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
March 19, 2024

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: March 19, 2024: 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: March 20, 2024: 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.

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Note: Proposals for diagnosis code topics are scheduled for March 20, 2024 and will be led by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS). 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.

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

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Jeanine DuVerney
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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. Restriction using Thoracoabdominal Branch Endoprosthesis* Pages 15-17 9:10 AM – 9:25 AM	Mady Hue, CMS Bjoern D. Suckow, MD, MS Vascular Surgery, Assistant Professor of Surgery Dartmouth Hitchcock Medical Center
2. Tibiotalocalcaneal Fusion with Internal Fixation Device* Pages 18-20 9:25 AM – 9:40 AM	Mady Hue, CMS Christopher Kreulen, MD Associate Professor, Department of Orthopedic Surgery UC Davis Medical Center
3. Endovascular Procedures using Fiber Optic 3D Guidance** Pages 21-23 9:40 AM – 9:55 AM	Jeanine DuVerney, CMS Dr. Marc Schermerhorn Chief of Vascular and Endovascular Surgery Beth Israel Deaconess Medical Center
4. Visualization and Analysis of Brain Networks in Magnetic Resonance Imaging* Pages 24-26 9:55 AM – 10:10 AM	Jeanine DuVerney, CMS Michael Sughrue, MD Neurosurgeon, Chief Medical Officer, Founder Omniscient Neurotechnology
5. Lymphatic Bypass Pages 27-29 10:10 AM – 10:25 AM	Jeanine DuVerney, CMS Lynn Kuehn President Kuehn Consulting, LLC
6. Performance of Extracorporeal Circulatory Filtration Pages 30-31 10:25 AM – 10:40 AM	Andrea Hazeley, CMS Lynn Kuehn President Kuehn Consulting, LLC
7. Quantitative Antimicrobial Susceptibility Testing of Blood Cultures using Small Molecule Sensor Array Technology** Pages 32-34 10:40 AM – 10:55 AM	Andrea Hazeley, CMS Shawn MacVane Lead Medical Scientist bioMérieux

8. Transcatheter Tricuspid Valve Replacement* Pages 35-36 10:55 AM – 11:10 AM	Andrea Hazeley, CMS Colin Barker, MD Director, Interventional & Structural Cardiology & Associate Professor of Medicine Vanderbilt University Medical Center
9. Cellular Assessment via Microfluidic Deformability Cytometry** Pages 37-38 11:10 AM – 11:25 AM	Jeanine DuVerney, CMS Robert Scoggins, M.D., PhD Chief Medical Officer Cytovale
10. Fixation of Lumbar Facet Joint** Pages 39-41 11:25 AM – 11:40 AM	Jeanine DuVerney, CMS Ahmed M. Khan, MD Assistant Clinical Professor Neurological Surgery, Chief of Neurosurgery Central Connecticut Neurosurgery and Spine
11. Extracorporeal Blood Pathogen Removal** Pages 42-44 11:40 AM – 11:55 AM	Jeanine DuVerney, CMS Jonathan Chow, M.D. Associate Professor of Anesthesiology and Critical Care Medicine George Washington University
12. Application of prademagene zamikeracel** Pages 45-47 11:55 AM – 12:10 PM	Mady Hue, CMS Madhav Vasanthavada, Ph.D. SVP, Chief Commercial Officer Head of Business Development Abeona Therapeutics
13. Administration of Non-CAR-T Immune Effector Cell Therapy Pages 48-49 12:10 PM – 12:25 PM	Mady Hue, CMS Kirsten Raehal, PhD Senior Project Manager UCHealth
LUNCH BREAK 12:30 PM to 1:30 PM	
14. Administration of dasiglucagon Pages 50-52 1:30 PM – 1:45 PM	Jeanine DuVerney, CMS Evan Charles Frary Senior Director, Head of Medical Affairs Zealand Pharma A/S

15. Drug-Eluting Resorbable Scaffold System**
    Pages 53-56
    1:45 PM – 2:00 PM

    Jeanine DuVerney, CMS
    Karine Ruster, PhD
    Associate Director, Clinical Research-Vascular
    Abbott

16. Continuous Monitoring and Assessment of Vascular Blood Flow*
    Pages 57-59
    2:00 PM – 2:15 PM

    Jeanine DuVerney, CMS
    Andrew Eibl
    Co-founder, VP Operations
    Flosonics Medical

17. Paclitaxel-Coated Balloon Catheter for Percutaneous Coronary Intervention**
    Pages 60-63
    2:15 PM – 2:30 PM

    Mady Hue, CMS
    Rodrigo Modolo, MD
    Medical Director, Interventional Cardiology
    Boston Scientific

18. Division of Bioprosthetic Aortic Valve Leaflets**
    Pages 64-67
    2:30 PM – 2:45 PM

    Mady Hue, CMS
    Philippe Genereux, MD
    Director of Structural Heart Program
    Morristown Medical Center

19. Computer-aided Triage and Notification for Measurement of Intracranial Cerebrospinal Fluid Flow*
    Pages 68-70
    2:45 PM – 3:00 PM

    Andrea Hazeley, CMS
    Rick Abramson, MD, MS
    Chief Medical Officer
    Annalise AI

20. Implantation of a Bioengineered Vessel**
    Pages 71-75
    3:00 PM – 3:15 PM

    Andrea Hazeley, CMS
    Laura Niklason MD, PhD
    Founder and CEO
    Humacyte

21. Rapid Antimicrobial Susceptibility Testing of Blood Cultures*
    Pages 76-78
    3:15 PM – 3:30 PM

    Andrea Hazeley, CMS
    Tiziana Di Martino
    Chief Medical Officer
    Q-linea

22. Stereoelectroencephalographic Radiofrequency Ablation of Brain and Nervous Tissue
    Pages 79-81
    3:30 PM – 3:45 PM

    Mady Hue, CMS
    Robert E. Gross, MD, PhD
    Joint Chair of the Dept. of Neurosurgery at RWJ Medical School and NJ Medical School
    Rutgers University

23. Administration of Antibiotic Using Temporary Joint Spacer System** Pages 82-84 3:45 PM – 4:00 PM	Mady Hue, CMS Bryan Springer, MD Fellowship Director, OthoCarolina Hip and Knee Center Professor of Orthopaedic Surgery Atrium Musculoskeletal Institute
24. Posterior Fixation of the Thoracolumbar Spine* Pages 85-87 4:00 PM – 4:15 PM	Mady Hue, CMS Maziyar A. Kalani, M.D. Neurosurgeon Mayo Clinic Scottsdale
25. Section X Updates Pages 88-99 4:15 PM – 4:30 PM	Jeanine DuVerney, CMS
26. Addenda and Key Updates Pages 100-110 4:30 PM – 4:45 PM	Andrea Hazeley, CMS
Closing Remarks	Mady Hue, CMS

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

27. Administration of bentracimab** Pages 111-113	Mady Hue, CMS
28. Administration of cefepime-taniborbactam* Pages 114-116	Jeanine DuVerney, CMS
29. Administration of ceftobiprole medocaril* Pages 117-118	Jeanine DuVerney, CMS
30. Administration of obecabtagene autoleucel** Pages 119-122	Mady Hue, CMS
31. Administration of odronextamab* Pages 123-125	Jeanine DuVerney, CMS

[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-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials.

32. Administration of Orca-T** Pages 126-127	Mady Hue, CMS
33. Administration of RP-L201 (marnetegragene autotemcel)** Pages 128-130	Mady Hue, CMS
34. Administration of zanidatamab** Pages 131-133	Mady Hue, CMS
35. Donislecel-jujn Allogeneic Pancreatic Islet Cellular Suspension for Hepatic Portal Vein Infusion* Pages 134-137	Jeanine DuVerney, CMS

** Requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2025.*
*** Requestor intends to submit a NTAP application for FY 2026 consideration.*

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

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

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

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

ICD-10 TIMELINE

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

March 19-20, 2024	The ICD-10 Coordination and Maintenance Committee Meeting.
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-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials
April 1, 2024	Any new or revised ICD-10 codes finalized from the September 2023 ICD-10 Coordination and Maintenance Committee meeting 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 the Omnibus Budget Reconciliation Act of 1986, Public Law 99-509 (Pub. L. 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/payment/prospective-payment-systems/acute-inpatient-pps
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 addenda 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-billing/icd-10-codes
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 Pub. L. 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/payment/prospective-payment-systems/acute-inpatient-pps
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-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials 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-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials
October 1, 2024	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes. Final addenda 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-billing/icd-10-codes
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-billing/icd-10-codes/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 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
  - April 19, 2024 for codes being considered for October 1, 2024 implementation
  - May 17, 2024 for codes being considered for April 1, 2025 or October 1, 2025 implementation
- Procedure comments to CMS: ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to NCHS: nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2024 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2024 C&M meeting

- August 2024 – Final rule with links to final codes to be implemented October 1, 2024
  - Includes any additional codes approved from March 19-20, 2024 C&M meeting
  - https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps

Addenda

- May/June 2024 – Final code updates and addenda posted
  - FY 2025 ICD-10-PCS (Procedures)
    https://www.cms.gov/medicare/coding-billing/icd-10-codes
  - FY 2025 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
  - April 19, 2024 for codes being considered for October 1, 2024 implementation
  - May 17, 2024 for codes being considered for April 1, 2025 or October 1, 2025 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 October 1, 2024 implementation

September 10-11, 2024 C&M Code Requests

- June 7, 2024 – Deadline for submitting topics for September 10-11, 2024 C&M meeting
  - Procedure requests to CMS: https://mearis.cms.gov
  - Diagnosis requests to NCHS: nchsicd10cm@cdc.gov

Topic # 01 – Restriction using Thoracoabdominal Branch Endoprosthesis

Issue: There are no unique ICD-10-PCS codes to describe the insertion of a thoracoabdominal branch endoprosthesis. 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? Yes. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) Device received FDA approval on January 12, 2024 under the Premarket Approval (PMA) process for the endovascular repair of thoracoabdominal aortic aneurysms and in high-surgical risk patients with pararenal aortic aneurysms who have the indicated anatomy.

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

Technology

The TAMBE Device is an endoprosthesis that provides endovascular treatment of aneurysms extending into the visceral segment of the aorta. The TAMBE Device is comprised of multiple required components including: 1) an Aortic Component, 2) Branch Components, 3) a Distal Bifurcated Component (DBC), and a 4) Contralateral Leg Component. For some patients a DBC Extender Component may be used to reinforce the seal between the Aortic Component and the Distal Bifurcated Component. Together, these components comprise the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) device. The proximal end is placed in the thoracic aorta and the distal end in the iliac arteries.

Procedure Description

1. A brief overview of the procedural steps for endovascular placement of the TAMBE Device are described below (refer to the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis Instructions for Use for full details):
    a. Following standard clinical practice, arterial access is gained via bi-lateral iliac/femoral and brachial/axillary vascular access with five through-and-through guidewires.
    b. The TAMBE Device Aortic Component (AC) has four removable guidewire tubes to facilitate pre-cannulation of guidewires through the portals.
    c. The TAMBE Device AC on the delivery catheter is tracked via femoral / iliac access through a 22 Fr sheath and positioned with portals in proximity to the target branch vessels (celiac, superior mesenteric, and renal arteries). With the AC positioned in the aorta at a level where the outlet of the proximal portals is 1 to 3 cm above the origin of the most proximal visceral artery, deployment initiates from the leading end and proceeds toward the trailing end of the delivery system.

d. Removing the white outer knob of the delivery system deploys the AC to approximately 50% of the final diameter while the proximal fixation anchors remain constrained. At this time the position can be adjusted. Once the desired position is confirmed, the gray nut on the delivery system is rotated counterclockwise to unconstrain the proximal end to engage the anchors into the aortic wall. From the upper extremity access, target branch vessels are sequentially cannulated from their respective pre-cannulated portal guidewires. Once all branch vessels are cannulated with appropriate wires exchanged and final positioning confirmed, the constraining system, which includes the secondary sleeve, can be removed. This is done by sliding the red safety lock on the delivery system back with rotating the secondary deployment knob counterclockwise and pulling back.
e. The Branch Components are introduced through each AC portal into its target branch vessel and deployed.
f. Once three of the four branches are deployed, the distal sleeve of the AC can be deployed to fully deploy the distal end of the TAMBE Device AC. This is accomplished by rotating the gray deployment knob counterclockwise and pulling back.
g. Once the final stage of the TAMBE Device AC is deployed, the delivery catheter may be removed, and the final branch may be deployed.
h. The Distal Bifurcated Component, which bifurcates the TAMBE Device, is introduced into the distal portion of the TAMBE Device AC and deployed.
i. Deployment of the Contralateral Leg Components and any necessary limb extensions complete the TAMBE Device by mating with the Distal Bifurcated Component and sealing in the common iliac arteries. To complete the procedure, all component seal zones and junctions are ballooned with appropriate balloon catheters. A final angiogram may be performed to confirm exclusion of the aneurysm and device seal integrity.

Current Coding: There are no unique ICD-10-PCS codes to describe restriction using a thoracoabdominal branched endoprosthesis. Code the procedure with two codes: in table 02V Restriction of Heart and Great Vessels, use the body part value W Thoracic Aorta, Descending, the device value D Intraluminal Device and the percutaneous approach; in table 04V, Restriction of Lower Arteries, use the body part value 0 Abdominal Aorta, the device value F Intraluminal Device, Branched or Fenestrated, Three or More Arteries and the percutaneous approach.

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

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

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **E** Intraluminal Device, Branched or Fenestrated, One or Two Arteries **F** Intraluminal Device, Branched or Fenestrated, Three or More Arteries **Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for restriction using a thoracoabdominal branched endoprosthesis. Continue coding as described in current coding.

Option 2. In section X New Technology table X2V, Restriction, Cardiovascular System, create new device value S Branched Intraluminal Device, Manufactured Integrated System, Four or More Arteries, applied to the new body part value E Descending Thoracic Aorta and Abdominal Aorta and the percutaneous approach, to identify restriction using thoracoabdominal branched endoprosthesis.

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

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

CMS Recommendation: Option 2, as described above.

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

Topic # 02 – Tibiotalocalcaneal Fusion with Internal Fixation Device

Issue: There are no unique ICD-10-PCS codes to describe the use of a gyroid-sheet lattice designed internal fixation device for tibiotalocalcaneal fusion to provide stabilization of the hindfoot and ankle. 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. The restor3d TIDAL™ Fusion Cage was granted Breakthrough Medical Device status by the FDA in June 2023. According to the requestor, 510(k) was submitted in September 2023 and is currently under active FDA review.

Background: Tibiotalocalcaneal (TTC) fusion (or arthrodesis) is performed to treat conditions such as severe arthritis in the ankle and hindfoot, severe arthropathy of the ankle and subtalar joint, complications from previous procedures, and other deformities. The current treatment option for limb salvage in the case of critical sized defects in the ankle is TTC fusion using a bulk femoral head allograft and intramedullary nail. This procedure can be effective in reducing pain, but there is a significant rate of non-fusion in patients with a history of smoking, diabetes, and Charcot arthropathy, even if there is no significant bone defect. Ford et al. evaluated fusion rates with a nitinol nail and identified a 71% fusion rate in patients with Charcot arthropathy as compared to 94% in those without. In patients with significant bone defects, non-fusion rates are higher.[1] Jeng et al. reported a fusion rate of 50% across all patients; however, 0% of diabetic patients and only 33% of Charcot patients demonstrated fusion in this study. A common reported complication included collapse of the graft.[2] Estimates suggest that 5-10% of TTC fusion procedures across all populations are not successful.

The restor3d TIDAL™ Fusion Cage System is intended for patients undergoing tibiotalocalcaneal fusion to provide stabilization of the hindfoot and ankle procedures. According to the requestor, the restor3d TIDAL™ Fusion Cage provides a solution to an unmet need for treatment of critical size bone defects for ankle fusion, and avoids complications related to bone graft resorption or failure, and infection. In a clinical study of similar custom cages, the percentage of patients ambulating post-surgery without assistance nearly doubled compared to the current standard of care, increasing from 46% (6/13) preoperatively to 85% (11/13) postoperatively.[3] The population indicated for the restor3d TIDAL™ Fusion Cage System includes those who do not have significant contraindications such as active infection or severe longitudinal deformity. The requestor stated that the restor3d TIDAL™ Fusion Cage System can also be used in patients who have bone defects, Charcot arthropathy, and in patients with diabetes who are at significant risk of complications.

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[1] Ford SE, Kwon JY, Ellington JK. Tibiotalocalcaneal Arthrodesis Utilizing a Titanium Intramedullary Nail With an Internal Pseudoelastic Nitinol Compression Element: A Retrospective Case Series of 33 Patients. J Foot Ankle Surg. 2019;58(2):266-272. doi:10.1053/j.jfas.2018.08.046

[2] eng CL, Campbell JT, Tang EY, Cerrato RA, Myerson MS. Tibiotalocalcaneal arthrodesis with bulk femoral head allograft for salvage of large defects in the ankle. Foot Ankle Int. 2013;34(9):1256-1266. doi:10.1177/1071100713488765

[3] Zhang H, Vogel M, Malarkey WM, Cush GJ. Charcot Arthropathy Limb Salvage with 3D Custom Cage and Dynamic Hindfoot Fusion Nail Combination Fixation: A Case-Series. Foot & Ankle Orthopaedics. 2022;7(4). doi:10.1177/2473011421S01018.

Technology
According to the requestor, the restor3d TIDAL™ Fusion Cage System is comprised of a set of cages (i.e., implants) available in a wide range of heights and diameters, permitting surgeons to choose the appropriate size for the patient's affected anatomy. Specifically, there are fusion cages available in the shape of a sphere, a cylinder, or cylinder with spherical distal region. Each fusion cage is a single, continuous piece of titanium alloy fabricated by laser powder bed fusion, an additive manufacturing technology. The fusion cage is intended to be used for tibiotalocalcaneal fusion by providing stabilization of the hindfoot and ankle in conjunction with an intramedullary nail for fixation. The system's fusion cages have a porous structure and are designed with a gyroid-sheet lattice that vary in shape and size to align with the patient's specific anatomy. The fusion cages also feature a central clearance hole to provide a channel for the intramedullary nail to pass through the device and to accommodate bone graft, if desired.

Procedure Description
The surgeon will first prepare the surgical site for the specific procedure that is being performed with the accepted technique (e.g., bone resection, talectomy, etc.). The fusion cage can only be implanted in the ankle joint between the talus and the tibia and only one fusion cage device is used for each ankle. While it is possible for a bilateral procedure to be performed, it would most likely occur during different operative episodes. Following resection of the bone, talectomy or preparation of the joint, the surgeon will determine the correct size and shape with the implant materials so the fusion cage can be placed to span the defect of the ankle and/or hindfoot.
The surgeon will then prepare the fusion cage implant including packing with bone graft material, if desired. Next, the surgeon will orient the implant correctly and carefully insert into the joint and verify the implant position. Following placement of the TIDAL™ Fusion Cage, the surgeon will place the intramedullary nail (or TTC fusion nail) through the central clearance hole of the cage according to the nail manufacturer's surgical technique. The surgeon will complete the surgical fixation procedure and confirm the TIDAL™ Fusion Cage and nail placement on fluoroscopy**.**

Current Coding: There are no unique ICD-10-PCS codes to describe a gyroid-sheet lattice designed porous internal fixation device for tibiotalocalcaneal fusion to provide stabilization of the hindfoot and ankle. Code the procedure using the appropriate ankle joint body part value in table 0SG, Fusion of Lower Joints, with approach value 0 Open and device value 4 Internal Fixation Device.

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

Body Part	*Approach*	*Device*	*Qualifier*
9 Hip Joint, Right **B** Hip Joint, Left **C** Knee Joint, Right **D** Knee Joint, Left **F** Ankle Joint, Right **G** Ankle Joint, Left **H** Tarsal Joint, Right **J** Tarsal Joint, Left **K** Tarsometatarsal Joint, Right **L** Tarsometatarsal Joint, Left **M** Metatarsal-Phalangeal Joint, Right **N** Metatarsal-Phalangeal Joint,	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**3** Internal Fixation Device, Sustained Compression **4** Internal Fixation Device **5** External Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

Left **P** Toe Phalangeal Joint, Right **Q** Toe Phalangeal Joint, Left			

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe a gyroid-sheet lattice designed internal fixation device for tibiotalocalcaneal fusion to provide stabilization of the hindfoot and ankle. Continue coding as described in current coding.

Option 2. In New Technology Fusion Table XRG, Fusion of Joints, create new device value C Internal Fixation Device, Gyroid-Sheet Lattice Design, applied to body part values J Ankle Joint, Right and K Ankle Joint, Left, to identify a gyroid-sheet lattice design fusion device for the ankle joint that is used to provide stabilization of the hindfoot and ankle.

Section	**X** New Technology		
Body System	**R** Joints		
Operation	**G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
J Ankle Joint, Right **K** Ankle Joint, Left	**0** Open	**ADD C** Internal Fixation Device, Gyroid-Sheet Lattice Design	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 03 – Endovascular Procedures using Fiber Optic 3D Guidance

Issue: There are no unique ICD-10-PCS codes to describe the utilization of fiber optic 3D guidance during endovascular procedures such as endovascular aortic repair (EVAR). An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. According to the requestor, the fiber optic 3D guidance device (LumiGuide) and (LumiGuide) 3D Hub are anticipated to attain FDA clearance by the end of the first quarter of 2024.

Background: Historically, for endovascular procedures, fluoroscopy has been the primary technology utilized to provide minimally invasive guidance for endovascular interventions. As the discipline has advanced, surgeons have refined endovascular techniques to address a wider spectrum of vascular diseases. For aortic diseases, these endeavors have led to the development of endovascular aortic repair (EVAR) methods capable of treating multiple target vessels and managing a more extensive range of conditions. Nevertheless, using fluoroscopy as guidance for these more complex endovascular interventions is limiting as it depends on a 2-dimensional (2D) imaging modality while navigating in a 3-dimensional (3D) anatomical space. Additionally, the increase in repair complexity requires greater fluoroscopy time and ionizing radiation doses, which has shown to lead to increased risk of radiation injuries for patients, physicians, and operating room staff.[1,2] Per the requestor, as compared to conventional methods described above, LumiGuide enables more purposeful and easier navigation of endovascular devices and reduces radiation exposure.[3]

Technology

The LumiGuide fiber optic 3D guidance device offers a new guidance option by enabling real-time and 3D device guidance by visualizing the full shape of a guidewire and catheter inside the body, without the need for X-ray. LumiGuide provides real-time 3D visualization by measuring light reflection differences caused by strain in optical fibers. LumiGuide, is comprised of a single-use angiographic guidewire with 3D visualization and a single-use 3D Hub. According to the requestor, the guidewire is intended to assist physicians in directing a catheter to a target vessel during endovascular procedures of the peripheral, aortic and aortic side branch vasculature. The 3D Hub connects to a catheter and tracks it over the LumiGuide guidewire enabling the physician to also visualize the catheter in real-time 3D. Both the LumiGuide guidewire and the 3D Hub enabled catheter are visualized in distinctive colors.

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[1] Lisle, M. P., Wakeford, R., Tawn, E. J., Bouffler, S. D., & Berrington de Gonzalez, A. (2009). Risks Associated with Low Doses and Low Dose Rates of Ionizing Radiation: Why Linearity May Be (Almost) the Best We Can Do. In Radiology (Vol. 251, Issue 1, pp. 6–12). Radiological Society of North America (RSNA).

[2] Wakeford, R. Radiation in the Workplace—a Review of Studies of the Risks of Occupational Exposure to Ionising Radiation. J Radiol Prot, 29 (2009), pp. A61-A79.

[3] Finnesgard, E. J., Simons, J. P., Jones, D. W., Judelson, D. R., Aiello, F. A., Boitano, L. T., Sorensen, C. M., Nguyen, T. T., & Schanzer, A. (2023). Initial single-center experience using Fiber Optic Real Shape guidance in complex endovascular aortic repair. In Journal of Vascular Surgery (Vol. 77, Issue 4, pp. 975–981). Elsevier BV.

Procedure Description
The fiber optic 3D guidance device (LumiGuide) is utilized in an inpatient setting and is documented in the operative report. At the initiation of the procedure utilizing the LumiGuide, vessel access is obtained via a percutaneous puncture. The physician secures vessel access most often through femoral arterial access although different vascular access points can be used (i.e., the brachial or axillary artery). An introducer sheath is placed at the entry point to facilitate device introduction.

After the introducer sheath is placed, the physician can load a preoperatively acquired 3D computed tomography (CT) roadmap to use 3D device navigation within a 3D roadmap. LumiGuide is unpacked, prepared, and set up by connecting the guidewire to the specialized capital visualization equipment. The guidewire (and 3D Hub enabled catheter) can now be inserted percutaneously into the patient's vasculature. After LumiGuide is registered with the interventional x-ray system, the operator can start using LumiGuide for 3D device guidance during the procedure and without the need for additional fluoroscopy. The physician can manually manipulate and navigate LumiGuide to reach the vessel of interest.

Once the target vessel has been reached, LumiGuide can be set aside for additional use if needed. Per the requestor, in-situ diagnosis or treatment delivery may now commence, for example by advancing a treatment device such as a balloon, stent and/or stent graft to the target vessel over a conventional guidewire. If LumiGuide is not required for additional navigation tasks in the procedure, it can be disposed of in accordance with hospital protocols.

According to the requestor, adverse effects associated with procedures that utilize LumiGuide are congruent with other endovascular procedures and include access site complications, dissection, perforation, embolism, and spasm.

Current Coding: There are no unique ICD-10-PCS codes to describe the utilization of fiber optic 3D guidance during endovascular procedures. Facilities would report the appropriate code(s) for the endovascular procedure performed, such as EVAR.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for fiber optic 3D guidance during endovascular procedures. Continue coding the endovascular procedure(s) performed as described in current coding.

Option 2. In table 8E0, Other Procedures, create new method value F Fiber Optic 3D Guided Procedure applied to existing body region value 2 Circulatory System and the percutaneous approach, to describe the utilization of fiber optic 3D guidance during endovascular procedures such as EVAR. Facilities would also report the appropriate code(s) for the endovascular procedure(s) performed.

Section **8** Other Procedures *Body System* **E** Physiological Systems and Anatomical Regions *Operation* **0** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease			
Body Region	*Approach*	*Method*	*Qualifier*
2 Circulatory System	**3** Percutaneous **X** External	**D** Near Infrared Spectroscopy	**Z** No Qualifier
2 Circulatory System	**3** Percutaneous	**ADD F** Fiber Optic 3D Guided Procedure	**Z** No Qualifier

CMS Recommendation: Option 2, as described above.

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

Topic # 04 – Visualization and Analysis of Brain Networks in Magnetic Resonance Imaging

Issue: There are no unique ICD-10-PCS codes to describe connectomic analysis and visualization of brain networks. 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? Yes. The Quicktome device received 510(k) clearance on March 09, 2021. The device is indicated for use in the processing of diffusion-weighted magnetic resonance imaging (MRI) sequences into three dimensional (3D) maps that represent white matter tracts based on constrained spherical deconvolution methods, and atlas-assisted visualization and segmentation. Additionally, Quicktome received expanded indications on May 30, 2023, to include the generation of motor, language, and vision resting state functional MRI correlation maps using task-analogous seeds.

Background: The clinical and economic burden associated with neurologic conditions such as brain tumors, epilepsy, and traumatic brain injury is substantial. The incidence of both primary malignant and non-malignant brain tumors in the US is ~14.8/100,000/year[1] and about 3.4 million Americans live with active epilepsy.[2] According to the requestor, patient and healthcare economic burdens associated with neurologic conditions encompass hospitalization and surgery costs, rehabilitation, and indirect costs such as productivity loss and caregiving due to iatrogenic damage to or degeneration of brain networks. Efforts to mitigate this burden include connectomic brain analysis, which provides clinicians with unprecedented information about the location and function of a patient's brain networks, providing information to the clinician that was previously only available in research settings. Clinicians have previously relied on various technologies and techniques that provide significantly less detail regarding brain networks and/or require highly trained personnel to process this information.

Per the requestor, 'tractography' is a brain imaging technique that broadly describes the mapping of the location and direction of white matter bundles and their constituent fibers within the human brain. While tractography can show the fiber bundles of the brain, it is limited by its lack of ability to label and differentiate between fibers. Tractography lacks the ability to show how these fiber bundles are grouped into brain networks and therefore limits users' ability to understand higher-order functions and the mental and neurological illnesses that present when they are damaged.

Functional MRI (fMRI) is another modality often used for preoperative planning primarily to map motor and language networks. Task-based fMRI (tb-fMRI) requires highly trained personnel to determine patient cognition and to choose suitable language paradigms. Thus, tb-fMRI can be challenging in brain tumor patients who may be cognitively impaired and are

[1] Therese A. Dolecek, Jennifer M. Propp, Nancy E. Stroup, Carol Kruchko, CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2005–2009, Neuro-Oncology, Volume 14, Issue suppl_5, November 2012, Pages v1–v49, https://doi.org/10.1093/neuonc/nos218

[2] Zack MM, Kobau R. National and State Estimates of the Numbers of Adults and Children with Active Epilepsy — United States, 2015. MMWR Morb Mortal Wkly Rep 2017;66:821–825. DOI: http://dx.doi.org/10.15585/mmwr.mm6631a1

unable to perform required tasks.[3] Resting-state fMRI is an alternative to tb-fMRI but also requires complex analysis by trained personnel through an unstandardized process.

Technology
Quicktome allows for the connectomic analysis of the location and function of a patient's unique brain networks, which are responsible for everything from language to movement to thought and emotion. Using data from a structural and/or a fMRI scan, Quicktome's proprietary artificial intelligence (AI) allows clinicians to assess the structural layout quickly and accurately (i.e., the locations and integrity) and/or the functional connectivity (i.e., how different brain regions are working together) of a patient's brain. The procedure involves the analysis and visualization of a subject's brain's interconnected functional networks, comprising of cortical grey matter regions and connective white matter tracts. The cortical surface of a subject is sub-divided, or parcellated, into functional areas based on the human connectome project multi-modal parcellation, version 1 (HCP-MMP1).

