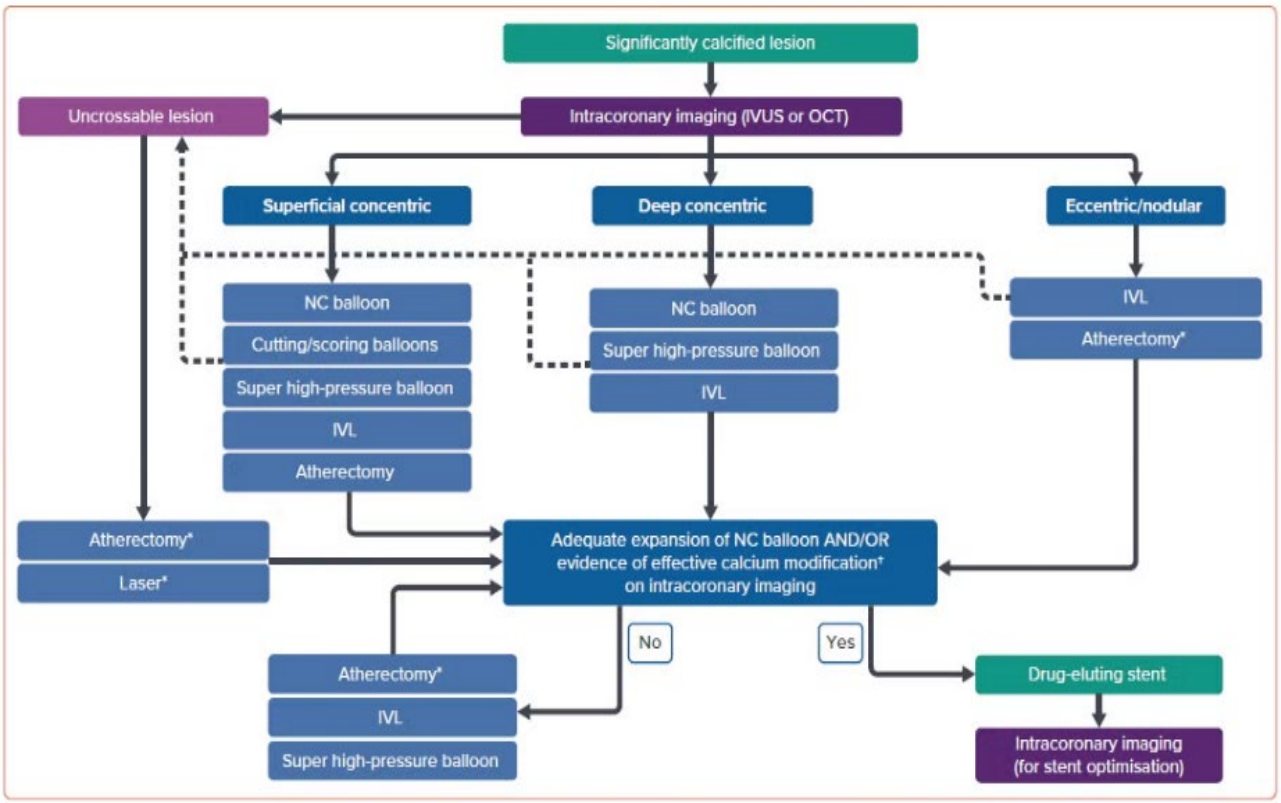

Figure 1: Algorithm for Calcium Modification. *IVL= intravascular lithotripsy; IVUS = intravascular ultrasound; NC = non-compliant; OCT = optical coherence tomography.*

**All proposed addenda updates are being considered for implementation on April 1, 2027.*

EXAMPLE*

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
0 Coronary Artery, One Artery **1** Coronary Artery, Two Arteries **2** Coronary Artery, Three Arteries **3** Coronary Artery, Four or More Arteries	**3** Percutaneous	**Z** No Device	**ADD 7** Cutting Balloon **ADD 8** Scoring Balloon **ADD 9** Super High-Pressure Balloon **ADD A** Cutting Balloon, Bifurcation **ADD B** Scoring Balloon, Bifurcation **ADD C** Super High-Pressure Balloon, Bifurcation

Valve-in-Valve Transcatheter Aortic Valve Replacement

Source	Description	Code specification
2026, public request with CMS internal review	In Medical and Surgical section table 02R, Replacement of Heart and Great Vessels, create new qualifier value K In Existing Valve, applied to the body part value F Aortic Valve, the device value 8 Zooplastic Tissue and the percutaneous approach. This change will enable the ability to uniquely identify valve-in-valve (ViV) transcatheter aortic valve replacement (TAVR) of failed bioprosthetic aortic valves. Aortic valve replacement is indicated for patients with severe symptomatic aortic valve stenosis, however bioprosthetic valves have limited durability. The best current valves can be expected to degenerate within 10 to 20 years, resulting in stenosis or insufficiency (regurgitation).[10] ViV	Add: 02RF38K (1 code)

[10] Webb JG, Dvir D. Transcatheter aortic valve replacement for bioprosthetic aortic valve failure: the valve-in-valve procedure. Circulation. 2013 Jun 25;127(25):2542-50. doi: 10.1161/CIRCULATIONAHA.113.000631. PMID: 23797741.

	TAVR was first approved in 2015 as a minimally invasive procedure that is being increasingly adopted as a treatment strategy for failed bioprosthetic valves instead of a high-risk open-heart reoperation.[11] During this procedure, a new bioprosthetic valve is delivered via a catheter inserted through the femoral artery and deployed directly inside the old, failing bioprosthesis, enabling a redo valve replacement to take place without subjecting the patient to an open surgical procedure. The transapical approach rare and is generally utilized only in patients who are ineligible for transfemoral TAVR due to poor femoral access and unsuitable anatomy.[12,13]	

EXAMPLE

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 **ADD K** In Existing Valve **N** Rapid Deployment Technique **Z** No Qualifier

Occlusion of Major Abdominal Aortic Branch Arteries

Source	Description	Code specification
2026, public request with CMS internal review	In Medical and Surgical section table 04L, Occlusion of Lower Arteries, create new qualifier values K Lumbar Artery and L Gonadal Artery, applied to the body part value 0 Abdominal Aorta, and all applicable approach and device values. This change will enable the reporting of the specific vessel treated when two major arterial branches of the abdominal aorta require occlusion. The abdominal aorta begins at the diaphragmatic hiatus. The vessel runs in front of the spine and to the left of the inferior vena cava until it bifurcates into the common iliac arteries. Along the way, the aorta gives	Add: 04L0[034][CDZ][KL] (18 codes)

[11] Chiu, H, Lam, S, Tang, G. Valve-in-Valve Transcatheter Aortic Valve Replacement (ViV-TAVR): The Past, Present, and Future. JACC: Asia. 2025 Oct, 5 (10) 1298–1301. https://doi.org/10.1016/j.jacasi.2025.08.003

[12] Watkins AR, El-Andari R, Mathew A, Nagendran J. Valve-in-Valve Transapical Transcatheter Aortic Valve Replacement with Concomitant Percutaneous Coronary Intervention: A Case Report. Am J Case Rep. 2025 Mar 2;26:e946582. doi: 10.12659/AJCR.946582. PMID: 40023763; PMCID: PMC11885597.

