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 Meeting
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Virtual Meeting
ICD-10-PCS Topics
September 12, 2023

Zoom Webinar and Dial-In Information

- This meeting will be conducted via Zoom Webinar. The URL to register to join the Zoom Webinar, the password, and the call-in numbers are the same for both days of the meeting. Meeting details for each day are as follows.
- Day 1: September 12, 2023: The meeting will begin promptly at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 12:30 PM to 1:30 PM.
- Day 2: September 13, 2023: The meeting will begin promptly at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 12:30 PM to 1:30 PM.

To minimize feedback to the maximum extent possible, join the meeting using only **ONE** of the options listed below.

Option 1: Remote participants (attendees wishing to both view slides and ask questions during the Q&A portions of the meeting) must register to join the Zoom Webinar via the web. To register to join this Zoom Webinar conference from a PC, MAC, iPad, iPhone or Android device as well as, connect to the audio portion of the conference:

Register in advance for this webinar:
https://cms.zoomgov.com/webinar/register/WN_lWLKuwKzQU6iJdvcDvXhdA
Webinar ID: 161 356 3434
Passcode: 037932

Option 2: Dial-in access is available for listen-only participants. Listen-only participants are participants who wish to only listen to the meeting and do not wish to comment or ask questions during the Q&A portions of the meeting.

1. From your phone, dial U.S.*: 669-254-5252 or 646-828-7666 or 833-568-8864 (Toll Free)
2. Enter the webinar ID: 161 356 3434

*If dialing in from outside of the U.S., visit https://cms.zoomgov.com/u/aZ1cD8cLy for a list of Zoom International Dial-in Numbers.

Option 3: To join this Zoom Webinar conference from an H.323/SIP room system:

1. From your room system, dial 161.199.138.10 (US West) or 161.199.136.10 (US East)
2. Enter the webinar ID: 161 356 3434
   Passcode: 037932

SIP: 1613563434@sip.zoomgov.com
Passcode: 037932

If you experience technical difficulties during the meeting, please contact Marvelyn Davis for assistance at marvelyn.davis1@cms.hhs.gov or 410-786-2580 Option 7.

Those participating in the Zoom Webinar may ask questions during the Q&A portions of the meeting using the "Raise Hand" feature. If time does not permit you to comment or ask a question during the Q&A session, you may submit comments and questions at any time using the "Q&A" feature. All comments and questions submitted using the "Q&A" feature, along with CMS's responses to them, will be posted as soon as possible after the meeting in the "Downloads" section of the CMS web page located at: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials. Remaining questions may be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov.

Note: Proposals for diagnosis code topics will be led by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and are scheduled to begin following completion of the CMS procedure code proposals on September 12, 2023. Remaining diagnosis code topics will continue to be presented on September 13, 2023. Please visit CDC's website for the Diagnosis agenda located at the following address: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm.

If you require reasonable accommodation with an interpreter, please contact Mady Hue at marilu.hue@cms.hhs.gov or Andrea Hazeley at andrea.hazeley@cms.hhs.gov at least 72 hours prior to the event.

For questions about the registration process, please contact Mady Hue at marilu.hue@cms.hhs.gov or Andrea Hazeley at andrea.hazeley@cms.hhs.gov.

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

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2. A new subscriber screen will appear. Confirm your primary email address.
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5. Check privacy box confirming your consent to our data privacy. Additional information on our data privacy policy can be found at www.cms.gov/privacy.
6. You should receive a SUCCESS message that states (your email address) has been successfully subscribed to ICD-10 Coordination and Maintenance
7. Click on the Finish button at bottom of screen.
8. You should now be on the Welcome Quick subscribe page. You can subscribe to receive information from a list of topics of your choice from our partner organizations by checking the boxes; unsubscribe by unchecking the boxes.
9. Scroll down to the bottom of the page. Check the data privacy policy box and click on Submit. Additional information on our data privacy policy can be found at www.cms.gov/privacy.
10. You should have now reached the SUCCESS page confirming that you have been successfully subscribed. Click on Finish.

Topics Being Considered for ICD-10-PCS Procedure Codes

Introductions & Overview 9:00 AM – 9:10 AM	Mady Hue, CMS Co-Chair, ICD-10 Coordination and Maintenance Committee
ICD-10-PCS Topics:	
1. Irreversible Electroporation for Cardiac Ablation** Pages 14-16 9:10 AM – 9:25 AM	Mady Hue, CMS Birce Onal, PhD Principal Clinical Research Specialist Medtronic Amy Palatiello Director, Reimbursement Medtronic
2. Computer-aided Anesthesia and Oxygen Delivery System*** Pages 17-19 9:25 AM – 9:40 AM	Jeanine DuVerney, CMS John W. Beard, MD Chief Medical Officer Patient Care Solutions, GE HealthCare Mary Erslon, RN, MS Principal Mary Erslon, LLC
3. Section X Updates Pages 20-29 9:40 AM – 9:55 AM	Jeanine DuVerney, CMS
4. Insertion of Palladium-103 Radioactive Implant* Pages 30-32 9:55 AM – 10:10 AM	Mady Hue, CMS David Brachman, MD Chief Technology Officer GT Medical Technologies
5. Introduction of Bone Void Filler*** Pages 33-35 10:10 AM – 10:25 AM	Mady Hue, CMS Tanner Howe President and CEO AgNovos™ Healthcare James Howe, MD Founder and Chief Medical Officer AgNovos™ Healthcare

6.	Electrical Biocapacitance for Assessment of Pressure Injuries** Pages 36-38 10:25 AM – 10:40 AM	Jeanine DuVerney, CMS Martin Burns CEO Bruin Biometrics, LLC William Padula, PhD Assistant Professor Department of Pharmaceutical and Health Economics, USC School of Pharmacy
7.	Addenda and Key Updates* Pages 39-51 10:40 AM – 10:55 AM	Andrea Hazeley, CMS

Therapeutic Agent Topics Also Under Consideration for ICD-10-PCS Codes[1]

8.	Administration of Iodine (^{131}I)-apamistamab (^{131}I-apamistamab)** Pages 52-54	Jeanine DuVerney, CMS
9.	Administration of Talquetamab** Pages 55-57	Jeanine DuVerney, CMS

** Request is for an April 1, 2024 implementation date.*
***Request is for an April 1, 2024 implementation date and the requestor intends to submit an NTAP application for FY 2025 consideration.*
****Requestor intends to submit an NTAP application for FY 2025 consideration.*

[1] *NTAP-related ICD-10-PCS procedure code requests that involve the administration of a therapeutic agent will not be presented at the virtual meeting. The slide presentations for these procedure code topics are available at:* https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.

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

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

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

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

Contact Information
Comments on the procedure code proposals presented at the ICD-10 Coordination and Maintenance Committee meeting should be sent to the following email address: ICDProcedureCodeRequest@cms.hhs.gov

Mady Hue
Marilu.Hue@cms.hhs.gov

Andrea Hazeley
Andrea.Hazeley@cms.hhs.gov

Jeanine DuVerney
Jeanine.DuVerney@cms.hhs.gov

ICD-10 TIMELINE

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

September 12-13, 2023	The September 2023 ICD-10 Coordination and Maintenance Committee Meeting will be held virtually by Zoom Webinar.
September 2023	Recordings and slide presentations of the September 12-13, 2023 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
October 1, 2023	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/Comprehensive-Listing-of-ICD-10-CM-Files.htm **Procedure addendum –** https://www.cms.gov/Medicare/Coding/ICD10/
October 13, 2023	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 12-13, 2023 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2024.**
November 2023	Any new ICD-10 codes that will be implemented the following April 1 will be announced. Information on any new codes to be implemented April 1, 2024 will be posted on the following websites: https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm https://www.cms.gov/Medicare/Coding/ICD10/Latest_News
November 15, 2023	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 12-13, 2023 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2024.**

December 1, 2023	**Deadline for requestors: Those members of the public requesting that topics be discussed at the March 19-20, 2024 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and to NCHS for diagnoses by this date.** **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, 2024 implementation date, or an April 1, 2025 implementation date. The ICD-10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an October 1, 2024 implementation date or an April 1, 2025 implementation date.
January 2024	Federal Register notice for the March 19-20, 2024 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
February 2024	Tentative agenda for the Procedure portion of the March 19, 2024 ICD-10 Coordination and Maintenance Committee Meeting posted on CMS webpage at: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis portion of the March 20, 2024 ICD-10 Coordination and Maintenance Committee Meeting posted on NCHS homepage at: https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm
February 1, 2024	ICD-10 MS-DRG Grouper software and related materials posted on CMS webpage at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software
February 1, 2024	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/Comprehensive-Listing-of-ICD-10-CM-Files.htm https://www.cms.gov/Medicare/Coding/ICD10/

February 1, 2024	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/Comprehensive-Listing-of-ICD-10-CM-Files.htm https://www.cms.gov/Medicare/Coding/ICD10/
March 19-20, 2024	The ICD-10 Coordination and Maintenance Committee Meeting is anticipated to be fully virtual by zoom and dial-in. Those who wish to attend must participate via Zoom Webinar or by dialing in.
March 2024	Recordings and slide presentations of the March 19-20, 2024 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
April 1, 2024	Any new or revised ICD-10 codes will be implemented on April 1, 2024.
April 19, 2024	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 19-20, 2024 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2024**.
April 2024	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This notice will include references to the FY 2025 ICD-10-CM diagnosis and ICD-10-PCS procedure codes finalized to date. It will also include proposed revisions to the MS-DRG system based on ICD-10-CM/PCS codes on which the public may comment. The proposed rule can be accessed at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps
May 17, 2024	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 19-20, 2024 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2025.** **Deadline for receipt of public comments on proposed new diagnosis codes and revisions discussed at the March 19-20, 2024**

	ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2025.
May/June 2024	Final addendum posted on web pages as follows: **Diagnosis addendum -** https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm **Procedure addendum -** https://www.cms.gov/Medicare/Coding/ICD10/index.html
June 7, 2024	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 10-11, 2024 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.** Requestors should indicate if they are submitting their code request for consideration for an April 1, 2025 implementation date or an October 1, 2025 implementation date. The ICD-10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an April 1, 2025 implementation date or an October 1, 2025 implementation date.
July 2024	Federal Register notice for the September 10-11, 2024 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
August 1, 2024	Hospital Inpatient Prospective Payment System final rule expected to be published in the Federal Register as mandated by Public Law 99-509. This rule will also include links to all the final codes to be implemented on October 1, 2024. This rule can be accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html
August 2024	Tentative agenda for the Procedure portion of the September 10, 2024 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the CMS webpage at – https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis portion of the September 11, 2024 ICD-10 Coordination and Maintenance Committee Meeting

	will be posted on the NCHS webpage at - https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm
September 10-11, 2024	The September 2024 ICD-10 Coordination and Maintenance Committee Meeting is anticipated to be fully virtual by zoom and dial-in. Those who wish to attend must participate via Zoom Webinar or by dialing in.
September 2024	Recordings and slide presentations of the September 10-11, 2024 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
October 1, 2024	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/Comprehensive-Listing-of-ICD-10-CM-Files.htm **Procedure addendum –** https://www.cms.gov/Medicare/Coding/ICD10/
October 11, 2024	**Deadline for receipt of public comments on proposed new codes discussed at the September 10-11, 2024 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2025.**
November 2024	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, 2025 will be posted on the following websites: https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm https://www.cms.gov/Medicare/Coding/ICD10/Latest_News
November 13, 2024	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 10-11, 2024 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2025.**

Introductions and Overview

- ICD-10 Coordination & Maintenance (C&M) Committee meeting is a public forum on ICD-10-CM & ICD-10-PCS code updates
- CMS & CDC Co-chair the meetings
  - CMS has lead responsibility on procedure issues
  - CDC has lead responsibility on diagnosis issues
- Coding proposals requested by the public are presented and public given opportunity to comment