According to the requestor, when performing personalized cortical parcellation, Quicktome uses two approaches: Structural Connectivity Atlas (SCA) and topography-based mapping. These approaches are optimized for particular use cases. For users, the SCA is most useful for establishing the general locations of the parcels of interest and the white-matter tracts that connect them, especially in subjects with deformed brain anatomy. For users, the topography-based map is most useful for analyzing data derived from the cortex, such as fMRI blood oxygen level dependent (BOLD) signals and delineating the boundaries of cortical parcels.

Procedure Description
Per the requestor, Quicktome connectomic analysis can be utilized in both inpatient and outpatient settings and would be documented in either progress notes or an operative report. Connectomic analysis is performed through a cloud-based application whereby data from an MRI scan is uploaded to the platform via a Gap Server. The Gap Server allows secure interfacing between a user site's firewall and security environment and Quicktome's cloud servers. It will receive data from picture archiving and communication system (PACS) or another digital imaging and communications in medicine (DICOM) conformant device and de-identify it before submitting to the processing cloud for processing. Once processed, the case can be accessed by the user through the Quicktome Client Application which runs on standard supported browsers (e.g., Google Chrome, Microsoft Edge), without additional required add-ons or configurations. Once a case is selected, the user can visualize structural and/or functional maps of a patient's connectome and perform connectomic brain analyses relevant to the patient's pathology and treatment plan.

Per the requestor, a Quicktome scan may be uploaded, processed, and analyzed repeatedly over the course of a patient's treatment. For example, a preoperative scan may be performed prior to brain tumor resection to assess the extent of brain network damage due to the tumor and plan out a surgical trajectory that will spare as much brain function as possible. Following the surgery, additional scans may be uploaded, processed, and analyzed at regular intervals to assess any iatrogenic neurologic deficits that may occur, inform personalized rehabilitation programs, and assess recovery of brain function.

[3] Kumar, V.A., Heiba, I.M., Prabhu, S.S. et al. The role of resting-state functional MRI for clinical preoperative language mapping. Cancer Imaging 20, 47 (2020). https://doi.org/10.1186/s40644-020-00327-w

Quicktome is a standalone procedure, but it does require data from anatomical and diffusion weighted imaging MRI techniques and /or via functional MRI with required MRI acquisition protocols. Additionally, the requestor states, there are no adverse effects reported with the use of connnectomic analysis.

Current Coding: The use of software for visualization and analysis of brain networks is not reported separately for inpatient hospital coding. Facilities can report the brain MRI/fMRI using the appropriate code in section B, Imaging.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for connectomic analysis and visualization of brain networks. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify connectomic analysis and visualization of brain networks.

Section **X** New Technology *Body System* **X** Physiological Systems *Operation* **E** Measurement: Determining the level of a physiological or physical function at a point in time			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Central Nervous	**X** External	**ADD 3** Brain Networks, Computer-aided Connectomic Analysis and Visualization	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 05 – Lymphatic Bypass

Issue: There are no unique ICD-10-PCS codes to describe direct lymphatic system bypass to a vein or to another lymphatic structure. An October 1, 2024 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Not applicable

Background: Lymphedema occurs when the lymphatic load exceeds the transport capacity of the lymphatic system, which causes filtered fluid to accumulate in the interstitium. This imbalance between interstitial fluid production and transport may be due to congenital malformation of the lymphatic system, or damage to lymphatic vessels or lymph nodes leading to a reduction in the numbers of lymph channels or obstruction of the available channels. The accumulation of protein-rich fluid in the interstitial spaces results in impairment in the lymphatic circulation that can impair the quality of life and cause considerable morbidity.

Operative management of lymphedema is categorized into two general approaches: physiologic techniques and reductive techniques. Physiologic techniques create new channels to increase the capacity of the lymphatic system to transport lymph fluid. The surgical approaches to accomplish this goal include lymphatic bypass procedures, flap transposition procedures, and vascularized lymph node transfers. Of these physiologic techniques, lymphatic bypass procedures are more commonly used and require a high level of technical skill and expertise in microvascular surgery.

Technology
According to the requestor, the goal of lymphatic bypass procedures is to establish normal outflow of lymphatic fluid via a bypass between a lymphatic vessel and a local vein to treat or prevent lymphedema. These procedures are typically performed by a plastic surgeon due to the need for skill in using operating microscopes and superfine microsurgical instruments to direct anastomosis of the two structures using microsutures. .

Procedure Description
Indocyanine green dye is used to assess the lymphatic flow and determine appropriate lymphatic pathways. The lymphatic duct and the local venule are both prepared for anastomosis using superfine microsurgical instruments. Anastomosis is completed in either an end-to-end anastomosis, with or without "dunking" the lymphatic duct into the destination vein, or in an end-to-side anastomosis when the lymphatic duct and vein are of different sizes. Following anastomosis, the patency of the anastomosis is assessed using isosulfan blue dye. The procedure is documented in the operative report.

According to the requestor, lymphatic bypass can be performed on an outpatient basis, but surgeons are performing this procedure on appropriate patients as a prophylactic measure with the mastectomy surgery during an inpatient stay in patients with extensive lymph node excision and/or those for which radiation therapy is required. The lymphatic bypasses are meant to be permanent and multiple bypasses may be performed to reduce or eliminate lymphedema from developing in the extremity. Some patients also may require this type of surgery simultaneously

with radical prostatectomy with associated pelvic and inguinal node chain resection. The requestor stated the most often reported complication of the procedure is spontaneous occlusion of the anastomosis over time.

Current Coding: There are no unique ICD-10-PCS codes for lymphatic bypass. Code the procedure using the appropriate code in table 07Q, Repair of Lymphatic and Hemic Systems.

Section	**0** Medical and Surgical
Body System	**7** Lymphatic and Hemic Systems
Operation	**Q** Repair: Restoring, to the extent possible, a body part to its normal anatomic structure and function

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	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for lymphatic bypass. Continue coding as described in current coding.

Option 2. Create new root operation table 071, Bypass of Lymphatic and Hemic Systems, with new qualifier values 3 Peripheral Vein, 4 Central Vein, 7 Lymphatic, K Thoracic Duct and L Cisterna Chyli, applied to the lymphatic body part values, the approach values 0 Open and 4 Percutaneous Endoscopic, and the device value Z No Device, to identify direct lymphatic system bypass to a vein or to another lymphatic structure.

Section	**0** Medical and Surgical
Body System	**7** Lymphatic and Hemic Systems
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular 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	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**ADD 3** Peripheral Vein **ADD 4** Central Vein **ADD 7** Lymphatic **ADD K** Thoracic Duct **ADD L** Cisterna Chyli

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			

CMS Recommendation: Option 2, as described above.

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

Topic # 06 – Performance of Extracorporeal Circulatory Filtration

Issue: There are currently no unique ICD-10-PCS codes to describe extracorporeal circulatory filtration performed during a percutaneous thrombectomy procedure. An October 1, 2024 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The AngioVac Cannula received FDA 510(k) clearance on March 5, 2014. The AngioVac Cannula is indicated for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal filtration procedure for up to 6 hours.

Background: Thoracic central venous obstruction (TCVO) is a common venous outflow condition defined as more than 50 percent stenosis or thrombosis of a thoracic central vein. TCVO can be asymptomatic or present with variable degrees of edema and pain involving the upper extremity, chest, head or neck, respiratory symptoms, or neurologic manifestations from cerebral edema. TCVO encompasses a broad spectrum of diseases and may be related to central venous access and devices, hemodialysis arteriovenous access, anatomic abnormalities associated with venous thoracic outlet syndrome, malignancy, or prothrombotic states, among others.[1] Central venous thrombosis is a complex problem, particularly in cases where the thrombus burden is large.

Treatment options traditionally include several interventional catheter-based thrombus removal techniques such as aspiration, fragmentation, extraction, or rheolytic thrombectomy, but the vast majority of these techniques still need the concomitant use of thrombolytics to achieve an optimal result. Bleeding risk associated with prolonged infusion of thrombolytic agents and its limited effectiveness to treat subacute and chronic thrombus remain as significant challenges to achieve good clinical outcomes. The AngioVac System is the first aspiration thrombectomy device capable of removing a larger burden of undesired intravascular material such as thrombus, tumor, and foreign bodies without the need of lytics.[2] The device may be used in target vessels for thrombus/embolus extraction including, but not limited to, the iliofemoral vein, inferior vena cava (IVC), superior vena cava (SVC) and right atrium (RA).

Technology
The AngioVac System offers an alternative to existing therapies that treat venous thromboembolism. The AngioVac System is a disposable intravenous system that is used with extracorporeal circulatory support. The system consists of a 22-F AngioVac Cannula with a self-expanding tip that is used in conjunction with a reinfusion cannula as part of a venous return circuit.

The proprietary balloon activated, self-expanding tip of the AngioVac Cannula enhances venous flow, prevents clogging of the cannula and facilitates the removal of fresh, soft thrombi emboli, or

[1] Mousa, A. (2022). Endovenous intervention for thoracic central venous obstruction. UpToDate. Retrieved December 20, 2023, from https://www.uptodate.com/contents/endovenous-intervention-for-thoracic-central-venous-obstruction?search=angiovac%20&source=search_result&selectedTitle=1~3&usage_type=default&display_rank=1

[2] Behrens G, Bjarnason H. Venous Thromboembolic Disease: The Use of the Aspiration Thrombectomy Device AngioVac. Semin Intervent Radiol. 2015 Dec;32(4):374-8. doi: 10.1055/s-0035-1564792. PMID: 26622100; PMCID: PMC4640912.

vegetations from the venous system into the filter. A centrifugal pump enables suction at the tip, which, when deployed through either the internal jugular or femoral veins, enables removal of undesirable intravascular material. A benefit of the AngioVac Cannula is that it allows for removal of clot material, while minimizing blood loss and helping to prevent hemodynamic instability by reinfusing the filtered blood back into the body through the reperfusion cannula.

Procedure Description
AngioVac procedures are performed under general anesthesia. The system requires two venous access sites—one for aspiration and one for reperfusion. The access points may include any combination of the femoral vein and/or internal jugular veins. To begin the procedure, both sides of the neck and both groins are prepped for possible access and all venous punctures are made under ultrasound guidance. The patient is then fully anticoagulated with heparin reaching an activated clotting time in longer than 300 seconds. After venous access is obtained, an extracorporeal venous return circuit is created outside the body consisting of an outflow line, a centrifugal pump, a filter and an inflow line. When the centrifugal pump is activated, suction is created, removing blood and debris from around the tip of the AngioVac cannula, circulating the blood through the filter, and then returning the blood to the patient via the venous return cannula. At the end of the procedure, the aspiration cannula and the introducer are removed. The vascular access can be closed using a purse-string suture, direct suture repair, or manual compression for 20 to 30 minutes.

Current Coding: There are no unique ICD-10-PCS codes to describe extracorporeal circulatory filtration during percutaneous thrombectomy. Report the percutaneous thrombectomy procedure using the appropriate code from one of the cardiovascular system root operation Extirpation tables in the Medical and Surgical section.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for extracorporeal circulatory filtration during percutaneous thrombectomy. Continue coding as described in current coding.

Option 2. In section 5, Extracorporeal or Systemic Assistance and Performance, add existing function value 0 Filtration to the root operation table 5A1 Performance, applied to body system value 5 Circulatory and duration value A Intraoperative, to identify extracorporeal circulatory filtration during percutaneous thrombectomy. Facilities would also report the appropriate code(s) for the percutaneous thrombectomy.

Section	**5** Extracorporeal or Systemic Assistance and Performance		
Body System	**A** Physiological Systems		
Operation	**1** Performance: Completely taking over a physiological function by extracorporeal means		
Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**A** Intraoperative	**ADD 0** Filtration	**ADD Z** No Qualifier

CMS Recommendation: Option 2, as described above.

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

Topic # 07 – Quantitative Antimicrobial Susceptibility Testing of Blood Cultures using Small Molecule Sensor Array Technology

Issue: There are no unique ICD-10-PCS codes to describe the quantitative antimicrobial susceptibility testing (AST) of organisms direct from positive blood culture using small molecule sensor array technology. An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. FDA granted breakthrough device designation to the VITEK® REVEAL™ Rapid AST System on August 10, 2022 for quantitative antimicrobial susceptibility testing of organisms direct from positive blood culture. It is currently under review by the FDA with targeted 510(k) clearance by March 31, 2024.

Background: Every year 11 million people worldwide die of sepsis and 1.3 million of these deaths are attributable to antibiotic-resistant bacteria.[1,2] Currently, bloodstream infections (BSI) are typically diagnosed by a positive blood culture and other clinical findings. Following a positive blood culture, the provider will typically order gram-staining, microbial identification, and/or AST. Clinical laboratories perform AST so that they can determine if the bacteria causing the BSI are susceptible (or resistant) to various antibiotic therapy options. The treatment management decision (e.g., targeted therapy) is determined or at a minimum impacted by the phenotypic AST results.

The main shortcoming of all traditional AST methods is the need to generate pure bacterial colonies as an intermediate step of the process, which leads to times to AST results of 24-48 hours after blood culture positivity. Genotypic methods can decrease the time to results significantly, as they allow for determination of the presence of antimicrobial resistance in BSI or sepsis-causing pathogens in about 2 hours. However, genotypic methods do not provide minimum inhibitory concentrations (MIC), and neither positive nor negative genotypic results necessarily translate into phenotypic antimicrobial resistance. In many instances, genotypic methods are used as supplemental technology, which means that genotypic AST methods still have to be validated with phenotypic results. Therefore, rapid phenotypic AST that gives access to MIC values within a few hours remains a major unmet need in clinical microbiology.

Technology
The VITEK® REVEAL™ RAPID AST System is an automated in-vitro diagnostic (IVD) system for quantitative and qualitative phenotypic antimicrobial susceptibility testing of organisms directly from positive blood culture. The system and its corresponding assays are indicated for antimicrobial susceptibility testing of clinically validated Gram-negative pathogenic bacteria commonly associated with or causing bacteremia. According to the requestor, VITEK® REVEAL™ Rapid AST System has the potential to reduce the duration of unnecessary empiric antimicrobial therapy compared with traditional diagnostic methods. By facilitating earlier

[1] Rudd KE, Johnson SC, Agesa KM, Shackelford KA, Tsoi D, Kievlan DR, et al. Global, regional, and national sepsis incidence and mortality, 1990-2017: analysis for the Global Burden of Disease Study. Lancet (London, England). 2020;395(10219):200-11.
[2] Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet. 2022 Feb 12;399(10325):629-655. doi: 10.1016/S0140-6736(21)02724-0. Epub 2022 Jan 19. Erratum in: Lancet. 2022 Oct 1;400(10358):1102. PMID: 35065702; PMCID: PMC8841637.

treatment optimization, the VITEK® REVEAL™ Rapid AST System may also have the potential to reduce hospitalization and mortality resulting from AMR.

The VITEK® REVEAL™ AST System technology detects bacterial growth by observing an array of proprietary chemical Small Molecule Sensors (SMS) which change color in the presence of various metabolic gases emitted by growing bacteria during incubation. Printed SMS sensor arrays are fitted atop each well of the inoculated drug plate in an AST disposable assembly. The VITEK® REVEAL™ Instrument functions as an incubator for the samples under test and optically reads the sensor colors as the change in bacterial growth occurs.

The technology contains the following components which are required to perform testing:

- VITEK® REVEAL™ Instrument
- VITEK® REVEAL™ Sealer
- VITEK® REVEAL™ Sensor Panel
- VITEK® REVEAL™ Antibiotic Panel

The VITEK® REVEAL™ Rapid AST System allows users to perform antimicrobial susceptibility testing directly from positive blood culture samples. The VITEK® REVEAL™ Instrument includes a software that automatically collects, stores, and analyzes the generated raw data and combines the MIC values and antimicrobial susceptibility categories for the different drug-pathogen combinations included in the specific test run (e.g., GN AST Assay) into a comprehensive AST test report. Results are intended to be used in conjunction with Gram stain, organism identification, and other clinical laboratory findings. Prior to performing a test on the VITEK® REVEAL™ AST System, a gram stain should be performed as pathogen identification is required in order to generate a pathogen results report.

According to the requestor, populations where rapid AST is expected to provide significant benefit are

- Patients with higher severity of illness (e.g., sepsis, septic shock);
- Patients who receive inadequate or suboptimal empiric antibiotic therapy;
- Patients infected with antibiotic resistant organisms; and
- Patients at a higher risk of developing sepsis.

Procedure Description

Aliquots of the positive blood culture broth are loaded onto the microtiter plates that are pre-filled with different concentrations of antibiotic drugs. The VITEK® REVEAL™ Sealer attaches the VITEK® REVEAL™ Sensor Panel to the plate which are then incubated in the Instrument. The Sensor detects volatile organic compounds like aldehydes or ketones that are emitted by pathogens as they grow. These sensor panels are made of printed color-active chemical sensors that are placed on top of the each well, and a change in color indicates that the incubated microorganism is growing despite the presence of antibiotic drugs. During the incubation, the VITEK® REVEAL™ Instrument – an incubator and scanner – monitors sensor color changes caused by bacterial growth in the GN AST Assay. Depending on the quantity of volatile organic compounds, sensor colors will change, and the system software will translate color changes into MICs for all antibiotics present on an GN AST Assay. The system delivers results in an average of 5.5 hours. The findings are used in conjunction with Gram stain, organism identification and other clinical laboratory findings to inform antibiotic drug therapy for patients with positive blood cultures.

Current Coding: There are no unique ICD-10-PCS codes to describe the quantitative antimicrobial susceptibility testing of organisms direct from positive blood culture using small molecule sensor array technology. If desired, facilities can report the collection of a patient's specimen from an indwelling vascular catheter using the following code:

8C02X6K Collection of blood from indwelling device in circulatory system

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the quantitative antimicrobial susceptibility testing of organisms direct from positive blood culture using small molecule sensor array technology. Continue coding as described in current coding.

Option 2. Create new codes in section X, New Technology, to identify quantitative antimicrobial susceptibility testing of organisms direct from positive blood culture using small molecule sensor array technology.

Section	**X** New Technology
Body System	**X** Physiological Systems
Operation	**E** Measurement: Determining the level of a physiological or physical function at a point in time

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Circulatory	**X** External	**ADD 4** Infection, Positive Blood Culture Small Molecule Sensor Array Technology	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 08 – Transcatheter Tricuspid Valve Replacement

Issue: There are currently no unique ICD-10-PCS codes to describe transcatheter tricuspid valve replacement using a multi-plane flex bioprosthetic valve. 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? Yes. The Edwards EVOQUE tricuspid valve replacement system received FDA Breakthrough Designation on December 18, 2019, and received FDA approval on February 1, 2024 (P230013). The indication for the EVOQUE tricuspid valve replacement system is for the improvement of health status in patients with symptomatic severe tricuspid regurgitation (TR) despite optimal medical therapy, for whom tricuspid valve replacement is deemed appropriate by a heart team.

Background: Tricuspid valve regurgitation is a heart valve disease in which the valve between the right ventricle and right atrium does not close properly. The tricuspid valve consists of three leaflets that flap open to allow blood to flow from the upper right atrium to the lower right ventricle. In TR, the tricuspid valve does not close tightly, allowing blood to leak backward into the right atrium. Greater amounts of backward flow can enlarge the right atrium which can change the pressure in the nearby chambers and blood vessels, leading to more severe disease. Patients may experience shortness of breath while being active, ongoing fatigue or weakness, and edema in the abdomen, legs, ankles and/or feet.

Several factors can increase the risk of TR, including infections, heart attack or failure, pulmonary hypertension, heart disease including congenital heart disease, use of certain medications, or radiation. Patients with TR are also at risk for kidney, liver, and heart failure. An echocardiogram is primarily performed for diagnosis; however, a cardiac MRI may be used to determine the severity of the disease and cardiac computed tomography utilized to measure the native valve annulus size.

Technology
The Edwards EVOQUE tricuspid valve replacement system is designed to replace the native tricuspid valve utilizing a bioprosthetic valve. The system consists of a tri-leaflet bovine pericardial tissue valve, nitinol self-expanding frame and an intra-annular sealing fabric skirt and includes a catheter-based delivery system and supporting accessories. The EVOQUE has a low-profile delivery system that allows three planes of motion for controlled positioning and greater maneuverability in the deployment of the valve in native anatomy. Primary flexion is first used to move perpendicular to the tricuspid annulus, and then secondary flexion is used to ensure coaxial alignment within the tricuspid valve. Finally, depth of implantation is adjusted with a depth knob while maintaining coaxial alignment.

Procedure Description
After general anesthesia is induced, the patient is intubated. A transesophageal echocardiography (TEE) probe is inserted and positioned to obtain appropriate views of the tricuspid valve. Femoral vein access is obtained, after which, under fluoroscopic guidance, a guidewire is inserted and advanced across the tricuspid valve. After the access site is dilated to accommodate the 28 French

delivery system, the transcatheter delivery system (with bioprosthetic valve) is advanced over the guidewire into the right atrium of the heart. A combination of fluoroscopic and echocardiographic guidance is used to advance the valve delivery catheter via the vena cava to the native tricuspid valve. The system is advanced across the tricuspid annulus and into the right ventricle (RV), and the position is confirmed for deployment of the valve within the tricuspid plane as determined by fluoroscopy and TEE. TEE and fluoroscopic guidance are used to monitor expansion of the bioprosthetic valve with nitinol frame, leaflet capture, and assure proper positioning throughout the deployment process. After deployment and release of the bioprosthetic valve, the delivery catheter and guidewire are withdrawn across the valve and from the right atrium. The catheter is retracted and removed from the access site; venous access is closed. Proper positioning and functioning of the bioprosthetic valve, including the assessment of any paravalvular leakage, is confirmed by TEE. Measurement of regurgitation and resultant gradient is assessed.

Current Coding: There are no unique ICD-10-PCS codes to describe transcatheter tricuspid valve replacement using a multi-plane flex bioprosthetic valve. Code the procedure in table 02R, Replacement of Heart and Great Vessels, using the device value 8 Zooplastic Tissue, applied to the body part value J Tricuspid Valve and the approach value 3 Percutaneous.

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

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for transcatheter tricuspid valve replacement using a multi-plane flex bioprosthetic valve. Continue coding as described in current coding.

Option 2. In section X table X2R, Replacement of Heart and Great Vessels, create new device value R Intraluminal Device, Multi-plane Flex Technology Bioprosthetic Valve, applied to the body part value J Tricuspid Valve and the percutaneous approach, to identify transcatheter tricuspid valve replacement using a multi-plane flex bioprosthetic valve.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD J Tricuspid Valve	**3** Percutaneous	**ADD R** Intraluminal Device, Multi-plane Flex Technology Bioprosthetic Valve	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 09 – Cellular Assessment via Microfluidic Deformability Cytometry

Issue: There are no unique ICD-10-PCS codes to describe the assessment of immune response using microfluidic deformability cytometry. An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. The IntelliSep device received 510 (k) clearance on December 19, 2022. The device is indicated for use as an aid to the early detection of sepsis in adult patients with signs and symptoms of infection who present to the Emergency Department.

Background: Sepsis is the leading cause of death in hospitals, taking the lives of over 270,000 people every year in the United States (US). Patients with confirmed sepsis are a subset of the approximately 30 million adults who present with signs and symptoms of infection to Emergency Departments in the US each year. Mortality from sepsis increases as much as 8% for every hour that treatment is delayed. As many as 80% of sepsis deaths could potentially be prevented with rapid diagnosis and treatment, making early detection essential. In addition, sepsis-related healthcare costs total over $38 billion every year, making it one of the most expensive conditions faced by the healthcare system as well.

There is no "classic" presentation of sepsis, as it is a heterogeneous syndrome with highly variable manifestation. In 2015, in lieu of any reference standard, sepsis was redefined as "a life-threatening organ dysfunction caused by a dysregulated host response to infection (Sepsis-3)."[1] Due to the need for rapid recognition and treatment of sepsis to positively impact outcomes in patients with the condition, international societies developed the Surviving Sepsis Campaign and authored a guideline to assist clinicians in management of the condition which places emphasis on early recognition and intervention.

Currently, healthcare providers must use a set of non-specific symptoms and laboratory findings to differentiate patients with sepsis from those with self-limiting infections or other conditions with similar presentations. This makes sepsis a very challenging condition to diagnose.

Technology
The IntelliSep test uses a benchtop instrument designed for the clinical laboratory to assess the state of innate immune activity in under 10 minutes. The instrument evaluates the mechanical properties of white blood cells (leukocytes), which differ in septic patients compared to non-septic patients. According to the requestor, microfluidic cell-handling techniques combined with the technological advances of high-speed imaging and machine learning allow IntelliSep to analyze the biophysical properties of thousands of leukocytes in a few seconds.

The results are organized into three interpretation bands, providing guidance to physicians as they triage patients. A Band 1 result indicates that the patient has a low probability of developing sepsis.

[1] Singer M, Deutschman CS, Seymour CW, et al. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA. 2016;315(8):801–810. doi:10.1001/jama.2016.0287

A Band 2 result suggests further investigation may be warranted, allowing for additional assessment. A Band 3 result indicates a high probability of sepsis and may support the expedited triage of patients.

Procedure Description
Per the requestor, in an inpatient setting, clinicians would order the IntelliSep test and document results in the progress notes or emergency room notes. At the initiation of a test, the laboratory operator transfers 100 µL of whole blood into the sample preparation tube which is then placed into the Cytovale System. The system automatically lyses red blood cells, and washes the purified leukocytes in a diluent, producing a total volume of approximately 1mL of prepared sample, which the operator then transfers to the IntelliSep cartridge for analysis on the Cytovale System.

A microfluidic deformability cytometry technique is used to measure the biophysical properties of thousands of individual leukocytes in rapid succession. According to the requestor, these properties have been shown to differ in quiescent white blood cell populations when compared to those in septic patients, enabling for rapid assessment of the host response and the likelihood of having sepsis with organ dysfunction manifesting within the first three days after testing. Based on these measurements, the test provides a single score, the IntelliSep Index (ISI), ranging from 0.1-10.0, stratified into three discrete interpretation bands (Band 1, Band 2, Band 3) of increasing sepsis likelihood. The requestor states that there have not been any adverse outcomes or complications associated with the use of the IntelliSep device.

Current Coding: The assessment of immune response using microfluidic deformability cytometry is not reported separately for inpatient hospital coding. If desired, facilities can report the collection of a patient's specimen from an indwelling vascular catheter using the following code:

8C02X6K Collection of blood from indwelling device in circulatory system

Coding Options

Option 1. Do not create new ICD-10-PCS codes for assessment of immune response using microfluidic deformability cytometry. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify assessment of immune response using microfluidic deformability cytometry.

Section **X** New Technology *Body System* **X** Physiological Systems *Operation* **E** Measurement: Determining the level of a physiological or physical function at a point in time			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Circulatory	**X** External	**ADD 5** Immune Response, Whole Blood Cellular Assessment via Microfluidic Deformability	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 10 – Fixation of Lumbar Facet Joint

Issue: There are no unique ICD-10-PCS codes to describe codes to describe lumbar facet joint fusion using paired titanium cages. An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. The requestor submitted a request for 510(k) market clearance for the Facet FiXation (FFX) device to the FDA on August 15, 2023. The FFX device received Breakthrough Device Designation from the FDA on October 29, 2021, for skeletally mature adults with lumbar facet syndrome and/ or lumbar spinal stenosis following laminectomy or decompression, with or without facet degeneration.

Background: Facet joint degeneration, or facet syndrome (FS), represents one of the most common sources of low back pain. The condition is brought upon by the loss of synovial joint space, narrowing, loss of synovial fluid and the loss of cartilage and bony overgrowth. As the facet joints degenerate over time, the resulting inflammation leads to local pain in the lumbar spine that can also radiate to the lower body. Facet joint degeneration is regarded as the most frequent form of facet pathology and is often present with other degenerative disorders, such as lumbar spinal stenosis (LSS).

Technology
Per the requestor, the FFX (Facet FiXation) implant is designed to prevent spinal instability and facet motion by enabling lumbar facet joint fusion following surgery to treat lumbar spinal stenosis and facet syndrome. The device is available in several sizes to ensure proper fit in the lumbar facet joint space. The implant is surgically implanted and positioned between the facet joints with two devices used per level in conjunction with a facet screw with autologous graft material placed inside and posterior to the implant. The implant is a sterile, single patient use, long-term implantable device made of titanium which is intended to be implanted bilaterally. The FFX implant is available in 6 different sizes.

According to the requestor, the FFX device has demonstrated the ability to reduce both pain and disability in patients with LSS and facet syndrome with a high fusion rate and a low reoperation rate while maintaining stability and preserving motion.[1] The requestor also states that FFX device placement has been shown to have reduced operative time and blood loss compared to placement of pedicle screw systems in patients with LLS.[2] A finite element simulation study comparing the FFX device with pedicle screw placement suggests facet fusion leads to lower mechanical loads at the adjacent levels, potentially lowering the risk of adjacent segment degeneration prior to fusion.[3]

[1] Srour R, Gdoura Y, Delaitre M, et al. Facet arthrodesis with the FFX device: One-year results from a prospective multicenter study. Int J Spine Surg. 2020;14:996-1002.
[2] Srour R. Comparison of operative time and blood loss with the FFX® device versus pedicle screw fixation during surgery for lumbar spinal stenosis: A retrospective cohort study. Cureus. 2022;14(3):e22931.
[3] Simon L, Millot F, Hoarau X, et al. Comparison of the biomechanical effect of the FFX device compared with other lumbar fusion devices: A finite element study. Int J Spine Surg. 2022;16:935-943.

Procedure Description
Per the requestor, insertion of the FFX device would take place in an inpatient hospital setting and would be documented in the operating report. During the procedure, the facet joint line is tracked with a facet chisel and treated with a rasp to promote fusion. After connecting the FFX implant onto the facet holder, autologous graft material is inserted into the empty space of the device. Two implants are used per level. While attached to the facet-holders and at the entry of the facet joint lines, the devices are inserted into the facet joint simultaneously on the right and left sides, under direct visualization. The devices are then pushed into place using an impactor supplied by the company and positioned appropriately. Autologous graft material is then added posterior to the inserted implants. Facet screws are then placed bilaterally at the same level that the FFX devices are implanted. Some patients require a device to be placed at more than one level in the range from L1 to S1, with an average of 1.9 levels per procedure. The FFX devices are intended to be left permanently in place.