[13] Zhou J, Li Y and Zhang H (2022) Case report: Transapical transcatheter double valve-in-valve replacement of degenerated aortic and mitral bioprosthetic valves with limited radiopaque landmarks. Front. Cardiovasc. Med. 9:1086457. doi: 10.3389/fcvm.2022.1086457

	rise to the arterial branches that are responsible for transmitting oxygenated blood to all the tissues of the body. The branches of the abdominal aorta include: • the paired branches - the middle adrenal, renal, gonadal, inferior phrenic, and lumbar arteries; • the unpaired branches - the celiac, superior mesenteric, inferior mesenteric, and median sacral arteries; and • the terminal branches - the common iliac arteries.[14] The lumbar arteries and the gonadal arteries (referred to as the testicular arteries in males or the ovarian arteries in females) have a higher incidence of various types of injuries, disease and complications than other arterial branches of the abdominal aorta. Research shows that segmental arteries, including the lumbar arteries, are injured in 68 percent of lateral approach spine surgeries.[15] Gonadal artery injury during colorectal surgery is not a rare complication as the gonadal arteries are susceptible to accidental injury due to their anatomical proximity to the colon and rectum.[16] Occlusion of the lumbar or gonadal arteries (via techniques such as embolization or surgical ligation) is primarily performed to stop life-threatening bleeding, treat vascular anomalies, or optimize complex aortic repairs.	

[14] Tran CT, Wu CY, Bordes SJ, et al. Anatomy, Abdomen and Pelvis: Abdominal Aorta. [Updated 2023 Jul 25]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK525964/

[15] Giotta Lucifero A, Gragnaniello C, Baldoncini M, Campero A, Savioli G, Tartaglia N, Ambrosi A, Luzzi S. Rating the incidence of iatrogenic vascular injuries in thoracic and lumbar spine surgery as regards the approach: A PRISMA-based literature review. Eur Spine J. 2021 Nov;30(11):3172-3190. doi: 10.1007/s00586-021-06956-4. Epub 2021 Aug 19. PMID: 34410504.

[16] Hsu CW, Chang MC, Wang JH, Wu CC, Chen YH. Incidence and Clinical Outcomes of Gonadal Artery Injury during Colorectal Surgery in Male Patients. J Gastrointest Surg. 2019 Oct;23(10):2075-2080. doi: 10.1007/s11605-019-04197-x. Epub 2019 Apr 1. PMID: 30937712.

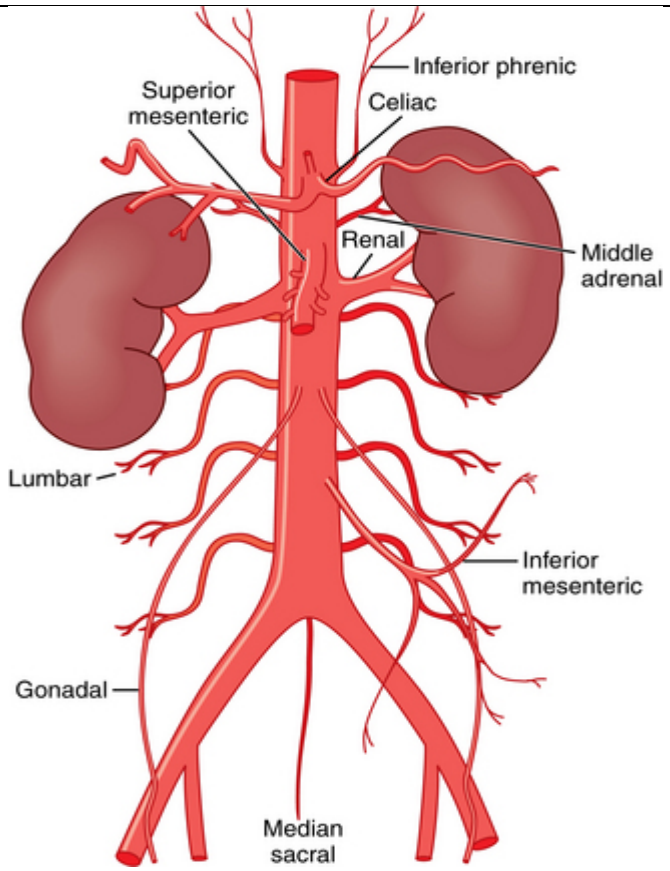

Figure 1. Anatomy of the abdominal aorta.

EXAMPLE

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**L** Occlusion: Completely closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta	**0** Open **3** Percutaneous	**C** Extraluminal Device **Z** No Device	**ADD K** Lumbar Artery **ADD L** Gonadal Artery **Z** No Qualifier
0 Abdominal Aorta	**0** Open **3** Percutaneous	**D** Intraluminal Device	**J** Temporary **ADD K** Lumbar Artery **ADD L** Gonadal Artery **Z** No Qualifier
0 Abdominal Aorta	**4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**ADD K** Lumbar Artery **ADD L** Gonadal Artery **Z** No Qualifier

Dilation of the Urethra with a Drug-Coated Balloon

Source	Description	Code specification
2026, public request with CMS internal review	In the Medical and Surgical section table 0T7, Dilation of the Urinary System, add the qualifier value 1 Drug-Coated Balloon, applied to body part value D Urethra, the approach value 8 Via Natural or Artificial Opening Endoscopic, and the device value Z No Device. This change will enable the	Add: 0T7D8Z1 (1 code)

	reporting of a procedure to dilate urethral strictures using a drug-coated balloon. The Optilume® Urethral Drug Coated Balloon is a minimally invasive medical device designed for use with rigid or flexible cystoscopy. It is used to treat urethral strictures (scar tissue narrowing the urethra) and benign prostatic hyperplasia (BPH). The technology combines mechanical balloon dilation for immediate symptomatic relief with targeted drug delivery (paclitaxel) to prevent scar tissue from recurring. The semi-compliant balloon expands the tissue creating a mechanical balloon dilation effect, rupturing the urethral mucosa and allowing direct, circumferential drug delivery to the exposed submucosa through micro-fissures across the length of the stricture to open the blocked passageway, while rapid uptake of the highly lipophilic drug, paclitaxel, limits hyperactive cell proliferation and the fibrotic scar tissue generation that results in stricture recurrence. [17,18,19]	

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
3 Kidney Pelvis, Right **4** Kidney Pelvis, Left **6** Ureter, Right **7** Ureter, Left **8** Ureters, Bilateral **B** Bladder **C** Bladder Neck **D** Urethra	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**D** Intraluminal Device **Z** No Device	**Z** No Qualifier
D Urethra	**8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**ADD** 1 Drug-Coated Balloon