Code Proposals

- ICD-10-PCS code proposals being considered for implementation on April 1, 2024 and October 1, 2024
- No final decisions are made at the meeting
- CMS will describe options and recommendations to facilitate discussion
- Public can comment during the meeting and send written comments

Comments on Code Proposals

- Submit written comments by
  - October 13, 2023 for codes being considered for April 1, 2024 implementation
  - November 15, 2023 for codes being considered for October 1, 2024 implementation
- Procedure comments to CMS: ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to NCHS: nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2023 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2023 C&M meeting

- August 2023 – Final rule with links to final codes to be implemented October 1, 2023
  - Includes any additional codes approved from March 7-8, 2023 C&M meeting
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS

Addendum

- May/June 2023 – Final code updates and addendum posted
  - FY 2024 ICD-10-PCS (Procedures)
    https://www.cms.gov/medicare/coding/icd10
  - FY 2024 ICD-10-CM (Diagnoses)
    https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm

Public Participation

- For this virtual meeting, the public may participate in the following ways:
  - Participate via Zoom Webinar
  - Listen to proceedings through free conference lines
  - Listen to recordings and view slide presentations

- CMS & CDC hope this provides greater opportunity for public participation

Written Comments

- No matter how you participate – please send written comments by
  - October 13, 2023 for codes being considered for April 1, 2024 implementation
  - November 15, 2023 for codes being considered for October 1, 2024 implementation
  - Procedure comments to CMS: ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis comments to NCHS: nchsicd10cm@cdc.gov

ICD-10-PCS Codes Implementation

- ICD-10-PCS codes discussed today under consideration for April 1, 2024 or October 1, 2024 implementation

March 19-20, 2024 C&M Code Requests

- December 1, 2023 – Deadline for submitting topics for March 19-20, 2024 C&M meeting
  - Procedure requests to CMS: https://mearis.cms.gov
  - Diagnosis requests to NCHS: nchsicd10cm@cdc.gov

Topic # 01 – Irreversible Electroporation for Cardiac Ablation

Issue: There are no unique ICD-10-PCS codes to describe irreversible electroporation of tissue of the heart and great vessels. An April 1, 2024 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-On Payment (NTAP) application for FY 2025 consideration.

Food & Drug Administration (FDA) Approval? No. According to the requestor, PMA approval for the PulseSelect™ Pulsed Field Ablation (PFA) System (Medtronic, Inc.) for the treatment of paroxysmal (PAF) or persistent (PsAF) atrial fibrillation is anticipated in the first half of 2024. The PulseSelect™ PFA technology received FDA Breakthrough Device designation for the treatment of atrial fibrillation in September 2018.

Background: In a normal heartbeat, the sinoatrial node in the right atrium generates a single electrical impulse. The atria contract and push blood into the ventricles, which contract in response to the normal propagation of the single impulse through the atrioventricular node. Ventricular contraction pushes blood out to the lungs and the rest of the body. In atrial fibrillation, electrical impulses generate from multiple sites in both atria. The atria contract irregularly and much faster, becoming out of sync with the ventricles. Blood is retained in the atria and may form clots, leading to increased risk of stroke.

Irreversible electroporation for cardiac ablation, also referred to as pulsed field ablation, is used to perform pulmonary vein isolation as a treatment for atrial fibrillation. The function of the pulmonary veins is to carry newly re-oxygenated blood from the lungs back to the heart, emptying into the left atrium. However, the pulmonary veins may generate aberrant impulses that contribute to atrial fibrillation. To disrupt the aberrant signals, pulmonary vein isolation is performed within the left atrium by ablating the tissue surrounding the openings of the four pulmonary veins. Conventionally, pulmonary vein isolation uses thermal energy, specifically radiofrequency and cryotherapy. Thermal energy is effective in ablating the cardiac tissue but also carries a known risk of significant complications, including esophageal injury, phrenic nerve damage, and pulmonary vein stenosis. Irreversible electroporation is an alternative to thermal energy sources. Ablation of tissue by irreversible electroporation is not a new technique and is currently used in other body systems, for example to treat hepatic and pancreatic cancer. However, its use in the heart to treat arrhythmias is more recent.

Technology

Irreversible electroporation is non-thermal. Electrical pulses are delivered resulting in destruction of the selected tissue by irreversibly increasing the porosity of the cell membranes, inducing cell death with an apoptosis-like effect. Myocardial cells are particularly susceptible to this effect while surrounding cells in nearby tissue, such as the esophagus and phrenic nerve, are believed to be more resistant and less likely to be collaterally injured. A pulsed field ablation application is delivered to tissue in milliseconds and can be repeated to achieve the desired irreversible electroporation.

According to the requestor, the PulseSelect™ PFA System is comprised of the PulseSelect™ PFA generator, PulseSelect™ PFA loop catheter, PulseSelect™ PFA remote control, PulseSelect™ PFA foot switch, power cord, PulseSelect™ PFA catheter interface cable, and

PulseSelect™ PFA EGM cable.

Procedure Description
Pulmonary vein isolation by irreversible electroporation is typically a percutaneous, transvenous procedure. Following peripheral venous access, a sheath is inserted, and a specially designed catheter is advanced into the right atrium of the heart. Transseptal puncture is performed, under guidance from transesophageal or intracardiac echocardiography, and the catheter is then advanced into the left atrium. Pulmonary vein isolation is then initiated with placement of the ablation catheter at the opening of each of the four pulmonary veins within the left atrium. Delivery of the non-thermal energy via the catheter creates a contiguous circumferential lesion around the opening of each pulmonary vein. Multiple applications are delivered to each vein with overlapping rotations of the catheter to achieve full circumferential isolation. The same catheter is used to ablate all four openings of the pulmonary veins. After successful pulmonary vein isolation is verified, the catheter and sheath are removed.

Pulmonary vein isolation is typically a stand-alone procedure. In some cases, it may be preceded by an electrophysiologic study (EPS). An EPS is more likely performed if other arrhythmias are suspected in addition to atrial fibrillation and, in those scenarios, ablations at other sites may also be performed.

In the PULSED AF pivotal trial[1], use of irreversible electroporation to ablate cardiac tissue resulted in a low complication rate of 0.7% in paroxysmal and persistent atrial fibrillation with no esophageal injury, phrenic nerve damage, or pulmonary vein stenosis. Reported complications include one instance of pericardial effusion with cardiac tamponade and one instance of documented cerebrovascular accident.

Current Coding: There are no unique ICD-10-PCS codes to describe irreversible electroporation for cardiac ablation. Code the procedure using the body part value 8 Conduction Mechanism in table 025, Destruction of Heart and Great Vessels, with approach value 3 Percutaneous.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent

Body Part	*Approach*	*Device*	*Qualifier*
4 Coronary Vein **5** Atrial Septum **6** Atrium, Right **8** Conduction Mechanism **9** Chordae Tendineae **D** Papillary Muscle **F** Aortic Valve **G** Mitral Valve **H** Pulmonary Valve **J** Tricuspid Valve **K** Ventricle, Right **L** Ventricle, Left **M** Ventricular Septum	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

[1] Verma A, Boersma L, Haines DE, Natale A, Marchlinski FE, Sanders P, Calkins H, Packer DL, Hummel J, Onal B, Rosen S, Kuck KH, Hindricks G, Wilsmore B. First-in-Human Experience and Acute Procedural Outcomes Using a Novel Pulsed Field Ablation System: The PULSED AF Pilot Trial. Circ Arrhythm Electrophysiol. 2022 Jan;15(1): e010168. doi: 10.1161/CIRCEP.121.010168. Epub 2021 Dec 29. PMID: 34964367; PMCID: PMC8772438.

N Pericardium **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava **W** Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch			

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify irreversible electroporation for cardiac ablation. Continue coding as described in current coding.

Option 2. In table 025, Destruction of Heart and Great Vessels, add qualifier value F Irreversible Electroporation, applied to the body part value 8 Conduction Mechanism and the approach value 3 Percutaneous, to identify irreversible electroporation for cardiac ablation.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent

Body Part	*Approach*	*Device*	*Qualifier*
8 Conduction Mechanism	**3** Percutaneous	**Z** No Device	**ADD F** Irreversible Electroporation **Z** No Qualifier

Option 3. In the New Technology section, create new table X25, Destruction of Heart and Great Vessels, with new sixth character technology value G Irreversible Electroporation, applied to the body part value 8 Conduction Mechanism, to identify irreversible electroporation for cardiac ablation.

Section	**X** New Technology
Body System	**2** Heart and Great Vessels
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 8 Conduction Mechanism	**3** Percutaneous	**ADD G** Irreversible Electroporation	**9** New Technology Group 9

CMS Recommendation: Option 2, as described above.

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

Topic # 02 – Computer-aided Anesthesia and Oxygen Delivery System

Issue: There are currently no unique ICD-10-PCS codes to describe computer-aided semi-closed loop delivery and adjustment of inhaled anesthetic agents and oxygen during surgical procedures. The requestor is seeking an October 1, 2024 implementation date.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) Application for FY 2025 consideration.

Food & Drug Administration (FDA) Approval? Yes. End-tidal Control (Et Control) obtained pre-market FDA approval (PMA# P210018) in March 2022 as a Class III software medical device that interfaces with the Datex-Ohmeda Aisys™ CS^2 (GE HealthCare Aisys™ CS^2) anesthesia system to enable the anesthesia clinician to perform semi-closed loop delivery of inhaled anesthetic agents and oxygen during surgical procedures. The Et Control feature is indicated for use with patients 18 years of age and older.

Background: Every year, millions of patients have surgery under general anesthesia with inhaled anesthetics. While administration of inhaled anesthetics is generally safe, there are risks associated with inhalational anesthesia arising from the predictable physiologic effects of the agents on the human body. Inhaled anesthesia is associated with both vasodilation and reduced myocardial contractility, which may lead to hypotension in susceptible patient populations. Populations at risk may include those with cardiac abnormalities or hypertension, which have increased prevalence in the aging population. Risks associated with over-administration of anesthetics include hypotension, which may result in patient harm from ischemia arising most rapidly from organs with the highest blood flow and oxygen requirements, such as the brain and heart. Under-administration of anesthetics is also associated with potential problematic health outcomes. Lower than required levels of anesthesia may lead to awareness under anesthesia or surgical recall. In addition, inadequate levels of anesthesia may contribute to increased physiologic response to surgical stimulation which may result in hypertension, tachycardia, and increased oxygen demand which could stress the hearts of patients with coronary artery disease.

Per the requestor, thousands of surgical procedures performed under general anesthesia with inhaled anesthetics may benefit from computer-aided, semi-closed loop delivery and adjustment of inhaled anesthetic agents and oxygen. Currently, administration of inhaled anesthetics during surgical procedures requires placement of a controlled airway (e.g., endotracheal tube). Anesthesia providers use anesthesia machines to adjust gas flows to deliver inhaled anesthetics and oxygen through a controlled airway based on patient need and provider-set determination of inhaled gas concentrations, which simultaneously provide sufficient oxygen for metabolic requirements and a level of anesthetic to ensure unconsciousness and immobility. During anesthesia delivery, the anesthesia provider manually adjusts multiple settings which control the input of anesthetic and fresh oxygen. Through induction, maintenance and emergence from anesthesia, the anesthesia provider continually monitors and manually adjusts settings to optimize the inhaled concentration and flow of oxygen and anesthetic for safe and effective care.