According to the requestor, over seventy percent of patients treated with the FFX device have had an improved fusion rate while approximately three and a half percent of patients have had reoperation within two years.

Current Coding: There are no unique ICD-10-PCS codes to describe lumbar facet joint fusion using paired titanium cages. Code the procedure in table 0SG, Fusion of Lower Joints, using the device value J Synthetic Substitute, applied to the applicable body part value and the approach value 0 Open. Assign codes as appropriate for any additional spinal fusion procedures performed.

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebral Joint **1** Lumbar Vertebral Joints, 2 or more **3** Lumbosacral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**0** Anterior Approach, Anterior Column **1** Posterior Approach, Posterior Column **J** Posterior Approach, Anterior Column
0 Lumbar Vertebral Joint **1** Lumbar Vertebral Joints, 2 or more **3** Lumbosacral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**A** Interbody Fusion Device	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

Coding Options

Option 1. Do not create new ICD-10-PCS codes for lumbar facet joint fusion using paired titanium cages. Continue coding as listed in current coding.

Option 2. In section X table XRG, Fusion of Joints, create new device value E Facet Joint Fusion Device, Paired Titanium Cages, applied to the appropriate body part values and the open approach, to lumbar facet joint fusion using paired titanium cages. Continue to assign codes as appropriate for any additional spinal fusion procedures performed.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
A Thoracolumbar Vertebral Joint **B** Lumbar Vertebral Joint **C** Lumbar Vertebral Joints, 2 or more **D** Lumbosacral Joint	**0** Open	**ADD E** Facet Joint Fusion Device, Paired Titanium Cages	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 11 – Extracorporeal Blood Pathogen Removal

Issue: There are no unique ICD-10-PCS codes to describe extracorporeal filtration of pathogens from the blood. An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. An emergency use authorization was approved on April 17, 2020. The Seraph® 100 is indicated for use in patients with laboratory confirmed and symptomatic COVID-19 with moderate to severe acute respiratory distress syndrome (ARDS), life threatening noncardiogenic pulmonary edema, rapidly progressive, dyspnea, tachypnea, and hypoxemia, inclusive of patients receiving high flow oxygen/non-invasive ventilation needs or intubated patients. Additionally, the Seraph® 100 is indicated as an adjunctive treatment for bacteremia in addition to antibiotics for hemodialysis patients, when the source of the infection is a heparin or heparan sulfate-binding bacteria, including antibiotic resistant bacteria.

Background: Most sepsis is caused by bacterial infections, but can also be caused by viral infections, such as COVID-19, or fungal infections. The Centers for Disease Control and Prevention (CDC) estimates that 1.7 million patients in the United States (US) suffer from sepsis. Sepsis management continues to be a major challenge for healthcare systems worldwide and is a leading cause of morbidity and mortality. Sepsis cases are not usually diagnosed until after admission, and those with increasing severity are associated with high economic burden and mortality. Despite advances in the care of patients with sepsis, in the US, sepsis is responsible for approximately 10% of Intensive Care Unit (ICU) admissions and reported in-hospital mortality rates vary from 10% to 40%.

In the US, patients with sepsis have high mortality rates approaching 35%[1], and once patients are admitted to the ICU, the mortality rate increases even further, as high as 54% in one study.[2] The World Health Organization (WHO) reported that 20% of global mortality occurs due to sepsis. The major challenge in sepsis treatment is obtaining source control of the offending pathogen. Treatment of the organisms typically starts with broad spectrum antibiotics, yet many patients still develop septic/distributive shock. The reasons for this include the high prevalence of antimicrobial resistance, which occurred in over 2.8 million patients in the US annually[3], and lead to the deaths of over 5 million people per year worldwide.[4]

Per the requestor, the Seraph® 100 is an extracorporeal pathogen removal device that can capture pathogens and remove them from the systemic circulation, which can dramatically reduce the

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[1] Rhee C, Kadri SS, Dekker JP, et al. Prevalence of Antibiotic-Resistant Pathogens in Culture-Proven Sepsis and Outcomes Associated With Inadequate and Broad-Spectrum Empiric Antibiotic Use. JAMA Netw Open. 2020;3(4):e202899. Published 2020 Apr 1. doi:10.1001/jamanetworkopen.2020.2899

[2] Khanna A, English SW, Wang XS, et al. Angiotensin II for the Treatment of Vasodilatory Shock. N Engl J Med. 2017;377(5):419-430. doi:10.1056/NEJMoa1704154

[3] Centers for Disease Control. Antibiotic Resistance Threats in the United States. 2019. https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

[4] Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis [published correction appears in Lancet. 2022 Oct 1;400(10358):1102]. Lancet. 2022;399(10325):629-655. doi:10.1016/S0140-6736(21)02724-0

burden of pathogens in the bloodstream, thereby helping patients recover from septic shock.

Technology
The Seraph® 100 Microbind® Affinity Blood Filter (Seraph® 100) is a single use, disposable column packed with ultra-high molecular weight polyethylene (UHMWPE) beads. It is a 3x9 inch device and consists of the following components: column body, endcap, heparinized PE endplate, silicone O-ring, heparinized UHMWPE beads, adhesive, and a vented endcap. The Seraph® 100 is part of the Seraph® platform technology that was developed as an extracorporeal broad-spectrum adsorbent hemoperfusion device for reduction of pathogens, bacteria, viruses, fungus, and other sepsis mediators from the bloodstream. The UHMWPE beads have been modified to contain covalently bound endpoint-attached heparin on the surface, thus forming a new chemical entity that exerts outward facing heparan sulfate receptors. According to the requestor, heparan sulfate is important because a similar compound, heparin sulfate, naturally exists on the lining of the blood vessels/endothelium in the body. Universally, many pathogens have evolved to bind to the heparin sulfate on blood vessels to gain entry and infect human cells, and therefore have natural affinity toward heparin sulfate.

Per the requestor, pathogens will bind to the Seraph® 100 beads when they flow through the Seraph® 100 device. Due to this biomimetic action, pathogens bind irreversibly to the heparin on the polyethylene beads of the Seraph and are thereby removed from the bloodstream.

Procedure Description
Extracorporeal pathogen removal utilizing the Seraph® 100 would occur in an inpatient setting and would be documented in the progress notes of the medical record. Prior to the initiation of treatment, sufficient anticoagulation must be established to minimize the risk of blood clotting in the extracorporeal circuit. The anticoagulation is accomplished with a bolus of heparin to an ACT of 160-210 seconds or to an aPTT of 60-80 seconds prior to the start of treatment. The procedure is initiated by attaching the inflow port of the Seraph® 100 to the arterial limb of a blood pump capable of delivering a blood flow rate between 50-450 mL/min. The outflow port of the Seraph® 100 is then connected to the venous limb of the blood pump, and the entire system is primed with normal saline to remove all the air from the tubing. Once the system is primed, the arterial line of the blood pump is connected to the arterial end of a large bore access catheter, and the venous line of the blood pump is connected to the venous end of the same access catheter.

Treatment begins by starting the extracorporeal pump and slowly increasing the blood pump speed to achieve a blood flow rate of 50-450 mL/min. The increase in flow must be performed slowly and in conjunction with intensive monitoring of the patient's arterial blood pressure to make sure that hypotension, shock, and cardiovascular collapse do not occur when initially starting this extracorporeal procedure. Furthermore, the arterial and venous pressures on the blood pump must be monitored carefully to detect and correct for any flow restrictions and inappropriate pressure readings in the circuit. Once a steady state blood flow has been reached, the treatment time may be extended for up to 24 hours to optimize sufficient exposure of the patient's blood to the Seraph® 100 adsorption media.

When the treatment is complete, the blood that is in the extracorporeal circuit must be returned to the patient to prevent hypotension and unnecessary wastage of the patient's blood. A blood rinse back procedure is performed, whereby the pump is first briefly paused. The arterial limb of the circuit is disconnected from the patient's access catheter and connected to a bag of normal saline to

prevent any additional blood from entering the extracorporeal circuit. The blood pump is then resumed at a low flow rate of ~50mL/min and the remaining blood in the extracorporeal circuit is then rinsed back to the patient through the venous limb of the circuit. When the venous limb is clear of the patient's blood, the pump is stopped, and the venous limb of the circuit is disconnected from the patient, thus terminating the procedure.

Per the requestor, while there have been no adverse outcomes or complications associated with the extracorporeal pathogen removal procedure, reported adverse events were predominantly associated with the vascular access portion of the procedure, such as phlebitis, thrombosis and hematoma. Due to the large surface area of the Seraph® 100 ($40m^2$), only one Seraph® 100 device is routinely utilized at a time. However, after 24 hours of therapy, the procedure can be repeated if the patient has not met adequate improvements in physiologic response, vasopressor requirement, or pathogen removal.

Current Coding: There are no unique ICD-10-PCS codes to describe extracorporeal filtration of pathogens from the blood.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for extracorporeal filtration of pathogens from the blood. Continue coding as listed in current coding.

Option 2. In the Section 5 table 5A1 Performance of Physiological Systems, add existing function value 0 Filtration applied to the body system value 5 Circulatory and the duration value 0 Continuous, to identify extracorporeal filtration of pathogens from the blood.

Section	**5** Extracorporeal or Systemic Assistance and Performance		
Body System	**A** Physiological Systems		
Operation	**1** Performance: Completely taking over a physiological function by extracorporeal means		
Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**0** Continuous	**ADD 0** Filtration	**Z** No Qualifier

Option 3. In the New Technology section, create new root operation table XX3 Performance of Physiological Systems, create new sixth character technology value 6 Filtration, Blood Pathogens. applied to the body system value 5 Circulatory and the approach value 3 Percutaneous, to identify extracorporeal filtration of pathogens from the blood.

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**ADD 3** Performance: Completely taking over a physiological function by extracorporeal means		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Circulatory	**3** Percutaneous	**ADD 6** Filtration, Blood Pathogens	**A** New Technology Group 10

CMS Recommendation: Option 3, as described above.

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

Topic # 12 – Application of prademagene zamikeracel

Issue: There are no unique ICD-10-PCS codes to describe the application of prademagene zamikeracel (pz-cel). An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. The FDA has granted pz-cel Regenerative Medicine Advanced Therapy (RMAT), Breakthrough Therapy, Orphan Drug, and Rare Pediatric Disease (RPD) designations. The requestor submitted a Biologics License Application (BLA) to the FDA on September 25, 2023. The FDA accepted the BLA submission and has granted a priority review with a PDUFA target action date of May 25, 2024.

Background: Recessive dystrophic epidermolysis bullosa **(**RDEB) is an ultra-rare, life-threatening, autosomal recessive form of epidermolysis bullosa (EB) with symptoms present at birth. RDEB is an ultra-rare disease that is estimated to affect approximately 1,500 people in the U.S. and is one of the most severe forms of EB, caused by mutations in both copies of the COL7A1 gene. Mutations in the COL7A1 gene lead to reduced or absent levels of biologically active collagen protein (C7) and result in a lack of anchoring fibrils. Anchoring fibrils are important because they bind the epidermal and dermal layers of the skin to one another. Because of this lack of anchoring fibrils, RDEB is characterized by mechanical fragility of the skin and other epithelial lined or surface tissues, resulting in painful chronic wounds, restrictive scarring, and aggressive squamous cell carcinoma (SCC). Consequently, patients and their caregivers face substantial clinical and quality-of-life burdens, and patients are at significant risk of shortened life expectancy due to infection and SCC from their open wounds.

Wound management historically consists of time and labor-intensive supportive care to limit contamination and infection, and reduction in mechanical forces that produce new blisters. Care usually includes treatment of new blisters by lancing and draining. Wounds are then dressed with a non-adherent material, covered with padding for stability and protection, and secured with an elastic wrap for integrity. RDEB patients also have periodic surgeries to relieve disease-related issues such as narrowing of their esophagus, fusing of fingers, and corneal abrasions. According to the requestor, there is an unmet need for collagen replacement gene therapies that address the underlying cause of the disease.

Until 2023, there were no approved treatments for RDEB. Recently, a topical gene therapy encapsulating the COL7A1 gene in an HSV-1 virus, was approved to treat Dystrophic EB (DEB) patients. Weekly application of the topical gene therapy (i.e., gel), is required on target wound(s) until healed. According to the requestor, studies conducted with this topical therapy primarily included wounds ranging from 2 to 57 cm^2 with a median of 10.6 cm^2 (74% of wounds less than 20cm2 and 19% from 20 to < 40cm2). The requestor asserts that pz-cel could be a treatment option for the toughest to treat RDEB wounds. In clinical trial studies, one-time application with pz-cel has shown multiple years of durable healing and associated pain reduction in large (>20cm^2) and/or chronic wounds (wounds open for at least 6 months) that carry the highest burden, including the need for frequent dressing changes, pain, pruritus, risk of infection, and developing skin cancer.

Description and Mechanism of Action
Pz-cel is an investigational genetically engineered autologous cell therapy. It is a biologic product manufactured as multilayer cellular epidermal sheets containing functional copies of collagen producing transgene (COL7A1).

The manufacturing process begins by first collecting two 8 mm punch biopsies of the patient's own skin from an unscarred region and extracting keratinocytes from the skin biopsy. The extracted keratinocytes are grown and transduced ex-vivo with functional copies of the COL7A1 transgene contained in a LZRSECol7A1 retrovirus vector. The gene-corrected keratinocytes are prepared to mature into epidermal sheets (pz-cel) that are fastened to a petrolatum gauze backing with surgical hemoclips. The sheets are then packaged and delivered to the site of care for administration. Upon arrival at site of care, sheets can be stored at ambient/room temperature.

Currently, all pz-cel epidermal sheets need to be applied to the patient within 36 hours of manufacturing completion. Upon transduction the COL7A1 transgene integrates into the host-cell genome, resulting in the durable expression and secretion of collagen 7 protein, which addresses the underlying mechanism of the disease resulting in wound healing and pain reduction.

Inpatient Administration of Prademagene Zamikeracel (pz-cel)
Pz-cel is applied under general anesthesia in a surgical suite. The average operating room time is 5-7 hours. All RDEB wounds intended for treatment are gently cleansed with normal saline or povidone-iodine solution. Overhanging epidermis, hyperkeratotic skin, or fibrinous material is gently debrided with a scalpel, scissors, and/or a cauterization technique at the treating surgeon's discretion. The manufactured pz-cel epidermal sheets are then placed at the wound beds and affixed with suture, non-adhesive dressing, and/or overlying dressing. A layer of topical antibiotics is also applied.

Following the application of pz-cel, patients may need to stay in the hospital for up to 7 days to immobilize wounds and enable uptake of pz-cel.

Current Coding: There are no unique ICD-10-PCS codes to describe application of prademagene zamikeracel (pz-cel). Code the procedure using the appropriate skin body part values in table 0HR, Replacement of Skin and Breast, with qualifier value 3 Full Thickness, and device value 7 Autologous Tissue Substitute.

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Skin, Scalp **1** Skin, Face **2** Skin, Right Ear **3** Skin, Left Ear **4** Skin, Neck **5** Skin, Chest **6** Skin, Back **7** Skin, Abdomen **8** Skin, Buttock **9** Skin, Perineum	**X** External	**7** Autologous Tissue Substitute	**2** Cell Suspension Technique **3** Full Thickness **4** Partial Thickness

A Skin, Inguinal **B** Skin, Right Upper Arm **C** Skin, Left Upper Arm **D** Skin, Right Lower Arm **E** Skin, Left Lower Arm **F** Skin, Right Hand **G** Skin, Left Hand **H** Skin, Right Upper Leg **J** Skin, Left Upper Leg **K** Skin, Right Lower Leg **L** Skin, Left Lower Leg **M** Skin, Right Foot **N** Skin, Left Foot			

Coding Options

Option 1. Do not create new ICD-10-PCS codes for application of prademagene zamikeracel (pz-cel). Continue coding as described in current coding.

Option 2. In New Technology table XHR, Replacement, Skin, Subcutaneous Tissue, Fascia and Breast, create new device value G Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, applied to the new skin region body part values 0 Skin, Head and Neck, 1 Skin, Chest, 2 Skin, Abdomen, 3 Skin, Back, 4 Skin, Right Upper Extremity, 5 Skin, Left Upper Extremity, 6 Skin, Right Lower Extremity, and 7 Skin, Left Lower Extremity, to identify application of prademagene zamikeracel (pz-cel).

Section	**X** New Technology		
Body System	**H** Skin, Subcutaneous Tissue, Fascia and Breast		
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 0 Skin, Head and Neck **ADD 1** Skin, Chest **ADD 2** Skin, Abdomen **ADD 3** Skin, Back **ADD 4** Skin, Right Upper Extremity **ADD 5** Skin, Left Upper Extremity **ADD 6** Skin, Right Lower Extremity **ADD 7** Skin, Left Lower Extremity	**X** External	**ADD G** Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 13 – Administration of Non-CAR-T Immune Effector Cell Therapy

Issue: There are no unique ICD-10-PCS codes to describe the administration of engineered (non-CAR T-cell) immune cell effector therapies. An October 1, 2024 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No.

Background: Immune effector cell therapies use an individual's own genetically engineered immune cells to treat disease. Many types of immune effector cell therapies are being developed and investigated for the treatment of a wide variety of cancers as well as other non-cancer disease such as multiple sclerosis, lupus nephritis and rheumatoid arthritis.

The ICD-10-PCS classification includes generic CAR T-cell related procedure codes that allow for accurate reporting of qualified investigational CAR T-cell therapies when administered in the inpatient setting, however, there are not any generic ICD-10-PCS codes to report the administration of qualified investigational non-CAR T-cell immune effector cell therapies.

The types of T-cell specific immune cell effector therapies being investigated include:

- T-cell Receptor-Engineered T-cell (TCR-T) Therapy
- T-cell Antigen Coupler T-cell (TAC-T) Therapy
- Tumor-Infiltrating Lymphocyte (TIL) Therapy

The creation of generic codes will allow for reporting of non-CAR-T immune effector cell therapies participating in qualified clinical trials.

Mechanism of Action
Immune effector cell therapies use genetically engineered human lymphocytes enabling them to effect or enhance the patient's immune response upon reinfusion back into the patient.

Inpatient Administration
Administration of immune effector cell therapies is via intravenous (IV) infusion of the investigational agent into a peripheral or central vein. The administration is completed by a health care professional and the dosing and infusion time will vary according to study protocols.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of other (non-CAR T-cell) engineered immune effector cell therapies. Facilities can report the intravenous administration of other engineered immune effector cell therapy using one of the following codes:

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of other engineered immune effector cell therapies. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of other engineered immune effector cell therapy.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD F** Other Engineered Immune Effector Cell Therapy	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 14 – Administration of dasiglucagon

Issue: There are no unique ICD-10-PCS codes to describe the administration of dasiglucagon. An October 1, 2024 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) for Part 1 of the New Drug Application (NDA) for dasiglucagon for the prevention and treatment of hypoglycemia in pediatric patients 7 days of age and older with congenital hyperinsulinism (CHI) for up to three weeks of dosing. The CRL is related to deficiencies identified following an inspection at a third- party contract manufacturing facility. These deficiencies are not specific to dasiglucagon. The CRL did not state any concerns about the clinical data package or safety of dasiglucagon. The requestor expects to resubmit the NDA for dasiglucagon for CHI for up to three weeks of dosing in the first half of 2024 contingent on successful reinspection of the third-party manufacturing facility.

Background: Current treatments for CHI include medical therapy, surgical management, and nutritional treatment.[1] Medical therapy of CHI consists of approved use of diazoxide in chronic dosage or off-label use of a single dose of glucagon for treatment of episodes of severe hypoglycemia.[2,3,4,5] Standard of care, however, also consists of other off-label therapies, such as somatostatin analogues (short-acting octreotide and long-acting lanreotide), mTOR inhibitors (sirolimus) and calcium channel blockers in combination with intensive nutritional support and/or chronic intravenous (IV) glucose infusion.[2,3,4,5,6,7,8]

Only 41-64% of patients with CHI respond to diazoxide (some inadequately), and the use of diazoxide carries the risk of serious adverse reactions such as sodium and fluid retention.[1] While IV administration of glucagon to patients with CHI is used short-term in the hospital setting, e.g., before pancreatectomy, there are currently no marketed glucagon products available for long-term use in the home setting.[2,3] Healthcare personnel (HCPs) cite the lack of responsiveness or incomplete response, along with the adverse events or intolerable side-effects, as the greatest treatment limitations with glucagon.[1,9]

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[1] Banerjee I, Raskin J, Arnoux JB, et al. Congenital hyperinsulinism in infancy and childhood: challenges, unmet needs and the perspective of patients and families. Orphanet J Rare Dis 2022;17(1):61. DOI: 10.1186/s13023-022-02214-y.

[2] Yorifuji T, Horikawa R, Hasegawa T, Adachi M, Soneda S, Minagawa M, Ida S, Yonekura T, Kinoshita Y, Kanamori Y, Kitagawa H, Shinkai M, Sasaki H, Nio M; (on behalf of The Japanese Society for Pediatric Endocrinology and The Japanese Society of Pediatric Surgeons). Clinical practice guidelines for congenital hyperinsulinism. Clin Pediatr Endocrinol. 2017;26(3):127-152. doi: 10.1297/cpe.26.127.

[3] GlucaGen HypoKit (Novo Nordisk): FDA Package Insert. MedLibrary.org. Published March 19, 2021. Accessed December 22, 2023.

[4] Arnoux J, -P., Verkarre V, Saint-Martin C, et al. Congenital hyperinsulinism: current trends in diagnosis and therapy. Orphanet J Rare Dis 2011; 6:63. DOI: 10.1186/1750-1172-6-63.

[5] Banerjee I, Salomon-Estebanez M, Shah P, Nicholson J, Cosgrove KE, Dunne MJ. Therapies and outcomes of congenital hyperinsulinism-induced hypoglycaemia. Diabet Med. 2019 Jan;36(1):9-21. doi: 10.1111/dme.13823.

[6] Demirbilek H, Hussain K. Congenital Hyperinsulinism: Diagnosis and Treatment Update. J Clin Res Pediatr Endocrinol. 2017 Dec 30;9(Suppl 2):69-87. doi: 10.4274/jcrpe.2017.S007.

[7] De Cosio AP, Thornton P. Current and Emerging Agents for the Treatment of Hypoglycemia in Patients with Congenital Hyperinsulinism. Paediatr Drugs. 2019 Jun;21(3):123-136. doi: 10.1007/s40272-019-00334-w.

[8] Congenital Hyperinsulinism. NORD (National Organization for Rare Disorders). https://rarediseases.org/rare-diseases/congenital-hyperinsulinism

[9] Zealand Pharma, Market Survey, 2020

Many patients experience neurodevelopmental delays because of delayed diagnosis or comorbid conditions.[10] These delays and CHI itself often require at least one parent (or another individual) to act as full-time caregiver[1,10] further adding to the burden of the disease.

Technology
Dasiglucagon is a glucagon receptor agonist, which increases blood glucose concentration by activating hepatic glucagon receptors, thereby stimulating glycogen breakdown and release of glucose from the liver. Hepatic stores of glycogen are necessary for dasiglucagon to produce an antihypoglycemic effect.[11]

Per the requestor, dasiglucagon is a stable glucagon analogue that has been specifically designed for long-term pump-use.[14] During two multinational phase 3 trials, the efficacy of dasiglucagon to reduce or eliminate the need for IV glucose and facilitate its wean-off in the early treatment phase was shown in the double-blind, placebo-controlled, cross-over Part 1 of Trial 17103. A mean reduction [95% CI] in IV glucose infusion rate (GIR) of 5.2 mg/kg/min [-8.3;-2.1] for dasiglucagon treatment versus placebo was demonstrated, corresponding to a relative treatment difference of 55%. The reduction in IV glucose was not facilitated by an increase in other sources of carbohydrate administration. In Part 2 of the trial, 83% of the patients achieved 12 or more hours off IV glucose, indicating substantial improvement, as reflected by the patients becoming independent of the IV glucose and being able to be discharged to continue treatment in home settings.[12,13]

Procedure Description
According to the requestor, the infusion is ordered in an inpatient setting and would be documented in progress notes. The dasiglucagon infusion is administered by continuous infusion via a subcutaneous catheter utilizing an infusion pump. The dose of the infusion should be individually determined and adjusted based on the patient's pharmacodynamic response (evaluated as plasma glucose/glycemic control, glucose needs (IV and/or gastric), and tolerability). The recommended starting dose of dasiglucagon is 10 µg/h. Every 2 hours, the dose can be adjusted by 10 µg/h (2.5 µL/h). The 2-hour dose-adjustment interval will allow drug plasma levels to approach steady-state before dose adjustments.

Additionally, the safety of dasiglucagon was evaluated in 44 patients aged 7 days to 12 years with CHI who were treated with dasiglucagon in controlled and uncontrolled clinical trials. The requestor stated that the adverse reaction rates observed in the clinical trials of dasiglucagon cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.[6] However, infusion site reactions were reported sporadically throughout administration of dasiglucagon. The most frequent infusion site disorders were infusion site infection, infusion site erythema, and infusion site abscess.

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[10] Raskin J, Pasquini TLS, Bose S, Tallis D, Schmitt J. Congenital Hyperinsulinism International: A Community Focused on Improving the Lives of People Living With Congenital Hyperinsulinism. Front Endocrinol (Lausanne) 2022;13:886552. DOI: 10.3389/fendo.2022.886552.
[11] Dasiglucagon US Package Insert (Proposed)
[12] De Leon DD, Banerjee I et al. Dasiglucagon Significantly Reduces Requirement for Intravenous Glucose in Children with Congenital Hyperinsulinism ages 7 Days to 12 Months. Presented at: European Society for Pediatric Endocrinology; September 2022; Rome, Italy
[13] Banerjee I, De Leon DD et al. Dasiglucagon Treatment Over 21 days in Infants with Congenital Hyperinsulinism Results in Glycemic Stability and Reduces Requirement for Intravenous Glucose. Presented at: European Society for Pediatric Endocrinology; September 2022; Rome, Italy

Overall, skin reactions were reported in 7 out of 12 patients treated with dasiglucagon in Trial 1. The most frequent skin disorders were various types of rashes. In addition, necrolytic migratory erythema (NME) has been reported in patients with CHI treated with dasiglucagon. Long-term treatment did not result in increased frequency or severity of skin reactions, including NME. In some patients, skin reactions may require a reduction of the dasiglucagon infusion rate, treatment interruption, or treatment discontinuation. Skin reactions may re-occur. Vomiting occurred in less than 2% of patients.

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

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

Coding Options

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

Option 2. Create new codes in section X, New Technology, to identify the subcutaneous administration of dasiglucagon.

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 6** Dasiglucagon	**A** New Technology Group **10**

CMS Recommendation: Option 2, as described above.

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

Topic # 15 – Drug-Eluting Resorbable Scaffold System

Issue: There are no unique ICD-10-PCS codes to describe transcatheter balloon dilation with insertion of an everolimus-eluting resorbable scaffold. An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System received Expedited Access Pathway (EAP) designation on June 28, 2017. A premarket approval (PMA) application is currently under review with the FDA, and approval is anticipated in Q2 2024.

Background: Chronic limb-threatening ischemia (CLTI) is associated with a high risk for cardiovascular events and mortality and accounts for approximately 90% of major amputations performed worldwide.[1,2] Historically CLTI in lesions below the knee (BTK) has been treated with autologous vein grafts, however many patients are precluded from having the procedure due to the absence of suitable venous conduits or the presence of significant underlying comorbidities. Over the last decade, various catheter-based endovascular techniques, including angioplasty, atherectomy, and stenting, have been developed, offering perfusion restoration alternatives to open bypass surgery. Currently there are no stents approved for use in the US for treatment of BTK lesions. However, restenosis remains the major drawback of infrapopliteal revascularization in CLTI patients. More recently, drug-coated and drug eluting solutions have emerged to increase long-term patency rates.

Per the requestor, the Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is a scaffold that will fully resorb over time and is indicated for improving luminal diameter in infrapopliteal lesions in patients with CLTI. The drug-eluting resorbable scaffold (DRS) is used to maintain lumen diameter while delivering everolimus to help treat the lesion and prevent restenosis.

Technology

Esprit™ BTK is composed of a balloon expandable scaffold and a rapid exchange delivery system and is indicated for improving luminal diameter in infrapopliteal lesions in patients with CLTI. Esprit™ BTK scaffold is a resorbable polymeric scaffold with a drug (everolimus) and resorbable polymeric coating and is placed in the treated vessel.

Procedure Description

Procedures utilizing the Esprit™ BTK would take place in an inpatient setting and would be documented in the operative report. The vessel selection for procedures utilizing Esprit™ BTK is obtained using standard femoral, radial, or pedal access techniques. Using a transcatheter delivery system, the technology is deployed within the vessel lumen where a lesion has developed in patients with CLTI. To optimize lumen gain, and ultimately blood flow, vessel preparation (also

[1] Uccioli L, Meloni M, Izzo V, et al. Critical limb ischemia: current challenges and future prospects. Vasc Health Risk Manag 2018;14:63–74.
[2] Karnabatidis D, Spiliopoulos S, Katsanos K, Siablis D. Below-the-knee drug-eluting stents and drug-coated balloons. Expert Rev Med Devices 2012;9:85–94.

called lesion preparation or "pre-dilation") should be performed using techniques such as percutaneous angioplasty, atherectomy, or intravascular lithotripsy. Multiple scaffolds may be used per procedure to accommodate the treated lesion length. After Esprit™ BTK is implanted in the treated vessel segment, the clinician post-dilates the device to ensure complete apposition to the vessel wall.

According to the requestor, once the Esprit™ BTK scaffold is resorbed (after approximately 36 months), there isn't a limitation on additional clinical interventions in cases where the disease progresses and the vessel re-stenoses or re-occludes. Clinical interventions are limited with a permanent metallic stent in the vessel.