[17] DeLong J, et al. Outcomes of Bulbar Urethral Stricture Treatment With Optilume: ROBUST I Study Results. J Urol. 2025 Jan;213(1):90-8.
[18] Srikanth, P., DeLong, J., Virasoro, R., & Elliott, S. P. (2025). A drug-coated balloon treatment for urethral stricture disease: Three-year results from the ROBUST III study. Journal of Endourology, 39(5), 567–574.
[19] Rosenfield K, Jaff MR, White CJ, et al. Trial of Paclitaxel-Coated Balloon for Artery Disease. NEJM 2015;372(2):145-53

Transfer of Bladder to Bladder Neck and Urethra

Source	Description	Code specification
2026, public request with CMS internal review	In the Medical and Surgical section table 0TX, Transfer of Urinary System, create new qualifier values F Bladder Neck and G Urethra, applied to the body part value B Bladder and the open and percutaneous endoscopic approaches, to describe pedicled transfers of the bladder to the bladder neck and/or urethra using different methods. Pedicled bladder transfer procedures, such as the Kropp, Mitchell, Mollard, Pippi Salle, and Young-Dees-Leadbetter procedures, are pediatric urological surgeries performed for bladder neck reconstruction (BNR) and urethral lengthening. Surgeons deploy these procedures to treat complex congenital and neurological anomalies in children for diagnoses such as epispadias, bladder exstrophy, cloacal anomalies, neurogenic incontinence, and congenital short urethra.[20] The Young-Dees-Leadbetter, Mollard, and Mitchell procedures involve tubularizing a strip of the native bladder trigone tissue to create a longer, tighter muscular tube at the base of the bladder. The Kropp and Pippi Salle procedures use a flap-valve mechanism where a tube or on-lay flap of bladder wall tissue is tunneled submucosally inside the bladder. When the bladder fills with urine, the increasing pressure compresses the tunneled tissue, naturally sealing it to prevent leaks.	Add: 0TXB[04]Z[FG] (4 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**T** Urinary System
Operation	**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*
B Bladder	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**6** Ureter, Right **7** Ureter, Left **ADD F** Bladder Neck **ADD G** Urethra

[20] Ferrer FA, Tadros YE, Gearhart J. Modified Young-Dees-Leadbetter bladder neck reconstruction: new concepts about old ideas. Urology. 2001 Nov;58(5):791-6. doi: 10.1016/s0090-4295(01)01345-0. PMID: 11711366.

Extracorporeal or Systemic Assistance and Performance Section
Axis 7 Qualifier
Continuous Renal Replacement Therapy for 18 or Less Hours

Source	Description	Code specification
2026, public request with CMS internal review	In the Extracorporeal or Systemic Assistance and Performance section table 5A1, create new duration value F Continuous, 18 or Less Hours Per Day, applied to body system value D Urinary, function value 0 Filtration, and all available qualifier values to describe continuous renal replacement (CRRT) that is discontinued before more than 18 hours of therapy have been completed. Multiple modalities of renal support may be used in the management of patients with kidney failure. These include CRRT, conventional intermittent hemodialysis (IHD), and prolonged intermittent renal replacement therapies (PIRRTs). CRRT comprises techniques that manage solute removal and fluid balance for a long period of time, typically 24 hours or more. It is commonly used to provide renal support for critically ill patients who are hemodynamically unstable. The slower solute clearance and removal of fluid per unit of time with CRRT, as compared with IHD, is thought to allow for better hemodynamic tolerance. A large-bore, double-lumen catheter is typically used for vascular access for CRRT. The preferred site for catheter insertion is the internal jugular vein or femoral vein.[21] Once initiated, CRRT may need to be discontinued once renal recovery has been confirmed or the decision is made to switch to another form of renal replacement because of the patient's clinical condition. For example, a switch to IHD may be appropriate if the patient is weaned off pressors, needs mobility, or is transferred out of the intensive care unit. Additionally, CRRT may need to be discontinued due to adverse effects such as hypotension, arrhythmias, fluid-balance and electrolyte disturbances (such as hypocalcemia, hypokalemia, and hypophosphatemia), nutrient losses, hypothermia, and bleeding.[22]	Add: 5A1DF0[1Z] (2 codes)

[21] Saunders H, Rehan A, Hashmi MF, et al. Continuous Renal Replacement Therapy. [Updated 2024 Mar 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK556028/
[22] Tolwani A. Continuous renal-replacement therapy for acute kidney injury. N Engl J Med. 2012 Dec 27;367(26):2505-14. doi: 10.1056/NEJMct1206045. PMID: 23268665.

EXAMPLE

Section	**5** Extracorporeal or Systemic Assistance and Performance
Body System	**A** Physiological Systems
Operation	**1** Performance: Completely taking over a physiological function by extracorporeal means

Body System	*Duration*	*Function*	*Qualifier*
D Urinary	**7** Intermittent, Less than 6 Hours Per Day **8** Prolonged Intermittent, 6-18 hours Per Day **9** Continuous, Greater than 18 hours Per Day **ADD F** Continuous, 18 or Less Hours Per Day	**0** Filtration	**1** Selective Cytopheresis **Z** No Qualifier

New Technology Section
Axis 4 Body Part
Introduction of AGN1 Bone Void Filler

Source	Description	Code specification
2026, public request with CMS internal review	In the New Technology section table XW0 Introduction, delete the body part value V Bones, applied to the axis 6 device/substance/technology value W AGN1 Bone Void Filler and the percutaneous approach. Additionally, add the body part values A Upper Femur, Right, and B Upper Femur, Left, applied to the axis 6 device/substance/technology value W AGN1 Bone Void Filler and the percutaneous approach. This change request is from the manufacturer. According to the requestor, additional detail is needed to further specify the anatomical body part and laterality of treatment in the ICD-10-PCS code that captures the introduction of bone void filler with osteo-enhancement material (AGN1) into the proximal femur. The AGN1 Local Osteo-Enhancement Procedure (LOEP) Kit—also referred to as the OSSURE kit—is a minimally invasive medical system used to rebuild and strengthen bone affected by osteoporosis. It delivers a proprietary, calcium-based synthetic material (AGN1) into bone voids, which naturally dissolves and is replaced by healthy new bone over time. According to the requestor, upon FDA approval, which is anticipated in 2027, the LOEP kit will be indicated to reduce the risk of hip fracture in patients at risk of fragility fracture.	Delete: XW0V3WA (1 code) Add: XW0[AB]3WA (2 codes)

EXAMPLE

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
DELETE V Bones **ADD A** Upper Femur, Right **ADD B** Upper Femur, Left	**3** Percutaneous	**W** AGN1 Bone Void Filler	**A** New Technology Group 10

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr A
Main Delete AGN1 Bone Void Filler XW0V3WA
Main Add AGN1 Bone Void Filler XW0

Lttr L
Main Delete LOEP(R) (Local Osteo-Enhancement Procedure) XW0V3WA
Main Add LOEP(R) (Local Osteo-Enhancement Procedure) XW0