Technology

Et Control is a new software feature integrated into an anesthesia machine to enable an alternative anesthesia delivery procedure: computer-aided, semi-closed loop delivery and adjustment of inhaled anesthetic agents and oxygen. The semi-closed loop delivery requires clinicians to select

clinical targets for the exhaled or "end-tidal" gas concentrations for oxygen while the software automatically adjusts gas and anesthetic inflows through the anesthesia machine, to meet targets from breath exhaled through the secured airway. Per the requestor, compared to inhaled concentrations, exhaled concentrations more closely estimate alveolar, or blood and brain levels, of oxygen and anesthetic, enabling the clinician to better estimate patient oxygen requirements and metabolic demands.

The underlying "fuzzy logic" software of Et Control drives the semi-closed loop titration of oxygen and anesthetic from the anesthesia machine. The delivery system is a semi-closed loop because like manual anesthesia administration, the anesthesia provider is responsible for the judgment, decision-making and therapeutic requirements involved in monitoring the patient and adjusting exhaled targets during the procedure to meet the requirements of care. Per the requestor, differentiation between exhaled settings versus inhaled concentrations to determine exhaled target values, and the ability to respond to software safety alerts, is necessary for safe and effective procedures.

The semi-closed loop delivery system is equipped with multiple automatic safety check mechanisms, including system checks, leak checks of the patient sampling line, and accuracy checks. The anesthesia professional is required to complete FDA-approved user training on the safety checks and fallback gas and anesthetic delivery modes to use during care. While Et Control continuously monitors the status of the anesthesia system for fault conditions, the anesthesia professional monitoring the patient can exit the clinician-guided module at any time via the user interface.

Procedure Description

In an inpatient surgical setting, anesthesia delivery for procedural care typically begins with the manual administration of oxygen to a spontaneously breathing patient and the administration of intravenous medications to induce general anesthesia. The patient's airway is controlled by the placement of an endotracheal tube or laryngeal mask for the delivery of inhaled anesthetics (e.g., desflurane, sevoflurane, or isoflurane). The semi-closed loop delivery and adjustment of inhaled anesthetic agents and oxygen using Et Control during surgical procedures is initiated once placement of the controlled airway is complete.

Prior to the procedure, the anesthesia professional determines the anesthesia care plan, which is defined as the target end-tidal or exhaled concentrations of oxygen and anesthetic agents in addition to total gas flow. Utilizing the Et Control user interface, the provider programs the targeted exhaled gas concentrations of inhaled anesthetic agents and oxygen and the total gas flow. The provider then activates the semi-closed loop software on the anesthesia machine, which switches the machine from manual administration to semi-closed loop delivery and adjustment of inhaled anesthetic agents and oxygen. The anesthesia professional adjusts the exhaled gas targets as needed based on the condition of the patient and the conduct of the surgical procedure.

Computer-aided semi-closed loop delivery and adjustment of inhaled anesthetic agents and oxygen results in continuous monitoring and adjustment of gas flow and anesthetic with each breath to meet concentration and flow targets. As the patient breathes, exhaled gases pass through the controlled airway and into the side stream gas analyzer, through which the software component takes breath-by-breath measurements, compares the measured values from the airway module to

the targeted concentrations, and adjusts or titrates gas composition and anesthetic vaporizers through the anesthesia machine to meet the targets set by the anesthesia professional.

Per the requestor, a patient airway (for example, endotracheal tube or laryngeal mask airway) must be in place and controlled while using Et Control mode. Et Control mode cannot be used with a mask airway. Et Control can be used in vent mode (mechanical ventilation) or bag mode (manual ventilation) if a patient airway is in place and ventilation meets the patient gas demand.

Current Coding: The use of a computer-aided anesthesia and oxygen delivery system is not reported separately for inpatient hospital coding. Facilities can report the administration of anesthesia using the following code:

3E0F7BZ	Introduction of anesthetic agent into respiratory tract, via natural or artificial opening

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the administration of inhaled anesthetics and oxygen using a computer-aided delivery system. Continue coding as listed in current coding.

Option 2. Create a new code in section X, New Technology, to identify the administration of inhaled anesthetics and oxygen using a computer-aided delivery system.

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*
ADD F Respiratory Tract	**7** Via Natural or Artificial Opening	**ADD 1** Inhaled Anesthetics and Oxygen, Computer-aided Adjustment of Concentration and Flow	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 03 - Section X Update
September 2023 ICD-10 Coordination and Maintenance Committee Meeting

For this September 2023 meeting we will be sharing our analysis results for the Group 5 section X Codes from FY 2020, 2021, and 2022. At the March 2024 meeting we will share an updated analysis to include the results for the Group 5 section X codes for FY 2023, along with the CMS recommendation.

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

- Was the procedure code related to a new technology add-on payment application (NTAP)?
- If yes, was the technology approved for the NTAP?
- What is the frequency (total number of cases) of this procedure code as reported in the 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)
    2. Reassign the code to the Med/Surg or other section of ICD-10-PCS and delete from Section X (e.g., NTAP has expired, data analysis and clinical review justifies incorporating this technology/procedure into the main Med/Surg section)
    3. Delete the Section X code (e.g., the procedure is not reported as anticipated in the data, therefore the absence of a unique code for this technology/procedure in the classification has minimal impact)
    4. Create a new code in Med/Surg or other section of ICD-10-PCS and delete the code from Section X. (e.g., NTAP has expired, data analysis and clinical review justifies uniquely identifying the technology in the Med/Surg section)

Section X – September 2023 Update
Group 5

ICD-10-PCS Code	Code Description	FY 2020		FY 2021		FY 2022		FY 2023				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
X27H385	Dilation of right femoral artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	173	NO	249	YES	277	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27H395	Dilation of right femoral artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	35	NO	61	YES	57	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27H3B5	Dilation of right femoral artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	30	NO	33	YES	27	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27H3C5	Dilation of right femoral artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	6	NO	13	YES	10	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27J385	Dilation of left femoral artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	165	NO	270	YES	237	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27J395	Dilation of left femoral artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	45	NO	66	YES	79	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27J3B5	Dilation of left femoral artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	22	NO	30	YES	35	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27J3C5	Dilation of left femoral artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	3	NO	10	YES	17	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27K385	Dilation of proximal right popliteal artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	45	NO	57	YES	67	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System

ICD-10-PCS Code	Code Description	FY 2020		FY 2021		FY 2022		FY 2023				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
X27K395	Dilation of proximal right popliteal artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	6	NO	9	YES	9	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27K3B5	Dilation of proximal right popliteal artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	0	NO	0	YES	3	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27K3C5	Dilation of proximal right popliteal artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	0	NO	1	YES	0	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27L385	Dilation of proximal left popliteal artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	49	NO	69	YES	61	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27L395	Dilation of proximal left popliteal artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	5	NO	7	YES	4	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27L3B5	Dilation of proximal left popliteal artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	3	NO	0	YES	1	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27L3C5	Dilation of proximal left popliteal artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	1	NO	1	YES	1	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27M385	Dilation of distal right popliteal artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	33	NO	52	YES	59	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27M395	Dilation of distal right popliteal artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	9	NO	5	YES	5	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System

ICD-10-PCS Code	Code Description	FY 2020		FY 2021		FY 2022		FY 2023				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
X27M3B5	Dilation of distal right popliteal artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	2	NO	3	YES	1	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27M3C5	Dilation of distal right popliteal artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	0	NO	0	YES	0	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27N385	Dilation of distal left popliteal artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	45	NO	74	YES	44	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27N395	Dilation of distal left popliteal artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	5	NO	4	YES	3	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27N3B5	Dilation of distal left popliteal artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	1	NO	2	YES	4	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27N3C5	Dilation of distal left popliteal artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	3	NO	0	YES	0	YES		NO		TBA at March meeting	Eluvia™ Drug-Eluting Vascular Stent System
X27P385	Dilation of right anterior tibial artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	14	NO	19	NO	20	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27P395	Dilation of right anterior tibial artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	3	NO	3	NO	1	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27P3B5	Dilation of right anterior tibial artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	2	NO	0	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System

ICD-10-PCS Code	Code Description	FY 2020		FY 2021		FY 2022		FY 2023				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
X27P3C5	Dilation of right anterior tibial artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	1	NO	0	NO	2	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27Q385	Dilation of left anterior tibial artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	23	NO	23	NO	19	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27Q395	Dilation of left anterior tibial artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	3	NO	5	NO	1	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27Q3B5	Dilation of left anterior tibial artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	1	NO	0	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27Q3C5	Dilation of left anterior tibial artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	2	NO	0	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27R385	Dilation of right posterior tibial artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	9	NO	14	NO	13	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27R395	Dilation of right posterior tibial artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	4	NO	1	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27R3B5	Dilation of right posterior tibial artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	0	NO	0	NO	1	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27R3C5	Dilation of right posterior tibial artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	1	NO	0	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System

ICD-10-PCS Code	Code Description	FY 2020		FY 2021		FY 2022		FY 2023				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
X27S385	Dilation of left posterior tibial artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	15	NO	11	NO	5	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27S395	Dilation of left posterior tibial artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	1	NO	2	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27S3B5	Dilation of left posterior tibial artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	0	NO	0	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27S3C5	Dilation of left posterior tibial artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	0	NO	1	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27T385	Dilation of right peroneal artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	14	NO	8	NO	8	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27T395	Dilation of right peroneal artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	2	NO	1	NO	1	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27T3B5	Dilation of right peroneal artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	0	NO	1	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27T3C5	Dilation of right peroneal artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	0	NO	0	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27U385	Dilation of left peroneal artery with sustained release drug-eluting intraluminal device, percutaneous approach, new technology group 5	9	NO	8	NO	6	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27U395	Dilation of left peroneal artery with two sustained release drug-eluting intraluminal	1	NO	1	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System

ICD-10-PCS Code	Code Description	FY 2020		FY 2021		FY 2022		FY 2023				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
	devices, percutaneous approach, new technology group 5											
X27U3B5	Dilation of left peroneal artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	0	NO	0	NO	0	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X27U3C5	Dilation of left peroneal artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, new technology group 5	0	NO	1	NO	1	NO		NO		TBA at March meeting	SAVAL™ Drug-Eluting Vascular Stent System
X2A6325	Cerebral embolic filtration, single deflection filter in aortic arch, percutaneous approach, new technology group 5	167	NO	134	NO	125	NO		NO		TBA at March meeting	Keystone Heart TriGuard 3™ Cerebral Embolic Protection Device
XT25XE5	Monitoring of kidney using fluorescent pyrazine, external approach, new technology group 5	2	NO	1	NO	0	NO		NO		TBA at March meeting	Transdermal GFR Measurement System
XW013F5	Introduction of other new technology therapeutic substance into subcutaneous tissue, percutaneous approach, new technology group 5	48	NO	126	NO	67	NO		NO		TBA at March meeting	
XW013W5	Introduction of caplacizumab into subcutaneous tissue, percutaneous approach, new technology group 5	13	YES	40	YES	14	YES		NO		TBA at March meeting	CABLIVI® (caplacizumab-yhdp)
XW033E5	Introduction of remdesivir anti-infective into peripheral vein, percutaneous approach, new technology group 5	7,639	NO	299,007	NCTAP[1]	218,066	YES		YES		TBA at March meeting	VEKLURY®
XW033F5	Introduction of other new technology therapeutic substance into peripheral vein, percutaneous approach, new technology group 5	435	NO	2,509	NO	618	NO		NO		TBA at March meeting	
XW033G5	Introduction of sarilumab into peripheral vein, percutaneous approach, new technology group 5	3	NO	136	NO	1,327	NO		NO		TBA at March meeting	Kevzara®