Current Coding: There are no unique ICD-10-PCS codes to describe transcatheter balloon dilation with insertion of everolimus-eluting resorbable scaffold. Code the procedure using the appropriate tibial or peroneal artery body part value, the applicable drug-eluting intraluminal device value, and the approach value 3 Percutaneous in table 047, Dilation of Lower Arteries.

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta **1** Celiac Artery **2** Gastric Artery **3** Hepatic Artery **4** Splenic Artery **5** Superior Mesenteric Artery **6** Colic Artery, Right **7** Colic Artery, Left **8** Colic Artery, Middle **9** Renal Artery, Right **A** Renal Artery, Left **B** Inferior Mesenteric Artery **C** Common Iliac Artery, Right **D** Common Iliac Artery, Left **E** Internal Iliac Artery, Right **F** Internal Iliac Artery, Left **H** External Iliac Artery, Right **J** External Iliac Artery, Left **K** Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Intraluminal Device, Drug-eluting **D** Intraluminal Device **Z** No Device	**1** Drug-Coated Balloon **Z** No Qualifier

V Foot Artery, Right **W** Foot Artery, Left **Y** Lower Artery			
0 Abdominal Aorta **1** Celiac Artery **2** Gastric Artery **3** Hepatic Artery **4** Splenic Artery **5** Superior Mesenteric Artery **6** Colic Artery, Right **7** Colic Artery, Left **8** Colic Artery, Middle **9** Renal Artery, Right **A** Renal Artery, Left **B** Inferior Mesenteric Artery **C** Common Iliac Artery, Right **D** Common Iliac Artery, Left **E** Internal Iliac Artery, Right **F** Internal Iliac Artery, Left **H** External Iliac Artery, Right **J** External Iliac Artery, Left **K** Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left **V** Foot Artery, Right **W** Foot Artery, Left **Y** Lower Artery	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**5** Intraluminal Device, Drug-eluting, Two **6** Intraluminal Device, Drug-eluting, Three **7** Intraluminal Device, Drug-eluting, Four or More **E** Intraluminal Device, Two **F** Intraluminal Device, Three **G** Intraluminal Device, Four or More	**Z** No Qualifier

In addition, assign a separate code for any atherectomy and/or intravascular lithotripsy performed at the site prior to balloon dilation and placement of the scaffold, using the applicable root operation Extirpation or Fragmentation as needed to identify the procedure.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for describe transcatheter balloon dilation with insertion of everolimus-eluting resorbable scaffold. Continue coding as described in current coding.

Option 2. In section X table X27, Dilation of Heart and Great Vessels, create new device value T Intraluminal Device, Everolimus-eluting Resorbable Scaffold, applied to the body part values P Anterior Tibial Artery, Right, Q Anterior Tibial Artery, Left, R Posterior Tibial Artery, Right, S Posterior Tibial Artery, Left, T Peroneal Artery, Right, and U Peroneal Artery, Left and the

percutaneous approach, to identify transcatheter balloon dilation with insertion of the everolimus-eluting resorbable scaffold.

Continue to assign a separate code for any atherectomy and/or intravascular lithotripsy performed at the site prior to balloon dilation and placement of the scaffold, using the applicable root operation Extirpation or Fragmentation as needed to identify the procedure.

Section	**X** New Technology		
Body System	**2** Cardiovascular System		
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
P Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left	**3** Percutaneous	**ADD T** Intraluminal Device, Everolimus-eluting Resorbable Scaffold	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 16 – Continuous Monitoring and Assessment of Vascular Blood Flow

Issue: There are no unique ICD-10-PCS codes to describe monitoring of vascular blood flow for assessment of fluid balance using an adhesive ultrasound patch technology. 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. An application for the monitoring of vascular blood flow for assessment of fluid balance using FloPatch FP120 technology is pending FDA approval for the indication of noninvasive assessment of blood flow in peripheral vasculature. The requestor anticipates FDA approval in the early part of 2024.

Background: Sepsis remains a critical healthcare challenge in the United States, affecting at least 1.7 million adults annually, with over 350,000 fatalities during hospitalization or discharge to hospice. A significant aspect of managing severe sepsis and septic shock involves fluid resuscitation. However, within the first 8 hours of resuscitation, over 90% of patients do not exhibit an increase in stroke volume or blood flow in response to intravenous (IV) fluids, and are categorized as "unresponsive". Continual fluid administration to these unresponsive patients leads to over-resuscitation, which lacks physiological benefit and can exacerbate clinical outcomes.

Preventing over-resuscitation requires a flow-guided approach to IV fluid administration, ensuring fluids are only given when beneficial changes in cardiac output or stroke volume are observed. Traditional methods for monitoring these changes involve invasive catheters or bulky, non-portable equipment, limiting their application in diverse care settings like ambulances, emergency departments, and general medical floors. Consequently, a significant patient population is ineligible for flow-guided fluid resuscitation due to the limitations of the current technology and the required skill level for its operation.

According to the requestor, the FloPatch FP120 addresses this gap. The FloPatch FP120 device is a wireless, wearable Doppler ultrasound, that enables non-invasive, real-time monitoring of stroke volume and cardiac output changes through carotid artery Doppler ultrasound. Studies have demonstrated that employing Doppler ultrasound for IV fluid administration can lead to reduced fluid usage, quicker resolution of hypotension, shorter hospital stays, and decreased incidence of mechanical ventilation, dialysis, and overall healthcare costs.

Thus, the requestor maintains that the FloPatch FP120 represents a technological advancement in precision fluid management by expanding the eligibility for flow-guided fluid resuscitation to a broader patient population, particularly in settings where traditional hemodynamic monitoring methods are impractical or unavailable.

Technology
Per the requestor, the distinctive feature of the FloPatch FP120 lies in the simultaneous assessment of jugular venous and carotid arterial blood flow, providing dynamic insights into cardiovascular function. The device employs a wireless, wearable format, integrating a patented sensor technology

that generates a broad-beam, wide ultrasonic curtain for concurrent insonation of both the internal jugular vein and common carotid artery.

The technology enables continuous, real-time monitoring of hemodynamic status, which according to the requestor is a significant advancement over traditional methods which typically allow only intermittent assessments. The FloPatch FP120 is designed for use in clinical maneuvers such as passive leg raises or fluid challenges, making it effective in dynamically fluctuating clinical conditions such as heart failure, sepsis, and hypovolemia.

The requester states that the device's non-invasive nature, coupled with its ability for continuous monitoring, aids in informed decision-making regarding fluid management and cardiovascular support, particularly in settings where rapid adjustment to therapy is necessary. Additionally, according to the requestor, the FloPatch FP120's real-time data collection reduces the potential for human error in assessments, ensuring a more consistent and reliable approach to patient care.

Procedure Description
The FloPatch FP120 is used in inpatient settings and is a single patient-use non-invasive device that can aid clinicians in making informed decisions about fluid administration. Clinicians may document its use in the progress notes after initiating the following steps.

1. Patient Preparation:
    - Identify a suitable patient, ensuring calmness and minimal motion.
    - Position the patient semi-recumbent, with the torso at a 30-45° angle.
2. Device Activation and Pairing:
    - Turn on the FloPatch FP120 and pair it with a smart device app.
    - Apply ultrasound gel to the transducer.
    - Confirm the device is live and paired with the app.
3. Obtaining Doppler Signals:
    - Position the device on the patient's neck, targeting the laryngeal prominence.
    - Adjust to detect the Doppler spectra of the carotid artery and jugular vein.
4. Optimizing Doppler Signals:
    - Observe and refine the carotid artery Doppler signal for a clear dicrotic notch.
    - Ensure consistent velocity measurements.
5. Adhering the Ultrasound Device:
    - Select the optimal neck site for the device based on signal clarity.
    - Adhere the device using an adhesive, ensuring the transducer faces the heart.
6. Performing a Preload Challenge (Passive Leg Raise - PLR):
    - Start with a baseline measurement in the semi-recumbent position.
    - Mark the beginning of the PLR on the app, then perform the PLR without disturbing the patient.
    - Monitor Doppler spectra changes during the PLR.
7. Observing and Saving Data:
    - After the PLR, note changes in the jugular Doppler spectrum and the carotid corrected flow time (ccFT) on the app.
    - Save the data in various formats for analysis.

Per the requestor, there have not been reports of adverse outcomes or complications related to the device.

Current Coding: There are no unique ICD-10-PCS codes to describe monitoring of vascular blood flow using adhesive ultrasound patch technology. Facilities can report the procedure by assigning both codes below:

4A13X51 Monitoring of arterial flow, peripheral, external approach
and
4A14X51 Monitoring of venous flow, peripheral, external approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for monitoring of vascular blood flow using adhesive ultrasound patch technology. Continue coding as listed in current coding.

Option 2. Create a new code in section X, New Technology, to identify monitoring of vascular blood flow using adhesive ultrasound patch technology.

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**2** Monitoring: Determining the level of a physiological or physical function repetitively over a period of time		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Circulatory	**X** External	**ADD 0** Blood Flow, Adhesive Ultrasound Patch Technology	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 17 – Paclitaxel-Coated Balloon Catheter for Percutaneous Coronary Intervention

Issue: There are currently no unique ICD-10-PCS codes to describe the treatment of a coronary artery using a drug coated balloon intraluminal device(s). An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. The AGENT™ Paclitaxel-Coated Balloon Catheter, which was granted Breakthrough Device designation and is used following mechanical dilation in the therapeutic drug treatment of coronary lesions to maintain vessel patency was granted FDA approval on February 29, 2024. The AGENT™ Drug-Coated Balloon (DCB) has been designated by the FDA as an implant for PMA purposes. Per FDA guidance, the drug component is considered a permanent implant because it remains in the body for greater than 30 days.

Background: Per the CDC, "coronary heart disease (CAD) is the most common type of heart disease, killing 382,820 people in 2020". Approximately 7.2% of adults have CAD. Per the Diagnostic Catheterization and Percutaneous Coronary Intervention (CathPCI) registry of the National Cardiovascular Data Registry (NCDR), in-stent restenosis (ISR) represents approximately 10% of all percutaneous coronary interventions (PCIs) with approximately 25% of patients presenting with acute myocardial infarction.

Existing treatments for coronary ISR include percutaneous coronary interventions such as repeat stenting with either a drug-eluting or bare-metal stent, repeated balloon dilation and coronary brachytherapy. Coronary artery bypass grafting is a surgical procedure for the treatment of coronary ISR.

According to the requestor, the majority of ISR procedures in the United States are currently treated by implantation of an additional stent. Repeated drug-eluting stent implantation has historically shown superior results for treating ISR compared with balloon dilation alone. However, use of a metallic scaffold further narrows the luminal diameter and multiple stent layers are associated with a progressively higher risk of recurrent ISR and negative clinical outcomes.

The AGENT™ DCB is intended to treat coronary ISR. The requestor stated it provides clinicians and patients with a new PCI technology for treatment of ISR that has demonstrated superior outcomes to balloon dilation with a non-drug coated balloon alone and provides sustained therapeutic drug delivery without requiring the implant of a metallic stent.

Technology
The AGENT™ DCB system is comprised of a catheter with a semi-compliant intracoronary balloon with a drug coating [paclitaxel/acetyl tributyl citrate (PTx/ATBC)] on the balloon component. When the AGENT™ balloon component is inflated to nominal pressure, the drug coating is transferred and absorbed by the surrounding coronary vessel tissue. Upon completion of the drug transfer process, the AGENT™ balloon is deflated, and the catheter is withdrawn from the

patient leaving only the drug coating in the coronary vessel tissue. The AGENT™ DCB drug remains in the treated tissue for 60-90 days post implant.

Procedure Description
PCI procedures involving the AGENT™ drug-coated balloon begin with the physician garnering arterial access (arm or groin) using standard interventional techniques. A guide catheter is advanced through the vasculature and positioned in the coronary artery (left main or right). Under fluoroscopic guidance, a steerable wire is advanced into the targeted coronary vessel, across and distal to the stenotic segment. An ultrasound catheter is threaded over the wire until it is distal to the narrowed segment. The ultrasound catheter is activated, and a cross-sectional image of the stenotic lesion is generated as the catheter is withdrawn through the coronary artery into the guide catheter. To prepare the lesion for treatment, a non-drug coated balloon angioplasty catheter is advanced and used to dilate the target vessel. For the treatment of in-stent restenosis, dilation using high pressures may be necessary to address under expansion of the existing stent. Cutting balloon or other specialty devices may be used as part of the vessel preparation, to address severe plaque and modify neointimal growth. Following lesion preparation, precise measurement of the area to be treated is calculated and a DCB is selected based on the lesion treatment size. Intravascular imaging is again performed to optimize placement of the DCB for therapeutic drug delivery. The DCB is delivered to the prepared lesion and positioned across the lesion treatment site precisely covering 2 mm both proximally and distally. Nominal pressure is applied to the DCB to appose the drug coating to the vessel lumen initiating drug transfer, and the DCB is held in place to complete the drug transfer process. Once vessel patency is confirmed, negative pressure is applied to the DCB to withdraw the device. Repeat imaging is performed to confirm a ≤30% residual stenosis, a TIMI (Thrombolysis In Myocardial Infarction) flow grade of 3 and absence of a flow-limiting dissection. To complete the procedure, the catheters and sheath are removed, the arterial access site is closed, and the patient is sent to recovery.

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

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

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

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Coronary Artery, One Artery **1** Coronary Artery, Two Arteries **2** Coronary Artery, Three Arteries **3** Coronary Artery, Four or More Arteries	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Intraluminal Device, Drug-eluting **5** Intraluminal Device, Drug-eluting, Two **6** Intraluminal Device, Drug-eluting, Three **7** Intraluminal Device, Drug-eluting, Four or More **D** Intraluminal Device **E** Intraluminal Device, Two	**6** Bifurcation **Z** No Qualifier

		F Intraluminal Device, Three **G** Intraluminal Device, Four or More **T** Intraluminal Device, Radioactive **Z** No Device	

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe the use of a Paclitaxel-Coated balloon catheter in PCI procedures. Continue coding as listed and described in current coding.

Option 2. In section X table XW0, Introduction, create new technology value H Paclitaxel-Coated Balloon Technology, applied to the coronary artery body part values and the percutaneous approach, to identify use of a Paclitaxel-Coated balloon catheter in PCI procedures.
Code the non-coated balloon angioplasty procedure performed to dilate the target vessel and prepare the lesion for balloon delivery of paclitaxel using device value Z No Device and the appropriate body part value in table 027, Dilation of Heart and Great Vessels. Separately, code the placement of any stents using the applicable code in table 027, Dilation of Heart and Great Vessels.

Section	**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 5 Coronary Artery, One Artery **ADD 6** Coronary Artery, Two Arteries **ADD 7** Coronary Artery, Three Arteries **ADD 8** Coronary Artery, Four or More Arteries	**3** Percutaneous	**ADD H** Paclitaxel-Coated Balloon Technology	**A** New Technology Group 10

Option 3. In section X table XW0, Introduction, create new technology values H Paclitaxel-Coated Balloon Technology, One Balloon, J Paclitaxel-Coated Balloon Technology, Two Balloons, K Paclitaxel-Coated Balloon Technology, Three Balloons, and L Paclitaxel-Coated Balloon Technology, Four or More Balloons, applied to the coronary artery body part values and the percutaneous approach, to identify use of a Paclitaxel-Coated balloon catheter in PCI procedures.
Code the non-coated balloon angioplasty procedure performed to dilate the target vessel and prepare the lesion for balloon delivery of paclitaxel using device value Z No Device and the appropriate body part value in table 027, Dilation of Heart and Great Vessels. Separately, code the placement of any stents using the applicable code in table 027, Dilation of Heart and Great Vessels.

Section	**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 0 Coronary Artery, One Artery **ADD 1** Coronary Artery, Two Arteries **ADD 2** Coronary Artery, Three Arteries	**3** Percutaneous	**ADD H** Paclitaxel-Coated Balloon Technology, One Balloon **ADD J** Paclitaxel-Coated Balloon Technology, Two Balloons	**A** New Technology Group 10

ADD 3 Coronary Artery, Four or More Arteries		**ADD K** Paclitaxel-Coated Balloon Technology, Three Balloons **ADD L** Paclitaxel-Coated Balloon Technology, Four or More Balloons	

CMS Recommendation: CMS is interested in audience input.

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

Topic # 18 – Division of Bioprosthetic Aortic Valve Leaflets

Issue: There are no unique ICD-10-PCS codes to describe splitting of pre-existing bioprosthetic aortic valve leaflets using a leaflet splitting device during a valve-in-valve transcatheter aortic valve replacement (TAVR) procedure. An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. The Pi-Cardia ShortCut™ Catheter leaflet modification technology to enable TAVR in patients at risk of coronary obstruction received Breakthrough Device Designation on January 22, 2024.

Background: Surgical aortic valve replacement (SAVR) and TAVR are effective treatments for symptomatic severe aortic stenosis. The requestor stated that while TAVR has been a treatment option for many patients who develop severe aortic valve stenosis, the technology utilizes bioprosthetic valves, which have primarily become available to the low surgical risk population in recent years, many of whom are younger and will require multiple interventions over their lifetime. The long-term durability of surgically implanted bioprosthetic aortic valves has been established, and such valves start to deteriorate at around 10 years post valve implantation. According to the requestor, if the long-term durability of the TAVR bioprosthetic valves is similar to that of the surgical counterparts, the need for repeated aortic valve replacement will be inevitable, as more and more patients are treated with bioprosthetic valves.

TAVR is an effective treatment for failure of bioprosthetic surgical or transcatheter aortic valves, a treatment known as valve and valve (ViV) TAVR, reported as a less invasive alternative to SAVR redo.[1] Coronary artery obstruction is a rare but devastating complication of TAVR, with an overall incidence ranging from 0.7% to 3%, but with 40%-50% mortality.[2] It is four to six-fold more common in ViV procedures than TAVR performed in the native aortic valve.[3]

According to the requestor, the reported risk of coronary obstruction is probably underestimated due to underdiagnosis when presentation is atypical (i.e., late obstruction) and because some high-risk patients may be excluded from TAVR for concern of this complication. Coronary artery ostium obstruction occurs when the transcatheter heart valve displaces the underlying surgical or native aortic valve leaflets outwards and obstructs the coronary artery ostium, either by sealing the sinus of Valsalva at the sinotubular junction or by the leaflet itself covering the coronary ostium due to low lying coronary ostium and a relatively narrow sinus.[4]

Coronary artery obstruction is significantly more common during ViV TAVR for native aortic stenosis, likely because most surgical prostheses are supra-annular in design, lowering coronary

[1] Ahmed A. Valve-in-valve transcatheter aortic valve replacement versus redo surgical aortic valve replacement: A systematic review and meta-analysis. J Card Surg 202.
[2] Ribeiro HB. Incidence, predictors, and clinical outcomes of coronary obstruction following transcatheter aortic valve replacement for degenerative bioprosthetic surgical valves: insights from the VIVID registry. Eur Heart J 2018;39(8):687-695.
[3] Jabbour RJ. Delayed Coronary Obstruction After Transcatheter Aortic Valve Replacement. J Am Coll Cardiol 2018;71(14):1513-1524.
[4] Khan JM. Transcatheter Laceration of Aortic Leaflets to Prevent Coronary Obstruction During Transcatheter Aortic Valve Replacement: Concept to First-in-Human. JACC Cardiovasc Interv 2018;11(7):677-689.

heights relative to the valve leaflets, and because valve suturing draws the coronary arteries closer, decreasing sinus width. The risk of coronary obstruction is highest during TAVR performed with surgical bioprosthetic designs intended to maximize effective aortic orifice area (both "stented" bioprostheses that have externally mounted leaflets, and "stent-less" surgical bioprostheses). When coronary obstruction does occur, the clinical presentation is usually characterized by severe hypotension and ST-segment changes that may require temporary cardiopulmonary support and revascularization. Treatment for coronary obstruction requires bail-out percutaneous coronary intervention, which may be extremely difficult with a valve leaflet obstructing the coronary artery, or emergency bypass surgery may be indicated. The complication of coronary obstruction preventing blood flow into the coronary arteries has become a risk carefully considered as a part of the redo SAVR versus TAVR clinical strategy.

Technology

The ShortCut™ Catheter is a transfemoral catheter leaflet modification device designed to split the pre-existing bioprosthetic aortic valve leaflets prior to TAVR, to reduce the risk of coronary obstruction and coronary access compromise and enable a ViV procedure. Splitting of a bioprosthetic aortic valve leaflet creates a triangular opening in the leaflet that allows blood flow into the adjacent coronary artery.[5,6] The ShortCut™ Catheter was designed to allow for a controlled mechanical leaflet splitting action. The distal end of the device is designed to ensure correct positioning of the device prior to splitting the targeted leaflet.

Procedure Description

Prior to TAVR, the risk of coronary ostium obstruction following the procedure is assessed for the coronary arteries by reviewing computed tomography angiography (CTA). If deemed required, leaflet splitting is performed.

Femoral access and left ventricle (LV) guidewire placement for the leaflet splitting and TAVR procedure are obtained. Over the LV guidewire the ShortCut™ Catheter leaflet splitting device is advanced around the aortic arch and placed at the level of the pre-existing bioprosthetic aortic valve. The ShortCut™ Catheter is then unsheathed, flexed, and rotated into the appropriate position utilizing both transesophageal echo and fluoroscopic guidance to advance to the base of the bioprosthetic aortic valve leaflet. Position is verified in different fluoroscopic guidance views to ensure the device is at the target position on the leaflet. Next, the device is activated, unflexed, and partially resheathed under TEE and fluoroscopic guidance. A combination of gentle traction on the ShortCut™ Catheter device and gentle pressure on the LV guidewire is then used to complete the split of the leaflet at the targeted cusp. Once the first split is achieved, the splitting element is folded, and the positioning arm may be positioned at the other coronary cusp to create an additional leaflet split in the same manner. Leaflet splitting with the ShortCut™ Catheter device creates a triangular opening in the leaflet that allows blood flow into the adjunct coronary artery. The ShortCut™ Catheter device is then fully resheathed, removed from the LV cavity and then withdrawn from the body. Following the completion of the leaflet splitting procedure, ViV TAVR is performed.

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[5] Tchétché, D., Kodali, S. K., & Dvir, D. (2022). First dedicated transcatheter leaflet splitting device: the ShortCut device. Eurointervention: Journal of Europcr in Collaboration with the Working Group on Interventional Cardiology of the European Society of Cardiology, EIJ-D.

[6] Dvir, D., Leon, M. B., Abdel-Wahab, M., Unbehaun, A., Kodali, S., Tchetche, D., ... & Kempfert, J. (2023). First-in-human dedicated leaflet splitting device for prevention of coronary obstruction in transcatheter aortic valve replacement. Cardiovascular Interventions, 16(1), 94-102.

Current Coding: There are no unique ICD-10-PCS codes to describe division of the aortic valve leaflets in a previously placed bioprosthetic aortic valve using an intraluminal bioprosthetic valve leaflet splitting technology. Code the procedure in table 02Q, Repair of Heart and Great Vessels, using the body part value F Aortic Valve, the approach value 3 Percutaneous and the qualifier value Z No Qualifier.

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

Body Part	*Approach*	*Device*	*Qualifier*
F Aortic Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**J** Truncal Valve **Z** No Qualifier

Facilities would also report the placement of the new valve in table 02R Replacement of Heart and Great Vessels, using the device value 8 Zooplastic Tissue, applied to the body part value F Aortic Valve, the approach value 3 Percutaneous and the qualifier value Z No Qualifier.

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

Body Part	*Approach*	*Device*	*Qualifier*
F Aortic Valve	**0** Open **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier
F Aortic Valve	**0** Open **4** Percutaneous Endoscopic	**8** Zooplastic Tissue	**N** Rapid Deployment Technique **Z** No Qualifier
F Aortic Valve	**3** Percutaneous	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**H** Transapical **Z** No Qualifier
F Aortic Valve	**3** Percutaneous	**8** Zooplastic Tissue	**H** Transapical **N** Rapid Deployment Technique **Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for division of the aortic valve leaflets in a previously placed bioprosthetic aortic valve. Continue coding as listed in current coding.

Option 2. Create new section X New Technology table X28, Division, Cardiovascular System, and create new device value V Intraluminal Bioprosthetic Valve Leaflet Splitting Technology in Existing Valve, applied to the body part value F Aortic Valve and the percutaneous approach, to identify division of the aortic valve leaflets of a previously placed bioprosthetic aortic valve. Continue to report the placement of the new bioprosthetic value using the appropriate code in table 02R Replacement of Heart and Great Vessels.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**ADD 8** Division: Cutting into a body part, without draining fluids and/or gases from the body part, in order to separate or transect a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD F Aortic Valve	**3** Percutaneous	**ADD V** Intraluminal Bioprosthetic Valve Leaflet Splitting Technology in Existing Valve	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 19 – Computer-aided Triage and Notification for Measurement of Intracranial Cerebrospinal Fluid Flow

Issue: There are currently no unique ICD-10-PCS codes to describe computer-aided triage and notification for measurement of intracranial cerebrospinal fluid flow. 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? Yes. Annalise Triage Obstructive Hydrocephalus was granted Breakthrough Device designation by the FDA on February 17, 2023. On August 15, 2023, the FDA granted 510(k) clearance for Annalise Triage Obstructive Hydrocephalus for use in the medical care environment to aid in triage and prioritization of non-contrast computed tomography (NCCT) head studies with features suggestive of obstructive hydrocephalus.

Background: Hydrocephalus is the symptomatic accumulation of cerebrospinal fluid (CSF) inside the cerebral ventricles.[1] Within the adult population, there are four different types: obstructive, communicating, hypersecretory, and normal pressure hydrocephalus (NPH); with obstructive being the most common and time-critical type. Obstructive hydrocephalus (OH) is a neurological condition that occurs when there is a block in the flow of CSF in one or more of the narrow passages that connect the ventricles in the brain. The blockage or obstruction leads to an accumulation of CSF, causing an enlargement of the ventricles and a build-up of pressure in the brain. OH can be the result of many acute critical neurologic disorders that cause blockage of the flow of CSF within the ventricular system, or due to obstructions that restrict normal resorptive mechanisms. The overall global prevalence of hydrocephalus is estimated to be 85 cases per 100,000 individuals, with a prevalence in North American adults of 33 cases per 100,000 individuals.[2]

Symptoms of OH (e.g., headache, loss of coordination or balance, nausea, vomiting, bladder control problems, impaired vision, and changes in concentration or memory) can mirror other conditions and thus make it challenging to diagnose. Once a physician suspects hydrocephalus, a complete neurological examination, including imaging tests (e.g., magnetic resonance imaging (MRI) or computed tomography (CT) scans), are usually recommended to confirm the diagnosis and assess for treatment options. Based on the underlying etiology, the condition may be treated directly by removing the cause of CSF obstruction or indirectly by diverting the excess fluid. The prognosis for hydrocephalus depends on the cause, the extent of symptoms and the timeliness of diagnosis and treatment.[3]

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[1] Rekate HL. A contemporary definition and classification of hydrocephalus. Semin Pediatr Neurol. 2009 Mar;16(1):9-15.
[2] Koleva M, De Jesus O. Hydrocephalus. [Updated 2023 Aug 23]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560875/
[3] Shuer, L. M., & Thakkar, R. (n.d.). Hydrocephalus. AANS. https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Hydrocephalus

Technology
Annalise Triage Obstructive Hydrocephalus is a medical device software application which uses an artificial intelligence (AI) algorithm to prioritize suspected OH findings in NCCT head scans within a clinical triage workflow of radiological imaging studies to be interpreted by trained clinicians who are qualified to interpret brain CT studies. It is compatible with image and order management systems such as picture archiving and communication systems (PACS) and radiological information systems (RIS). The AI algorithm used in the device is a convolutional neural network, trained on over 200,000 computed tomography brain (CTB) imaging studies. The images used to train the algorithm were sourced from datasets with a range of patient demographics and technical characteristics, including different CT manufacturers and machines. Annalise Triage Obstructive Hydrocephalus only provides notification for the suspected finding and is not intended to direct attention to specific portions of an image, or to be used on a standalone basis for clinical decision making.

Procedure Description
Annalise Triage Obstructive Hydrocephalus is a distinct and stand-alone procedure. The technology uses the images and data from a NCCT head scan to triage, prioritize, and notify in cases of suspected OH.

1. The device interfaces with image and order management systems (such as PACS/RIS) to obtain NCCT head studies for processing by the AI algorithm.
2. The device then encodes the scan into readable format for the algorithms to read. If the study does not meet the minimum requirements for AI processing, an error message is displayed on the user interface.
3. The pre-trained fixed AI model then analyzes the data and makes a prediction as to the presence of the finding of OH. Outputs of the model include the presence of the suspected OH finding and the confidence score based on the likelihood that the finding is present. In NCCT head studies for which Annalise Triage Obstructive Hydrocephalus does not detect suspected OH, the device outputs the following text to the worklist: “AI processing complete”.
4. The above noted confidence score is then compared with the customer’s preconfigured operating point to determine whether the finding is assigned a priority level.
5. The device then outputs the priority and the name of the identified finding, i.e., OH, to a worklist as well as to an active notification service which forwards alerts using the hospital’s alert systems (e.g., Short Message Service (SMS), paging, pop-up notifications) to designated specialists.
6. The device may also output to the Annalise Viewer (non-diagnostic viewer), which synchronizes with the hospital’s diagnostic viewer to display the device output when a case is opened.

Current Coding: The use of software to aid in the detection of obstructive hydrocephalus is not reported separately for inpatient hospital coding. Facilities can report the head CT scan using the appropriate code in section B, Imaging.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for computer-aided triage and notification for measurement of intracranial cerebrospinal fluid flow. Continue coding as described in current coding.

Option 2. Create a new code in section X, New Technology, to identify computer-aided triage and notification for measurement of intracranial cerebrospinal fluid flow.

