



## 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 7, 2023

### Zoom Webinar and Dial-In Information

- This meeting will be conducted via Zoom Webinar. The URL to register to join the Zoom Webinar, the password, and the call-in numbers are the same for both days of the meeting. Meeting details for each day are as follows.
- Day 1: March 7, 2023: The meeting will begin promptly at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 12:30 PM to 1:30 PM.
- Day 2: March 8, 2023: The meeting will begin promptly at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 12:30 PM to 1:30 PM.

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

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

Register in advance for this webinar:

[https://cms.zoomgov.com/webinar/register/WN\\_\\_piUmNYaRjmkcYczb3ePIQ](https://cms.zoomgov.com/webinar/register/WN__piUmNYaRjmkcYczb3ePIQ)

Webinar ID: 160 600 6403

Passcode: 357110

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

1. From your phone, dial U.S.\*: 669-254-5252 or 646-828-7666 or 833-568-8864 (Toll Free)
2. Enter the webinar ID: 160 600 6403

\*If dialing in from outside of the U.S., visit <https://cms.zoomgov.com/join/91756178961> for a list of Zoom International Dial-in Numbers.

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

1. From your room system, dial 161.199.138.10 (US West) or 161.199.136.10 (US East)
2. Enter the webinar ID: 160 600 6403  
Passcode: 357110

SIP: 1606006403@sip.zoomgov.com  
Passcode: 357110

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

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

**Note:** Proposals for diagnosis code topics will be led by the Centers for Disease Control and Prevention’s (CDC) National Center for Health Statistics (NCHS) and are scheduled to begin following completion of the CMS procedure code proposals on March 7, 2023. Remaining diagnosis code topics will continue to be presented on March 8, 2023. Please visit CDC’s website for the Diagnosis agenda located at the following address: [http://www.cdc.gov/nchs/icd/icd10cm\\_maintenance.htm](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](mailto:marilu.hue@cms.hhs.gov) or Andrea Hazeley at [andrea.hazeley@cms.hhs.gov](mailto: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](mailto:marilu.hue@cms.hhs.gov) or Andrea Hazeley at [andrea.hazeley@cms.hhs.gov](mailto:andrea.hazeley@cms.hhs.gov).

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

To sign up go to CMS website:

[https://public.govdelivery.com/accounts/USCMS/subscriber/new?topic\\_id=USCMS\\_124\\_20](https://public.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS_124_20)

To sign up for updates or to access your subscriber preferences, please enter your contact information below.

1. Email Address

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

## Topics Being Considered for ICD-10-PCS Procedure Codes

Introductions & Overview  
9:00 AM – 9:10 AM

Mady Hue, CMS  
Co-Chair, ICD-10 Coordination  
and Maintenance Committee

### ICD-10-PCS Topics:

1. Implantation of Bioprosthetic Femoral Venous Valves  
Pages 16-18  
9:10 AM – 9:25 AM

Andrea Hazeley, CMS  
Rob Berman  
CEO  
enVVenio Medical

2. Announcements  
9:25 AM – 9:40 AM

3. Insertion of a Dual-Chamber Leadless Cardiac Pacemaker\*  
Pages 19-21  
9:40 AM – 9:55 AM

Andrea Hazeley, CMS  
Dr. Leonard Ganz  
Chief Medical Officer, Cardiac  
Rhythm Management Division  
Abbott

4. Percutaneous Femoral-Popliteal Artery Bypass\*  
Pages 22-24  
9:55 AM – 10:10 AM

Mady Hue, CMS  
Scott Creecy  
Director of Field Medical  
Affairs  
Endologix

5. Insertion of Lengthening Device for Esophageal Atresia  
Pages 25-27  
10:10 AM – 10:25 AM

Mady Hue, CMS  
Mario Zaritzky, MD  
Assistant Professor of  
Radiology  
University of Chicago Medicine

6. Extraluminal Autologous Saphenous Vein Graft Support\*  
Pages 28-29  
10:25 AM – 10:40 AM

Mady Hue, CMS  
Daniel Goldstein, MD  
Vice Chairman, Cardiothoracic  
and Vascular Surgery, Director,  
Mechanical Assistance  
Program, Co-Director, Center  
for Advanced Cardiac Therapy,  
Surgical Director of Cardiac  
Transplantation, Professor,  
Cardiothoracic and Vascular  
Surgery  
Montefiore Medical Center

Rotem Katzenellenbogen  
VP, Business Development

7. Insertion of a Short-term External Heart Assist System with Conduit  
Pages 30-33  
10:40 AM – 10:55 AM

Vascular Graft Solutions

Andrea Hazeley, CMS  
Scott Silvestry, MD  
Surgical Director, Thoracic  
Transplant Programs,  
Transplant Institute  
Advent Health

Sanjeev Aggarwal, MD  
VP, Global Clinical and  
Medical Affairs, Surgical  
Therapies  
Abiomed

8. Ultrasound Ablation of Renal Sympathetic Nerves\*  
Pages 34-36  
10:55 AM – 11:10 AM

Andrea Hazeley, CMS  
Neil Barman, MD  
Chief Scientific Officer  
ReCor Medical

9. Computer-aided Detection of Heart Failure in Echocardiography \*  
Pages 37-38  
11:10 AM – 11:25 AM

Andrea Hazeley, CMS  
Ross Upton  
Founder and CEO  
Ultromics

10. Insertion of Percutaneous Mechanical Circulatory Support Device into Thoracic Aorta  
Pages 39-43  
11:25 AM – 11:40 AM

Mady Hue, CMS  
Jace Heuring, PhD  
Chief Science Officer  
Procyrion

Matheen A. Khuddus, MD,  
FACC, FSCAI  
Director of Cardiovascular  
Research at The Cardiac and  
Vascular Institute  
Associate Professor of Internal  
Medicine at the University of  
Central Florida

11. Measurement of Intracranial Electrical Activity for Status Epilepticus\*  
Pages 44-45  
11:40 AM – 11:55 AM

Mady Hue, CMS  
Josef Parvizi, MD, PhD  
Professor of Neurology and  
Neurological Sciences, Stanford  
Medical Center  
Founder and Chief Medical  
Advisor  
Ceribell, Inc.

12. Monitoring of Intracranial Electrical Activity for Delirium\*  
Pages 46-47  
11:55 AM – 12:10 PM
- Mady Hue, CMS  
Jake Adams, MD  
Nationals Tele-ICU Director  
Sound Physicians
13. Rapid Antimicrobial Susceptibility Testing System for Blood and Body Fluid Cultures\*  
Pages 48-50  
12:10 PM – 12:25 PM
- Andrea Hazeley, CMS  
John Wilson  
Chief Commercial Officer  
Selux Diagnostics
- LUNCH BREAK 12:30 PM to 1:30 PM**
14. Percutaneous Hepatic Perfusion with Administration of Melphalan Hydrochloride\*\*  
Pages 51-53  
1:30 PM – 1:45 PM
- Andrea Hazeley, CMS  
Johnny John, MD  
Senior Vice President  
Clinical Development and  
Medical Affairs  
Delcath Systems
15. Monitoring of Muscle Compartment Pressure\*  
Pages 54-55  
1:45 PM – 2:00 PM
- Andrea Hazeley, CMS  
Dr. Ed Harvey  
Chief Medical Officer  
MY01 Inc.
- Abdelkrim Temzi  
Sr. Manager Professional  
Education & Clinical Affairs  
MY01 Inc.
16. Insertion of Tibial Extension Implant during Total Knee Arthroplasty\*  
Pages 56-58  
2:00 PM – 2:15 PM
- Mady Hue, CMS  
Dr. Nitin Goyal  
Chief Science Tech and  
Innovation Officer  
Zimmer Biomet
17. Total Ankle Talar Replacement\*  
Pages 59-61  
2:15 PM – 2:30 PM
- Mady Hue, CMS  
Brian C. Law, MD, FAAOS  
President – Wisconsin  
Orthopaedic Society  
Associate Professor, Division  
of Foot and Ankle Surgery  
Department of Orthopaedic  
Surgery – Medical College of  
Wisconsin

18. Implantation of Open-Truss Ankle Fusion Device\*  
Pages 62-64  
2:30 PM – 2:45 PM

Mady Hue, CMS  
Brian C. Law, MD, FAAOS  
President – Wisconsin  
Orthopaedic Society  
Associate Professor, Division  
of Foot and Ankle Surgery  
Department of Orthopaedic  
Surgery – Medical College of  
Wisconsin

19. Computer-aided Triage and Notification for  
Measurement of Intracranial Vessel Flow  
Pages 65-66  
2:45 PM – 3:00 PM

Andrea Hazeley, CMS  
Dr. Greg Albers  
Co-Founder & Scientific Lead  
RapidAI

20. Extravascular Implantable Defibrillator Leads  
Pages 67-70  
3:00 PM – 3:15 PM

Andrea Hazeley, CMS  
Amy Thompson  
Director of Clinical Research  
for the Defibrillation Portfolio  
Medtronic

Bridget Cavanagh  
Senior Engineering Manager  
Therapy Delivery within  
Cardiac Rhythm Management  
Medtronic

21. Section X Updates  
Pages 71-73  
3:15 PM – 3:30 PM

Jeanine DuVerney, CMS

22. Addenda and Key Updates  
Pages 74-78  
3:30 PM – 3:45 PM

Andrea Hazeley, CMS

Closing Remarks  
3:45 PM

Mady Hue, CMS

## Therapeutic Agent Topics Also Under Consideration for ICD-10-PCS Codes<sup>1</sup>

23. Fluorescence-guided surgery using CYTALUX <sup>®</sup> (Pafolacianine)* Pages 79-81	Mady Hue, CMS
24. Administration of Glofitamab* Pages 82-85	Andrea Hazeley, CMS
25. Administration of Posoleuce <sup>l***</sup> Pages 86-89	Andrea Hazeley, CMS
26. Administration of Rezafungin* Pages 90-91	Mady Hue, CMS
27. Administration of SER-109* Pages 92-93	Andrea Hazeley, CMS
28. Administration of Sulbactam-Durlobactam* Pages 94-96	Andrea Hazeley, CMS
29. Administration of Quizartinib* Pages 97-98	Mady Hue, CMS
30. Administration of Elranatamab* Pages 99-100	Andrea Hazeley, CMS
31. Administration of Epcoritamab* Pages 101-102	Mady Hue, CMS

\* Requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024.

\*\* Requestor intends to submit a NTAP application for FY 2025 consideration.

\*\*\*Requestor intends to submit a NTAP application for FY 2026 consideration.

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



### **Continuing Education Credits:**

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

### **Continuing Education Information for American Academy of Professional Coders (AAPC)**

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

### **Continuing Education Information for American Health Information Management Association (AHIMA)**

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

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

### **Contact Information**

Comments on the procedure code proposals presented at the ICD-10 Coordination and Maintenance Committee meeting should be sent to the following email address:

[ICDProcedureCodeRequest@cms.hhs.gov](mailto:ICDProcedureCodeRequest@cms.hhs.gov)

Mady Hue

[Marilu.hue@cms.hhs.gov](mailto:Marilu.hue@cms.hhs.gov)

Andrea Hazeley

[Andrea.hazeley@cms.hhs.gov](mailto:Andrea.hazeley@cms.hhs.gov)

## ICD-10 TIMELINE

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

March 7-8, 2023	ICD-10 Coordination and Maintenance Committee Meeting.
March 2023	Recordings and slide presentations of the March 7-8, 2023 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages:  <b>Diagnosis code portion of the recording and related materials–</b> <a href="https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm">https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm</a>  <b>Procedure code portion of the recording and related materials–</b> <a href="https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html">https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html</a>
April 1, 2023	Any new ICD-10 codes will be implemented on April 1, 2023.
<b>April 7, 2023</b>	<b>Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 7-8, 2023 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2023.</b>
April 2023	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This notice will include references to the FY 2024 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: <a href="https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps">https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps</a>
<b>May 5, 2023</b>	<b>Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 7-8, 2023 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2024.</b>  <b>Deadline for receipt of public comments on proposed new diagnosis codes and revisions discussed at the March 7-8, 2023 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2024.</b>
May/June 2023	Final addendum posted on web pages as follows: <b>Diagnosis addendum -</b>

<https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm>

**Procedure addendum -**

<https://www.cms.gov/Medicare/Coding/ICD10/index.html>

**June 9, 2023**

**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 12-13, 2023 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, 2024 implementation date or an October 1, 2024 implementation date.

July 2023

Federal Register notice for the September 12-13, 2023 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.

August 1, 2023

Hospital Inpatient Prospective Payment System final rule expected to be published in the Federal Register as mandated by Public Law 99-509. This rule will also include links to all the final codes to be implemented on October 1, 2023.

This rule can be accessed at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>

August 2023

Tentative agenda for the Procedure portion of the September 12, 2023 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the CMS webpage at –

<https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html>

Tentative agenda for the Diagnosis portion of the September 13, 2023 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the NCHS webpage at -

[https://www.cdc.gov/nchs/icd/icd10cm\\_maintenance.htm](https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm)

September 12-13, 2023

The September 2023 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 2023

Recordings and slide presentations of the September 12-13, 2023 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages:

**Diagnosis code portion of the recording and related materials–**  
[https://www.cdc.gov/nchs/icd/icd10cm\\_maintenance.htm](https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm)

**Procedure code portion of the recording and related materials–**  
<https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html>

October 1, 2023

New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes. Final addendum available on web pages as follows:

**Diagnosis addendum –**  
<https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm>

**Procedure addendum –**  
<https://www.cms.gov/Medicare/Coding/ICD10/>

October 13, 2023

**Deadline for receipt of public comments on proposed new codes discussed at the September 12-13, 2023 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2024.**

November 2023

Any new ICD-10 codes that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2024 will be posted on the following websites:

<https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm>

<https://www.cms.gov/Medicare/Coding/ICD10/>

November 15, 2023

**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 12-13, 2023 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2024.**

## Medicare Electronic Application Request Information System™ (MEARIS™)

Effective January 5, 2022, the new electronic application request intake system, Medicare Electronic Application Request Information System™ (MEARIS™), became available as an initial release for users to begin gaining familiarity with a new approach and process to submit ICD-10-PCS procedure code requests. The ICD-10-PCS code request application can be accessed at: <https://mearis.cms.gov>.

Effective March 1, 2022, the full release of MEARIS™ became active for ICD-10-PCS code request submissions.

CMS will only accept ICD-10-PCS code request applications submitted via MEARIS™. Requests submitted through the ICDProcedureCodeRequest mailbox will no longer be considered. Within MEARIS™, we have built in several resources to support requestors:

- Please refer to the “Resources” section for guidance regarding the request submission process at: <https://mearis.cms.gov/public/resources>.
- Technical support is available under “Useful Links” at the bottom of the MEARIS™ site
- Request related questions can be submitted to CMS using the form available under “Contact” at: <https://mearis.cms.gov/public/resources?app=icd-10-pcs>
- The time required for application request submission, including the time needed to gather relevant information as well as to complete the form may be extensive depending on the nature of the code request. Requestors are, therefore, encouraged to start in advance of the due date to ensure adequate time for submission.

Requests submitted through MEARIS™ will not only help CMS track requests and streamline the review process, but it will also create efficiencies for requestors when compared to the previous submission process.

**ICD-10-PCS code request submissions are due no later than June 9, 2023 to be considered for the September 12-13, 2023 ICD-10 Coordination and Maintenance Committee Meeting.**

An updated release for MEARIS™ was made publicly available in mid-October 2022 for users to continue submitting ICD-10-PCS code requests. The updated release provides additional resources including templates and sample background papers for submitting a code request for either the administration of a drug/therapeutic agent or for a device/technology/service or procedure.

Requests for new procedure codes must include both a background paper utilizing the format of the sample template provided and an accompanying 508 compliant presentation slide deck. Requestors must also indicate if the code request is for consideration for an October 1 implementation date or an April 1 implementation date at the time of submission to be considered complete.

## **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, 2023
- 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 7, 2023 for codes being considered for October 1, 2023 implementation
  - May 5, 2023 for codes being considered for April 1, 2024 or October 1, 2024 implementation
- Procedure comments to CMS: [ICDProcedureCodeRequest@cms.hhs.gov](mailto:ICDProcedureCodeRequest@cms.hhs.gov)
- Diagnosis comments to NCHS: [nchsicd10cm@cdc.gov](mailto:nchsicd10cm@cdc.gov)

## **Proposed and Final Rules**

- April 2023 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2023 C&M meeting
- August 2023 – Final rule with links to final codes to be implemented October 1, 2023
  - Includes any additional codes approved from March 7-8, 2023 C&M meeting
  - <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS>

## **Addenda**

- May/June 2023 – Final code updates and addenda posted
  - FY 2024 ICD-10-PCS (Procedures)  
<http://www.cms.gov/Medicare/Coding/ICD10/index.html>
  - FY 2024 ICD-10-CM (Diagnoses)  
<https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm>

## **Public Participation**

- For this virtual meeting, the public may participate in the following ways:
  - Participate via Zoom Webinar
  - Listen to proceedings through free conference lines
  - Listen to recordings and view slide presentations
- CMS & CDC hope this provides greater opportunity for public participation

## **Written Comments**

- No matter how you participate – please send written comments by
  - April 7, 2023 for codes being considered for October 1, 2023 implementation
  - May 5, 2023 for codes being considered for April 1, 2024 or October 1, 2024 implementation
  - Procedure comments to CMS: [ICDProcedureCodeRequest@cms.hhs.gov](mailto:ICDProcedureCodeRequest@cms.hhs.gov)
  - Diagnosis comments to NCHS: [nchsicd10cm@cdc.gov](mailto:nchsicd10cm@cdc.gov)

## **ICD-10-PCS Codes Implementation**

- ICD-10-PCS codes discussed today under consideration for October 1, 2023 implementation

## **September 12-13, 2023 C&M Code Requests**

- June 9, 2023 – Deadline for submitting topics for September 12-13, 2023 C&M meeting
  - Procedure requests to CMS: <https://mearis.cms.gov>
  - Diagnosis requests to NCHS: [nchsicd10cm@cdc.gov](mailto:nchsicd10cm@cdc.gov)

## Topic # 01 – Implantation of Bioprosthetic Femoral Venous Valves

**Issue:** There are no unique ICD-10-PCS codes to describe the implantation of a bioprosthetic femoral venous valve for chronic venous insufficiency.

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

**Food & Drug Administration (FDA) Approval?** No. VenoValve<sup>®</sup> was granted Breakthrough Device Designation on August 3, 2021 as a treatment for chronic venous insufficiency (CVI). VenoValve<sup>®</sup> is currently under review by the FDA for Premarket Approval.

**Background:** During normal blood flow, the veins are responsible for returning blood to the heart from all of the body's organs. Chronic venous insufficiency (CVI) is caused by incompetent valves in the veins of the leg. Incompetent valves cause blood to flow backwards (reflux) and pool in the lower leg which results in increased pressure in the venous system (venous hypertension). CVI can occur in the superficial veins located right beneath the skin, the deep veins located within the center core of the leg below the muscle and fascia, and the perforating veins which connect the superficial and deep venous systems. CVI causes pain, swelling, edema, and in the most severe cases, venous ulcers that are extremely difficult to heal and even if healed, have a high recurrence rate. There are approximately 175 million people in the United States that suffer from CVI<sup>1</sup>. Patients with CVI also have higher incidences of deep vein thromboses (DVTs) and pulmonary embolisms. CVI occurs more frequently in people over the age of 50 and more often in women than men<sup>2</sup>.

While medical interventions have been developed to diagnose and treat superficial CVI, the current standard of care for treating deep venous CVI are compression garments and leg elevation, which the requestor states are inadequate. The requestor asserts that bioprosthetic femoral venous valve implantation is a suitable option for CVI of the deep venous system.

### Technology

The VenoValve<sup>®</sup> is a single use device that is permanently implanted in the femoral vein via an open surgical approach for the treatment of patients with deep venous CVI. It consists of a one-inch porcine monocuspid biological component mounted in a rigid supporting metal frame that is designed to function as a one-way valve to support proper directional blood flow through the deep veins of the legs towards the heart.

### Procedure Description

Following general or regional anesthesia, a 6 to 8 inch "lazy S" incision is made in the mid to upper thigh. A cautery is used to separate skin, tissue, and fascia to expose the femoral sheath. Once the femoral vein is dissected away from the femoral artery, vessel loops are used to mobilize the vein to control blood flow. Following intravenous heparin anticoagulation, atraumatic vascular clamps are used to stop blood flow through the exposed area of the femoral vein, and a longitudinal venotomy of approximately 2 to 3 centimeters is made in the vein between the clamps. The in-

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<sup>1</sup> Yost, Mary, The Sage Group, Chronic Venous Disease, Epidemiology, Costs, and Consequences, 2016

<sup>2</sup> <https://my.clevelandclinic.org/health/diseases/16872-chronic-venous-insufficiency-cvi>



flow clamp is temporarily opened to allow the insertion of the 9 mm Bakes Dilator to size the vein. Once the vein is sized, the VenoValve® is then removed from the packaging using forceps and the device is placed in sterile saline.

The VenoValve® is then inserted in the vein through the venotomy with the base or apex of the “V” of the valve frame pointing towards the patient’s foot (the direction of in-flow), and the sinus bulge facing towards the venotomy, allowing the leaflet to open against the non-stitched portion of the native vein. The in-flow stabilization ring of the valve frame is tacked to the native vein using a mattress stitch of monofilament suture, to stabilize the device and to reduce the potential for blood to flow around the VenoValve® leaflet. The venotomy is closed. The clamps are removed to restore blood flow and the calf muscle is then compressed to ensure that the closed venotomy does not leak under pressure, and that blood flows through the VenoValve®. Pressure is then applied to the groin area to ensure that the VenoValve® leaflet deploys and reduces the backwards flow of blood. Once proper functioning of the VenoValve® is confirmed, the wound is closed. The procedure to implant the VenoValve® is primarily a standalone procedure, however, if the patient also has stenosis of the femoral vein or deep vein thrombosis clot, a stent may be placed or thrombectomy may be performed separately.

The VenoValve® is currently being studied for the treatment of patients with Clinical, Etiological, Anatomical and Pathophysiological (CEAP) classification of venous disease C4-C6 indicating they have changes in skin and subcutaneous tissue (C4), a previously healed venous ulcer (C5), or an active venous ulcer (C6).

**Current Coding:** There are no unique ICD-10-PCS codes to describe implantation of a bioprosthetic femoral venous valve. Facilities can report the procedure using the device value D Intraluminal Device and the appropriate femoral vein body part value from the table below.

<i>Section</i>	<b>0</b> Medical and Surgical		
<i>Body System</i>	<b>6</b> Lower Veins		
<i>Operation</i>	<b>H</b> 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		
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>1</b> Splenic Vein <b>2</b> Gastric Vein <b>3</b> Esophageal Vein <b>4</b> Hepatic Vein <b>5</b> Superior Mesenteric Vein <b>6</b> Inferior Mesenteric Vein <b>7</b> Colic Vein <b>8</b> Portal Vein <b>9</b> Renal Vein, Right <b>B</b> Renal Vein, Left <b>C</b> Common Iliac Vein, Right <b>D</b> Common Iliac Vein, Left <b>F</b> External Iliac Vein, Right <b>G</b> External Iliac Vein, Left <b>H</b> Hypogastric Vein, Right <b>J</b> Hypogastric Vein, Left <b>M</b> Femoral Vein, Right <b>N</b> Femoral Vein, Left <b>P</b> Saphenous Vein, Right <b>Q</b> Saphenous Vein, Left	<b>0</b> Open <b>3</b> Percutaneous <b>4</b> Percutaneous Endoscopic	<b>3</b> Infusion Device <b>D</b> Intraluminal Device	<b>Z</b> No Qualifier

T Foot Vein, Right			
V Foot Vein, Left			

### Coding Options

**Option 1.** Do not create new ICD-10-PCS codes to identify implantation of a bioprosthetic femoral venous valve. Continue coding as described in current coding.

**Option 2.** In section X add new table X2H Insertion of Cardiovascular System, and create new device value R Intraluminal Device, Bioprosthetic Valve applied to the body part values 2 Femoral Vein, Right and 3 Femoral Vein, Left, to identify insertion of a bioprosthetic femoral venous valve.

<i>Section</i> <b>X</b> New Technology			
<i>Body System</i> <b>2</b> Cardiovascular System			
<i>Operation</i> <b>ADD H</b> 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			
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>ADD 2</b> Femoral Vein, Right <b>ADD 3</b> Femoral Vein, Left	<b>0</b> Open	<b>ADD R</b> Intraluminal Device, Bioprosthetic Valve	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

### Topic # 03 – Insertion of a Dual-Chamber Leadless Cardiac Pacemaker

**Issue:** There are currently no unique ICD-10-PCS codes to describe the percutaneous insertion of a dual-chamber leadless pacemaker or a right atrium leadless pacemaker.

**New Technology Application?** Yes. The requestor has submitted two New Technology Add-on Payment (NTAP) applications for FY 2024 consideration. One application was submitted for the Aveir™ System, a modular programmable system composed of a ventricular leadless pacemaker intended for direct implantation into the right ventricle and an atrial leadless pacemaker intended for direct implantation into the right atrium to provide dual chamber pacing therapy. A separate application was submitted for the Aveir™ AR System, a programmable system composed of a single implanted leadless pacemaker into the right atrium that provides single-chamber pacing therapy.

**Food & Drug Administration (FDA) Approval?** No. The atrial and dual-chamber leadless pacemaker systems have received Breakthrough Device Designation from the FDA. According to the requestor, PMA approval is anticipated by July 1, 2023.

**Background:** Cardiac pacemakers are implanted either to alleviate symptoms caused by bradycardia or to prevent severe symptoms in patients in whom symptomatic bradycardia is likely to develop. By providing an appropriate heart rate and heart rate response, cardiac pacing can reestablish effective circulation and normalize hemodynamics that are compromised by a slow heart rate. Despite the myriad of clinical situations in which permanent pacing is considered, most management decisions regarding permanent pacemaker implantation are driven by the following clinical factors: the association of symptoms with a bradyarrhythmia, the location of the conduction abnormality and the absence of a reversible cause.<sup>1</sup>

Cardiac pacemakers generally consist of two components: a pulse generator, which provides the electrical impulse for myocardial stimulation; and one or more electrodes (commonly referred to as leads), which deliver the electrical impulse from the pulse generator to the myocardium. Epicardial cardiac pacemaker systems utilize a pulse generator with leads that are surgically attached directly to the epicardial surface of the heart. In transvenous pacing systems, leads are usually placed percutaneously or with a cephalic cutdown, without the need for intrathoracic surgery and inherent associated morbidities. However, transvenous leads have potential long-term complications (e.g., venous thrombosis, infection, lead malfunction, etc.). In response to the limitations of both transvenous and epicardial pacing systems, efforts have been made to develop leadless cardiac pacing systems.<sup>2</sup>

#### Technology

The Aveir™ leadless system is a modular programmable system that consists of implanted pacemaker devices that are placed within the myocardium and paces the heart without the need for traditional “wired” leads. While there are other systems also in development, the Aveir™ System

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<sup>1</sup> Link, M. (2022). Permanent cardiac pacing: Overview of devices and indications, UptoDate. Available from [https://www.uptodate.com/contents/permanent-cardiac-pacing-overview-of-devices-and-indications?search=pacemaker%20indications&source=search\\_result&selectedTitle=1~150&usage\\_type=default&display\\_rank=1#references](https://www.uptodate.com/contents/permanent-cardiac-pacing-overview-of-devices-and-indications?search=pacemaker%20indications&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#references)

<sup>2</sup> Auricchio A, Delnoy PP, Butter C, et al. Feasibility, safety, and short-term outcome of leadless ultrasound-based endocardial left ventricular resynchronization in heart failure patients: results of the wireless stimulation endocardially for CRT (WiSE-CRT) study. *Europace* 2014; 16:681.

will be the first dual-chamber leadless pacemaker on the market to provide pacing therapy to indicated patients, through a minimally invasive catheter-based procedure. Each leadless pacemaker within the Aveir™ System contains both the generator and electrodes within the device, and the device independently paces on senses in the chamber where fixated.