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

ICD-10-PCS Code	Code Description	FY 2020		FY 2021		FY 2022		FY 2023				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW033H5	Introduction of tocilizumab into peripheral vein, percutaneous approach, new technology group 5	583	NO	13,374	NO	15,057	NO		NO		TBA at March meeting	ACTEMRA®
XW033K5	Introduction of fosfomycin anti-infective into peripheral vein, percutaneous approach, new technology group 5	7	NO	33	YES (conditional[2])	95	YES (conditional)		NO		TBA at March meeting	CONTEPO™ (fosfomycin)
XW033N5	Introduction of meropenem-vaborbactam anti-infective into peripheral vein, percutaneous approach, new technology group 5	806	YES	1,244	NO	1,070	NO		NO		TBA at March meeting	VABOMERE™ (meropenem-vaborbactam)
XW033Q5	Introduction of tagraxofusp-erzs antineoplastic into peripheral vein, percutaneous approach, new technology group 5	6	YES	6	YES	4	YES		NO		TBA at March meeting	ELZONRIS™ (tagraxofusp, SL–401)
XW033S5	Introduction of iobenguane i-131 antineoplastic into peripheral vein, percutaneous approach, new technology group 5	3	YES	0	YES	2	YES		NO		TBA at March meeting	AZEDRA® (Ultratrace® iobenguane Iodine-131) Solution
XW033U5	Introduction of imipenem-cilastatin-relebactam anti-infective into peripheral vein, percutaneous approach, new technology group 5	7	NO	75	YES	116	YES		YES (HABP/VABP only[3])		TBA at March meeting	RECARBRIO™
XW033W5	Introduction of caplacizumab into peripheral vein, percutaneous approach, new technology group 5	4	YES	21	YES	20	YES		NO		TBA at March meeting	CABLIVI® (caplacizumab-yhdp)
XW043E5	Introduction of remdesivir anti-infective into central vein, percutaneous approach, new technology group 5	539	NO	7,980	NCTAP	4,318	YES		YES		TBA at March meeting	VEKLURY®
XW043F5	Introduction of other new technology therapeutic substance into central vein, percutaneous approach, new technology group 5	30	NO	96	NO	22	NO		NO		TBA at March meeting	

[2]Conditional - Approval for NTAP for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products that does not receive FDA marketing authorization by the July 1 deadline provided that the technology otherwise meets the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the NTAP sooner, effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for NTAP.

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

ICD-10-PCS Code	Code Description	FY 2020		FY 2021		FY 2022		FY 2023				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW043G5	Introduction of sarilumab into central vein, percutaneous approach, new technology group 5	0	NO	6	NO	31	NO		NO		TBA at March meeting	Kevzara®
XW043H5	Introduction of tocilizumab into central vein, percutaneous approach, new technology group 5	66	NO	643	NO	715	NO		NO		TBA at March meeting	ACTEMRA®
XW043K5	Introduction of fosfomycin anti-infective into central vein, percutaneous approach, new technology group 5	2	NO	4	YES (conditional)	5	YES (conditional)		NO		TBA at March meeting	CONTEPO™ (fosfomycin)
XW043N5	Introduction of meropenem-vaborbactam anti-infective into central vein, percutaneous approach, new technology group 5	152	YES	203	NO	85	NO		NO		TBA at March meeting	VABOMERE™ (meropenem-vaborbactam)
XW043Q5	Introduction of tagraxofusp-erzs antineoplastic into central vein, percutaneous approach, new technology group 5	21	YES	10	YES	13	YES		NO		TBA at March meeting	ELZONRIS™ (tagraxofusp, SL–401)
XW043S5	Introduction of iobenguane i-131 antineoplastic into central vein, percutaneous approach, new technology group 5	0	YES	0	YES	1	YES		NO		TBA at March meeting	AZEDRA® (Ultratrace® iobenguane Iodine-131) Solution
XW043U5	Introduction of imipenem-cilastatin-relebactam anti-infective into central vein, percutaneous approach, new technology group 5	0	NO	7	YES	31	YES		YES (HABP/ VABP only)		TBA at March meeting	RECARBRIO™
XW043W5	Introduction of caplacizumab into central vein, percutaneous approach, new technology group 5	3	YES	7	YES	5	YES		NO		TBA at March meeting	CABLIVI® (caplacizumab-yhdp)
XW097M5	Introduction of Esketamine Hydrochloride into Nose, Via Natural or Artificial Opening, New Technology Group 5	0	YES	1	YES	2	YES		NO		TBA at March meeting	SPRAVATO (Esketamine)
XW0DXF5	Introduction of other new technology therapeutic substance into mouth and pharynx, external approach, new technology group 5	188	NO	1,309	NCTAP	675	NO		NO		TBA at March meeting	

ICD-10-PCS Code	Code Description	FY 2020		FY 2021		FY 2022		FY 2023				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW0DXJ5	Introduction of apalutamide antineoplastic into mouth and pharynx, external approach, new technology group 5	10	YES	8	NO	27	NO		NO		TBA at March meeting	ERLEADA™ (Apalutamide)
XW0DXL5	Introduction of erdafitinib antineoplastic into mouth and pharynx, external approach, new technology group 5	2	YES	3	YES	6	YES		NO		TBA at March meeting	Balversa™ (Erdafitinib)
XW0DXR5	Introduction of venetoclax antineoplastic into mouth and pharynx, external approach, new technology group 5	923	NO	1,274	NO	1,600	NO		NO		TBA at March meeting	Venclexta® (venetoclax tablets)
XW0DXT5	Introduction of ruxolitinib into mouth and pharynx, external approach, new technology group 5	254	YES	611	YES	831	YES		NO		TBA at March meeting	JAKAFI® (ruxolitinib)
XW0DXV5	Introduction of gilteritinib antineoplastic into mouth and pharynx, external approach, new technology group 5	62	YES	126	YES	109	YES		NO		TBA at March meeting	XOSPATA® (gilteritinib)
XW13325	Transfusion of convalescent plasma (nonautologous) into peripheral vein, percutaneous approach, new technology group 5	4,672	NO	94,772	NCTAP	1,415	NCTAP		NCTAP		TBA at March meeting	
XW14325	Transfusion of convalescent plasma (nonautologous) into central vein, percutaneous approach, new technology group 5	415	NO	3,548	NCTAP	63	NCTAP		NCTAP		TBA at March meeting	
XXE5XM5	Measurement of infection, whole blood nucleic acid-base microbial detection, new technology group 5	1	YES	2	YES	7	YES		NO		TBA at March meeting	T2Bacteria® Panel (T2 Bacteria Test Panel)

Topic # 04 – Insertion of Palladium-103 Radioactive Implant

Issue: There are currently no unique ICD-10-PCS codes to describe the insertion of a Palladium-103 radioactive collagen tile implant. An April 1, 2024 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The requestor (GT Medical™ Technologies) plans to submit a premarket notification 510k application for the Palladium-103 (Pd-103) radioactive collagen tile implant by December 31 for patients with newly diagnosed malignant intracranial neoplasms and patients with recurrent intracranial neoplasms. A Cesium-131 (Cs-131) GammaTile® is FDA-cleared through the 510(k) pathway for use in recurrent intracranial neoplasms since 2018 and was cleared for use in malignant intracranial neoplasms in 2020.

Background: According to the American Brain Tumor Association, there were ~84,000 new brain tumor diagnoses in 2021 and more than 700,000 Americans have a brain tumor history and are at risk for a recurrence.[1] Tumor recurrence after surgery is common, and after recurrence, complete tumor control with surgery alone is very difficult to achieve. For this reason, adjuvant radiation treatment after brain tumor resection is very commonly prescribed.[2] GammaTile® use is a form of adjuvant radiation treatment.

GammaTile® treatment with Cs-131 is currently being used in over 95 U.S. hospitals and has been prescribed for more than 1000 patients to date. As a result of supply chain disruptions from the only worldwide source of Cs-131 in the fall of 2022, domestic Cs-131 isotope production, as well as other alternative therapies are being explored. According to the requestor, it is expected that use of Pd-103 would be both a supply chain risk mitigator and a clinical benefit of an additional therapeutic choice for clinicians. Pd-103 has multiple current domestic suppliers.

As with Cs-131 GammaTiles®, Pd-103 GammaTiles® deliver radiation to the tumor bed immediately following surgical resection of the tumor. The collagen matrix formulation, titanium source encapsulation, manufacturing, sterilization, and handling procedures are essentially identical for both Cs-131 and Pd-103 containing GammaTiles®. The requestor stated that one potential clinical advantage of Pd-103 over Cs-131 is that Pd-103 has a lower average energy, 21 kiloelectronvolt (keV) vs 30 keV for Cs-131 and with the lower Pd-103 energy, a modestly shallower depth of penetration occurs, and thus this isotope could be useful to patients and clinicians in situations where a shallower depth of penetration is desired. Examples of this are tumors with less expected residual infiltration such as brain metastasis, or in situations of radiation re-treatment where exposing smaller cavity adjacent volumes to re-radiation is desirable. The requestor reported that because the safety profile of Cs-131 GammaTile® treatments to date has been excellent, the shallower depth of penetration for Pd-103 and safety profile is anticipated to be the same or better. Additionally, the requestor maintains that the same advantages patients have received by Cs-131 GammaTile® use (no need to return for outpatient external beam treatments, and assured treatment compliance) carry over to the use of Pd-103 GammaTile® therapy.

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[1] American Brain Tumor Association. Brain Tumor Education. American Brain Tumor Association website. https://www.abta.org/about-brain-tumors/brain-tumor-education/. Accessed [24 May 2023].

[2] Lin AJ et al. Radiologic Response and Disease Control of Recurrent Intracranial Meningiomas Treated with Reirradiation. Int J Radiation Oncol Biol Phys. 2018;102(1):194-203.

Technology
GammaTiles® are bioresorbable, conformable, 20 mm x 20 mm x 4 mm collagen tiles that contain four radioactive titanium-encapsulated seeds per tile (Figure 1). This permanently implanted device functions as both a seed carrier and three-dimensional spacer that offsets the seeds 3 mm from the tissue surface and 10 mm from each other, thereby preventing direct seed-to-brain contact while maintaining uniform inter-source spacing after the completion of the procedure.

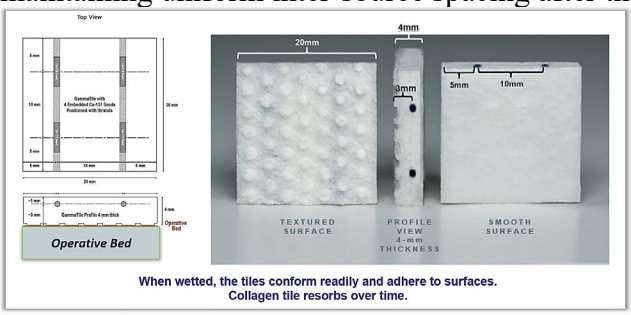

Figure 1: Engineering diagram showing seed locations and offsets in a GammaTile®

This radiation source to brain offset has yielded a rate of radiation-related brain changes of ~8%, a favorable reduction as compared to previously reported rates (10-37%) in studies using standard-of-care external beam radiation.[2,3,4,5,6,7]

Procedure Description
Patients receiving GammaTile® undergo an open craniotomy and tumor resection. After completion of the resection, the tumor bed is lined with sufficient GammaTiles® to adequately cover the surfaces at risk for tumor recurrence; depending on tumor size, this has ranged from 2-18 GammaTiles® in usage to date. Once placed, the GammaTiles® start to deliver radiation therapy to any tumor cells that remain in proximity to the resection cavity.

GammaTiles® have been designed to establish a 0.3 cm offset between the radiation sources and brain surface to achieve the desired source-to-brain offset. Wound closure is accomplished in the standard fashion, with replacement of native cranium whenever possible. Following surgery, patients undergo usual and customary post-surgical care. Documentation of the number of tiles implanted is included in the operative record.