Lttr N
Main New Technology
Delete AGN1 Bone Void Filler XW0V3WA
Add AGN1 Bone Void Filler XW0

Lttr O
Main Delete OSSURE(R) XW0V3WA
Main Add OSSURE(R) XW0

Topic # 18 – Administration of cefepime-zidebactam

Issue: There are no unique ICD-10-PCS codes to describe the administration of cefepime-zidebactam. An April 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? Yes. ZAYNICH™ (cefepime and zidebactam) was approved by the FDA on May 29, 2026 and is indicated for the treatment of adult patients with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following Gram-negative susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterobacter cloacae complex,* and *Pseudomonas aeruginosa.*

Background: Urinary tract infections are a major public health concern in the United States, affecting millions of people each year and occur when pathogens, particularly bacteria, enter the urinary system, leading to inflammation and infection. Complicated urinary tract infections (cUTIs) are infections beyond the bladder, including pyelonephritis, and infections in immunocompromised patients, males, pregnant patients, and those associated with fevers, stones, sepsis, urinary obstruction, catheters.[1] If left untreated or if appropriate effective antibiotic therapy is delayed, cUTIs can lead to serious complications, including life-threatening urosepsis or septic shock.

cUTIs are responsible for over 600,000 hospitalizations in the U.S. annually. A growing number of cUTIs are caused by antimicrobial resistant bacteria, including multidrug-resistant bacteria, a leading cause of bacteremia and associated with significant morbidity and mortality and a burden on the health care system.[2] The development of multidrug-resistant organisms has prompted the investigation of older antimicrobials (primarily aminoglycosides and tetracyclines) as well as the development of new antibiotics and combinations, such as ZAYNICH™.

Mechanism of Action
ZAYNICH™ (cefepime-zidebactam) is indicated for the treatment of adult patients with cUTI, including pyelonephritis, caused by the designated Gram-negative susceptible microorganisms. It is a combination of cefepime, a cephalosporin antibacterial drug and zidebactam, a betalactamase inhibitor and non-beta-lactam antibacterial. Cefepime primarily targets penicillin-binding protein-3 (PBP3) and PBP1a/b in Enterobacterales and PBP3 in other Gram-negative bacterial pathogens, while zidebactam selectively inhibits penicillin-binding protein-2 (PBP2). Cefepime and zidebactam work together by binding multiple penicillin-binding proteins (PBP), leading to bacterial killing. This synergy occurs even in the presence of beta-lactamases, including metallo-beta-lactamases (MBLs), which are not inhibited by zidebactam, and other non-enzymatic cefepime resistance mechanisms, such as hyper-efflux and downregulation of outer membrane porin channels. This is hypothesized to be due to cefepime's ability to bind to its PBP targets at a faster rate than it is hydrolyzed by betalactamases. Zidebactam, as a non-beta-lactam, is less

[1] Sabih A, Leslie SW. Complicated Urinary Tract Infections. [Updated 2024 Dec 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK436013/
[2] Marantidis, J., & Sussman, R. D. (2023). Unmet needs in complicated urinary tract infections: Challenges, recommendations, and emerging treatment pathways. Infection and Drug Resistance, 16, 1391–1405. https://doi.org/10.2147/IDR.S382617 Retrieved May 27, 2026, from https://pubmed.ncbi.nlm.nih.gov/36937144/

susceptible to degradation by betalactamases. Zidebactam demonstrates in vitro activity against certain Enterobacterales and *P. aeruginosa*. The zidebactam component of ZAYNICH™ exhibits in vitro activity against Ambler Class A and Class C beta-lactamases.

According to the requestor, ZAYNICH™ was evaluated in a phase 3 study in subjects with cUTI, including pyelonephritis which included 352 patients treated with cefepime-zidebactam, three grams every eight hours, infused over one hour for seven to ten days. The most common adverse reactions occurring in 2% or more of the cUTI patients were: diarrhea (4%) headache (33%) low blood potassium (3%) and increased blood pressure (3%). Treatment discontinuation due to an adverse event occurred in 1.4% of patients and no deaths were reported in the trial.

Inpatient Administration of Cefepime-zidebactam
ZAYNICH™ is supplied as a sterile white to pale yellow dry powder in a single-dose vial that must be reconstituted and further diluted prior to intravenous infusion. The recommended dosage of ZAYNICH™ is 3 grams (2 grams cefepime and 1 gram zidebactam) administered every 8 hours by intravenous (IV) infusion over 1 hour in adult patients with an eGFR greater than or equal to 60 mL/min. The duration of treatment is 7 days to 10 days.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of cefepime-zidebactam. Facilities can report the intravenous administration of cefepime-zidebactam 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 cefepime-zidebactam. Continue as described in current coding.

Option 2. In section X table XW0, Introduction of Anatomical Regions, create new substance value D Cefepime-zidebactam 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 cefepime-zidebactam.

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 D** Cefepime-zidebactam Anti-infective	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 19 – Administration of tanruprubart

Issue: There are no unique ICD-10-PCS codes to describe the administration of tanruprubart. An April 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. Tanruprubart has received Orphan Drug designations in Europe (October 13, 2023) and the United States (January 19, 2017) for the treatment of Guillain-Barré Syndrome (GBS). In January 2026, the marketing authorization application (MAA) was filed with the European Medicines Agency (EMA) for the approval of tanruprubart for the treatment of GBS in adult patients and in pediatric patients with a body weight of ≥40 kg. Submission of a United States Biologics License Application (BLA) is planned in 2026, including interim data from the FORWARD trial in the United States and Europe.

Background: GBS is an acute and devastating neuroinflammatory disease involving damage to peripheral nerves necessary for movement and breathing, and often rapidly progresses to severe weakness or complete paralysis. GBS typically presents with ascending paralysis; most cases require hospitalization and intensive care. GBS is associated with significant acute morbidity and mortality, with 1-year mortality rates in the Americas and Europe at 5% and up to 20% for patients on mechanical ventilation. This sudden, life-threatening disease affects at least 150,000 people worldwide each year with no United States FDA approved disease modifying treatments. According to the requestor, currently used treatments, intravenous immunoglobulin (IVIg) that is administered over 5 days, and plasmapheresis (PLEX) that is administered up to 14 days, have not been shown to stop underlying neuroinflammation. Per the requestor, patients who survive GBS frequently have life-altering residual symptoms which can have a substantial effect on daily activities and quality of life.

Tanruprubart is under investigation for the treatment of GBS, a rare neuromuscular emergency and the most common and severe cause of acute paralytic inflammatory disease resulting from an acute autoantibody and classical complement-mediated attack on peripheral nerves that generally occurs post-infection in otherwise healthy people. C1q is the initiating molecule of the classical complement pathway. The aim of an effective treatment in GBS is to rapidly stop the neuroinflammatory damage on nerve cells, allowing patients to recover sooner, regain independence and return to pre-illness activities. According to the requestor, tanruprubart is a first-in-class targeted, and rapid-acting monoclonal antibody designed to target C1q to block the classical complement pathway at the start to halt nerve damage and destruction and to allow for recovery phase and repair of damaged nerves.