Section **X** New Technology *Body System* **X** Physiological Systems *Operation* **E** Measurement: Determining the level of a physiological or physical function at a point in time			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Central Nervous	**X** External	**ADD 1** Intracranial Cerebrospinal Fluid Flow, Computer-aided Triage and Notification	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 20 – Implantation of a Bioengineered Vessel

Issue: There are currently no unique ICD-10-PCS codes to describe the replacement of an extremity artery using a bioengineered human acellular vessel. An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. In May 2023, Human Acellular Vessel™ (HAV™) received the Regenerative Medicine Advanced Therapy (RMAT) Designation from the FDA for urgent arterial repair following extremity vascular trauma. On December 11, 2023, Humacyte, Inc. submitted a Biologics License Application (BLA). On February 8, 2024, the FDA accepted and granted Priority Review to Humacyte's BLA. According to the requestor, the FDA assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 10, 2024. The HAV™ is a bioengineered, implantable biologic vessel anticipated to be indicated for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and when autologous vein use is not feasible.

Background: Trauma to the extremities represents one of the most common injury patterns seen in emergency medical and surgical practice. Vascular trauma to the upper or lower extremities can occur in either the civilian or military setting, typically in the setting of wound bed contamination or infection and is categorized by the mechanism of injury (blunt, penetrating, or combination). Blunt trauma occurs secondary to crush injuries, fractures or dislocations which can be caused by motor vehicle accidents and falls, whereas penetrating trauma can be caused by objects (e.g., bullets), fragments from a blast, or stabs.[1]

The current options for treatment of a significantly damaged or missing arterial segment in the context of traumatic injuries often rely on interposition or bypass grafting. This type of reconstruction is performed by using either autologous vein from the patient, nonautologous (e.g., cryopreserved) grafts, or by using a synthetic graft such as expanded polytetrafluoroethylene (ePTFE) or Dacron. However, there are significant unmet needs in the treatment options for patients who may not have adequate autologous vein for harvest, where the urgency of the repair may preclude additional operating time for harvesting the autologous vein, or where the susceptibility to infection from a contaminated wound may preclude the use of synthetic grafts.[2]

The HAV™, a bioengineered tissue, is under investigation as an infection-resistant, universally implantable conduit for use in vascular repair. Designed to be ready off-the-shelf, the HAV™ has the potential to save valuable time for surgeons and to improve outcomes and reduce complications for patients. The HAV™'s immediate availability can accelerate the initiation of

[1] Huber GH, Manna B. Vascular Extremity Trauma. [Updated 2022 Sep 12]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK536925/

[2] See Alarhayem AQ, Cohn SM, Cantu-Nunez O, Eastridge BJ, Rasmussen TE. Impact of Eme to repair on outcomes in patients with lower extremity arterial injuries. J Vasc Surg. 2019;69(5):1519-1523; Rasmussen T, Sen I, 2022. Severe lower extremity injury in the adult patient. Wolters Kluwer UpToDate, available online at: https://www.uptodate.com/contents/severe-lower-extremity-injury-in-the-adult-patient#; and Teixeira PGR, DuBose J. Surgical Management of Vascular Trauma. Surg Clin North Am; 2017; 97(5):1133-1155.

vascular repair. Unlike traditional methods that can require time-consuming processes such as autologous vein harvesting or thawing of cryopreserved veins, the HAV™ can be deployed quickly.

Technology

The HAV™, once approved, will offer a new treatment option for vascular replacement and repair, and restoration of blood flow to distal tissues. Like human blood vessels, the HAV™ is tubular in shape and has a similar wall thickness. The wall of the HAV™ is composed of human extracellular matrix (ECM) proteins (collagen types I, III and VI, fibronectin, and other matrix proteins). The HAV™ is manufactured using a proprietary process beginning with human vascular cells that are seeded onto a tubular biodegradable scaffold and cultivated in a sterile bioreactor bag that simulates the pulsatile flow of blood in human arteries. This process creates precise and consistent, fully formed, and functional bioengineered human blood vessels. A final decellularization process thoroughly removes cellular and genetic material that could be responsible for immune rejection, while retaining an intact ECM structure and key ECM proteins found in native vessels. To date in clinical studies, there have been no reports of immunogenicity or rejection. The ECM of the HAV™ wall works to support regeneration or remodeling after implantation.

The HAV™ is surgically implanted to repair or replace an injured artery following traumatic injury. It is supplied within a sealed package containing one sterile HAV™ unit for implantation in a single patient only. The HAV™ is ready for immediate implantation or can be placed in a basin of regular sterile saline at room temperature while the patient is being prepared for surgical implantation. The HAV™ is 6 mm in inner diameter and 42 cm in length. Once removed from its packaging, its usable length is approximately 40 cm. The anatomical location and length of the HAV™ to be implanted are decided by the surgeon. Once implanted, the HAV™ is repopulated by the patient's own cells over time, resulting in a remodeled, revascularized, and living blood vessel.[3]

Procedure Description

The first step in implanting the HAV™ is to remove the product from the primary packaging. Once removed, the surgeon then carefully determines the appropriate length of the HAV™ to use, based on the results from preoperative clinical evaluation, vessel mapping and/or imaging, taking into consideration the patient's body weight and posture, and the range of motions likely to be encountered around the anatomical region of the implantation.

The HAV™ is then cut with sharp vascular scissors in a manner similar to trimming a human blood vessel. Next, the surgeon makes a longitudinal incision over the site of injury to expose the damaged artery. The artery is carefully dissected and isolated proximally and distally to the injury. To ensure vascular control, non-crushing vascular (atraumatic) clamps are applied to control bleeding. The surgeon makes an anastomosis between the HAV™ and the host vessel in a precise manner using nonabsorbable, monofilament sutures of an appropriate size. Static blood is flushed from the lumen of the HAV™ while completing the second anastomosis. The clamps are released to restore blood flow and check for leaks at the anastomosis site. As undue anastomotic bleeding may occur if gaps are present between the HAV™ and the host vessel, appropriate suture

[3] Kirkton RD, Santiago-Maysonet M, Lawson JH, Tente WE, Dahl SLM, Niklason LE, Prichard HL. Bioengineered human acellular vessels recellularize and evolve into living blood vessels after human implantation. Sci Transl Med. 2019 Mar 27;11(485):eaau6934. doi: 10.1126/scitranslmed.aau6934. PMID: 30918113; PMCID: PMC7557107.

placement and tension are key. Topical hemostatic agents may be used to minimize anastomotic bleeding. After implantation, the surgeon inspects the operative site carefully prior to closure to ensure that there are no twists, kinks, redundancy, or HAV™ impingement before and during the tissue closure portion of the case. At the conclusion of the operation, the surgeon inspects the circulation to ensure that perfusion to the distal vascular bed has not been compromised.

Current Coding: There are no unique ICD-10-PCS codes to describe the replacement of an extremity artery using a bioengineered human acellular vessel. Code the procedure using the appropriate extremity artery body part value and the device value K Nonautologous Tissue Substitute in tables 03R, Replacement of Upper Arteries and 04R, Replacement of Lower Arteries.

Section	**0** Medical and Surgical
Body System	**3** Upper Arteries
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Internal Mammary Artery, Right **1** Internal Mammary Artery, Left **2** Innominate Artery **3** Subclavian Artery, Right **4** Subclavian Artery, Left **5** Axillary Artery, Right **6** Axillary Artery, Left **7** Brachial Artery, Right **8** Brachial Artery, Left **9** Ulnar Artery, Right **A** Ulnar Artery, Left **B** Radial Artery, Right **C** Radial Artery, Left **D** Hand Artery, Right **F** Hand Artery, Left **G** Intracranial Artery **H** Common Carotid Artery, Right **J** Common Carotid Artery, Left **K** Internal Carotid Artery, Right **L** Internal Carotid Artery, Left **M** External Carotid Artery, Right **N** External Carotid Artery, Left **P** Vertebral Artery, Right **Q** Vertebral Artery, Left **R** Face Artery **S** Temporal Artery, Right **T** Temporal Artery, Left **U** Thyroid Artery, Right **V** Thyroid Artery, Left **Y** Upper Artery	**0** Open **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta **1** Celiac Artery **2** Gastric Artery **3** Hepatic Artery **4** Splenic Artery **5** Superior Mesenteric Artery	**0** Open **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

6 Colic Artery, Right **7** Colic Artery, Left **8** Colic Artery, Middle **9** Renal Artery, Right **A** Renal Artery, Left **B** Inferior Mesenteric Artery **C** Common Iliac Artery, Right **D** Common Iliac Artery, Left **E** Internal Iliac Artery, Right **F** Internal Iliac Artery, Left **H** External Iliac Artery, Right **J** External Iliac Artery, Left **K** Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left **V** Foot Artery, Right **W** Foot Artery, Left **Y** Lower Artery			

Coding Options

Option 1. Do not create new ICD-10-PCS codes for replacement of an extremity artery using a bioengineered human acellular vessel. Continue coding as described in current coding.

Option 2. In section X table X2R, Replacement of Cardiovascular System, create new body part values 5 Upper Extremity Artery, Right, 6 Upper Extremity Artery, Left, 7 Lower Extremity Artery, Right, and 8 Lower Extremity Artery, Left, and new device value W Bioengineered Human Acellular Vessel, applied to the open approach, to identify replacement of an extremity artery using a bioengineered human acellular vessel.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 5 Upper Extremity Artery, Right **ADD 6** Upper Extremity Artery, Left **ADD 7** Lower Extremity Artery, Right **ADD 8** Lower Extremity Artery, Left	**0** Open	**ADD W** Bioengineered Human Acellular Vessel	**A** New Technology Group 10

Option 3. In Medical and Surgical tables 03R, Replacement of Upper Arteries and 04R, Replacement of Lower Arteries, create new device value L Bioengineered Human Acellular Vessel, applied to the extremity artery body part values, to identify replacement of an extremity artery using a bioengineered human acellular vessel.

Section	**0** Medical and Surgical
Body System	**3** Upper Arteries
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
3 Subclavian Artery, Right **4** Subclavian Artery, Left **5** Axillary Artery, Right **6** Axillary Artery, Left **7** Brachial Artery, Right **8** Brachial Artery, Left **9** Ulnar Artery, Right **A** Ulnar Artery, Left **B** Radial Artery, Right **C** Radial Artery, Left **D** Hand Artery, Right **F** Hand Artery, Left	**0** Open **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **ADD L** Bioengineered Human Acellular Vessel	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
C Common Iliac Artery, Right **D** Common Iliac Artery, Left **E** Internal Iliac Artery, Right **F** Internal Iliac Artery, Left **H** External Iliac Artery, Right **J** External Iliac Artery, Left **K** Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left **V** Foot Artery, Right **W** Foot Artery, Left	**0** Open **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **ADD L** Bioengineered Human Acellular Vessel	**Z** No Qualifier

CMS Recommendation: Option 2, as described above.

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

Topic # 21 – Rapid Antimicrobial Susceptibility Testing of Blood Cultures

Issue: There are no unique ICD-10-PCS codes to describe rapid quantitative antimicrobial susceptibility testing of blood cultures found positive for gram-negative organisms using phenotypic susceptibility. 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. A 510(k) application for the ASTar® System was submitted on 6/8/2022.

Background: Bloodstream infections (BSI) are infectious diseases defined by the presence of viable bacterial or fungal microorganisms in the bloodstream (later demonstrated by the positivity of one or more blood cultures) that elicit or have elicited an inflammatory response characterized by the alteration of clinical, laboratory and hemodynamic parameters.[1] BSI can be preceded, followed or be concomitant to a localized infectious disease, like endocarditis, pneumonia, urinary tract infection, meningitis and others. BSI are a major cause of morbidity and mortality despite the availability of broad spectrum and effective antimicrobials and major advances in supportive care.[2]

The current workflow for the diagnosis and treatment of blood stream infections relies on culture-based methods for antimicrobial susceptibility testing (AST) that usually require a sub-culture from positive blood culture bottles on agar plates followed by a 12-18 hour automated AST. Some systems on the market can identify organisms and certain resistant genes via molecular methods, but these systems typically only indicate which antibiotic may not work due to a resistant gene being present but do not give an information which drugs will work and at what concentration. This is key information needed for choosing the optimal therapy for the treatment of these critically ill patients. Early initiation of adequate therapy reduces the risk of disease progression and improves patient outcomes.

Technology
The ASTar® System is used for positive blood cultures confirmed to contain Gram-negative bacteria by Gram stain. Organism identification is required to be entered into the ASTar® Instrument for results to be reported, but ASTar® can be started prior to, during, or after organism identification. AST is initiated directly from a positive blood culture, which means that the total time to adequate antimicrobial treatment is potentially shortened by approximately 25 hours compared with current practice. The fully automated AST solution reduces hands-on time to a few minutes and improves data quality.

According to the requestor, the novel disc design supporting a comprehensive AST panel makes the simultaneous measurement of a broad range antimicrobial dilutions for Minimum Inhibitory Concentration (MIC) determination possible, supporting potential reductions in the need for follow up testing. In optimizing the care for patients with a BSI, it is particularly advantageous to

[1] Viscoli C. Bloodstream Infections: The peak of the iceberg. Virulence. 2016 Apr 2;7(3):248-51. doi: 10.1080/21505594.2016.1152440. Epub 2016 Feb 18. PMID: 26890622; PMCID: PMC4871637.
[2] Core Concepts in Clinical Infectious Diseases (CCCID) https://doi.org/10.1016/B978-0-12-804423-0.00002-0

have rapid access to precise MIC results. MIC-driven selection of the optimal dosing regimen in an MIC-driven dosing regimen can support preventing antimicrobial overdosing and underdosing and reduce the risks of side effects from prolonged broad-spectrum antibiotic exposure. In addition, according to the requestor, faster identification and therefore administration of the appropriate treatment option for patients with bloodstream infections using the ASTar® System can have the potential to reduce intensive care unit length of stay.

The ASTar® System consists of the ASTar® Instrument, ASTar® BC G- Kit, and ASTar® BC G- Frozen Insert. The ASTar® Instrument includes instrument control software, firmware, and software. The ASTar® BC G- Kit includes the sample preparation Cartridge and AST Disc. The ASTar® BC G- Kit tests the following Gram negative non-fastidious species: Acinetobacter baumannii, Citrobacter freundii, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, and Serratia marcescens.

The ASTar® BC G- Frozen Insert contains frozen reagents for sample preparation to be inserted into the Cartridge before use. The Cartridge contains all reagents and disposable articles needed for sample preparation, concentration determination, dilution, and growth medium adaption. The Cartridge contains pre-deposited reagents in a combination of freeze-dried and room-temperature liquids, generates controlled inoculum for AST, and is stored at room temperature. A frozen insert is added to the Cartridge before use.

The AST Disc, which is stored at room temperature, is used for AST and concentration determination, contains more than 330 culturing chambers prefilled with antimicrobials in various concentrations used for AST, chambers without antimicrobials used as controls, and chambers used to determine the concentration in the purified sample. According to the requestor, the extensive AST capabilities of the AST Disc delivers clinically actionable results in a single run. The unique proprietary technology allows automated time-lapse imaging of bacterial population growth in wells containing different concentrations of antimicrobial agents.

Procedure Description
ASTar® is a fully automated, random access benchtop instrument for rapid antimicrobial susceptibility testing. The proprietary AST technology allows automated time-lapse imaging of bacterial population growth in wells containing different concentrations of antimicrobial agents. ASTar® requires a Gram-stain procedure from positive blood culture bottles to ensure that the Gram-negative panel is suitable, and the sample is monomicrobial. The system also requires the identification of the pathogen to be able to generate the result report with the respective breakpoints.

Once gram-negative organisms have been identified, one ml of blood culture broth is transferred into the sample preparation Cartridge with a frozen insert which contains all reagents and consumables for the purification of the sample and to produce a controlled inoculum with a defined number of bacteria. This is required by the relevant standards (e.g., from the Clinical & Laboratory Standards Institute (CLSI) or European Committee on Antimicrobial Susceptibility Testing (EUCAST)) in susceptibility testing to ensure a correct determination of the minimum inhibitory

concentration (MIC).[3,4,5] The inoculum is then transferred inside the instrument onto a second consumable which is the disk containing the dried antimicrobials in various concentrations. The disk is transferred to an incubator hotel and read periodically through a high-speed microcopy camera to assess growth/no growth in the wells with the different antimicrobials. After a total time of approximately six hours, a MIC is determined. At this time, the identification of the organism in separate diagnostic systems should become available and is input to ASTar® to produce the final results report with the corresponding breakpoints. The system can run six cartridges and 12 disks at the same time with a total capacity of 36 tests/24 hours. The hands-on time is two minutes.

Current Coding: Rapid quantitative antimicrobial susceptibility testing of blood cultures found positive for gram-negative organisms using phenotypic susceptibility is not reported separately for inpatient hospital coding. If desired, facilities can report the collection of a patient's specimen from an indwelling vascular catheter using the following code:

8C02X6K Collection of blood from indwelling device in circulatory system

Coding Options

Option 1. Do not create new ICD-10-PCS codes for rapid quantitative antimicrobial susceptibility testing of blood cultures found positive for gram-negative organisms using phenotypic susceptibility. Continue coding as described in current coding.

Option 2. Create a new code in section X, New Technology, to identify rapid quantitative antimicrobial susceptibility testing of blood cultures found positive for gram-negative organisms using phenotypic susceptibility.

Section	**X** New Technology
Body System	**X** Physiological Systems
Operation	**E** Measurement: Determining the level of a physiological or physical function at a point in time

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Circulatory	**X** External	**ADD 2** Infection, Phenotypic Fully Automated Rapid Susceptibility Technology with Controlled Inoculum	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

[3] Smith KP, Kirby JE. The inoculum effect in the era of multidrug resistance: Minor differences in inoculum have dramatic effect on MIC Determination. Antimicrob Agents Chemother. 2018;62(8). doi:10.1128/AAC.00433-18

[4] Miller WR,Seas C, Carvajal LP, et al. The cefazolin inoculum effect is associated with increased mortality in methicillin-susceptible staphylococcus aureusbacteremia. Open Forum Infect Dis. 2018;5(6):1–9. doi:10.1093/ofi d/ofy123

[5] Lenhard JR, Bulman ZP. Inoculum effect of β-lactam antibiotics. JAntimicrob Chemother. 2019;74(10):2825–2843. doi:10.1093/jac/dkz226

Topic # 22 – Stereoelectroencephalographic Radiofrequency Ablation of Brain and Nervous Tissue

Issue: There are no unique ICD-10-PCS codes to describe the destruction of brain and nervous tissue by temperature-controlled stereoelectroencephalographic (sEEG) radiofrequency ablation (RFA) to create lesions in patients with drug-resistant epilepsy. An October 1, 2024 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The OneRF™ Ablation System received 510(k) clearance in December 2023.

Background: Resection and destruction of the epileptogenic zone (EZ), the region indispensable for seizure onset, is the gold standard for the surgical treatment of drug-resistant epilepsy. Development and investigation of minimally invasive surgical techniques has grown due to potential advantages including fewer complications, shorter and fewer hospitalizations, faster postoperative recovery, minimally disruptive stereotactic approaches, less risk to eloquent function, and patient preference. Radiofrequency ablation (RFA) is an effective technique to create thermocoagulative lesions for the treatment of epilepsy. Currently available RFA devices are limited in effectiveness because they cannot control temperature and perform sEEG recordings.

Currently available techniques such as laser interstitial thermal therapy (LITT) require magnetic resonance (MR) imaging guidance, which presents challenges for performing procedures in awake patients. LITT cannot perform post-procedure sEEG recordings and requires multiple hospital admissions with multiple implantations and removals of neuroelectrodes and/or neuroprobes.

According to the requestor, the OneRF™ Ablation System enables the delivery of RF energy through previously implanted combination Evo® sEEG-RF probes, which also allows for temperature-controlled ablative procedures. These probes are intended for both diagnostic and ablation use. When RFA via Evo® sEEG-RF electrodes is performed, MR guidance is not necessary, enabling treatment at the bedside or the operating room in an awake patient. Effectiveness of the intervention is measured at the sEEG identified seizure focus through the same electrodes. The requestor stated this provides the patient with the opportunity for reduced seizure burden, or in some cases, freedom from seizures, which may create the opportunity to delay or avoid the need for further surgery. Reduction in seizures and/or time of being seizure free after a temperature-controlled sEEG radiofrequency ablation may be predictive of the effectiveness of future procedures.

Patients with documented focal epilepsy experiencing multiple seizures not well-controlled on more than one anti-seizure medication are the most likely to experience the greatest benefit of sEEG RF ablation treatment.

Technology
The OneRF™ Ablation System is a RFA System consisting of the NeuroOne Radiofrequency Generator, Generator Interface Cable (GIC), Foot Pedal (optional), Cart, and Temperature

Accessory Kit (which includes Temperature Accessory (TA), to measure and monitor temperature, Spacer Tubes to position the TA at the desired sEEG contact and Radiofrequency Connection Box (RFCB), used to connect TA and sEEG contact pins to GIC). The system supports 1) monopolar RF delivery between a single sEEG-RF Probe contact or electrode and a ground pad (off the shelf) and 2) bipolar RF delivery between two electrodes on a single sEEG-RF Probe. RF energy is regulated by temperature/time control depending on the configured settings to create lesions in nervous tissue.

The RF Generator enables the capability to transmit energy to the sEEG-RF Probe for the creation of RF ablation lesions in nervous tissue. The neurosurgeon or treating clinician has the capability to select the Generator settings and sEEG-RF Probe connection configurations to create desired lesions at specific electrode contact location(s) on the Probe. The RF Generator is connected to the sEEG-RF Probe and the Temperature Accessory using a Generator Interface Cable. The Generator touchscreen displays the graphical user interface. The operator controls delivery through RF switch activations or foot pedal activations. A Power Delivery Indicator LED is included on the front panel of the Generator and is illuminated any time RF power delivery is occurring. Alerts that occur during therapy, such as those triggered by high temperatures or unexpected impedance changes, are brought to the attention of the operator by an on-screen message accompanied by an audible tone and RF delivery automatically halts.

Procedure Description

The ablation procedure performed using the OneRF™ Ablation technology is conducted at the bedside in the Epilepsy Monitoring Unit (EMU) or in the operating room, under the observation of the clinical care team. The OneRF™ Ablation System enables the delivery of RFA through the previously implanted combination Evo® sEEG-RF probes in the brain. The OneRF™ Ablation System allows for temperature controlled ablative procedures. The probes are not permanent. The implantation and removal of the combination Evo® sEEG-RF probes are separate procedures from the RFA. The implantation of the sEEG-RF probes occurs for the purpose of diagnostic monitoring and the removal of the probes occurs prior to patient discharge post-RFA, when performed.

Procedure summary: Identify the specific contacts of the sEEG-RF probe as per the montage sheet and as directed by the neurologist. Disconnect the selected sEEG-RF probe contact pin(s) from the sEEG recording head box. Connect the Generator Interface Cable (GIC) to the Generator. Choose and insert the spacer tube corresponding to the contact number to be ablated. Insert the Temperature Accessory (TA) into the sEEG-RF probe, connect TA to RFCB, connect RFCB to the GIC. Connect the contact pin corresponding to the sEEG-RF probe electrode contact to be ablated into the RFCB.

On the Generator, choose treatment mode, set Time for ablation (up to 10 minutes per ablation), select Temperature to ablate to (if in Temperature mode), select Power (if Temperature Mode, Power is up to 2W), initiate ablation, and then monitor the progress of the ablation through the Generator Display. The Display shows a graphic representation of real-time temperature, impedance and power. If an alert or error occurs at any point, RF delivery will automatically halt, and a message will be displayed. Repeat in next set of sEEG contacts as needed (could be repeated in multiple sEEGs, and multiple contacts in each sEEG, per procedure/patient). At the end of the ablation disconnect all the accessories.

An81xamplee of a protocol is as follows:

- Disconnect sEEG contact pins (corresponding to contacts chosen to be ablated)
- Choose the appropriate spacer tube corresponding to the contact(s) to be ablated and position it onto the sEEG-RF probe
- Insert TA into sEEG
- Insert sEEG chosen contact pins into RFCB, connect TA to RFCB
- Connect RFCB to GIC/Generator
- In Generator choose treatment mode, time, power and initiate ablation
- Monitor ablation in real time using graphic display
- Repeat in next set of sEEG contacts as needed (could be repeated in multiple sEEGs, and multiple contacts in each sEEG, per procedure/patient)
- At the end of the ablation disconnect all the accessories

Current Coding: There are no unique ICD-10-PCS codes to describe sEEG radiofrequency ablation of nervous tissue in the brain. Code the procedure using the following code.

00503ZZ Destruction of brain, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for sEEG radiofrequency ablation of nervous tissue in the brain. Continue coding as listed in current coding.

Option 2. In table 005, Destruction of Central Nervous System and Cranial Nerves, create new qualifier value 4 Stereoelectroencephalographic Radiofrequency Ablation, applied to the body part value 0 Brain and the percutaneous approach, to identify sEEG radiofrequency ablation of nervous tissue in the brain.

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Brain	**3** Percutaneous	**Z** No Device	**3** Laser Interstitial Thermal Therapy **ADD 4** Stereoelectroencephalographic Radiofrequency Ablation **Z** No Qualifier

CMS Recommendation: Option 2, as described above.

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

Topic # 23 – Administration of Antibiotic Using Temporary Joint Spacer System

Issue: There are no unique ICD-10-PCS codes to describe local antibiotic irrigation (cyclic instillation and removal) using a temporary joint spacer system, following removal of an infected hip or knee joint prosthesis. An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. The requestor intends to submit its New Drug Application (NDA) to the FDA in the second half of 2024 for the administration of VT-X7 (Vancomycin Hydrochloride and Tobramycin Sulfate x 7 days) in the treatment of periprosthetic joint infection. VT-X7 received Qualified Infectious Disease Product (QIDP) designation from the FDA on May 09, 2019.

Background: Periprosthetic Joint Infection (PJI) is a rare but serious complication of joint replacement surgery, also known as arthroplasty. Arthroplasty is performed to relieve pain and restore function in a diseased joint. Approximately 0.5% to 2% of patients who receive replacement hip or knee joints develop a PJI. The signs and symptoms of PJI include fever, chills, drainage from the surgical site, and increasing redness, tenderness, swelling and pain of the affected joint. Patients suffering from PJI are at increased risk of irreversible morbidity or mortality. In fact, Zmistowski and co-workers reported mortality rates of 3.7% at 90 days, 10.6% at 1 year, 13.6% at 2 years and 26.1% at 5 years post-surgical intervention for PJI. Average treatment duration is 16-weeks and 40-50% of Medicare patients fail to complete treatment.[1]

PJIs can be difficult to treat due to formation of biofilms within the joint. Biofilms are multicellular aggregates of microbes encased in extracellular polymeric substances, which form a physical barrier against antibiotics and act as a shield between the microbes and the patient's immune system. Per the requestor, intravenous administration of systemic antibiotics to treat PJI does not result in adequate therapeutic concentrations to eradicate biofilm at the site of infection. Safely achieving locally therapeutic levels of antibiotics is crucial for clinical success; however, this is difficult or impossible because most PJI pathogens are biofilm-forming and many of the most common antibiotics are systemically toxic.

According to the requestor, there are currently no therapies specifically approved for the treatment of PJI in the U.S. As such, the current standard of care (SOC) for treatment of PJI is two stage exchange arthroplasty. Stage 1 of the procedure includes removal of the infected implant, radical debridement, and insertion of a temporary, antibiotic-impregnated cement spacer followed by administration of systemic antibiotic therapy as needed, typically for a minimum period of six weeks. Stage 2 of the procedure is performed when patients are considered infection-free and includes removal of the temporary spacer, debridement, and implantation of a new permanent prosthesis. Cochran et al., in their review of 16,622 Medicare patients treated for PJI from October 2005 through December 2011, reported that 80.3% of reinfections occurred in the first postoperative year. Looking at all treatment options, two-stage revision has the lowest reinfection rate (19%) of all first-line treatment options for PJI other than amputation. When

[1] Zmistowski B, Karam JA, Durinka JB, Casper DS, Parvizi J. Periprosthetic joint infection increases the risk of one-year mortality. J Bone Joint Surg Am. 2013;95(24):2177-84.

accounting for patients who undergo repeat surgeries during the interstage period or do not complete the stage 2 surgery, Gomez et al. found that just 285 of 416 patients (68.5%) were considered a treatment success at one-year follow-up. A contributing factor is the morbidity associated with the lengthy interstage period. Gomez's reported an average interval period of 4.2 months.

Description and Mechanism of Action
VT-X7 contains 2 drug components, vancomycin hydrochloride and tobramycin sulfate. VT-X7 treats PJI by local irrigation of the joint space with these 2 drug components. Local irrigation includes instillation of a solution of the antibiotic, soaking of the antibiotic solution at the infection site followed by vacuum removal. The antibiotics are delivered and removed separately in a cyclical fashion.

Vancomycin's mechanism of action is inhibition of cell wall biosynthesis. Specifically, vancomycin binds to the acyl-D-ala-D-ala portion of the cell walls in proliferating susceptible gram-positive bacteria. The binding of vancomycin prevents the bacteria from creating a robust cell wall.

Tobramycin's mechanism of action is inhibition of bacterial protein synthesis. Specifically, tobramycin binds to a site on the bacterial 30S and 50S ribosome which prevents the formation of the 70S complex. Following binding of tobramycin, the bacterial mRNA cannot be translated into protein which leads to cell death.

Inpatient Administration of VT-X7
There are two stages to the inpatient administration of VT-X7. Stage 1 consists of surgical removal of the prosthetic implant from the infected joint, debridement per standard of care (SOC) and insertion of the VT-X7 spacer device, in lieu of an antibiotic-impregnated cement spacer. Local antibiotic irrigation with VT-X7 is initiated in the operating room at the conclusion of the Stage 1 surgery.

Administration of local antibiotic irrigation occurs for 7 days, consisting of alternating instillation and vacuum, beginning with tobramycin sulfate at the completion of Stage 1 surgery. The VT-X7 investigational drug regimen provides 7 days of local irrigation of tobramycin sulfate 80 mg once daily with a two-hour dwell time, and vancomycin hydrochloride 3,000 mg in 50-ml hourly increments with a 30-minute dwell time.

The daily investigational drug regimen is repeated on consecutive days until the time of the Stage 2 surgery. The patient remains inpatient for the duration of the therapy. Stage 2 surgery is performed at the completion of the local antibiotic therapy and consists of removal of the VT-X7 spacer device, debridement, and replacement with a new permanent prosthesis.

