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

CENTER FOR MEDICARE

Agenda

ICD-10 Coordination and Maintenance Committee Update
Department of Health and Human Services
Centers for Medicare & Medicaid Services
ICD-10-PCS Topics Open for Public Comment
Fall 2025

CMS will not be presenting the Fall 2025 ICD-10-PCS procedure code topics during a public meeting. Instead, CMS will be posting the procedure code topic materials and soliciting public comments regarding any clinical questions or coding options consistent with the approach we utilized for the Spring 2025 update and have utilized as of March 2021 for the procedure code requests that involve a new technology add-on payment (NTAP) application for the administration of a therapeutic agent. The deadline to submit comments for procedure code topics being considered for an April 1, 2026 implementation is October 10, 2025, and the deadline to submit comments for procedure code topics being considered for an October 1, 2026 implementation is November 14, 2025.

Members of the public should send any questions or comments related to the procedure code topics that are under consideration for an April 1, 2026 implementation or an October 1, 2026 implementation to the CMS mailbox at: ICDProcedureCodeRequest@cms.hhs.gov by the respective deadline.

All procedure code topic materials and related documents will be made available on the CMS web site at https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials. Additionally, CMS will post a question-and-answer document to address any clinical or coding questions that members of the public may have submitted by the designated October 10, 2025 or November 14, 2025 deadline.

Note: Proposals for diagnosis code topics will be presented virtually by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and are scheduled for both days, September 9-10, 2025. Please visit the CDC's website for the diagnosis code topics agenda located at: https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html.

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

To sign up go to CMS website:
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2. A new subscriber screen will appear. Confirm your primary email address.
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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.
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.
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Topics Being Considered for ICD-10-PCS Procedure Codes

Overview	Mady Hue, CMS Co-Chair, ICD-10 Coordination and Maintenance Committee
ICD-10-PCS Topics:	
1. Transcatheter Division of Interventricular Myocardial Septum*** Pages 13-15	Mady Hue, CMS Toby Rogers, MD Valvular & Structural Heart Disease Medstar Washington Hospital Center
2. Dilation using Electromechanical Obstetrical Dilator** Pages 16-18	Mady Hue, CMS Daniel W. Skupski, MD Professor of Obstetrics & Gynecology Weill Cornell Medical College
3. Dilation of the Inferior Vena Cava and the Iliocaval Confluence with an Open-Structure Lattice Stent** Pages 19-22	Andrea Hazeley, CMS Dr. Kush Desai Chief, Division of Interventional Radiology Northwestern Memorial Hospital Gabe Donatell Product Specialist W.L. Gore & Associates, Inc.
4. Insertion of a Lumenless Small Diameter Defibrillation Lead** Pages 23-26	Andrea Hazeley, CMS Chad Bounds Principal Systems Engineer Medtronic
5. Measurement of Whole-Body Mass Composition* Pages 27-29	Jeanine Du Verney, CMS Alex Urlando Managing Director COSMED USA, Inc.
6. Computer-aided Assessment of Glucose*** Pages 30-32	Jeanine Du Verney, CMS Donald E. Fetterolf, Consultant Glytec, LLC
7. Cardiovascular Bypass with Autologous Cell Seeded Tissue Engineered Resorbable Scaffold* Pages 33-36	Jeanine Du Verney, CMS Christopher Breuer, MD Dir. Regenerative Medicine Nationwide Children's Hospital

8. Section X Updates Pages 37-47	Jeanine Du Verney, CMS
9. Addenda and Key Updates Pages 48-63	Andrea Hazeley, CMS
10. Intracochlear Administration of DB-OTO* Pages 64-66	Mady Hue, CMS Peter C. Weber, MD Professor, Boston University Chobanian & Avedisian School of Medicine Boston Medical Center
11. Administration of CPI-601* Pages 67-68	Jeanine Du Verney, CMS
12. Administration of ZEMAIRA®** Pages 69-70	Jeanine Du Verney, CMS
13. Administration of anitocabtagene autoleucel** Pages 71-73	Mady Hue, CMS

**Request is for an April 1, 2026 implementation date.*
***Request is for an April 1, 2026 implementation date and the requestor intends to submit a New Technology Add-on Payment (NTAP) application for future consideration.*
****Request is for an October 1, 2026 implementation data and the requestor intends to submit an NTAP application for future consideration.*

Continuing Education Credits:
Continuing education (CEU) credits may be awarded by the American Academy of Professional Coders (AAPC) or the American Health Information Management Association (AHIMA) for participation in CMS ICD-10 Coordination and Maintenance (C&M) Committee 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 CEUs or either statement, please contact the respective organization, not CMS.

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

Mady Hue
Marilu.Hue@cms.hhs.gov

Andrea Hazeley
Andrea.Hazeley@cms.hhs.gov

Jeanine Du Verney
Jeanine.DuVerney@cms.hhs.gov

ICD-10 TIMELINE

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

September 9-10, 2025	The diagnosis code portion of the September 2025 ICD-10 Coordination and Maintenance Committee Meeting will be fully virtual by zoom and dial-in. Those who wish to attend must participate via Zoom Webinar or by dialing in. The procedure code topics will be open for public comment.
September 2025	Recordings and slide presentations of the September 9-10, 2025 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials–** https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials
October 1, 2025	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes. Final addenda available on web pages as follows: **Diagnosis addendum –** https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **Procedure addendum –** https://www.cms.gov/medicare/coding-billing/icd-10-codes
October 10, 2025	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 9-10, 2025 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2026.**
November 2025	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, 2026 will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd-10-cm/files.html https://www.cms.gov/medicare/coding-billing/icd-10-codes

November 14, 2025	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 9-10, 2025 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2026.**
December 5, 2025	**Deadline for requestors: Those members of the public requesting that topics be discussed at the March 17-18, 2026 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. **Please be advised that new guidance on proposal submissions for diagnosis-related topics will be available by mid-October 2025 at:** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm Requestors should indicate if they are submitting their code request for consideration for an October 1, 2026 implementation date, or an April 1, 2027 implementation date. The ICD-10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an October 1, 2026 implementation date or an April 1, 2027 implementation date.
January 2026	Federal Register notice for the March 17-18, 2026 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
February 2026	Tentative agenda for the procedure portion of the March 17, 2026 ICD-10 Coordination and Maintenance Committee Meeting posted on CMS webpage at: https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials Tentative agenda for the diagnosis portion of the March 18, 2026 ICD-10 Coordination and Maintenance Committee Meeting posted on NCHS homepage at: https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html
February 1, 2026	ICD-10 MS-DRG Grouper software and related materials posted on CMS webpage at:

	https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software
February 1, 2026	Any updates to the ICD-10-CM and ICD-10-PCS Coding Guidelines will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd-10-cm/files.html https://www.cms.gov/medicare/coding-billing/icd-10-codes
February 1, 2026	All ICD-10-CM and ICD-10-PCS code update files (includes April 1 update and full files from prior October 1) will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd-10-cm/files.html https://www.cms.gov/medicare/coding-billing/icd-10-codes
March 17-18, 2026	The ICD-10 Coordination and Maintenance Committee Meeting is anticipated to be fully virtual by zoom and dial-in. Those who wish to attend must participate via Zoom Webinar or by dialing in.
March 2026	Recordings and slide presentations of the March 17-18, 2026 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/icd-10-maintenance/meetings.html **Procedure code portion of the recording and related materials–** https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials
April 1, 2026	Any new or revised ICD-10 codes will be implemented on April 1, 2026.
April 17, 2026	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 17-18, 2026 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2026**.
April 2026	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by the Omnibus Budget Reconciliation Act of 1986, Public Law 99-509 (Pub. L. 99-509). This notice will include references to the FY 2027 ICD-10-CM diagnosis and ICD-10-PCS procedure codes finalized to date. It will also include proposed revisions to the MS-DRG system based on ICD-10-CM/PCS codes