Aveir™ is a modular programmable system comprising of two implanted leadless pacemakers that provide dual chamber pacing therapy: a ventricular leadless pacemaker is intended for direct implantation into the right ventricle, and an atrial leadless pacemaker is intended for direct implantation into the right atrium. Each leadless pacemaker is delivered to the target heart chamber (right atrial and right ventricular) percutaneously via the femoral vein. The single-chamber leadless pacemaker system, referred to as the Aveir™ AR System, is a programmable system comprising of a single implanted leadless pacemaker into the right atrium that provides single-chamber pacing therapy. The leadless pacemaker is delivered to the right atrial heart chamber percutaneously via the femoral vein.

The Aveir™ System can provide intra-operative mapping capability so physicians can assess viability of fixation target and if necessary, reposition the device during a patient's procedure to avoid unnecessary repeat procedures. Aveir™ i2i (“implant to implant”) technology enables beat-by-beat and bidirectional communication between the two leadless pacemakers, and enables two leadless separate pacemakers to function as one dual-chamber pacing system. Aveir™ is designed to be retrievable, allowing the individual leadless pacemakers of the implanted system to be removed and replaced at end of service or as clinical circumstances dictate, utilizing a dedicated retrieval catheter. Both the atrial leadless pacemaker as well as the dual-chamber leadless system are currently being evaluated in Abbott’s Aveir™ DR i2i IDE study. The Dual Chamber Leadless Pacemaker System has not had any adverse outcomes or complications to date.

### **Procedure Description**

The Aveir™ System dual-chamber pacing can be achieved in two ways:

- First, the full dual chamber leadless pacemaker system is implanted with one leadless pacemaker placed in the right atrium and one leadless pacemaker placed in the right ventricle, as a ‘de novo’ system.
- Second, a patient who has a single right ventricular leadless pacemaker in-situ is upgraded to dual chamber leadless pacemaker system by having one leadless pacemaker inserted into the right atrium only.

To insert the ‘de novo’ Aveir™ leadless system, access is obtained via puncture of the femoral vein using ultrasound guidance. A guidewire is advanced into the heart and an introducer is inserted. Under fluoroscopic guidance the leadless pacemaker delivery catheter is inserted through the inferior vena cava into the right atrium and through the tricuspid valve into the right ventricle. The leadless pacemaker is fixed to the endocardium and programming is performed to confirm communication. Upon confirmation of communication, the delivery catheter and sheath are removed. The surgical steps are repeated through the same access for insertion of the right atrium leadless pacemaker. The two leadless pacemakers are connected via Aveir™ i2i technology to allow communication between the two leadless pacemakers for functionality as one dual-chamber pacing system.

To upgrade to a dual chamber leadless pacemaker system, access is obtained via puncture of the femoral vein using ultrasound guidance. A guidewire is advanced into the heart and an introducer is inserted. Under fluoroscopic guidance the leadless pacemaker delivery catheter is inserted through the inferior vena cava into the right atrium. The leadless pacemaker is fixed to the endocardium and programming is performed to confirm communication. Upon confirmation of communication, the delivery catheter and sheath are removed. The in-situ right ventricular leadless pacemaker and the Aveir™ right atrium leadless pacemaker are connected via Aveir™ i2i technology to allow communication between the two leadless pacemakers for functionality as one dual-chamber pacing system.

**Current Coding:** There are no unique ICD-10-PCS codes to describe the percutaneous insertion of a dual-chamber leadless pacemaker or a right atrium leadless pacemaker. Facilities report the percutaneous insertion of a dual-chamber leadless pacemaker procedure using the following codes:

- 02H63NZ      Insertion of intracardiac pacemaker into right atrium, percutaneous approach and
- 02HK3NZ      Insertion of intracardiac pacemaker into right ventricle, percutaneous approach

When upgrading to dual-chamber pacing by implanting a leadless pacemaker into the atrium only, report the following code:

- 02H63NZ      Insertion of intracardiac pacemaker into right atrium, percutaneous approach

**Coding Options**

**Option 1.** Do not create new ICD-10-PCS codes for the percutaneous insertion of a dual-chamber leadless cardiac pacemaker or a right atrium leadless pacemaker. Continue coding as listed in current coding.

**Option 2.** In New Technology Insertion table X2H, Insertion of Cardiovascular System, create new device value V Intracardiac Pacemaker, Dual-Chamber applied to the body part values 6 Atrium, Right and K Ventricle, Right, to identify the percutaneous insertion of a dual-chamber leadless cardiac pacemaker system. Both codes would be reported for this procedure. If upgrading to dual-chamber pacing by implanting a leadless pacemaker into the atrium only, code the procedure using body part value 6 Atrium, Right in table X2H, New Technology, Insertion of Cardiovascular System, with approach value 3 Percutaneous and device value V Intracardiac Pacemaker, Dual-Chamber.

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>2</b> Cardiovascular System		
<i>Operation</i>	<b>H</b> 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		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>6</b> Atrium, Right <b>K</b> Ventricle, Right	<b>3</b> Percutaneous	<b>ADD V</b> Intracardiac Pacemaker, Dual-Chamber	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## **Topic # 04 –Percutaneous Femoral-Popliteal Artery Bypass with Conduit Through the Femoral Vein**

**Issue:** There are currently no unique ICD-10-PCS codes to describe percutaneous femoral-popliteal artery bypass using a conduit through the femoral vein.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. The DETOUR® System (formerly known as the PQ Bypass System) received Breakthrough Device Designation from the FDA on September 2, 2020, and is indicated for percutaneous revascularization of symptomatic femoropopliteal lesions 200mm to 460mm with a chronic total occlusion 100mm to 425mm, and/or moderate-to-severe calcification, and/or in-stent-restenosis in patients with severe peripheral arterial disease. According to the requestor, FDA approval is anticipated by second quarter 2023.

**Background:** Peripheral artery disease (PAD) is caused by atherosclerosis or plaque buildup on the inner lining of the arteries, that reduces the flow of blood in the peripheral arteries that carry blood away from the heart to other parts of the body. In the United States, more than 6.5 million people ages 40 and older have peripheral artery disease.<sup>1</sup> Although, PAD can develop at any age the risk increases with age, doubling approximately per decade. Risk factors for PAD include family history and genetics, lifestyle habits such as smoking or regularly breathing in secondhand smoke, lack of physical activity, eating foods high in saturated fats, and co-morbidities. such as hypertension, diabetes mellitus, and obesity.

The most common type of peripheral artery disease (PAD) affects the lower extremities by reducing blood flow to the legs and feet. The clinical manifestations of PAD (e.g. claudication, rest pain, ulceration, and gangrene) are predominantly due to progressive luminal narrowing (stenosis/occlusion), although thrombosis or embolism of unstable atherosclerotic plaque or thrombotic material can also occur.

The diagnosis of PAD can be established with the measurement of an ankle-brachial index (ABI)  $\leq 0.9$ . The ABI is a comparison of the resting systolic blood pressure at the ankle to the higher systolic brachial pressure. Duplex ultrasonography is commonly used in conjunction with the ABI to identify the location and severity of arterial obstruction. Advanced vascular imaging (computed tomographic [CT] angiography, magnetic resonance [MR] angiography, catheter-based arteriography) is usually reserved for patients in whom there remains uncertainty following noninvasive testing, or in whom intervention is anticipated.

Current standard of care for PAD includes heart-healthy lifestyle changes, medicinal interventions, angioplasty, atherectomy, surgical bypass and amputation.

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<sup>1</sup> Tsao et al. Heart disease and stroke statistics—2022 update: a report from the American Heart Association. *Circulation*. 2022;145:e153-e639.

## **Technology**

The DETOUR<sup>®</sup> System (formally PQ Bypass System) is intended to treat extremely long, complex blockages in the superficial femoral artery (SFA). The DETOUR<sup>®</sup> System uses a fully percutaneous approach to femoral-popliteal bypass and incorporates the use of a TORUS<sup>™</sup> Stent Graft Delivery System, TORUS<sup>™</sup> Stent Grafts and an ENDOCROSS<sup>®</sup> device. The TORUS<sup>™</sup> Stent Graft Delivery System is 8 Fr and 0.035” wire compatible and has 135 cm of working length. It has a tri-axial shaft design with an ergonomic handle. The TORUS<sup>™</sup> Stent Graft is a self-expanding endoprosthesis made of nitinol wire frame and is encapsulated in an expanded polytetrafluorethylene (ePTFE) film. The ENDOCROSS<sup>®</sup> device is a spring-loaded dual guidewire delivery tool.

The endograft bypass created by the DETOUR<sup>®</sup> System with TORUS<sup>™</sup> Stent graft is a permanent implant. According to the requestor, revisions and removals have not been observed in the IDE study. Surgical removal is possible; however, it is unlikely to be a first line approach for a complication. According to the requestor, a pivotal trial showed a freedom from major adverse events rate of 93% using a broad definition and an independent clinical events committee.

## **Procedure Description**

Under fluoroscopic guidance the TORUS<sup>™</sup> Stent Graft Delivery System is deployed from the popliteal artery or superficial femoral artery into the femoral vein, and from the femoral vein into the superficial femoral artery (SFA) in a continuous, overlapping fashion through two independent anastomoses. The intended result is a large lumen endograft bypass, that delivers unobstructed, pulsatile flow from the SFA ostium to the popliteal artery.

The ENDOCROSS<sup>®</sup> Device and the TORUS<sup>™</sup> Stent Graft Delivery System are used to create two arteriovenous anastomoses (superficial femoral artery into the femoral vein, and femoral vein into the popliteal artery) by delivering a guidewire from the arterial segment, proximal to the target lesion, through the femoral vein and back into the artery distal to the target lesion. The ENDOCROSS<sup>®</sup> device is used to create the bypass, then a .014” wire is advanced through the popliteal artery into one of the tibial arteries for stability, in preparation for stent graft deployment. Transcatheter placement of the intravascular TORUS<sup>™</sup> Stent Grafts is then performed in continuous, overlapping fashion through the anastomoses until the bypass is complete. The stent grafts are then dilated along the entire bypass. Post-procedure imaging is obtained for assessment of the flow through the bypass at the conclusion of the procedure. In the IDE clinical trial, an average of 2.9 TORUS<sup>™</sup> Stent Grafts included in the DETOUR<sup>®</sup> System were used to complete the bypass procedures.

According to the requestor, it is estimated that 1,000 percutaneous femoral-popliteal bypass procedures using the DETOUR<sup>®</sup> System will be performed in fiscal year (FY) 2024.

**Current Coding:** There are no unique ICD-10-PCS codes to describe percutaneous femoral-popliteal artery bypass using a conduit through the femoral vein. Code the procedure using the appropriate femoral artery body part values in table 041, Bypass of Lower Arteries, with qualifier value Q Lower Extremity Artery, approach value 3 percutaneous, and device value J Synthetic Substitute.

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>4</b> Lower Arteries			
<i>Operation</i> <b>1</b> Bypass: Altering the route of passage of the contents of a tubular body part			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>K</b> Femoral Artery, Right <b>L</b> Femoral Artery, Left	<b>3</b> Percutaneous	<b>J</b> Synthetic Substitute	<b>Q</b> Lower Extremity Artery <b>S</b> Lower Extremity Vein

### Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for percutaneous femoral-popliteal artery bypass using a conduit through the femoral vein. Continue coding as described in current coding.

**Option 2.** Create new codes in New Technology table X2K, Bypass of Cardiovascular System, to identify percutaneous femoral-popliteal artery bypass using a conduit through the femoral vein.

<i>Section</i> <b>X</b> New Technology			
<i>Body System</i> <b>2</b> Cardiovascular System			
<i>Operation</i> <b>K</b> Bypass: Altering the route of passage of the contents of a tubular body part			
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>ADD F</b> Femoral Artery, Right <b>ADD G</b> Femoral Artery, Left	<b>3</b> Percutaneous	<b>ADD D</b> Conduit through Femoral Vein to Superficial Femoral Artery <b>ADD E</b> Conduit through Femoral Vein to Popliteal Artery	<b>9</b> New Technology Group 9

**Option 3.** In table 041, Bypass of Lower Arteries, add existing qualifier value L Popliteal Artery, applied to the femoral artery body part values, approach value 3 Percutaneous, and device value J Synthetic Substitute to identify percutaneous femoral-popliteal artery bypass using a conduit through the femoral vein.

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>4</b> Lower Arteries			
<i>Operation</i> <b>1</b> Bypass: Altering the route of passage of the contents of a tubular body part			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>K</b> Femoral Artery, Right <b>L</b> Femoral Artery, Left	<b>3</b> Percutaneous	<b>J</b> Synthetic Substitute	<b>ADD L</b> Popliteal Artery <b>Q</b> Lower Extremity Artery <b>S</b> Lower Extremity Vein

**CMS Recommendation:** Option 2, as described above.

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



## Topic # 05 – Insertion of Lengthening Device for Esophageal Atresia

**Issue:** There are currently no unique ICD-10-PCS codes to describe insertion of magnetic devices for non-surgical lengthening of the esophagus.

**New Technology Application?** No.

**Food & Drug Administration (FDA) Approval?** Yes. The Flourish<sup>®</sup> Pediatric Esophageal Atresia Device was granted a humanitarian use device (HUD) by the FDA on October 28, 2010 and Humanitarian Device Exemption (HDE) on May 12, 2017. It is indicated for use in lengthening atretic esophageal ends and creating an anastomosis with a non-surgical procedure in pediatric patients up to one year of age, with a gap less than 4cm, without a tracheoesophageal fistula (TEF) or in pediatric patients up to one year of age for whom a concurrent TEF has been closed as a result of a prior procedure.

**Background:** Esophageal atresia (EA) is a medical condition in which an infant is born with an upper esophagus that ends in a pouch rather than connecting normally to the stomach, resulting in the inability for food to pass from the mouth to the stomach. The condition can also lead to the accumulation of saliva in the upper pouch. One or more fistulae may occur between the malformed esophagus and the trachea. There are five types of tracheoesophageal anomalies:

- Type A – Esophageal atresia without tracheoesophageal fistula (TEF; 10 percent)
- Type B – Esophageal atresia with a TEF to the proximal esophageal segment (<1 percent)
- Type C – Esophageal atresia with a TEF to the distal esophageal segment (85 percent)
- Type D – Esophageal atresia with TEF to both the proximal and distal esophageal segments (<1 percent)
- Type E – TEF with no esophageal atresia (4 percent)

The overall incidence of EA/TEF ranges from 1/2500 to 1/4500 live births. Infants usually present with excessive oral secretions, feeding intolerance, and/or respiratory difficulties which necessitates suctioning and feed through gastrostomy tube. Morbidity/mortality is dependent on associated conditions; EA/TEF are conditions commonly found in patients with VACTERL syndrome (vertebral, anal, cardiac, tracheal, esophageal, renal, limb) and CHARGE association (coloboma, heart, atresia, choanal, retarded growth, genital hypoplasia, ear deformities).

Current standard of care includes surgical repair via thoracotomy or thoracoscopy to create an anastomosis. If this is unsuccessful, colonic, gastric, or jejunal interposition are options. According to the requestor, the Flourish<sup>®</sup> device offers a minimally invasive approach to treat pediatric patients with esophageal atresia.

### Technology

The Flourish<sup>®</sup> Pediatric Esophageal Atresia Anastomosis Device consists of an oral/esophageal catheter and a gastric catheter. The oral/esophageal catheter is a 10 Fr two-lumen catheter. One lumen is for injection of contrast to confirm anastomosis and suction of saliva; the other is for a

wire guide. The gastric catheter is a modified two-lumen 18 Fr/ 5 cc balloon retention catheter. One lumen is for balloon inflation/deflation. The second lumen is modified by the addition of the gastric magnet catheter, essentially creating a lumen within a lumen. This modified arrangement allows for initial placement of a wire to guide introduction of the gastric magnet catheter assembly. Once the wire guide is removed from the gastric magnet catheter, flushing can occur through this created lumen or through an added accessory lumen. Feed is delivered through the original accessory feed port adjacent to the adapted central port. The inflated balloon holds 5 ml of liquid. The distal end of each of the internal catheters is fitted with a bullet-shaped neodymium iron boron (NdFeB) magnet, which features a central hole for insertion of up to a 0.038-inch guide wire. When the two catheters are aligned tip to tip the magnets have opposite polarities; thus attracting each other. They are “bullet” shaped and have a diameter of 6.35 mm. Each magnet catheter is 56.5" in length.

### **Procedure Description**

In eligible candidates for the Flourish<sup>®</sup> device, the distance between the atretic segments is assessed under fluoroscopy using radiopaque flexible catheters and metal probes. After identification of the pouches, the oral/esophageal catheter is inserted orally and advanced until the magnet is located at the distal end of the upper pouch. The gastric catheter is inserted over a wire guide, under fluoroscopy through a mature stoma and advanced until the magnet is located at the distal end of the lower pouch. The gastric catheter is secured to the stomach wall internally with a balloon and externally with a bolster.

Within three to thirteen days, the traction caused by the magnets allows the esophageal sacs to approximate. Daily biplane chest radiographs are taken to assess the distance between magnets. Once approximated, the surrounding tissues grow together while the tissue between the magnets undergoes necrosis, causing development of an anastomosis, thereby creating a connected passage from mouth to stomach.

Once an anastomosis has been confirmed through fluoroscopy, the magnets are removed. The proximal end of the oral/esophageal inner magnet catheter is cut. A new wire is introduced through the oral/esophageal inner magnet catheter through the newly formed anastomosis and exits through the gastrostomy port. The oral/esophageal catheter is pushed distally toward the stomach until magnets are in the stomach, below the anastomosis. Then, the oral/esophageal inner magnet catheter is gently pushed, and the gastric catheter is pulled until the system exits from gastrostomy site, thus removing the gastrostomy tube, oral/esophageal and gastric inner magnet catheters, and the magnet pair as a unit. A new orogastric tube or nasogastric tube is placed for one to three days.

The Flourish<sup>®</sup> device is used in the inpatient setting only, as patients must be interned throughout the indwelling days. One single use device consists of a 2-lumen oral/esophageal catheter and a 2-lumen gastric catheter is used per operative episode. Use of the device will be dictated into the procedure section of the operative notes in the medical record.

Since 2017, 42 procedures were performed with a 60% success rate. Failures reported are heavily associated with gaps longer than 4cm on the day of the procedure. Complications associated with the Flourish<sup>®</sup> device are similar to those of open surgical anastomosis, which include multiple dilations and stenosis. If the device fails, and there are no complications, the patient can have surgical repair if needed.

**Current Coding:** There are no unique ICD-10-PCS codes to describe transoral and percutaneous gastrostomy insertion of magnetic devices in the esophagus for non-surgical lengthening of the esophagus. Code the procedure by assigning both codes below, found in table 0DH, Insertion of Gastrointestinal System.

- 0DH57YZ Insertion of Other Device into Esophagus, Via Natural or Artificial Opening and  
 0DH53YZ Insertion of Other Device into Esophagus, Percutaneous Approach

<i>Section</i> 0 Medical and Surgical			
<i>Body System</i> D Gastrointestinal System			
<i>Operation</i> 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			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
5 Esophagus	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	1 Radioactive Element 2 Monitoring Device 3 Infusion Device D Intraluminal Device U Feeding Device Y Other Device	Z No Qualifier
5 Esophagus	7 Via Natural or Artificial Opening 8 Via Natural or Artificial Opening Endoscopic	1 Radioactive Element 2 Monitoring Device 3 Infusion Device B Intraluminal Device, Airway D Intraluminal Device U Feeding Device Y Other Device	Z No Qualifier

### Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for insertion of magnetic devices for non-surgical lengthening of the esophagus. Continue coding as listed in current coding.

**Option 2.** In section X New Technology table XDH, Insertion of Gastrointestinal System, create new device value J Magnetic Lengthening Device, applied to the body part values 2 Esophagus, Middle and 3 Esophagus, Lower, to identify transoral and percutaneous gastrostomy insertion of magnetic devices for non-surgical lengthening of the esophagus.

<i>Section</i> X New Technology			
<i>Body System</i> D Gastrointestinal System			
<i>Operation</i> 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			
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
ADD 2 Esophagus, Middle	7 Via Natural or Artificial Opening	ADD J Magnetic Lengthening Device	9 New Technology Group 9
ADD 3 Esophagus, Lower	3 Percutaneous	ADD J Magnetic Lengthening Device	9 New Technology Group 9

**CMS Recommendation:** CMS is interested in audience input.

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

## **Topic # 06 – Extraluminal Vein Graft Support during Coronary Artery Bypass Grafting**

**Issue:** There are currently no unique ICD-10-PCS codes to describe placement of an extraluminal vein graft support device during coronary artery bypass grafting (CABG).

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. Vascular Graft Solutions, Ltd. is seeking premarket approval from the FDA for VEST™ Venous External Support with the indication to prevent vein graft intimal hyperplasia (IH) by providing permanent support to saphenous vein grafts which are being used as conduits in patients who undergo coronary artery bypass graft procedures. The requestor anticipates receiving FDA marketing authorization by July 1, 2023.

**Background:** The standard of care treatment for severe multivessel coronary disease is CABG. However, these procedures have a high incidence of vein graft failure due to high wall tension, high shear stress, lumen irregularities and flow disturbances.

Saphenous vein grafts (SVG) are the most frequently used bypass conduits in coronary artery CABG surgery. SVG disease, early after CABG, is typically dominated by intimal hyperplasia which predisposes the graft to accelerated atherosclerosis. Arterial pressure coupled with abnormal flow patterns generated mainly by luminal irregularities is the main contributor to both focal and diffuse intimal hyperplasia. However, despite major advances in surgical techniques and perioperative care, vein grafts continue to have high failure rates, limiting the long-term outcome of CABG. SVG failure rates range from 35% to 50% 5 to 10 years following CABG surgery. This doubles the risk for re-interventions.

### **Technology**

According to the requestor, VEST™ is a novel, first of its kind, external support device which can be fitted over the saphenous vein bypass conduit in CABG surgery. The requestor states it is the only technology that has been proven to prevent common vein graft failures as a result of graft kinking and vein graft disease. In doing so, the requestor asserts VEST™ ultimately improves the outcome of CABG by reducing clinical events associated with vein graft failure such as coronary re-intervention (PCI or re-do CABG), MI, angina, and death.

VEST™ is a kink-resistant cobalt chrome external support device that targets the underlying mechanism of vein graft disease: disturbed flow pattern and high wall tension. By providing the vein with arterial biomechanical properties, VEST™ prevents the graft non-uniform dilatation post-implantation, mitigates the formation of disturbed flow patterns, and the subsequent development of intimal hyperplasia.

The VEST™ product family includes VEST™ and VEST™ 2.0 models. While made from the same material, and having the same structure, VEST™ 2.0 is braided of thinner wires and can be cut intraoperatively by the surgeon to fit the desired vein graft length. In addition, according to the requestor, VEST™ 2.0 is more pliable and compatible with the vein graft geometry.

## Procedure Description

VEST™ is used in CABG surgery in which at least one saphenous vein is used as the bypass conduit. It is implanted in a similar way to standard grafting techniques. After the saphenous vein has been harvested, the correct size external support device is chosen using the specific selection tool that is provided with the device. During CABG, VEST™ is threaded over the vein graft towards the distal anastomosis, then manipulated to cover the distal end of the graft. Next, it is expanded by gently squeezing until it covers the entire vessel length. In doing so, VEST™ elongates and simultaneously reduces in diameter. Expansion can be done either before or after stitching the proximal anastomosis.

As an external vein graft support implanted during the bypass procedure, VEST™ remains in the body as a permanent implant to provide external mechanical support to the vein graft wall. According to the requestor, in the acute phase, VEST™ prevents graft kinking. In the long term, it is wrapped around the vein to prevent abrupt conduit dilation, attenuates higher arterial pressure to which the graft is exposed, prevents any associated increase in wall tension, and enhances lumen uniformity. As a result, the requestor asserts that VEST™ reduces smooth muscle cell proliferation and migration, and mitigates intimal hyperplasia and atherosclerosis in the vein graft.

Multiple devices can be used depending on the number of saphenous veins used during the surgical procedure. According to the target number of bypasses, the saphenous vein may be segmented into multiple shorter grafts. VEST™ can fit as an external support to each of these graft segments. The requestor states there have been no adverse outcomes or complications related to the VEST™ technology.

**Current Coding:** The placement of an extraluminal vein graft support device during CABG is not reported separately for hospital inpatient coding.

## Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for placement of an extraluminal vein graft support device during CABG. Continue coding as listed in current coding.

**Option 2.** In New Technology table X2U, Supplement, Cardiovascular System, create new device value 7 Vein Graft Extraluminal Support Device(s), applied to the appropriate coronary artery body part value(s), to identify placement of an extraluminal vein graft support device during CABG.

<i>Section</i> <b>X</b> New Technology			
<i>Body System</i> <b>2</b> Cardiovascular System			
<i>Operation</i> <b>U</b> Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part			
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>ADD 0</b> Coronary Artery, One Artery	<b>0</b> Open	<b>ADD 7</b> Vein Graft Extraluminal Support Device(s)	<b>9</b> New Technology Group 9
<b>ADD 1</b> Coronary Artery, Two Arteries			
<b>ADD 2</b> Coronary Artery, Three Arteries			
<b>ADD 3</b> Coronary Artery, Four or More Arteries			

**CMS Recommendation:** Option 2, as described above.

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

## **Topic # 07 – Insertion of a Short-term External Heart Assist System with Conduit**

**Issue:** There are currently no unique ICD-10-PCS codes to describe the insertion of a short-term external heart assist system using an axillary artery or ascending thoracic aorta conduit that allows patient ambulation.

**New Technology Application?** No.

**Food & Drug Administration (FDA) Approval?** Yes. The Impella® 5.5 with SmartAssist® System was approved by the FDA on September 24, 2019.

**Background:** Cardiogenic shock occurs when cardiac output is insufficient to meet the metabolic demands of the body, resulting in inadequate tissue perfusion. This pathophysiology frequently leads to multi-system organ failure and death. The most common cause of cardiogenic shock is acute myocardial infarction (MI) resulting in a loss of more than 40% of the functional myocardium. Cardiogenic shock complicates 8% to 10% of all hospital admissions for acute MI. Other causes include myocarditis, endocarditis, papillary muscle rupture, left ventricular free wall rupture, acute ventricular septal defect, decompensated congestive heart failure, end-stage cardiomyopathy, severe valvular dysfunction, acute cardiac tamponade, cardiac contusion, massive pulmonary embolus, or overdose of drugs such as beta blockers or calcium channel blockers. Cardiogenic shock has been associated with extremely high mortality rates of approximately 50 percent for the past twenty years. Patients with suspected cardiogenic shock must undergo immediate cardiac catheterization for the assessment of coronary anatomy, intracardiac pressures, valvular dysfunction, and other structural impairments. Cardiogenic shock treatment focuses on reducing the damage from lack of oxygen to the heart muscle and other organs by rapidly restoring normal tissue perfusion. Cardiogenic shock has few other treatment options outside of the use of ventricular assist devices and mechanical circulatory support.

The Impella® 5.5 with SmartAssist® System is a temporary ventricular support device intended for short-term use and is indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or following open-heart surgery. It is indicated for the treatment of cardiogenic shock in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure. The Impella® 5.5 with SmartAssist® is designed for longer-duration support (up to 14 days) than other femoral access percutaneous ventricular assist devices (pVADs) that treat cardiogenic shock (up to 4 days).