Per the requestor, preliminary analysis of safety data collected in a prospective randomized controlled trial indicate VT-X7 has a safety profile similar to the SOC two-stage exchange revision arthroplasty with the benefit of significantly reduced treatment time, total operating time and minimal systemic exposure to antibiotics.

Current Coding: There are no unique ICD-10-PCS codes to describe local antibiotic instillation using a temporary irrigation joint spacer system. Facilities can report the local antibiotic instillation using the following code:

3E0U029 Introduction of other anti-infective into joints, open approach

Code the procedure for removal of the infected hip or knee joint prosthesis in table 0SP, Removal of Lower Joints, using the applicable body part value, the device value J Synthetic Substitute, the qualifier value Z No Qualifier, and the open approach.

Section	**0** Medical and Surgical
Body System	**S** Lower Joints
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device*	*Qualifier*
9 Hip Joint, Right **B** Hip Joint, Left	**0** Open	**0** Drainage Device **3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **7** Autologous Tissue Substitute **8** Spacer **9** Liner **B** Resurfacing Device **E** Articulating Spacer **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier
C Knee Joint, Right **D** Knee Joint, Left	**0** Open	**J** Synthetic Substitute	**C** Patellar Surface **Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for local antibiotic instillation using a temporary irrigation joint spacer system. Continue coding as listed in current coding.

Option 2. Create a new code in section X, New Technology, to identify local antibiotic instillation using a temporary irrigation joint spacer system. Code separately the procedure for removal of the infected hip or knee joint prosthesis in table 0SP, Removal of Lower Joints, using the applicable body part value, the device value J Synthetic Substitute, the qualifier value Z No Qualifier, and the open approach.

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 U Joints	**0** Open	**ADD G** Vancomycin Hydrochloride and Tobramycin Sulfate Anti-Infective, Temporary Irrigation Spacer System	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 24 – Posterior Fixation of the Thoracolumbar Spine

Issue: There are no unique ICD-10-PCS codes to describe the insertion of a Carbon/PEEK spinal stabilization device for spinal infection. 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? Yes. The FDA granted 510(k) clearance for the VADER® Pedicle System on February 26, 2024 (K232628) and was granted Breakthrough Device Designation on July 31st, 2023 for the indication to stabilize the thoracic and/or lumbar spinal column as an adjunct to fusion in patients diagnosed with an active spinal infection (e.g., spondylodiscitis, osteomyelitis, etc.) who are at risk of spinal instability, progressive spinal deformity, or neurologic compromise, following surgical debridement.

Background: Spinal infections are a serious medical condition occurring either spontaneously or after surgery and/or injury with an estimated 10,000 cases per year in the U.S. While treatment has improved, the mortality rate for spinal infection is still estimated to be approximately 20%. Of these 10,000 cases, 50% are estimated to become neurologically or sensomotorically symptomatic and therefore need surgery for spinal stabilization.

The standard of care for patients suffering from symptomatic spinal infection is surgery with debridement of the infected tissues and segments as well as posterior (or 360°) stabilization of the treated segments to avoid neurologic or sensomotoric problems. Additionally, concurrent antibiotic treatment is an essential component of managing local and/or systemic infection. Surgical stabilization of the spine is paramount to reduce pain, and the risk of paralysis or paraplegia. Without stabilization, spinal infections could lead to deterioration and misalignment of bony structures with neurological compromise. Furthermore, maintaining spinal stability allows the patient to be mobile during completion of antibiotic treatment and recovery from the spinal infection, allowing a faster return to normal life and social interaction.

Technology
The VADER® Pedicle System is a pedicle screw system used to stabilize the thoracic and/or lumbar spine. The implants of the VADER® Pedicle System are manufactured from high strength carbon fiber reinforced polyether-ether-ketone (PEEK, "Carbon/PEEK," branded as BlackArmor®). This material provides low-artifact imaging (MRI, CT, etc.), which brings advantages in post-operative assessments of the patient's status when indicated. According to the requestor, in the specific case of treatment for spinal infection patients, the success of the standard-of-care antibiotic treatment and healing of spinal structures from the infection can be monitored very accurately with magnetic resonance imaging (MRI). In the case of spinal fixation with more conventional metal implants, imaging is compromised with artifacts that make interpretation of local situations and effects impossible.

The VADER® Pedicle System is supplied sterile and features a variety of screw sizes and posterior rod shapes to accommodate patient anatomy. The pedicle screw components are partially coated with rough titanium to facilitate bone growth and healing. The BlackArmor® material utilizes high strength, continuous carbon fiber reinforced PEEK with a carbon fiber content in the range of 50%.

BlackArmor® is radiolucent in all diagnostic imaging modes (MRI, CT, and X-ray). Embedded tantalum/titanium markers ensure the required radiologic visibility of the implant during surgery and follow-up. Components are manufactured through proprietary processes termed Composite Flow Molding (CFM) or Composite Compression Molding (CCM). The requestor stated these manufacturing processes are designed to provide improved mechanical performance compared to other Carbon/PEEK devices due to the continuous nature of the fibers versus the more standard "truncated" fibers.

Procedure Description
Posterior fixation for stabilization of spinal segments (e.g., 2 vertebral bodies with the intervertebral disk between them) using the VADER® Pedicle System involves the following procedural steps.

- With the patient being in a prone position, a posterior incision is made.
- Access through the posterior tissues and muscles is performed for the identification of the pedicles.
- Cleaning and debridement of the infected tissues, including intervertebral disc material, infected vertebral endplates and bone mass occurs.
- Optional: insertion of an intervertebral or VBR (vertebral body replacement) device to secure anterior support to the stabilization, if indicated. If this anterior part of the stabilization is applied, specialists refer to it as a 360° stabilization of the spinal segment, including anterior and posterior (pedicle screw system) elements.
- Opening of the pedicles, definition of screw trajectory into the vertebral body.
- Insertion of bilateral pedicle screws into the vertebral bodies above and below the spinal infection, choosing the right size and type of screw to best match the patient's anatomy
- Insertion of bilateral posterior rods to connect the right or left pedicle screws of adjacent vertebral bodies with each other.
- Anatomic alignment of vertebral bodies, correcting angles, distances, positions of the vertebral bodies to each other, and final fixation of the posterior rods to the pedicle screws, final tightening (this step leads to a solid connection of the two (or more) vertebral bodies to each other for posterior stabilization of spinal segment)
- Closure of the wound in layers, followed by skin closure.

After the surgery, stabilization is immediately load bearing, allowing the patient to move and start their rehabilitation as indicated. The patient will be mobile (if possible, based on their systemic disease and status). Antibiotic treatment will start or be continued to heal the systemic and local infection.

Current Coding: Code the procedure to insert a Carbon/PEEK spinal stabilization device from tables 0RH and 0SH, Insertion of Upper and Lower Joints. Separately assign the applicable ICD-10-PCS code from table 0RG or 0SG if spinal fusion is also performed.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
6 Thoracic Vertebral Joint **A** Thoracolumbar Vertebral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Spinal Stabilization Device, Pedicle Based	**Z** No Qualifier

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Lumbar Vertebral Joint **3** Lumbosacral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Spinal Stabilization Device, Pedicle Based	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the use of a Carbon/PEEK spinal stabilization device. Continue coding as described in current coding.

Option 2. Create new codes in section X, New Technology, to identify the use of a carbon/PEEK spinal stabilization device. Separately assign the applicable ICD-10-PCS code(s) from table 0RG or 0SG if spinal fusion is also performed.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 6 Thoracic Vertebral Joint **ADD 7** Thoracic Vertebral Joints, 2 to 7 **ADD 8** Thoracic Vertebral Joints, 8 or more **ADD A** Thoracolumbar Vertebral Joint **ADD B** Lumbar Vertebral Joint **ADD C** Lumbar Vertebral Joints, 2 or more **ADD D** Lumbosacral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD F** Carbon/PEEK Spinal Stabilization Device, Pedicle Based	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 25 - Section X Update
March 2024 ICD-10 Coordination and Maintenance Committee Meeting

For this March 2024 meeting we are sharing our analysis results for the Group 5 section X Codes from FY 2020, 2021, 2022, and 2023.

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 – March 2024 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	296	NO	995	Option 4-Create new codes in Med/Surg Table 047 with new qualifier "sustained release."	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	62	NO	215		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	34	NO	124		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	8	NO	37		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	247	NO	919		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	49	NO	239		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	29	NO	116		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	9	NO	39		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	76	NO	245		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	9	NO	33	Option 4-Create new codes in Med/Surg Table 047 with new qualifier "sustained release."	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	0	NO	3		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	2	NO	3		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	56	NO	235		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	4	NO	20		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	0	NO	4		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	1	NO	4		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	50	NO	194		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	4	NO	23		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	1	NO	7	Option 4-Create new codes in Med/Surg Table 047 with new qualifier "sustained release."	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	1	NO	1		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	48	NO	211		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	5	NO	17		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	1	NO	8		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	0	NO	3		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	17	NO	70		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	3	NO	10		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	0	NO	2		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	0	NO	3	Option 4-Create new codes in Med/Surg Table 047 with new qualifier "sustained release."	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	15	NO	80		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	1	NO	11		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	0	NO	1		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	0	NO	2		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	8	NO	44		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	3	NO	8		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	1	NO	2		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	0	NO	1		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	9	NO	40	Option 4-Create new codes in Med/Surg Table 047 with new qualifier "sustained release."	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	0	NO	3		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	0	NO	0		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	0	NO	1		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	7	NO	37		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	2	NO	6		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	0	NO	1		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	1	NO	1		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	4	NO	27		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	1	NO	3		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	0	NO	0	Option 4-Create new codes in Med/Surg table 047 with new qualifier "sustained release."	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	0	NO	2		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	77	NO	503	Option 1- Leave the code in Section X	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	3	NO	6	Option 1- Leave the code in Section X	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	8	NO	249	Option 1- Leave the code in Section X	
XW013W5	Introduction of caplacizumab into subcutaneous tissue, percutaneous approach, new technology group 5	13	YES	40	YES	14	YES	15	NO	82	Option 1- Leave the code in Section X	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	116,399	YES	641,111	Option 1- Leave the code in Section X	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	185	NO	3,747	Option 1- Leave the code in Section X	
XW033G5	Introduction of sarilumab into peripheral vein, percutaneous approach, new technology group 5	3	NO	136	NO	1,327	NO	9	NO	1,475	Option 1- Leave the code in Section X	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	1,871	NO	30,885	Option 1- Leave the code in Section X	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)	126	NO	261	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate an anti-infective was administered via the peripheral vein.	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	669	NO	3,789	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate an anti-infective was administered via the peripheral vein.	VABOMERE™ (meropenem-vaborbactam)
XW033Q5	Introduction of tagraxofusp-erzs antineoplastic into peripheral vein, percutaneous approach, new technology group 5	6	YES	6	YES	4	YES	5	NO	21	Option 1- Leave the code in Section X	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	2	NO	7	Option 1- Leave the code in Section X	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	154	YES (HABP/VABP only[3])	352	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate an anti-infective was	RECARBRIO™

[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
											administered via the peripheral vein.	
XW033W5	Introduction of caplacizumab into peripheral vein, percutaneous approach, new technology group 5	4	YES	21	YES	20	YES	16	NO	61	Option 1- Leave the code in Section X	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	2,341	YES	15,178	Option 1- Leave the code in Section X	VEKLURY®
XW043F5	Introduction of other new technology therapeutic substance into central vein, percutaneous approach, new technology group 5	30	NO	96	NO	22	NO	6	NO	154	Option 1- Leave the code in Section X	
XW043G5	Introduction of sarilumab into central vein, percutaneous approach, new technology group 5	0	NO	6	NO	31	NO	2	NO	39	Option 1- Leave the code in Section X	Kevzara®
XW043H5	Introduction of tocilizumab into central vein, percutaneous approach, new technology group 5	66	NO	643	NO	715	NO	255	NO	1,679	Option 1- Leave the code in Section X	ACTEMRA®
XW043K5	Introduction of fosfomycin anti-infective into central vein, percutaneous approach, new technology group 5	2	NO	4	YES (conditional)	5	YES (conditional)	5	NO	16	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate an anti-infective was administered via the central vein.	CONTEPO™ (fosfomycin)
XW043N5	Introduction of meropenem-vaborbactam anti-infective into central vein, percutaneous approach, new technology group 5	152	YES	203	NO	85	NO	90	NO	530	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate an anti-infective was administered via the central vein.	VABOMERE™ (meropenem-vaborbactam)

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
XW043Q5	Introduction of tagraxofusp-erzs antineoplastic into central vein, percutaneous approach, new technology group 5	21	YES	10	YES	13	YES	7	NO	51	Option 1- Leave the code in Section X	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	1	NO	2	Option 1- Leave the code in Section X	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	26	YES (HABP /VABP only)	64	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate an anti-infective was administered via the central vein.	RECARBRIO™
XW043W5	Introduction of caplacizumab into central vein, percutaneous approach, new technology group 5	3	YES	7	YES	5	YES	2	NO	17	Option 1- Leave the code in Section X	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	2	NO	5	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate other therapeutic substance was administered via the nose. Also, consider adding a qualifier of "Other Anti-depressant".	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	1,646	NO	3,818	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate a therapeutic	

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
											substance was administered via the mouth and pharynx.	
XW0DXJ5	Introduction of apalutamide antineoplastic into mouth and pharynx, external approach, new technology group 5	10	YES	8	NO	27	NO	36	NO	81	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate antineoplastic was administered via the mouth and pharynx. Proposing to revise Substance key entries for ERLEADA™ (Apalutamide).	ERLEADA™ (Apalutamide)
XW0DXL5	Introduction of erdafitinib antineoplastic into mouth and pharynx, external approach, new technology group 5	2	YES	3	YES	6	YES	3	NO	14	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate antineoplastic was administered via the mouth and pharynx. Proposing to revise Substance key entries for Balversa™ (Erdafitinib).	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	1,842	NO	5,639	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate antineoplastic was administered via the mouth and pharynx. Proposing to revise Substance key entries for Venclexta® (venetoclax tablets).	Venclexta® (venetoclax tablets)
XW0DXT5	Introduction of ruxolitinib into mouth and pharynx, external approach, new technology group 5	254	YES	611	YES	831	YES	776	NO	2,472	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate a therapeutic substance was	JAKAFI® (ruxolitinib)

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
											administered via the mouth and pharynx. Proposing to revise Substance key entries for JAKAFI® (ruxolitinib).	
XW0DXV5	Introduction of gilteritinib antineoplastic into mouth and pharynx, external approach, new technology group 5	62	YES	126	YES	109	YES	106	NO	467	Option 3-Existing codes in Administration Table 3E0 can be reported that indicate antineoplastic was administered via the mouth and pharynx. Proposing to revise Substance key entries for XOSPATA® (gilteritinib).	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	172	NCTAP	101,031	Option 1- Leave the code in Section X	
XW14325	Transfusion of convalescent plasma (nonautologous) into central vein, percutaneous approach, new technology group 5	415	NO	3,548	NCTAP	63	NCTAP	32	NCTAP	4,058	Option 1- Leave the code in Section X	
XXE5XM5	Measurement of infection, whole blood nucleic acid-base microbial detection, new technology group 5	1	YES	2	YES	7	YES	24	NO	34	Option 3- Delete Section X code. We are proposing to also delete the Index entry.	T2Bacteria® Panel (T2 Bacteria Test Panel)

Topic # 26 - ICD-10-PCS Index Addenda*

Lttr A
Main Add Adductor pollicis muscle
use Hand Muscle, Right
use Hand Muscle, Left

Main Add AMTAGVI(tm) use Lifileucel Immunotherapy

Main Add Anconeus muscle
use Lower Arm and Wrist Muscle, Right
use Lower Arm and Wrist Muscle, Left

Lttr C
Main Add CASGEVY(tm) use Exagamglogene Autotemcel

Main Computerized Tomography (CT Scan)
Vein
Delete Spanchnic B52T
Delete Intravascular Optical Coherence B52TZ2Z
Add Splanchnic B52T
Add Intravascular Optical Coherence B52TZ2Z

Lttr E
Main Add EBVALLO(tm) use Tabelecleucel Immunotherapy
Main Add ELREXFIO(tm) use Elranatamab Antineoplastic

Main Add Exploratory
Add see Laparotomy
Add see Thoracotomy

Lttr F
Main Add Fish Skin use Nonautologous Tissue Substitute

Main Add Fistulization, Tracheoesophageal 0B110D6

Main Fluoroscopy
Pancreatic Duct BF1
Delete Gallbladder and Bile Buct BF14
Add Gallbladder and Bile Duct BF14

Main Fluoroscopy
Delete Pharynix B91G
Add Pharynx B91G

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

Main Fluoroscopy
Vein
Delete Spanchnic B51T
Add Splanchnic B51T

Lttr H
Main Add Hamstring muscle
use Upper Leg Muscle, Right
use Upper Leg Muscle, Left

Lttr I
Main Add Iliopsoas muscle
use Hip Muscle, Right
use Hip Muscle, Left

Main Add Innova(tm) Stent use Intraluminal Device

Main Add Inspiris Resilia Aortic Valve use Zooplastic Tissue in Heart and Great Vessels

Lttr K
Main Add Kerecis(R) (GraftGuide) (MariGen) (SurgiBind) (SurgiClose)
use Nonautologous Tissue Substitute
Lttr L
Main Add LimFlow(tm) TADV (Transcatheter Arterialization of the Deep Veins)
Procedure
see Bypass of Lower Arteries 041

Main Add LimFlow(tm) Transcatheter Arterialization of the Deep Veins (TADV) System
use Synthetic Substitute in Lower Arteries

Main Add LYFGENIA(tm) use Lovotibeglogene Autotemcel

Lttr M
Main Magnetic Resonance Imaging (MRI)
Vein
Delete Spanchnic B53T
Add Splanchnic B53T

Lttr P
Main Delete Petrous part of temoporal bone
Delete use Temporal Bone, Right
Delete use Temporal Bone, Left
Main Add Petrous part of temporal bone
Add use Temporal Bone, Right
Add use Temporal Bone, Left

Main Revise from Pharyngogram see Fluoroscopy, Pharynix B91G
Revise to Pharyngogram see Fluoroscopy, Pharynx B91G

Main Add Piscine skin use Nonautologous Tissue Substitute

Main Add Plantaris muscle
use Lower Leg Muscle, Right
use Lower Leg Muscle, Left

Main Add Prevesical space
use Pelvic Cavity

Main Plain Radiography
Vein
Delete Spanchnic B50T
Add Splanchnic B50T

Lttr R
Main Add Resuscitative thoracotomy
Add see Control bleeding in, Mediastinum 0W3C
Add see Control bleeding in, Pericardial Cavity 0W3D

Main Plain Radiography
Vein
Delete Spanchnic B50T
Add Splanchnic B50T

Lttr S
Main Delete Synchra CRT-P use Cardiac Resynchronization Pacemaker Pulse Generator in 0JH
Add Syncra CRT-P use Cardiac Resynchronization Pacemaker Pulse Generator in 0JH

Lttr T
Main Revise from Thoracotomy see Drainage, Anatomical Regions, General 0W9
Revise to Thoracotomy
Add see Control bleeding in, Mediastinum 0W3C
Add see Control bleeding in, Pericardial Cavity 0W3D
see Drainage, Anatomical Regions, General 0W9
Add Exploratory see Inspection, Mediastinum 0WJC

Main Add Tracheoesophageal Puncture (TEP) 0B110D6

Main Delete Tympanic part of temoporal bone
Delete use Temporal Bone, Right
Delete use Temporal Bone, Left

Main	Add	Tympanic part of temporal bone
	Add	use Temporal Bone, Right
	Add	use Temporal Bone, Left

Lttr	U	
Main		Ultrasonography
		Vein
	Delete	Spanchnic, Intravascular B54TZZ3
	Add	Splanchnic, Intravascular B54TZZ3

ICD-10-PCS Body Part Key Addenda

Section 0		Medical and Surgical
Axis 4		Body Part
Term		Hand Muscle, Right
Term		Hand Muscle, Left
Includes	Add	Adductor pollicis muscle

Section 0		Medical and Surgical
Axis 4		Body Part
Term		Hip Muscle, Right
Term		Hip Muscle, Left
Includes	Add	Iliopsoas muscle

Section 0		Medical and Surgical
Axis 4		Body Part
Term		Lower Arm and Wrist Muscle, Right
Term		Lower Arm and Wrist Muscle, Left
Includes	Add	Anconeus muscle

Section 0		Medical and Surgical
Axis 4		Body Part
Term		Lower Leg Muscle, Right
Term		Lower Leg Muscle, Left
Includes	Add	Plantaris muscle

Section 0		Medical and Surgical
Axis 4		Body Part
Term		Pelvic Cavity
Includes	Add	Prevesical space

Section 0		Medical and Surgical
Axis 4		Body Part
Term		Temporal Bone, Left
Term		Temporal Bone, Right
Includes	Delete	Petrous part of temoporal bone

Includes	Delete	Tympanic part of temoporal bone
Includes	Add	Petrous part of temporal bone
Includes	Add	Tympanic part of temporal bone

Section 0		Medical and Surgical
Axis 4		Body Part
Term		Upper Leg Muscle, Right
Term		Upper Leg Muscle, Left
Includes	Add	Hamstring muscle

ICD-10-PCS Device Key Addenda

Axis 6		Device
Row		
Term		Cardiac Resynchronization Pacemaker Pulse Generator for Insertion in Subcutaneous Tissue and Fascia
Includes	Delete	Synchra CRT-P
Includes	Add	Syncra CRT-P

Row		
Term		Intraluminal Device
Includes	Add	Innova(tm) stent

Row		
Term		Nonautologous Tissue Substitute
Includes	Add	Fish skin
Includes	Add	Kerecis(R) (GraftGuide) (MariGen) (SurgiBind) (SurgiClose)
Includes	Add	Piscine skin

Row		
Term		Synthetic Substitute in Lower Arteries
Includes	Add	LimFlow(tm) Transcatheter Arterialization of the Deep Veins (TADV) System

Row		
Term		Zooplastic Tissue in Heart and Great Vessels
Includes	Add	Inspiris Resilia valve

ICD-10-PCS Substance Key Addenda

Section X		New Technology
Axis 6		Device / Substance / Technology
Row	Add	
Term	Add	Elranatamab Antineoplastic
Includes	Add	ELREXFIO(tm)

Row
Term Exagamglogene Autotemcel
Includes Add CASGEVY(tm)

Row
Term Lifileucel Immunotherapy
Includes Add AMTAGVI(tm)

Row Add
Term Add Lovotibeglogene Autotemcel
Includes Add LYFGENIA(tm)

Row
Term Tabelecleucel Immunotherapy
Includes Add EBVALLO(tm)

ICD-10-PCS Table Addenda

Medical and Surgical Section

Axis 5 Approach
Transorifice Endoscopic Hepatobiliary Procedures

Source	Description	Code specification
2023, public request with CMS internal review	In the Hepatobiliary and Pancreas body system of the Medical and Surgical section, add the approach value 8 Via Natural or Artificial Opening Endoscopic to the root operations Removal and Revision for the body part values 4 Gallbladder and G Pancreas, to capture detail for procedures such as the removal or revision of a lumen-apposing metal stent drainage device. Endoscopic drainage procedures of the pancreas and gallbladder are typically done to drain infection from the gallbladder, pancreatic pseudocysts or other walled off necrotic lesions into the duodenum or the stomach. The drainage devices used for these procedures are generically called lumen-apposing metal stents (LAMS). These stents typically stay in place for a period of months and are then removed during a subsequent procedure.	Add: 0FP[4G]80Z (2 codes) 0FW[4G]80Z (2 codes)

EXAMPLES

Section	**0** Medical and Surgical
Body System	**F** Hepatobiliary System and Pancreas
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device*	*Qualifier*

4 Gallbladder **G** Pancreas	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **Y** Other Device	**Z** No Qualifier
4 Gallbladder **G** Pancreas	**X** External	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device	**Z** No Qualifier
4 Gallbladder **G** Pancreas	**ADD 8** Via Natural or Artificial Opening Endoscopic	**0** Drainage Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**F** Hepatobiliary System and Pancreas
Operation	**W** Revision: Correcting, to the extent possible, a portion of a malfunction device or the position of a displaced device

Body Part	*Approach*	*Device*	*Qualifier*
4 Gallbladder **G** Pancreas	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **Y** Other Device	**Z** No Qualifier
4 Gallbladder **G** Pancreas	**X** External	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device	**Z** No Qualifier
4 Gallbladder **G** Pancreas	**ADD 8** Via Natural or Artificial Opening Endoscopic	**0** Drainage Device	**Z** No Qualifier

Axis 6 Device
External Fixation Device in Head and Facial Bones

Source	Description	Code specification
2021, public request with CMS internal review	In the Head and Facial Bones body system of the Medical and Surgical section, add the device value 5 External Fixation Device to the root operation tables Removal 0NP and Revision 0NW, for the body part values B Nasal Bone and W Facial Bone, to enable capture of procedures such as the removal or revision of the facial or nasal bone external fixation device.	Add: 0NP[BW][034X]5Z (8 codes) 0NW[BW][034X]5Z (8 codes)

EXAMPLES

Section	**0** Medical and Surgical
Body System	**N** Head and Facial Bones
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Skull	**0** Open	**0** Drainage Device **3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator	**Z** No Qualifier

		N Neurostimulator Generator **S** Hearing Device	
0 Skull	**3** Percutaneous **4** Percutaneous Endoscopic	**0** Drainage Device **3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator **S** Hearing Device	**Z** No Qualifier
0 Skull	**X** External	**0** Drainage Device **3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **M** Bone Growth Stimulator **S** Hearing Device	**Z** No Qualifier
B Nasal Bone **W** Facial Bone	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Drainage Device **4** Internal Fixation Device **ADD 5** External Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator	**Z** No Qualifier
B Nasal Bone **W** Facial Bone	**X** External	**0** Drainage Device **4** Internal Fixation Device **ADD 5** External Fixation Device **M** Bone Growth Stimulator	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**N** Head and Facial Bones
Operation	**W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	*Approach*	*Device*	*Qualifier*
0 Skull	**0** Open	**0** Drainage Device **3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator **N** Neurostimulator Generator **S** Hearing Device	**Z** No Qualifier
0 Skull	**3** Percutaneous **4** Percutaneous Endoscopic **X** External	**0** Drainage Device **3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator **S** Hearing Device	**Z** No Qualifier
B Nasal Bone **W** Facial Bone	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**0** Drainage Device **4** Internal Fixation Device **ADD 5** External Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator	**Z** No Qualifier

Axis 7 Qualifier
Lower Artery Bypass

Source	Description	Code specification
2023, Coding Clinic Editorial Advisory Board & CMS internal review	In Medical and Surgical section table 041, Bypass of Lower Arteries, add the qualifier value R Lower Artery, applied to body parts 3 Hepatic Artery and 4 Splenic Artery. These changes will enable the capture of detail for bypass procedures from the hepatic artery or its branches to lower arteries other than the renal arteries.	Add: 041[34][04][9AJKZ]R (20 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**4** Anatomical Regions, Upper Extremities
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
3 Hepatic Artery **4** Splenic Artery	**0** Open **4** Percutaneous Endoscopic	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**3** Renal Artery, Right **4** Renal Artery, Left **5** Renal Artery, Bilateral **ADD R** Lower Artery

Lumbar Artery Perforator Flap

Source	Description	Code specification
2024, Coding Clinic Editorial Advisory Board & CMS internal review	In Medical and Surgical section table 0HR, Replacement of Skin and Breast, add new qualifier value B Lumbar Artery Perforator Flap, applied to body parts T Breast, Right, U Breast, Left and V Breast, Bilateral. This change enables the capture of additional detail for autologous breast reconstruction with lumbar artery perforator (LAP) flaps.	Add: 0HR[TUV]07B (3 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
T Breast, Right **U** Breast, Left **V** Breast, Bilateral	**0** Open	**7** Autologous Tissue Substitute	**5** Latissimus Dorsi Myocutaneous Flap **6** Transverse Rectus Abdominis Myocutaneous Flap **7** Deep Inferior Epigastric Artery Perforator Flap **8** Superficial Inferior Epigastric Artery Flap **9** Gluteal Artery Perforator Flap **ADD B** Lumbar Artery Perforator Flap **Z** No Qualifier

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr L
Main Add Lumbar Artery Perforator Flap
Add Bilateral 0HRV07B
Add Left 0HRU07B
Add Right 0HRT07B

New Technology Section
Axis 6 Device / Substance / Technology

Radiofrequency Ablation of Renal Sympathetic Nerves

Source	Description	Code specification
2023, public request with CMS internal review	In the New Technology section, add the axis 6 device/substance/technology value 3 Radiofrequency Ablation to table X05, Destruction of Nervous System, for the body part value 1 Renal Sympathetic Nerve(s), to enable the capture of procedures such as the radiofrequency ablation of renal sympathetic nerves. The Symplicity Spyral™ renal denervation system is indicated to reduce blood pressure as an adjunctive treatment in essential hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. The system consists of two main components. The first component is the Symplicity Spyral™ multi-electrode denervation catheter which delivers radiofrequency energy to the renal sympathetic nerves surrounding the renal artery wall. The second component is the Symplicity G3 renal denervation generator. The catheter is the only component that enters the body. During ablation, the radiofrequency energy passes through the wall of the artery and preferentially heats the perivascular adipose tissue where the sympathetic renal nerves reside outside the artery. This carefully generated heat irreversibly destroys the nerve tissue. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2025 consideration.	Add: X05133A (1 code)

EXAMPLE

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
1 Renal Sympathetic Nerve(s)	**3** Percutaneous	**2** Ultrasound Ablation **ADD 3** Radiofrequency Ablation	**A** New Technology Group 10

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr D
Main Destruction
Delete Renal Sympathetic Nerve(s), Ultrasound Ablation X051329
Add Renal Sympathetic Nerve(s)
Add Radiofrequency Ablation X05133A
Add Ultrasound Ablation X051329

Lttr N
Main New Technology
Destruction
Delete Renal Sympathetic Nerve(s), Ultrasound Ablation X051329
Add Renal Sympathetic Nerve(s)
Add Radiofrequency Ablation X05133A
Add Ultrasound Ablation X051329

Lttr R
Main Add Radiofrequency Ablation, Destruction, Renal Sympathetic Nerve(s) X05133A

Lttr S
Main Add Symplicity Spyral(tm) Renal Denervation System X05133A

Topic # 27 – Administration of bentracimab

Issue: There are no unique ICD-10-PCS codes to describe the administration of bentracimab, an investigational monoclonal antibody fragment designed to reverse the antiplatelet activity of ticagrelor, an oral $P2Y_{12}$ inhibitor. An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. A Biologics License Application (BLA) is projected to be submitted to the FDA in the first half of 2024, with a request for Priority Review. Bentracimab is under investigation and upon FDA approval would be the only $P2Y_{12}$ inhibitor reversal agent specific to ticagrelor[1], an oral $P2Y_{12}$ inhibitor that is marketed in the U.S. under the brand name Brilinta®.