	on which the public may comment. The proposed rule can be accessed at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps
May 18, 2026	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 17-18, 2026 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2027.** **Deadline for receipt of public comments on proposed new diagnosis codes and revisions discussed at the March 17-18, 2026 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2027**.
May/June 2026	Final addenda posted on web pages as follows: **Diagnosis addendum -** https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **Procedure addendum -** https://www.cms.gov/medicare/coding-billing/icd-10-codes
June 5, 2026	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 15-16, 2026 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.** **Procedure code requests should be directed to CMS at:** https://mearis.cms.gov **Diagnosis code requests should be directed to NCHS at:** nchsicd10cm@cdc.gov Requestors should indicate if they are submitting their code request for consideration for an April 1, 2027 implementation date or an October 1, 2027 implementation date. The ICD-10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an April 1, 2027 implementation date or an October 1, 2027 implementation date.
July 2026	Federal Register notice for the September 15-16, 2026 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.

August 1, 2026	Hospital Inpatient Prospective Payment System final rule expected to be published in the Federal Register as mandated by Pub. L. 99-509. This rule will also include links to all the final codes to be implemented on October 1, 2026. This rule can be accessed at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps
August 2026	Tentative agenda for the procedure portion of the September 15, 2026 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the CMS webpage at – https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials Tentative agenda for the diagnosis portion of the September 16, 2026 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the NCHS webpage at – https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html
September 15-16, 2026	The September 2026 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 2026	Recordings and slide presentations of the September 15-16, 2026 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/icd-10-maintenance/meetings.html **Procedure code portion of the recording and related materials–** https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials
October 1, 2026	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes. Final addendum available on web pages as follows: **Diagnosis addendum –** https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **Procedure addendum –** https://www.cms.gov/medicare/coding-billing/icd-10-codes

Overview

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

Code Proposals

- ICD-10-PCS code proposals are being considered for implementation on April 1, 2026 and October 1, 2026
- CMS will provide code options and recommendations
- The public can send comments
- No final decisions are made until public comments have been reviewed

Comments on Code Proposals

- Submit public comments by
  - October 10, 2025 for codes being considered for April 1, 2026 implementation
  - November 14, 2025 for codes being considered for October 1, 2026 implementation
- Procedure topic comments to CMS: ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis topic comments to NCHS: nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2025 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to the Spring 2025 ICD-10 Coordination and Maintenance Committee Update

- August 2025 – Final rule with links to final codes to be implemented October 1, 2025
  - Includes any additional codes approved from the Spring 2025 ICD-10 Coordination and Maintenance Committee Update
  - https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps

Addenda

- June 2025 – Final code updates and addendum posted
  - FY 2026 ICD-10-PCS (Procedures)
    https://www.cms.gov/medicare/coding-billing/icd-10-codes
  - FY 2026 ICD-10-CM (Diagnoses)
    https://www.cdc.gov/nchs/icd/icd-10-cm/files.html

Public Participation

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

Public Comments

- Public comments should be submitted by:
  - October 10, 2025 for codes being considered for April 1, 2026 implementation
  - November 14, 2025 for codes being considered for October 1, 2026 implementation
  - Procedure comments to CMS: ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis comments to NCHS: nchsicd10cm@cdc.gov

ICD-10-PCS Codes Implementation

- ICD-10-PCS code proposals are under consideration for April 1, 2026 (FY 2026) or October 1, 2026 (FY 2027) implementation

March 17-18, 2026 C&M Code Requests

- December 5, 2025 – Deadline for submitting topics for the March 17-18, 2026 C&M meeting
  - Procedure requests to CMS: https://mearis.cms.gov
  - Diagnosis requests to NCHS: nchsicd10cm@cdc.gov

Topic # 01 – Transcatheter Division of Interventricular Myocardial Septum

Issue: There is no unique ICD-10-PCS code to describe a transcatheter myotomy of the interventricular myocardial septum. An October 1, 2026 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No.

Background: Left ventricular outflow tract (LVOT) obstruction is a source of morbidity in patients diagnosed with hypertrophic cardiomyopathy (HCM) and is a life-threatening complication of transcatheter mitral valve replacement (TMVR). Hypertrophic cardiomyopathy (HCM) is the most common genetic cardiomyopathy that results in a thickening of the heart muscles, particularly in the left ventricle which can produce a wide variety of hemodynamic conditions and symptoms. Some patients may be asymptomatic while others can have severe impairment of their daily function or experience sudden cardiac death. It affects an estimated 1 in 200 to 1 in 500 individuals in the general population. Of these, approximately 70% exhibit LVOT obstruction, yet only 10–15% of cases are clinically diagnosed. Per the requestor, this suggests a U.S. prevalence of approximately 690,000 to 1.7 million individuals with HCM, many of whom remain undiagnosed, and globally, the estimated prevalence of HCM ranges from 16 to 40 million, with a significant proportion having obstructive disease. The requestor reported that with the expansion of public awareness campaigns, direct-to-consumer marketing, and artificial intelligence (AI)-driven ECG screening, the number of diagnosed cases is expected to rise substantially.

According to the requestor, all symptomatic patients with HCM represent potential candidates for Septal Scoring Along Mid-Line Endocardium (SESAME), a procedure that is anticipated to replace the current gold standard, surgical myotomy/myectomy, as well as replace existing septal reduction therapies and potentially eliminate the need for lifelong pharmacologic management. Also, it is anticipated that SESAME will provide a treatment for patients with symptomatic LVOT obstruction or to facilitate TMVR.

Technology
SESAME is an electrosurgical transcatheter myotomy system designed to lacerate the interventricular myocardial septum wall to treat LVOT obstruction (LVOTO) in patients with HCM. The system has two deflectable catheters that position the radiofrequency (RF) cutting electrode within the left ventricle accurately and operate within an external catheter management platform to maintain the desired catheter position during the procedure. The system consists of the following components: Outer Deflectable Catheter, Inner Deflectable Catheter with a RF cutting electrode, Transmural SESAME Stabilizer System, and Transmural SESAME Management Catheter Platform. The Outer and Inner Deflectable Catheters are reinforced with a stainless steel hypotube and different durometers of Pebax® outer jackets. The Outer Deflectable Catheter is also supplied with a dilator constructed out of Pebax®. The Platinum/Iridium (90%-10%) electrode delivering the RF energy is coated with electrically insulated biocompatible coating (Electrobond™, Surface Solutions Inc.) except at the cutting edge. The RF electrode is connected to the 32 American Wire Gauge (AWG) copper wire covered with polyester with polyamide-imide insulative overcoating and it is embedded into the Pebax® catheter shaft. The Stabilizer System is

made of nitinol Drawn Filled Tube (DFT) wires and stainless-steel micro machine parts. The handles for coaxial deflectable catheters and the catheter management platform are non-patient contact and are constructed of injection molded parts made of acrylonitrile butadiene styrene (ABS), Delrin, and stainless-steel materials.