Mechanism of Action
Tanruprubart is designed to protect peripheral nerves to support faster, more complete and durable recovery in GBS. Tanruprubart is a humanized, full-length recombinant immunoglobulin G4 (IgG4) monoclonal antibody produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology. Tanruprubart exhibits selective, high affinity binding to C1q, the initiating molecule of the classical complement pathway. Clinical studies in patients with GBS indicate that tanruprubart blocks free C1q, inhibiting functional classical complement activity, thereby blocking

autoantibody-driven neuroinflammation and preventing acute and ongoing nerve damage. Tanruprubart does not inhibit the alternative and lectin complement pathways, leaving them available for normal immune function.

Per the requestor, in clinical studies, patients with GBS achieved significant improvement with tanruprubart treatment, with a favorable risk/benefit analysis. Patients who received tanruprubart 30 mg/kg were more likely to be in a better health state as measured by GBS disability score (GBS-DS) at Week 8, the primary endpoint, compared with patients who received placebo (adjusted odds ratio [aOR] 2.41: 95% confidence interval [CI]: 1.289, 4.495; p = 0.0058). Based on available data from adult and pediatric patients weighing at least 40 kg with GBS who received tanruprubart in clinical studies, the most commonly reported adverse reactions are infusion-related reactions (IRRs) of rash (including erythema, rash papular, rash macular, rash erythematous, rash maculopapular). The average time to onset of an IRR was approximately 11 hours (toward the end of bag 1 of the 3-bag infusion), and majority of the reactions occurred during the first 16 hours of the infusion and were transient rashes, with the majority mild (Grade 1) to moderate (Grade 2). The development of rash was not predictive of developing other signs or symptoms such as hypotension.

Inpatient Administration of Tanruprubart
The recommended dose of tanruprubart is a single administration at 30 mg/kg of body weight (BW), administered as an intravenous (IV) infusion. It is supplied in 20 mL single-use glass vials of sterile concentrate for infusion containing 400 mg tanruprubart (20 mg/mL). Tanruprubart must be diluted with sodium chloride 9 mg/mL (0.9%) solution for injection. Each infusion will consist of 3 separate 500 mL sodium chloride 9 mg/mL (0.9%) solution for injection dosing IV bags prepared as follows. First, calculate the dose and total drug volume required for the recommended dose according to the patient's BW; Bag 1: 9 mg x BW in kg ÷ 20; Bag 2: 6 mg x BW in kg ÷ 20; Bag 3: 15 mg x BW in kg ÷ 20. Next, withdraw and discard a volume of normal saline from each 500 mL bag that is approximately equal to the calculated volume of tanruprubart to be added, then slowly add the calculated volume of tanruprubart to each bag and mix. The diluted solution of tanruprubart is to be administered via IV infusion over approximately 18 hours following the recommended infusion plan: Bag 1 at an infusion rate of 44 mL/hour over 12 hours; Bag 2 at an infusion rate of 131 mL/hour over 4 hours; and Bag 3 at an infusion rate of 263 mL/hour over 2 hours. Within 2 hours prior to infusion, recommended premedications are to be administered. Patients are to be adequately hydrated prior to the infusion and must be monitored for IRRs during infusion. At the end of administration of tanruprubart, the entire infusion line will be flushed with preservative free sodium chloride 9 mg/mL (0.9%) solution for injection to ensure complete delivery of tanruprubart. Other medications must not be injected into infusion line side ports or mixed with tanruprubart.

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

3E033GR	Introduction of other therapeutic monoclonal antibody into peripheral vein, percutaneous approach
3E043GR	Introduction of other therapeutic monoclonal antibody into central vein, percutaneous approach

Coding Options

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

Option 2. In section X New Technology table XW0, Introduction, Anatomical Regions, create new substance value F Tanruprubart Complement Inhibitor, applied to the body part values 3 Peripheral Vein and 4 Central Vein with the percutaneous approach, to identify the intravenous administration of tanruprubart.

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 F** Tanruprubart Complement Inhibitor	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 20 – Administration of ristoglogene autogetemcel

Issue: There are no unique ICD-10-PCS codes to describe the administration of ristoglogene autogetemcel (risto-cel). An April 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. Ristoglogene autogetemcel received Orphan Drug Designation, as well as Regenerative Medicine Advanced Therapy (RMAT) Designation, from the FDA in 2025 for the treatment of sickle cell disease. Ristoglogene autogetemcel (risto-cel) is currently being evaluated in an open-label, single-arm, multicenter, Phase 1/2 study (NCT05456880) evaluating the safety and efficacy of the administration of autologous base edited CD34+ hematopoietic stem and progenitor cells (BEAM-101) in patients with severe sickle cell disease.

Background: Sickle cell disease is a group of inherited autosomal recessive blood disorders caused by missense mutations in the gene encoding β-globin that leads to the production of abnormal sickle hemoglobin. The sickle cells have a shortened lifespan, which causes a constant shortage of red blood cells. Also, when they travel through small blood vessels, sickle cells get stuck and clog the blood flow. This can cause pain and other serious complications such as infection, acute chest syndrome, and stroke. The Centers for Disease Control and Prevention (CDC) estimates that sickle cell disease affects about 100,000 people in the United States, and the estimated life expectancy of those with sickle cell disease in the United States is more than 20 years shorter than the average expected.[1] Patients with sickle cell disease often have recurrent severe vaso-occlusive crises with progressive end-organ damage that causes substantial complications and early mortality.

Mechanism of Action
Ristoglogene autogetemcel (risto-cel) is an investigational genetically modified cell therapy consisting of ex vivo base-edited autologous CD34+ hematopoietic stem and progenitor cells (HSPCs) that are designed to increase the production of anti-sickling fetal hemoglobin (HbF) and decrease the production and levels of circulating sickle hemoglobin (HbS). Risto-cel is manufactured from CD34+ HSPCs collected via leukapheresis. The patient's isolated autologous CD34+ HSPC cells are then base-edited to target the HBG1 and HBG2 promoters and inhibit BCL11A repressor binding without altering BCL11A expression, yielding a switch in hemoglobin production from HbS to anti-sickling HbF.

The risto-cel editing process uses electroporation to deliver an adenine base editor encoding messenger and guide ribonucleic acid molecules to HSPCs to introduce A-to-G substitutions in the HBG1 and HBG2 gene promoter regions. Per the requestor, this process disrupts BCL11A repressor binding sites and mimics the increased expression of HbF that is seen in persons with hereditary persistence of fetal hemoglobin. Unlike other gene-therapy strategies, the risto-cel editing process directly targets the BCL11A binding site of the HBG1 and HBG2 promoters to inhibit BCL11A binding, without altering BCL11A expression. The requestor states that this

[1]Data and Statistics on Sickle Cell Disease, https://www.cdc.gov/sickle-cell/data/index.html. Accessed 21 July 2026.

method, in which the HBG1 and HBG2 promoter BCL11A–binding site is disrupted to up-regulate HbF, preserves the normal expression of BCL11A and its roles in erythroid differentiation and other lineages, such as lymphoid cells. Through the use of a Cas9 nickase, a modified CRISPR-Cas9 enzyme engineered to cut only one strand of a double-stranded DNA molecule, and a base-editing enzyme, the risto-cel editing process generates precise and uniform edits, avoids insertions or gene rearrangements, and prevents p53 activation by precluding the formation of double-strand breaks.