Current Coding: There are no unique ICD-10-PCS codes to describe insertion of the Palladium-103 radioactive collagen tile implant. Code the procedure in table 00H, Insertion, Central Nervous System and Cranial Nerves, using the device value 1 Radioactive Element, applied to the body part value 0 Brain and the approach value 0 Open.

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[3] Sneed PK et al. Adverse radiation effect after stereotactic radiosurgery for brain metastases: incidence, time course, and risk factors. J Neurosurg. (2015) 123:373–86. doi: 10.3171/2014.10. JNS141610
[4] McKay et al. Repeat stereotactic radiosurgery as salvage therapy for locally recurrent brain metastases previously treated with radiosurgery. J Neurosurg. 2017. doi 10.3171/2016.5. JNS153051
[5] Brachman, D. G. et al. Resection and permanent intracranial brachytherapy using modular, biocompatible cesium-131 implants: results in 20 recurrent, previously irradiated meningiomas. J_Neurosurg. 131, 1819–1828 (2019).
[6] Nakaji, P. et al. Resection and Surgically Targeted Radiation Therapy for the Treatment of Larger Recurrent or Newly Diagnosed Brain Metastasis: Results from a Prospective Trial. Cureus 12, e11570 (2020).
[7] Smith, K. et al. Safety and patterns of survivorship in recurrent GBM following resection and surgically targeted radiation therapy: Results from a prospective trial. Neuro-oncology 24, S4–S15 (2022).

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Brain	**0** Open	**1** Radioactive Element **2** Monitoring Device **3** Infusion Device **4** Radioactive Element, Cesium-131 Collagen Implant **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for insertion of the Palladium-103 radioactive collagen tile implant. Continue coding as described in current coding.

Option 2. In table 00H, Insertion, Central Nervous System and Cranial Nerves, create new device value 5 Radioactive Element, Palladium-103 Collagen Implant, applied to the body part value 0 Brain and the approach value 0 Open, to identify insertion of Palladium-103 radioactive collagen tile implant.

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Brain	**0** Open	**1** Radioactive Element **2** Monitoring Device **3** Infusion Device **4** Radioactive Element, Cesium-131 Collagen Implant **ADD 5** Radioactive Element, Palladium-103 Collagen Implant **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier

CMS Recommendation: Option 2, as described above.

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

Topic # 05 – Introduction of Bone Void Filler

Issue: There are currently no unique ICD-10-PCS codes to describe the introduction of bone void filler with osteo-enhancement material to strengthen the proximal femur and reduce the risk of fragility fractures of the hip. An October 1, 2024 implementation date is being requested.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2025 consideration.

Food & Drug Administration (FDA) Approval? No. FDA approval of the AGN1 Local Osteo-Enhancement Procedure (LOEP) Kit for the indication to reduce the risk of hip fracture in patients at risk of fragility fracture is anticipated in 2026.

Background: Osteoporosis is a disease characterized by bone loss and weakening of bone over time. While more prevalent in women, osteoporosis is a common condition that affects both women and men. Estimates suggest about 54 million Americans have osteoporosis or lowered bone mass that leads to increased risk for osteoporosis.[1] Studies have shown that approximately one in two women and one in four men over the age of 50 will suffer a broken bone due to osteoporosis. Other risk factors for osteoporosis include low body weight, smoking, family history of the disease, a previous fragility fracture, excessive alcohol consumption or medical conditions such as rheumatoid arthritis, inflammatory bowel disease, and cancer.

Existing treatments for osteoporosis include lifestyle changes and medications such as bisphosphonates and hormone therapy, however these therapies have associated side effects and patients must adhere to their prescribed medication regimen. The osteo-enhancement procedure is designed to mechanically strengthen the proximal femur to reduce the risk of hip fractures in patients who are known to have weakened bones or other factors leading to a high risk of hip fracture.

Technology
According to the requestor, the osteo-enhancement material (AGN1) is a triphasic implant material consisting of calcium sulfate, brushite, and β-tricalcium phosphate. It is a resorbable, osteoconductive implant material intended to form new bone in voids of the proximal femur of patients with osteopenia or osteoporosis. The material consists of a powder component and an aqueous liquid solution that when mixed, forms a paste that is able to be injected, but then hardens and cures in situ. The resorption process creates a microenvironment that facilitates cellular infiltration, neovascularization, collagen deposition, mineralization and rapid bone formation. As a result, over time, the material is resorbed by the body as new bone forms.

The implant material is provided in a single-use medical device kit that contains the implant material components, instruments to mix the material and instruments to deliver the implant material. A single kit is used for each implantation procedure. The requestor reports it is possible for bilateral implant procedures to be performed in a single operative session, therefore, it is possible to use two kits in a single operative episode.

[1] Wright NC, Looker AC, Saag KG, Curtis JR, Delzell ES, Randall S, Dawson-Hughes B. The recent prevalence of osteoporosis and low bone mass in the United States based on bone mineral density at the femoral neck or lumbar spine. J Bone Miner Res. 2014 Nov;29(11):2520-6. doi: 10.1002/jbmr.2269. PMID: 24771492; PMCID: PMC4757905.

Procedure Description
The patient is positioned in a supine position with the hip to be treated in neutral extension with the femoral neck parallel to the floor. Local anesthesia is administered to the area of the incision. A small skin incision is made to allow access to the lateral femoral cortex. The tissue protector, canulated centering obturator and guide pin are inserted into the incision up to the lateral femoral cortex and position is confirmed with fluoroscopy. Under fluoroscopic guidance the guide pin is advanced until it reaches the apex of the femoral neck. The centering obturator is removed, and a 5.3 mm cannulated drill is inserted over the guide pin up to the lateral femoral cortex to drill to the proximal intersection of the compressive and tensile trabeculae. Once drilling is complete the tissue protector and drill are removed and the blunt probe debrider is inserted to define the margins of the enhancement site. Suction and irrigation of the enhancement site are used to clear the area and create space for the injection of AGN1.

The AGN1 material is mixed according to instructions and filled in the syringe. An injection cannula is inserted and while under fluoroscopic guidance, the implant material is injected proximal to distal with continuous retraction of the cannula. The injection is stopped when the implant material reaches the lateral cortex. Once injection is completed, the injection cannula is removed, and the incision is closed.

According to the requestor, the procedure may be performed under any one of the following three clinical scenarios 1) unilateral, standalone case: a patient has 1 hip treated in a scheduled procedure, 2) bilateral, standalone case: a patient has both hips treated in a scheduled procedure, or 3) concomitant to an index hip fragility fracture in the unfractured, contralateral hip: a patient has their index hip fracture repaired and then the procedure utilizing the LOEP kit is performed to treat the unfractured, contralateral hip during the same operative session. Therefore, there may be situations where the procedure could be performed in conjunction with another procedure.

The requestor reports that there have been approximately 335 procedures performed as of May 2023 across the U.S., Europe, Japan and Hong Kong. In clinical trials there have been complications primarily related to surgery, including nausea related to anesthesia: ~7%, cardiovascular events including venous thrombosis and sequelae: <2%, wound-related such as infection and dehiscence: ~3.5%. Additional complications related to calcium implants include material extravasation: ~9% and tissue inflammation: <2%.

Current Coding: There are no unique ICD-10-PCS codes to describe the introduction of AGN1 bone void filler to strengthen the proximal femur and reduce the risk of fragility fractures of the hip. Facilities can report the introduction of AGN1 bone void filler using the following code:

3E0V3GC	Introduction of other therapeutic substance into bones, percutaneous approach

Facilities would also report any concomitant procedure to treat an upper femur fracture with the appropriate code from the Lower Bones body system of the Medical and Surgical section.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the introduction of AGN1 bone void filler. Continue to report the fracture repair procedure if performed, as described in current coding.

Option 2. Create a new code in section X, New Technology, to identify introduction of AGN1 bone void filler.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
V Bones	**3** Percutaneous	**ADD W** AGN1 Bone Void Filler	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 06 – Electrical Biocapacitance for Assessment of Pressure Injuries

Issue: There are currently no unique ICD-10-PCS codes to describe electrical biocapacitance for assessment of early-stage pressure injuries/ulcers (PI/PUs) and deep tissue injuries (DTIs). The requestor is seeking an April 1, 2024 implementation date.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2025 consideration.

Food & Drug Administration (FDA) Approval? Yes. The Provizio® Sub-Epidermal Moisture (SEM) Scanner was granted De Novo authorization/clearance on December 20, 2018, as a class I device intended to be used by healthcare professionals as an adjunct to the standard of care when assessing the heels and sacrum of patients at increased risk for PI/PU. The requestor plans to submit an application for Breakthrough Device designation in the third quarter of 2023, for the prevention of pressure injuries and deep tissue injuries based on the detection of sub-epidermal moisture or focal edema accomplished by the Provizio® SEM Scanner.

Background: PI/PUs are a widespread and serious problem for hospital patients, including Medicare beneficiaries throughout the United States. Injuries to the skin and underlying tissue, primarily caused by prolonged pressure, can lead to complications, such as infection or, in severe cases, tissue necrosis and sepsis, prolonging hospital stays and increasing morbidity and mortality.[1] Each year, more than 2.5 million people in the United States develop PI/PUs with more than 60,000 annual deaths from complications related to PI/PUs - mortality rates that are equivalent to those in the opioid crisis.[2] Pressure redistribution is the most important factor in preventing pressure-induced skin or soft tissue injuries and may be accomplished in two ways: appropriate use of pressure-reducing devices and surfaces and proper patient positioning. Appropriate and timely intervention is therefore key in PI/PU reduction and prevention.

Cell and tissue damage from sustained pressure, deformation, shear, and friction generate acute inflammatory responses. This immune response results in a build-up of plasma fluids in the interstitial tissue spaces, forming focal edema or sub-epidermal moisture (SEM), an early indicator on non-visible, below the surface tissue damage.

Per the requestor, existing and conventional care pathways for detecting and preventing deep and early-stage PI/PUs are problematic and outdated with: (i) subjective, paper-based risk assessment scales (ii) lack of anatomy specific measurement, (iii) inability to detect cellular damage below the skin surface where it starts, particularly with dark skin tones, and (iv) delay in pinpointing PI/PU until it becomes visible, and damage becomes more severe. The result is a delay in providing timely and anatomy-specific treatment.[3]

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[1] Okonkwo, H., Bryant, R., Milne, J., Molyneaux, D., Sanders, J., Cunningham, G., Brangman, S., Eardley, W., Chan, G. K., Mayer, B., Waldo, M. & Ju, B. 2020. A blinded clinical study using a subepidermal moisture biocapacitance measurement device for early detection of pressure injuries. Wound Repair Regen

[2] Internet Citation: Preventing Pressure Ulcers in Hospitals. Content last reviewed April 2023. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/patientsafety/settings/hospital/resource/pressureulcer/tool/index.html

[3] Moore, Z., et al. 2022. Measuring subepidermal moisture to detect early pressure ulcer development: a systematic review. Journal of Wound Care, 31, 634-647.

Technology
The Provizio® SEM scanner is a wireless, hand-held, portable, non-invasive, bedside device used for the purposes of detecting, measuring, and monitoring SEM, persistent focal edema, or localized edema by electrical biocapacitance of skin tissue, to specifically detect early-stage PI/PU and deep tissue injuries. The device is provided with single-use sensors, an inductive charging/transmission hub, and a digital gateway dashboard. The device measures the electrical capacitance of tissue ("biocapacitance") to approximately 4 mm below the surface of the skin when applied to the patient's skin and reports this as a SEM value. The device can detect damage which begins at the microscopic level in interstitial tissue.

