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

CENTER FOR MEDICARE

Agenda

ICD-10 Coordination and Maintenance Committee Meeting
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Virtual Meeting
ICD-10-PCS Topics
September 13, 2022

Zoom Webinar and Dial-In Information

- This meeting will be conducted via Zoom Webinar. The URL to join the Zoom Webinar, the password, and the call-in numbers are the same for both days of the meeting. Meeting details for each day are as follows.
- Day 1: September 13, 2022: The meeting will begin promptly at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 12:30 PM to 1:30 PM.
- Day 2: September 14, 2022: 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 join the Zoom Webinar via the web. 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:

Click the following URL:
https://cms.zoomgov.com/j/1618774054?pwd=RzlGenRwL09TbHZKVEcrNnJDRi90QT09
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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)
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*If dialing in from outside of the U.S., visit https://cms.zoomgov.com/u/ahSKgrsLu for a list of Zoom International Dial-in Numbers.

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

1. From your room system, dial 161.199.138.10 (US West) or 161.199.136.10 (US East)
2. Enter the webinar ID: 161 877 4054
   Passcode: 703819

SIP: 1618774054@sip.zoomgov.com
Passcode: 703819

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

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

Note: Proposals for diagnosis code topics will be led by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and are scheduled to begin following completion of the CMS procedure code proposals on September 13, 2022. Remaining diagnosis code topics will continue to be presented on September 14, 2022. Please visit CDC's website for the Diagnosis agenda located at the following address: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm.

***Please note that registration is not required to attend the Zoom Webinar.**

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

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

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

Introductions & Overview 9:00 AM – 9:30 AM	Mady Hue, CMS Co-Chair, ICD-10 Coordination and Maintenance Committee
ICD-10-PCS Topics:	
1. Implantation of Extraluminal Support Device During Arteriovenous Fistula Creation Pages 14-17 9:30 AM – 9:50 AM	Mady Hue, CMS Ellen Dillavou, MD, FACS Chief of Vascular Surgery Wakemed Heart & Vascular Barb Peterson President & CEO Emerson Consultants, Inc.
2. Implantation of Ultrasound Penetrable Cranioplasty Plates* Pages 18-20 9:50 AM – 10:10 AM	Mady Hue, CMS Erez Nossek, MD Director, Cranial Bypass Program NYU Langone Brad Rabinovitz, COO Longeviti
3. Insertion of Transcatheter Bicaval Valve System* Pages 21-24 10:10 AM – 10:30 AM	Stacey Murphy, CMS Katharina Kiss, MD Honorable Professor Products and Features GmbH Jeffrey Voigt Principal Medical Device Consultants of Ridgewood, LLC
4. Medicare Electronic Application Request Information System™ (MEARIS™) Page 25 10:30 AM – 10:50 AM	Andrea Hazeley, CMS
5. Intubated Prone Positioning Pages 26-28 10:50 AM – 11:10 AM	Stacey Murphy, CMS Anica Law, MD, MS Assistant Professor of Medicine Boston University American Thoracic Society American College of Chest

Physicians

Scott Manaker, MD, PhD
Professor of Medicine
University of Pennsylvania
American Thoracic Society
American College of Chest Physicians

6. Section X Updates — Mady Hue, CMS
   Pages 29-31
   11:10 PM – 11:45 PM

7. Addenda and Key Updates — Andrea Hazeley, CMS
   Pages 32-38
   11:45 PM – 12:20 PM

Closing Remarks — Mady Hue, CMS
12:20 PM

LUNCH BREAK 12:30 PM to 1:30 PM

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

8. Administration of Lovotibeglogene autotemcel (lovo-cel)* — Andrea Hazeley, CMS
   Pages 39-41

9. Administration of Exagamglogene autotemcel (exa-cel)** — Andrea Hazeley, CMS
   Pages 42-43

**Requestor intends to submit a new technology add-on payment (NTAP) application for FY 2024 consideration.*
***Request is for an April 1, 2023 implementation date. The requestor intends to submit an NTAP application.*

****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.

Contact Information

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

Mady Hue
Marilu.hue@cms.hhs.gov

Andrea Hazeley
Andrea.hazeley@cms.hhs.gov

Stacey Murphy
Stacey.murphy@cms.hhs.gov

ICD-10 TIMELINE

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

September 13-14, 2022	The September 2022 ICD-10 Coordination and Maintenance Committee Meeting.
September 2022	Recordings and slide presentations of the September 13-14, 2022 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
October 1, 2022	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 14, 2022	**Deadline for receipt of public comments on proposed new codes discussed at the September 13-14, 2022 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2023.**
November 2022	Any new ICD-10 codes required to capture new diseases or technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2023 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 14, 2022	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 13-14, 2022 ICD-10**

	Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2023.
December 2, 2022	**Deadline for requestors: Those members of the public requesting that topics be discussed at the March 7-8, 2023 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and to NCHS for diagnoses by this date.** Procedure code requests should be directed to CMS at https://mearis.cms.gov. Diagnosis code requests should be directed to NCHS at nchsicd10cm@cdc.gov. Requestors should indicate if they are submitting their code request for consideration for an October 1, 2023 implementation date, or an April 1, 2024 implementation date.
January 2023	The ICD-10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an October 1, 2023 implementation date or an April 1, 2024 implementation date. Federal Register notice for the March 7-8, 2023 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
February 2023	Tentative agenda for the Procedure portion of the March 7, 2023 ICD-10 Coordination and Maintenance Committee Meeting posted on CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis portion of the March 8, 2023 ICD-10 Coordination and Maintenance Committee Meeting posted on NCHS homepage as follows: https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm
February 1, 2023	ICD-10 MS-DRG Grouper software and related materials posted on CMS webpage at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software
February 1, 2023	Any updates to the ICD-10-CM and ICD-10-PCS Coding Guidelines will be posted on the following websites:

	https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm https://www.cms.gov/Medicare/Coding/ICD10/
February 1, 2023	All ICD-10-CM and ICD-10-PCS code update files (includes April 1 update and full files from prior October 1) will be posted on the following websites: https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm https://www.cms.gov/Medicare/Coding/ICD10/
March 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: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
April 1, 2023	Any new ICD-10 codes will be implemented on April 1, 2023.
April 7, 2023	**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**.
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: https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps
May 5, 2023	**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.**

	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.
May/June 2023	Final addendum posted on web pages as follows: **Diagnosis addendum -** https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm **Procedure addendum -** https://www.cms.gov/Medicare/Coding/ICD10/index.html
June 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
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 **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.**

Introductions and Overview

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

Code Proposals

- ICD-10-PCS code proposals being considered for implementation on April 1, 2023 and 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
  - October 14, 2022 for codes being considered for April 1, 2023 implementation
  - November 14, 2022 for codes being considered for October 1, 2023 implementation
- Procedure comments to CMS: ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to NCHS: nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2022 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2022 C&M meeting
- August 2022 – Final rule with links to final codes to be implemented October 1, 2022
  - Includes any additional codes approved from March 8-9, 2022 C&M meeting
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS

Addendum

- May/June 2022 – Final code updates and addendum posted
  - FY 2023 ICD-10-PCS (Procedures) http://www.cms.gov/Medicare/Coding/ICD10/index.html
  - FY 2023 ICD-10-CM (Diagnoses) https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm