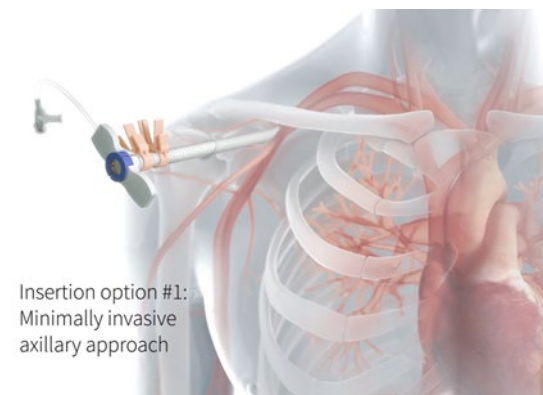
### **Technology**

The Impella® 5.5 with SmartAssist® delivers full hemodynamic support with maximum cardiac unloading of 5.5 L/min of forward flow, allowing the heart to rest and recover. It is a surgically implanted heart pump that unloads the left ventricle, reduces ventricular work, and provides the circulatory support necessary to allow heart and organ recovery and early assessment of residual myocardial function. It is designed for longer-duration support and enables patient mobilization and ambulation to optimize recovery. The device uses real-time SmartAssist® intelligence for improving outcomes with management and weaning. The technology is designed to enable native heart recovery, allowing patients to return home with their own hearts.

The Impella® 5.5 with SmartAssist® surgical pump can be inserted either into the ascending aorta through an open chest approach (median sternotomy or anterior thoracotomy) or through an infraclavicular surgical incision into the axillary artery. In the axillary approach, the axillary artery is exposed and isolated from the surrounding structures. A surgical graft conduit is anastomosed to the axillary artery by a surgeon in the operating room. The device is positioned across the aortic valve, with the inlet located in the left ventricle and the outlet in the ascending aorta. This position uniquely allows the device to directly unload the left ventricle along the physiologic blood flow pathway, supporting both coronary and systemic perfusion. The device enables the optimization of left ventricular kinetics, improves blood flow, protects end-organ function, and decreases right ventricular afterload. While the Impella® 5.5 with SmartAssist® is typically implanted as a standalone procedure, there are some instances when the patient requires right heart support during the same operative procedure; in those cases, a device may be inserted to support the right ventricle. The Impella® 5.5 surgical heart pump is not considered permanent and is removed prior to discharge from the hospital. The device may require surgical percutaneous or external revision due to the duration of support.

### Procedure Description

#### *Axillary Insertion of the Impella® 5.5 with SmartAssist®*



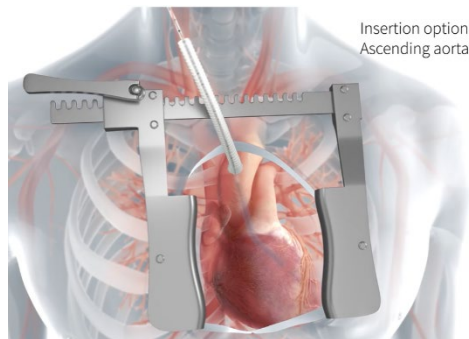
Axillary implantation of the Impella® 5.5 with SmartAssist® is performed in the cardiac surgical operating room. Patients are placed under general anesthesia with appropriate invasive hemodynamic monitoring. After the patient is prepped and draped, a 4-5cm infraclavicular incision is made below the middle third of the clavicle. The soft tissues are dissected with attention to hemostasis. The clavipectoral fascia is identified and incised. The axillary artery is exposed and isolated free from the surrounding structures including the axillary vein and

brachial plexus. The artery is clamped proximally and distally and opened. A Dacron vascular graft is beveled at 60-degree and sewn to the edges of the arterial wall constructing an end-to-side anastomosis using continuous monofilament suture. The graft is occluded with a vascular clamp just above the anastomosis, blood flow restored to the axillary artery, and hemostasis assessed. The introducer is inserted into the graft and secured with a graft lock (the graft may also be secured over the introducer using heavy sutures or umbilical tape). The vascular clamp on the graft is then removed, and a diagnostic guidewire is inserted with a 4–6 Fr diagnostic catheter into the introducer. The diagnostic guidewire is removed and exchanged for a placement guidewire. With the placement guidewire properly positioned in the left ventricle, the diagnostic catheter is removed. Once removed, a silicone-coated dilator is inserted to lubricate the valves of sheath and is then removed.

The graft is clamped again with a vascular clamp just above the anastomosis. The Impella® Catheter is loaded onto the placement guidewire and advanced into the catheter over the guidewire through the introducer into the graft, so the entire pump cannula and motor housing reside in the graft. The vascular clamp is removed, then the Impella® Catheter is inserted into the aorta. The catheter is advanced across the aortic valve using fluoroscopic imaging guidance to properly position the cannula bend at the aortic valve annulus. The inlet is positioned approximately 5 cm

below the aortic valve in the left ventricle. The placement guidewire is removed, and Impella<sup>®</sup> support is initiated. After placement, a soft-jawed clamp is used at the anastomosis so the introducer can be removed. The introducer is fully removed from the graft before peeling it away. The graft is trimmed so that skin can be closed over the graft. The infraclavicular incision is then closed in layers using absorbable suture and the device secured externally.

#### *Direct Aortic Insertion of the Impella<sup>®</sup> 5.5 with SmartAssist<sup>®</sup>*



The Impella<sup>®</sup> 5.5 with SmartAssist<sup>®</sup> System is surgically implanted directly into the ascending aorta when the central mediastinum is exposed through a median sternotomy or anterior thoracotomy. Transesophageal echocardiography (TEE) is required to guide placement. Using the supplied sterile incision template for positioning, a sidebiter clamp is placed on the greater curvature of the distal ascending aorta at least 7 cm above the plane of the aortic valve. With partial occlusion of the aorta, a 6mm longitudinal

incision is made in the aorta. A vascular graft (10 mm x 15 cm) is then beveled and sewn to the opening in the aorta in an end-to-side fashion using a continuous monofilament suture. When the anastomosis is complete, the distal end of the graft is clamped, the sidebiter clamp at the base of the anastomosis removed, and hemostasis ensured. The Impella<sup>®</sup> 5.5 Catheter is placed into the open end of the graft up to the level of the rear plug and advanced into the aorta. As soon as the motor housing has passed into the aorta, a ligature is used to loosely secure the front silicone plug flush to the graft. The silicone plug should be in the most proximal portion of the graft. The front plug should not be allowed to advance beyond the base of the graft. The catheter is then gently advanced forward until the inlet crosses the aortic valve and the bend of the catheter is at the level of the aortic valve annulus. Appropriate device placement is confirmed with intra-operative TEE prior to initiating support.

**Current Coding:** There are no unique ICD-10-PCS codes to describe the insertion of a short-term external heart assist system using an axillary artery or ascending thoracic aorta conduit that allows patient ambulation.

If the heart assist system is inserted via the minimally invasive axillary artery approach, code the procedure by assigning both codes below, found in tables 02H, Insertion of Heart and Great Vessels and 03H, Insertion of Upper Arteries respectively.

- 02HA3RZ      Insertion of short-term external heart assist system into heart, percutaneous approach
- and
- 03HY0YZ      Insertion of other device into upper artery, open approach



If inserted via the open ascending aorta approach, code the procedure by assigning the following codes found in table 02H, Insertion of Heart and Great Vessels and 03H, Insertion of Upper Arteries respectively:

- 02HA0RZ Insertion of short-term external heart assist system into heart, open approach and
- 03HY0YZ Insertion of other device into upper artery, open approach

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>2</b> Heart and Great Vessels			
<i>Operation</i> <b>H</b> 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			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>A</b> Heart	<b>0</b> Open	<b>R</b> Short-term External Heart Assist System	<b>J</b> Intraoperative
	<b>3</b> Percutaneous		<b>S</b> Biventricular
	<b>4</b> Percutaneous Endoscopic		<b>Z</b> No Qualifier

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>3</b> Upper Arteries			
<i>Operation</i> <b>H</b> 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			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>Y</b> Upper Artery	<b>0</b> Open	<b>2</b> Monitoring Device	<b>Z</b> No Qualifier
	<b>3</b> Percutaneous	<b>3</b> Infusion Device	
	<b>4</b> Percutaneous Endoscopic	<b>D</b> Intraluminal Device	
		<b>Y</b> Other Device	

### Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for the insertion of a short-term external heart assist system using an axillary artery or ascending thoracic aorta conduit. Continue coding as described in current coding.

**Option 2.** In table X2H, Insertion of Cardiovascular System, create new device value F Conduit to Short-term External Heart Assist System, applied to the body part values 5 Axillary Artery, Right, and X Thoracic Aorta, Ascending to identify insertion of short-term external heart assist system using a conduit attached to the right axillary artery or to the ascending aorta respectively. A separate code would continue to be reported for the insertion of the external heart assist system as described in current coding.

<i>Section</i> <b>X</b> New Technology			
<i>Body System</i> <b>2</b> Cardiovascular System			
<i>Operation</i> <b>H</b> 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			
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>ADD 5</b> Axillary Artery, Right <b>ADD X</b> Thoracic Aorta, Ascending	<b>0</b> Open	<b>ADD F</b> Conduit to Short-term External Heart Assist System	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 08 – Ultrasound Ablation of Renal Sympathetic Nerves

**Issue:** There are currently no unique ICD-10-PCS codes to describe the ultrasound ablation of renal sympathetic nerves.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. The Paradise™ Ultrasound Renal Denervation System was designated Breakthrough Device status by the FDA in December 2020. According to the requestor, FDA pre-market approval is anticipated by June 2023.

**Background:** Hypertension develops when blood flows through the arteries at higher-than-normal pressures. The global prevalence of hypertension is high, and over 47% or 116 million adults in the U.S. are diagnosed with hypertension according to the Centers for Disease Control and Prevention (CDC).<sup>1</sup> In addition, only approximately 1 in 4 adults diagnosed with hypertension have adequate blood pressure control.<sup>2</sup> Treatment of hypertension is the most common reason for office visits and for the use of chronic prescription medications. The CDC estimates high blood pressure costs of \$131 billion each year from 2003 to 2014.<sup>1</sup>

Renal sympathetic efferent and afferent nerves, which lie adjacent to the wall of the renal artery, are crucial for production of catecholamines which contribute to hypertension.<sup>3</sup> Increased Renal sympathetic nerve activity (RSNA) has been demonstrated to contribute to the rise in blood pressure through three major mechanisms which include: (1) an increase in tubular reabsorption of urinary sodium and water, (2) a reduction of renal blood flow and glomerular filtration rate (GFR), and (3) release of renin from the juxtaglomerular apparatus, thereby activating the renin–angiotensin–aldosterone cascade.<sup>4</sup>

The Paradise™ Ultrasound Renal Denervation System is intended to reduce blood pressure by treating the overactive renal sympathetic nerves. The Paradise™ Ultrasound Renal Denervation System is designed to maximize the potential of renal denervation, with a simplified procedure enabled by SonoWave 360™ ultrasound technology.

### Technology

The Paradise™ Ultrasound Renal Denervation System is an endovascular catheter-based system indicated to reduce blood pressure in adult patients 22 years of age and older with uncontrolled hypertension, who may be inadequately responsive to, or who are intolerant to anti-hypertensive medications. The goal of the procedure is to achieve a reduction in systemic arterial blood pressure by using a minimally invasive procedure to treat overactive renal nerves with ultrasound energy.

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<sup>1</sup> CDC. “Facts About Hypertension.” Accessed November 30, 2022.

<https://www.cdc.gov/bloodpressure/facts.htm#:~:text=Nearly%20half%20of%20adults%20in,are%20taking%20medication%20for%20hypertension.>

<sup>2</sup> Percent of controlled hypertension varies depending on the definition of hypertension used. This estimate (1 in 4) is consistent with the estimate using the criteria in the 2017 ACC/AHA guideline (<https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html>).

<sup>3</sup> Kannan A, Medina RI, Nagajothi N, Balamuthusamy S. Renal sympathetic nervous system and the effects of denervation on renal arteries. *World J Cardiol.* 2014 Aug 26;6(8):814-23. doi: 10.4330/wjc.v6.i8.814. PMID: 25228960; PMCID: PMC4163710.

<sup>4</sup> DiBona GF, Kopp UC. Neural control of renal function. *Physiol Rev* (1997) 77:75–197. 10.1152/physrev.1997.77.1.75

The Paradise™ Ultrasound Renal Denervation System thermally ablates and disrupts the renal sympathetic nerves with complete 360-degree energy delivery at a targeted ablation depth of 1-6 mm, the location of the majority of sympathetic nerves surrounding the renal arteries. The Paradise™ System incorporates a generator with automated energy emission and the catheter which provides simultaneous cooling through a balloon cooling system to protect the arterial wall from thermal damage. The Paradise™ Catheter protects the artery walls with its HydroCooling System that keeps the near field cool to protect the wall of the renal arteries during periods of ultrasound energy emission (sonication).

### Procedure Description

In a typical scenario, a patient presents with moderate to severe hypertension, in spite of multiple efforts at pharmacological treatment. After assessment of the patient, the provider orders ultrasound renal denervation in order to improve the patient’s management of hypertension. The patient undergoes a baseline renal angiogram to confirm candidacy for the procedure and then proceeds to endovascular ultrasound renal denervation using the Paradise™ System. During the procedure, the system delivers an appropriate number of sonications (ablation caused by ultrasound energy emission) bilaterally within each renal artery, based on the individualized treatment plan determined by the physician. Specifically, a catheter is placed into the lumen of the renal artery and the system delivers 7 seconds of ultrasound energy to thermally ablate the renal sympathetic nerves at a 1-6 mm target depth beyond the arterial wall. The Paradise™ Generator detects the catheter size and adjusts the energy level accordingly. On average, 2-3 sonications along the main renal artery to each kidney are recommended. In addition, accessory arteries of suitable size are treated where present. Typically, the patient’s blood pressure is taken 1-6 months after the procedure to assess the procedure’s impact.

**Current Coding:** There are no unique ICD-10-PCS codes to describe the percutaneous ultrasound ablation of renal sympathetic nerves. Code the procedure using the body part value M Abdominal Sympathetic Nerve in table 015, Destruction of Peripheral Nervous System, with approach value 3 Percutaneous.

<i>Section</i>	0 Medical and Surgical			
<i>Body System</i>	1 Peripheral Nervous System			
<i>Operation</i>	5 Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent			
	<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
	0 Cervical Plexus			
	1 Cervical Nerve			
	2 Phrenic Nerve			
	3 Brachial Plexus			
	4 Ulnar Nerve			
	5 Median Nerve			
	6 Radial Nerve			
	8 Thoracic Nerve	0 Open		
	9 Lumbar Plexus	3 Percutaneous	Z No Device	Z No Qualifier
	A Lumbosacral Plexus	4 Percutaneous Endoscopic		
	B Lumbar Nerve			
	C Pudendal Nerve			
	D Femoral Nerve			
	F Sciatic Nerve			
	G Tibial Nerve			
	H Peroneal Nerve			
	K Head and Neck Sympathetic Nerve			

L Thoracic Sympathetic Nerve M Abdominal Sympathetic Nerve N Lumbar Sympathetic Nerve P Sacral Sympathetic Nerve Q Sacral Plexus R Sacral Nerve			
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**Coding Options**

**Option 1.** Do not create new ICD-10-PCS codes for the ultrasound ablation of renal sympathetic nerves. Continue coding as described in current coding.

**Option 2.** Create a new code in section X table X05, Destruction of Nervous System, with new technology value 2 Ultrasound Ablation and new body part value 1 Renal Sympathetic Nerve(s), to identify percutaneous ultrasound ablation of renal sympathetic nerves.

<i>Section</i> <b>X</b> New Technology			
<i>Body System</i> <b>0</b> Nervous System			
<i>Operation</i> <b>5</b> Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent			
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>ADD 1</b> Renal Sympathetic Nerve(s)	<b>3</b> Percutaneous	<b>ADD 2</b> Ultrasound Ablation	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 09 – Computer-aided Detection of Heart Failure in Echocardiography

**Issue:** There are currently no unique ICD-10-PCS codes to describe computer-aided detection of heart failure in echocardiography.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** Yes. EchoGo Heart Failure 1.0 was designated Breakthrough Device status by the FDA on February 24, 2022. FDA 501(k) clearance for EchoGo Heart Failure 1.0 was granted on November 23, 2022.

**Background:** Heart failure affects over 6 million adults in the United States according to the CDC.<sup>1</sup> The American College of Cardiology (ACC) and American Heart Association (AHA) clinical guidelines for the management of heart failure define heart failure “a complex clinical syndrome with symptoms and signs that result from any structural or functional impairment of ventricular filling or ejection of blood.”<sup>2</sup> Heart failure with preserved ejection fraction (HFpEF) accounts for 50% of the heart failure population. The ACC/AHA guidelines define HFpEF as patients with at least 50% or greater left ventricular ejection fraction (LVEF) and evidence of spontaneous or provokable increased left ventricular filling pressures. The guidelines note the importance of appropriately classifying heart failure patients to inform optimal treatment regimens for patients.

### Technology

EchoGo Heart Failure 1.0 is an automated machine learning-based decision support system, indicated as a diagnostic aid for adult patients over 25 years of age undergoing routine functional cardiovascular assessment using echocardiography. When utilized by an interpreting clinician, this device provides information that may be useful in detecting HFpEF.

The device takes as an input a Digital Imaging and Communications in Medicine (DICOM) file containing a two-dimensional echocardiogram imaging data with an apical 4-chamber view. The software functions using an artificial intelligence (AI) model developed using a convolutional neural network (CNN) that produces a HFpEF classification result. More specifically, the EchoGo Heart Failure 1.0 proprietary algorithm is comprised of a series of 3D CNN layers designed to operate on two-dimensional videos over two in-plane spatial dimensions within the image frames, and across the time dimension. The model input is comprised of all non-overlapping sequences of consecutive 30 frames from all consecutive cardiac cycles from the entire A4C videoclip. All A4C videoclips were subjected to automated image pre-processing prior to being fed into the neural network, which included extraction of DICOM ultrasound region and resizing. CNN input data are fed into the model 30 consecutive frames at a time, with a class prediction made for each 30 frame sequence. Final prediction score is computed as the mean of the class prediction obtained when evaluating all consecutive sequences of 30 frames in a videoclip, that overlapped with a stride of one frame.

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<sup>1</sup> CDC. “Heart Failure.” [https://www.cdc.gov/heartdisease/heart\\_failure.htm](https://www.cdc.gov/heartdisease/heart_failure.htm)

<sup>2</sup> Heidenreich, Paul A., Boxkurt, B., et.al. “2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines.” April 2022. *Circulation*. 2022;145:e895–e1032. <https://doi.org/10.1161/CIR.0000000000001063>

The EchoGo Heart Failure 1.0 software gives an estimate of the presence or absence of HFpEF to the interpreting practitioner following an analysis of a 2D electrocardiogram. The software-only medical device is a cardiovascular status indicator for adjunctive use by the practitioner together with other vital signs and patient information to aid in the diagnosis of the patient. Patient management decisions should not be made solely on the results of the EchoGo Heart Failure 1.0 analysis.

### Procedure Description

EchoGo Heart Failure 1.0 ingests the required DICOM series from a DICOM cardiac ultrasound study with required metadata to output a report in multiple formats, indicating the presence or absence of systolic or diastolic heart failure, with given degrees of confidence.

1. DICOM compliant 2D echocardiogram consisting of an apical 4-chamber view with preserved ejection fraction are securely sent to EchoGo Heart Failure 1.0.
2. EchoGo Heart Failure 1.0 software performs automated, technical quality control checks on the input DICOM and additional automated image pre-processing is applied to the input prior to being fed into an AI neural network.
3. Based on a pre-specified certainty threshold and the certainty of the classification, the pre-trained fixed AI model either provides a categorical recommendation or a “no classification” recommendation which is outputted in a form of a “report”.
4. If the study is rejected due to technical reasons or software failure, the reason for rejection is provided on the report.

**Current Coding:** The use of software to aid in the detection of heart failure in echocardiography is not reported separately for inpatient hospital coding. Facilities can report the echocardiogram using the appropriate code in section B, Imaging.

### Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for computer-aided detection of heart failure in echocardiography. Continue coding as described in current coding.

**Option 2.** Create new codes in section X, New Technology, to identify computer-aided detection of heart failure in echocardiography. Continue to report the echocardiogram using the appropriate code in section B, Imaging, as listed in current coding.

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>X</b> Physiological Systems		
<i>Operation</i>	<b>E</b> Measurement: Determining the level of a physiological or physical function at a point in time		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>ADD 2</b> Cardiac	<b>X</b> External	<b>ADD 1</b> Output, Computer-aided Assessment	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 10 – Insertion of Percutaneous Mechanical Circulatory Support Device into Thoracic Aorta

**Issue:** There are currently no unique ICD-10-PCS codes to describe insertion of a percutaneous short-term external heart assist pump into the thoracic aorta, for the treatment of chronic heart failure.

**New Technology Application?** No.

**Food & Drug Administration (FDA) Approval?** No. Procyrion, Inc. received Breakthrough Device Designation by the FDA for its Aortix™ System in July 2019 for chronic heart failure patients on medical management who have been hospitalized for acute decompensated heart failure (ADHF) with worsening renal function. According to the requestor, approval for the Aortix™ System is anticipated in FY 2026.

**Background:** For patients with chronic, stable heart failure (HF) there are multiple pharmacologic and device-based treatment options.<sup>1,2,3,4</sup> However, for patients with acute decompensated heart failure (ADHF), many medical therapies have been tested in this patient population without success<sup>5,6,7</sup> and, as a result, acute HF care remains largely homogenous and unchanged over the past 40 years.<sup>8,9</sup> The majority of acute HF patients are treated with intravenous loop diuretics with consideration of vasodilator therapies.<sup>10</sup> High-risk patients with decompensated HF failing conventional therapies are rarely (<2%<sup>11,12</sup>) considered for temporary or permanent mechanical circulatory support (MCS) due to a lack of evidence in this population, risk, and cost.<sup>8</sup> Positive inotropes are used in this patient population (6-12% of these patients) but data has shown that they are linked to worsened outcomes and higher mortality.<sup>13,14</sup> Despite

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<sup>1</sup> Benjamin, E. J. et al. Heart Disease and Stroke Statistics—2017 Update: A Report From the American Heart Association. *Circulation* CIR.0000000000000485 (2017). doi:10.1161/cir.0000000000000485

<sup>2</sup> McMurray, J. J. et al. Angiotensin–Neprilysin Inhibition versus Enalapril in Heart Failure. *New Engl J Medicine* 371, 993–1004 (2014).

<sup>3</sup> Swedberg, K. et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomised placebo-controlled study. *Lancet* 376, 875–85 (2010).

<sup>4</sup> Abraham, W. T. et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. *Lancet* 377, 658–66 (2011).

<sup>5</sup> Massie, B. M. et al. Rolofylline, an adenosine A1-receptor antagonist, in acute heart failure. *The New England journal of medicine* 363, 1419–28 (2010).

<sup>6</sup> Konstam, M. A. et al. Effects of Oral Tolvaptan in Patients Hospitalized for Worsening Heart Failure: The EVEREST Outcome Trial. *JAMA* 297, 1319–1331 (2007).

<sup>7</sup> O'Connor, C. et al. Effect of Nesiritide in Patients with Acute Decompensated Heart Failure. *New Engl J Medicine* 365, 32–43 (2011).

<sup>8</sup> Yancy, C. W. et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. *Circulation* 128, e240-327 (2013).

<sup>9</sup> Ramirez, A. & Abelmann, W. Cardiac decompensation. *The New England journal of medicine* 290, 499–501 (1974).

<sup>10</sup> Ambrosy, A. P. et al. The global health and economic burden of hospitalizations for heart failure: lessons learned from hospitalized heart failure registries. *J Am Coll Cardiol* 63, 1123–1133 (2014).

<sup>11</sup> Adams, K. F. et al. Characteristics and outcomes of patients hospitalized for heart failure in the United States: Rationale, design, and preliminary observations from the first 100,000 cases in the Acute Decompensated Heart Failure National Registry (ADHERE). *Am Heart J* 149, 209–216 (2005).

<sup>12</sup> Newton, P. J. et al. Acute heart failure admissions in New South Wales and the Australian Capital Territory: the NSW HF Snapshot Study. *Med J Australia* 204, 113 (2016).

<sup>13</sup> Heywood, J. et al. High prevalence of renal dysfunction and its impact on outcome in 118,465 patients hospitalized with acute decompensated heart failure: a report from the ADHERE database. *J Card Fail* 13, 422–30 (2007).

<sup>14</sup> Valente, M. A. et al. Diuretic response in acute heart failure: clinical characteristics and prognostic significance. *European heart journal* 35, 1284–93 (2014).

optimal medical therapy, 33% of ADHF patients are discharged with persistent congestion.<sup>15</sup>

Renal dysfunction (at least moderate [Stage III] dysfunction), occurs in up to 64% of ADHF admissions.<sup>13</sup> These patients represent a particularly high-risk population with poor outcomes. Data from the ADHERE registry of over 110,000 ADHF admissions showed that in-hospital mortality increased from 1.9% for patients with normal renal function to 7.6% in patients with severe dysfunction.<sup>13</sup> In these patients, outcomes are poor due to persistent congestion (90% have persistent congestion after 3 days of pharmacologic therapy<sup>16</sup>), increased dose of diuretics,<sup>17</sup> and decreased diuretic efficiency.<sup>18</sup> Existing percutaneous impeller pumps placed in the heart and pulsatile balloon pumps placed in the aorta have not been shown to be effective in this patient population. Likewise, the use of ultrafiltration in this patient population has also failed to show benefit. Additionally, existing continuous flow percutaneous impeller pumps are placed across the aortic valve, and have a high incidence of hemolysis<sup>19</sup> and migration.

### **Technology**

According to the requestor, a clinical need exists for a minimally invasive device for treating both acute decompensated (congestive) heart failure and acute on chronic (congestive) heart failure that provides cardiac blood flow support to improve outcomes in the ADHF patient population. Aortix™ is a percutaneous mechanical circulatory support (pMCS) device positioned in the thoracic aorta designed to treat acute decompensated heart failure patients who are currently treated with medication and unresponsive to medication alone.

The requestor states Aortix™ is a continuous flow axial flow pump design that harnesses fluid entrainment to pump blood without the need of a valve, which allows for intra-aortic placement and physiological natural delivery of therapy. For the percutaneous insertion procedure, the Aortix™ device consists of a delivery system with introducer sheath and the delivery system contains the pump. The implantable portion of the system is the Aortix™ pump consisting of the pump body and a thin power lead. The pump body includes the motor, the rotor assembly (impeller) and the struts for localizing and centering the pump in the aorta. Once the pump is inserted, the control system (comprised of a controller and cradle), enables continuous monitoring via Bluetooth communication. For the percutaneous removal procedure, the Aortix™ device consists of a retrieval system that allows full control of the arteriotomy after retrieval.

### **Procedure Description**

Insertion of the Aortix™ system is performed under general anesthesia. Using fluoroscopic guidance, the position for placement of the Aortix™ pump and delivery sheath is determined. By Seldinger technique, femoral artery access is obtained and pre-closed sutures are placed at the arteriotomy site. Femoral artery access allows for advancement of the delivery sheath and dilator over the guidewire into the femoral artery, continuing into the descending thoracic aorta. The

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<sup>15</sup> Wattad, M. et al. Interaction Between Worsening Renal Function and Persistent Congestion in Acute Decompensated Heart Failure. *Am J Cardiol* 115, 932–937 (2015).