The device compares the SEM values at the damaged tissue site with those from adjacent, healthy tissue sites to identify the maximum difference between the SEM values, the 'SEM-delta.' The greater the SEM-delta, the greater the tissue damage at the specific anatomy. A SEM delta ≥ 0.6 at a specific anatomical site indicates developing localized edema/early tissue damage and anatomy-specific increased risk of developing more severe PI/PUs or deep tissue injuries. Clinical studies and meta-analyses from systematic reviews of the Provizio® SEM scanner show early detection of early-stage PI/PUs and DTIs five (5) days earlier than diagnosis via visual skin assessments.[1]

The device is indicated for inpatient settings where the integrated barcode scanner and pre-configured workflows allow clinicians to extract patient identifiers. The scanner integrates with EHR/EMR systems via a standalone gateway dashboard application, allowing for data-driven stratification of patients by type of intervention, care setting, and demographics. The data are point in time and longitudinal and track the patient through care settings from admission to discharge. Per the requestor, real-time monitoring of patient-specific SEM data allows the collection, reporting, and analysis of standardized data to enhance clinical decision-making at the bedside, at the facility level and at the enterprise level, thus improving net patient health outcomes and enhancing patient safety at the individual and population levels.

Procedure Description
After a patient at risk for PI/PUs is identified using standard risk assessment tools like the Braden Scale, the clinician initiates the installation of the single use sensor on the device. Using the integrated barcode reader, the patient identification is read. The clinician selects a body location on the device (heel or sacrum) and begins the scanning session. Ensuring that the skin is debris free and dry, the sensor is applied flat against the patient's skin. Pressure is continuously increased on the area until the scan is triggered. Six measurements are taken at the sacrum in a side-by-side motion including the gluteal cleft, and the area around S3 of the sacral bone. The device stores the measurements, allowing the user to provide immediate treatment interventions or scan other areas, if needed. Following the sacral scan, the clinician would press the previous screen button on the device to begin scanning the heels. Four measurements are taken at the site inclusive of the back of the heel around the calcaneus, medial and lateral side, and the heel pad. A final reading result of a SEM-delta value greater than or equal to 0.6 indicates an increased risk of PI development at the specific anatomy. At the end of the session the single-use sensor is removed and disposed. The device is then cleaned per manufacturer guidelines and placed back into the charging hub to initiate automatic wireless data transfer to the hospital's electronic medical records, and to be included in hospital progress notes.

Current Coding: The use of a hand-held device to aid in the assessment of pressure injury is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the use of electrical biocapacitance for early assessment of pressure injuries. Continue coding as listed in current coding.

Option 2. Create a new code in section X, New Technology, to identify the use of electrical biocapacitance for early assessment of pressure injury.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD K Subcutaneous Tissue	**X** External	**ADD P** Interstitial Fluid Volume, Sub-Epidermal Moisture using Electrical Biocapacitance Sensor	**9** New Technology Group 9

CMS Recommendation: Option 2, as described above.

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

Topic # 07 - ICD-10-PCS Index Addenda*

Lttr A
Main Annuloplasty
Add see Restriction, Heart and Great Vessels 02V

Main Add Aortic isthmus use Thoracic Aorta, Ascending/Arch

Lttr C
Main Add Columvi(tm) use Glofitamab Antineoplastic

Main Add Cryoanalgesia see Destruction, Peripheral Nervous System 015

Main Add CryoICE(R) cryo-ablation probe (Cryo2) see Destruction, Nerve, Thoracic 0158
Main Add CryoICE(R) CryoSPHERE(R) cryoablation probe (CryoS, CryoS-L) see Destruction, Nerve, Thoracic 0158

Lttr D
Main Delete DynaClip(R) (Forte)
Delete use Internal Fixation Device, Sustained Compression in 0RG
Delete use Internal Fixation Device, Sustained Compression in 0SG

Main Add DynaClip(R) (Delta)(Forte)(Quattro)
Add use Internal Fixation Device, Sustained Compression in 0RG
Add use Internal Fixation Device, Sustained Compression in 0SG

Lttr E
Main Add EPKINLY(tm) use Epcoritamab Monoclonal Antibody

Lttr J
Main Add Juxtaductal aorta use Thoracic Aorta, Ascending/Arch

Lttr O
Main Add Omisirge(R) use Omidubicel

Lttr P
Main Add Popliteal fossa
use Knee Region, Right
use Knee Region, Left

Lttr S
Main Add SPEVIGO(R) use Spesolimab Monoclonal Antibody

Lttr T
Main Delete Thrombolysis, Ultrasound assisted see Fragmentation, Artery

**All proposed addenda updates are being considered for implementation on April 1, 2024.*

Main Add TECVAYLI(tm) use Teclistamab Antineoplastic

Main Add Thrombolysis
Add Catheter-directed see Fragmentation
Add Systemic see Introduction of substance in or on, Physiological Systems and Anatomical Regions 3E0
Add Ultrasound assisted
Add see Fragmentation, Artery
Add see Fragmentation, Vein

Main Transplantation
Revise from Bone marrow see Transfusion, Circulatory 302
Revise to Bone marrow
Add see Transfusion, Vein, Peripheral 30233G
Add see Transfusion, Vein, Central 30243G

Lttr V
Main Add VOWST(tm) use SER-109

Lttr X
Main Add Xacduro(R) use Sulbactam-Durlobactam

ICD-10-PCS Body Part Key Addenda

Section 0 Medical and Surgical
Axis 4 Body Part
Term Thoracic Aorta, Ascending/Arch
Includes Add Aortic isthmus
Includes Add Juxtaductal aorta

Section 0 Medical and Surgical
Axis 4 Body Part
Term Knee Region, Right
Term Knee Region, Left
Includes Add Popliteal fossa

ICD-10-PCS Device Key Addenda

Axis 6		Device
Row		
Term		Internal Fixation Device, Sustained Compression for Fusion in Lower Joints
Includes	Delete	DynaClip(R) (Forte)
Includes	Add	DynaClip(R) (Delta)(Forte)(Quattro)
Row		
Term		Internal Fixation Device, Sustained Compression for Fusion in Upper Joints
Includes	Delete	DynaClip(R) (Forte)
Includes	Add	DynaClip(R) (Delta)(Forte)(Quattro)

ICD-10-PCS Substance Key Addenda

Section X		New Technology
Axis 6		Device / Substance / Technology
Row		
Row	Add	
Term	Add	Epcoritamab Monoclonal Antibody
Includes	Add	EPKINLY(tm)
Row	Add	
Term	Add	Glofitamab Antineoplastic
Includes	Add	Columvi(tm)
Row	Add	
Term	Add	Omidubicel
Includes	Add	Omisirge(R)
Row	Add	
Term	Add	SER-109
Includes	Add	VOWST(tm)
Row	Add	
Term	Add	Spesolimab Monoclonal Antibody
Includes	Add	SPEVIGO(R)
Row		
Term		Sulbactam-Durlobactam
Includes	Add	Xacduro(R)

**All proposed addenda updates are being considered for implementation on April 1, 2024.*

Row	Add	
Term	Add	Teclistamab Antineoplastic
Includes	Add	TECVAYLI(tm)

ICD-10-PCS Table Addenda

Medical and Surgical Section

Axis 4 Body Part
Choanal Dilation

Source	Description	Code specification
2023, public request with CMS internal review	In the Medical and Surgical section table 097, Dilation of Ear, Nose, Sinus, add body part value N Nasopharynx, applied to the device value Z No Device and all applicable approaches, to identify procedures such as choanal dilation performed to treat choanal atresia. Choanal atresia is a congenital disorder in which the nasal choanae (paired openings that connect the nasal cavity with the nasopharynx) are occluded by soft tissue, bone, or a combination of both, due to the failure of the nasopharynx to form an open connection between the nasal passages and the nasopharynx during fetal development.	Add: 097N[078]ZZ (3 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**9** Ear, Nose, Sinus
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
ADD N Nasopharynx	**0** Open **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**Z** No Qualifier

Pedicled Omentoplasty

Source	Description	Code specification
2023, public request with CMS internal review	In the Medical and Surgical section table 0DX, Transfer of Gastrointestinal System, add the body part value U Omentum, applied to the approach values 0 Open and 4 Percutaneous Endoscopic and new qualifier values V Thoracic Region, W	Add: 0DXU[04]Z[VWXY] (8 codes)

	Abdominal Region, X Pelvic Region and Y Inguinal Region. These changes enable capture of procedures documented as pedicled omentoplasty or pedicled omental patch, in which omentum that is still attached to its vascular and nervous supply is used to cover or fill a defect. The vascularized nature of the pedicled omental flap allows the omentum to bring its own blood supply to any structure to which it can be tunneled or stretched.	

EXAMPLE

Section **0** Medical and Surgical
Body System **D** Gastrointestinal 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*
ADD U Omentum	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**ADD V** Thoracic Region **ADD W** Abdominal Region **ADD X** Pelvic Region **ADD Y** Inguinal Region

Axis 7 Qualifier
Thumb Amputation

Source	Description	Code specification
2023, public request with CMS internal review	In the Medical and Surgical section table 0X6, Detachment of Anatomical Regions, Upper Extremities, delete the qualifier value 2 Mid currently applied to body parts L Thumb, Right and M Thumb, Left. Because the thumb does not have a middle phalanx, the qualifier mid is considered clinically invalid.	Delete: 0X6[LM]0Z2 (2 codes)

EXAMPLE

Section **0** Medical and Surgical
Body System **X** Anatomical Regions, Upper Extremities
Operation **6** Detachment: Cutting off all or a portion of the upper or lower extremities

Body Part	*Approach*	*Device*	*Qualifier*
L Thumb, Right **M** Thumb, Left	**0** Open	**Z** No Device	**0** Complete **1** High **DELETE 2** Mid **3** Low

First Toe Amputation

Source	Description	Code specification
2023, public request with CMS internal review	In the Medical and Surgical section table 0Y6, Detachment of Anatomical Regions, Lower Extremities, delete the qualifier value 2 Mid currently applied to body parts P 1st Toe, Right and Q 1st Toe, Left. Because the first toe only has one interphalangeal joint, the qualifier mid is considered clinically invalid.	Delete: 0Y6[PQ]0Z2 (2 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**Y** Anatomical Regions, Lower Extremities
Operation	**6** Detachment: Cutting off all or a portion of the upper or lower extremities

Body Part	*Approach*	*Device*	*Qualifier*
P 1st Toe, Right **Q** 1st Toe, Left	**0** Open	**Z** No Device	**0** Complete **1** High **DELETE 2** Mid **3** Low

Laparoscopic Hand-Assisted Surgeries

Source	Description	Code specification
2023, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section, create new qualifier value G Hand-Assisted, applied to the following root operation Excision and Resection tables, to support complete coding for laparoscopic surgical procedures where abdominal access is obtained to allow involvement of the surgeon's hand to assist in the performance of the procedure: – 07T Resection of Lymphatic and Hemic Systems – 0DB Excision of Gastrointestinal System – 0DT Resection of Gastrointestinal System – 0FB Excision of Hepatobiliary System and Pancreas – 0FT Resection of Hepatobiliary System and Pancreas – 0TT Resection of Urinary System	Add: 07TP4ZG (1 code) 0DB[FGJLMN]4ZG (6 codes) 0DT[FGJLMN]4ZG (6 codes) 0FB[012G]4ZG (4 codes) 0FT[0124G]4ZG (5 codes) 0TT[012]4ZG (3 codes)