Procedure Description
Procedure details for the Transmural SESAME transcatheter myotomy system:
Step 1 - A .035" guidewire is introduced through the pigtail catheter in the right femoral artery and placed in the left ventricle and the pigtail catheter is removed.
Step 2 - The Transmural SESAME outer-deflectable catheter and dilator are advanced over the 0.035" guidewire into the left ventricle, below the aortic valve. The dilator and guidewire are removed, leaving the outer catheter as a supportive conduit for the inner deflectable catheter.
Step 3 - The Transmural SESAME inner deflectable RF catheter is then advanced through the outer deflectable catheter to the left ventricle. While the inner catheter is positioned inside the outer catheter, the distal end of the outer catheter is deflected to achieve perpendicular orientation to the septum below the target site of the myotomy. After achieving desired deployment orientation and location, using the stabilizer rail pusher, the temporary fixation element is inserted into the septum. If necessary, engagement of stabilizer element with tissue is confirmed using angiography.
Step 4 - The outer deflectable catheter then is pulled back into the aortic arch to expose the inner deflectable catheter. Using the catheter management platform rotation knob, adjust the orientation of the inner deflectable catheter to ensure electrode is in direct contact with tissue.
Step 5 - To achieve the laceration, the inner deflectable catheter is retracted and advanced over the rail between the temporary fixation element and pig tail (using as landmark to locate aortic valve), while it is connected to an RF generator and energized at 10-25W.
Step 6 - Once the myotomy is complete, the inner catheter is advanced to the temporary fixation element, and the temporary fixation element is retracted into the inner deflectable catheter. The system is then removed from the body.

The Transmural SESAME system is a single use disposable device utilized in a standalone procedure. It is not yet in clinical trials and there are no adverse events to report, however, the requestor stated that based on experience gained using off-label and off-the-shelf tools, approximately 300 procedures using the Transmural SESAME system have been successfully performed over the past 24 months.

Current Coding: There is no unique ICD-10-PCS code to describe transcatheter division of the interventricular myocardial septum. Code the procedure in table 02Q Repair of Heart and Great Vessels, with the body part value M Ventricular Septum and the percutaneous approach.

Section **0** Medical and Surgical *Body System* **2** Heart and Great Vessels *Operation* **Q** Repair: Restoring, to the extent possible, a body part to its normal anatomic structure and function			
Body Part	*Approach*	*Device*	*Qualifier*
0 Coronary Artery, One Artery **1** Coronary Artery, Two Arteries **2** Coronary Artery, Three Arteries **3** Coronary Artery, Four or More Arteries **4** Coronary Vein **5** Atrial Septum **6** Atrium, Right **7** Atrium, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

8 Conduction Mechanism **9** Chordae Tendineae **A** Heart **B** Heart, Right **C** Heart, Left **D** Papillary Muscle **H** Pulmonary Valve **K** Ventricle, Right **L** Ventricle, Left **M** Ventricular Septum **N** Pericardium **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava **W** Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch			
F Aortic Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**J** Truncal Valve **Z** No Qualifier
G Mitral Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**E** Atrioventricular Valve, Left **Z** No Qualifier
J Tricuspid Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**G** Atrioventricular Valve, Right **Z** No Qualifier

Coding Options

Option 1. Do not create a new ICD-10-PCS code for transcatheter division of the interventricular myocardial septum. Continue coding as described in current coding.

Option 2. In section X New Technology table X28, Division of Cardiovascular System, add body part value M Ventricular Septum, applied to the new technology value D Transcatheter Septal Scoring Technique and the percutaneous approach, to identify transcatheter division of the interventricular myocardial septum.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
F Aortic Valve	**3** Percutaneous	**V** Intraluminal Bioprosthetic Valve Leaflet Splitting Technology in Existing Valve	**A** New Technology Group 10
F Aortic Valve	**3** Percutaneous	**W** Leaflet Laceration, Radiofrequency Energy	**B** New Technology Group 11
ADD M Ventricular Septum	**3** Percutaneous	**ADD D** Transcatheter Septal Scoring Technique	**C** New Technology Group 12

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 02 – Dilation using Electromechanical Obstetrical Dilator

Issue: There is no unique ICD-10-PCS code to describe dilation using an electromechanical obstetrical dilator. An April 1, 2026 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. Materna Medical Inc. intends to submit a De Novo Classification Request for the Ellora™ Obstetrical System in July 2025 and anticipates marketing authorization in April of 2026.

Background: Each year, roughly 140 million women give birth worldwide, and roughly 2.5 million give birth vaginally in the U.S. During delivery, the baby passes through the vaginal canal and quickly stretches the tissue and muscles from a baseline diameter of 2.6 cm to 9-10 cm. This extreme dilation may create a tremendous amount of pelvic tissue damage, with significant consequences. Resistance from pelvic tissue can lead to pelvic tissue injury, such as lacerations that are immediately visible after delivery (affecting at least 80% of women after giving birth) and occult injuries or pelvic floor trauma when the pubovisceral muscle is completely separated from the pelvic bone, which can only be detected and diagnosed with imaging (affecting 10-30% of deliveries). Occult injuries are the leading factor in developing pelvic floor disorders including pelvic organ prolapse and urinary incontinence. The prevalence of pelvic organ prolapse identified by clinical examination is up to 50%, and the estimated lifetime risk of surgery for either stress urinary incontinence or pelvic organ prolapse is 20% by 80 years of age. However, many women in and outside the U.S. suffer from post-childbirth symptoms but do not seek or have access to treatment.

According to the requestor, there is currently no standardized approach for preparing the vagina for delivery to avoid trauma and injury to the pelvic floor, although there are a myriad of perineal techniques which can be employed to slow down the birth of the baby's head and allow the perineum to stretch slowly to prevent perineal injury. In addition to perineal massage, passive descent, hot compresses, and "hands-on" delivery are the most common forms of intervention used to prepare the vagina for delivery; however, there is significant variability in these methods, timing, and applied forces. Thus, the requestor stated that evidence supporting the clinical benefit of these interventions in reducing pelvic muscle injury is unclear and inconsistent.

Existing vaginal dilators are used for a variety of other, non-labor and delivery related indications and are typically self-administered by women in their homes for conditions such as vaginismus or dyspareunia and may or may not be prescription products. These types of vaginal dilators are not appropriate for use during labor and delivery and do not support the level of dilation required to reduce the risk of injury during childbirth. They are typically provided in sets of 6-8 dilators in sequentially larger sizes, with the largest size approximately the starting diameter of the Ellora™ dilator.

Technology
The Ellora™ System consists of a single use, semi-automated, electromechanical obstetrical dilator and a retention set. The dilator is used during the first phase of labor in order to prepare the pelvic floor muscles for vaginal delivery. Muscle and connective tissues are viscoelastic and strain-rate

dependent meaning, the slower a muscle is stretched, the easier it is to stretch. As muscle is elongated slowly, it exhibits relaxation behavior, the stress in the tissue decreases over time, thereby reducing the risk of rupture. By slowly pre-stretching the vagina and surrounding pelvic tissues during labor, the device is essentially dictating the strain rate of the tissue during labor. In previous feasibility studies, the elastic recovery of the tissue has been shown to be on the order of several hours, allowing the benefits of pre-stretching the vagina and surrounding pelvic tissues to last throughout labor. The dilator is inserted into the birth canal during the first phase of labor, while the cervix is dilating, and stretches the pelvic floor muscles using 4 radially expanding arms. Device use fits into the current workflow of labor and delivery. It would typically reside with any other devices used in labor and delivery (L&D) and be inserted after a standard cervical check confirming labor progression. The retention set is used externally to support maintaining the dilator in the birth canal for the entirety of treatment. The dilator expands slowly over approximately 1 hour to a final diameter of 8 cm, coming close to the size of the baby's head. The device is intended to be removed prior to the initiation of the second stage of labor, for delivery to occur unobstructed.