<sup>16</sup> Bart, B. A. et al. Ultrafiltration in Decompensated Heart Failure with Cardiorenal Syndrome. *New Engl J Medicine* 367, 2296–2304 (2012).

<sup>17</sup> Hasselblad, V. et al. Relation between dose of loop diuretics and outcomes in a heart failure population: Results of the ESCAPE Trial. *European Journal of Heart Failure* 9, 1064–1069 (2007).

<sup>18</sup> Damman, K. et al. Renal impairment, worsening renal function, and outcome in patients with heart failure: an updated meta-analysis. *Eur Heart J* 35, 455–69 (2014).

<sup>19</sup> Badiye, A. P., Hernandez, G. A., Novoa, I. & Chaparro, S. V. Incidence of Hemolysis in Patients with Cardiogenic Shock Treated with Impella Percutaneous Left Ventricular Assist Device. *Asaio J* 62, 11–14 (2016).



distal tip of the delivery sheath is placed superior to the renal arteries approximately lateral to the superior aspect of the T10 vertebral body. After testing and preparation of the delivery system, the dilator is removed and the delivery system is connected to the delivery/introducer sheath. The inner catheter is then advanced through the distal handle until the transfer stop mates with the distal handle. Proper placement of the non-deployed pump is confirmed using fluoroscopy or ultrasound. Once positioning is confirmed, the Aortix™ pump is deployed by retracting the introducer sheath. Using fluoroscopy, the Aortix™ delivery sheath and delivery system are then withdrawn over the power lead. The next step is to maintain hemostasis at the femoral arteriotomy. Post deployment, confirmation that the Aortix™ pump is superior to the renal arteries is performed with anteroposterior (AP) fluoroscopy. The pump is connected to the controller and confirmation that the Aortix™ pump is ready to run is viewed on the screen of the Aortix™ cradle. Using the cradle, the Aortix™ pump is started. Lastly, hemostasis is achieved using the pre-closed sutures at the arteriotomy site.

Removal of the Aortix™ system is performed under general anesthesia. A fluoroscopic image of the final pump position should be taken and documented before the pump is retrieved. Fluoroscopy is used during the removal procedure. After the Aortix™ Retrieval system components are prepared and assembled, the pump is turned off with the Aortix™ control system. Then the power lead connector is cut off and a distal-locking stylet or guidewire is deployed in the central lumen of the power lead. Next the retrieval sheath and dilator are advanced over the power lead to the arteriotomy, the knotted sutures at the arteriotomy site are non-invasively released, and access is gained to the femoral artery. The retrieval sheath and dilator are then advanced to the bottom of the pump and the retrieval dilator is unlocked from the retrieval hub. While holding the retrieval dilator, the sheath is advanced to the back of pump, the pump is pulled into the sheath by fixing the position of the sheath while retracting the dilator. Finally, the pump is removed from the sheath and the arteriotomy is closed by standard large bore closure techniques to achieve hemostasis.

The Aortix™ percutaneous mechanical circulatory support device is utilized in the inpatient setting and is typically implanted in the cardiac catheterization lab/O.R., is used for up to 7 days, and subsequently removed in the cardiac catheterization lab/O.R. Monitoring is generally performed in the intensive care unit, cardiac critical care unit, or an intermediate critical care unit. Adverse events reported include bleeding, pump migration during dressing change, and vascular complications or injuries.

**Current Coding:** There are no unique ICD-10-PCS codes to describe insertion of a percutaneous short-term external heart assist impeller pump into the thoracic aorta. Code the procedure described, using the body part value A Heart and the device value R Short-term External Heart Assist System in tables 02H, 02P, and 02W, Insertion, Removal, and Revision of Heart and Great Vessels respectively, with approach value 3 Percutaneous and qualifier value Z No Qualifier.

Facilities would also report the cardiac support using the following code:

5A0221D Assistance with Cardiac Output using Impeller Pump, Continuous

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>2</b> Heart and Great Vessels			
<i>Operation</i> <b>H</b> 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			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>A</b> Heart	<b>0</b> Open	<b>R</b> Short-term External Heart Assist System	<b>J</b> Intraoperative
	<b>3</b> Percutaneous		<b>S</b> Biventricular
	<b>4</b> Percutaneous Endoscopic		<b>Z</b> No Qualifier

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>2</b> Heart and Great Vessels			
<i>Operation</i> <b>P</b> Removal: Taking out or off a device from a body part			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>A</b> Heart	<b>0</b> Open	<b>R</b> Short-term External Heart Assist System	<b>S</b> Biventricular
	<b>3</b> Percutaneous		<b>Z</b> No Qualifier
	<b>4</b> Percutaneous Endoscopic		

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>2</b> Heart and Great Vessels			
<i>Operation</i> <b>W</b> Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>A</b> Heart	<b>0</b> Open	<b>R</b> Short-term External Heart Assist System	<b>S</b> Biventricular <b>Z</b> No Qualifier
	<b>3</b> Percutaneous		
	<b>4</b> Percutaneous Endoscopic		
	<b>X</b> External		

### Coding Options

**Option 1.** Do not create new ICD-10-PCS codes to describe the insertion of a percutaneous short-term external heart assist pump into the thoracic aorta. Continue coding as described in current coding.

**Option 2.** In tables 02H, 02P, and 02W, Insertion, Removal, and Revision of Heart and Great Vessels, add existing body part value W Thoracic Aorta, Descending, applied to the device value R Short-term External Heart Assist System to identify insertion of a percutaneous short-term external heart assist pump into the thoracic aorta. Continue to report the cardiac monitoring procedure as described in current coding.

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>2</b> Heart and Great Vessels			
<i>Operation</i> <b>H</b> 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			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>ADD W</b> Thoracic Aorta, Descending	<b>3</b> Percutaneous	<b>R</b> Short-term External Heart Assist System	<b>Z</b> No Qualifier

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>2</b> Heart and Great Vessels			
<i>Operation</i> <b>P</b> Removal: Taking out or off a device from a body part			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>ADD W</b> Thoracic Aorta, Descending	<b>3</b> Percutaneous	<b>R</b> Short-term External Heart Assist System	<b>Z</b> No Qualifier

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>2</b> Heart and Great Vessels			
<i>Operation</i> <b>W</b> Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>ADD W</b> Thoracic Aorta, Descending	<b>3</b> Percutaneous	<b>R</b> Short-term External Heart Assist System	<b>Z</b> No Qualifier

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 11 – Measurement of Intracranial Electrical Activity for Status Epilepticus

**Issue:** There are currently no unique ICD-10-PCS codes to describe computer-aided measurement of intracranial electrical activity for status epilepticus.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. The Ceribell® Status Epilepticus Monitor received FDA Breakthrough Designation October 25, 2022. The Ceribell® Status Epilepticus Monitor software is indicated for the diagnosis of Electrographic Status Epilepticus in adult patients at risk for seizure. The Ceribell® Status Epilepticus Monitor software analyzes EEG waveforms and identifies patterns consistent with electrographic status epilepticus as defined in the American Clinical Neurophysiology Society’s Guideline 14. According to the requestor, FDA approval is anticipated in March 2023.

**Background:** Status epilepticus is a neurological emergency requiring immediate evaluation and management within an inpatient hospital intensive care unit. Status epilepticus is defined as a seizure with 10 minutes or more of continuous clinical and/or electrographic seizure activity or lasting for a total duration of  $\geq 20\%$  of any 60-minute period.<sup>1</sup> The diagnosis of status epilepticus is made clinically with emergent neuroimaging (CT scan, MRI, and EEG) and laboratory studies to identify a potential etiology.

Status epilepticus may be convulsive, non-convulsive, focal motor, myoclonic, and refractory. The optimal evaluation and treatment of patients requires an understanding of the type of status epilepticus and the underlying cause. Classifying the type of status epilepticus is necessary in determining morbidity and the aggressiveness of treatment required. Electroencephalograms (EEG) are crucial in distinguishing the different etiologies and types of status epilepticus and to guide treatment.<sup>2</sup> According to the requestor, current EEG technology can present challenges to standards of care due to limitations in equipment and delays of EEG study results.

### Technology

The Ceribell® Status Epilepticus Monitor is a medical device system consisting of a single-use patient headband, bedside recorder, and proprietary software that utilizes a machine learning model to obtain and analyze EEG signals to detect features indicative of electrographic status epilepticus. The system displays results or triggers alarms based on the output of the Status Epilepticus Monitor. The Ceribell® Status Epilepticus Monitor provides 24/7 real-time streaming to a secure cloud portal allowing physicians to review data from anywhere.

### Procedure Description

The Ceribell® Status Epilepticus Monitor is for hospital inpatient use. According to the requestor, the bedside clinician:

- places the single use headband on the patient

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<sup>1</sup>The American Clinical Neurophysiology Society’s (ACNS) Guideline 14 (“Standardized Critical Care EEG Terminology: 2021 Edition”).

<sup>2</sup>Wylie T, Sandhu DS, Murr N. Status Epilepticus. [Updated 2022 May 15]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK430686>

- connects the patient’s headband to the Ceribell® recorder
- enters patient information into the recorder, ensures that the headband’s EEG electrodes are properly connected
- selects the record function to begin the EEG recording and selects “status epilepticus” on the recorder to begin measuring the EEG for patterns that may be indicative of status epilepticus.

According to the requestor, the device provides clinicians the ability to render treatment immediately and receive precise feedback about treatment outcomes. Analysis results obtained from the Ceribell® Status Epilepticus System are able to be entered into the electronic medical record and be included in the hospital progress notes. The Ceribell® Status Epilepticus Monitor has not had any adverse outcomes or complications to date.

**Current Coding:** The use of software to aid in the detection and classification of status epilepticus is not reported separately for inpatient hospital coding. Facilities can report the EEG (electroencephalograph) measurement with the following ICD-10-PCS code:

4A00X4Z      Measurement of central nervous electrical activity, external approach

### Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for computer-aided measurement of intracranial electrical activity for status epilepticus. Continue coding as listed in current coding.

**Option 2.** Create new codes in section X, New Technology, to identify computer-aided measurement of intracranial electrical activity for status epilepticus.

<i>Section</i> <b>X</b> New Technology			
<i>Body System</i> <b>X</b> Physiological Systems			
<i>Operation</i> <b>E</b> Measurement: Determining the level of a physiological or physical function at a point in time			
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>0</b> Central Nervous	<b>X</b> External	<b>ADD 8</b> Brain Electrical Activity, Computer-aided Detection and Notification	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 12 – Monitoring of Intracranial Electrical Activity for Delirium

**Issue:** There are currently no unique ICD-10-PCS codes to describe computer-aided monitoring of intracranial electrical activity for delirium.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. The Ceribell® Delirium Monitor received FDA Breakthrough Designation on August 11, 2022. The Ceribell® Delirium Monitor software is intended to analyze electroencephalogram (EEG) patterns that may be indicative of delirium. According to the requestor, FDA market clearance is anticipated to be received in Q2 2023.

**Background:** Delirium is an acute confusional state characterized by an alteration of consciousness with reduced ability to focus, sustain, or shift attention. This results in a cognitive or perceptual disturbance. Delirium develops over a short period of time (usually hours to days) and tends to fluctuate during the course of the day. Delirium is typically caused by a medical condition, substance intoxication, or medication side effect. Delirium may manifest as hyperactive or hypoactive. Hyperactive delirium includes agitation, aggression, mood swings, insomnia, hallucinations and psychosis. Conversely, hypoactive delirium is indicative of lower activity levels including lethargy, apathy, fatigue, delayed response and can be misdiagnosed as depression.

Any condition that results in a hospital admission increases the chance of an individual experiencing delirium, regardless of age. The circumstances surrounding delirium diagnosis often include post-op recovery and stays in intensive care units (ICU). Patients with delirium can experience prolonged hospitalizations, functional and cognitive decline, higher mortality, and higher risk for institutionalization. There are two important aspects to the diagnostic evaluation of delirium: recognizing that the disorder is present and uncovering the underlying medical illness that has caused delirium. An assessment emphasizing the level of consciousness, degree of attention or inattention, visual fields, and unambiguous cranial nerve and motor deficits is important to identify individuals that are at risk for developing delirium.

In the absence of an obvious cause for delirium, testing can include neuroimaging, lumbar puncture, and electroencephalography (EEG).

### Technology

The Ceribell® Delirium Monitor is a medical device system consisting of a single-use patient headband, bedside recorder, and proprietary software that utilizes a machine learning model to analyze EEG signals to detect delirium and guide caregiving decisions. According to the requestor, use of the Ceribell® Delirium Monitor at the bedside can allow for objective assessments in real-time allowing providers to trend and treat patients appropriately and without unnecessary delays in care.

The system displays results and triggers alarms based on the output of the Ceribell® Delirium Monitor. The headband is connected to a bedside recorder and is continually worn by the patient. One disposable headband per day is required. Multiple headbands may be required for the patient beyond the first day of monitoring for delirium. Once EEG data is collected, the software utilizes a machine learning model to analyze EEG signals to detect features indicative of delirium. The

Ceribell® Delirium Monitor is enabled with 24/7 real-time streaming to a secure cloud portal to enable physicians to review the data from anywhere and make the updates to the treatment plan.

**Procedure Description**

The Ceribell® Delirium Monitor is for hospital inpatient use. According the requestor, the bedside clinician:

- places the single-use headband on the patient
- connects the patient’s headband to the Ceribell® recorder
- enters patient information into the recorder, ensures that the headband’s EEG electrodes are properly connected and then
- selects the record function to begin the EEG recording and selects “delirium” on the recorder to begin measuring and monitoring the EEG for patterns that may be indicative of delirium

Analysis results obtained from the Ceribell® Delirium Monitor are able to be entered into the electronic medical record and can be included in the hospital progress notes. According to the requestor, the Ceribell® Delirium Monitor has not had any adverse outcomes or complications to date.

**Current Coding:** The use of software to aid in the detection and classification of delirium is not reported separately for inpatient hospital coding. Facilities can report the EEG (electroencephalograph) monitoring with the following ICD-10-PCS code:

4A10X4Z      Monitoring of central nervous electrical activity, external approach

**Coding Options**

**Option 1.** Do not create new ICD-10-PCS codes for computer-aided monitoring of intracranial electrical activity for delirium. Continue coding as listed in current coding.

**Option 2.** Create new codes in section X, New Technology, to identify computer-aided monitoring of intracranial electrical activity for delirium.

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>X</b> Physiological Systems		
<i>Operation</i>	<b>2</b> Monitoring: Determining the level of a physiological or physical function repeatedly over a period of time		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>0</b> Central Nervous	<b>X</b> External	<b>ADD 8</b> Brain Electrical Activity, Computer-aided Detection and Notification	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 13 – Rapid Antimicrobial Susceptibility Testing System for Blood and Body Fluid Cultures

**Issue:** There are currently no unique ICD-10-PCS codes to describe the rapid antimicrobial susceptibility testing of positive blood and body fluid cultures using phenotypic susceptibility.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. The Selux Rapid AST Platform was designated Breakthrough Device status by the FDA on September 21, 2021. According to the requestor, FDA 501(k) clearance for Selux Rapid AST Platform is anticipated by June 2023.

**Background:** Sepsis is a global health threat responsible for at least 11 million deaths per year.<sup>1</sup> Sepsis is the number one cause of death<sup>2</sup> and readmission<sup>3</sup> in hospitals, the number one contributor to healthcare cost,<sup>4</sup> and are most often caused by bacterial blood stream infections (BSIs). Blood stream infections are diagnosed by a positive blood culture followed by gram-staining, microbial identification, and antimicrobial susceptibility testing (AST). AST is performed by clinical laboratories to determine if disease causing bacteria are phenotypically resistant or susceptible to various antibiotic therapy options. Phenotypic AST results are critical to guide targeted therapy.

Currently, prior to beginning AST testing, a positive blood culture must be subcultured for ~18 hours before AST testing can begin. Once subculture is complete and there is sufficient growth on the culture plate, AST testing is performed via broth microdilution, disk diffusion or automated AST instrumentation such as Vitek 2, Phoenix or Microscan. These legacy AST options vary in time-to-result from ~10 hours to greater than 24 hours. This 10 to 24-hour time-to-result assumes that the bacteria are not multi-drug resistant, in which case another ~10-24 hours are required for reflex testing.

### Technology

The Selux Rapid AST Platform is a phenotypic antimicrobial susceptibility testing (AST) system, intended to assist medical professionals in the identification of in vitro susceptibility or resistance to specific antimicrobial agents. The technology is intended for use with bacteria separated from monomicrobial positive blood cultures or sterile body fluid culture samples from non-charcoal-containing types of BACTEC, BacT/ALERT, VIRTUO and VersaTREK blood culture bottles. The Selux Rapid AST System supports antimicrobial susceptibility testing on a subset of aerobic and facultative anaerobic gram-negative and gram-positive species, enabling AST result reporting of relevant drugs in <6.5-hours for patients being confirmed as bacteremic.<sup>5</sup> The Selux Positive Blood

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<sup>1</sup> Rudd, Kristina E., Johnson, Charlotte, and et. al. "[Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study.](#)" Volume 395, Issue 10219, p200-211, January 18, 2020.

<sup>2</sup> Rhee C, Jones TM, Hamad Y, et al. "[Prevalence, Underlying Causes, and Preventability of Sepsis-Associated Mortality in US Acute Care Hospitals.](#)" JAMA Netw Open. 2019;2(2):e187571.

<sup>3</sup> Mayr FB, Talisa VB, Balakumar V, Chang CH, Fine M, Yende S. "[Proportion and Cost of Unplanned 30-Day Readmissions After Sepsis Compared With Other Medical Conditions.](#)" JAMA. 2017;317(5):530–531.

<sup>4</sup> Torio, Celeste and Brian Moore. "[National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2013.](#)" Agency for Healthcare Research and Quality. May 2016.

<sup>5</sup> van Belkum A., Burnham C.A., Rossen J.W.A., Mallard F., et al (2020). Innovative and rapid antimicrobial susceptibility testing systems. Nature Reviews Microbiology. 18, 299-311.



Culture (PBC) Separator and Analyzer could eliminate the need for the 18-hour bacterial subculture and decrease the AST time-to-result to ~6 hours, therefore providing definitive AST results potentially days sooner than legacy methods.

According to the requestor, the Selux Rapid AST is unique in its ability to simultaneously provide rapid, comprehensive results for up to 40 drugs in parallel per sample. Additionally, the system is designed so that only Gram stain information is required to perform AST. While result reporting requires species-level identification (ID), this information is not required at any point during testing and may be entered after AST testing is complete. Species ID can be performed by any appropriate method and this information can be either manually input to the Selux system or automatically downloaded from the laboratory information system (LIS) at any time, once the sample ID is entered into the LIS.

### **Procedure Description**

The Positive Blood Culture (PBC) Separator is designed to enable users to initiate AST testing from a positive blood culture bottle. It is an automated sample preparation device that utilizes a user-loaded consumable to automatically prepare a tuned microorganism suspension in saline (an inoculum) from an aliquot of a positive blood culture bottle. The PBC Separator removes interfering substances from intact microorganisms with centrifugation and a targeted, mammalian cell-specific lytic reagent. It then automatically tunes the optical density of the inoculum through iterative dilution/spectroscopic measurement steps.

When the inoculum is prepared, the user transfers it to the Inoculator together with the appropriate gram-positive or gram-negative panel (based on Gram stain results). Selux's consumable panels are 384-well microplates that provide 3-6-fold more tests per sample than competitive AST platforms. This enables a significant number of gram-positive (15) and gram-negative (24) drugs routinely used in clinical care to each be present on a single panel and further provides room for inclusion of future antibiotics. After inoculation, the panel is loaded into the random-access Analyzer for walk-away processing, which averages 5.6 hours. After the sample ID is available, either electronically from the LIS or manually entered, the system displays the AST results.

**Current Coding:** The rapid antimicrobial susceptibility testing of positive blood and body fluid cultures 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 antimicrobial susceptibility testing of positive blood and body fluid cultures using phenotypic susceptibility. Continue coding as listed in current coding.

**Option 2.** Create new codes in section X, New Technology, to identify rapid antimicrobial susceptibility testing of positive blood and body fluid cultures using phenotypic susceptibility.

<i>Section</i> <b>X</b> New Technology			
<i>Body System</i> <b>X</b> Physiological Systems			
<i>Operation</i> <b>E</b> Measurement: Determining the level of a physiological or physical function at a point in time			
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>5</b> Circulatory	<b>X</b> External	<b>ADD Y</b> Infection, Other Positive Blood/Isolated Colonies Bimodal Phenotypic Susceptibility Technology	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## **Topic # 14 – Percutaneous Hepatic Perfusion with Administration of Melphalan Hydrochloride**

**Issue:** There are currently no unique ICD-10-PCS codes to describe percutaneous arterial hepatic perfusion with administration of melphalan hydrochloride.

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

**Food & Drug Administration (FDA) Approval?** No. Delcath intends to submit a New Drug Application (NDA) to the FDA in Quarter 1 2023 with a proposed indication for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM) as first-line treatment, or in patients who have been previously treated.

**Background:** Ocular melanoma (OM) is a rare and aggressive cancer with an estimated 3,320 new cases and 400 deaths in the US in 2021. More than half of patients diagnosed with OM develop metastatic ocular melanoma (mOM), the majority of which (93%) metastasizes to the liver. The reported incidence of mOM is 4.637 per million in the US. Due to a lack of effective treatment options, metastatic ocular melanoma (mOM) has a poor prognosis with a recent meta-analysis reporting overall survival of 10.2 months, 1-year overall survival of 43%, and median progression-free survival of 3.3 months.

Where possible, metastatic ocular melanoma is treated through surgical resection, although this is not always feasible, and clinicians may employ a range of liver-directed and systemic therapies. Liver-directed therapies can be utilized to deliver targeted treatment to the liver, including regional isolation perfusion of the liver, embolization techniques, and ablative procedures. Systemic therapies use drugs to deliver treatment throughout the body via blood circulation so as to have an effect on all cells throughout the body, including cancerous cells. However, there are currently no systemic therapies that have reliably demonstrated improvement in overall survival outcomes in patients with mOM in the liver. While other therapies are being studied to treat mOM, there are currently no FDA-approved liver-directed therapies for patients with liver-dominant mOM.

### **Technology**

The HEPZATO™ KIT (melphalan hydrochloride/Hepatic Delivery System) is a drug/device combination intended for the treatment of patients with unresectable primary and metastatic tumors in the liver. The kit consists of a closed circuit of double balloon catheters, infusion catheters, venous sheaths and filters utilized to deliver chemotherapeutic agent (melphalan hydrochloride) to the hepatic artery of the liver to allow for hemofiltration and delivery of the chemotherapy. Melphalan hydrochloride (HCl) is a well-established, broadly effective anticancer chemotherapeutic agent belonging to the alkylating class and is responsible for the combination product's primary mode of action. The HEPZATO™ KIT allows for isolation of the hepatic arterial inflow and hepatic venous outflow, which allows melphalan HCl to be delivered directly to unresectable liver metastases while sparing healthy liver tissue and limiting systemic exposure.

The Hepatic Delivery System (HDS) is used to perform Percutaneous Hepatic Perfusion (PHP), an intensive local hepatic chemotherapy procedure in which the alkylating agent melphalan HCl, is delivered intra-arterially to the liver with simultaneous extracorporeal filtration of hepatic venous

blood return (hemofiltration). During PHP, three catheters are placed percutaneously through standard interventional radiology techniques. The liver is temporarily isolated from the body's circulatory system by occluding the inferior vena cava (IVC) above the highest hepatic vein and also below the lowest hepatic vein, during which time a 30-minute infusion of the chemotherapeutic agent melphalan HCl directly to the liver occurs. The blood is collected as it exits the liver for filtration by proprietary filters prior to returning it to the patient. All items inserted are removed at the end of the procedure and are not considered permanent. Additionally, the hemofiltration system is extracorporeal.

In the United States, Delcath's system for PHP has been evaluated in a Phase III study for patients with unresectable ocular and cutaneous liver metastases. In the Phase III study, the following adverse events were reported: Among the 94 patients assessed for safety after treatment with PHP, 42.6% of patients experienced a serious treatment-emergent adverse event (TEAE), the majority of which were hematological, transient in nature, and were resolved without sequelae.

### **Procedure Description**

In PHP, all procedures are performed under general anesthesia due to the length of the procedure and hemodynamic changes that occur with the extracorporeal hemofiltration circuit and inferior caval vein occlusion. The patient has an arterial line placed (for monitoring of arterial pressure), triple lumen catheter placed (for central venous pressure), and Foley catheter placed (for fluid management). The contralateral internal jugular vein is accessed with a 10F venous return sheath, the common femoral artery (CFA) is accessed with a 5F sheath and common femoral vein (CFV) is accessed with a 18F sheath. After all lines are placed, heparin is administered as needed, commencing with 300 U/kg body weight, followed by repeated smaller bolus injections as required to maintain an activated clotting time (ACT) above 400 seconds, which is mandatory for safe extracorporeal hemofiltration.

A double-balloon catheter is inserted via the CFV under fluoroscopic guidance into the IVC and connected to extracorporeal hemofiltration circuit. The cephalad balloon of the catheter is inflated in the right atrium and retracted into the IVC. A centrifugal pump is used to achieve appropriate flow rates. The hemofiltration filters are brought online after the cartridges are completely filled with blood (in preparation to initiate hemofiltration following chemotherapy). Fluoroscopy/venogram is then performed to confirm correct balloon positions. Venous bypass lines are occluded using the cephalad balloon to occlude the IVC above the highest hepatic vein and the caudal balloon to occlude the IVC below the lowest hepatic vein. When the hemofiltration circuit is running adequately and the patient is hemodynamically stable, intra-hepatic arterial infusion of melphalan HCl is started (3 mg/kg correct for the patient's body weight) and infused for 30 minutes. Following arterial infusion, hemofiltration is performed for 30 minutes.

After the melphalan HCl hemofiltration procedure, filtration is discontinued and protamine sulphate is infused to reverse heparinization. Blood products are transfused to replace clotting factors if needed. The caudal and then cephalad balloons are deflated. Once the patient's coagulation profile normalizes, vascular sheaths are removed and pressure is held on all catheter sites for 45 minutes. Procedural data is then retrospectively collected from radiology reports and interventional protocols.

**Current Coding:** There are no unique ICD-10-PCS codes to describe percutaneous hepatic perfusion with administration of melphalan hydrochloride. Code the procedure by assigning both codes below, found in tables 5A1 Extracorporeal or Systemic Assistance and Performance, 3E0, Introduction respectively.

5A1C00Z      Performance of biliary filtration, single  
and  
3E05305      Introduction of other antineoplastic into peripheral artery, percutaneous  
approach

### Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for percutaneous hepatic perfusion with administration of melphalan hydrochloride. Continue coding as listed in current coding.

**Option 2.** Create new codes in section X, New Technology, to identify percutaneous hepatic artery administration of melphalan hydrochloride. A separate code would continue to be reported for the hepatic filtration procedure from table 5A1, Extracorporeal or Systemic Assistance and Performance, as described in current coding.

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>W</b> Anatomical Regions		
<i>Operation</i>	<b>0</b> Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>ADD 5</b> Peripheral Artery	<b>3</b> Percutaneous	<b>ADD T</b> Melphalan Hydrochloride Antineoplastic	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 15 – Monitoring of Muscle Compartment Pressure

**Issue:** There are currently no unique ICD-10-PCS codes to describe monitoring of muscle compartment pressure.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** Yes. The MY01 Continuous Compartmental Pressure Monitor received FDA clearance on May 24, 2022.