Public Participation

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

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

Written Comments

- No matter how you participate – please send written comments by
  - October 14, 2022 for codes being considered for April 1, 2023 implementation
  - November 14, 2022 for codes being considered for October 1, 2023 implementation
  - Procedure comments to CMS: ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis comments to NCHS: nchsicd10cm@cdc.gov

ICD-10-PCS Codes Implementation

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

March 7-8, 2023 C&M Code Requests

- December 2, 2022 – Deadline for submitting topics for March 7-8, 2023 C&M meeting
  - Procedure requests to CMS: https://mearis.cms.gov
  - Diagnosis requests to NCHS: nchsicd10cm@cdc.gov

Topic # 01 – Implantation of Extraluminal Support Device During Arteriovenous Fistula Creation

Issue: There are currently no unique ICD-10-PCS codes to describe the implantation of an extraluminal support device during arteriovenous (AV) fistula creation.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The VasQ™ External Support device (Laminate Medical, Ltd) was granted Breakthrough Device Designation in June 2020 for use as an external support for autologous vascular conduits created by means of vascular surgery. The requestor anticipates FDA approval in December 2022.

Background: Vascular access complications are experienced by the majority of end stage renal disease (ESRD) patients on hemodialysis, resulting in a high rate of hospitalization and morbidity. Appropriate care of hemodialysis patients requires constant attention to the maintenance of vascular access patency and function. An ideal access delivers a flow rate to the dialyzer adequate for the dialysis prescription, has a long use-life, and has a low rate of complications (e.g., infection, stenosis, thrombosis, aneurysm, repeat interventions, and limb ischemia). Of the currently available vascular access options, the surgically created fistula is the gold standard as it most closely meets the standards of an ideal vascular access, with the lowest relative complication rate. However, approximately half of all AV fistulas still require an additional procedure or are abandoned within the first six months of creation.

The AV fistula is created by suturing together an artery and a vein, usually in the arm below the elbow (brachio-cephalic) or above the wrist (radio-cephalic) and allowing arterial pressure to enlarge the vein to accommodate a large needle. To be used for dialysis, a newly created fistula must maintain patency and mature; that is, the artery and vein must undergo dilation and remodeling to accommodate the markedly increased blood flow that results from creating the AV anastomosis. The process of maturation occurs within the first one to six months and often requires additional procedures (e.g. balloon angioplasty, surgical revision, etc.) to assist the venous remodeling. Some veins are too deep to be adequately punctured with a dialysis needle and are subsequently transposed to a more superficial position during creation.

Studies have demonstrated that native AV fistulas have the best 4 to 5 year patency rates and require the fewest interventions compared with other access types. However, despite the clear benefits of native arteriovenous (AV) fistulas over other access methods, early failure occurs in over 40% of these fistulas. Most of these failures occur in the peri-anastomotic region that has been mobilized from its native surrounding tissue and left without extraluminal support. The unsupported vein can undergo significant geometric changes post-surgery that result in poor hemodynamics and negative remodeling ultimately resulting in fistula failure. According to the requestor, no FDA cleared technologies exist to address the underlying failure mechanisms at the point of fistula creation.

Technology
The VasQ™ External Support device (VasQ™) is a nitinol implant which incorporates a conical braided wire portion that fits around the vein, welded to a laser cut brace that fits over the artery at

the anastomosis. The extraluminal support was designed to retain the ideal anastomotic geometry for optimized hemodynamics and remodeling into a functional fistula.

The VasQ™ is available in 6 dimensions in an effort to comply with vessel diameters and ensure optimal fit with the fistula. An accessory to the VasQ™ External Support device is the dedicated Selection Tool, which is used during the procedure to gauge the artery diameter and select the best fitting VasQ™ dimension.

Procedure Description

The VasQ™ is implanted by the vascular surgeon during the AV fistula creation procedure. Two surgical fistula creation procedures currently exist for which VasQ™ may be indicated for use: 1) *Cimino type fistula* and 2) *Transpositions*. Cimino type fistulas describe the direct connection of a vein to an artery for the purposes of facilitating hemodialysis. Transpositions similarly describe a direct connection but also add a mobilization of the entire vein to move it to a more superficial position to help facilitate needle access for hemodialysis. Below briefly describes the additional steps required to implant VasQ™ during either AV fistula creation procedure:

Cimino type fistula: The subcutaneous tissue is carefully dissected until the artery and vein are located. The artery is measured with a designated sizing tool to select the appropriate external support device size. The device is moved proximally on the vein away from the dissected end and held in that position with a vascular clamp to prevent interference with the suturing of the anastomosis. A single suture is threaded within the eyelets of the device and under the artery. The two eyelets are sutured together under the artery to hold the device in place without constricting the artery.

Transpositions: An incision is made into the skin over the cephalic, basilic, or forearm vein from the elbow toward the shoulder for a distance long enough to accomplish the transposition. The artery is measured with a designated sizing tool to select the appropriate external support device size. After the transposition is performed, the device is placed on the vein in preparation for the anastomosis to be created. The device is moved proximally on the vein away from the dissected end and held in that position with a vascular clamp to prevent interference with the suturing of the anastomosis. A single suture is threaded within the eyelets of the device and under the artery. The two eyelets are sutured together under the artery to hold the device in place without constricting the artery.

Current Coding: There are no unique ICD-10-PCS codes to describe implantation of an extraluminal support device during AV fistula creation. Facilities can report the procedure using the device value J Synthetic Substitute and the appropriate body part value from the table below. The Bypass procedure performed to create the AV fistula would be coded separately.

Section	**0** Medical and Surgical
Body System	**5** Upper Veins
Operation	**U** Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Azygos Vein **1** Hemiazygos Vein **3** Innominate Vein, Right **4** Innominate Vein, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

5 Subclavian Vein, Right **6** Subclavian Vein, Left **7** Axillary Vein, Right **8** Axillary Vein, Left **9** Brachial Vein, Right **A** Brachial Vein, Left **B** Basilic Vein, Right **C** Basilic Vein, Left **D** Cephalic Vein, Right **F** Cephalic Vein, Left **G** Hand Vein, Right **H** Hand Vein, Left **L** Intracranial Vein **M** Internal Jugular Vein, Right **N** Internal Jugular Vein, Left **P** External Jugular Vein, Right **Q** External Jugular Vein, Left **R** Vertebral Vein, Right **S** Vertebral Vein, Left **T** Face Vein, Right **V** Face Vein, Left **Y** Upper Vein			

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify implantation of an extraluminal support device during AV fistula creation. Continue coding as described in current coding.

Option 2. In section X add new table X2U, Supplement of Cardiovascular System, and create new device value P Synthetic Substitute, Extraluminal Support Device applied to the body part values Q Upper Extremity Vein, Right and R Upper Extremity Vein, Left, to identify implantation of an extraluminal support device during AV fistula creation. The Bypass procedure performed to create the AV fistula would be coded separately.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**ADD U** Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD Q Upper Extremity Vein, Right **ADD R** Upper Extremity Vein, Left	**0** Open	**ADD P** Synthetic Substitute, Extraluminal Support Device	**9** New Technology Group 9

Option 3. In section X add new table X2H, Insertion of Cardiovascular System, and create new device value P Extraluminal Support Device applied to the body part values Q Upper Extremity Vein, Right and R Upper Extremity Vein, Left, to identify implantation of an extraluminal support device during AV fistula creation.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**ADD H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD Q Upper Extremity Vein, Right **ADD R** Upper Extremity Vein, Left	**0** Open	**ADD P** Extraluminal Support Device	**9** New Technology Group 9

CMS Recommendation: Option 2, as described above.