In the BEACON clinical trial (NCT05456880), eligible patients for risto-cel were 12 to 35 years of age, with a documented diagnosis of sickle cell disease, an eligible genotype (βS/βS, βS/β0, or βS/β+), at least four severe vaso-occlusive crises despite standard-care measures, in the prior two-year period, no available human leukocyte antigen-matched sibling donor, and no history of overt stroke. Patients treated with risto-cel achieved rapid neutrophil and platelet engraftment, median 17.5 days and 19 days, respectively. Following treatment with risto-cel, durable, high editing efficiency was observed along with a mean peripheral blood editing of 67.4% at month 6 and 72.8% by 12 months. The requestor states no patients experienced any investigator-reported severe vaso-occlusive crises post-engraftment. Patients achieved rapid and robust HbF induction of greater than 60% by month 1, maintained through follow up, with corresponding HbS reduction of <40% sustained through follow up, similar to levels seen in those with sickle cell trait.

According to the requestor, the BEACON trial demonstrated that the majority of patients who received risto-cel were able to undergo fewer leukapheresis cycles, which significantly reduced treatment burden in comparison with commercially available gene therapies indicated for sickle cell disease. Of the 31 patients in the BEACON trial, 20 patients required one collection cycle, five patients required two collection cycles, and six patients required three or more collection cycles to manufacture risto-cel. The requestor also states that the study indicates that risto-cel's safety profile is consistent with busulfan conditioning, autologous hematopoietic stem cell transplant, and underlying sickle cell disease. Of the 31 patients treated in the BEACON clinical trial, the most common treatment-emergent adverse events were stomatitis (24 patients) and febrile neutropenia (22 patients). Other common treatment-emergent adverse events were decreased appetite, hypokalemia, skin hyperpigmentation, decreased platelet count, anemia, hypomagnesemia, constipation, hypertension, and nausea. Per the requestor, these adverse events are consistent with busulfan conditioning, hematopoietic stem cell transplant, and sickle cell disease.

Inpatient Administration of Ristoglogene Autogetemcel
Prior to the administration of risto-cel, patients undergo pharmacokinetic myeloablative conditioning with busulfan (cumulative area-under-the-curve target, 80 hr-mg per liter [target range, 68 to 92]). Risto-cel is administered as a single intravenous infusion, with a minimum cell dose of 3.0x106 viable CD34+ cells per kilogram of body weight. Patients are monitored for neutrophil and platelet engraftment in the inpatient setting until the occurrence of neutrophil engraftment, with further monitoring until 24 months after transplantation.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of ristoglogene autogetemcel (risto-cel). Facilities can report the intravenous administration of ristoglogene autogetemcel (risto-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 ristoglogene autogetemcel (risto-cel). Continue as described in current coding.

Option 2. In section X table XW1, Transfusion of Anatomical Regions, create new substance value G Ristoglogene Autogetemcel, applied to the body part values 3 Peripheral Vein and 4 Central Vein and the percutaneous approach, to identify the intravenous administration of ristoglogene autogetemcel (risto-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 G** Ristoglogene Autogetemcel	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 21 – Administration of mivocabtagene autoleucel

Issue: There are no unique ICD-10-PCS codes to describe the administration of mivocabtagene autoleucel (miv-cel). An April 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. Mivocabtagene autoleucel (miv-cel) received Regenerative Medicine Advanced Therapy (RMAT), Orphan Drug designation and fast track designation. The Biologics License Application (BLA) process has been initiated, and the PDUFA date is anticipated first quarter (1Q) 2027.

Background: Stiff person syndrome (SPS) is a rare, progressive, and severely debilitating autoimmune neurological disease characterized by progressive muscle stiffness, heightened sensitivity to sensory stimuli, and painful episodic muscle spasms. Approximately 80% of patients eventually lose the ability to walk independently, and many suffer from profound functional disability, social isolation, and reduced quality of life. SPS affects an estimated one to two people per 100,000, with a higher prevalence among women. According to the requestor, recent epidemiological analyses suggest true prevalence may be meaningfully higher than historically published estimates, likely reflecting longstanding underdiagnosis and misclassification of the condition. SPS is associated with autoimmune dysfunction affecting inhibitory neuronal pathways in the central nervous system. Most patients have detectable antibodies against glutamic acid decarboxylase 65 (GAD65), which provide evidence of the autoimmune pathophysiology of the disease, although their precise role in causing SPS remains incompletely understood.

Despite its severity, there are currently no FDA-approved therapies for SPS, per the requestor. Current management relies on off-label use of agents including symptomatic treatment with benzodiazepines or muscle relaxants, and immunomodulatory treatment with intravenous immunoglobulin (IVIG), rituximab, and plasmapheresis (PLEX), which provide incomplete and non-durable symptomatic relief without addressing the underlying immune dysregulation. A significant unmet need therefore exists for treatments that can provide durable remissions in this patient population. According to the requestor, miv-cel is being developed specifically to address this unmet need through a single-infusion immune reset strategy. The requestor stated its registrational Phase 2 trial (KYSA-8) demonstrated statistically significant and clinically meaningful improvements across all primary and secondary endpoints, including a significant improvement in change in T25FW from baseline ($p=0.0003$) with a 45% median improvement and 81% of patients achieving a clinically meaningful ≥20% improvement. Notably, 25 of 26 patients (96%) showed improvement in at least one endpoint. All patients discontinued chronic immunosuppressive therapies following treatment and remained off those therapies through week 16 or last follow up for the primary analysis, an outcome not previously observed in this disease.

Mechanism of Action
Miv-cel is a fully human, autologous CD19-targeting CAR T-cell therapy. Unlike murine-derived or humanized single-domain antibody (sdAb) CAR T constructs, miv-cel uses a fully human single-chain variable fragment (scFv) binding domain for CD19 recognition, minimizing the risk of immunogenic responses against the CAR construct itself. Upon intravenous infusion, miv-cel CAR T-cells recognize CD19, a pan-B-cell surface antigen highly expressed on the B-cells which are

implicated in driving the autoimmune pathology in SPS. The CD28 costimulatory domain incorporated in the construct is associated with potent T-cell activation, proliferation, and effector function. Binding of the CAR to CD19 on B-cells triggers cytolytic activity, resulting in deep and B-cell depletion. This depletion is hypothesized to eliminate the pathogenic B-cell clones and autoantibody-producing plasma cell precursors that sustain autoimmune disease activity, thereby resetting the immune system and enabling sustained clinical remission.