**Background:** Compartments are groupings of muscles, nerves, and blood vessels in the arms and legs. Covering these tissues is a tough membrane called a fascia. The role of the fascia is to keep the tissues in place, and, therefore, the fascia does not stretch or expand easily. Compartment syndrome develops when swelling or bleeding occurs within a compartment, usually after a traumatic event. Because the fascia does not stretch, this can cause increased pressure on the capillaries, nerves, and muscles in the compartment. Blood flow to muscle and nerve cells is disrupted. Without a steady supply of oxygen and nutrients, nerve and muscle cells can be damaged or die. In acute compartment syndrome, unless the pressure is relieved quickly, permanent disability and tissue death may result. This does not usually happen in chronic (exertional) compartment syndrome. Compartment syndrome most often occurs in the anterior (front) compartment of the lower leg (calf). It can also occur in other compartments in the leg as well as in the arms, hands, feet, and buttocks.

Currently, physicians rely on the clinical indicators of Compartment Syndrome as the main method of diagnosis. The six clinical indicators are known as the six P's. The six P's include: (1) Pain, (2) Poikilothermia, (3) Paresthesia, (4) Paralysis, (5) Pulselessness, and (6) Pallor.

### Technology

The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of muscle compartment pressure. The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician.

The MY01 device is supplied sterile for single patient use and intended to be used up to 18 hours, it contains two major components that are referred to as the Introducer (plastic housing and 17-gauge stainless-steel needle) and the Pressure Monitor. The Pressure Monitor consists of a capacitive Micro-Electro-Mechanical System (MEMS) pressure sensor, which allows for the measurement of intracompartmental pressure relative to a secondary atmospheric pressure sensor. It is embedded on a flexible PCB circuit, which extends via a lead-wire to a rigid PCB circuit within the Pressure Monitor. The Introducer allows for placement of the pressure sensor into muscle compartments. The Pressure Monitor continuously outputs pressure values on the LCD screen and can be attached on the patient's skin using the provided adhesive strip on the underside. The MY01 device then enables continuous monitoring of pressure in the muscle compartment to aid in diagnosis of Compartment Syndrome. The measured muscle compartment pressure can be used as an aid in the diagnosis of Compartment Syndrome (Acute and Chronic). Diagnosis should always be made in conjunction with clinical assessments.

## Procedure Description

The MY01 Continuous compartmental Pressure Monitor is switched ON using the push-button. The device will display zero value on display, at this point the device is ready to use. Using the introducer, the sensor is inserted in the desired position. Once the sensor is in the desired position and the readings have stabilized, the pressure monitor can be separated from the Introducer by pressing through the back opening of the introducer and rotating it at 180 degrees to eject the introducer from the monitor. Peelable adhesive strip will be exposed at the back of ejected pressure monitor, this is used to attach the monitor on patients' intact skin.

MY01 device uses wireless communication protocol, a secure and encrypted BLE link, to transmit data to the MY01 mobile application. Once a secure connection is established, authenticated users of the MY01 mobile application can login to view real-time pressure data measurements. Users can view the pressure data as a duplicate display and as a graph. The graphical display option offers physicians visual cues on sudden excursions in real-time. The MY01 Application allows users to manually input diastolic pressure measurement for retrospective calculation of perfusion pressure. Both diastolic and compartment pressures are sent to cloud-based server for data logging, archival and perfusion pressure calculation.

The MY01 device is not considered permanent. The device allows for 5 single-point insertions before inserting it into a muscle compartment for continuous monitoring for up to 18 hours. Only one device is routinely inserted. However, as per physician's discretion, multiple devices may be used to monitor different muscle compartments at-risk.

**Current Coding:** There are no unique ICD-10-PCS codes to describe the monitoring of muscle compartment pressure. Facilities can report the procedure using the following code:

4A0F3BE Measurement of musculoskeletal pressure, compartment, percutaneous approach

## Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for the monitoring of muscle compartment pressure. Continue coding as listed in current coding.

**Option 2.** Create new codes in section X, New Technology, to identify the monitoring of muscle compartment pressure.

<i>Section</i>	X New Technology		
<i>Body System</i>	X Physiological Systems		
<i>Operation</i>	2 Monitoring: Determining the level of a physiological or physical function repetitively over a period of time		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
ADD F Musculoskeletal	3 Percutaneous	ADD W Muscle Compartment Pressure, Micro-Electro-Mechanical System	9 New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 16 – Insertion of Tibial Extension Implant during Total Knee Arthroplasty

**Issue:** There are currently no unique ICD-10-PCS codes to describe insertion of a tibial extension containing motion sensors during Total Knee Arthroplasty (TKA).

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** Yes. The Canary Medical, Inc. Canturio™ Tibial Extension with Canary Health Implanted Reporting Processor (CHIRP™) System received FDA 510(k) De Novo clearance on August 27, 2021. The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension. The system is intended to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care.

**Background:** Total knee arthroplasty (TKA) is one of the most performed orthopedic procedures. As of 2010, over 600,000 TKAs were being performed annually in the United States and were increasingly common.<sup>1</sup> TKA is usually performed on an elective basis and is considered after exhaustion of appropriate nonsurgical therapies and extensive discussion of the risks, benefits, and alternatives. Patients who have tried other treatments but continue to suffer from painful osteoarthritis or damaged knee joints are eligible for a total knee arthroplasty. TKA consists of resection of the diseased articular surfaces of the knee, followed by resurfacing with metal and polyethylene prosthetic components. Successful total knee arthroplasty (TKA) depends in part on re-establishment of normal lower extremity alignment, proper implant design and orientation, secure implant fixation, and adequate soft tissue balancing and stability.<sup>2</sup>

Currently, fixation techniques involve either using cement to fix the prosthesis to the bone or relying on bone growth into and onto the prosthesis surface without embedded electronics or motion sensors. Several technologies have been developed to enable the surgeon to implant the TKA implant more accurately. Manual instruments referencing the bony alignment and surfaces, navigation systems, and patient-specific guides are used to assist surgeons in making the required bony cuts to facilitate the placement of the prosthetic components.

### Technology

The Canturio™ te (CTE) with Canary Health Implanted Reporting Processor (CHIRP™) is a tibial extension containing electronics and software. The requestor states it can only be used with Zimmer Biomet's Persona® The Personalized Knee® prosthesis. Combined, the technology is named Persona IQ® The Smart Knee®. Using internal motion sensors (3-D accelerometers and 3-D gyroscopes), the CTE implant collects kinematic data pertaining to a patient's gait and activity level following TKA.

The kinematic data produced by the CTE implant is intended as an adjunct to other physiological parameter measurement tools used post-TKA procedure as directed by the physician. In addition to

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<sup>1</sup> HCPUnet, Healthcare Cost and Utilization Project. Agency for Healthcare Research and Quality. <http://hcupnet.ahrq.gov> (Accessed on December 20, 2012).

<sup>2</sup> Cram P, Lu X, Kates SL, et al. Total knee arthroplasty volume, utilization, and outcomes among Medicare beneficiaries, 1991-2010. JAMA 2012; 308:1227.



its data collection capabilities, the CTE implant also provides stability to the knee implant in the same manner as a traditional tibial extension.

According to the requestor, the device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58mm sized tibial stem extension. Additional components of the CTE with CHIRP™ system include the following subsystems: Surgical Base Station System (“BS1”), Home Base Station System (“BS2”), Canary Cloud Data Management Platform (“Cloud” or “CMDP”), and Canary Medical Gait Parameters (CMGP) software module (a stand-alone software module).

### Procedure Description

The Canary Medical Canturio™ Tibial Extension (CTE) is designed for single use and assembled with the Zimmer Biomet Persona® Personalized Knee System. It is implanted during a standard unilateral or bilateral total knee arthroplasty procedure in an inpatient hospital or outpatient facility. Prior to TKA surgery the CTE implant must be paired with the O.R. base station. The surgeon can choose a midvastus approach, a subvastus approach, or a parapatellar medial arthrotomy. Also, depending on surgeon preference, the patella can be either everted or subluxed. The femur, tibia, and patella are prepared independently, and can be cut in any sequence using the principle of measured resection or gap balancing. Measure and select the optimal component(s) sizes and drill the fixation holes. Size the tibia for the appropriate implant and prepare the bone. To ensure limb alignment, soft tissue and ligamentous balance and prosthetic interactions trial components are used and then removed. Clean the bony surfaces with pulsatile lavage. Cement the final implants into place. Reconfirm knee stability, ROM, and alignment. The tourniquet is released, hemostasis obtained, a deep drain placed and the wound is closed in layers. Post-operatively, the Persona IQ® implant is wirelessly linked with the patient's personal account for ongoing device monitoring.

Documentation of the Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP™) System implant procedure will be included in the operative report. The tibial extension embedded with electronics and motion sensors is a permanent implant. A single tibial extension is implanted in either the right or left knee joint during a single operative session. Patients who have significant wear, instability or infection may need a revision, removal or replacement procedure. According to the requestor, the Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP™) System has not had any adverse outcomes or complications to date.

**Current Coding:** There are no unique ICD-10-PCS codes to describe insertion of a tibial extension containing motion sensors during TKA. Code the procedure using the knee region body part values in table 0YH, Insertion of Anatomical Regions, Lower Extremities, with approach value 0 Open and device value Y Other Device. Facilities would also report the total knee arthroplasty.

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>Y</b> Anatomical Regions, Lower Extremities			
<i>Operation</i> <b>H</b> 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			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>0</b> Buttock, Right	<b>0</b> Open	<b>1</b> Radioactive Element	<b>Z</b> No Qualifier
<b>1</b> Buttock, Left	<b>3</b> Percutaneous	<b>3</b> Infusion Device	
<b>5</b> Inguinal Region, Right	<b>4</b> Percutaneous Endoscopic	<b>Y</b> Other Device	

<b>6</b> Inguinal Region, Left <b>7</b> Femoral Region, Right <b>8</b> Femoral Region, Left <b>9</b> Lower Extremity, Right <b>B</b> Lower Extremity, Left <b>C</b> Upper Leg, Right <b>D</b> Upper Leg, Left <b>F</b> Knee Region, Right <b>G</b> Knee Region, Left <b>H</b> Lower Leg, Right <b>J</b> Lower Leg, Left <b>K</b> Ankle Region, Right <b>L</b> Ankle Region, Left <b>M</b> Foot, Right <b>N</b> Foot, Left			
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### Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for insertion of a tibial extension containing motion sensors. Continue coding as described in current coding.

**Option 2.** In New Technology Insertion table XNH, Insertion of Bones, create new device value D Tibial Extension with Motion Sensors, applied to the body part values G Tibia, Right and H Tibia, Left, to identify insertion of a tibial extension containing motion sensors. Continue to report the total knee arthroplasty.

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>N</b> Bones		
<i>Operation</i>	<b>H</b> 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		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>ADD G</b> Tibia, Right <b>ADD H</b> Tibia, Left	<b>0</b> Open	<b>ADD D</b> Tibial Extension with Motion Sensors	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 17 – Implantation of Total Talar Prosthesis with Total Ankle Replacement

**Issue:** There are currently no unique ICD-10-PCS codes to describe implantation of a total talar prosthesis with a total ankle replacement.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. The requestor is seeking approval for the Total Ankle Talar Replacement™ (TATR) indicated for talar dysfunction with patients who require mating to a total ankle replacement system. The anatomical landmarks necessary for the design and creation of the patient specific TATR device must be present and identifiable on appropriate radiography scans. According to the requestor, FDA clearance is anticipated by June 30, 2023.

**Background:** The talus is involved in the transmission of force between the lower leg and the foot and bears the weight of the body, and thus it is composed of dense bone. The superior surface of the talus bears a greater load per unit area than any other bone.<sup>1</sup> Dysfunctions of the talus are often associated with diagnoses such as ankle arthritis, talar osteomyelitis, talar trauma, avascular necrosis, degenerative joint disease, and failed ankle arthroplasty. Current standards of care for management of talus dysfunction include pharmacological and surgical interventions. Total ankle replacement (TAR) can relieve pain and improve function while preserving the range of motion of the ankle joint.<sup>2</sup> Eligibility for TAR is dependent on the patient's talar function and if sufficient talar bone stock is present.<sup>3</sup> Replacing part or all of the talus with a customized prosthesis has been developed for the treatment of the pathologies affecting the talus. The requestor states that the current technology does not replace talus bone and function with ankle replacements simultaneously.

### Technology

According to the requestor, 4WEB® Medical's Total Ankle Talar Replacement™ (TATR) devices are patient specific, metallic spacers that are solid, polished cobalt chrome replicas of a patient's physiologic talus, comprised of the talar dome, body and head. The device utilizes patient radiographic data (e.g., CT) to create talar volume and is indicated for talar dysfunction with patients who require mating to a total ankle replacement system. The technology is designed to mimic a patient's physiologic talar body/head and articulates to the surrounding native bone anatomy. Specifically, the talar replacement is shaped to match patient anatomy at talonavicular and talocalcaneal joint surfaces.

However, the dome is mapped so that it matches that of a third-party ankle system. Therefore, the body and head are patient-specific, while the dome mimics third-party dome specifications. The Total Ankle Talar Replacement™ (TATR) device is used with a premarket authorized total ankle arthroplasty system as part of an ankle replacement procedure. The purpose of the TATR device is to preserve ankle joint movement by mating to ankle replacement tibial components, preserve movement in talonavicular and talocalcaneal joints by mating to native anatomy, and to replace the entire talar volume. Per the requestor, implantation of the device allows restoration of function due to losses attributed to talar dysfunction.

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<sup>1</sup> Schachter AK, Chen AL, Reddy PD, Tejwani NC. Osteochondral lesions of the talus. *J Am Acad Orthop Surg* 2005; 13:152.

<sup>2</sup> Morita S, Taniguchi A, Miyamoto T, et al. The Long-Term Clinical Results of Total Talar Replacement at 10 Years or More After Surgery. *J Bone Joint Surg Am.* 2022;104(9):790-795. doi:10.2106/JBJS.21.00922.

<sup>3</sup> Harnroongroj T, Vanadurongwan V. The talar body prosthesis. *J Bone Joint Surg Am.* 1997;79(9):1313-1322.

## Procedure Description

In the inpatient setting, implantation of the Total Ankle Talar Replacement™ (TATR) device is performed unilaterally with a total ankle replacement procedure or retroactively, as part of an ankle replacement revision.

In general, the implantation procedure for a TATR device involves the following steps:

1. Tibial preparation and resection per ankle replacement surgical technique
2. Native talus removed
3. Total Ankle Talar Replacement™ trial implants used to determine appropriate implant size
4. Total Ankle Talar Replacement™ device deployed
5. Ankle replacement components deployed

The procedure will be documented in the operative report. The requestor indicated the 4WEB Total Ankle Talar Replacement™ is a novel device and has not had any adverse events or complications reported to date.

**Current Coding:** There are no unique ICD-10-PCS codes to describe implantation of a total talar prosthesis with a total ankle replacement. When the total talar prosthesis is implanted concurrently with an initial total ankle replacement, code the procedure using the appropriate tarsal bone body part values in table 0QR, Replacement of Lower Bones, with approach value 0 Open and device value J Synthetic Substitute. Facilities would also report the total ankle replacement with the appropriate code from table 0SR, Replacement of Lower Joints.

When the total talar prosthesis is implanted for revision of a prior total ankle replacement, facilities would code the procedure using the Tarsal Bone body part values L or M in table 0QR, Replacement of Lower Bones, with approach value 0 Open and device value J Synthetic Substitute. Facilities would also report the appropriate diagnosis code from subcategory Z96.66- (Presence of artificial ankle joint) to identify the presence of an ankle joint prosthesis.

<i>Section</i>	0 Medical and Surgical		
<i>Body System</i>	Q Lower Bones		
<i>Operation</i>	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		
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
0 Lumbar Vertebra			
1 Sacrum			
2 Pelvic Bone, Right			
3 Pelvic Bone, Left			
4 Acetabulum, Right			
5 Acetabulum, Left			
6 Upper Femur, Right			
7 Upper Femur, Left			
8 Femoral Shaft, Right			
9 Femoral Shaft, Left	0 Open	7 Autologous Tissue Substitute	
B Lower Femur, Right	3 Percutaneous	J Synthetic Substitute	Z No Qualifier
C Lower Femur, Left	4 Percutaneous Endoscopic	K Nonautologous Tissue Substitute	
D Patella, Right			
F Patella, Left			
G Tibia, Right			
H Tibia, Left			
J Fibula, Right			
K Fibula, Left			
L Tarsal, Right			
M Tarsal, Left			

N Metatarsal, Right P Metatarsal, Left Q Toe Phalanx, Right R Toe Phalanx, Left S Coccyx			
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**Coding Options**

**Option 1.** Do not create new ICD-10-PCS codes for implantation of talar prosthesis with total ankle replacement. Continue coding as described in current coding.

**Option 2.** In New Technology Replacement table XNR, Replacement of Bones, create new device value 9 Synthetic Substitute, Talar Prosthesis, applied to the body part values L Tarsal, Right and M Tarsal, Left, to identify implantation of talar prosthesis. Continue to report the total ankle replacement as described in current coding.

<i>Section</i> <b>X</b> New Technology			
<i>Body System</i> <b>N</b> Bones			
<i>Operation</i> <b>R</b> 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			
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>ADD L</b> Tarsal, Right <b>ADD M</b> Tarsal, Left	<b>0</b> Open	<b>ADD 9</b> Synthetic Substitute, Talar Prosthesis	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 18 – Implantation of Open-Truss Ankle Fusion Device

**Issue:** There are currently no unique ICD-10-PCS codes to describe an open-truss fusion device for the ankle and subtalar joint that is used to restore height and provide stabilization during an ankle joint fusion.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. The 4WEB<sup>®</sup> Ankle Truss System<sup>™</sup> (ATS) received Breakthrough Device Designation from the FDA on October 4, 2022 for use with a premarket authorized tibiototalcalcaneal (TTC) nail as part of a TTC fusion system. According to the requestor, clearance is anticipated by June 30, 2023.

**Background:** Defects to the ankle bones can cause disabling conditions that cause substantial functional impairment and decreased quality of life.<sup>1</sup> Multiple etiologies may threaten a patient's lower extremity, including acute trauma, nonhealing wounds due to underlying peripheral vascular disease or diabetes, infection, degenerative disease, osteonecrosis, resection for malignancy, and congenital deformities.<sup>2</sup> Total ankle replacement (TAR) and ankle joint fusion procedures are the two primary surgical options for patients experiencing symptoms that are not alleviated by non-invasive measures.

TAR was developed as an alternative to ankle fusion. The preserved mobility of the ankle joint in TAR can be accompanied by a more successful functional outcome and a better protection of adjacent articulations.<sup>3</sup> However, there are also disadvantages in that TAR may be more sensitive to complications, failure and subsequent re-operations when compared to ankle fusion.<sup>4</sup> Studies show that 28% of the patients that underwent total ankle replacement had to undergo one or more reoperation(s) due to complications.<sup>5</sup> The major complications in ankle fusion occurred 1.8 times more often compared to TAR but had a 29% lower risk of a minor complication after adjusting for patient and hospital factors, such as gender, age, and health-status.<sup>6</sup>

While current standards of care for ankle defects is fusion or TAR, unsuccessful outcomes associated with these procedures are linked to intramedullary nails that cannot address large ankle defects leading to limb length discrepancy, malalignment and malunion. Additionally, grafting within the procedure elicited a complication rate of 67% and nonunion rate of 42%. Per the requestor, the 4WEB<sup>®</sup> Ankle Truss System<sup>™</sup> (ATS) provides structural support to allow bone fusion across ankle bone defects, while preserving limb length that is needed for realignment.

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<sup>1</sup> Saltzman CL, Zimmerman MB, O'Rourke M, Brown TD, Buckwalter JA, Johnston R. Impact of comorbidities on the measurement of health in patients with ankle osteoarthritis. *J Bone Joint Surg Am.* 2006; 88:2366–72.

<sup>2</sup> Lachica RD. Evidence-Based Medicine: Management of Acute Lower Extremity Trauma. *Plast Reconstr Surg* 2017; 139:287e.

<sup>3</sup> R.W. Jordan, G.S. Chahal, A. Chapman Is end-stage ankle arthrosis best managed with total ankle replacement or arthrodesis? a systematic review *Adv Orthop* (2014), pp. 9862-9885.

<sup>4</sup> N.F. SooHoo, D.S. Zingmond, C.Y. Ko, Comparison of reoperation rates following ankle arthrodesis and total ankle arthroplasty *J Bone Jt Surg Am*, 89 (10) (2007), pp. 2143-2149, 10.2106/JBJS.F.01611

<sup>5</sup> A.A. Spirt, M. Assal, S.T. Hansen Jr. Complications and failure after total ankle arthroplasty *J Bone Jt Surg Am*, 86 (6) (2004), pp. 1172-1178, 10.2106/00004623-200406000-00008

<sup>6</sup> S.M. Odum, B.A. Van Doren, R.B. Anderson, W.H. Davis In-hospital complications following ankle arthrodesis versus ankle arthroplasty: a matched cohort study *J Bone Jt Surg Am*, 99 (17) (2017), pp. 1469-1475

**Technology**

According to the requestor, the 4WEB® Ankle Truss System™ (ATS) has an advanced structural design that incorporates the 4WEB® Truss Implant Technology’s™ open architecture design that consists of an empirically derived interconnected web of truss elements called struts. Under normal loading conditions, the struts in the truss implant transfer strain to adjacent cellular material which stimulates a mechanobiologic response. The requestor states that the open-truss architecture in the ATS devices allows for packing with bone graft, enabling fusion to occur across an ankle bone defect. The device features a central hole that accommodates a pre-market authorized intramedullary nail and is also designed to restore limb height while providing structural integrity for the limb during TTC fusions. The ATS implants are available in three general shapes: a spherical implant (ArthroSphere™), a spherical implant with a flat side, and a cuboidal implant (ArthroBlock™). The shape utilized is dependent on the size and shape of the bony defect. According to the requestor, the truss implant functions as a high-strength, lightweight structure with a significant amount of open space to accommodate bone growth throughout the entire construct.

**Procedure Description**

The 4WEB® Ankle Truss System™ (ATS) is a single, permanent device implanted via an open surgical procedure. The patient’s anatomy is prepared by performing resections and/or reaming via an anterior or trans-fibular approach. The nail trajectory is established based on the specific nail surgical technique. Next, the appropriate implant size is determined. Following selection of the implant, the central hole is plugged and graft material is packed into the implant. Once the ATS is in the desired position, the intramedullary nail is then deployed through the device. On a rare occasion, replacement or removal of the ATS device may be required due to loss of function or infection and would take place unilaterally during a single operative session.

Performance of the procedure will be documented in the operative report in the inpatient hospital setting. According to the requestor, the 4WEB® Ankle Truss System is a novel device and has not had any adverse outcomes or complications.

**Current Coding:** There are no unique ICD-10-PCS codes to describe an open-truss fusion device for the ankle and subtalar joint that is used to restore height and provide stabilization during an ankle joint fusion. Code the procedure using two codes with the appropriate ankle joint and tarsal joint body part values in table 0SG, Fusion of Lower Joints, with approach value 0 Open and device value 4 Internal Fixation Device.

<i>Section</i>	<b>0</b> Medical and Surgical			
<i>Body System</i>	<b>S</b> Lower Joints			
<i>Operation</i>	<b>G</b> Fusion: Joining together portions of an articular body part rendering the articular body part immobile			
	<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	
	<b>9</b> Hip Joint, Right		<b>3</b> Internal Fixation Device, Sustained Compression <b>4</b> Internal Fixation Device <b>5</b> External Fixation Device <b>7</b> Autologous Tissue Substitute <b>J</b> Synthetic Substitute <b>K</b> Nonautologous Tissue Substitute	
	<b>B</b> Hip Joint, Left			
	<b>C</b> Knee Joint, Right	<b>0</b> Open		
	<b>D</b> Knee Joint, Left	<b>3</b> Percutaneous		
	<b>F</b> Ankle Joint, Right	<b>4</b> Percutaneous		
	<b>G</b> Ankle Joint, Left	Endoscopic		
	<b>H</b> Tarsal Joint, Right			
	<b>J</b> Tarsal Joint, Left			
	<b>K</b> Tarsometatarsal Joint, Right			
				<b>Z</b> No Qualifier

<b>L</b> Tarsometatarsal Joint, Left			
<b>M</b> Metatarsal-Phalangeal Joint, Right			
<b>N</b> Metatarsal-Phalangeal Joint, Left			
<b>P</b> Toe Phalangeal Joint, Right			
<b>Q</b> Toe Phalangeal Joint, Left			

**Coding Options**

**Option 1.** Do not create new ICD-10-PCS codes for an open-truss fusion device for the ankle and subtalar joint that is used to restore height and provide stabilization during an ankle joint fusion. Continue coding as described in current coding.

**Option 2.** In New Technology Fusion Table XRG, Fusion of Joints, create new device value B Internal Fixation Device, Open-truss Design, applied to body part values J Ankle Joint, Right and K Ankle Joint, Left, and body part values L Tarsal Joint, Right and M Tarsal Joint, Left to identify an open-truss fusion device for the ankle and subtalar joint that is used to restore height and provide stabilization during an ankle joint fusion.

<i>Section</i> <b>X</b> New Technology			
<i>Body System</i> <b>R</b> Joints			
<i>Operation</i> <b>G</b> Fusion: Joining together portions of an articular body part rendering the articular body part immobile			
	<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>
	<b>ADD J</b> Ankle Joint, Right <b>ADD K</b> Ankle Joint, Left <b>ADD L</b> Tarsal Joint, Right <b>ADD M</b> Tarsal Joint, Left	<b>0</b> Open	<b>ADD B</b> Internal Fixation Device, Open-truss Design
			<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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



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

**Issue:** Currently, there are no unique ICD-10-PCS codes to describe computer-aided measurement of intracranial vessel flow.

**New Technology Application?** No.

**Food & Drug Administration (FDA) Approval?** No. Rapid NCCT Stroke received FDA Breakthrough Designation status on January 6, 2021, and currently has a 510(k) application pending.

**Background:** A stroke is a life-threatening condition that happens when part of the brain doesn't have enough blood flow. Without a steady supply of blood, the brain cells start to die from a lack of oxygen. The two broad categories of stroke, hemorrhagic and ischemic, are diametrically opposite conditions: hemorrhage is characterized by too much blood within the closed cranial cavity, while ischemia is characterized by too little blood to supply an adequate amount of oxygen and nutrients to a part of the brain.<sup>1</sup> Approximately 800,000 primary (first-time) or secondary (recurrent) strokes occur each year in the U.S., with the majority being primary strokes (roughly 600,000). Of these strokes, approximately 87% are ischemic infarctions, 10% are primary hemorrhages, and 3% are subarachnoid hemorrhage.

Bleeding in intracerebral hemorrhage (ICH) is usually derived from arterioles or small arteries. The bleeding is directly into the brain, forming a localized hematoma which spreads along white matter pathways. Accumulation of blood occurs over minutes or hours. The most common causes of ICH are hypertension, trauma, bleeding diatheses, amyloid angiopathy, illicit drug use (mostly amphetamines and cocaine), and vascular malformations. Less frequent causes include bleeding into tumors, aneurysmal rupture, and vasculitis.

Acute ischemic stroke (AIS) is a leading cause of morbidity and mortality worldwide.<sup>2</sup> Large vessel occlusions (LVOs), defined as blockages of the proximal intracranial anterior and posterior circulation, account for approximately 24% to 46% of AISs. The most disabling strokes are those due to LVOs, and treatment of these strokes has the largest therapeutic benefits. Ischemic strokes with an LVO tend to be more severe as LVOs often result in insufficient blood flow to brain parenchyma, causing cellular bioenergetic failure and inflammatory cascades that culminate in the death of neurons, glia, and endothelial cells.<sup>3</sup> Mechanical thrombectomy (MT) preceded by intravenous thrombolysis with alteplase has become standard treatment in stroke patients with acute ischemic stroke caused by LVO.<sup>4</sup>

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<sup>1</sup> Caplan LR. Basic pathology, anatomy, and pathophysiology of stroke. In: Caplan's Stroke: A Clinical Approach, 4th edition, Saunders Elsevier, Philadelphia 2009. p.22.