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

Topic # 02 – Implantation of Ultrasound Penetrable Cranioplasty Plates

Issue: There are currently no unique ICD-10-PCS codes to describe the implantation of an ultrasound penetrable cranioplasty plate.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

Food & Drug Administration (FDA) Approval? Yes. The Longeviti ClearFit® OTS (off-the-shelf) Cranial Implant (Longeviti Neuro Solutions, LLC) manufactured to correct and/or restore bony voids and/or defects of the cranium received 510(k) clearance on September 8, 2021 (K212058). The Longeviti ClearFit® Cranial Implant (Longeviti Neuro Solutions, LLC) designed and manufactured individually for each patient to correct bony voids and/or defects in the adult cranium with acoustically transparent properties received 510(k) clearance on December 16, 2020 (K203349).

Background: Cranial reconstruction procedures are generally performed following open brain surgery for a number of conditions including brain tumor resection, hydrocephalus shunt implantation, cerebral aneurysm clipping, evacuation of a brain hemorrhage, microvascular decompression, lobectomy, and more, that require removing a portion of the skull. The resulting cranial defect may be subsequently reconstructed by either replacing the portion of the skull that was removed and fastening it with fixation devices (e.g. plates and screws), or by applying a cranial prosthetic device to address the bony void and/or defect.

In addition to protecting the brain, the skull also acts as a barrier to sound and prevents using sonography for post-operative imaging. Currently, post-operative imaging for neurosurgical patients is limited to computed tomography (CT) and magnetic resonance imaging (MRI) which are currently the standard of care. However, the requestor reported that CT and MRI usually require patient transport during the inpatient recovery period which can be risky, and CT also exposes patients to ionizing radiation. Following discharge, most neurosurgical pathologies also require periodic CT or MRI follow-up scans. According to the requestor, the logistical effort and other considerations limit the quantity of imaging studies that can be reasonably performed on a patient. Avoiding additional radiation exposure and enabling the use of bedside, real time imaging would also be beneficial to the patient.

The Longeviti ClearFit® Cranial Implant and the Longeviti ClearFit® OTS Cranial Implant have lower attenuation than skull bone and therefore enable sonography: Trans-Cranioplasty Ultrasound (TCUS). According to the requestor, TCUS does not require patient transport since the devices are mobile. The availability of point of care ultrasound may also reduce the need to obtain follow-up CT or MRI imaging. According to the requestor, as an adjunct screening tool, neurosurgical imaging with TCUS may, for example, identify a tumor recurrence after surgical resection weeks or months in advance of the next scheduled CT or MRI.

Technology
Both the customized Longeviti ClearFit® Cranial Implants and the Longeviti ClearFit® OTS Cranial Implants products are manufactured from polymethylmethacrylate (PMMA) materials and can be fixated to cranial bone using commercially available fasteners.

The Longeviti ClearFit® Cranial Implants are customized prosthetic cranioplasty plates created using the patient's pre-operative computed tomography (CT) scan data. The implants are designed to either: 1) Fill an existing cranial defect that is present in the CT or 2) Restore bone in a predicted area where the skull will be removed ("single stage" procedure). Customized ClearFit® devices are delivered sterile, their design is approved by the surgeon, and they take approximately 10 business days to manufacture from receipt of the scan. Customized ClearFit® devices are "made to order".

The Longeviti ClearFit® OTS Cranial Implants are fixed-size prosthetic cranioplasty plates and come in common universal sizes and shapes. They are manufactured at scale, delivered sterile, and readily available for the surgeon at the time of surgery. ClearFit® OTS devices are not "made to order".

The customized Longeviti ClearFit® Cranial Implants and the Longeviti ClearFit® OTS Cranial Implants products are available in two device options: 1) ClearFit® Disc and 2) ClearFit® Cover. The ClearFit® Disc implants can be curved or flat to fit the shape of the skull, are intended to restore cranial bone voids and allow for the use of ultrasound after surgery. The ClearFit® Cover implants are designed to be low-profile while also allowing for visualization with ultrasound after surgery.

According to the requestor, the implants aim to restore the natural contours of the skull while maintaining the required functionality of such a device, including the required mechanical properties and ease of visualization of the underlying tissue. The attenuation of the ClearFit® device enables ultrasound imaging.

Note: The InvisiShunt® is also a Longeviti product used in cranioplasty procedures and provides a lower profile shunt to allow for a significant difference in projection, typically in hydrocephalus management. That product is not included for purposes of the code request related to ClearFit® Cranial Implants and the Longeviti ClearFit® OTS Cranial Implants.

Procedure Description
After the principal neurosurgical procedure has been performed, the selected ClearFit® device is implanted intra-operatively during "closing" or reconstructing the dura, skull, and scalp. The ClearFit® device typically replaces the bone that was removed at the beginning of the procedure to access the brain, replaces part of that bone, or replaces the titanium fasteners that are used to secure the skull flap to the native cranium. Post-operatively, the attenuation of the ClearFit® device enables ultrasound imaging approximately 24-48 hours post procedure, after swelling has subsided.

Current Coding: There are no unique ICD-10-PCS codes to describe implantation of an ultrasound penetrable cranioplasty plate. Facilities can report the procedure using the device value J Synthetic Substitute and the skull body part value from the table below. The post-operative trans-cranioplasty ultrasound (TCUS) would be reported separately with an appropriate code from the Imaging section. A code to identify the surgical procedure performed on the brain would also be reported separately.

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

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify implantation of an ultrasound penetrable cranioplasty plate. Continue coding as listed in current coding.

Option 2. In section X add new table XNR Replacement of Bones, and create new device value D Synthetic Substitute, Ultrasound Penetrable applied to the body part value 8 Skull, to identify implantation of an ultrasound penetrable cranioplasty plate.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 8 Skull	**0** Open	**ADD D** Synthetic Substitute, Ultrasound Penetrable	**9** New Technology Group 9

CMS Recommendation: Option 2, as described above.

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

Topic # 03 – Insertion of Transcatheter Bicaval Valve System

Issue: There are no unique ICD-10-PCS codes to describe the heterotopic implantation of a transcatheter bicaval valve system for tricuspid regurgitation.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

Food & Drug Administration (FDA) Approval? No. The TricValve® Transcatheter Bicaval Valve System was granted Breakthrough Device Designation on December 15, 2020 for treatment of severe tricuspid regurgitation.

Background: Tricuspid regurgitation (TR) is a condition that occurs as a consequence of malcoaptation of the tricuspid valve leaflets. This results in retrograde blood flow to the right atrium and subsequent loss of forward flow into the right ventricle. TR can cause dyspnea, hepatic congestion, ascites and edema; however, clinical sequelae may not present until TR progresses in severity. TR is usually present in patients with comorbid conditions such as: pulmonary hypertension, heart failure, atrial fibrillation, mitral valve disease, or in patients with implanted cardiac devices[1]. Severity of TR is graded as mild, moderate or severe under echocardiography[2].