EXAMPLES

Section	**0** Medical and Surgical
Body System	**7** Lymphatic and Hemic Systems
Operation	**T** Resection: Cutting out or off, without replacement, all of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Lymphatic, Head **1** Lymphatic, Right Neck **2** Lymphatic, Left Neck **3** Lymphatic, Right Upper Extremity **4** Lymphatic, Left Upper Extremity **5** Lymphatic, Right Axillary **6** Lymphatic, Left Axillary **7** Lymphatic, Thorax **8** Lymphatic, Internal Mammary, Right **9** Lymphatic, Internal Mammary, Left **B** Lymphatic, Mesenteric **C** Lymphatic, Pelvis **D** Lymphatic, Aortic **F** Lymphatic, Right Lower Extremity **G** Lymphatic, Left Lower Extremity **H** Lymphatic, Right Inguinal **J** Lymphatic, Left Inguinal **K** Thoracic Duct **L** Cisterna Chyli **M** Thymus **P** Spleen	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier
P Spleen	**4** Percutaneous Endoscopic	**Z** No Device	**ADD G** Hand-Assisted

Section	**0** Medical and Surgical
Body System	**D** Gastrointestinal System
Operation	**B** Excision: Cutting out or off, without replacement, a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
1 Esophagus, Upper **2** Esophagus, Middle **3** Esophagus, Lower **4** Esophagogastric Junction **5** Esophagus **7** Stomach, Pylorus **8** Small Intestine **9** Duodenum **A** Jejunum **B** Ileum **C** Ileocecal Valve **E** Large Intestine **F** Large Intestine, Right **H** Cecum **J** Appendix **K** Ascending Colon **P** Rectum	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**X** Diagnostic **Z** No Qualifier
6 Stomach	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**3** Vertical **X** Diagnostic **Z** No Qualifier

G Large Intestine, Left **L** Transverse Colon **M** Descending Colon **N** Sigmoid Colon	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**X** Diagnostic **Z** No Qualifier
ADD F Large Intestine, Right **G** Large Intestine, Left **ADD J** Appendix **L** Transverse Colon **M** Descending Colon **N** Sigmoid Colon	**4** Percutaneous Endoscopic	**Z** No Device	**ADD G** Hand-Assisted
G Large Intestine, Left **L** Transverse Colon **M** Descending Colon **N** Sigmoid Colon	**F** Via Natural or Artificial Opening With Percutaneous Endoscopic Assistance	**Z** No Device	**Z** No Qualifier
Q Anus	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic **X** External	**Z** No Device	**X** Diagnostic **Z** No Qualifier
R Anal Sphincter **U** Omentum **V** Mesentery **W** Peritoneum	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**X** Diagnostic **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**D** Gastrointestinal System
Operation	**T** Resection: Cutting out or off, without replacement, all of a body part

Body Part	*Approach*	*Device*	*Qualifier*
1 Esophagus, Upper **2** Esophagus, Middle **3** Esophagus, Lower **4** Esophagogastric Junction **5** Esophagus **6** Stomach **7** Stomach, Pylorus **8** Small Intestine **9** Duodenum **A** Jejunum **B** Ileum **C** Ileocecal Valve **E** Large Intestine **F** Large Intestine, Right **H** Cecum **J** Appendix **K** Ascending Colon **P** Rectum **Q** Anus	**0** Open **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**Z** No Qualifier
G Large Intestine, Left **L** Transverse Colon **M** Descending Colon **N** Sigmoid Colon	**0** Open **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic **F** Via Natural or Artificial Opening With Percutaneous Endoscopic Assistance	**Z** No Device	**Z** No Qualifier

ADD F Large Intestine, Right **G** Large Intestine, Left **ADD J** Appendix **L** Transverse Colon **M** Descending Colon **N** Sigmoid Colon	**4** Percutaneous Endoscopic	**Z** No Device	**ADD G** Hand-Assisted
R Anal Sphincter **U** Omentum	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**F** Hepatobiliary System and Pancreas
Operation	**B** Excision: Cutting out or off, without replacement, a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Liver **1** Liver, Right Lobe **2** Liver, Left Lobe	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**X** Diagnostic **Z** No Qualifier
0 Liver **1** Liver, Right Lobe **2** Liver, Left Lobe **G** Pancreas	**4** Percutaneous Endoscopic	**Z** No Device	**ADD G** Hand-Assisted
4 Gallbladder **G** Pancreas	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**X** Diagnostic **Z** No Qualifier
5 Hepatic Duct, Right **6** Hepatic Duct, Left **7** Hepatic Duct, Common **8** Cystic Duct **9** Common Bile Duct **C** Ampulla of Vater **D** Pancreatic Duct **F** Pancreatic Duct, Accessory	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**X** Diagnostic **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**F** Hepatobiliary System and Pancreas
Operation	**T** Resection: Cutting out or off, without replacement, all of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Liver **1** Liver, Right Lobe **2** Liver, Left Lobe **4** Gallbladder **G** Pancreas	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier
0 Liver **1** Liver, Right Lobe **2** Liver, Left Lobe **4** Gallbladder **G** Pancreas	**4** Percutaneous Endoscopic	**Z** No Device	**ADD G** Hand-Assisted
5 Hepatic Duct, Right **6** Hepatic Duct, Left **7** Hepatic Duct, Common **8** Cystic Duct **9** Common Bile Duct **C** Ampulla of Vater **D** Pancreatic Duct **F** Pancreatic Duct, Accessory	**0** Open **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**T** Urinary System
Operation	**T** Resection: Cutting out or off, without replacement, all of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Kidney, Right **1** Kidney, Left **2** Kidneys, Bilateral	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier
0 Kidney, Right **1** Kidney, Left **2** Kidneys, Bilateral	**4** Percutaneous Endoscopic	**Z** No Device	**ADD G** Hand-Assisted
3 Kidney Pelvis, Right **4** Kidney Pelvis, Left **6** Ureter, Right **7** Ureter, Left **B** Bladder **C** Bladder Neck **D** Urethra	**0** Open **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**Z** No Qualifier

Administration Section
Axis 4 Body System/Region

Administration of tPA into Pleural Cavity with DNase (Deoxyribonuclease)

Source	Description	Code specification
2023, public request with CMS internal review	In the Administration section root operation Introduction table 3E0, add substance value 1 Thrombolytic and qualifier value 7 Other Thrombolytic applied to body region value L Pleural Cavity, to capture the administration of tissue plasminogen activator (tPA) in the pleural cavity. In addition, add DNase (Deoxyoribonuclease) to the Substance key to identify the substance value that should be assigned when this therapeutic is administered. These changes enable capture of additional detail for administration of DNase. The introduction of tPA and DNase into the pleural cavity is used to treat pleural infections such as empyema that have caused sepsis. The combination of tPA and DNase breaks up the waste materials that develop from the infection, to avoid pleural clean-out procedures that involve decortication of the lung rind caused by the empyema. Under this proposal, facilities wishing to capture introduction of tPA and DNase into the pleural cavity can capture this information using two codes.	Add: 3E0L317 (1 code)

EXAMPLE

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
L Pleural Cavity	**0** Open	**5** Adhesion Barrier	**Z** No Qualifier
L Pleural Cavity	**3** Percutaneous	**0** Antineoplastic	**4** Liquid Brachytherapy Radioisotope **5** Other Antineoplastic **M** Monoclonal Antibody
L Pleural Cavity	**3** Percutaneous	**ADD 1** Thrombolytic	**ADD 7** Other Thrombolytic
L Pleural Cavity	**3** Percutaneous	**2** Anti-infective	**8** Oxazolidinones **9** Other Anti-infective

Index and Substance Key entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr D
Main Add DNase (Deoxyoribonuclease) use Other Substance

ICD-10-PCS Substance Key Addenda

Section 3 Administration
Axis 6 Substance
Row
Term Other Substance
Includes Add DNase (Deoxyoribonuclease)

Extracorporeal or Systemic Assistance and Performance Section
Axis 7 Qualifier

High Flow/Velocity Cannula

Source	**Description**	**Code specification**
2023, public request with CMS internal review	In the Extracorporeal or Systemic Assistance and Performance table 5A0, revise qualifier value A from High Nasal Flow/Velocity to High Flow/Velocity Cannula, to identify ventilatory assistance provided by high flow or high velocity cannula devices. This change was requested to recognize that high flow oxygen can also be provided via a tracheostomy and not only via a nasal cannula.	Revise: 5A09[345]5A (3 codes)

EXAMPLE

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

Body System	*Duration*	*Function*	*Qualifier*
9 Respiratory	**3** Less than 24 Consecutive Hours **4** 24-96 Consecutive Hours **5** Greater than 96 Consecutive Hours	**5** Ventilation	**7** Continuous Positive Airway Pressure **8** Intermittent Positive Airway Pressure **9** Continuous Negative Airway Pressure **Revise from: A** High Nasal Flow/Velocity **Revise to: A** High Flow/Velocity Cannula **B** Intermittent Negative Airway Pressure **Z** No Qualifier

Mental Health Section
Axis 4 Qualifier

Multiple-Seizure Electroconvulsive Therapy

Source	Description	Code specification
2023, public request with CMS internal review	In Mental Health Section table GZB, delete qualifier values 1 Unilateral-Multiple Seizure and 3 Bilateral-Multiple Seizure. This deletion removes clinically invalid codes that identify multiple electroconvulsive therapy (MECT). MECT is a form of treatment in which two to eight adequate seizures are induced in the same treatment session under continuous anesthesia. Studies demonstrated an increased risk of adverse effects with multiple seizures[1] and, MECT is not considered reasonable and necessary for the treatment of psychiatric and non-psychiatric conditions in any setting. Of note, MECT does not describe treatment sessions where more than one charge is delivered to determine the patient's seizure threshold and or those where one or more failed attempts to induce an adequate seizure precede a successful induction. These are considered instances of single ECT.	Delete: GZB[13]ZZZ (2 codes)

[1] American Psychiatric Association Committee on Electroconvulsive Therapy. (2001). The practice of electroconvulsive therapy: Recommendations for treatment, training, and privileging: A task force report of the American Psychiatric Association (2nd ed.). American Psychiatric Association.

EXAMPLE

Section	**G** Mental Health
Body System	**Z** None
Operation	**B** Electroconvulsive Therapy: The application of controlled electrical voltages to treat a mental health disorder

Qualifier	*Qualifier*	*Qualifier*	*Qualifier*
0 Unilateral-Single Seizure **DELETE 1** Unilateral-Multiple Seizure **2** Bilateral-Single Seizure **DELETE 3** Bilateral-Multiple Seizure **4** Other Electroconvulsive Therapy	**Z** None	**Z** None	**Z** None

Topic # 08 - Administration of Iodine (^{131}I)-apamistamab (^{131}I-apamistamab)

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of iodine (^{131}I)-apamistamab (^{131}I-apamistamab). The requestor is seeking an April 1, 2024 implementation date.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2025 consideration.

Food & Drug Administration (FDA) Approval? No. The requestor intends to submit a Biologics License Application (BLA) to the FDA in the second half of 2023 for the use of ^{131}I-apamistamab as a targeted radiation directly to leukemic cells.

Background: Acute myeloid leukemia (AML) is a cancer of the myeloid line of blood cells, characterized by the rapid growth of abnormal white blood cells that accumulate in the bone marrow and interfere with the production of normal white blood cells. AML is the most common acute leukemia affecting adults and is frequently diagnosed among people aged 65-74, with the median age diagnosis of 69.[1] Treatment of AML in fit adults usually begins with intensive induction chemotherapy that can be highly toxic and typically entails hospitalization for several weeks. Targeted agents such as hypomethylating agents with or without Bcl-2 inhibitors (venetoclax) and IDH inhibitors are being increasingly used as induction therapy for AML, especially in older and unfit patients, and can be administered as outpatient. Toxicities of induction therapy include cytopenia, infections, bleeding/coagulation abnormalities, tumor lysis syndrome, electrolyte imbalances, impaired nutritional status, and other complications. Treatment-related mortality increases with age.