Inpatient Administration of Mivocabtagene autoleucel
Miv-cel is administered as a single intravenous infusion, via a peripheral or central vein, following lymphodepletion. The patient's T-cells are first collected via leukapheresis at an authorized treatment center, then sent to a manufacturing facility for CAR transduction and expansion. Once the manufactured product passes quality release testing, it is shipped back to the treatment center for infusion. Administration may occur in an inpatient hospital or outpatient facility, as clinically appropriate. According to the requestor, no high-grade cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) was observed in the KYSA-8 Phase 2 study as of the applicable data cutoff.

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

XW033C7 Introduction of autologous engineered chimeric antigen receptor T-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7

XW043C7 Introduction of autologous engineered chimeric antigen receptor T-cell immunotherapy into central vein, percutaneous approach, new technology group 7

Coding Options

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

Option 2. In section X New Technology table XW0, Introduction, Anatomical Regions, create new substance value H Mivocabtagene Autoleucel, applied to the body part values 3 Peripheral Vein and 4 Central Vein, with the percutaneous approach, to identify the intravenous administration of mivocabtagene 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 H** Mivocabtagene Autoleucel	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 22 – Administration of anzutresgene autoleucel

Issue: There are no unique ICD-10-PCS codes to describe the administration of anzutresgene autoleucel (anzu-cel). An October 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. Anzutresgene autoleucel (anzu-cel), previously called IMA203, received Orphan Drug Designation, as well as Regenerative Medicine Advanced Therapy (RMAT) Designation, from the FDA for the treatment of both cutaneous and uveal melanoma. Anzu-cel is currently being evaluated in a prospective, multicenter, open-label, randomized, actively controlled, parallel-group Phase 3 clinical trial (NCT06743126) to evaluate the efficacy, safety and tolerability of treatment in patients with previously treated, unresectable or metastatic cutaneous melanoma who are human leukocyte antigen (HLA)-A*02:01 positive.

Background: Melanoma is an immunogenic cancer characterized by a high likelihood of metastasizing; and is projected to increase over time. The rate of new cases of melanoma has more than doubled in the last 30 years. According to the Surveillance, Epidemiology, and End Results (SEER) Program, cutaneous melanoma has an estimated lifetime risk of 2.1%.[1] While there were about 38,000 projected metastatic melanoma patients in the United States in 2025, it is estimated about 40% or 15,200 patients express HLA-A∗02:01.[2] Preferentially Expressed Antigen in Melanoma (PRAME) is a tumor-associated cancer-testis antigen that plays a critical role in inhibiting retinoic acid signaling, which is essential for cell differentiation and proliferation. PRAME is an intracellular target with mRNA correlated with nuclear expression.[3] According to the requestor, it is homogenously overexpressed in multiple tumor types, including melanoma and is associated with more aggressive tumor phenotypes, positioning PRAME as both a potential diagnostic and prognostic marker.

Immune checkpoint inhibitors are the most commonly selected first-line systemic treatment for patients with advanced melanoma based on their improved survival outcomes over historical treatments. Following immune checkpoint inhibition failure, there is no clear standard treatment, and effective and tolerable options are limited. Additional checkpoint inhibition-based therapy can result in durable remissions, but response rates are low.[4] While checkpoint inhibition has improved outcomes in solid tumors, targets have largely been restricted to cell surface targets. However, potential therapeutic targets can also originate from inside the cell. T-cell receptor (TCR) based interventions, a type of immunotherapy that uses a patient's own immune cells, enable recognition of intracellular tumor antigens presented by HLA on cancer cells, expanding the therapeutic potential of cell therapy to include intracellular targets. In TCR T-cell therapy, T-

[1] Global cancer observatory. Melanoma of the skin fact sheet, pp Accessed Feb 2, 2025
[2] Gallicchio L, Devasia TP, Tonorezos E, Mollica MA, Mariotto A. Estimation of the Number of Individuals Living with Metastatic Cancer in the United States. J Natl Cancer Inst. 2022 Nov 14;114(11):1476-1483. doi: 10.1093/jnci/djac158. PMID: 35993614; PMCID: PMC9949565.
[3] Britten CM, Araujo DM, Backert L, et al: The PRAME opportunity – high peptide copy numbers, homogenous expression and high prevalence to address a broad patient population across different solid cancers with TCR-based therapeutics. J Immunother Cancer 10:A1-A1603 (abstract 713), 2022
[4] Ribas A, Puzanov I, Dummer R, et al: Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE-002): a randomised, controlled, phase 2 trial. Lancet Oncol 16:908-18, 2015

cells are obtained via leukapheresis, modified in the lab to better recognize and attack cancer cells, grown in the lab to increase their numbers, and then infused back into the patient.

Mechanism of Action
Anzu-cel is an investigational autologous T-cell receptor (TCR) T-cell therapy designed precisely target the PRAME gene, and to direct a patient's own immune system to recognize and eliminate melanoma cells. In this approach, T-cells are collected from the patient and genetically modified to express a TCR that is optimized to recognize the cancer-associated antigen intracellular PRAME-derived peptides when it is presented on the cell surface by the HLA-A02:01 molecule. PRAME-derived peptides are processed intracellularly and presented on tumor cell surface HLA molecules, thereby enabling immune targeting beyond surface restricted therapies.

After the engineered T-cells are expanded and infused back into the patient, the modified TCR binds specifically to the PRAME/HLA-A02:01 complex on melanoma cells, triggering T-cell activation. This activation leads the T-cells to attack and kill the cancer cells in a manner similar to how they would respond to an infected cell, with the intent of providing a targeted, one-time cellular immunotherapy for patients with melanoma.

Unlike targeted therapy or checkpoint inhibitors that require continuous administration until disease progression or toxicity, anzu-cel is administered as a one-time infusion. According to the requestor, the phase 1a dose-escalation study reported that a formal maximum tolerated dose of anzu-cel was not reached and the highest dose level of 1-10×109 total transduced CD8+ TCR-T cells was selected for further clinical development. The most frequent treatment-emergent adverse events were anticipated cytopenias associated with lymphodepletion. Expected and manageable cytokine release syndrome (CRS) was mostly Grades 1 and 2, which is consistent with the mechanism of action. No patients experienced long-term CRS. Immune effector cell-associated neurotoxicity syndrome (ICANS) occurred infrequently, was manageable and mostly mild.[5]

Inpatient Administration of Anzutresgene Autoleucel
Anzu-cel is given as a single intravenous infusion administered through the central or peripheral vein. Patients are preconditioned with non-myeloablative lymphodepleting chemotherapy (fludarabine and cyclophosphamide) given daily for four days from days -6 to -3, then receive an intravenous infusion of 1 to 10×10^9 autologous anzu-cel CD8+ TCR T cells on day 0. Low-dose, subcutaneous interleukin-2 (IL-2) (1 million IU/dose) is given about 24 hours post anzu-cel infusion, daily until day 5, and twice daily for the following five days. Individual modifications of IL-2 are allowed [per study protocol] based on observed toxicity at the investigator's discretion.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of anzutresgene autoleucel (anzu-cel). Facilities can report the intravenous administration of anzutresgene autoleucel (anzu-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