It is estimated that approximately 1.6 million people in the US have been diagnosed with moderate to severe TR and therapies for management of severe TR are limited[3,4]. Current therapies consist of drug therapy and surgery. Diuretic therapy can treat systemic congestion in patients with severe symptomatic TR[3]. In patients with dilation of the tricuspid valve annulus, pulmonary vasomodulators may help reduce right ventricle overload in patients with pulmonary hypertension. According to the requestor, drug therapy may improve the symptoms but not the underlying condition in severe TR. These patients are quite sick and have a 3- and 5-year survival rate of 27% and 19% respectively[5]. In patients with signs and symptoms of right sided heart failure and TR attributable to malcoaptation of the tricuspid leaflets and-who are poorly responsive to medical therapy, tricuspid valve surgery can be beneficial to reduce symptoms. However, tricuspid valve surgery when indicated has an operative mortality of 10.9%[6,7]. Patients diagnosed with severe symptomatic TR for which there are no other treatment options due to the

[1] Bhave NM, Ward RP. Echocardiographic assessment and clinical management of tricuspid regurgitation. Curr Cardiol Rep. 2011;12:258-264.
[2] Zoghbi WA, Adams D, Bonow RO, et al. Recommendations for noninvasive evaluation of native valvular regurgitation. A report from the American Society of Echocardiography developed in collaboration with the Society for Cardiovascular Magnetic Resonance. JASE 2017;30(4):303-371.
[3] Stuge O, Liddicoat J. Emerging opportunities for cardiac surgeons within structural heart disease. JTCS. 2006;132:1258-1261.
[4] Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease. A report of the American College of Cardiology/American Heart Association joint committee on clinical practice guidelines. Circulation. 2021;143:e72-e227.
[5] Neuhold S, Huelsmann M, Pernicka E, Graf A, Bonderman D, Adlbrecht C, et al. Impact of tricuspid regurgitation on survival in patients with chronic heart failure: unexpected findings of a long-term observational study. Eur Heart Jrl. 2013;34:844-852.
[6] Alquhanti F, Berzingi CO, Aljohani S, Hijazi M, Al-Hallak A, Alkouli M, et al. Contemporary trends in the use and outcomes of surgical treatment of tricuspid regurgitation. JAHA. 2017;6e007597. DOI: 10.1161/ JAHA.117.007597
[7] Kadri AN, Menon V, Sammour YM, Gajulapalli RD, Meenakshisundaram C, Nusairat L, et al. Outcomes of patients with severe tricuspid regurgitation and congestive heart failure. Heart. 2019;105:1813-1817

advanced stage of TR and comorbidities (e.g. heart failure) associated with severe TR may benefit from a new bicaval valve system[8]. These patients are commonly not eligible for open surgery.

Technology

The TricValve® Transcatheter Bicaval Valve System is a bicaval transcatheter tricuspid valve implantation system, which includes the TricValve® Transcatheter Bicaval Valve for heterotopic placement of a Superior Vena Cava (SVC) valve and for an Inferior Vena Cava (IVC) valve. These heterotopic valves are intended to replace the function of the defective regurgitant tricuspid valve. The TricValve® Transcatheter Bicaval Valves are already pre-mounted into the TricValve® Delivery System. The bioprosthesis consists of a tubular metallic structure of nitinol which is self-expandable and radiopaque with three valve leaflets of bovine pericardium sutured and complemented by a skirt of polyester to avoid paravalvular leaks. The bioprosthesis leaflets are processed with anti-calcification treatment as well as chemical dehydration. It is available in two different diameters for each model (SVC and IVC) specifically designed to adapt to the anatomic features of the superior and inferior vena cava. The 25mm valve is used for SVC sizes ranging from 21mm to 31mm and the 29mm valve is used for IVC sizes ranging from 27mm to 34mm both with a frame height of 65mm at a relaxed state.

The TricValve® Delivery System catheter is an enclosure retraction type system and used to deploy the bioprosthesis. It has anchors in its system for safe and accurate bioprosthesis valve deployment. The distal end of the system has an atraumatic radiopaque tip and protective sheath. A capsule at the distal end covers and maintains the bioprosthesis in a crimped position. A stabilizer tube is fixed at the handle and extends outside the catheter shaft. It provides a barrier between the inner catheter shaft and vessel walls, thus enabling the catheter to retract freely. The delivery system is compatible with 0.889 mm (0.035 inch) guide wire. The handle includes a macro slider for opening and closing the bioprosthesis housing and a micro adjusting knob to facilitate accurate release of the bioprosthesis. The micro knob rotates clockwise to open the housing and in anticlockwise direction for close the capsule. The delivery system has a flush port which is used to hydrate the bioprosthesis leaflets and remove air before usage.

Procedure Description

The left and right femoral veins are accessed percutaneously and a 6 Fr. introducer sheath is inserted into each vein. A pulmonary catheter is placed via the left femoral vein access through the sheath in the right pulmonary artery to mark the crossing of the right pulmonary artery with the SVC. A 6 Fr pigtail catheter is introduced in the right femoral vein and an angiogram of the SVC is obtained. The pigtail catheter is then exchanged for a straight 0.036 inch stiff guidewire with a soft tip. The SVC valve (bioprosthesis) is hydrated and the delivery system is advanced over the guidewire through the right femoral vein and the IVC into the right atrium and the SVC. The upper part of the SVC valve is placed in the confluence of the brachiocephalic veins (where they converge to form the SVC) with the belly of the SVC valve positioned above the right pulmonary artery crossing. The valve position is confirmed under fluoroscopic and echocardiographic visualization. Once confirmation is made, the upper most 20 mm of the valve is partially deployed and full deployment is then made by unsheathing the bioprosthesis using the delivery system. The

[8] TricValve FDA pivotal clinical trial protocol. TricValve v.1.0 _10NOV2021.

IVC delivery system and bioprosthesis are properly hydrated and loaded over the guidewire at the right puncture site. The IVC bioprosthesis is positioned at the height of the diaphragm with the skirt of the bioprosthesis visible just above the hepatic vein inflow. The IVC bioprosthesis is then deployed using the delivery system. Post deployment of both the SVC and IVC bioprostheses, all catheters and introducer sheaths are removed and the access site is closed per hospital protocol. Administration of anticoagulation and/or antiplatelet therapy is administered intraprocedurally.

Current Coding: There are no unique ICD-10-PCS codes to describe the insertion of transcatheter bioprosthetic valves in the IVC and SVC. Facilities can report the procedures performed using the device value D Intraluminal Device and the appropriate body part values V, Superior Vena Cava and 0, Inferior Vena Cava from the tables below.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device*	*Qualifier*
P Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava **W** Thoracic Aorta, Descending	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Monitoring Device, Pressure Sensor **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **Y** Other Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**6** Lower Veins
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Inferior Vena Cava	**0** Open **3** Percutaneous	**D** Intraluminal Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify the insertion of transcatheter bioprosthetic valves in the IVC and SVC. Continue coding as listed 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 0 Inferior Vena Cava and 1 Superior Vena Cava, to identify the insertion of transcatheter bioprosthetic valves in the IVC and SVC.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**ADD H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 0 Inferior Vena Cava **ADD 1** Superior Vena Cava	**3** Percutaneous	**ADD R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9

CMS Recommendation: Option 2, as described above.