Procedure Description
The Ellora™ dilator is powered on and inserted into the birth canal during the first phase of labor, typically in the later, active stage when contractions are consistent, and the cervix has dilated to 6cm. Once the distal portion of the device is inserted, the expansion program is initiated by the clinician by pressing the + button on the device handle. This begins the ~1 hour program to stretch the pelvic floor muscles. The dilator includes an intuitive design that measures the expansion forces, and if needed adjusts expansion time accordingly to ensure dilation takes place at a rate that is appropriate for each individual. It also includes a force sensor at the distal end to indicate if fetal descent is occurring while the device is in place. The dilator can be used in conjunction with urinary catheters, intrauterine pressure catheters (IUPCs) and fetal scalp electrodes (FSEs). Ensuring any urinary catheter is routed in between the top arms of the device and any other ancillary device such as an IUPC or a FSE are routed between the bottom arms of the device. The retention set is intended to support retaining the dilator in the birth canal. The retention set is comprised of 2 soft straps and a retention adaptor. The clinician wraps the ends of a strap over each leg, under the buttocks and attaches the Velcro high on the hip, securing each strap. The retention adaptor is placed on the device handle; each strap is routed through the arms of the retention adapter to support device retention. The straps are adjusted or tightened as needed. The display on the dilator handle will indicate the current diameter as the therapy progresses. When the dilator reaches 8cm and the therapy is complete (approximately 1 hour), the retention straps are detached from the adaptor, the device is retracted by pressing the minus (-) button, and the Ellora™ dilator and the retention set are removed and discarded per the hospital's standards.

The performance of the procedure that utilizes the Ellora™ dilator is currently in clinical trials.

Current Coding: There is no unique ICD-10-PCS code to describe electromechanical obstetrical dilation performed to facilitate vaginal delivery. Code the procedure in table 0U7 Dilation of Female Reproductive System, with the body part value G Vagina, the device value Z No Device and the approach value 7 Via Natural or Artificial Opening.

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

Body Part	*Approach*	*Device*	*Qualifier*
5 Fallopian Tube, Right **6** Fallopian Tube, Left **7** Fallopian Tubes, Bilateral **9** Uterus **G** Vagina	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**D** Intraluminal Device **Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create a new ICD-10-PCS code for electromechanical obstetrical dilation. Continue coding as described in current coding.

Option 2. In section X New Technology create new table XU7, Dilation of Female Reproductive System, with sixth character technology value 1 Intraluminal Device, Temporary Electromechanical, applied to the body part value G Vagina and approach value 7 Via Natural or Artificial Opening, to identify electromechanical obstetrical dilation.

Section	**X** New Technology
Body System	**ADD U** Female Reproductive System
Operation	**ADD 7** Dilation: Expanding an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD G Vagina	**7** Via Natural or Artificial Opening	**ADD 1** Intraluminal Device, Temporary Electromechanical	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 03 – Dilation of the Inferior Vena Cava and the Iliocaval Confluence with an Open-Structure Lattice Stent

Issue: There is no unique ICD-10-PCS code to describe the dilation of the inferior vena cava and the iliocaval confluence using an open-structure, polymer lattice stent. An April 1, 2026 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. The GORE® VIABAHN® VIAFORT Venous Stent was granted Breakthrough Medical Device Status by the FDA on July 20, 2020, and is indicated for treatment of symptomatic inferior vena cava (IVC) obstruction with or without combined iliofemoral obstruction. FDA approval is anticipated in 2026.

Background: The peripheral venous system channels deoxygenated blood back to the heart through one-way bicuspid valves, working against gravity. The patency of these veins is essential for proper blood flow; any obstruction can lead to venous insufficiency. Chronic Venous Insufficiency (CVI) is a progressive condition characterized by impaired venous return due to valve dysfunction or venous obstruction. If left untreated, CVI leads to sustained venous hypertension in the lower extremities. It affects a significant portion of the population, with approximately 150,000 new cases diagnosed annually.

An estimated 10–35% of the United States (U.S.) population lives with CVI, and approximately 4% of adults aged 65 or older develop venous ulcers. Ulcer formation is associated with poorer outcomes, with 40% of patients experiencing recurrence despite standard treatments. Studies indicate that 1–17% of men and 1–40% of women may experience some level of CVI in their lifetime, with higher prevalence in industrialized nations. Risk factors include obesity, pregnancy, prior deep vein thrombosis (DVT), prolonged standing, and sedentary lifestyles.[1]

Primary CVI, which accounts for approximately 70% of cases, occurs without an identifiable precipitating event and is often attributed to congenital abnormalities or biochemical changes in the venous wall. These changes may involve reduced elastin, increased extracellular matrix remodeling, and inflammatory infiltrates, ultimately leading to valvular dysfunction. Secondary CVI, present in about 30% of cases, resulting from an inflammatory response that compromises venous function typically following a DVT.

Management of CVI is tiered based on disease severity. Initial treatment focuses on conservative measures such as leg elevation, physical activity, weight management, and, most importantly, compression therapy, which remains the cornerstone of care. Pharmacologic agents and meticulous wound care are also essential components.

CVI is not a benign disorder. Without appropriate intervention, it becomes progressively debilitating. In its advanced stages, patients often develop painful, non-healing venous ulcers that are challenging to treat. Persistent venous hypertension leads to phlebitis in approximately 60%

[1] Patel SK, Surowiec SM. Venous Insufficiency. [Updated 2024 Feb 14]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430975/

of cases, which can progress to DVT in up to 50% of those affected. Complications include recurrent ulcers, DVT, infections, and chronic pain, all of which can significantly impair quality of life.

In advanced or refractory cases, interventional procedures, such as stenting, are essential to providing vessel wall stability and support. In cases of vein stenosis or occlusion—particularly involving the common iliac veins—endovascular stenting has surpassed other interventions due to a lower risk of restenosis, with 85-90% of patients remaining ulcer-free five years post-stenting.

Technology
Per the requestor, once approved, the GORE® VIABAHN® VIAFORT Venous Stent, which is part of the GORE® VIABAHN® Device family, will be the first FDA approved open-structure polymer lattice stent device indicated for treatment of symptomatic IVC obstruction with or without combined iliofemoral obstruction in the U.S. market. Currently, there are no approved devices or device systems in the U.S. that would provide similar potential benefits for the treatment of patients who require stent placement in the IVC and the iliac veins at the iliocaval confluence.

The GORE® VIABAHN® VIAFORT Venous Stent is an open-structured, self-expanding, permanently implantable stent constructed of a nitinol frame and an FEP-ePTFE (fluorinated ethylene propylene - expanded polytetrafluoroethylene) polymer lattice. The implants are equipped with radiopaque markers at each end to facilitate fluoroscopic visualization. The GORE® VIABAHN® VIAFORT Venous Stent is delivered to the intended treatment site on a flexible delivery catheter using established endovascular procedures common to other commercially available stents and stent-grafts.

According to the requestor, iliocaval stenting is optimized using the GORE® VIABAHN® VIAFORT Venous Stent due to its high resistance to radial compression or ovalization, and minimization of implant migration. The open structure allows for perfusion from branch vessels, and the ability to axially compress during respiration to mimic natural iliocaval movement. Additionally, the polymer lattice design allows a high degree of flexibility while maintaining low material strains when subjected to bending and torsional deflections of the iliocaval veins.