<sup>2</sup> Malhotra K, Liebeskind DS. Imaging in endovascular stroke trials. *J Neuroimaging* (2015) 25(4):517–27. 10.1111/jon.12272

<sup>3</sup> Brouns R, De Deyn PP. The complexity of neurobiological processes in acute ischemic stroke. *Clin Neurol Neurosurg*. 2009;111(6):483-495.

<sup>4</sup> Goyal M, Menon BK, van Zwam WH, Dippel DW, Mitchell PJ, Demchuk AM, et al; HERMES Collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. *Lancet*. 2016; 387:1723–1731. doi: 10.1016/S0140-6736(16)00163-X

## Technology

Rapid NCCT Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of NCCT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings. The device integrates the ICH, ASPECTS and HVS algorithms to evaluate the NCCT scan to determine the suspicion of stroke (ICH or LVO). According to the requestor, this workflow improvement allows for a single scan to accelerate the workflow prioritizing patients with suspected LVO for urgent evaluation for thrombectomy and/or other reperfusion therapies. The product also identifies suspected ICH patients for evaluation of the use of urgent surgical or medical therapies.

## Procedure Description

Rapid NCCT Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with detected (1) ICH or (2) NCCT LVO on the Rapid server on premise or in the cloud in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH or LVO findings via PACS, email or mobile device. Time to notification is typically less than five minutes. Notifications include compressed preview images that are meant for informational purposes only and are not intended for diagnostic use beyond notification. The device does not alter the original medical image, and it is not intended to be used as a primary diagnostic device.

**Current Coding:** There are no unique ICD-10-PCS codes to describe computer-aided measurement of intracranial vessel flow. Facilities can report the procedure using the following code:

XXE0X07      Measurement of intracranial vascular activity, computer-aided assessment, new technology group 7

## Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for computer-aided measurement of intracranial vessel flow. Continue coding as listed in current coding.

**Option 2.** Create new codes in section X, New Technology, to identify computer-aided measurement of intracranial vessel flow.

<i>Section</i> <b>X</b> New Technology			
<i>Body System</i> <b>X</b> Physiological Systems			
<i>Operation</i> <b>E</b> Measurement: Determining the level of a physiological or physical function at a point in time			
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>ADD 0</b> Central Nervous	<b>X</b> External	<b>ADD 7</b> Intracranial Vessel Flow, Computer-Aided Triage and Notification	<b>ADD 9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 20 – Extravascular Implantable Defibrillator Leads

**Issue:** There are currently no unique ICD-10-PCS codes to describe the implantation, removal and revision of extravascular implantable defibrillator leads.

**New Technology Application?** No.

**Food & Drug Administration (FDA) Approval?** No. The pivotal trial was completed in April 2022 and results were published in October 2022 and US FDA submission is complete. According to the requestor, premarket approval by the FDA is anticipated in the first half of 2023.

**Background:** Implantable cardioverter defibrillators (ICDs) have been an established therapy for over three decades. The devices treat life-threatening ventricular arrhythmias, including ventricular tachycardia and ventricular fibrillation, by delivering a shock to terminate the arrhythmia. The two components of an ICD system are the defibrillator generator and one or more leads which deliver the shock. The defibrillator generator is typically implanted in a subcutaneous pocket on the chest.

In conventional ICD systems, defibrillation leads are advanced transvenously into the right ventricle of the heart. Leads may also be placed transvenously into the right atrium and/or the coronary sinus over the left ventricle to provide anti-tachycardia pacing and bradycardia pacing in addition to delivering shocks.

Individuals who are unable to accommodate transvenous lead placement, for example due to obstructed or tortuous central veins, may receive a subcutaneous defibrillator lead. This is generally placed in the subcutaneous tissue to one side of the sternum. Although the lead is not in direct contact with heart tissue, the pulse can travel through the intervening layers to deliver the shock. However, subcutaneous leads cannot provide pacing for tachycardia or bradycardia.

### Technology

Extravascular implantable defibrillator leads (EV ICD) are an alternative to transvenous leads and subcutaneous leads. Rather than being situated in the heart or in subcutaneous tissue to the side of the sternum, EV leads are placed in the anterior mediastinum against the underside of the sternum. For this reason, EV leads are also sometimes referred to as substernal leads. Notably, EV leads can provide lifesaving shocks, anti-tachycardia pacing and pause prevention pacing. Placement of an EV lead is commonly, but not always, performed with placement of an EV ICD generator in a subcutaneous pocket in the chest.

In the pivotal trial, freedom from procedure-related and device-related complications was about 92% at 6 months and remained over 90% at one year. As with any implanted lead, reported complications include lead dislodgement, infection, and inappropriate shocks. These complications can result in removal, revision, or replacement of the lead.

### Procedure Description

To insert an EV lead, an incision is made proximate to the xiphoid process. After dissecting any diaphragmatic attachments, a tunneling rod is inserted under fluoroscopic guidance into the anterior mediastinum, i.e., into the narrow region between the underside of the sternum and the outside of

the pericardial sac. The tunneling rod is removed, leaving a sheath in place. The lead is then inserted into the sheath and deployed into position by removing the sheath to expose the electrodes along the length of the lead. After confirmation of proper lead position and electrode function, the lead is secured to the fascia near the xiphoid incision region using an anchoring sleeve. The incision proximate to the xiphoid process is closed.

Only one lead is placed for an EV ICD system. The anatomic location of the distal (substernal) end of the lead is the anterior mediastinum. The lead is against the underside of the sternum but is not affixed or connected to it. Likewise, the lead is against the outer surface of the pericardial sac but does not enter it. The lead is held in place by the narrowness of the anterior mediastinal tunnel, the areolar and adipose tissues composing the mediastinum, the shape of the EV lead, and the anchoring sleeve near the xiphoid incision site.

If the lead and generator are placed during the same operative episode, as is usually the case, the proximal end of the lead is tunneled subcutaneously across the chest to the site of the generator pocket where it is connected to the generator.

The EV lead is a permanent implant. However, it may need to be removed, e.g., for infection, or revised, e.g., for dislodgement. Removal involves cutting the sutures, reopening the subxiphoid incision, freeing the lead from any adhesions, and removing the lead by extraction tools or traction. If connected to a generator, the generator pocket must also be opened to disconnect the lead from the generator. Revision involves similar steps to free up the lead and reposition it within the anterior mediastinum.

**Current Coding:** There are no unique ICD-10-PCS codes to describe procedures involving extravascular implantable defibrillator leads. Code the procedure to the appropriate root operation in body system W General Anatomical Regions, using the body part value C Mediastinum and the device value Y Other Device.

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>W</b> Anatomical Regions, General			
<i>Operation</i> <b>H</b> 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			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>C</b> Mediastinum	<b>0</b> Open	<b>1</b> Radioactive Element	<b>Z</b> No Qualifier
	<b>3</b> Percutaneous	<b>3</b> Infusion Device	
	<b>4</b> Percutaneous Endoscopic	<b>Y</b> Other Device	

<i>Section</i> <b>0</b> Medical and Surgical			
<i>Body System</i> <b>W</b> Anatomical Regions, General			
<i>Operation</i> <b>P</b> Removal: Taking out or off a device from a body part			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>C</b> Mediastinum	<b>0</b> Open	<b>0</b> Drainage Device	<b>Z</b> No Qualifier
	<b>3</b> Percutaneous	<b>1</b> Radioactive Element	
	<b>4</b> Percutaneous Endoscopic	<b>3</b> Infusion Device	
	<b>X</b> External	<b>7</b> Autologous Tissue Substitute	
		<b>J</b> Synthetic Substitute	
		<b>K</b> Nonautologous Tissue Substitute	
		<b>Y</b> Other Device	

<i>Section</i>	<b>0</b> Medical and Surgical		
<i>Body System</i>	<b>W</b> Anatomical Regions, General		
<i>Operation</i>	<b>W</b> Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device		
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>C</b> Mediastinum	<b>0</b> Open <b>3</b> Percutaneous <b>4</b> Percutaneous Endoscopic <b>X</b> External	<b>0</b> Drainage Device <b>1</b> Radioactive Element <b>3</b> Infusion Device <b>7</b> Autologous Tissue Substitute <b>J</b> Synthetic Substitute <b>K</b> Nonautologous Tissue Substitute <b>Y</b> Other Device	<b>Z</b> No Qualifier

### Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for procedures involving extravascular implantable defibrillator leads. Continue coding as described in current coding.

**Option 2.** In tables 0WH, 0WP and 0WW, root operations Insertion, Removal and Revision respectively of the General Anatomical Regions body system, create new device value G Defibrillator Lead applied to body part value C Mediastinum to identify procedures involving extravascular implantable defibrillator leads.

<i>Section</i>	<b>0</b> Medical and Surgical		
<i>Body System</i>	<b>W</b> Anatomical Regions, General		
<i>Operation</i>	<b>H</b> 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		
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>C</b> Mediastinum	<b>0</b> Open <b>3</b> Percutaneous <b>4</b> Percutaneous Endoscopic	<b>1</b> Radioactive Element <b>3</b> Infusion Device <b>ADD G</b> Defibrillator Lead <b>Y</b> Other Device	<b>Z</b> No Qualifier

<i>Section</i>	<b>0</b> Medical and Surgical		
<i>Body System</i>	<b>W</b> Anatomical Regions, General		
<i>Operation</i>	<b>P</b> Removal: Taking out or off a device from a body part		
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>C</b> Mediastinum	<b>0</b> Open <b>3</b> Percutaneous <b>4</b> Percutaneous Endoscopic <b>X</b> External	<b>0</b> Drainage Device <b>1</b> Radioactive Element <b>3</b> Infusion Device <b>7</b> Autologous Tissue Substitute <b>ADD G</b> Defibrillator Lead <b>J</b> Synthetic Substitute <b>K</b> Nonautologous Tissue Substitute <b>Y</b> Other Device	<b>Z</b> No Qualifier

<i>Section</i>	<b>0</b> Medical and Surgical		
<i>Body System</i>	<b>W</b> Anatomical Regions, General		
<i>Operation</i>	<b>W</b> Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device		
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
<b>C</b> Mediastinum	<b>0</b> Open <b>3</b> Percutaneous <b>4</b> Percutaneous Endoscopic <b>X</b> External	<b>0</b> Drainage Device <b>1</b> Radioactive Element <b>3</b> Infusion Device <b>7</b> Autologous Tissue Substitute <b>ADD G</b> Defibrillator Lead <b>J</b> Synthetic Substitute <b>K</b> Nonautologous Tissue Substitute <b>Y</b> Other Device	<b>Z</b> No Qualifier

**CMS Recommendation:** Option 2, as described above.

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

**Topic # 21 - Section X Update**  
**March 2023 ICD-10 Coordination and Maintenance Committee Meeting**

**Background:**

At the September 11-12, 2018 ICD-10 C&M Committee Meeting we announced our plans to begin analyzing the frequency of the New Technology Group 1 codes within Section X as it has been 3 years since the implementation of these codes. We stated that we would 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 FYs 2016, 2017 and 2018?
- 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)

For the March 2019 ICD-10 C&M meeting we provided the findings from our initial analysis with regard to the frequency in which the New Technology Group 1 codes had been reported in the data.

At the September 2019 meeting we did not propose any changes to the New Technology Group 1 codes and stated we would continue to monitor the data.

For the March 2020 ICD-10 C&M meeting we shared the results of our analysis for the New Technology Group 2 codes within Section X as it has been 3 years since the implementation of those codes. We provided the frequency (total number of cases) of the New Technology Group 2 procedure codes as reported in the data for FYs 2017, 2018, and 2019. We also updated the data for the New Technology Group 1 codes to include the frequency of the codes for FY 2019.

We revised the format in which we display the findings from our analyses. We created an Excel spreadsheet with 2 specific tabs labeled accordingly as Group 1 Codes and Group 2 Codes. On each tab is the list of ICD-10-PCS codes, code description, frequency by fiscal year and if the technology was approved for the NTAP.

At the September 2020 ICD-10 C&M meeting we reviewed the updated analysis results in more detail and encouraged participants to consider the options listed above while reviewing the data for discussion. Commenters suggested adding another option for consideration.

At the March 2021 ICD-10 C&M meeting we proposed changes based on the public comments received and discussed a new approach to consider for future proposals.

At the September 2021 ICD-10 C&M meeting we reviewed the finalized changes based on the public comments received and shared our analysis results for the Group 3 Codes from FY 2018, 2019 and 2020.

At the March 2022 ICD-10 C&M meeting we displayed the updated data for Group 2 and Group 3 codes with the CMS recommendation.

At the September 2022 ICD-10 C&M meeting we reviewed the finalized changes based on the public comments received and shared our analysis results for the Group 4 Codes from FY 2019, 2020, and 2021.

#### *Fourth Option Issue*

We received overall support for the addition of the fourth option for the Section X codes which was described as creating a unique code in another section of ICD-10-PCS and deleting the existing section X code. As a result, based on review of the data and the clinical aspects of each section X procedure code, we will continue to propose one of the four options listed 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)

We also received support for

- establishing guiding principles in connection with the fourth option
- adding another column to the far right to identify the CMS recommendation
- reminding requestors that Section X codes are temporary and may be subject to one of the four listed options at a future meeting
- CMS continuing to present recommendations for the Section X codes and allowing the public to comment versus having the public submit specific requests



**Section X – March 2023 Update  
Group 4**

ICD-10-PCS Code	Code Description	FY 2019		FY 2020		FY 2021		FY 2022		Total Freq.	CMS Recommendation	Technology Brand Name
		Freq.	NTAP	Freq.	NTAP	Freq.	NTAP	Freq.	NTAP			
XV508A4	Destruction of prostate using robotic waterjet ablation, via natural or artificial opening endoscopic, new technology group 4	38	YES	27	YES	127	NO	289	NO	481	Option 3. Existing code 0V508ZZ (Destruction of prostate, via natural or artificial opening endoscopic) can be reported. Proposing to revise Index entry for Aquablation therapy, prostate.	The AquaBeam System (Aquablation)
XW033G4	Introduction of plazomicin anti-infective into peripheral vein, percutaneous approach, new technology group 4	3	YES	4	YES	2	YES	0	YES	9	Option 3. Existing codes in Table 3E0 can be reported. Proposing to revise Substance key entries for ZEMDRI™ (Plazomicin).	ZEMDRI™ (Plazomicin)
XW033H4	Introduction of synthetic human angiotensin ii into peripheral vein, percutaneous approach, new technology group 4	180	YES	400	YES	327	NO	336	NO	1,243	Option 3. Existing codes in Table 3E0 can be reported. Proposing to revise Substance key entries for GIAPREZA™ (synthetic human angiotensin ii).	GIAPREZA™
XW043G4	Introduction of plazomicin anti-infective into central vein, percutaneous approach, new technology group 4	1	YES	1	YES	2	YES	0	YES	4	Option 3. Existing codes in Table 3E0 can be reported. Proposing to revise Substance key entries for ZEMDRI™ (Plazomicin).	ZEMDRI™ (Plazomicin)
XW043H4	Introduction of synthetic human angiotensin ii into central vein, percutaneous approach, new technology group 4	441	YES	851	YES	379	NO	303	NO	1,974	Option 3. Existing codes in Table 3E0 can be reported. Proposing to revise Substance key entries for GIAPREZA™ (synthetic human angiotensin ii).	GIAPREZA™

## Topic # 22 - ICD-10-PCS Index Addenda

Lttr	A	
Main	Add	Appendiceal Orifice use Appendix
Lttr	C	
Main	Add	Chin use Subcutaneous Tissue and Fascia, Face
Lttr	C	
Main	Delete	Core needle biopsy see Excision with qualifier Diagnostic
Main	Add	Core needle biopsy see Biopsy
Lttr	L	
Main	Add	LUNSUMIO (tm) use Mosunetuzumab Antineoplastic
Lttr	M	
Main	Add	Middle meningeal artery, intracranial portion use Intracranial Artery
Lttr	Z	
Main	Add	ZYNTEGLO (R) use Betibeglogene Autotemcel

## ICD-10-PCS Body Part Key Addenda

Section 0	Medical and Surgical
Axis 4	Body Part
Term	Appendix
Includes	Add Appendixal Orifice
Section 0	Medical and Surgical
Axis 4	Body Part
Term	Intracranial Artery
Includes	Add Middle meningeal artery, intracranial portion
Section 0	Medical and Surgical
Axis 4	Body Part
Term	Subcutaneous Tissue and Fascia, Face
Includes	Add Chin

## ICD-10-PCS Device Key Addenda

Axis 6	Device
Row	
Term	Stimulator Generator, Multiple Array for Insertion in Subcutaneous Tissue and Fascia
Includes	Add Vanta(tm) PC Neurostimulator

Row  
 Term Stimulator Generator, Multiple Array Rechargeable for Insertion in Subcutaneous Tissue and Fascia  
 Includes Add Intellis(tm) Neurostimulator

### ICD-10-PCS Substance Key Addenda

Section X New Technology  
 Axis 6 Device / Substance / Technology  
 Row  
 Term Betibeglogene Autotemcel  
 Includes Add ZYNTEGLO (R)

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

### ICD-10-PCS Table Addenda

#### Medical and Surgical Section Axis 4 Body Part

#### Reduction of Thyroid Cartilage Fracture

Source	Description	Code specification
2023, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0CS, Reposition of Mouth and Throat, add the body part value S Larynx to identify procedures such as the repositioning of thyroid cartilage.	Add: 0CSS[078]ZZ (3 codes)

#### EXAMPLE

<i>Section</i> 0 Medical and Surgical			
<i>Body System</i> C Mouth and Throat			
<i>Operation</i> S Reposition: Moving to its normal location, or suitable location, all or a portion of a body part			
<i>Body Part</i>	<i>Approach</i>	<i>Device</i>	<i>Qualifier</i>
R Epiglottis			
ADD S Larynx	0 Open		
T Vocal Cord, Right	7 Via Natural or Artificial Opening	Z No Device	Z No Qualifier
V Vocal Cord, Left	8 Via Natural or Artificial Opening Endoscopic		

**New Technology Section**  
**Axis 6 Device / Substance / Technology**

**Patient Specific Intervertebral Body Fusion**

Source	Description	Code specification
2022, public request with CMS internal review	In the New Technology section, revise the axis 6 device/substance/technology value from Interbody Fusion Device, Customizable to Interbody Fusion Device, Custom-Made Anatomically Designed. This change request is from the manufacturer to help minimize misinterpretation of the term “customizable”.	Revise: XRG[ABCD][034]R7 (12 codes)

**EXAMPLES**

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>R</b> Joints		
<i>Operation</i>	<b>G</b> Fusion: Joining together portions of an articular body part rendering the articular body part immobile		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>A</b> Thoracolumbar Vertebral Joint	<b>0</b> Open	<b>REVISE from R</b> Interbody Fusion Device, Customizable	<b>7</b> New Technology Group 7
<b>B</b> Lumbar Vertebral Joint	<b>3</b> Percutaneous	<b>REVISE to</b> Interbody Fusion Device, Custom-Made Anatomically Designed	
<b>C</b> Lumbar Vertebral Joints, 2 or more	<b>4</b> Percutaneous Endoscopic		
<b>D</b> Lumbosacral Joint			

Index entries to accompany this addenda proposal:

**ICD-10-PCS Index Addenda**

Ltr        I  
Main    Revise from    Interbody Fusion Device, Customizable  
Main    Revise to        Interbody Fusion Device, Custom-Made Anatomically Designed  
                         Lumbar Vertebral XRGB  
                         2 or more XRGC  
                         Lumbosacral XRGD  
                         Thoracolumbar Vertebral XRGA

Ltr        N  
Main        New Technology  
                 Fusion  
                 Lumbar Vertebral  
          Delete        2 or more Interbody Fusion Device, Customizable XRGC  
          Add            2 or more Interbody Fusion Device, Custom-Made Anatomically  
                         Designed XRGC  
Delete      Interbody Fusion Device, Customizable XRGB  
Add         Interbody Fusion Device, Custom-Made Anatomically  
                 Designed XRGB

Delete Lumbosacral, Interbody Fusion Device, Customizable XRGD  
 Add Lumbosacral, Interbody Fusion Device, Custom-Made Anatomically Designed XRGD  
 Delete Thoracolumbar Vertebral, Lumbosacral, Interbody Fusion Device, Customizable XRGA  
 Add Thoracolumbar Vertebral, Lumbosacral, Interbody Fusion Device, Custom-Made Anatomically Designed XRGA

Device Key entries to accompany this addenda proposal:

**ICD-10-PCS Device Key Addenda**

Axis 6 Device  
 Row  
 Term Delete Interbody Fusion Device, Customizable in New Technology  
 Term Add Interbody Fusion Device, Custom-Made Anatomically Designed in New Technology  
 Includes aprevo(tm)

**Bromelain-enriched Proteolytic Enzyme name revised**

Source	Description	Code specification
2023, public request with CMS internal review	In the New Technology section, revise the axis 6 device/substance/technology value from Bromelain-enriched Proteolytic Enzyme to Anacaulase-bcdb. This change request is from the manufacturer and reflects the final generic name of the drug.	Revise: XW0[01]X27 (2 codes)

**EXAMPLE**

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>W</b> Anatomical Regions		
<i>Operation</i>	<b>0</b> Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>0</b> Skin			
<b>1</b> Subcutaneous Tissue	<b>X</b> External	<b>REVISE from 2</b> Bromelain-enriched Proteolytic Enzyme <b>REVISE to 2</b> Anacaulase-bcdb	<b>7</b> New Technology Group 7

Index entries to accompany this addenda proposal:

**ICD-10-PCS Index Addenda**

Ltr A  
 Main Add Anacaulase-bcdb XW0  
  
 Ltr B  
 Main Delete Bromelain-enriched Proteolytic Enzyme XW0  
  
 Ltr N  
 Main New Technology  
 Delete Bromelain-enriched Proteolytic Enzyme XW0  
 Add Anacaulase-bcdb XW0

Substance Key entries to accompany this addenda proposal:

**ICD-10-PCS Substance Key Addenda**

Section X	New Technology
Axis 6	Device / Substance / Technology
Term	Delete Bromelain-enriched Proteolytic Enzyme
Term	Add Anacaulase-bcdb
Includes	NexoBrid(tm)
Includes	Bromelain-enriched Proteolytic Enzyme

## Topic # 23 - Fluorescence-guided Surgery using CYTALUX® (Pafolacianine)

**Issue:** There are currently no unique ICD-10-PCS codes to describe fluorescence-guided surgery using CYTALUX® (pafolacianine), an optical imaging agent used as an adjunct for intraoperative identification of ovarian cancer or lung cancer.

**New Technology Application?** Yes. The requestor has submitted two New Technology Add-on Payment (NTAP) applications for FY 2024 consideration. One is specific to ovarian cancer and the other is specific to known or suspected non-malignant or malignant cancer of the lung.

**Food & Drug Administration (FDA) Approval?** Yes. The requestor received FDA approval for CYTALUX® in the intraoperative identification of ovarian cancer (November 29, 2021) and for lung cancer (December 16, 2022). The FDA approved ovarian cancer indication is: CYTALUX® is indicated as an adjunct for intraoperative identification of malignant lesions in adult patients with ovarian cancer. The FDA approved lung cancer indication is: CYTALUX® is indicated as an adjunct for intraoperative identification of malignant and non-malignant pulmonary lesions in adult patients with known or suspected cancer in the lung.

### *Ovarian Cancer*

**Background:** Approximately 22,000 women are diagnosed with ovarian cancer per year in the U.S. and 70% of patients diagnosed with ovarian cancer will have a recurrence. Ovarian cancer remains the leading cause of death from gynecologic malignancies and ranks fifth as a cause of cancer-related deaths among women.

The 5-year survival rate for extensive-stage disease remains low at 30% to 40%, with limited therapeutic options; and overall survival (OS) of patients with advanced-stage ovarian cancer showed little improvement in the last 30 years despite progress in surgery and therapy. Recurrent ovarian cancer remains a major challenge, and it is associated with > 80% patient mortality within 5 years.

Standard treatment of patients with ovarian cancer is debulking cytoreductive surgery and chemotherapy. The goal of a debulking operation is localization and accurate delineation of malignant and benign tissue to maximize removal of cancer, while minimizing removal of noncancerous tissue. The standard surgical approach is open surgery, although in selected cases, minimally invasive surgery has been shown to be safe regarding postoperative complications and short-term mortality. Tumor prognosis depends on the effectiveness of cytoreductive surgery in removing cancerous tissue. Debulking surgery followed by chemotherapy in most cases ends in recurrent chemo resistant disease. The amount of residual disease is an independent prognostic factor of survival, and the absence of macroscopic residual disease is associated with a significantly lower risk of recurrence. In a retrospective study of 496 eligible patients, those with residual disease of 1 to 10 mm had better progression-free survival and overall survival than patients left with residual disease greater than 10 mm. Studies have shown that complete resection of all macroscopic gynecologic disease (at primary or interval surgery) was the strongest independent variable in predicting overall survival.

Although tumor debulking surgery is the cornerstone of current treatment in patients, the lesions can be diffuse and numerous, of various sizes, and often not readily visible in the surgical field, leading to varying rates of optimal cytoreduction among surgeons. Patient survival is greater

among patients who receive complete cytoreduction.

### *Lung Cancer*

**Background:** Lung cancer is the third most common cancer in the United States. The American Cancer Society approximates 236,740 new cases of lung cancer per year (117,910 in men and 118,830 in women). It is the leading cause of cancer deaths. It is estimated that there are 130,180 deaths from lung cancer (68,820 in men and 61,360 in women).

Surgery remains the cornerstone of lung cancer treatment which may provide disease-free long-term survival or possible cures. Preoperative radiologic evaluation is essential to determine the appropriateness of surgical resection and the type of resection. The standard major pulmonary operative procedures include sublobar resection, lobectomy, bilobectomy, and pneumonectomy. Sublobar resections include wedge resection for peripheral lesions and segmentectomy. These surgical procedures can be performed by standard access (i.e., thoracotomy) or thoracoscopic access.

Five-year survival rate for lung cancer remains concerningly low at 61.2% for localized disease and 33.5% for regional disease. 30-55% of patients who undergo surgical resection develop a recurrence and do not survive, and up to 24% of patients recur locally following lung cancer surgery. The rates of local recurrence suggest that surgeons are unable to completely detect and remove primary tumor nodules. One study showed 8-9% of patients had malignant lesions that were not identified by preoperative CT imaging and thus could be left behind during surgery. Positive surgical resection margins also contribute to the recurrence rate. An increased margin distance has been shown to be associated with a lower risk of local recurrence, with a 10-mm margin distance having a 45% lower recurrence risk than a 5-mm distance. During minimally invasive thoracic surgery, smaller and deeper nodules are not always able to be located. Surgical oncologists continue to strive for greater effectiveness in achieving complete resection of lung tumors. Incomplete resection of non-small cell lung cancer negatively impacts survival rates. Survival time following local recurrence, including those patients who receive salvage treatment is less than one year on average.

### *Mechanism of Action*

CYTALUX<sup>®</sup> is a small molecule that circulates quickly through the body. Most ovarian and lung cancers overexpress folate receptors on their surface. CYTALUX<sup>®</sup> binds to the folate receptors on these cancer cells and is endocytosed into folate receptor positive cancer cells. Using a near-infrared imaging system, CYTALUX<sup>®</sup> illuminates, making cancer visible within the surgical field.