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

Topic # 04 - 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. We encouraged users to register and begin using this system to provide feedback on their experience with this initial version.

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 December 2, 2022 to be considered for the March 7-8, 2023 ICD-10 Coordination and Maintenance Committee Meeting.

We anticipate an updated release for MEARIS™ will be made publicly available by mid-October 2022 for users to continue submitting ICD-10-PCS code requests. The updated release will provide 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.

Topic # 05 – Intubated Prone Positioning

Issue: There are no unique ICD-10-PCS codes to describe therapeutic intubated prone positioning for acute respiratory distress syndrome.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No.

Background: Prone positioning has been shown to be beneficial in patients with moderate-to-severe acute respiratory distress syndrome (ARDS), which is a common form of acute respiratory failure in critically ill patients with high mortality. Patients with moderate-to-severe ARDS require the support of mechanical ventilation which is traditionally delivered with the patient lying in the supine position. In the proned position, the weight of the heart, abdomen, and chest wall are shifted off the lungs, and the mechanics of the diaphragm and rib cage are altered. As such, lung compression is relieved and alveolar ventilation is distributed more equally across the lung, improving oxygenation.

Prone positioning is one of only two evidence-based treatments that are strongly guideline-recommended for moderate-to-severe ARDS; the other is low tidal volume ventilation1,2. Other adjunctive treatments with weaker evidence include use of vasodilators, paralytics agents, corticosteroids, and extracorporeal membrane oxygenation.

Procedure Description
Prone positioning is the coordinated turning of a patient from lying on the back (supine position) to the chest (prone position) by a team of skilled healthcare providers. Because patients with moderate-to severe ARDS are dependent on a mechanical ventilator and often simultaneously connected to multiple life-sustaining tubes, catheters, and monitors, several preparatory steps are needed to prevent accidental dislodgement of the endotracheal tube, catheters and lines. The team prepares the patient by: (1) ensuring that the tip of the endotracheal tube is located 2-4 cm above the main carina (verified on imaging or bronchoscopy), then taping the endotracheal tube securely, (2) ensuring sufficient tube/catheter length and securing all tubes and catheters (e.g., emanating from waist to head gathered at the head of the bed, emanating from waist to feet gathered at the foot of the bed), (3) holding enteral feeding for 45 minutes to 1 hour prior to proning to reduce risk of aspiration, and (4) applying lubricant to the eyes and prophylactic hydrocolloid dressings to bony prominences (e.g., knees, iliac crest, shoulders, chin) to reduce risk of pressure ulcers. Staff should also obtain support for the head (e.g., foam donut-shaped pillow), chest/pelvis bolsters (e.g., pillows or rolled bed linens to reduce pressure of the abdomen on the bed), and ensure emergency airway and resuscitation equipment is available at the bedside in case of endotracheal tube dislodgment or hemodynamic compromise.

[1] Fan E, Del Sorbo L, Goligher EC, et al. An Official American Thoracic Society/European Society of Intensive Care Medicine/Society of Critical Care Medicine Clinical Practice Guideline: Mechanical Ventilation in Adult Patients with Acute Respiratory Distress Syndrome. Am J Respir Crit Care Med 2017;195(9):1253–63.
[2] Guerin C, Reignier J, Richard J-C, Beuret P, Gacouin A, Boulain T, et al.; PROSEVA Study Group. Prone positioning in severe acute respiratory distress syndrome. N Engl J Med 2013;368:2159–2168.

A team of 5 to 6 specially trained health care practitioners is required for a single patient. The team includes an airway expert at the head of the bed, the bedside nurse, and at least 4 additional team members with a minimum of 2 staff members positioned on each side of the bed. A review of available equipment and preparatory steps should be conducted as part of an official time out. When all equipment and team members are ready to turn the patient, the patient's airway should be suctioned and 100% oxygen administered. The team member at the head of the bed manages the airway and directs the team; while other staff members ensure the patient's neck, airway, tubes, and catheters are safely positioned and secured throughout. Techniques used to physically turn the patient to a prone position vary, but many protocols include a "log roll" method. The patient's arms are tucked at the side, the patient is pulled to the edge of one side of the bed, a new sheet is placed on the bed, the patient is turned to a lateral decubitus position, and then finally repositioned to a prone position in the center of the bed, with bolsters positioned to support the pelvis, chest, and head.

The patient's respiratory and hemodynamic status should be carefully monitored once they are placed in the fully proned position. Staff should be prepared to return the patient to the supinated position immediately if respiratory or hemodynamic status declines. Otherwise, patients tolerating the proned position may remain proned for 16 to 24 hours at a time. The entire procedure is complete when the patient is returned to the supinated position following the same preparatory and turning steps above.

Current Coding: There are no unique ICD-10-PCS codes to describe intubated prone positioning performed in the context of mechanical ventilation. Facilities can report the mechanical ventilation procedure using the appropriate code from the table below.

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

Body Part	*Approach*	*Device*	*Qualifier*
9 Respiratory	**3** Less than 24 consecutive hours **4** 24 - 96 consecutive hours **5** Greater than 96 consecutive hours	**5** Ventilation	Z No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify intubated prone positioning. Continue coding as listed in current coding.

Option 2. In section 5 table 5A0, Assistance of Physiological Systems, create new qualifier value K Intubated Prone Positioning applied to the body system value 9 Respiratory, the function value 5 Ventilation and the duration values shown in the table below to identify intubated prone positioning performed in the context of mechanical ventilation.

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

Body System	*Duration*	*Function*	*Qualifier*
9 Respiratory	**3** Less than 24 Consecutive Hours **4** 24-96 Consecutive Hours **5** Greater than 96 Consecutive Hours	**5** Ventilation	**7** Continuous Positive Airway Pressure **8** Intermittent Positive Airway Pressure **9** Continuous Negative Airway Pressure **A** High Nasal Flow/Velocity **B** Intermittent Negative Airway Pressure **ADD K** Intubated Prone Positioning **Z** No Qualifier

CMS Recommendation: Option 2, as described above.

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

Topic # 06 - Section X Update
September 2022 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 reviewied 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.