The device is considered permanent. In the GORE® VIABAHN® VIAFORT Venous Stent IVC Study (NCT05409976/ VNS 21-05) which is investigating the use of the stent for symptomatic IVC obstruction with or without combined iliofemoral obstruction, of the 111 patients treated, 94% required stents placed in the IVC and bilateral common iliac veins at the iliocaval confluence, with an average of 5.2 stents used per case. Based on current knowledge from the field, the GORE® VIABAHN® VIAFORT Venous Stent has similar inherent risks as other endovascular devices used in analogous applications.

Procedure Description
Typical procedures using the GORE® VIABAHN® VIAFORT Venous Stent involve gaining vessel access using a common percutaneous vascular access technique and intraluminally transversing the lesion.

Once in the diseased vessel, intravascular ultrasound (IVUS) is often utilized to achieve accurate vessel measurements, correctly identifying both diseased and healthy vessel segments, and

ensuring precise sizing and placement of the GORE® VIABAHN® VIAFORT Venous Stent. Pre-dilation of the diseased vessel using a percutaneous transluminal angioplasty (PTA) balloon, inflated to nominal pressure, is recommended prior to stent implantation, using the balloon manufacturer's directions for use, ensuring full expansion of the balloon in the vessel.

The GORE® VIABAHN® VIAFORT Venous Stent is then advanced in the vessel, using fluoroscopic guidance for proper placement and the stent is deployed. After deployment, a recommended balloon touch-up may be performed to ensure complete apposition of the device to the venous wall.

Once the GORE® VIABAHN® VIAFORT Venous Stent has been deployed into the IVC, including post-dilation balloon touch-up, the smaller devices being implanted into the common iliac veins are extended 3 cm into the larger IVC GORE® VIABAHN VIAFORT® Stent and the deployment and balloon touch-up process is repeated. The procedure should be followed up by IVUS or contrast angiography to evaluate the treated segment prior to procedure completion.

The GORE® VIABAHN® VIAFORT Venous Stent is not indicated for patients with non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during the pre-dilation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system.

Current Coding: There is no unique ICD-10-PCS code to describe the dilation of the inferior vena cava and the iliocaval confluence using an open-structure, polymer lattice stent. Code the procedure in table 067 Dilation of Lower Veins, with the body part value 0 Inferior Vena Cava, the device value D Intraluminal Device and the percutaneous approach.

Section	**0** Medical and Surgical
Body System	**6** Lower Veins
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Inferior Vena Cava **1** Splenic Vein **2** Gastric Vein **3** Esophageal Vein **4** Hepatic Vein **5** Superior Mesenteric Vein **6** Inferior Mesenteric Vein **7** Colic Vein **8** Portal Vein **9** Renal Vein, Right **B** Renal Vein, Left **C** Common Iliac Vein, Right **D** Common Iliac Vein, Left **F** External Iliac Vein, Right **G** External Iliac Vein, Left **H** Hypogastric Vein, Right **J** Hypogastric Vein, Left **M** Femoral Vein, Right **N** Femoral Vein, Left **P** Saphenous Vein, Right **Q** Saphenous Vein, Left **T** Foot Vein, Right **V** Foot Vein, Left **Y** Lower Vein	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**D** Intraluminal Device **Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create a new ICD-10-PCS code for dilation of the inferior vena cava and the iliocaval confluence using an open-structure, polymer lattice stent. Continue coding as described in current coding.

Option 2. In section X New Technology table X27, Dilation of Cardiovascular System, create new device value C Intraluminal Device, Open-structure Polymer Lattice, applied to the new body part value shown and the percutaneous approach, to identify dilation of the inferior vena cava and the iliocaval confluence using an open-structure, polymer lattice stent.

Section	**X** New Technology		
Body System	**2** Cardiovascular System		
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 2 Inferior Vena Cava and Iliocaval Confluence	**3** Percutaneous	**ADD C** Intraluminal Device, Open-structure Polymer Lattice	**B** New Technology Group 11
3 Pulmonary Artery, Right **4** Pulmonary Artery, Left	**3** Percutaneous	**9** Intraluminal Device, Expandable	**B** New Technology Group 11
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 **E** Cephalic Vein, Left	**3** Percutaneous	**5** Intraluminal Device, Cell Impermeable	**B** New Technology Group 11
P Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left	**3** Percutaneous	**T** Intraluminal Device, Everolimus-eluting Resorbable Scaffold(s)	**A** New Technology Group 10
W Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch	**3** Percutaneous	**9** Intraluminal Device, Expandable	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 04 – Insertion of a Lumenless Small Diameter Defibrillator Lead

Issue: There are no unique ICD-10-PCS codes to describe the insertion of a lumenless small diameter defibrillation lead. An April 1, 2026 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? Yes. The OmniaSecure™ MRI SureScan™ Lead was granted Breakthrough Device Designation by the FDA on November 23, 2021. On April 22, 2025, Premarket Approval (PMA) was granted. The OmniaSecure™ MRI SureScan™ Lead is indicated for single use in the right ventricle (RV) for pacing, sensing, cardioversion, and defibrillation to treat patients who have experienced, or are at significant risk of, developing life-threatening ventricular tachyarrhythmias when a cardiac implantable electronic device is indicated. This includes adolescent pediatric patients who are at least 30 kg and are also at least 12 years of age, and whose cardiac anatomy is conducive to RV coil placement. The requestor anticipates approval for placement in the ventricular septum in 2026.

Background: Ventricular tachyarrhythmia is a term designated to those tachycardias, or fast heart rhythms, that originate from the lower ventricles. These rhythm disturbances are varied, most often linked to structural heart disease with or without coronary artery disease. Ventricular tachycardias (VT) are potentially the most dangerous heart rhythm disturbances, requiring the most aggressive therapy. VT is a potentially life-threatening arrhythmia, and it is responsible for the majority of sudden cardiac deaths in the United States.[1]

VT is a wide complex arrhythmia of ventricular origin, defined as three or more consecutive beats at a rate of more than 100 beats per minute. Sustained VT is defined as tachycardia that continues for more than 30 seconds or leads to hemodynamic compromise within 30 seconds and requires intervention. On the other hand, non-sustained VT lasts less than 30 seconds and does not cause hemodynamic instability. VT has a wide range of clinical presentations, including palpitations, chest pain, shortness of breath, syncope, and cardiac arrest.

Implantable cardioverter-defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) prevent sudden cardiac arrest in those who experience or are at risk for VT or ventricular fibrillation (VF). In ICD systems, the transvenous lead remains a vulnerable point because of lead degradation and fracture, resulting in various adverse outcomes.[2] Modern cohorts of patients receiving ICDs have greater comorbidities and longer life spans, and the ICD generator has increased longevity, influencing the need for more durable leads with a favorable safety profile.[3,4]

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[1] Tang PT, Shenasa M, Boyle NG. Ventricular Arrhythmias and Sudden Cardiac Death. Card Electrophysiol Clin. 2017 Dec;9(4):693-708.