[5] Davar, et al, Oral Presentation, ASCO 2026. Abstract 9508

Coding Options

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

Option 2. In section X table XW0, Introduction of Anatomical Regions, create new substance value K Anzutresgene Autoleucel, applied to the body part values 3 Peripheral Vein and 4 Central Vein and the percutaneous approach, to identify the intravenous administration of anzutresgene 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 K** Anzutresgene Autoleucel	**D** New Technology Group 13

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 23 – Administration of imlifidase

Issue: There are no unique ICD-10-PCS codes to describe the administration of imlifidase. An April 1, 2027 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. Imlifidase was granted Orphan Drug Designation from the FDA in 2015 for the prevention of antibody mediated organ rejection in solid organ transplant patients and in 2018 for the treatment of Guillain-Barré Syndrome (GBS) and anti-glomerular basement membrane (anti-GBM) disease. Imlifidase was evaluated in an open-label, controlled, randomized Phase 3 trial evaluating 12-month kidney function in highly sensitized (calculated panel reactive antibodies (cPRA) ≥99.9%) adult kidney transplant patients with positive crossmatch against a deceased donor, comparing desensitization using imlifidase with standard of care. The target Prescription Drug User Fee Act (PDUFA) date is December 19, 2026.

Background: Chronic kidney disease (CKD) is defined as the presence of kidney damage (usually detected as urinary albumin excretion of ≥30 mg/day or equivalent) or decreased kidney function (defined as estimated glomerular filtration rate [eGFR] <60 mL/min/1.73 m^2) for three or more months, irrespective of the cause. The persistence of the damage or decreased function for at least three months is necessary to distinguish CKD from acute kidney injury (AKI). The staging of CKD according to cause, glomerular filtration rate (GFR), and albuminuria, helps to guide management, including stratification of risk for progression and complications. End-stage renal disease (ESRD), or kidney failure, is the final, permanent stage of CKD. It occurs when kidneys lose 85% to 90% of their function. Once a patient has reached the stage of ESRD (eGFR <15 mL/min/1.73 m2), signs and symptoms related to uremia begin to occur, such as malnutrition, anorexia, nausea, vomiting, fatigue, sexual dysfunction, platelet dysfunction, pericarditis, and neuropathy.

Kidney transplantation is the treatment of choice for ESRD. A successful kidney transplant improves the quality of life and reduces the mortality risk for most patients when compared with maintenance dialysis. Based on the 2025 United States Renal Data System Annual Data Report, ESRD patients on dialysis have a mortality rate 3.4 times higher than those who received a kidney transplant.[1] However, not all patients are appropriate candidates for a kidney transplant. A significant portion of patients on kidney transplant waiting lists have preformed anti-human leukocyte antigen (HLA) antibodies against potential donor tissues due to prior exposure to foreign antigens (e.g., pregnancy, blood transfusion, or previous transplants).[2] The presence of donor-specific antibodies (DSA) is either an absolute or relative contraindication to transplantation, depending on the specificity, breadth and strength of the antibody response,

[1] United States Renal Data System. 2025 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2025.
[2] Huang, E., & Jordan, S. C. (2026). Kidney transplantation in adults: HLA-incompatible transplantation. In A. Q. Lam (Ed.), UpToDate. Retrieved from UpToDate Kidney Transplantation

which means patients with a wide range of anti-HLA antibodies face extreme difficulty in finding compatible donors. If not adequately suppressed, the presence of such antibodies is likely to result in antibody-mediated rejection (ABMR) and early graft loss.

Several reports have documented the benefits of desensitization for improving access to transplantation and enhancing long-term patient survival compared to dialysis.[3,4] However, current therapies are often incomplete, especially for those in the highest cPRA categories. Recent data reflect that patients with cPRA ≥99.9% have the longest waiting time and the lowest rate of deceased donor transplantation; in this group, more patients die or are removed from the waiting list than are transplanted. Current transplant center specific experimental desensitization protocols aimed at removing donor-specific antibodies (DSA) show variable efficacy and are inefficient, taking days to weeks to reduce DSA levels, and rarely reduce DSA to a level consistent with crossmatch conversion to proceed with transplantation. Overall, these multifaceted and multimodal interventions have not consistently produced clinically meaningful reduction in DSA among highly sensitized patients. Consequently, patients with cPRA ≥99.9% represent a population with significant unmet medical need for efficient therapies that reduce DSA and enable access to deceased donor kidney transplantation.

Mechanism of Action
Imlifidase is an investigational cysteine protease enzyme, derived from the Immunoglobulin G (IgG)-degrading enzyme of *Streptococcus pyogenes,* that cleaves the heavy chains of all human IgG subclasses but no other immunoglobulins. The cleavage of IgG leads to elimination of Fc-dependent effector functions, including complement dependent cytotoxicity (CDC), antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody dependent cell-mediated phagocytosis (ADCP). IgG of the B-cell receptor complex is also cleaved by imlifidase, resulting in a subset of B-cells temporarily incapable of responding to their antigen. By cleaving all IgG, imlifidase inactivates donor-specific antibodies (DSA) to a level consistent with crossmatch conversion to enable HLA-incompatible kidney transplantation.

According to the requestor, the most frequent adverse events (AEs) seen in the developmental program for imlifidase likely reflect typical post-transplant complications and AEs associated with current post-operative immunosuppressive practice. In pooled safety analysis of 78 transplanted patients who received at least one dose of imlifidase in completed clinical trials (including Phase 2 trials and the Phase 3 ConfIdeS trial - NCT04935177), the following adverse reactions occurred in ≥2% of transplanted patients: urinary tract infection (4%), anemia (4%), infusion-related reaction (3%), hyperglycemia (3%), hypomagnesemia (3%), and hypophosphatemia (3%).

Inpatient Administration of Imlifidase
Imlifidase is given as an intravenous infusion administered through central or peripheral vein over a period of 15 minutes, generally 24 hours prior to kidney transplantation. The dose of imlifidase is based on patient body weight (kg). The recommended dose of imlifidase is 0.25

[3] Orandi BJ, Luo X, Massie AB, et al. Survival Benefit with Kidney Transplants from HLA-Incompatible Live Donors. N Engl J Med. 2016;374:940-950. 10.1056/NEJMoa1508380
[4] Montgomery RA, Lonze BE, King KE, et al. Desensitization in HLA-incompatible kidney recipients and survival. N Engl J Med. 2011;365:318-326. 10.1056/NEJMoa1012376

mg/kg administered as a single dose. A second dose may be administered within 24 hours of the first dose, if the first is considered not to have had sufficient effect.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of imlifidase. Facilities can report the intravenous administration of imlifidase 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 imlifidase. Continue as described in current coding.

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

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 J** Imlifidase	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.