For this September 2022 ICD-10 C&M meeting we are reviewing the finalized changes based on the public comments received and sharing 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 - September 2022 Update
Group 4

ICD-10-PCS Code	Code Description	FY 2019		FY 2020		FY 2021		FY 2022				
		Freq.	NTAP	Freq.	NTAP	Freq.	NTAP	Freq.	NTAP	Total Freq.	CMS Recommendation	Technology Brand Name
XV508A4	Destruction of prostate using robotic waterjet ablation, via natural or artificial opening endoscopic, new technology group 4	38	YES	27	YES	127	NO		NO	192	TBA at March meeting	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		YES	9	TBA at March meeting	ZEMDRI™ (Plazomicin)
XW033H4	Introduction of synthetic human angiotensin ii into peripheral vein, percutaneous approach, new technology group 4	180	YES	400	YES	327	NO		NO	907	TBA at March meeting	GIAPREZA™
XW043G4	Introduction of plazomicin anti-infective into central vein, percutaneous approach, new technology group 4	1	YES	1	YES	2	YES		YES	4	TBA at March meeting	ZEMDRI™ (Plazomicin)
XW043H4	Introduction of synthetic human angiotensin ii into central vein, percutaneous approach, new technology group 4	441	YES	851	YES	379	NO		NO	1,671	TBA at March meeting	GIAPREZA™

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

Lttr	C	
Main	Add	COMIRNATY(R)
		use COVID-19 Vaccine
		use COVID-19 Vaccine Booster
		use COVID-19 Vaccine Dose 1
		use COVID-19 Vaccine Dose 2
		use COVID-19 Vaccine Dose 3
Lttr	D	
Main	Delete	DynaNail(R) (Hybrid) (Mini)
	Delete	use Internal Fixation Device, Sustained Compression in 0RG
	Delete	use Internal Fixation Device, Sustained Compression in 0SG
Main	Add	DynaNail(R) (Helix) (Hybrid) (Mini)
	Add	use Internal Fixation Device, Sustained Compression in 0RG
	Add	use Internal Fixation Device, Sustained Compression in 0SG
Lttr	O	
Main		Oxygenation
	Delete	Supersaturated see Assistance, Circulatory 5A05
	Add	Supersaturated see Assistance, Cardiac 5A02
Lttr	P	
Main	Add	Space of Retzius use Pelvic Cavity
Lttr	S	
Main	Add	SPIKEVAX(tm)
		use COVID-19 Vaccine
		use COVID-19 Vaccine Booster
		use COVID-19 Vaccine Dose 1
		use COVID-19 Vaccine Dose 2
		use COVID-19 Vaccine Dose 3
Main	Delete	Supersaturated Oxygen therapy
	Delete	5A0512C
	Delete	5A0522C
Lttr	T	
Main		Transfusion
	Delete	Immunotherapy see New Technology, Anatomical Regions XW2
	Add	New Technology see New Technology, Anatomical Regions XW1

***All Addenda updates are being considered for implementation on April 1, 2023.*

Lttr V
Main Add Vertebral artery, intracranial portion use Intracranial Artery

ICD-10-PCS Body Part Key Addenda

Section 0 Medical and Surgical
Axis 4 Body Part
Term Intracranial Artery
Includes Add Vertebral artery, intracranial portion

Axis 4 Body Part
Row Add
Term Add Pelvic Cavity
Includes Add Space of Retzius

ICD-10-PCS Device Key Addenda

Axis 6 Device
Row
Term Internal Fixation Device, Sustained Compression for Fusion in Lower Joints
Includes Delete DynaNail(R) (Hybrid) (Mini)
Includes Add DynaNail(R) (Helix) (Hybrid) (Mini)

Row
Term Internal Fixation Device, Sustained Compression for Fusion in Upper Joints
Includes Delete DynaNail(R) (Hybrid) (Mini)
Includes Add DynaNail(R) (Helix) (Hybrid) (Mini)

ICD-10-PCS Substance Key Addenda

Section X New Technology
Axis 6 Device / Substance / Technology
Row
Term COVID-19 Vaccine
Includes Add COMIRNATY(R)
Includes Add SPIKEVAX(tm)

Term COVID-19 Vaccine Booster
Includes Add COMIRNATY(R)
Includes Add SPIKEVAX(tm)

***All Addenda updates are being considered for implementation on April 1, 2023.*

Term		COVID-19 Vaccine Dose 1
Includes	Add	COMIRNATY(R)
Includes	Add	SPIKEVAX(tm)

Term		COVID-19 Vaccine Dose 2
Includes	Add	COMIRNATY(R)
Includes	Add	SPIKEVAX(tm)

Term		COVID-19 Vaccine Dose 3
Includes	Add	COMIRNATY(R)
Includes	Add	SPIKEVAX(tm)

ICD-10-PCS Table Addenda

Medical and Surgical Section

Axis 5 Approach
Temporary Balloon Occlusion

Source	Description	Code specification
2022, public request with CMS internal review	In the Medical and Surgical section table 02L, Occlusion of Heart and Great Vessels, add the approach value 0 Open, applied to the body part value W Thoracic Aorta, Descending, for the device value D Intraluminal Device and qualifier value J Temporary. Also, in table 04L, Occlusion of Lower Arteries, add the approach value 0 Open applied to the body part value, 0 Abdominal Aorta for the device value D Intraluminal Device and qualifier value J Temporary. These changes enable the capture of procedures such as the open temporary occlusion of the descending or abdominal aorta using a balloon.	Add: 02LW0DJ (1 code) 04L00DJ (1 code)

EXAMPLES

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

Body Part	*Approach*	*Device*	*Qualifier*
7 Atrium, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**K** Left Atrial Appendage
H Pulmonary Valve **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **S** Pulmonary Vein, Right	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**Z** No Qualifier

T Pulmonary Vein, Left **V** Superior Vena Cava			
R Pulmonary Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**T** Ductus Arteriosus **Z** No Qualifier
W Thoracic Aorta, Descending	**ADD 0** Open **3** Percutaneous	**D** Intraluminal Device	**J** Temporary

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

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

Axis 7 Qualifier

Laser Interstitial Thermal Therapy (LITT)

Source	Description	Code specification
2022, public request with CMS internal review	In the Upper Bones body system of the Medical and Surgical section, add qualifier value 3 Laser Interstitial Thermal Therapy, and add to the root operation Destruction table 0P5 for the body part values 3 Cervical Vertebra and 4 Thoracic Vertebra. Also, in the Lower Bones body system of the Medical and Surgical section, add qualifier value 3 Laser Interstitial Thermal Therapy, and add to the root operation Destruction table 0Q5 for the body part values 0 Lumbar Vertebra and 1 Sacrum. These changes enable capture of detail for procedures such as Laser Interstitial Thermal Therapy (LITT) of the vertebra.	Add: 0P5[34][034]Z3 (6 codes) 0Q5[12][034]Z3 (6 codes)

EXAMPLES

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Sternum **1** Ribs, 1 to 2 **2** Ribs, 3 or More **5** Scapula, Right **6** Scapula, Left **7** Glenoid Cavity, Right **8** Glenoid Cavity, Left **9** Clavicle, Right **B** Clavicle, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

C Humeral Head, Right **D** Humeral Head, Left **F** Humeral Shaft, Right **G** Humeral Shaft, Left **H** Radius, Right **J** Radius, Left **K** Ulna, Right **L** Ulna, Left **M** Carpal, Right **N** Carpal, Left **P** Metacarpal, Right **Q** Metacarpal, Left **R** Thumb Phalanx, Right **S** Thumb Phalanx, Left **T** Finger Phalanx, Right **V** Finger Phalanx, Left			
3 Cervical Vertebra **4** Thoracic Vertebra	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**ADD 3** Laser Interstitial Thermal Therapy **Z** No Qualifier

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebra **1** Sacrum	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**ADD 3** Laser Interstitial Thermal Therapy **Z** No Qualifier
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 **B** Lower Femur, Right **C** Lower Femur, Left **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	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