[2] Swerdlow, C.D., Kalahasty, G. · Ellenbogen, K.A. Implantable cardiac defibrillator lead failure and management. J Am Coll Cardiol. 2016; 67:1358-1368

[3] Ajibawo, T. , Okunowo, O., Okunade, A. Impact of comorbidity burden on cardiac implantable electronic devices outcomes Clin Med Insights Cardiol. 2022; 16, 11795468221108212

[4] Hauser, R.G., Casey, S.A., Gitter, C.B. Reliability and longevity of implantable defibrillators. J Interv Card Electrophysiol. 2021; 62:507-518

Technology
The OmniaSecure™ MRI SureScan™ Lead is a lumenless, catheter-delivered, integrated bipolar, small-diameter (4.7 Fr) defibrillation lead. According to the requestor, it is the world's smallest defibrillation lead, with high durability, and the small size makes it particularly suitable for pediatric adolescent patients and those with undersized or narrowed vessels and heart chambers, in addition to any patient indicated for a transvenous ICD or cardiac resynchronization therapy (CRT-D). Conventional defibrillation leads use a central stylet lumen for lead delivery. The lumenless design of the OmniaSecure™ MRI SureScan™ Lead eliminates the stylet, which allows for a smaller diameter with targeted lead delivery by catheter. The lumenless design also makes the lead less likely to be subject to complications such as lead fracture and may reduce complications such as venous occlusion or valve interaction. The OmniaSecure™ MRI SureScan™ Lead body has a single cable running to the distal end of the lead, connecting to the fixed helix used as the tip electrode. The inner coil conductor of the lead connects with the outer defibrillation coil electrode, and the lead has tip to coil, or integrated bipolar sensing. The lead is capable of right ventricular pacing, sensing, defibrillation (shocking), and cardioversion as well as anti-tachycardia pacing.

The OmniaSecure™ MRI SureScan™ Lead is a permanent implant. Like any transvenous lead, it may need to be removed, e.g., for infection, or revised, e.g., for dislodgement. Adverse events in the Lead EvaluAtion for Defibrillation and Reliability (LEADR) Global Pivotal Trial (NCT04863664) through 12-month follow-up included lead dislodgement, oversensing, cardiac perforation, issues with device capture, and Twiddler's syndrome occurring in 19 of 657 patients. Zero lead fractures were seen through all follow-up (17.8 ± 6.0 months). There was 96.9% freedom from lead-related major complications at two years.[5]

Procedure Description
The OmniaSecure™ MRI SureScan™ Lead is placed via a transvenous approach under fluoroscopic guidance. From a peripheral insertion site, the lead is advanced through a delivery catheter, through the vena cava into the right atrium, then through the tricuspid valve and into the right ventricle. The helix at the distal tip of the lead may be secured at the right ventricular apex or on the ventricular septum. Placement in the ventricular septum at the left bundle branch, is currently undergoing clinical trial (NCT04863664) and not yet FDA approved but is intended to engage the heart's intrinsic conduction system. The catheter is removed after electrical evaluation of the lead.

The lumenless, small diameter defibrillation lead is typically inserted with a defibrillator generator as part of a defibrillator system. Only one OmniaSecure™ MRI SureScan™ Lead is placed for a defibrillation system, regardless of configuration. For example, if a CRT system is placed, including a generator in a subcutaneous pocket, only the right ventricular lead will be the OmniaSecure™ MRI SureScan™ Lead. The right atrial lead and the coronary sinus lead will be conventional leads.

[5] Safety, efficacy, and reliability evaluation of a novel small-diameter defibrillation lead: Global LEADR pivotal trial results. Crossley, George H.Sanders, Prashanthan et al. Heart Rhythm, Volume 21, Issue 10, 1914 - 1922

Current Coding: There are no unique ICD-10-PCS codes to describe insertion of a lumenless, small-diameter defibrillation lead into the right ventricle or the ventricular septum. If inserted into the right ventricle or the ventricular septum, code the procedure in table 02H Insertion of Heart and Great Vessels, with the body part value K Ventricle, Right, the device value K Cardiac Lead, Defibrillator and the percutaneous approach.

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*
4 Coronary Vein **6** Atrium, Right **7** Atrium, Left **K** Ventricle, Right **L** Ventricle, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Monitoring Device, Pressure Sensor **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **J** Cardiac Lead, Pacemaker **K** Cardiac Lead, Defibrillator **M** Cardiac Lead **N** Intracardiac Pacemaker **Y** Other Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the insertion of a lumenless, small-diameter defibrillation lead into the right ventricle or the ventricular septum. Continue coding as described in current coding.

Option 2. In section X New Technology table X2H, Insertion of Cardiovascular System, create new device value G Defibrillator Lead, Lumenless Small-diameter, applied to the body part values M Ventricular Septum and K Ventricle, Right and the percutaneous approach to identify the insertion of a lumenless, small-diameter defibrillation lead into the right ventricle or the ventricular septum.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Inferior Vena Cava	**3** Percutaneous	**B** Volume Sensor Management Device	**B** New Technology Group 11
0 Inferior Vena Cava **1** Superior Vena Cava	**3** Percutaneous	**R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9
1 Superior Vena Cava	**3** Percutaneous	**X** Temporary Phrenic Nerve/Diaphragm Stimulation Electrodes	**B** New Technology Group 11
2 Femoral Vein, Right **3** Femoral Vein, Left	**0** Open	**R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9
6 Atrium, Right **K** Ventricle, Right	**3** Percutaneous	**V** Intracardiac Pacemaker, Dual-Chamber	**9** New Technology Group 9
L Axillary Artery, Right **M** Axillary Artery, Left	**0** Open	**F** Conduit to Short-term External Heart Assist System	**9** New Technology Group 9
N Ventricle, Left	**3** Percutaneous	**7** Endocardiac Pacing Electrode	**B** New Technology Group 11
P Anterior Tibial Artery, Right	**3** Percutaneous	**8** Intraluminal Device, Temporary	**B** New Technology Group 11

Q Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left			
ADD M Ventricular Septum **K** Ventricle, Right	**3** Percutaneous	**ADD G** Defibrillator Lead, Lumenless Small-diameter	**B** New Technology Group 11
X Thoracic Aorta, Ascending	**0** Open	**F** Conduit to Short-term External Heart Assist System	**9** New Technology Group 9

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 05 – Measurement of Whole-Body Mass Composition

Issue: There are no unique ICD-10-PCS codes to describe the analysis of infant body composition using air displacement plethysmography. An April 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The PEA POD® Air Displacement Plethysmography (ADP) system was granted class II 510(k) premarket approval by the FDA on March 1, 2004, and is indicated for measuring body mass and estimating the body composition (i.e., the body fat and lean body mass) of infants between 1 and 8 kilograms. It is not intended for use with infants requiring life support.

Background: According to the requestor, in the United States, approximately 10% of infants (380,000 annually) are born preterm, and up to 15% (570,000) are low birth weight, with higher risks of growth abnormalities and long-term metabolic complications. These infants require precise nutritional interventions to optimize development and reduce morbidity. Current methods, such as anthropometric measurements (e.g., skinfold thickness, length, and weight), bioimpedance assessment (BIA), and Dual-Energy X-ray Absorptiometry (DEXA) scans are less accurate, operator-dependent, and inappropriate for use in fragile infants. The PEA POD® ADP system is indicated for assessing body composition in infants to monitor growth, nutritional status, and health outcomes, particularly in preterm, low-birthweight, or medically complex infants. Conditions such as intrauterine growth restriction, neonatal malnutrition, and early obesity risk adversely affect a significant portion of the pediatric population.