### *Inpatient Administration of CYTALUX<sup>®</sup> (pafolacianine)*

CYTALUX<sup>®</sup> would primarily be administered in the inpatient setting for both ovarian and lung cancer, however, it may also be administered as an outpatient for lung cancer. It is administered via IV infusion 1 to 9 hours prior to surgery for ovarian cancer and 1 to 24 hours prior to surgery for non-malignant or known or suspected lung cancer. The proposed dosing for CYTALUX<sup>®</sup> is a single intravenous infusion of 0.025 mg/kg diluted in 250 mL of 5% Dextrose Injection, administered over 60 minutes using a dedicated infusion line.



**Current Coding:** There are no unique ICD-10-PCS codes to describe fluorescence-guided surgery using CYTALUX<sup>®</sup> (pafolacianine). Code the procedure using the body region value W Trunk Region in table 8E0, Other Procedures, with the appropriate approach value and the method value E Fluorescence Guided Procedure for either the lung or ovarian indication. Facilities would also report the appropriate code(s) for any lesion(s) excised.

<i>Section</i> <b>8</b> Other Procedures			
<i>Body System</i> <b>E</b> Physiological Systems and Anatomical Regions			
<i>Operation</i> <b>0</b> Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease			
<i>Body Region</i>	<i>Approach</i>	<i>Method</i>	<i>Qualifier</i>
<b>W</b> Trunk Region	<b>0</b> Open	<b>C</b> Robotic Assisted Procedure <b>E</b> Fluorescence Guided Procedure	<b>Z</b> No Qualifier
	<b>3</b> Percutaneous		
	<b>4</b> Percutaneous Endoscopic		
	<b>7</b> Via Natural or Artificial Opening		
	<b>8</b> Via Natural or Artificial Opening Endoscopic		

### Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for fluorescence-guided surgery using pafolacianine. Continue coding as described in current coding.

**Option 2.** In table 8E0, Other Procedures, create new qualifier value N Pafolacianine applied to existing body region value W Trunk Region for the lung indication and add new body region value U Female Reproductive System for the ovarian indication, applied to existing method value E Fluorescence Guided Procedure and to all available approach values, to identify the fluorescence-guided surgery using pafolacianine. Facilities would also report the appropriate code(s) for any lesion(s) excised.

<i>Section</i> <b>8</b> Other Procedures			
<i>Body System</i> <b>E</b> Physiological Systems and Anatomical Regions			
<i>Operation</i> <b>0</b> Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease			
<i>Body Region</i>	<i>Approach</i>	<i>Method</i>	<i>Qualifier</i>
<b>W</b> Trunk Region	<b>0</b> Open	<b>E</b> Fluorescence Guided Procedure	<b>ADD N</b> Pafolacianine <b>Z</b> No Qualifier
	<b>3</b> Percutaneous		
	<b>4</b> Percutaneous Endoscopic		
	<b>7</b> Via Natural or Artificial Opening		
	<b>8</b> Via Natural or Artificial Opening Endoscopic		
<b>ADD U</b> Female Reproductive System	<b>0</b> Open	<b>E</b> Fluorescence Guided Procedure	<b>ADD N</b> Pafolacianine <b>Z</b> No Qualifier
	<b>3</b> Percutaneous		
	<b>4</b> Percutaneous Endoscopic		
	<b>7</b> Via Natural or Artificial Opening		
	<b>8</b> Via Natural or Artificial Opening Endoscopic		

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 24 - Administration of Glofitamab

**Issue:** There are currently no unique ICD-10-PCS codes to describe the administration of glofitamab.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food and Drug Administration (FDA) Approval?** No. Genentech is seeking accelerated approval from the FDA for the treatment of adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) after two or more prior therapies. According to the requestor, approval is anticipated in the second or third quarter of 2023.

**Background:** Diffuse large B-cell lymphoma (DLBCL), the most common form of non-Hodgkin Lymphoma (NHL), involves the malignant proliferation of B lymphocytes or B cells during different stages of development, often resulting in rapidly growing and spreading masses in the lymph nodes.<sup>1,2</sup> Although DLBCL can affect all ages, it is primarily a disease of older people; the median age at diagnosis is 66 years old.<sup>3,4</sup> Based on Surveillance, Epidemiology, and End Results Programs (SEER) 2015-2019 age-adjusted data, the incidence of new cases of DLBCL was 5.6 per 100,000 people per year and the death rate was 1.8 per 100,000 people per year.<sup>5</sup> The incidence of DLBCL cases in the United States is projected to increase by 11% from 2020 to 2025 as a result of the aging population and the underlying higher incidence rate of DLBCL with older age.<sup>6</sup>

The standard of care for first-line (1L) DLBCL treatment is a combination of 5 drugs: rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP). Even though DLBCL is an aggressive cancer, approximately 60% of patients will achieve long-term remission with R-CHOP.<sup>7,8</sup> Of the remaining 40%, approximately 10% to 15% will have primary refractory disease (defined as incomplete response or relapse within 6 months after treatment) and 20% to 25% will relapse, usually within the first 2 years of treatment.<sup>9,10,11</sup> Outcomes are poor for patients for whom 1L R-CHOP treatment fails.

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<sup>1</sup> Types of B-cell Lymphoma. American Cancer Society. 2019:1-3.

<sup>2</sup> Liu Y, Barta SK. Diffuse large B-cell lymphoma: 2019 update on diagnosis, risk stratification, and treatment. *Am J Hematol*. 2019;94(5):604-16.

<sup>3</sup> Types of B-cell Lymphoma. American Cancer Society. 2019:1-3.

<sup>4</sup> Institute NC. SEER Cancer Stat Facts -Diffuse Large B-Cell Lymphoma. 2022.

<sup>5</sup> Id.

<sup>6</sup> Id.

<sup>7</sup> Crump M, Neelapu SS, Farooq U, Van Den Neste E, Kuruvilla J, Westin JR, et al. Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. *Blood*. 2017;130:1800-9.

<sup>8</sup> Kanas G, Ge W, Quek RGW, Keeven K, Nersesyan K, Jon EA. Epidemiology of diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) in the United States and Western Europe: population-level projections for 2020-2025. *Leuk Lymphoma*. 2022;63(1):54-63.

<sup>9</sup> Crump M, Neelapu SS, Farooq U, Van Den Neste E, Kuruvilla J, Westin JR, et al. Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. *Blood*. 2017;130:1800-9

<sup>10</sup> Fox CP, Townsend W, Gribben J, Menne T, Kalakonda N, Lynes J. Clinical outcomes in patients with relapsed/refractory large B-cell lymphoma receiving conventional third-line therapy: a multicenter, retrospective, real-world study in the United Kingdom. *EHA*. 2021;EP539

<sup>11</sup> Morrison VA, Shou Y, Bell JA, Hamilton L, Ogonnaya A, Raju A. Evaluation of treatment patterns and survival among patients with diffuse large B-cell lymphoma in the USA. *Future Oncology*. 2019;15:1021-34.

Although numerous treatment options are available, there is currently no standard of care for the treatment of patients with R/R DLBCL. Treatment strategies are largely dependent on specific patient factors, including whether patients are eligible for autologous stem cell transplant (ASCT). ASCT is potentially curative; however, only approximately half of the patients who are R/R after 1L therapy are candidates for this treatment approach owing to advanced age or comorbidities.<sup>12</sup> Of eligible patients, about half do not respond sufficiently to salvage chemotherapy to undergo ASCT.<sup>13</sup> More recently, chimeric antigen receptor (CAR) T-cell therapies have become available for patients with R/R DLBCL. Similar to ASCT, about half of patients who undergo CAR T-cell therapy can achieve long-term remissions.<sup>14,15,16</sup>

#### *Description and Mechanism of Action for Glofitamab*

Glofitamab is a novel T-cell engaging bispecific antibody that activates the patient's own immune system to eradicate malignant B cells. Glofitamab is designed to simultaneously bind CD20 on malignant B cells and CD3 on T cells, bringing them into close proximity. Glofitamab binding to CD3 also activates the T cell which induces proliferation and targeted killing of B cells (1).<sup>17</sup> The lysis of B cells mediated by Glofitamab is CD20 specific and does not occur in the absence of the simultaneous binding of the T cell and the target B cell. According to the requestor, the novel structure of Glofitamab (2 CD20 binding domains, 1 CD3 binding domain [2:1 structure]) enables high-avidity, bivalent binding to CD20 that can result in activity against malignant B cells even under low effector-to-target cell ratios (2, 3).<sup>18,19</sup>

In the pivotal NCT03075696 study, glofitamab was well tolerated with a low rate of treatment discontinuation. The most frequent adverse events (AE) was cytokine release syndrome (CRS), with the majority being grade 1 (fever) and occurring on the first dose of glofitamab. AEs of all grades that were reported in  $\geq 15\%$  of patients include: cytokine release syndrome (63.0%), neutropenia (37.7%), anemia (30.5%), thrombocytopenia (24.7%), pyrexia (18.2%), and hypophosphatemia (17.5%).

Glofitamab demonstrated clinically meaningful outcomes in patients with DLBCL with 2 or more lines of prior therapy, including those who were heavily pretreated (59.7% of patients had more than 3 prior lines of therapy) and were highly refractory (90.3% were refractory to a prior therapy). Approximately a third of the patients on the glofitamab pivotal trial had prior CAR T-cell therapy and 90.2% of those patients were refractory to CAR T-cell therapy. Despite the difficult-to-treat characteristics of the patients in the pivotal study, the overall response rate (ORR) was 51.6% with

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<sup>12</sup> Sehn LH, Salles G. Diffuse large B-cell lymphoma. *N Engl J Med.* 2021;384(9):842-58.

<sup>13</sup> Gisselbrecht C, Glass B, Mounier N, Singh Gill D, Linch DC, Trneny M, et al. Salvage regimens with autologous transplantation for relapsed large B-cell lymphoma in the rituximab era. *J Clin Oncol.* 2010;28(27):4184-90.

<sup>14</sup> Kuhl A, Kirkwood AA, O'Reilly M, Sanderson R, Tholouli E, Patel A. Outcome of large B-cell lymphoma patients failing CD19 targeted CAR T therapy. Presented at: The 16th International Conference on Malignant Lymphoma; June 18-22, 2021; Virtual 2021.

<sup>15</sup> Vercellino L, Di Blasi R, Kanoun S, Tessoulin B, Rossi C, D'Aveni-Piney M, et al. Predictive factors of early progression after CAR T-cell therapy in relapsed/refractory diffuse large B-cell lymphoma. *Blood Adv.* 2020;4(22):5607-15.

<sup>16</sup> Chong EA, Ruella M, Schuster SJ. Five-year outcomes for refractory B-cell lymphomas with CAR T-cell therapy. *N Engl J Med.* 2021;384(7):671-3.

<sup>17</sup> Broske AE, Korfi K, Belousov A, Wilson S, Ooi CH, Bolen CR, et al. Pharmacodynamics and molecular correlates of response to glofitamab in relapsed/refractory non-Hodgkin lymphoma. *Blood Adv.* 2022;6(3):1025-37.

<sup>18</sup> Bacac M, Colombetti S, Herter S, Sam J, Perro M, Chen S, et al. CD20-TCB with obinutuzumab pretreatment as next-generation treatment of hematologic malignancies. *Clin Cancer Res.* 2018;24(19):4785-97.

<sup>19</sup> Bacac M, Umaña P, Herter S, Colombetti S, Sam J, Le Clech M, et al. CD20 Tcb (RG6026), a novel "2:1" T cell bispecific antibody for the treatment of B cell malignancies. *Blood.* 2016;128(22):1836

39.4% of patients achieving a complete response (CR). The median time to first CR was 42 days (95% CI: 42–44).

### *Inpatient Administration of Glofitamab*

The dosing for glofitamab will be determined upon FDA approval. Subject to FDA approval, glofitamab will be administered as an intravenous infusion through a dedicated infusion line according to the dose step-up schedule leading to the recommended dosage of 30 mg (as shown in Table 1), after completion of pre-treatment with obinutuzumab on Cycle 1 Day 1. Each cycle is 21 days. The dose schedule of glofitamab also has a fixed duration (maximum of 12 cycles) in contrast to other therapies that are used until disease progression.

Table 1.

Glofitamab Monotherapy Dose Step-Up Schedule for Patients with Relapsed or Refractory DLBCL

Treatment Cycle, Day		Dose of Glofitamab	Duration of infusion
Cycle 1 (Pre-treatment and step-up dose)	Day 1	Pre-treatment with obinutuzumab	
	Day 8	2.5 mg	4 hours <sup>a</sup>
	Day 15	10 mg	
Cycle 2	Day 1	30 mg	
Cycle 3 through 12	Day 1	30 mg	2 hours <sup>b</sup>

<sup>a</sup> For patients who experience CRS with their previous dose of glofitamab, the duration of infusion may be extended up to 8 hours.

<sup>b</sup> At the discretion of the treating physician, if the previous infusion was well tolerated. If the patient experienced CRS with a previous dose, the duration of infusion should be maintained at 4 hours.

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

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

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>W</b> Anatomical Regions		
<i>Operation</i>	<b>0</b> Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>3</b> Peripheral Vein	<b>3</b> Percutaneous	<b>ADD P</b> Glofitamab Antineoplastic	<b>9</b> New Technology Group 9
<b>4</b> Central Vein			

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 25 - Administration of Posoleucel

**Issue:** There are currently no unique ICD-10-PCS codes to describe the administration of posoleucel.

**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. Posoleucel has been granted a Regenerative Medicine Advanced Therapy (RMAT) designation and is being studied in a pivotal, randomized Phase 3 trial for virus associated hemorrhagic cystitis (vHC). The requestor (AlloVir) plans on submitting a Biologics License Application (BLA) for posoleucel following an analysis of the Phase 3 data.

**Background:** Conditioning regimens for potentially life-saving transplantations – the two most common types of which are allogeneic hematopoietic stem cell transplants (HSCT) and solid organ transplants (SOT), often require the complete elimination of a patient’s own stem cells to prevent rejection of the transplanted cells or organs, leaving patients without a functioning immune system and highly prone to devastating viral infections or diseases, which can cause end-organ damage and mortality.

Infections that can be caused by various types of microorganisms are a major root of mortality and morbidity during this phase of immune deficiency. For 90% of allogeneic HSCT patients, their suppressed immune system allows viruses that were previously in a latent state to reactivate, with more than 60% of HSCT patients experiencing reactivation of more than one potentially fatal virus. Overall, 11% of post HSCT deaths are caused by infections, with one-third of these being viral infections.<sup>1</sup> Currently, there are no approved therapies for most viral infections in the post-transplant setting, with the standard of care treatments having limited efficacy and associated with significant toxicity.

Virus Associated Hemorrhagic Cystitis (vHC) is considered as one of the major difficulties after HSCT<sup>2</sup>. vHC is classified into four grades according to its severity: microscopic hematuria (grade 1), macroscopic hematuria (grade 2), hematuria with clots and need for transfusion (grade 3), and hematuria with clots and impaired renal function (grade 4).<sup>3,4</sup> Current standard of care is supportive, including diuresis and continuous bladder irrigation to mitigate urinary obstruction, antispasmodics and narcotics to alleviate suffering, hyperbaric oxygen, nephrostomies, and/or dialysis for acute renal failure. In some cases, a cystectomy has been required to control life-threatening hemorrhage caused by vHC. The most frequently used antiviral drug for vHC

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<sup>1</sup> Kaeuferle T, Krauss R, Blaeschke F, Willier S, Feuchtinger T. Strategies of adoptive T-cell transfer to treat refractory viral infections post allogeneic stem cell transplantation. *J Hematol Oncol.* 2019;12:13–23.

<sup>2</sup> Mohammadi Najafabadi M, Soleimani M, Ahmadvand M, Soufi Zomorrod M, Mousavi SA. Treatment protocols for BK virus associated hemorrhagic cystitis after hematopoietic stem cell transplantation. *Am J Blood Res.* 2020 Oct 15;10(5):217-230. PMID: 33224566; PMCID: PMC7675133.

<sup>3</sup> Lunde LE, Dasaraju S, Cao Q, Cohn CS, Reding M, Bejanyan N, Trottier B, Rogosheske J, Brunstein C, Warlick E, Young JA, Weisdorf DJ, Ustun C. Hemorrhagic cystitis after allogeneic hematopoietic cell transplantation: risk factors, graft source and survival. *Bone Marrow Transplant.* 2015;50:1432–1437.

<sup>4</sup> Cesaro S, Dalianis T, Hanssen Rinaldo C, Koskenvuo M, Pegoraro A, Einsele H, Cordonnier C, Hirsch HH. ECIL guidelines for the prevention, diagnosis and treatment of BK polyomavirus-associated haemorrhagic cystitis in haematopoietic stem cell transplant recipients. *J Antimicrob Chemother.* 2018;73:12–21.

treatment is cidofovir, however cidofovir is associated with nephrotoxicity.

Posoleucel is a polyclonal multi virus-specific T cell (VST) product that recognizes and eradicates actively replicating virus-infected cells. These cells are currently being evaluated for the treatment of viral infections in adults and children after allogeneic HSCT. Posoleucel recognizes and kills virus-infected cells via their native T cell receptor (TCR), which binds to HLA molecules expressed on target cells that present virus-derived peptides. Post allogeneic HSCT, posoleucel provides an immunological bridge between conditioning and reconstitution of the patient's immune systems to treat or prevent viral re-activation until the patient's natural immunity is restored. According to the requestor, restoring immunity during this time of severe immune compromise may substantially reduce or prevent virus-associated morbidity and mortality, and dramatically improve patient outcomes.

#### *Description and Mechanism of Action for Posoleucel*

Posoleucel is an investigational, allogeneic, off-the-shelf human leukocyte antigen (HLA)-matched virus-specific T-cell (VST) product reactive to six clinically significant viruses: cytomegalovirus (CMV), Epstein-Barr virus (EBV), BK virus (and the related polyoma JC virus), adenovirus and human herpesvirus-6 (HHV-6). The cells are derived from peripheral blood mononuclear cells (PBMCs) from donors seropositive for all six of these viruses. The cells are expanded and co-cultured with 15-mer peptides overlapping by 11 amino acids spanning antigenic proteins from polyomaviruses BK and JC (VP1 and large T), from adenovirus (hexon and penton), from cytomegalovirus (IE1 and pp65), from Epstein-Barr virus (LMP2, EBNA1, BZLF1), and from human herpesvirus-6 (U90, U11 and U14). The cells have specific anti-virus reactivity for each virus above a pre-specified potency threshold, and predominantly express CD3 (generally greater than 95%) with a mixture of CD4 positive (average 60%) and CD8 positive (average 34%) subsets, including both central (CD45RA-/62L+/CCR7+) and effector (CD45RA-/62L-/CCR7-) memory markers.

Posoleucel is comprised of both CD8+ and CD4+ virus-specific T-cells capable of recognizing actively replicating virus-infected cells, proliferating in response to antigenic stimulation and mediating antiviral effects including the production of cytokines (e.g. interferon (IFN) gamma) and killing of infected cells in patients with infections/diseases associated with the target viruses. The antiviral activities of posoleucel may additionally include the production of other effector cytokines including TNF-alpha and/or GM-CSF and/or effector molecules (e.g. granzyme B and/or perforin). These polyclonal cells recognize viral peptides presented in the context of HLA class I and class II alleles, respectively. The partial HLA match between the allogeneic VST-cell line and infected patient allows the infused T-cells to recognize and selectively kill virus-infected cells.

According to the requestor, safety findings from a completed Phase 2 clinical trial (NCT02108522) in 58 allogeneic hematopoietic stem cell transplant (HCT) recipients with persistent and/or refractory viral infections were consistent with those expected in this patient population, including the known risks of graft-versus-host disease (GVHD). No overt safety signal attributable to posoleucel was detected above and beyond the safety findings expected to be found in patients who have already undergone allogeneic HCT and who then present with a severe viral infection caused by 1 or more of the viruses targeted by posoleucel. While all participants in all virus groups experienced treatment-emergent adverse events (TEAEs) during this study, fewer than half of them (43.1%) experienced TEAEs assessed by the Investigator as treatment-related (i.e., possibly, probably, or definitely related to study treatment as judged by the Investigator); TEAEs occurring

in more than 50% of treated participants included: anemia, decreased platelet count, decreased white blood cell count, hypomagnesaemia, decreased neutrophil count, hypokalemia, hyperglycemia, hypoalbuminemia, hypocalcemia, decreased lymphocyte count, and increased aspartate aminotransferase (AST). The most common treatment-related adverse events (greater than 5% of participants) included pyrexia, increased AST, increased bilirubin, decreased neutrophil count, decreased white blood cell count, and maculopapular rash.

#### *Inpatient Administration of Posoleucel*

For treatment of viral infections, posoleucel is administered as a course of two intravenous infusions separated by approximately 14 days. An appropriately HLA-matching posoleucel cell line is identified from AlloVir’s bank of available drug product lots for an identified patient requiring treatment. Posoleucel is supplied in 6 mL capacity AT-Closed Vials® (Aseptic technologies) at a concentration of  $1 \times 10^7$  virus-specific T-cells (VSTs)/mL in a volume of approximately 2.5 mL/vial. The cryopreserved cells are shipped in the frozen state to the treatment facility. Once the patient is ready for treatment, the cells for a single infusion are thawed, and administered by a health care professional via intravenous infusion by syringe within 30 minutes of thawing. The infusion may be administered through either a central or peripheral intravenous catheter.

The administered dose is based on the patient’s body weight:  $2 \times 10^7$  cells (in a volume of 2 mL) per infusion for patients weighing less than 40 kg, and  $4 \times 10^7$  cells (in a volume of 4 mL) per infusion for patients weighing greater than or equal to 40 kg. The total infusion time is approximately 5 minutes. Following infusion of posoleucel, the syringe and intravenous tubing are flushed with normal saline.

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

- 3E033WK Introduction of immunostimulator into peripheral vein, percutaneous approach
- 3E043WK Introduction of immunostimulator into central vein, percutaneous approach

#### **Coding Options**

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

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

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>W</b> Anatomical Regions		
<i>Operation</i>	<b>0</b> Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>3</b> Peripheral Vein	<b>3</b> Percutaneous	<b>ADD Q</b> Posoleucel	<b>9</b> New Technology Group 9
<b>4</b> Central Vein			



**CMS Recommendation:** Option 2, as described above.

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

## Topic # 26 - Administration of Rezafungin

**Issue:** There are currently no unique ICD-10-PCS codes to describe the administration of rezafungin.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. In the United States, rezafungin was designated by the FDA as a Qualified Infectious Disease Product (QIDP) in 2017. In September 2022, the FDA granted priority review to Melinta Therapeutics for its New Drug Application (NDA) for rezafungin for the treatment of candidemia and invasive candidiasis in patients 18 years of age or older. According to the requestor, the FDA assigned a Prescription Drug User Fee Act (PDUFA) target action date of March 22, 2023.

**Background:** Candidemia and invasive candidiasis are rare, serious, and life-threatening infections. According to the Centers for Disease Control and Prevention (CDC), the average rate of new infections is approximately 9 per 100,000 people, and there are approximately 25,000 cases per year.<sup>1</sup> These infections occur in patients who are already sick with other diseases and are associated with high morbidity and mortality. Patients who are at risk of invasive fungal infections include the critically ill, immunosuppressed, post-surgical, and those with central venous catheters. Invasive infection with *Candida* in this already vulnerable patient population often results in severe illness and death.

In a recent analysis of a large United States (US) patient database, *Candida* infections accounted for 40% of all invasive fungal infections.<sup>2</sup> Patients with these invasive infections can suffer from a range of comorbidities on top of their underlying condition, including fever and septic shock. Candidemia and invasive candidiasis are associated with a long length of hospital stay, with an estimated additional 3 to 13 days of hospitalization after diagnosis. Additionally, the mortality rate in patients with these infections is greater than 40%.<sup>3,4,5,6,7,8,9,10,11</sup>

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<sup>1</sup> Centers for Disease Prevention and Control (CDC). Fungal Diseases: Statistics. August 24, 2021. <https://www.cdc.gov/fungal/diseases/candidiasis/invasive/statistics.html>.

<sup>2</sup> Menzin J, Meyers JL, Friedman M et al. Mortality, length of hospitalization, and costs associated with invasive fungal infections in high risk patients. *Am J Health Syst Pharm.* 2009; 66: 1711–1717.

<sup>3</sup> Wisplinghoff H, Bischoff T, Tallent SM, Seifert H, Wenzel RP, et al. Nosocomial bloodstream infections in US hospitals: Analysis of 24,179 cases from a prospective nationwide surveillance study. *Clin Infect Dis.* 2004; 39: 309–317.

<sup>4</sup> Falagas ME, Apostolou KE, Pappas VD. Attributable mortality of candidemia: a systematic review of matched cohort and case-control studies. *Eur J Clin Microbiol Infect Dis.* 2006; 25(7): 419–425.

<sup>5</sup> Pfaller MA, Diekema DJ. Epidemiology of Invasive Candidiasis: a Persistent Public Health Problem. *Clin Microbiol Rev.* 2007; 20(1): 133–163.

<sup>6</sup> Labelle AJ, Micek ST, Roubinian N, Kollef MH. Treatment-related risk factors for hospital mortality in *Candida* bloodstream infections. *Crit Care Med.* 2008; 36(11): 2967–2972.

<sup>7</sup> Pfaller MA, Diekema DJ. Epidemiology of invasive mycoses in North America. *Crit Rev Microbiol.* 2010; 36: 1–53.

<sup>8</sup> Slavin MA, Sorrell TC, Marriott D, Thursky KA, Nguyen Q, Ellis DH, et al.; Australian Candidemia Study, Australasian Society for Infectious Diseases. Candidaemia in adult cancer patients: risks for fluconazole-resistant isolates and death. *J Antimicrob Chemother.* 2010; 65(5): 1042–1051.

<sup>9</sup> Andes DR, Safdar N, Baddley JW, et al. Impact of treatment strategy on outcomes in patients with candidemia and other forms of invasive candidiasis: a patient-level quantitative review of randomized trials. *Clin Infect Dis.* 2012; 54: 1110–1122.

<sup>10</sup> Mikulska M, Del Bono V, Ratto S, Viscoli C. Occurrence, presentation and treatment of candidemia. *Expert Rev Clin Immunol.* 2012; 8(8): 755–765.

<sup>11</sup> Mylonakis E, Clancy CJ, Ostrosky-Zeichner L, Garey KW, Alangaden GJ, et al. T2 Magnetic Resonance Assay for the Rapid Diagnosis of Candidemia in Whole Blood: A Clinical Trial. *Clin Infect Dis.* 2015; 60(6): 892–899.

Echinocandins are recommended as first-line antifungal agents by practice guidelines for the treatment of candidemia and invasive candidiasis due to their well-established efficacy and safety profile and strong fungicidal activity. Currently approved echinocandins include caspofungin, micafungin, and anidulafungin, however, no new antifungal agents have been approved for treatment of candidemia and invasive candidiasis since anidulafungin in 2007.

*Mechanism of Action*

Rezafungin is an echinocandin, a class of antifungal drugs that inhibits the synthesis of 1,3-beta-D-glucan, an essential component of fungal cell walls. It is a sterile, lyophilized product that contains rezafungin acetate, a semisynthetic lipopeptide synthesized from a fermentation product of *Aspergillus nidulans*. Rezafungin acetate is a hygroscopic, white to off-white powder, freely soluble in water, soluble in methanol, and sparingly soluble in ethanol.

*Inpatient Administration of Rezafungin*

Rezafungin is administered once a week, via intravenous infusion of a loading dose over approximately one hour on day 1, followed by a maintenance dose on day 8. An infusion may be slowed, or paused and restarted at a lower rate, if infusion-related reactions occur.