Administration Section
Axis 4 Body System/Region

Intraosseous Administration of Blood Products

Source	Description	Code specification
2022, Coding Clinic Editorial Advisory Board & CMS internal review	In the Administration section root operation Transfusion table 302, add the body part value T Bone Marrow, applied to the approach value, 3 Percutaneous for the blood product substance values below and qualifier values 0 Autologous and 1 Nonautologous. These changes enable the capture of procedures such as the intraosseous administration of blood products.	Add: 302T3[HJKLNPR][01] (14 codes)

EXAMPLE

Section	**3** Administration
Body System	**0** Circulatory
Operation	**2** Transfusion: Putting in blood or blood products

Body System / Region	*Approach*	*Substance*	*Qualifier*
ADD T Bone Marrow	**3** Percutaneous	**H** Whole Blood **J** Serum Albumin **K** Frozen Plasma **L** Fresh Plasma **N** Red Blood Cells **P** Frozen Red Cells **R** Platelets	**0** Autologous **1** Nonautologous

New Technology Section
Axis 6 Device / Substance / Technology

Administration of REGN-COV2 Monoclonal Antibody

Source	Description	Code specification
2022, CMS internal review	In New Technology Section table XW0, add substance value G REGN-COV2 Monoclonal Antibody, applied to body part value 1 Subcutaneous Tissue and approach value 3 Percutaneous, to identify the subcutaneous administration of REGN-COV (Casirivimab and imdevimab). These changes enable the efficient tracking of this therapeutic when used in the treatment of COVID-19.	Add: XW013G6 (1 code)

EXAMPLE

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

Body Part	*Approach*	*Substance*	*Qualifier*
1 Subcutaneous Tissue	**3** Percutaneous	**ADD G** REGN-COV2 Monoclonal Antibody	**6** New Technology Group 6
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**G** REGN-COV2 Monoclonal Antibody	**6** New Technology Group 6

Administration of Sabizabulin

Source	Description	Code specification
2022, CMS internal review	In New Technology Section table XW0, Introduction, create new substance value K Sabizabulin. Sabizabulin is an orally administered antiviral/anti-inflammatory therapeutic. These changes enable the efficient tracking of this therapeutic when used in the treatment of COVID-19.	Add: XW0DXK8 (1 code) XW0[GH]7K8 (2 codes)

EXAMPLE

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
D Mouth and Pharynx	**X** External	**ADD K** Sabizabulin	**8** New Technology Group 8
G Upper GI **H** Lower GI	**7** Via Natural or Artificial Opening	**ADD K** Sabizabulin	**8** New Technology Group 8

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr S
Main Add Sabizabulin XW0

Lttr N
Main New Technology
Add Sabizabulin XW0

Topic # 08 - Administration of Lovotibeglogene autotemcel (lovo-cel)

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of lovotibeglogene autotemcel (lovo-cel), an autologous ex vivo gene addition therapy.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

Food & Drug Administration (FDA) Approval? No. A Biologics License Application (BLA) is projected to be submitted to the FDA in the first quarter of 2023, with a request for Priority Review.

Background: Sickle cell disease (SCD)[1] is a serious, progressive and debilitating genetic disease caused by a single mutation in the Beta (β)-globin gene that leads to the production of abnormal sickle hemoglobin (HbS).[2,3,4] In low oxygen conditions, high HbS concentrations cause red blood cells (RBCs) to become sickled, sticky and rigid with a shorter lifespan, which manifests acutely as hemolytic anemia, vasculopathy and vaso-occlusion.[2-4] Repeated, painful vaso-occlusive events (VOEs), progressive vasculopathy and prolonged hemolytic anemia can result in chronic complications leading to disease progression and end-organ damage.[2,3] Chronic complications of SCD increase in prevalence and severity with age.[5,6] The median age of survival of patients with SCD is estimated to be in the fifth or sixth decade of life, which is about 20-30 years shorter than the general population.[7]

Current management of SCD relies on the lifelong use of acute and chronic therapies with suboptimal clinical benefits. Despite these therapies, patients continue to experience clinical symptoms, progressive organ damage, and other substantial morbidities, which contribute to decreased quality of life, sociopsychological challenges, significant healthcare resource utilization, and early mortality.[2,8,9] Allogeneic hematopoietic-cell transplantation with matched sibling donor (MSD) remains the sole potentially curative treatment in, though its use is limited by donor availability and the risk of graft-versus-host disease and graft rejection.[2,10]

Lovotibeglogene autotemcel (lovo-cel) is an investigational one-time ex vivo gene addition therapy product being evaluated for the treatment of sickle cell disease (SCD).[1] According to the requestor, lovo-cel has the potential to treat the pathophysiological basis of the disease, reducing or eliminating downstream complications. A recent publication in the *New England Journal of Medicine*[11] reported interim analyses of efficacy and safety for patients with SCD treated with lovo-cel in the ongoing open label non-randomized Phase 1/2 study HGB-206.[1] As reported by Kanter et al,[9] as of the February 17, 2021 data cutoff, there had been no reports of graft versus host disease (GvHD), graft failure, replication-competent lentivirus, or vector-mediated insertional oncogenesis

[1] https://clinicaltrials.gov/ct2/show/NCT02140554?term=lentiglobin&cond=sickle+cell&draw=2&rank=2
[2] Kato GJ, et al. Nat Rev Dis Primers. 2018;4:18010.
[3] Sundd P, et al. Annu Rev Pathol. 2019;14:263-292.
[4] Ware RE, et al. Lancet. 2017;390:311–323
[5] Kanter, et al. Blood Rev. 2013;27(6):279- 287.
[6] Serjeant, GR. Cold Spring Harb Perspect Med. 2013;3(10):a011783.
[7] Elmariah H, et al. Am J Hematol. 2014;89(5):530-535.
[8] Buchanan GR, et al. 2014. Available at https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf.
[9] Brousseau DC, et al. JAMA. 2010;303(13) :1288-1294.
[10]Shenoy S. Hematology Am Soc Hematol Educ Program. 2011;2011:273-279.
[11] Kanter J, et al. N Engl J Med. 2022;386:617-628.

in subjects from Group C or any subject treated in HGB-206. The safety data from Group C patients in HGB-206 remain generally consistent with the known side effects of autologous hematopoietic stem cell collection and myeloablative single-agent busulfan conditioning, as well as underlying SCD.

Mechanism of Action
Gene therapy with lovo-cel consists of the autologous transplantation of hematopoietic stem and progenitor cells (HSPCs) transduced with the BB305 lentiviral vector encoding a modified β-globin gene, which results in the production of antisickling hemoglobin HbA^{T87Q}. HbA^{T87Q} is a modified adult hemoglobin (Hb) with an amino-acid substitution (threonine to glutamine at position 87) designed to sterically inhibit polymerization of HbS.[11] Lovo-cel administration results in the engraftment of hematopoietic stem cells (HSCs) containing the $\beta^{A\text{-}T87Q}$-globin gene permanently integrated into their genomic DNA, enabling durable expression of $\beta^{A\text{-}T87Q}$-globin, which prevents the root cause of the disease burden of SCD (polymerization of HbS) by increasing total hemoglobin (Hb) concentration and therefore decreasing the concentration of HbS in the blood.[12,13,14]

Inpatient Administration of Lovotibeglogene autotemcel (lovo-cel)
Lovo-cel is a cell suspension for intravenous infusion. The minimum recommended dose is 3.0×10^6 CD34+ cells/kg, shipped to the hospital in one or more (up to four) patient-specific infusion bags, in metal cassette(s) in a cryoshipper.