The goal of induction therapy is to achieve a complete remission (CR; <5 percent blast cells in bone marrow and complete clearance of blasts in blood) as CR is essential for improved outcomes in AML, including a cure. Depending upon age, patient characteristics, and various prognostic features, approximately two-thirds of adults achieve a CR with such regimens, but, unfortunately, relapse rates are high (approximately 50%). For patients who do not achieve a CR following induction therapy, a second, briefer course of re-induction therapy may be given. Response to therapy is determined by doing a bone marrow aspirate and biopsy 14 days after the completion of re-induction chemotherapy and again upon count recovery (day 28 to 35 from start of induction). Nearly all patients who initially achieve CR will relapse unless consolidation (post-remission) therapy is given. The goal of consolidation therapy, which includes chemotherapy and/or allogeneic hematopoietic stem cell transplantation (alloHCT), is to eliminate residual, undetectable disease and achieve long-term disease control and cure.

Relapsed or refractory (R/R) AML presents as one of the following: 1) primary induction failure after 2 or more cycles of therapy, or 2) first early relapse after a remission duration of fewer than 6 months, or 3) relapse refractory to salvage combination therapy, or 4) second or subsequent relapse.[2] Prognosis for patients with R/R AML is extremely poor. Management is variable and ranges from re-induction with salvage chemotherapy followed by alloHCT to best supportive

[1] SEER database, accessed May 2023.
[2] Schmid C et al. *Blood.* 2006 ;108(3) :1092-9.

care. While alloHCT may be curative, most subjects, especially older patients, and those with active disease, are not considered for transplant due to failure to achieve remission, poor tolerance of conditioning, and substantial transplant-related mortality.[2,3] Outcomes of alloHCT in R/R AML patients using reduced-intensity conditioning regimens are poor due to high post-transplant relapse rates.

Significant challenges must be overcome to enable potentially curative alloHCT in a broader population: the alloHCT candidate 1) must first attain a CR, 2) must tolerate and survive effective conditioning; the recipient 3) must achieve engraftment and post-transplant CR and 4) must surmount alloHCT-related complications including graft failure and serious side effects of sepsis and/or graft versus host disease (GVHD).

Mechanism of Action
^{131}I-apamistamab is an investigational anti-CD45 murine monoclonal antibody (BC8) covalently bound with radioactive isotope iodine (^{131}I). CD45 is expressed on all hematopoietic cells and on most hematopoietic malignancies, including AML. Per the requestor, the use of ^{131}I-apamistamab allows targeted delivery of the radiation dose directly to leukemic cells while sparing healthy organs such as lungs, heart, and GI tract. The requestor states that ^{131}I-apamistamab has been studied in approximately four hundred patients including Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory AML (SIERRA) trial, which was a multicenter, open-label, randomized, controlled, 2 arm, optional 1-way crossover study of ^{131}I-apamistamab versus the investigator's choice of conventional care (CC) in subjects aged 55 or older with active, R/R AML.

Inpatient Administration of ^{131}I-apamistamab
The therapeutic regimen of ^{131}I-apamistamab takes place in the inpatient setting. The dosimetric infusion will be performed in the outpatient setting, and patients will be admitted as hospital inpatient prior to receiving the therapeutic infusion of ^{131}I-apamistamab. After receiving the therapeutic dose, patients stay in radiation isolation for about 3-7 days following which there are two possible scenarios: 1) the patient remains inpatient and proceeds with fludarabine and low-dose total body irradiation (TBI) followed by alloHCT and engraftment/recovery or 2) the patient is discharged after the therapeutic dose of ^{131}I-apamistamab and receives fludarabine as outpatient to be readmitted for TBI and alloHCT and engraftment/recovery.

The ^{131}I-apamistamab therapeutic dose is administered following a dosimetric dose. The patient is premedicated with antiemetics, antihistamines, hydrocortisone, and acetaminophen prior to initiation of infusion and repeated as needed for any infusion reactions. The therapeutic dose for each subject is individualized, based on the dosimetric findings to deliver 24 Gy radiation to the dose limiting organ (typically liver), or 48 Gy to the bone marrow, whichever is predicted to receive the highest estimated dose of radiation. The therapeutic infusion is to be administered 6 to 14 days after the dosimetric infusion. The day of therapeutic infusion is considered Day -12 relative to the timing of the allogeneic HCT (Day 0).

^{131}I-apamistamab is administered via continuous intravenous infusion over 6-8 hours and is followed by a 1-hour saline flush. Following the administration of the therapeutic infusion of ^{131}I-apamistamab, patients will be scheduled to receive fludarabine on days -4, -3, and -2 prior to

[3] Gyurkocza et al. Late Breaking Abstract, Transplantation & Cell Therapy (TCT) 2023.

the alloHCT, and an immunosuppression regimen will be initiated per the institutional GvHD prophylaxis protocol being used. On Day 0, patients will receive low-dose total body irradiation (TBI), that will be followed by the infusion of the donor hematopoietic stem cells.

^{131}I- apamistamab enabled 100% of patients to undergo alloHCT after receiving the therapeutic dose, compared with 17% of CC treated subjects.[3] Efficacy was measured by the percentage of subjects achieving durable complete remission (dCR) defined as initial CR/complete platelet recovery (CRp) assessed 28-56 days post alloHCT or 28-42 days post initiation of therapy on the CC arm, that lasted ≥180 days. Compared to no subjects achieving dCR in the CC group (0/77, 0%), the dCR rate for the ^{131}I- apamistamab group was 17.1% (13/76) in the Intent to Treat (ITT) Analysis Set and 22.0% (13/59) in the Per Protocol (PP) Analysis Set ($p<0.0001$).[3] The incidence of sepsis was greater than four times lower (6.1% vs. 28.6%); while febrile neutropenia (43.9% vs. 50.0%), mucositis (15.2% vs. 21.4%) and acute GvHD (26.1% vs. 35.7%) were lower in favor of ^{131}I-apamistamab.[3] Per the requestor, ^{131}I-apamistamab infusion can be associated with infusion reactions commonly experienced when patients receive monoclonal antibodies.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of ^{131}I-apamistamab. Facilities can report the intravenous administration of ^{131}I-apamistamab using one of the following codes:

3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04305	Introduction of other antineoplastic into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of ^{131}I-apamistamab. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of ^{131}I-apamistamab.

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 V** Iodine-131 Radiolabeled Apamistamab Antineoplastic	**9** New Technology Group 9

CMS Recommendation: Option 2, as described above.

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

Topic # 09 - Administration of Talquetamab

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of talquetamab. The requestor is seeking an April 1, 2024 implementation date.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-On Payment (NTAP) application for FY 2025 consideration.

Food and Drug Administration (FDA) Approval? Yes. The requestor received FDA accelerated approval for TALVEY™ (talquetamab) on August 9, 2023. TALVEY™ (talquetamab) is a bispecific antibody indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody. The indication is approved under accelerated approval based on response rate and durability of response. The requestor received Orphan Drug designation for the treatment of multiple myeloma by the FDA and PRIME designation by the European Commission (2021) and Breakthrough Therapy designation (June 2022).

Background: Multiple myeloma (MM) is a rare blood cancer that affects plasma cells. MM occurs when healthy cells turn into abnormal cells that multiply and produce abnormal antibodies called M proteins. The abnormalities can affect bones, kidneys, and the body's ability to make healthy white and red blood cells and platelets. Multiple myeloma remains incurable, and most patients eventually relapse, even with the advent of new treatments.[1] Novel, innovative therapies are needed to improve long-term survival and outcomes.

Immunotherapies, which include chimeric antigen receptor T-cell (CAR-T) therapy as well as some antibody-based therapies, engage the patient's immune system to fight cancer. These therapies (bispecifics) essentially use the patient's own immune system to fight cancer by binding to the patient's T-cells, and to multiple myeloma cells expressing a specific surface antigen.

Bispecific antibodies (bsAbs) are a new class of drug, which can facilitate T-cell engagement without the need for patient cell collection and external manipulation. G protein-coupled receptor class C group 5 member D (GPRC5D) is an orphan, seven transmembrane G-protein coupled receptor that is normally expressed in plasma cells. GPRC5D mRNA is overexpressed in the bone marrow of patients with multiple myeloma with low expression in normal tissues. Additionally, GPRC5D protein is overexpressed on multiple myeloma cells from bone marrow samples with a distribution that mimics BCMA.[2] According to the requestor, taken together, data suggests that GPRC5D is a potential target for anti-myeloma therapy.

[1] Rajkumar, SV. Multiple myeloma: Every year a new standard? *Hematological Oncology*. 2019; 37(S1): 62– 65. https://doi.org/10.1002/hon.2586

[2] Smith, Eric L et al. GPRC5D is a target for the immunotherapy of multiple myeloma with rationally designed CAR T cells. *Science translational medicine* 2019; 11(485): eaau7746. doi:10.1126/scitranslmed.aau7746

Mechanism of Action
TALVEY™ (talquetamab) is a full-sized bispecific antibody that binds to CD3-expressing T-cells to myeloma cells that express GPRC5D, resulting in activation of the T-cell receptor pathway and lysis of GPRC5D-expressing MM cells. This is mediated by secreted perforin and various granzymes stored in the secretory vesicles of cytotoxic T-cells. These activated T-cells also lead to the production of cytokines, chemical signals that activate other T-cells to create a microenvironment that leads to further immune activation, augmenting the anti-tumor response.[1] Talquetamab was developed by controlled fragment antigen binding arm exchange from two parental antibodies using the DuoBody platform which generates a full-sized antibody. Per the requestor, this structure is advantageous as it is designed to mimic naturally occurring IgG antibodies resulting in longer stability. Additionally, talquetamab can be administered subcutaneously (SC) and does not require bolus or continuous intravenous (IV) infusion.

Inpatient Administration of Talquetamab
Talquetamab is a drug administered via subcutaneous injection. Patients will follow either a weekly or biweekly (every two weeks) treatment schedule. Under both the weekly and biweekly dosing schedule, patients should be admitted to the hospital for the priming doses. It is expected that the subsequent treatment doses will be administered in an ambulatory care setting. Patients on the weekly dosing schedule will receive three priming doses during the first five days of treatment: 10 μg/kg for the first priming dose, 60 μg/kg for the second priming dose, and 40 μg/kg for the third priming dose and once per week for the treatment dose thereafter. Patients receiving treatment on a biweekly dosing schedule will receive four priming doses during the first seven days of treatment: 10 μg/kg for the first priming dose, 60 μg/kg for the second priming dose, 40 μg/kg for the third priming dose, and 80 μg/kg for the fourth priming dose and once every two weeks for the treatment dose thereafter.

Most of the high-grade adverse events (AE) were cytopenias, which were limited to the first few cycles of administration. The most common AEs were cytokine release syndrome (CRS), skin related events and dysgeusia.[3] Low rates of grade 3/4 nonhematologic AEs were observed and low rates of discontinuation due to AEs were observed with once weekly (QW) (4.9%) and once every 2 weeks (Q2W) (6.2%) dosing schedules. Cytokine Release Syndrome (CRS) occurred in 79% and 72% of patients respectively, but 2% and 1% of patients developed grade 3 CRS.

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

3E01305	Introduction of other antineoplastic into subcutaneous tissue, percutaneous approach

Coding Options

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

[3] Chari A, et al. Presented at 64th American Society of Hematology (ASH) Annual Meeting; December 10-13, 2022; New Orleans, LA.

Option 2. Create a new code in section X, New Technology, to identify the subcutaneous administration of talquetamab.

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
1 Subcutaneous Tissue	**3** Percutaneous	**ADD 2** Talquetamab Antineoplastic	**9** New Technology Group 9

CMS Recommendation: Option 2, as described above.

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