Background: Ticagrelor (Brilinta®) is indicated to 1) reduce the risk of cardiovascular death, myocardial infarction (MI) and stroke in patients with acute coronary syndrome or a history of MI, 2) to reduce the risk of a first MI or stroke in patients with coronary artery disease at high risk for such events, and 3) to reduce the risk of stroke in patients with acute ischemic stroke. While the clinical benefit of ticagrelor is well established, there is a trade-off to clinical benefits, as antiplatelet therapy also increases risk and severity of major bleeding and of bleeding associated with surgery or invasive procedures.[2,3] Neither the specific agents that reverse the anticoagulation effect of direct-acting oral anticoagulants (DOAC) nor a blood coagulation factor replacement factor indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) can reverse $P2Y_{12}$ inhibitor antiplatelet effect. Further, the antiplatelet effects of ticagrelor cannot be reliably reversed with platelet transfusion.[1,4]

According to the ticagrelor prescribing information[1], there is no known treatment to reverse ticagrelor's antiplatelet effects, and ticagrelor is not expected to be dialyzable. If a non-deferrable surgery is indicated for a patient on ticagrelor antiplatelet therapy, the surgeon must either proceed while accepting the increased bleeding risk or postpone the procedure for several days while accepting the incrementally but steadily increasing thrombotic risks associated with delaying a clinically indicated procedure without antiplatelet protection.[2] All major guidelines recommend cessation of oral $P2Y_{12}$ receptor antagonists at least 3 to 5 days before surgery[5], which places the patient at interim risk for thrombotic complications. Significant patient risk factors for major bleeding in patients on ticagrelor antiplatelet therapy include advanced age, chronic kidney disease, and diabetes; all are also factors for ischemic risk.[6] Many other risk factors exist, including

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[1] Brilinta (ticagrelor), prescribing information. Astra Zeneca.
[2] Bhatt DL, et al. Bentracimab for ticagrelor reversal in patients undergoing urgent surgery. *NEJM Evidence;* DOI:10.1056/EVIDoa2100047, December 2021.
[3] Bhatt DL, et al. Antibody-based ticagrelor reversal agent in healthy volunteers. *N Engl J Med* 2019;380:1825-33. DOI:10.1056/NEJMoa1901778, March 2019.
[4] Teng J, et al. Effects of autologous platelet transfusion on platelet inhibition in ticagrelor-treated and clopidogrel-treated subjects. *J Thromb Haemost.* 2016;14:2342-2352.
[5] Valgimigli M, et al. 2017 ESC focused update on dual antiplatelet therapy in coronary artery disease developed in collaboration with EACTS. *Eur Heart J.* 2018;39 :213-260.
[6] Levine GN, et al. 2016 ACC/AHA Guideline Focused Update. *Circulation*. 2016 ;134 :e123-e155.

anemia, heart failure, and certain concomitant medications (including oral anticoagulant therapy, chronic steroid, and chronic NSAID), among others.[6] Unlike other $P2Y_{12}$ inhibitors, ticagrelor is a reversible inhibitor. Patients treated with ticagrelor who experience major bleeding or those who require surgery that cannot be delayed will be candidates for bentracimab to reverse the antiplatelet effect of ticagrelor.

Mechanism of Action
Bentracimab is a specific and selective recombinant human neutralizing antibody fragment (molecular weight 47.4 kDa) that binds to ticagrelor and its active metabolite with high affinity (K_D 20 pmol/L). The mechanism of action of ticagrelor is to occupy the $P2Y_{12}$ receptor on platelets; that receptor is the binding site for adenosine diphosphate, one of the human body's most potent activators of platelet activity. "Activated" platelets are required to generate a stable blood clot; while ticagrelor's occupation of that receptor helps prevent pathologic thrombosis, it also leads to impaired hemostasis when platelet activation is needed in the setting of bleeding. According to the requestor, bentracimab's unique mechanism of action provides immediate and sustained sequestering of active ticagrelor and its active metabolite to prevent inactivation of the $P2Y_{12}$ receptor, providing for rapid reversal of ticagrelor's antiplatelet effects within 5-10 minutes of intravenous infusion. The requestor reports that restoration of platelet function as measured by the $P2Y_{12}$ reaction units (PRU) and vasodilator-stimulated phosphoprotein (VASP) assays has been demonstrated *in vivo* in preclinical animal models and in humans in Phase 1, 2, and 3 clinical studies.

Inpatient Administration of bentracimab
Bentracimab is administered via IV infusion in either the inpatient or outpatient setting and is intended to provide immediate and sustained reversal of the antiplatelet activity of ticagrelor for 24 hours or a duration determined by the clinician. The following information summarizes the dosing and administration of bentracimab that will be submitted with the BLA.

- Dosage form and strength: Bentracimab is available in single-use 6 gram (g) dose glass vials (ready for infusion, no reconstitution needed). For each patient, the administration regimen will use 3 x 6 g dose vials.
- Administration regimen: Initiate treatment with an IV bolus of 6 g over 10 minutes (immediate reversal in 5 minutes); immediately follow with a loading infusion of 6 g over 4 hours (target rate of 25 mg/minute); then immediately follow with a maintenance infusion of 6 g over 12 additional hours.
- How supplied: Bentracimab will be packaged in cartons of 3 x 6 g dose vials (ready for infusion; no reconstitution needed). Store at 2-8ºC.

Results from the pre-specified interim analysis of the Phase 3, REVERSE-IT study[2] (NCT04286438) demonstrate clinically meaningful and potentially life-saving benefits of bentracimab for patients taking ticagrelor who are in need of non-deferrable surgery or an invasive procedure or who experience major bleeding. With immediate and sustained restoration of platelet function, it is anticipated that bentracimab will contribute to an improved, streamlined, and consistent patient care pathway and will relieve patients and physicians from making difficult choices between accepting the higher bleeding risk to perform non-deferrable procedures while taking ticagrelor and attempting to delay necessary invasive procedures with potential thrombotic risk after ticagrelor is discontinued. According to the requestor, given the rapid onset and offset of action of bentracimab, patients will be able to remain on ticagrelor for the benefit of platelet inhibition until surgery, risks associated with surgery will be mitigated, and physicians will be able

to restart oral antiplatelet therapy once hemostasis is reached, as needed for individual patients. In addition, the requestor stated that if bentracimab becomes a new standard of care, the benefit-risk profile in ticagrelor-treated patients will be enhanced by supporting adequate hemostasis and improvement in management of major bleeding or by improved risk mitigation in non-deferrable surgery or invasive procedure when ticagrelor washout is not feasible or desirable**.**

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

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

Coding Options

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

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of bentracimab.

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 3** Bentracimab, Ticagrelor Reversal Agent	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 28 – Administration of cefepime-taniborbactam

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

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. A new drug application (NDA) for cefepime-taniborbactam is currently under review by the FDA. The NDA was submitted on June 22, 2023 with Qualified Infectious Disease Product (QIDP), Fast Track, and Priority Review designations, and is pending approval. The target Prescription Drug User Fee Act (PDUFA) date is February 22, 2024.

Background: In a recent report, the U.S. Centers for Disease Control and Prevention (CDC) reported that rates of antimicrobial resistance (AMR) have increased significantly in the U.S. among bacterial pathogens including those commonly causing complicated UTI (cUTI), pyelonephritis, and bacteremia. The report noted there are over 2.8 million AMR infections annually, directly related to over 35,000 deaths, which may be an underestimate. A Premier analysis estimates that in 2020 approximately 4 million (cUTI) inpatients were treated in a U.S. healthcare facility. Data analysis from 2014 and 2019 of U.S. urinary tract infection (UTI) patients determined that 4.4% of cases were carbapenem resistant (CR) and 24.5% of U.S. UTI patients were bacteremic with 1.7% of cases due to CR pathogens. The indication that 176,000 cases of CR cUTI and ~17,000 bacteremic CR cUTI patients warrants new interventions.

According to the requestor, Cefepime-taniborbactam is an investigational intravenous (IV) beta-lactam antibiotic/beta-lactamase inhibitor (BL/BLI) combination under development for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis, melioidosis, and hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP). Cefepime-taniborbactam has also demonstrated in vitro coverage against antibiotic resistant gram-negative bacteria, most notably extended spectrum beta-lactamase (ESBL)-expressing Enterobacterales (ESBL-E), carbapenem-resistant Enterobacterales (CRE), and multidrug-resistant (MDR) *Pseudomonas aeruginosa* (MDR-PA), which can include carbapenem-resistant *P. aeruginosa* (CRPA).

Mechanism of Action
Cefepime inhibits bacterial cell wall synthesis by covalently binding penicillin-binding protein (PBP) enzymes responsible for the final step in transpeptidation during peptidoglycan wall synthesis. This binding causes defects in the bacterial cell wall leading to autolysis and bactericidal activity. The zwitterionic nature of cefepime provides the advantage of enhanced penetration of the gram-negative bacterial outer membrane relative to many other cephalosporins, thus more readily reaching its PBP targets before being inactivated by β-lactamases. Taniborbactam protects cefepime from hydrolysis by serine β-lactamases and metallo-β-lactamases, which are AMR mechanisms. It restores the activity of cefepime against many drug-resistant gram-negative pathogens, including *e*xtended-spectrum-β-lactamase-expressing (ESBL) Enterobacterales (ESBL-E), carbapenem-resistant Enterobacterales (CRE), and multidrug-resistant *P. aeruginosa* (MDR-PA) including carbapenem-resistant *P. aeruginosa* (CRPA). Taniborbactam on its own has no antibacterial activity. Cefepime-taniborbactam has demonstrated in vitro coverage against

antibiotic resistant gram-negative bacteria, most notably ESBL-E, CRE, and MDR-PA including some CRPA.

Inpatient Administration of Cefepime-Taniborbactam
Cefepime-taniborbactam is administered together by a health care professional via intravenous infusion to adult patients with cUTI, including pyelonephritis for 7 days. Patients with concurrent bacteremia could also receive cefepime-taniborbactam for up to 14 days. The therapy is supplied as one vial of cefepime and one vial of taniborbactam in a co-packaged presentation. The recommended dose of cefepime-taniborbactam is 2 g cefepime and 0.5 g taniborbactam administered together every 8 hours by intravenous infusion over 2 hours to adult patients with complicated urinary tract infections (cUTI), including pyelonephritis, and with or without concurrent bacteremia caused by susceptible gram-negative pathogens. Dosage adjustments are required for patients with estimate glomerular filtration rate (eGFR) less than 50 mL/min/1.73 m^2 and patients with eGFR greater than or equal to 120 mL/min/1.73 m^2.

Dosage Adjustment in Patients with Renal Impairment (eGFR <50 mL/min/1.73 m^2):
Dosage adjustment is recommended in patients with renal impairment who have an eGFR less than 50 mL/min/1.73 m^2. The recommended cefepime-taniborbactam dosage in adults with varying degrees of renal impairment is presented in Table 1. Monitor renal function in adult patients with changing renal function and adjust the dosage of cefepime-taniborbactam accordingly.

Dosage Adjustment in Patients with Augmented Renal Clearance (eGFR ≥120 mL/min/1.73 m^2):
For patients with eGFR greater than or equal to 120 mL/min/1.73 m2, cefepime-taniborbactam 2.5 g administered every 6 hours by IV infusion over 2 hours is recommended. Monitor renal function in adult patients with changing renal function and adjust the dosage of cefepime-taniborbactam accordingly.

Table 1: Dosage Table of Cefepime-Taniborbactam in Patients with Renal Impairment

eGFR* (mL/min/1.73 m^2	**Recommended Dosage Regimen for cefepime 2g and taniborbactam 0.5g****	**Dosing Interval**
30 to 49	2 g/0.5 g	q12h
20 to 29	1 g/0.25 g	q8h
15 to 19	1 g/0.25 g	q12h
5 to 14	Dose 1: 1 g/0.25 g Subsequent doses: 0.5 g/0.125 g	q24h
<5	Dose 1: 1 g/0.25 g Subsequent doses: 0.5 g/0.125 g	q48h

eGFR: Estimate Glomerular Filtration Rate
*As calculated using the Modified Diet in Renal Disease Formula
**All Doses of cefepime-taniborbactam administered over 2 hours
**The total duration of treatment is 7 days or up to 14 days for patients with concurrent bacteremia

According to the requestor, cefepime-taniborbactam's safety profile indicates the most common adverse effects exhibited were headache, diarrhea, constipation, and nausea.

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

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of cefepime-taniborbactam.

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of cefepime-taniborbactam.

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 4** Cefepime-taniborbactam Anti-infective	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 29 – Administration of ceftobiprole medocaril

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

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. The requestor submitted a New Drug Application (NDA) for ceftobiprole medocaril on October 3, 2023. The FDA has reviewed and accepted the ceftobiprole medocaril NDA for 3 indications: *Staphylococcus aureus* Bacteremia (SAB), including right sided infective endocarditis (RIE), Acute Bacterial Skin and Skin Structure Infections (ABSSSI), and Community Acquired Bacterial Pneumonia (CABP). The requestor received Qualified Infectious Disease Product (QIDP) priority review status for each of the three indications. The FDA set a Prescription Drug User Fee Act (PDUFA) action date of April 3, 2024.

Background: Antibiotic resistance poses a major threat to human health. Infections caused by antibiotic-resistant organisms, including Methicillin-resistant *Staphylococcus aureus* (MRSA), increase morbidity and mortality and increase hospital burden. The CDC estimates 2 million patients/year have infections due to drug-resistant bacteria[1]; resulting in 23,000 deaths annually in the U.S. MRSA contributes to a substantial portion of burden and is classified as a high-priority serious threat that is in urgent need of new treatment options. Additionally, there have been more than 100,000 deaths worldwide due to MRSA that are attributable to antibiotic resistance.

According to the requestor, ceftobiprole medocaril is an advanced generation intravenous bactericidal cephalosporin antibiotic for the treatment of challenging infections that are caused by Gram positive bacteria such as *Staphylococcus aureus*, including MRSA, *Streptococcus pneumoniae*, including *Penicillin-non-susceptible pneumococci* (PNSP) and *Enterococcus faecalis*, as well as non- extended spectrum beta-lactamase producing (non-ESBL) Enterobacterales. Ceftobiprole medocaril retains potent activity against clinically important and commonly encountered pathogens, such as Gram-positive and Gram-negative bacteria that are often resistant to other antibiotics. Ceftobiprole is the active moiety of the prodrug ceftobiprole medocaril, specifically developed and designed to treat these difficult, often resistant infections.

Mechanism of Action
Bactericidal activity is mediated through binding to multiple essential penicillin-binding proteins (PBPs) and inhibiting their transpeptidase activity, which is essential for the synthesis of the peptidoglycan layer of the bacterial cell wall, this inhibition leads to bacterial cell death. Ceftobiprole has a high affinity for *Staphylococcus aureus* PBPs 1 – 4, including PBP2a in methicillin resistant *Staphylococcus aureus,* and PBP2x and PBP2b in penicillin resistant *Streptococcus pneumoniae*. This differentiates ceftobiprole from almost all other beta-lactams that do not have activity against methicillin resistant *Staphylococcus aureus* (MRSA). Ceftobiprole is stable against *Staphylococcus aureus* PC-1 β-lactamases, and in Gram-negatives Class A TEM-1 β-lactamase, SHV-1 β-lactamase, the AmpC enzymes (unless expressed at high levels), and the SME-type carbapenem-hydrolyzing class A β-lactamases.

Inpatient Administration of ceftobiprole medocaril
The proposed dosing for ceftobiprole medocaril is administered as a 500mg, 2-hour intravenous infusion three times a day (Q8h) for 5-14 days for CABP and ABSSSI. For SAB including cases of infective endocarditis, ceftobiprole is administered four times daily (Q6h) as a 2-hour infusion for the first 8 days followed by a three times daily infusion for the subsequent days up to a total of 42 days.

According to the requestor, ceftobiprole medocaril's safety profile is consistent with the cephalosporin drug classification. However, severe adverse effects are 2.8% less than comparators. Common side effects experienced with Ceftobiprole Medocaril therapy includes nausea, diarrhea, vomiting and headache.

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

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

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of ceftobiprole medocaril.

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of ceftobiprole medocaril.

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 5** Ceftobiprole Medocaril Anti-infective	**A** New Technology Group **10**

CMS Recommendation: Option 2, as described above.

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

Topic # 30 – Administration of obecabtagene autoleucel

Issue: There are no unique ICD-10-PCS codes to describe the administration of obecabtagene autoleucel (obe-cel), an autologous CD19 CAR T-cell investigational therapy for the treatment of adult patients with relapsed/refractory (R/R) B-cell precursor acute lymphoblastic leukemia (B-ALL). An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. The Biologics License Application (BLA) for obe-cel was submitted to the FDA on November 27, 2023.

Background: Acute Lymphocytic Leukemia (ALL) is classified as being either of B-cell or T-cell lineage. In adults, B-cell ALL accounts for approximately 82% of ALL cases.[1] B-cell ALL is a neoplastic disorder that originates from the clonal overgrowth of a single B lymphocyte progenitor that occurs in both children and adults. ALL is a serious and life-threatening disease and will progress rapidly if left untreated. The National Cancer Institute's SEER (Surveillance, Epidemiology, and End Results Program)[2] reports the rate of new ALL cases were 1.8 per 100,000 per year with an estimated 6,540 new cases in 2023. Median overall survival (OS) is <1 year in adult R/R ALL, with deaths highest among people aged 65-74 years of age. Currently, allogeneic stem cell transplant (allo-SCT) is the only curative treatment for adult R/R ALL. However, older patients or those with overall poor health may not be eligible to receive an allo-SCT, as they may not be able to tolerate pre-transplant conditioning therapy. With current treatment options, up to 90% of adults with newly diagnosed ALL will enter complete remission; only 30-40% of these will achieve long-term remission.[3,4] Current T-cell therapies for adult patients with R/R ALL have limitations, including short duration of response (DOR), poor tolerability, and a need for consolidation with allo-SCT post-treatment.[5,6,7] Specifically, current CD19 CAR T-cell therapy induces increased rates of severe cytokine release syndrome (CRS) and high rates of severe immune effector cell-associated neurotoxicity syndrome (ICANS) with limited persistence of CAR T-cell activity and short duration of response.[8,9] Older patients or those with high tumor burden may not be eligible for CAR T therapies because of these treatment-related toxicities.[10] For adults with R/R ALL, new treatment options are needed to achieve high response rates and long-term remissions, with manageable safety and an improved patient journey.

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[1] Moorman AV, et al. *Blood* 2010;115(2):206-14.

[2] Surveillance, Epidemiology, and End Results (SEER) Program; Cancer Stat Facts: ALL. https://seer.cancer.gov/; accessed October 2023.

[3] American Cancer Society. https://www.cancer.org/cancer/acute-lymphocytic-leukemia/treating/typical-treatment.html (accessed January 2023).

[4] Sheykhhasan M, et al. *Cancer Gene Ther* 2022;29:1080–96

[5] Kantarjian H, et al. *N Engl J Med* 2017;376:836–47.

[6] Hadjivassileva T, et al. ZUMA-3 three-year follow-up [presented at EBMT-EHA 2023].

[7] Shah BD, et al. *Lancet* 2021;398:491–502.

[8] Hay KA, et al. *Blood* 2017; 130:2295–306.

[9] Hay KA. *Br J Haematol* 2018; 183:364–74.

[10] Roddie C, et al. J Clin Oncol 2023;41 (suppl 16):7000 [presented at ASCO 2023]

Mechanism of Action
Obe-cel is an autologous CD19 CAR T-cell investigational therapy with a unique mechanism of action designed to overcome the limitations in clinical activity and safety compared to current CD19 CAR T-cell therapies. Obe-cel specifically binds to and eliminates CD19-expressing B cells, including the cancerous blasts responsible for ALL.[11,12,13] Obe-cel has been purposely designed, with features such as a 4-1BB costimulatory domain and a unique CAT19 binder, to enhance T-cell expansion and persistence, and enable long-term DOR.[14,15,16] The novel CAT19 CAR is designed to have a fast target binding off-rate, a shorter half-life of interactions, and substantially lower affinity to CD19 than the FMC63 binder used in other CAR T-cell therapies. This unique design has the potential to minimize excessive activation of the CAR T-cells and thereby reduce toxicity and be less prone to T-cell exhaustion, which could enhance persistence and improve the ability of the CAR T-cells to engage in serial killing of target cancer cells. [17,18]

Inpatient Administration of obecabtagene autoleucel(obe-cel)
Obe-cel is produced from the patient's own T-cells, which are collected via leukapheresis and genetically modified to express a CD19 CAR. Obe-cel will be shipped and stored in vapor-phase liquid nitrogen shipping containers (below -150ºC) and will be thawed in a 37ºC water bath under sterile conditions prior to administration. Prior to receiving obe-cel treatment, patients receive pre-conditioning beginning Day -6 (fludarabine 30 mg/m^2 followed by cyclophosphamide 500 mg/m^2 on Days -6 and -5; then fludarabine 30mg/m^2on Days -4 and -3). Obe-cel is supplied as a cryopreserved autologous cell suspension packaged in three or more infusion bags overall containing a cell dispersion of the target dose of 410 x 10^6 CD19 CAR-positive viable T-cells:

- 10 x 10^6 CAR-positive viable T-cells in one 50 mL bag
- 100 x 10^6 CAR-positive viable T-cells in one or more 50 mL or 250 mL bags
- 300 x 10^6 CAR-positive viable T-cells in one or more 250 mL bags

The first-in-class tumor burden guided dosing of obe-cel is personalized to each patient based on the levels of disease present in their bone marrow. It was designed to minimize treatment-related toxicity associated with increased tumor burden. Obe-cel will be administered via two intravenous infusions (Day 1 and Day 10) using a syringe or gravity assisted infusion through a central or peripheral venous line over a few minutes (maximum 30 minutes from obe-cel being thawed to preserve cell viability). If there are multiple bags of obe-cel to be administered, one bag should be thawed and safely infused before the next bag is thawed. The first dose (Day 1) is determined by the patient's bone marrow disease burden within 7 days prior to lymphodepletion; the second dose (Day 10) is tailored for a total dose of 410 x 10^6 CAR T-cells.

- If the patient has <20% bone marrow blasts, the Day 1 dose is 100 x 10^6 CAR T-cells; the second dose (Day 10) is 310 x 10^6 CAR T-cells.
- If the patient's tumor burden is >20% bone marrow blasts, the Day 1 dose is 10 x 10^6 CAR T cells and the second dose (Day 10) is 400 x 10^6 CAR T-cells.

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[11] Scheuermann RH and Racila E. *Leuk Lymphoma* 1995;18:385–97.
[12] Roddie C, et al. J Clin Oncol 2021;39:3352–63.
[13] Maude SL, et al. *Blood* 2015;125:4017–23.
[14] Ghorashian S, et al. *Nat Med* 2019;25:1408–14
[15] Ying Z, et a. *Mol Ther Oncolytics* 2019;15:60-8.
[16] Roddie C, et al. *Blood* 2022;140 (suppl 1):7452–3 [presented at ASH 2022].
[17] Long AH, et al. *Nat Med* 2015;21:581–90.
[18] Tantalo DGM, et al. *J Immunother Cancer* 2021;9:e002555.

- Patients with Grade 2 CRS and/or Grade 1 ICANS following the first dose may receive the second dose on Day 10 (±2 days) only if CRS has resolved to Grade 1 or less and ICANS has completely resolved. If necessary, the infusion of the second dose may be postponed beyond Day 10 (±2 days) up to Day 21 to allow for the resolution of the adverse events.

In the pivotal FELIX trial, 94% of infused patients received both obe-cel infusions. In clinical studies, obe-cel has been administered in the inpatient setting; however, the requestor stated its clinical profile supports both hospital inpatient and hospital outpatient administration. According to the requestor, the pivotal FELIX study population represents the largest and most diverse patient population studied for R/R B-ALL with CAR T therapy, including a strong representation of Medicare-eligible patients: a total of 94 patients were treated ranging in age from 20-81 years of age; 48 of the 94 patients were 50 years of age or older, with 21 over 65 years of age. 30% of patients identified as Hispanic, a population with a higher prevalence for B-ALL. Patients were heavily pre-treated with high disease burden at study entry: 29 (30.9%) had ≥3 prior lines of therapy. FELIX study results[19] suggest an improved safety and efficacy profile for obe-cel vs results reported for current standard of care for adult R/R B-ALL in FDA-approved product labels. Of the 94 patients infused with obe-cel, 76% achieved disease response (CR/Cri) (95% CI 66,84), p<0.0001, with a median DOR of 14.1 months (range 1.9 to 19 months) based on a median follow up of 9.5 months; only 13% of patients received subsequent allo-SCT post treatment and were censored from the DOR analysis. The most common Grade ≥3 treatment-emergent adverse events (TEAEs) were neutropenia (36.2%), thrombocytopenia (25.5%), febrile neutropenia (25.5%) and anemia (19.1%). One death (1/94; 1%) was considered obe-cel-related per investigatory assessment (hemophagocytic lymphohistiocytosis [HLH] and neutropenic sepsis). Low rates of ≥3 CRS and/or ICANS were observed. Across all 94 infused patients, CRS grade ≥3 was reported in 3 (3.2%) patients; ICANS grade ≥3 was reported in 7 (7.4%) patients. Tocilizumab and steroid was used to treat CRS in 56% and 17% of patients, respectively. Three (3%) patients required vasopressor for treatment of CRS. Six of the 7 patients (86%) with grade ≥3 ICANS were observed among patients with >75% bone marrow blasts at pre-conditioning.

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

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

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

Coding Options

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

[19] Roddie C, et al. presented at European Hematology Association 2023.

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of obecabtagene autoleucel.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 8** Obecabtagene Autoleucel	**A** New Technology Group **10**

CMS Recommendation: Option 2, as described above.

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

Topic # 31 – Administration of odronextamab

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

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. Odronextamab was granted Orphan Drug Designation, Fast Track Designation, and Priority Review by the FDA. The requestor submitted a Biologics License Application (BLA) to the FDA seeking approval to market odronextamab for the treatment of adult patients with relapsed or refractory follicular lymphoma (R/R FL) after at least two prior systemic therapies and for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) after at least two prior systemic therapies, including patients with or without prior CAR T therapy. FDA accepted the BLA filing on September 29, 2023. The anticipated Prescription Drug User Fee Act (PDUFA) date is March 31, 2024.

Background: Follicular Lymphoma (FL) is a heterogeneous clinicopathologic entity that includes tumors derived from germinal center B cells. It is the second most common subtype of non-Hodgkin lymphoma (NHL) and is the most common of the clinically indolent NHLs. In the United States as a whole, FL accounts for approximately 35 percent of NHLs and has an estimated incidence of 3.18 cases per 100,000 people. The median age of diagnosis is 64 years with a majority of the patients having advanced stage disease (Stage III/IV) at the time of diagnosis. The 5-year relative survival rate for FL is 90.6%. Approximately 20% of patients experience early disease progression within years of first line treatment (POD24), which is associated with poor outcomes. Despite current improvements in survival rates for FL patients, treating individuals with third line treatments is difficult. Patients with R/R FL face diminishing durability of response with each additional line of therapy. When disease progression is seen within 24 months of initiating first line therapy patients face a poor prognosis. Roughly, 20% of patients with third line treated FL achieve complete response with existing therapies. Studies have shown the median overall survival rate decreased with each line of therapy. The median overall survival not reached in the first line treatment decreased the rate to 11.67 years in the second line treatment and 3.31 years after the fifth line of treatment.

Conversely, diffuse large B-cell lymphoma (DLBCL) is the most common histologic subtype of non-Hodgkin lymphoma (NHL) accounting for approximately 25 percent of NHL cases with around 7 cases per 100,000 persons per year. DLBCL can be classified according to the cell of origin as germinal center B-cell-like (GCB), activated B-cell-like (ABC), or non-GCB DLBCL. The most common cytogenetic abnormalities in DLBCL involve the oncogenes B-cell-lymphoma 2 (BCL2), B-cell lymphoma 6 (BCL6), and myelocytomatosis (MYC), which are implicated in the development of high-grade B-cell lymphoma. First line treatments have a 59% complete response rate. However, patients who respond to first line therapy have a 5-year survival rate of 78%. The response and survival rates decrease with each subsequent line of therapy. Outcomes for patients with R/R DBCL are poor. The median overall survival rate after third line therapy is 7.7 months and decreases to 4.4 months after the fourth line of therapy.

According to the requestor, odronextamab is a novel, fully human CD20×CD3 bispecific antibody with an immunoglobulin G4 (IgG4)-based structure that is designed to simultaneously bind to two types of antigens, CD20 found on both healthy and cancerous B cells, and CD3 found on T cells. Simultaneous engagement of both arms of odronextamab results in the activation of immune system T cells, causing it to generate cytotoxic T cells that can destroy the targeted cells, including cancerous B cells. Odronextamab is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (R/R FL) after at least two prior systemic therapies and for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) after at least two prior systemic therapies, including patients with or without prior CAR T therapy.