For the 400 mg dose, aseptically reconstitute 2 vials with 9.5 mL of sterile water for injection, to provide a concentration of 20 mg/mL in each vial. For the 200 mg dose, aseptically reconstitute 1 vial with 9.5 mL of sterile water for injection, to provide a concentration of 20 mg/mL.

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

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

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>W</b> Anatomical Regions		
<i>Operation</i>	<b>0</b> Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>3</b> Peripheral Vein	<b>3</b> Percutaneous	<b>ADD R</b> Rezafungin	<b>9</b> New Technology Group 9
<b>4</b> Central Vein			

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 27 - Administration of SER-109

**Issue:** There are currently no unique ICD-10-PCS codes to describe the administration of SER-109.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. In 2015, the FDA granted SER-109 Orphan Drug Designation and Breakthrough Designation for the treatment of *Clostridioides difficile* (*C. diff*) infection (CDI). According to the requestor, the FDA accepted the Biologics License Application (BLA) for SER-109 on October 26, 2022, and provided a Prescription Drug User Fee Act (PDUFA) action date of April 26, 2023.

**Background:** *C. diff* is the leading cause of hospital-acquired infections (HAIs) in the United States, and is connected with over 20,000 deaths.<sup>1,2</sup> *C. diff* colonizes the human intestinal tract after the normal gut flora has been disrupted and is the causative organism of antibiotic-associated colitis including pseudomembranous colitis. The primary risk factor for CDI is exposure to broad-spectrum antibiotics, which leads to compositional and functional changes in the gastrointestinal microbiome and renders patients susceptible to increased germination of *C. diff* spores.<sup>3</sup> Antibiotic-induced loss of Firmicutes bacteria enables *C. diff* spore germination and launches a cycle of recurrence; most CDI recurrences occur within the days and weeks after completion of an antibiotic regimen, as the disrupted microbiome facilitates increased *C. diff*.<sup>4</sup>

While antibiotics are necessary to treat CDI, antibiotics alone are often insufficient to achieve a sustained clinical response. Antibiotics kill the toxin-producing *C. diff* bacteria, but also kill beneficial flora, including Firmicutes bacteria. Furthermore, antibiotics do not kill dormant *C. diff* spores. After treatment discontinuation, these spores germinate into toxin-producing vegetative bacteria, which thrive in an environment depleted of Firmicutes bacteria, thereby causing recurrent infections. According to the requestor, a two-pronged approach of first using antibiotics to kill vegetative *C. diff* bacteria, followed by SER-109 to repair the microbiome, is key to managing CDI and preventing recurrence.<sup>5,6,7</sup>

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<sup>1</sup> Guh AY, Mu Y, Winston LG, et al. Trends in U.S. burden of *Clostridioides difficile* infection and outcomes. *N Engl J Med* 2020; 382: 1320– 1330.

<sup>2</sup> Ressler A, Wang J, Rao K. Defining the black box: a narrative review of factors associated with adverse outcomes from severe *Clostridioides difficile* infection. *Ther Adv Gastroenterol* 2021, Vol. 14: 1–16.

<sup>3</sup> Theriot CM, Bowman AA, Young VB. Antibiotic-induced alterations of the gut microbiota alter secondary bile acid production and allow for *Clostridium difficile* spore germination and outgrowth in the large intestine. *mSphere* 2016;1(1):e00045-15.

<sup>4</sup> Abujamel T, Cadnum JL, Jury LA, et al. Defining the vulnerable period for re-establishment of *Clostridium difficile* colonization after treatment of *C. difficile* infection with oral vancomycin or metronidazole. *PLoS One* 2013;8(10):e76269- e76269.

<sup>5</sup> McGovern B, Ford C, Henn M, SER-109, an Investigational Microbiome Drug to Reduce Recurrence After *Clostridioides difficile* infection: Lessons Learned from a Phase 2 trial. *Clin Infect Dis* 2021 Jun 15; 72(12): 2132-2140.

<sup>6</sup> Feuerstadt P, Louie T, Lashner M. SER-109, an oral microbiome therapy for recurrent *Clostridioides difficile* Infection. *N Engl J Med* 2022; 386:200-9.

<sup>7</sup> Khanna S, Pardi DS, Kelly CR, et al., A Novel Microbiome Therapeutic Increases Gut Microbial Diversity and Prevents Recurrent *Clostridium difficile* Infection, *The Journal of Infectious Diseases*, Volume 214, Issue 2, 15 July 2016, Pages 173–181, <https://doi.org/10.1093/infdis/jiv766>

### *Description and Mechanism of Action for SER-109*

SER-109, an investigational microbiome therapeutic, is a consortium of purified Firmicutes bacteria spores administered to prevent recurrent *C. diff* infection. SER-109 prevents recurrent CDI by repairing the microbiome by replenishing Firmicutes bacteria. While the specific mechanism of action of SER-109 is still under investigation, findings from the ECOSPOR III clinical trial indicate that SER-109 results in more rapid and durable engraftment of the Firmicutes bacteria relative to placebo, producing bile-acid profiles that are known to inhibit *C. diff* spore germination and bacterial replication, and thus reduce rates of recurrent infection.<sup>8</sup> Types of adverse events (AEs) were primarily gastrointestinal and mild to moderate in nature.<sup>9</sup> AEs remained consistent across clinical trials for SER-109, even when dosage amount increased from Phase II to Phase III.

### *Inpatient Administration of SER-109*

SER-109 is administered to patients with recurring CDI who first completed a standard of care course of prescribed antibiotics. The proposed dose is four capsules taken orally once daily on an empty stomach before the first meal of the day for three consecutive days. Each capsule contains a minimum of  $1 \times 10^6$  spore colony-forming units. One day before the first dose of SER-109, patients should be administered 10 oz of magnesium-citrate or, based on medical judgment, 250 mL polyethylene glycol electrolyte solution, to reduce residual antibiotics in the gastrointestinal tract. The recommended dosage and administration are subject to final FDA approval.

**Current Coding:** There are no unique ICD-10-PCS codes to describe the administration of SER-109. Facilities can report the oral administration of SER-109 using the following code:

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

### **Coding Options**

**Option 1.** Do not create new ICD-10-PCS codes for the oral administration of SER-109. Continue coding as listed in current coding.

**Option 2.** Create new codes in section X, New Technology, to identify the oral administration of SER-109.

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>W</b> Anatomical Regions		
<i>Operation</i>	<b>0</b> Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>D</b> Mouth and Pharynx	<b>X</b> External	<b>ADD N</b> SER-109	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

<sup>8</sup> Feuerstadt P, Louie T, Lashner M. SER-109, an oral microbiome therapy for recurrent *Clostridioides difficile* Infection. *N Engl J Med* 2022; 386:200-9.

<sup>9</sup> Lee Y, Lim W, Bloom C, Bezlotoxumab (Zinplava) for *Clostridium Difficile* Infection: The First Monoclonal Antibody Approved to Prevent the Recurrence of a Bacterial Infection. *Drug Forecast* 2017;42:735-738.

## Topic # 28 - Administration of Sulbactam-Durlobactam

**Issue:** There are currently no unique ICD-10-PCS codes to describe the administration of sulbactam-durlobactam (SUL-DUR).

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** SUL-DUR was granted Fast Track and Qualified Infectious Disease Product (QIDP) Designation on July 21, 2017, for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia and bloodstream infections due to *Acinetobacter*. On September 30, 2022, Entasis Therapeutics submitted a New Drug Application (NDA) for SUL-DUR to the FDA with a proposed indication of the treatment of adults with infections due to *Acinetobacter baumannii-calcoaceticus* complex (ABC) organisms, including multi-drug resistant and carbapenem-resistant strains. According to the requestor, SUL-DUR was accepted for priority review on November 29, 2022 and the target Prescription Drug User Fee Act (PDUFA) date is May 29, 2023.

**Background:** *Acinetobacter baumannii* (*A. baumannii*) is a Gram-negative bacterial pathogen that has emerged globally as a major cause of hospital-acquired infections. While pneumonia and bacteremia are the most common infections caused by ABC, these organisms can also cause urinary tract infections, skin and soft tissue infections, wound infections, osteomyelitis, and meningitis.

According to the requestor, treatment of infections due to ABC is a serious unmet need. Infections caused by *A. baumannii* are associated with high morbidity and mortality and have become increasingly difficult to treat due to the emergence of multi-drug resistant (MDR) and carbapenem-resistant *Acinetobacter baumannii* strains (CRAB). Globally, *A. baumannii* was among the five leading pathogens contributing to the most deaths attributable to antimicrobial resistance in 2019. In 2019, an estimated 326,000 deaths globally were associated with carbapenem-resistant *A. baumannii*. The rise in carbapenem-resistant *A. baumannii* is of particular concern, leaving no clear “standard of care” antibiotic regimen for these infections. Carbapenem-resistant *Acinetobacter* is classified by the United States Centers for Disease Control and Prevention as an “urgent threat” pathogen and is ranked as “priority 1, critical” on the World Health Organization (WHO) global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics<sup>1</sup>.

### *Description and Mechanism of Action for Sulbactam-Durlobactam*

SUL-DUR is a pathogen-targeted  $\beta$ -lactam/ $\beta$ -lactamase inhibitor combination of sulbactam and durlobactam being developed for the treatment of infections caused by ABC, including carbapenem-resistant and multidrug-resistant isolates. Sulbactam is a penicillin derivative and classified as a beta-lactamase inhibitor but also has intrinsic antibacterial activity against *Acinetobacter baumannii* and other members of the ABC. Sulbactam is bactericidal due to its inhibition of penicillin-binding proteins PBP1 and PBP3, which are essential enzymes required for

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<sup>1</sup> Antibiotic Resistance Threats in the United States, 2019/ <https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf>

bacterial cell wall synthesis. Sulbactam is susceptible to degradation by many beta-lactamases expressed in ABC.

Durlobactam is a covalent, reversible, diazabicyclooctane beta-lactamase inhibitor with a broad spectrum of activity against Ambler Classes A, C and D beta-lactamases, including those that degrade sulbactam. Durlobactam effectively restores sulbactam activity against ABC organisms due to its potent inhibition of serine  $\beta$ -lactamases.

The clinical development program for SUL-DUR consists of six Phase 1 studies, one Phase 2 study, and one Phase 3 study. SUL-DUR has shown a favorable clinical profile with demonstration of linear pharmacokinetics (PK), minimal drug interactions, and good penetration into the lung. According to the requestor, SUL-DUR has been generally well-tolerated, with no drug-related serious adverse events or deaths in Phase 1 studies. In the Phase 3 study, SUL-DUR met the primary efficacy and safety objectives of the study, achieving noninferiority versus colistin in 28-day all-cause mortality and a statistically significant reduction in the incidence of nephrotoxicity. Adverse events in the safety population were comparable between treatment groups. The most common adverse reaction reported in more than one patient (>2% of patients) treated with SUL-DUR was diarrhea, which was reported in 4/91 (4.4%) of patients.

#### *Inpatient Administration of Sulbactam-Durlobactam*

Upon FDA approval, the recommended dose of SUL-DUR will be 1 g sulbactam and 1 g durlobactam every six hours by intravenous (IV) infusion over three hours in adults with a creatinine clearance (CLcr) of 45 to 129 mL/min. SUL-DUR is supplied in 3-vials that contain sterile powders that must be reconstituted with sterile water and further diluted in a 100 mL infusion bag of 0.9% Sodium Chloride for Injection using aseptic technique prior to intravenous infusion. The prepared solution should be brought to ambient room temperature (over 15-30 min) prior to infusion to the patient. Adjustments to the dosing regimen for SUL-DUR are recommended for patients with CLcr <45 mL/min. A higher dose of SUL-DUR (1.5 g sulbactam/1.5 g durlobactam every six hours) is recommended for patients with CLcr  $\geq$ 130 mL/min.

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

**Option 2.** Create new codes in section X, New Technology, to identify the intravenous administration of sulbactam-durlobactam.

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>W</b> Anatomical Regions		
<i>Operation</i>	<b>0</b> Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>3</b> Peripheral Vein	<b>3</b> Percutaneous	<b>ADD K</b> Sulbactam-Durlobactam	<b>9</b> New Technology Group 9
<b>4</b> Central Vein			

**CMS Recommendation:** Option 2, as described above.

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



## Topic # 29 - Administration of Quizartinib

**Issue:** There are currently no unique ICD-10-PCS codes to describe the administration of quizartinib.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. Quizartinib has been designated by the FDA as an orphan drug for the treatment of acute myeloid leukemia (AML). On October 20, 2022, the FDA granted quizartinib priority review status. According to the requestor, the FDA assigned a Prescription Drug User Fee Act (PDUFA) target action date of April 24, 2023.

**Background:** AML is a rapidly growing type of blood cancer in which immature bone marrow cells are overproduced and accumulate in bone marrow and other tissues. Quizartinib is a novel kinase inhibitor with a proposed indication in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, and as continuation monotherapy following consolidation, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FMS-like tyrosine kinase 3 internal tandem duplication (FLT3-ITD) positive as detected by an FDA-approved test.

Quizartinib is an orally administered, highly selective and potent second-generation type II FMS-like tyrosine kinase 3 inhibitor. It is the only small-molecule FLT3 inhibitor to be expressly developed and optimized to target and treat FLT3-ITD AML, present in approximately 27% of AML patients.<sup>1</sup> ITD is the primary driver mutation associated with aggressive disease, resulting in increased relapse rate and reduced overall survival.<sup>2</sup>

### *Mechanism of Action*

Quizartinib is a small molecule inhibitor of the receptor tyrosine kinase FLT3. Quizartinib and its major metabolite AC886 competitively bind to the adenosine triphosphate (ATP) binding pocket of FLT3 with high affinity ( $K_d = 1.3$  nM and 0.54 nM, respectively). Quizartinib and AC886 inhibit FLT3 kinase activity, preventing autophosphorylation of the receptor, thereby inhibiting further downstream FLT3 receptor signaling and blocking FLT3-ITD-dependent cell proliferation.

### *Inpatient Administration of Quizartinib*

The proposed dosing for quizartinib is 35.4 mg orally by mouth in combination with standard chemotherapy once daily for two weeks in each cycle of induction. For patients who achieved complete remission (CR) or complete remission with incomplete hematologic recovery (CRi), quizartinib should be administered at 35.4 mg once daily for two weeks in each cycle of consolidation chemotherapy followed by quizartinib continuation monotherapy initiated at 26.5 mg once daily. After two weeks, the continuation dose should be increased to 53 mg once daily if the QT interval corrected by Fridericia's formula (QTcF) is less than or equal to 450 ms. Continuation therapy may be continued for up to 36 cycles.

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<sup>1</sup> Levis, M. *Future Oncol.* 2014, 10(9):1571-1579.

<sup>2</sup> See: NCCN AML Guidelines (February 2022). Grimwade D, et al. *Blood* 2016, 127(1): 29-41. Schneider F, et al. *Ann Hematol* 2012, 1(9): 18. Kottaridis PD, et al. *Blood* 2001, 98(6): 1752-1759.

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

3E0DX05 Introduction of other antineoplastic into mouth and pharynx, external approach

**Coding Options**

**Option 1.** Do not create a new ICD-10-PCS code for the oral administration of quizartinib. Continue coding as listed in current coding.

**Option 2.** Create new codes in section X, New Technology, to identify the oral administration of quizartinib.

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>W</b> Anatomical Regions		
<i>Operation</i>	<b>0</b> Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>D</b> Mouth and Pharynx	<b>X</b> External	<b>ADD J</b> Quizartinib Antineoplastic	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 30 - Administration of Elranatamab

**Issue:** There are currently no unique ICD-10-PCS codes to describe the administration of elranatamab.

**New Technology Application?** Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

**Food & Drug Administration (FDA) Approval?** No.

**Background:** Multiple myeloma (MM) is an incurable malignancy that affects a type of white blood cell called plasma cells. In 2020, it is estimated that more than 32,000 people were diagnosed and nearly 13,000 died from multiple myeloma in the US. Multiple myeloma is associated with substantial morbidity and mortality and approximately 25% of patients have a median survival of two years or less. Treatment of relapsed and refractory multiple myeloma (RRMM) constitutes a specific unmet medical need. Patients with relapsed and refractory disease are defined as those who, having achieved a minimal response or better, experience disease progression while on therapy, or experience disease progression within 60 days of completion of their last therapy. Patients generally experience multiple lines of therapy before eventually succumbing to their disease.

According to the requestor, elranatamab offers a new mechanism of action for the treatment of RRMM. If FDA-approved, elranatamab will potentially be used for the treatment of adult patients with RRMM who have received at least four prior lines, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

### *Description and Mechanism of Action for Elranatamab*

Elranatamab is a heterodimeric humanized full-length bispecific antibody directed to B cell maturation antigen (BCMA) and CD3. According to the requestor, bispecific antibodies offer an emerging immunotherapeutic approach that allows the direct targeting of cytotoxic T cells to tumor cells. For elranatamab, the two targets are BCMA (which has high specific expression on normal plasma cells and on myeloma cells) and CD3 (which is expressed on T-cells). Elranatamab is proposed to act through direct bridging of the BCMA cell-surface antigen and the extracellular CD3 subunit expressed on T cells. Elranatamab binds to the CD3 on the T-cells and binds to the BCMA on the myeloma cells thereby bringing the cells in close proximity. The engagement of the CD3 on the T-cell activates the T-cell, leading to the T-cells releasing cytokines that result in the killing of the close-proximity MM cell.

Immuno-oncology therapies that harness T-cell activation are associated with cytokine release syndrome (CRS) and immune cell-associated neurotoxicity syndrome (ICANS). There were 123 patients in the safety population (meaning safety is assessed for all of these patients) of the MagnetisMM3 (MM3) clinical study cohort A (no prior exposure to BCMA therapies). The first four patients in the MM3 study received a single 44 mg step-up dose while the remaining 119 patients received the 12mg/32mg step-up regimen. For the analysis of CRS and ICANS, the first four patients who received a different step-up regimen (44 mg) were excluded from the analyses. For analysis of all other side effects, all 123 patients were analyzed. The most common side effect in the MM3 study was CRS that occurred in 67 (56.3%) of the 119 participants.

All of these events were mild (Grade 1, 42.0%) to moderate (Grade 2, 14.3%) in nature (no grade 3 or higher events were reported), and most CRS events occurred after the first (44.5%) or second (20.2%) step-up dose. Immune effector cell-associated neurotoxicity syndrome occurred in 4 (3.4%) of 119 participants and all of these events were mild (Grade 1, 0.8%) to moderate (Grade 2, 2.5%) in nature. The most common hematologic side effects seen in 20% or more of participants were anemia in 48.0%, neutropenia in 48.0%, thrombocytopenia in 30.1%, and lymphopenia in 26.0%. These were also the most common severe (Grade 3) or life threatening (Grade 4) side effects. The most common non-hematologic side effects seen in 20% or more of participants were diarrhea in 39.0%, decreased appetite in 32.5%, fatigue in 34.1%, injection site reaction in 26.0%, nausea in 26.0%, COVID-19 related in 25.2%, hypokalemia in 23.6%, pyrexia in 23.6%, cough in 22.0% and headache in 22.0%. Most of these side effects were mild to moderate in severity. Infections of any grade were reported in 66.7% of patients. A total of 35.0% of patients had Grade 3/4 infections.

### *Inpatient Administration of Elranatamab*

Elranatamab is provided as a solution in a histidine buffer at pH 5.8, in 40 mg/mL single-dose vials for subcutaneous injection. Elranatamab therapy begins with a priming regimen for the first two subcutaneous injections with 12 mg given on day 1 and 32 mg on day 4 of the first cycle (1 cycle = 4 weeks). Premedication with dexamethasone, diphenhydramine, and acetaminophen is required prior to the two priming doses and the first full dose. Dosing thereafter is 76 mg once weekly by subcutaneous injection. Dosing frequency is reassessed after 6 months, and dose frequency may be reduced to every two weeks (Q2W) in patients with a response persisting for  $\geq 2$  months.

**Current Coding:** There are no unique ICD-10-PCS codes to describe the subcutaneous injection of elranatamab. Facilities can report the subcutaneous injection of elranatamab with the following ICD-10-PCS code:

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

### **Coding Options**

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

**Option 2.** Create new codes in section X, New Technology, to identify the subcutaneous injection of elranatamab.

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

**CMS Recommendation:** Option 2, as described above.

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

## Topic # 31 - Administration of Epcoritamab

**Issue:** There are currently no unique ICD-10-PCS codes to describe the administration of epcoritamab, a novel CD3xCD20 bispecific monoclonal antibody.

**New Technology Application?** Yes, the requestor has submitted a New Technology Add-on Payment (NTAP) application for FY2024 consideration.

**Food & Drug Administration (FDA) Approval?** No. The requestor, Genmab US, Inc. (Genmab) and AbbVie, Inc. (AbbVie), submitted a Biologics License Application (BLA) to the FDA who granted priority review for epcoritamab for the treatment of adult patients with relapsed or refractory (R/R) Large B-Cell Lymphoma (LBCL), after two or more lines of systemic therapy. According to the requestor, the FDA assigned a Prescription Drug User Fee Act (PDUFA) target action date of May 21, 2023.

**Background:** Lymphomas represent a disease characterized by the transformation of cells lymphoid tissue, lymphocytes, and histiocytes. Lymphomas can be morphologically divided into Hodgkin's and non-Hodgkin's Lymphomas (NHL). NHLs, which account for 90% of all lymphomas, are a heterogeneous group of lymphoproliferative diseases arising from transformed B-lymphocyte progenitor cells (85-90%) or, more rarely, transformed T-lymphocyte progenitor cells (10-15%).<sup>1,2,3</sup> With an estimated 509,000 new cases globally, NHL is the most common form of hematologic malignancy.<sup>4</sup> Clinically, B-cell lymphomas can be characterized indolent (slow growing) and aggressive (fast growing). An aggressive subtype, LBCL, characterized by B-cells greater than 17µm in diameter, is a constellation of B-cell lymphomas consisting of Diffuse Large B-cell Lymphoma (DLBCL), Primary Mediastinal B-cell Lymphoma (PMBCL), High Grade B-cell Lymphoma (HGBCL), and Grade 3B Follicular Lymphoma (G3b FL).<sup>5,6</sup> DLBCL is the most common making up ~90% of all LBCLs (and 30% of all NHLs more generally). PMBCL, HGBCL and G3b FL make up less than 5% of all LBCLs.<sup>7,8</sup>

As R/R LBCL patients progress through lines of treatment, prognosis decreases.<sup>9</sup> While treatment of R/R LBCL has improved in recent years due to increased therapeutic options, patients who have

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<sup>1</sup> Parihar, A., Singh, R., Shaik, S., Negi, B., Rajguru, J., Patil, P., & Sharma, U. (2020). Non-Hodgkin's lymphoma: A review. *Journal of Family Medicine and Primary Care*, 9(4), 1834. [https://doi.org/10.4103/jfmpe.jfmpe\\_1037\\_19](https://doi.org/10.4103/jfmpe.jfmpe_1037_19)

<sup>2</sup> Singh, R., Shaik, S., Negi, B. S., Rajguru, J. P., Patil, P. B., Parihar, A. S., & Sharma, U. (2020). Non-Hodgkin's lymphoma: A review. *Journal of family medicine and primary care*, 9(4), 1834–1840.

<sup>3</sup> Gouveia, G. R., Siqueira, S. A., & Pereira, J. (2012). Pathophysiology and molecular aspects of diffuse large B-cell lymphoma. *Revista brasileira de hematologia e hemoterapia*, 34(6), 447–451.

<sup>4</sup> NHL Subtypes | Leukemia and Lymphoma Society. (n.d.). Retrieved September 13, 2022, from <https://www.lls.org/lymphoma/non-hodgkin-lymphoma/nhl-subtypes>

<sup>5</sup> Swerdlow, S. H., & Cook, J. R. (2020). As the world turns, evolving lymphoma classifications-past, present and future. *Human pathology*, 95, 55–77.

<sup>6</sup> Ganapathi, K. A., Brown, L. E., Prakash, S., & Bhargava, P. (2021). New developments in non-Hodgkin lymphoid malignancies. *Pathology*, 53(3), 349–366.

<sup>7</sup> Ganapathi, K. A., Brown, L. E., Prakash, S., & Bhargava, P. (2021). New developments in non-Hodgkin lymphoid malignancies. *Pathology*, 53(3), 349–366.

<sup>8</sup> Thandra, K. C., Barsouk, A., Saginala, K., Padala, S. A., Barsouk, A., & Rawla, P. (2021). Epidemiology of Non-Hodgkin's Lymphoma. *Medical sciences (Basel, Switzerland)*, 9(1), 5.

<sup>9</sup> Crump, M., Neelapu, S. S., Farooq, U., Van Den Neste, E., Kuruville, J., Westin, J., Link, B. K., Hay, A., Cerhan, J. R., Zhu, L., Boussetta, S., Feng, L., Maurer, M. J., Navale, L., Wiezorek, J., Go, W. Y., & Gisselbrecht, C. (2017). Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. *Blood*, 130(16), 1800–1808.

failed at least two prior therapies still have very poor prognosis.<sup>10,11,12</sup> According to the requestor, for these third line patients there is a high unmet need for a treatment option that is well tolerated, provides a deep and durable response, and is widely available for all patient subtypes.

*Mechanism of Action*

Epcoritamab is a full-length IgG1 bispecific antibody derived from a humanized mouse anti-human CD3 mAb and a human anti-CD20 mAb. CD3 is a protein complex and T-cell co-receptor involved in activating both CD8+ T-cells (cytotoxic T-cells) and CD4+ T-cells (T helper cells). CD20 is a B-cell specific marker, which is expressed on mature B-cells, including malignant B-cells of LBCL and not expressed on hematopoietic stem cells and lymphoid progenitor cells. By simultaneously binding CD3 expressing T-cells and CD20 expressing B-cells, epcoritamab induces activation and cytotoxic activity of the T-cells against the malignant B-cells in a process that is strictly dependent on epcoritamab binding to both targets.

*Inpatient Administration of Epcoritamab*

Epcoritamab is administered by subcutaneous injection over the course of 28-day cycles.

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

3E0130M Introduction of antineoplastic, monoclonal antibody, into subcutaneous tissue, percutaneous approach

**Coding Options**

**Option 1.** Do not create a new ICD-10-PCS code for the subcutaneous injection of epcoritamab. Continue coding as listed in current coding.

**Option 2.** Create a new code in section X, New Technology, to identify the subcutaneous injection of epcoritamab.

<i>Section</i>	<b>X</b> New Technology		
<i>Body System</i>	<b>W</b> Anatomical Regions		
<i>Operation</i>	<b>0</b> Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
<i>Body Part</i>	<i>Approach</i>	<i>Device / Substance / Technology</i>	<i>Qualifier</i>
<b>1</b> Subcutaneous Tissue	<b>3</b> Percutaneous	<b>ADD S</b> Epcoritamab Monoclonal Antibody	<b>9</b> New Technology Group 9

**CMS Recommendation:** Option 2, as described above.

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

<sup>10</sup> Susanibar-Adaniya, S., & Barta, S. K. (2021). 2021 Update on Diffuse large B cell lymphoma: A review of current data and potential applications on risk stratification and management. *American Journal of Hematology*, 96(5), 617–629.

<sup>11</sup> Snider, J. T., McMorrow, D., Song, X., Diakun, D., Wade, S. W., & Cheng, P. (2022). Burden of Illness and Treatment Patterns in Second-line Large B-cell Lymphoma. *Clinical therapeutics*, 44(4), 521–538.

<sup>12</sup> Jalbert, J. J., Wu, N., Chen, C. I., Ambati, S., Ge, W., & Arnason, J. E. (2022). Real-World Treatment Patterns After CD19-Directed CAR T Cell Therapy Among Patients with Diffuse Large B Cell Lymphoma. *Advances in Therapy*, 39(6), 2630–2640.