Conversely, the requestor maintains that BIA and DEXA scans both utilize completely different mechanisms of assessment and present distinct challenges for patients. BIA and DEXA are both more commonly used in adults and older children, and neither method is ideally suited for infants. BIA requires subjects to remain relatively still and depends on proper electrode placement. BIA is particularly sensitive to hydration status, which can fluctuate rapidly in neonates and can skew results. Additionally, the predictive equations used in most BIA devices are based on data from older populations, making them less accurate when applied to infants. DXA, while more versatile, also presents challenges in this age group, as it requires the infant to remain completely motionless during the scan, which can be difficult without some form of restraint or sedation. Although DEXA is generally more precise than BIA, its ability to differentiate between fat and lean mass in very small bodies is limited. Therefore, the lower tissue density of neonates can result in measurement errors. Lastly, DEXA exposes the subject to low levels of ionizing radiation, making these scans less appealing or even inappropriate for very young patients.

Per the requestor, the PEA POD® ADP system offers a non-invasive, highly accurate alternative that provides objective data on fat and fat-free mass as a guide for clinical decision-making. Compared to traditional techniques, the PEA POD® is reported to improve precision, reproducibility, and safety, enabling tailored nutritional management and early intervention to prevent under- or over-nutrition. The target population includes infants weighing 1-8 kg, particularly those in neonatal intensive care units (NICUs) or at risk for growth-related complications.

Technology
The PEA POD® Air Displacement Plethysmography (ADP) system, developed by COSMED USA Inc., delivers non-invasive diagnostic body composition measurement of infants. The system is comprised of a transparent, biocompatible infant chamber, a volume perturbation unit, high-precision pressure transducers, an integrated digital scale, and proprietary software for data analysis. The chamber is constructed from durable, medical-grade materials to ensure safety and comfort, maintaining a stable temperature during testing.

Per the requestor, the PEA POD® employs air displacement plethysmography, a technique that measures body volume by detecting minute changes in air pressure within the sealed chamber. By combining body volume with body mass (weight), the system calculates body density and derives fat mass and fat-free mass using validated two-compartment models. The PEA POD® is a diagnostic tool, not an implant or permanent device. It is used solely for measurement and does not remain in or on the body. Multiple devices are not utilized in a single assessment, as the system is designed to measure one infant at a time. The device does not target specific anatomical sites, such as vessels or vertebrae.

Procedure Description
The PEA POD® Air Displacement Plethysmography (ADP) procedure is conducted in a controlled clinical setting, such as a neonatal intensive care unit (NICU) or pediatric outpatient clinic, by trained personnel to ensure accuracy and safety. The procedure begins with carefully undressing the infant to minimize extra volume and eliminate any air pockets trapped in clothing. A fitted hair cap is then placed on the infant's head to minimize air trapped in hair, which could affect measurement precision. The infant's body mass (weight) is then recorded using the PEA POD®'s integrated high-precision scale. The infant is then gently placed inside the transparent PEA POD® chamber, which is designed to provide a comfortable and secure environment, and the chamber door is sealed, creating an airtight space.

The system initiates a 2-minute volume measurement cycle, during which air displacement plethysmography is performed by introducing a controlled volume perturbation. Pressure transducers detect air pressure changes and calculate the infant's body volume. The PEA POD®'s proprietary software processes the body volume data combined with the recorded body mass. The computation of body density, fat mass, fat-free mass, and percentage body fat results is displayed on the system's interface and stored for clinical review. Upon completion, the infant is carefully removed from the chamber, and the device is thoroughly cleaned according to the manufacturer's protocols to prepare it for the next use.

According to the requestor, the procedure takes 7 minutes, is highly precise (coefficient of variation <2%), and safe for fragile infants, making it a gold standard for body composition analysis in neonatal care and research. Additionally, clinical studies and post-market surveillance conducted by the requestor reported minimal adverse events associated with the use of the PEA POD® ADP. Of the over 1,000 documented infant assessments, minor issues were observed in less than 0.5% of cases (approximately five incidents), including transient discomfort or brief crying during positioning in the chamber. No instances of device failure, skin irritation, respiratory complications, or other sequelae have been documented. The PEA POD® ADP procedure is standalone, performed independently of other diagnostic or therapeutic interventions. It may be used as part of a broader clinical evaluation (e.g., nutritional assessment); it does not require concurrent procedures.

Current Coding: Analysis of infant body composition using air displacement plethysmography is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create a new ICD-10-PCS code for analysis of infant body composition using air displacement plethysmography. Continue coding as described in current coding.

Option 2. In section 4 table 4A0, Measurement of Physiological Systems, create new function value E Body Composition and new qualifier value J Air Displacement Plethysmography, applied to the body system value F Musculoskeletal and the external approach, to identify analysis of infant body composition using air displacement plethysmography.

Section **4** Measurement and Monitoring *Body System* **A** Physiological Systems *Operation* **0** Measurement: Determining the level of a physiological or physical function at a point in time			
Body System	*Approach*	*Function / Device*	*Qualifier*
F Musculoskeletal	**X** External	**ADD E** Body Composition	**ADD J** Air Displacement Plethysmography

Option 3. In section X New Technology table XXE, Measurement of Physiological Systems, create new technology value G Body Composition, Air Displacement Plethysmography applied to the body part value F Musculoskeletal and the external approach, to identify analysis of infant body composition using air displacement plethysmography.

Section **X** New Technology *Body System* **X** Physiological Systems *Operation* **E** Measurement: Determining the level of a physiological or physical function at a point in time			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD F Musculoskeletal	**X** External	**ADD G** Body Composition, Air Displacement Plethysmography	**B** New Technology Group 11

CMS Recommendation: Option 3, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 06 – Computer-aided Assessment of Glucose

Issue: There are no unique ICD-10-PCS codes to describe computer-aided monitoring of blood glucose for insulin administration. An October 1, 2026 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? Yes. Glytec Glucommander® was granted class II 510(k) premarket approval by the FDA on August 4, 2017, and is indicated for use in adult and pediatric patients as a glycemic management tool intended to evaluate current and cumulative patient blood glucose values and coupled with patient information including age, weight and height, and, based on the aggregate of these measurement parameters, whether one or many, recommend an IV dosage of insulin, glucose or saline or a subcutaneous basal and bolus insulin dosing recommendation to adjust and maintain the blood glucose level towards a configurable clinician determined target range.

Background: In 2020, hospital discharge data estimated that approximately 7.86 million adults had a diabetes diagnosis. Arguably, the number of individuals being treated for diabetes in inpatient settings continues to be significant. According to the requestor, patients with diabetes have a 3-fold greater chance of hospitalization compared to those without diabetes. As such, there is a substantial correlation between hyperglycemia and hypoglycemia events leading to adverse patient outcomes. Although adverse glycemic events may be common, these events can be avoided. Hyperglycemia, a blood glucose greater than 140 mg/dl, is reported in 22-46% of non-critically ill hospitalized diabetic and non-diabetic patients. Furthermore, inpatient data highlights that hyperglycemia is often associated with an increased risk of patient complications, mortality, larger admission rates to the intensive care unit (ICU) with longer hospital stays, and an increased need for transitional post-discharge care.

Extensive research has been conducted about the impact of hypoglycemic risk factors on patients. A study conducted in 2018 by the Department of Health and Human Services' Office of Inspector General determined that hypoglycemia was among the top 5 medication-related harmful events for Medicare patients, in addition to opioid-related events. The severity of the outcomes associated with hypoglycemic events has led to targeted prevention plans with specific protocols under the National Action Plan for Adverse Drug Event Prevention. According to the requestor, despite the availability of this information, nearly 1/3 of hospitals have no glucose management metrics, and 59 percent do not have an automated method of pulling data on glycemic adverse events.