Mechanism of Action
Odronextamab is a fully human CD20xCD3 bispecific antibody with an IgG4-based structure in B-cell non-Hodgkin lymphoma (B-NHL) created from Veloci-Bi® technology. CD20 is a highly regulated transmembrane protein confined to normal and malignant B cells. It is a well-validated target for B-cell malignancies because it is tightly restricted to the B cell lineage. Odronextamab is designed to simultaneously bind CD20 on cancer cells with CD3-expressing T cells, triggering T-cell-mediated cytotoxicity independent of T-cell-receptor recognition. The fully human design is intended to help reduce potential for immunogenicity and anti-drug antibodies, distinguishing it from the other CD20xCD3 bispecific antibodies in B-NHL, which are humanized IgG1-based bispecific antibodies. Furthermore, IgG4-based antibodies are referred to as "blocking antibodies" because of their reduced ability to elicit an inflammatory immune response.

Inpatient Administration of Odronextamab
Odronextamab is administered inpatient by a health care professional intravenously using a split and step-up dosing design. Cycle 1 for R/R DLBCL initial dose is 0.2 mg and by day 15 and 16 increases to 10mg. During cycles 2 through 4 the dose is 160 mg. The maintenance dose is 320 mg and begins one week after the end of cycle 4, biweekly. Cycle 1 for R/R FL initial dose is 0.2 mg and increases to 10 mg by day 15 and 16. Cycles 2 through 4 the dose is 80 mg. The maintenance dose is 160 mg and begins one week after the end of cycle 4, biweekly. Maintenance will continue until disease progression, or an unacceptable toxicity occurs.

According to the requestor, Odronextamab's safety profile in patients with R/R FL experienced adverse effects such as pneumonia, progressive multifocal leukoencephalopathy, and systemic mycosis. Additionally, treatment was discontinued due to adverse effects less than 8% of the time. The safety profile in patients with R/R DLBCL includes pneumonia, COVID-19 and pseudomonal sepsis, with less than 8% of treatments being discontinued.

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

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of odronextamab.

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 9** Odronextamab Antineoplastic	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

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

Topic # 32 – Administration of Orca-T Allogeneic T-cell Immunotherapy

Issue: There are no unique ICD-10-PCS codes to describe the administration of Orca-T, an allogeneic T-cell immunotherapy. An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. On April 10, 2020 the FDA granted Orphan Drug designation (ODD) and on July 30, 2020 the FDA granted Regenerative Medicine Advanced Therapy (RMAT) designation to Orca-T. Orca Bio is currently enrolling in a registrational Phase 3 trial and will be seeking approval for a Biologics License Application (BLA).

Background: The incidences of acute leukemias and myelodysplastic syndrome (MDS) in the United States are 20,380 new cases per year and approximately 10,000 new cases per year respectively. Initial treatment options for acute leukemias and MDS is influenced by the severity of symptoms and risk classification, medical fitness, and pathologic features. In general, for medically fit patients, therapy includes induction chemotherapy, post-remission consolidation chemotherapy followed by maintenance therapy. For patients who receive a standard allo-transplant, nearly half die within 3 years due to relapse, Graft-versus-host disease (GvHD), infection, or organ failure. Patients with GvHD experience an increase in hospitalizations, drug utilization and mortality.

Orca-T is an allogeneic stem cell and T-cell immunotherapy biologic derived from a Human Leukocyte Antigen (HLA) matched donor and is being evaluated in a phase 3 study for the prevention of moderate-to-severe chronic GvHD or death in patients with acute leukemias and MDS following cytoreductive conditioning.

Mechanism of Action
The primary mechanism of action of Orca-T's hematopoietic stem progenitor cells is to reconstitute the blood and immune system of the recipient with that of a health, matched donor. Orca-T's goal is to safely and effectively build both a long-term and short-term immune system from a healthy matched donor inside of a patient while protecting the patient's tissue and organs from toxicities such as GvHD. The CD34+ cellular drug product of Orca-T acts to build a long-term immune system of a matched donor in the patient. The high precision regulatory Treg cellular drug product of Orca-T, a specialized CD4+ T-cell subset, acts to protect the patient's tissue and organs from any GvHD and other toxicities that result in non-relapse mortality. Treg cells are critical for establishing and maintaining self-tolerance from the immune system. The conventional Tcons cellular drug product of Orca-T acts to rapidly reconstitute the donor's immune system, mediating the graft-versus-leukemic effect, graft-versus-infection and the inflammatory responses, providing protection against infections by inserting a bridge immune system from a matched donor in the recipient undergoing cellular therapy. Stimulation of an inflammatory response against the recipient's solid organs such as liver, skin and gut can result in GvHD. GvHD is a potentially serious complication of allogeneic stem cell transplantation and is understood to be caused by the graft (allogeneic donor) T-cells reacting against host (recipient) organs.

Inpatient Administration of Orca-T
Orca-T is for allogeneic use only and infusions should be performed at room temperature. A leukodepleting filter and blood warmers should not be used. Central venous access is recommended for the infusion of Orca-T. After confirming the patient's identity matches the patient identifiers on each of the Orca-T cell therapy infusion bags, prime the tubing with normal saline prior to infusion. Infuse the entire contents of the Orca-T CD34+ infusion bag on Day 0 beginning by either gravity or a peristaltic pump at a rate of up to 5 mL/min and also infuse the entire contents of the Orca-T Treg infusion bag on Day 0 as soon as the CD34+ infusion bag has been infused. Infuse the Orca-T Treg infusion bag by either gravity or a peristaltic pump at a rate of up to 5 mL/min. Infuse the entire contents of the Orca-T Tcon infusion bag on Day +2 (48-72 hours) after the start of the CD34+ infusion bag. Infusion of the Orca-T Tcon infusion bag may be delayed up to Day +5~~/~~. Begin infusion of Orca-T CD34+ and Treg infusion bags before the expiration time printed on the product label. The Orca-T Tcon infusion bag is thawed and diluted at the clinical site. Gently agitate each infusion bag to prevent cell clumping. Begin infusion of Tcon within 1 hour after thaw. Following infusion of Orca-T CD34+, Treg and Tcon infusion bags, patients should be monitored per institutional guidelines for patients who have received an allograft with vital signs recorded.

Vital signs checks (weight excluded) should be initiated within 30 minutes after the start of infusion for each Orca-T cellular product or the SoC control allograft. Vital sign checks should then be repeated every 30 ± 5 min until 2 hours after the start of infusion. Participants in the Orca-T group receive the CD34+ and Treg Drug Products sequentially on day 0. Once the Treg Drug Product is administered, the timing of vital signs checks should be based on the start of infusion of this drug product.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of Orca-T allogeneic T-cell immunotherapy. Facilities can report the intravenous administration of Orca-T immunotherapy using one of the following codes:
3E033GC Introduction of other therapeutic substance into peripheral vein, percutaneous approach
3E043GC Introduction of other therapeutic substance into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of Orca-T immunotherapy. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of Orca-T immunotherapy.

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 B** Orca-T Allogeneic T-cell Immunotherapy	**A** New Technology Group **10**

CMS Recommendation: Option 2, as described above.

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

Topic # 33 – Administration of RP-L201 (marnetegragene autotemcel)

Issue: There are no unique ICD-10-PCS codes to describe the administration of RP-L201 (marnetegragene autotemcel), an autologous gene therapy. An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? Marnetegragene autotemcel (RP-L201) was granted U.S. Orphan Drug designation in November 2016, Rare Pediatric designation in November 2018, Fast Track designation in December 2018, and Regenerative Medicine Advanced Therapy (RMAT) designation in March 2021, for the treatment of severe Leukocyte Adhesion Deficiency Type I (LAD-I). A Biologics License Application (BLA) for RP-L201 was submitted on August 1, 2023. The target Prescription Drug User Fee Act (PDUFA) date is June 30, 2024.

Background: Severe LAD-I is an extremely rare, pediatric disease caused by mutations in the *ITGB2* gene that encodes the CD18 protein, the common beta subunit of the β2 integrins, which is expressed on the surface of leukocytes and is crucial for neutrophil mediated responses to viral, bacterial, and fungal intrusion. Low neutrophil CD18 expression leads to a loss of immune response, resulting in recurrent severe infections. The global prevalence is approximately one case per every million individuals, of which >60% are categorized as severe based on well-established biomarkers.[1,2] Patients with severe LAD-I face mortality rates of 60-75% before reaching the age of 2, and those who surpass the age of 5 are rare.

Allogeneic hematopoietic stem cell transplant (HSCT) is the only current intervention for severe LAD-I capable of conferring long-term survival beyond early childhood years. However, complications are frequent and include high incidences of graft failure, graft-versus-host disease (GvHD), and resistant viral or fungal infections.[3,4] Furthermore, timely identification of a human leukocyte antigen (HLA)-matched donor is challenging and has been estimated to occur only in approximately 25-30% of cases.[5] Unmatched allogeneic HSCT is possible but is less effective. Overall, allogeneic HSCT requires rapid identification of a suitable donor and confers therapy associated risks including short-term mortality, chronic GvHD, and graft failure. According to the requestor, RP-L201 provides an efficacious treatment option that does not require a donor and was well-tolerated in 100% of documented patients treated in a clinical trial

[1] Cox D, Weathers D. Leukocyte adhesion deficiency type 1: an important consideration in the clinical differential diagnosis of prepubertal periodontitis. A case report and review of the literature. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2008;105:86–90.
[2] Almarza Novoa, Elena et al. Leukocyte adhesion deficiency-I: A comprehensive review of all published cases. *The journal of allergy and clinical immunology. In practice* vol. 6,4 (2018): 1418-1420.e10.
[3] Qasim et al. Allogeneic hematopoietic stem-cell transplantation for leukocyte adhesion deficiency. *Pediatrics*. 2009 Mar;123(3):836-40.
[4] Bakhtiar S, Salzmann-Manrique E, Blok H-J, Eikema D-J, Hazelaar S, Ayas M, et al. Allogeneic hematopoietic stem cell transplantation in leukocyte adhesion deficiency type I and III. *Blood Advances.* 2021;5:262-273.
[5] Acevedo, Mary Joseph et al. Outcomes of Related and Unrelated Donor Searches Among Patients with Primary Immunodeficiency Diseases Referred for Allogeneic Hematopoietic Cell Transplantation. *Biology of blood and marrow transplantation: journal of the American Society for Blood and Marrow Transplantation* vol. 25,8 (2019): 1666-1673.

compared to current available treatment that does not confer the same outcomes. [6]

Description and Mechanism of Action
RP-L201 is an autologous gene therapy comprised of a patient's hematopoietic stem cells (autologous HSCs) that have been genetically modified ex vivo and then infused into the patient. Given the severity of LAD-I, RP-L201 treatment is administered as soon as possible after diagnosis. Patients receive anti-inflammatory therapy approximately 2 weeks prior to initiation of hematopoietic stem and progenitor cell (HSPC) mobilization and 1–2 weeks prior to infusion of RP-L201. Mobilization and selection of $CD34^+$ HSPCs from blood is followed by transduction with a lentiviral vector (LV) encoding for functional human CD18 *ITGB2* gene (Chim-CD18-WPRE LV), followed by cryopreservation of the transduced HSPCs.

If the amount of $CD34^+$ cells available for infusion is at least 2×10^6 viable $CD34^+$ cells/kg, patients receive myeloablative conditioning with I.V. busulfan over 4 days and receive an infusion of gene-corrected HSPCs 24–48 hours after the final busulfan dose. Patients are infused with RP-L201 in the inpatient setting and hospitalized until HSPC reconstitution is determined.

RP-L201 adds functional *ITGB2* genes into patients' hematopoietic stem cells (HSCs) through transduction of autologous $CD34^+$ cells with Chim-CD18-WPRE LV. The *ITGB2* gene encodes for the CD18 protein, which is expressed on leukocytes.

After RP-L201 infusion, gene-modified $CD34^+$ HSCs engraft in the bone marrow enabling hematopoiesis in which the *ITGB2* gene will be transcribed and translated to produce the therapeutic CD18 protein with a preferential expression in mature myeloid cells. Functional CD18 protein is essential for formation of a functional β2 integrin heterodimer on the surface of leukocytes. Leukocytes expressing this heterodimer can adhere to the endothelial cell surface via binding to an intercellular adhesion molecule (ICAM-1) which mediates extravasation to infectious and inflammatory sites in tissues. The transformed leukocytes allow patients' bodies to effectively fight infections, in contrast to the defective leukocytes in patients with LAD-I.

Inpatient Administration of RP-L201
All patients are infused with RP-L201 through the central vein in the inpatient setting after appropriate mobilization, apheresis and myeloablative conditioning. A single dose of RP-L201 is composed of one to two infusion bags which contain 0.3 to 20×10^6 $CD34^+$ cells/mL suspended in a cryopreservation solution. Each infusion bag contains approximately 30 mL of RP-L201. The minimum recommended dose of RP-L201 is 2×10^6 $CD34^+$ cells/kg.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of RP-L201. Facilities can report the intravenous administration of RP-L201 with the following code:

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

[6] Kohn, DB, Booth, C, Navarro, JS. et al. Gene Therapy for Leukocyte Adhesion Deficiency-I (LAD-I): A Phase I/II Clinical Trial to Evaluate the Safety and Efficacy of the Infusion of Autologous Hematopoietic Stem Cells Transduced With a Lentiviral Vector Encoding the *ITGB2* Gene. Presented at European Society of Gene & Cell Therapy Annual Meeting, Clinical Trials Session, October 12, 2022.

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for intravenous administration of marnetegragene autotemcel. Continue using the codes as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of marnetegragene autotemcel.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**1** Transfusion: Putting in blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 7** marnetegragene autotemcel	**A** New Technology Group **10**

CMS Recommendation: Option 2, as described above.

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

Topic # 34 – Administration of zanidatamab

Issue: There are no unique ICD-10-PCS codes to describe the administration of zanidatamab, an investigational human epidermal growth factor receptor 2 (*HER2*)-targeted bispecific antibody under evaluation for the treatment of adult patients with previously treated, locally advanced/metastatic *HER2*-positive biliary tract cancer (BTC). An October 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 2026 consideration.

Food & Drug Administration (FDA) Approval? No. Results from phase IIb HERIZON-BTC-01 will form the basis for the Biologics License Application (BLA). The company initiated the zanidatamab BLA submission in 2023 for accelerated approval in previously treated, adult locally advanced (unresectable) /metastatic HER2-positive BTC and expects to complete the BLA in 1H 2024.

Background: BTC is a highly heterogeneous group of malignancies that affect both the small intrahepatic and large extrahepatic bile ducts (cholangiocarcinoma) or the gallbladder (gallbladder cancer, the most common form of BTC.[1] BTC was ranked as the fifth most common alimentary tract cancer in the U.S. in 2018, after colorectal, pancreatic, stomach, and liver cancers.[2] There are approximately 12,000 *HER2*-positive BTC cases annually[3] in the U.S., Europe, and Japan. Most patients with BTC present with incurable, locally advanced or metastatic disease and are ineligible for surgery.[4] The symptoms of BTC usually present in the later stages and are typically associated with a blockage in the bile duct.[5] The symptoms may include jaundice, itching, light-colored or greasy stool, dark urine, abdominal pain, loss of appetite or weight loss, fever, nausea, or vomiting and depend on whether the cancer is intrahepatic or extrahepatic.[5] In the first-line setting, patients can be treated with palliative cisplatin-gemcitabine or cisplatin-gemcitabine plus durvalumab, which results in improved overall survival (OS) compared with cisplatin-gemcitabine alone.[6] For patients with locally advanced/metastatic BTC who progress after first-line treatment, standard second-line and later-line treatments offer limited clinical benefit with overall response rate (ORR) of 5-15%[7,8] and median progression-free survival (mPFS) of 4.0 months.[7] *HER2* amplification/overexpression is observed in 20% of gallbladder cancer, 15% of extrahepatic cholangiocarcinoma, and 7% of intrahepatic cholanglocarcinoma.[1] There are no approved *HER2*-targeted therapies for BTC.

[1] Moeini A, et al. *JHEP Rep*. 2021;3(2):100226.
[2] Jiang Y, et al. *BMC Gastroenterol*. 2022;22(1):546.
[3] Incidence sources: Kantar reports; ToGA surveillance report; SEER, cancer.gov ; ClearView Analysis; GLOBOCAN; data on file. Europe represents major markets, U.K., France, Germany, Spain, Italy.
[4] Tella SH, et al. *Lancet Oncol*. 2020;21(1):e29–e41.
[5] American Cancer Society. Signs and Symptoms of Bile Duct Cancer. Accessed May 2023. Available from https://www.cancer.org/cancer/bile-duct-cancer/detection-diagnosis-staging/signs-symptoms.html.
[6] Harding JJ, et al. *Lancet Oncol*, published online 2 June 2023. DOI: https://doi.org/10.1016/S1470-2045(23)00242-5.
[7] Lamarca A, et al. *Lancel Oncol* 2021 ;22 :690-701.
[8] Yoo C et al. *Lancet Oncol* 2021 ;22 :1560-72.

Mechanism of Action
Zanidatamab is an investigational bispecific antibody that can simultaneously bind two non-overlapping epitopes of *HER2*, known as biparatopic binding.[9] Zanidatamab exerts its antitumor effects through multiple mechanisms of action including dual *HER2* signal blockade, increased binding and removal of *HER2* protein from the cell surface, complement-dependent cytotoxicity, antibody-dependent cellular cytotoxicity, and antibody-dependent cellular phagocytosis.[9] Zanidatamab is under evaluation for the treatment of patients with previously treated, locally advanced (unresectable)/metastatic, *HER2*-positive BTC. Continued development of zanidatamab is currently ongoing for the treatment of *HER2*-positive BTC in combination with standard first-line cisplatin-gemicitabine and for other *HER2*-expressing solid tumors, including in a phase III study for first-line treatment of gastroesophageal adenocarcinoma (GEA).

Zanidatamab has shown a manageable safety profile and encouraging antitumor activity in patients with *HER2*-expressing BTC in a Phase 1 trial.[10] Results from the global, multicenter, single-arm, phase IIb HERIZON-BTC-01 study(N=80, Cohort 1) have been recently reported[6,11], including rapid and durable responses: confirmed objective response rate (cORR) by independent central review of 41.3% with most responses identified at first disease assessment, mPFS of 5.5 months, and median duration of response (mDOR) of 12.9 months. According to the requestor, these results demonstrate meaningful clinical benefit with a manageable and tolerable safety profile and support the potential for zanidatamab as a future treatment option in *HER2*-positive BTC.

Inpatient Administration of zanidatamab
Zanidatamab will be supplied as a sterile, single-use, preservative-free, lyophilized powder in a glass vial containing 300 mg of drug product. In phase IIb HERIZON-BTC-01, zanidatamab was administered to patients at 20 mg/kg every 2 weeks (Q2W) on Days 1 and 15 of each 28-day cycle. Zanidatamab is administered by intravenous infusion in 0.9% normal saline over approximately 120 to 150 minutes during Cycle 1. In the HERIZON-BTC-01 study, if the first 2 doses were well tolerated by a given subject, the infusion duration for that subject could be decreased to 90 minutes. If the next 2 doses were well tolerated, the infusion duration could be further decreased to less than 90 minutes; however, the infusion rate was not to exceed 250 mL/hour. Zanidatamab is not to be administered as an intravenous push or bolus and is not to be mixed with other medications. The final zanidatamab dosing and administration instructions, including recommendations for potential dose modifications for zanidatamab-associated toxicity, will be provided in the FDA-approved label. In phase IIb HERIZON-BTC-01, the median duration of treatment was 5.6 months (0.5, 19.8+).[6,11] Zanidatamab will be administered in both the inpatient and outpatient treatment settings.

Between 15 September 2020 and 16 March 2022, 80 patients were enrolled in phase IIb HERIZON-BTC-01 cohort 1: median age 64 (32,79), 45 (56%) female and 35 (44%) male, 65% Asian, 89% Stage IV and 11% Stage III at baseline, with median of 1 (1,7) prior therapies in the locally advanced (unresectable)/metastatic setting. Treatment-related adverse events (TRAEs), any Grade, occurring in ≥10% of patients or Grade ≥3 in ≥2 patients were diarrhea (40%) and infusion-related reaction (35%), both predominantly low-grade and reversible.[6,11] Two TRAEs (decreased ejection fraction and non-infectious pneumonitis) led to zanidatamab discontinuation.[6,11] Three patients had TRAEs that led to dose reductions (1 grade 3 diarrhea, 1 grade 3 diarrhea and grade 3

[9] Weisser NE, et al. Nature Commun 2023; 14:1394.
[10] Merci-Bernstam F, et al. Lancet Oncol 2022 ;23 :1558-1570.
[11] Pant S, et al. J Clin Oncol 41, 2023 (suppl 16; abstr 4008).

nausea, and 1 grade 2 weight decreased).[6,11] No serious TRAEs occurred in more than 1 patient.[6,11] There were no Grade 4 TEAEs and no treatment-related deaths.[6,11] Seven patients were enrolled in Cohort 2 and did not reveal any responses nor unique safety signals.[11]

The median duration of HERIZON-BTC-01 follow-up was 12.4 months (7,24). cORR by independent central review was observed in 33 patients in cohort 1 (41.3%, 95% confidence interval [CI] 30.4-52.8).[6,11] Median time to first response was 1.8 months (range, 1.6-5.5)[6,11]. Median duration of response was 12.9 months (1.5,16.9+). mPFS was 5.5 months (0.3-18.5); OS data are not yet mature.[6,11]

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

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of zanidatamab.

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 C** Zanidatamab Antineoplastic	**A** New Technology Group **10**

CMS Recommendation: Option 2, as described above.

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

Topic # 35 – Administration of Donislecel-jujn (Lantidra™)

Issue: There are no unique ICD-10-PCS codes to describe the administration of Donislecel-jujn (Lantidra™). 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? Yes. The FDA approved Donislecel-jujn (Lantidra™) on June 28, 2023. Donislecel-jujn is FDA approved as an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with Type 1 diabetes (T1D) who are unable to approach target HbA1c because of current, repeated episodes of severe hypoglycemia despite intensive diabetes management and education.

Background: T1D is characterized by the autoimmune-mediated loss of insulin-producing β-cells within the islets of Langerhans in the pancreas and results in the complete deficiency of insulin, causing several potentially life-threatening conditions such as hyper- and hypoglycemia, ketoacidosis, and dehydration. Approximately 1.4 million Americans suffer from T1D.[1] A subset of this population suffers from hard-to-control diabetes, also known as brittle or labile diabetes. This is a particularly difficult form of T1D to treat and is characterized by severe instability of blood glucose levels with frequent and unpredictable episodes of hypoglycemia often requiring hospitalization.

According to the requestor, hypoglycemia unawareness is especially dangerous because the hypoglycemic individual will not know to take corrective action to prevent further deterioration. If left untreated, hypoglycemia may become severe, resulting in confusion, disorientation, loss of consciousness, or, in extreme cases of prolonged hypoglycemia, permanent brain damage or death.[2] Secondary complications, including neuropathy, cardiovascular disease, and retinopathy can be especially common in this hard-to-control form of T1D and there is a significant excess mortality in these patients despite intensive insulin therapy.[3]

Keeping blood glucose levels tightly controlled represents the most effective way to prevent or reduce both the symptoms and chronic complications of T1D.[4] For most T1D patients, insulin therapy is sufficient to manage blood glucose levels in a way that preserves an adequate quality of life. However, for hard-to-control T1D, insulin therapy, even in its most state-of-the-art and intensive form, often remains insufficient. Despite intensive insulin therapy and frequent blood sugar monitoring, these patients still suffer from debilitating symptoms and are left susceptible to numerous secondary complications of T1D. Furthermore, the risk of severe hypoglycemia increases with more intensive insulin regimens[5] and is further elevated in patients with

[1] Centers for Disease Control and Prevention: National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States., Atlanta, GA, USA (2020)
[2] Cryer, P.E., Davis, S.N., Shamoon, H.: Hypoglycemia in diabetes. Diabetes Care. 26, 1902– 12 (2003). hGps://doi.org/10.2337/diacare.26.6.1902
[3] Lind, M., Svensson, A.-M., Kosiborod, M., Gudbjörnsdovr, S., Pivodic, A., Wedel, H., Dahlqvist, S., Clements, M., Rosengren, A.: Glycemic control and excess mortality in type 1 diabetes. N Engl J Med. 371, 1972–82 (2014). hGps://doi.org/10.1056/NEJMoa1408214
[4] The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med. 329, 977–986 (1993)
[5] Hypoglycemia in the Diabetes Control and Complications Trial. The Diabetes Control and Complications Trial Research Group. Diabetes. 46, 271–86 (1997)

hypoglycemia unawareness, with a reported 6-fold increase in the frequency of severe hypoglycemia in these patients.[6]

Over the past few years, advanced medical devices that combine blood sugar monitoring and insulin delivery have been developed. Closed-loop systems (also referred to as an "artificial pancreas") automate subcutaneous insulin delivery via a pump and have shown promise for reestablishing glycemic control in patients with T1D.[7][8][9] However, these products cannot adequately control blood sugar in all patients with brittle T1D, and severe hypoglycemia remains an ongoing and debilitating problem in these patients.[7] Furthermore, sudden death associated with severe hypoglycemia has been reported even with the use of these advanced sensor-pump devices.[10] Beyond intensive insulin therapy, whether by pump or manual administration, treatment for patients with hard-to-control T1D was limited to whole pancreas transplant, which carries with it both surgical and post-procedural risk and is not appropriate for all patients.[11]

The requestor states that Donislecel-jujn (Lantidra™) offers a safe and effective, minimally invasive alternative, as an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Donislecel-jujn (Lantidra™) consists of a suspension of allogeneic pancreatic islets in buffered transplant medium containing sodium chloride, dextrose, minerals, amino acids, vitamins, and other compounds supplemented with HEPES (2-[4-(2-hydroxyethyl) piperazin-1-yl] ethanesulfonic acid; 10 mM final concentration) and human serum albumin (0.5% final concentration).

Mechanism of Action

The active ingredient in Donislecel-jujn (Lantidra™) is allogeneic islets of Langerhans derived from a donor pancreas. Islets contain several types of endocrine (hormone-secreting) cells, including β-, α-, pancreatic peptide- (PP-), δ-, and ε-cells. Pancreatic islets regulate blood glucose levels through secretion of multiple hormones in response to increases and decreases in blood glucose. Endocrine cells within pancreatic islets release insulin, glucagon, somatostatin, pancreatic peptide, and ghrelin. Insulin stimulates glucose uptake by peripheral tissues; glucagon mobilizes glucose from the liver into circulation; somatostatin inhibits both α- and β-cell secretions; pancreatic peptide inhibits pancreatic exocrine secretion; and ghrelin inhibits insulin secretion. The primary mechanism of action of Donislecel-jujn (Lantidra™) is believed to be secretion of insulin by infused (transplanted) β- cells.

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[6] Gold, A.E., MacLeod, K.M., Frier, B.M.: Frequency of severe hypoglycemia in patients with type I diabetes with impaired awareness of hypoglycemia. Diabetes Care. 17, (1994). hGps://doi.org/10.2337/diacare.17.7.697

[7] Brown, S.A., Kovatchev, B.P., Raghinaru, D., Lum, J.W., Buckingham, B.A., Kudva, Y.C.,Laffel, L.M., Levy, C.J., Pinsker, J.E., Wadwa, R.P., Dassau, E., Doyle, F.J., Anderson, S.M., Church, M.M., Dadlani, V., Ekhlaspour, L., Forlenza, G.P., Isganaitis, E., Lam, D.W., Kollman, C., Beck, R.W.: Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes. New England Journal of Medicine. 381, (2019). hGps://doi.org/10.1056/NEJMoa1907863

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[9]Kovatchev, B.: A Century of Diabetes Technology: Signals, Models, and Artificial Pancreas Control. Trends Endocrinol Metab. 30, 432–444 (2019). hGps://doi.org/10.1016/j.tem.2019.04.008

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[11] Maffi, P., Secchi, A.: Islet Transplantation Alone Versus Solitary Pancreas Transplantation: an Outcome-Driven Choice? Curr Diab Rep. 19, 26 (2019). hGps://doi.org/10.1007/s11892-019-1145-2

Inpatient Administration of Donislecel-jujn (Lantidra™) Allogeneic Pancreatic Islet Cellular Suspension

The proposed dosing for Donislecel-jujn (Lantidra™) is equal to Islet Equivalents (IE) per kilogram of a recipient's body weight (IE/kg). The recommended dosage is greater than or equal to 5,000 IE/kg for initial transplant; greater than or equal to 4,500 IE/kg for subsequent transplants. Patients receive a minimum of 1 infusion and a max of 3 infusions. A second infusion may be performed if the patient does not achieve independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after a previous infusion. A third infusion may be performed using the same criteria as for the second infusion.

Each dose of Donislecel-jujn (Lantidra™) is provided as two (2) infusion bags connected to each other via sterile connector. One bag contains Donislecel-jujn (Lantidra™) up to a maximum of 1 x 10^6 EIN in 400mL of transplant media and the second bag (Rinse Bag) contains transplant media (light yellow liquid only with no cellular aggregates present) used to rinse the Donislecel-jujn (Lantidra™) bag and the infusion line. Interventional radiologists and surgeons with expertise in islet cell infusion may administer the therapy in an interventional radiology suite or operating suite under controlled aseptic conditions. Donislecel-jujn (Lantidra™) is infused into the hepatic portal vein, via percutaneous or transvenous transhepatic access, or if these are not feasible, via laparoscopic or open surgical (mini laparotomy) access. Following transplant, the patient is monitored for graft function, immunosuppression levels, and safety in the hospital for a minimum of 24 hours.

According to the requestor, the islet transplantation procedure is minimally invasive, generally safe, and includes less procedural risk than whole pancreas transplantation. The primary risk is related to concomitant medications, especially immunosuppressants, and the long-term safety outcomes of Donislecel-jujn (Lantidra™) clinical trials (and the clinical trials of other allogeneic islet products) are consistent with what has been observed with chronic immunosuppressant use.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of donislecel-jujn. Facilities can report the intravenous portal vein administration of donislecel-jujn using the following code:

3E033U1	Introduction of nonautologous pancreatic islet cells into peripheral vein, percutaneous approach

Coding Options

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

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of donislecel-jujn.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein	**3** Percutaneous	**ADD D** Donislecel-jujn Allogeneic Pancreatic Islet Cellular Suspension	**A** New Technology Group **10**

CMS Recommendation: Option 2, as described above.

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