The patient journey or treatment regimen for SCD patients treated with lovo-cel comprises mobilization/apheresis to collect the patient's own stem cells, manufacturing of the gene therapy product utilizing those cells as the starting material (during which the patient remains out of the hospital), myeloablative conditioning, intravenous infusion of lovo-cel and recovery (during which the patient is in hospital). The lovo-cel infusion should be completed as soon as possible and no more than four hours after thawing. Each infusion bag will be administered via intravenous infusion over a period of less than 30 minutes. If more than one infusion bag, all infusion bags must be administered consecutively. The entire volume of each infusion bag should be infused. The myeloablative conditioning, lovo-cel infusion and monitoring through engraftment is expected to occur in the inpatient setting. In most cases, the mobilization and apheresis procedures also take place in the inpatient setting. Similar to an autologous or allogeneic stem cell transplant, following lovo-cel infusion the patient is expected to remain hospitalized for a period of time to allow for engraftment and reconstitution of the immune system. As reported by Kanter et al, 2022, in the interim analysis of Study HGB-206 Group C, the median (min, max) duration of hospitalization from admission for myeloablative conditioning to post-infusion discharge was 35 (26, 65) days (N=35).[9]

Current Coding: There are no unique ICD-10-PCS codes to describe the intravenous transfusion of lovotibeglogene autotemcel (lovo-cel). Facilities can report the intravenous transfusion of lovotibeglogene autotemcel (lovo-cel) with one of the following ICD-10-PCS codes:

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

[12] Kato GJ, et al. Blood Rev. 2007;21:37-47.
[13] Shaeffer JR, et al. Nature. 1978;276 :631-3.
[14] Ngo DA, et al. Br J Haematol. 2012;156 :259-64.

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous transfusion of lovotibeglogene autotemcel (lovo-cel). Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the intravenous transfusion of lovotibeglogene autotemcel (lovo-cel).

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD H** Lovotibeglogene Autotemcel	**ADD 9** New Technology Group 9

CMS Recommendation: Option 2, as described above.

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

Topic # 09 - Administration of Exagamglogene autotemcel (exa-cel)

Issue: There are no unique ICD-10-PCS codes to describe the administration of exagamglogene autotemcel (exa-cel), an autologous ex vivo gene-edited biological product.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application. The requestor is seeking an April 1, 2023 implementation date.

Food & Drug Administration (FDA) Approval? No.

Background: The Beta (β)-hemoglobinopathies, which include β-thalassemia and sickle cell disease (SCD), are among the most prevalent monogenic (meaning caused by variation in a single gene) disorders worldwide. β-thalassemia is an autosomal recessive disease caused by a mutation in or near the beta-globin (HBB) gene that results in reduced or absent production of functional beta-globin. When beta-globin is absent, alpha-globin and its degradation products precipitate, which can cause intracellular hemichrome precipitation, ineffective erythropoiesis, chronic hemolysis, and profound anemia. In transfusion-dependent β-thalassemia (TDT), the most clinically severe form of the disease, patients require long-term red-cell transfusions for survival and the prevention of serious complications.

SCD, an inherited disorder that affects red blood cells, is caused by mutations in the HBB gene that contains instructions to make a component of hemoglobin. In sickle cell disease, at least one HBB gene copy contains instructions for making hemoglobin S, while the second gene copy may contain instructions for making another faulty version of the protein, such as hemoglobin C. Red blood cells containing faulty hemoglobin can become misshapen and rigid, making it difficult to pass through small blood vessels, slowing or blocking blood flow. This in turn can compromise oxygen delivery to different tissues and organs, causing damage and inflammation. Blood vessel blockage also can result in episodes of sudden and severe pain, known as vaso-occlusive crises (VOCs). Sickled red blood cells usually break apart and die much quicker than healthy rounded red blood cells are made, causing a shortage of red blood cells, or anemia, the most common symptom of the sickle cell.

The current standard of care for patients with TDT consists of lifelong, regular red-cell transfusions and iron chelation. The risks of serious complications from transfusion-related iron toxicity and viral infections persist despite improvements in care. In SCD, commonly used medications include antibiotics to prevent infections and painkillers to manage pain. Other treatments also are available to reduce the frequency of pain crises, including hydroxyurea and Adakveo (crizanlizumab). The only potentially curative option for both β-thalassemia and SCD is allogeneic hematopoietic-cell transplantation. Such transplants are complex, however, and carry risks such as graft rejection, graft-versus-host disease, and other treatment-related toxic effects.

Exa-cel, also known as CTX001™, is an investigational therapy based on the clustered regularly interspaced short palindromic repeats (CRISPR) and CRISPR-associated protein 9 (Cas9) gene-editing tool. CRISPR/Cas9 edits genes by precisely cutting DNA and then letting natural DNA repair processes to take over. Exa-cel is designed to modify a patient's blood cell precursors to produce high levels of fetal hemoglobin (HbF). HbF is a form of oxygen-carrying hemoglobin found in newborn red blood cells that transports oxygen more efficiently than its adult equivalent

(Hb). HbF can substitute for the diseased hemoglobin in TDT and SCD patients, reducing or eliminating symptoms.

Mechanism of Action
As a therapy, exa-cel involves isolating a patient's own hematopoietic stem cells (HSCs), editing them with CRISPR/Cas9 to increase HbF in the red blood cells, and then returning the edited cells to the patient through a stem cell transplant. The target of CRISPR/Cas9 editing is the erythroid-specific enhancer region of BCL11A. Reducing BCL11A expression increases fetal hemoglobin expression. According to the requestor, the elevation of HbF by exa-cel has the potential to alleviate or eliminate transfusion requirements for patients with TDT and reduce painful and debilitating sickle crises for patients with SCD. Exa-cel is being studied in clinical trials. The safety data reported to date for exa-cel has been consistent with an autologous stem cell transplant and myeloablative conditioning with busulfan.

Inpatient Administration of Exagamglogene autotemcel (exa-cel)
Exa-cel is prepared from a patient's own HSCs, which are collected from the peripheral blood. The cells are edited at a manufacturing facility, cryopreserved and shipped back to the authorized treatment center (e.g., hospital). Once the cells are received at the authorized treatment center, the patient undergoes myeloablative conditioning with busulfan before the cells are infused. Exa-cel is then administered via a stem cell transplant procedure as a single dose through a central venous catheter, at least 48 hours and within 7 days after the last busulfan dose. Monitoring for adverse events and engraftment occurs along with the administration of any supportive therapy that may be required. Once engraftment occurs, the cells begin production of red blood cells that express fetal hemoglobin.

Current Coding: There are no unique ICD-10-PCS codes to describe the intravenous transfusion of exagamglogene autotemcel (exa-cel). Facilities can report the intravenous transfusion of exagamglogene autotemcel (exa-cel) with one of the following ICD-10-PCS codes:

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous transfusion of exagamglogene autotemcel (exa-cel). Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the intravenous transfusion of exagamglogene autotemcel (exa-cel).

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**1** Transfusion: Putting in blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD J** Exagamglogene Autotemcel	**ADD 8** New Technology Group 8

CMS Recommendation: Option 2, as described above.

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