Moreover, hospital data reports that the number of inpatients being treated with insulin has increased, in some cases to as high as 50% or more, as insulin therapy is utilized as an adjunct treatment of multiple other conditions. Historically, inpatient management of diabetic patients requires various methods of adjusting insulin, including largely manual methods using as needed or handwritten sliding scale methods, resulting in significant episodes of both hypoglycemia and hyperglycemia. Given the high and rising prevalence of conditions requiring insulin, the relative historic lack of adoption of tight controls, and the rising interest of government and professional societies in this issue, the requestor maintains that the Glytec Glucommander® facilitates the use of real-time, patient-specific, evidence-based knowledge at the point of care integrated with

medical care workflows to optimize management of patients using trackable technology to improve rates of inpatient hypoglycemia and hyperglycemia events.

Technology
Glytec Glucommander® is a glycemic management system that is a Health Information Trust Alliance (HITRUST) certified technology designed to properly maintain blood glucose in hospitalized patients. Per the requestor, the cloud-based, user-friendly insulin management software device with electronic medical record (EMR) integration is unique in design and performance. The cloud-hosted software-as-a-service (SaaS) delivery model allows for rapid implementation and anytime, anywhere access. The software is installed as an integrated component of the electronic medical record that also connects with laboratory (LIS) interfaces, pharmacy, and other systems to optimize clinician management of insulin-based glycemic patient workflows. Attached analytic capabilities and intelligent algorithms work together with clinicians, as well as clinical executives, to optimize glycemic control across a facility or facilities in a health care system.

According to the requestor, the Glytec Glucommander® system has been shown to more evenly control blood glucose levels and has been well-documented to be a useful tool in the broader management of patients receiving insulin therapy in the hospital, including extended clinical use and testing in academic hospitals. An initial period of training is required, but the clinical interface is relatively intuitive. The interface is addressed through an incorporated tab in the hospital's existing electronic medical record, with seamless integration with MAR records, lab results tracking, and clinical activities. The software device integrates into existing clinician activity, collecting patient information, monitoring progress, and directing the operational workflow.

The requestor maintains that the device is more than just software; the intelligent process being managed by Glytec's software is an integral part of the care delivery process. The software can select and direct insulin dosing, provide alerts, and advise specific care strategies that need to be altered and monitored closely. The system incorporates individualized patient clinical input, such as insulin history, food consumption, activity, and activity, with clinical output that includes the recommended next dose of insulin, which is tracked ongoing during the day, with the appropriate reminder alerts for staff to optimize the next calculated dose. Clinical outputs include dynamic glucose values over time, graphically and in chart form. This output is configured for the ongoing delivery of patient care but is also capable of aggregating values at the hospital unit, facility, and system levels by hospital administrators, administrative clinicians, and other designated individuals.

Glucommander® is uniquely equipped to support all varieties of insulin, including long-acting basal preparations, NPH (intermediate-acting), rapid-acting analogues, and regular insulin. The technology performs titration for outpatients, whether they're prescribed a basal insulin regimen or a basal bolus insulin regimen. The technology is temporary and non-invasive. The software incorporates clinical recommendations from the American Diabetes Association's 2025 diabetes management guidelines.

Procedure Description
Glytec Glucommander® system is used in an inpatient setting during hospitalizations when close insulin management and glycemic control are needed. The software device is for per-patient use. The technology is used in conjunction with multiple other pieces of technology, including the

hospital electronic medical record system, laboratory information systems, pharmacy systems, and, by extension, even to the equipment for administering insulin, if the hospital is so equipped. Its software integrates closely with these other electronic systems, which should be attached as part of the installation.

According to the manufacturer's website, algorithm-driven insulin dosing decision support software sits at the core of eGlycemic Management System (eGMS). eGMS integrates directly with the EMR to support one-click access, reduce redundant data entry, reduce transcription errors, and improve workflow efficiency for providers. The system then provides insights into organizational glycemic management performance by tracking KPIs like incidence of hyperglycemia and hypoglycemia, time to target, patient utilization, and more. Providers can use eGMS to view a dashboard of glycemic status indicators for all patients in a unit, helping nurses track the last blood glucose test results and current infusion rates and see precisely when the next check is due. Lastly, eGMS interfaces with laboratory information systems to continuously analyze patient blood glucose values of patients not using Glucommander® and alert staff about at-risk patients. Over the past decade, there have been no reports of significant adverse events associated with the ongoing use of the software.

Current Coding: Computer-aided monitoring of blood glucose is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for computer-aided monitoring of blood glucose. Continue coding as described in current coding.

Option 2. In section X New Technology table XX2, Monitoring of Physiological Systems, create new technology value F Blood Glucose, Computer-aided Assessment and Notification, applied to the body part value 5 Circulatory and the external approach, to identify computer-aided monitoring of blood glucose.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Central Nervous	**X** External	**8** Brain Electrical Activity, Computer-aided Detection and Notification	**9** New Technology Group 9
5 Circulatory	**X** External	**0** Blood Flow, Adhesive Ultrasound Patch Technology	**A** New Technology Group 10
5 Circulatory	**X** External	**ADD F** Blood Glucose, Computer-aided Assessment and Notification	**C** New Technology Group 12
F Musculoskeletal	**3** Percutaneous	**W** Muscle Compartment Pressure, Micro-Electro-Mechanical System	**9** New Technology Group 9
K Subcutaneous Tissue	**X** External	**D** Interstitial Glucose, Wearable Sub-Epidermal Sensor	B New Technology Group 11
K Subcutaneous Tissue	**X** External	**P** Interstitial Fluid Volume, Sub-Epidermal Moisture using Electrical Biocapacitance	**9** New Technology Group 9

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 07 – Cardiovascular Bypass with Autologous Cell Seeded Tissue Engineered Resorbable Scaffold

Issue: There are no unique ICD-10-PCS codes to describe cardiovascular bypass using an autologous cell-seeded tissue-engineered resorbable scaffold. An April 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The requestors, Nationwide Children's Hospital and Christopher Breuer, MD, received investigational device exemption (IDE) approval from the FDA on August 22, 2019, for an autologous cell seeded tissue engineered resorbable scaffold (ACSTERS). Breakthrough Device Designation was granted by the FDA for use in the surgical treatment of children with single ventricle disease in December 2024. The requestor intends to submit a Humanitarian Device Exemption (HDE) application and a Premarket Approval Application (PMA) to the FDA at a later date.

Background: Single ventricle cardiac anomalies are critical cardiac defects that are life-threatening without surgical intervention.[1] They arise from any congenital cardiac anomaly that results in the formation of a single functional ventricle. The modified Fontan surgical operation represents the current standard of care for patients with single ventricle disease.[2] There are currently approximately 1000 Fontan procedures performed per year in the United States. While the modified Fontan operation is typically performed on children between 2 and 4 years of age, redo Fontan operations can be performed on patients of any age.

According to the requestor, the currently available vascular grafts for the Fontan operation include both biological and synthetic vascular conduits. Synthetic grafts are used more commonly than biological conduits due to the high incidence of calcification in biological vascular conduits in the first few years after implantation.[3,4] Synthetic options include polytetrafluoroethylene (PTFE) grafts or polyethylene terephthalate (PETE) grafts. PTFE grafts now represent the current standard of care, given the high incidence of stenosis due to neointimal hyperplasia from PETE grafts.[5,6] Nevertheless, PTFE grafts are associated with a significant risk of graft-related complications. Increasingly, evidence-based literature highlights calcification in

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[1] Rychik J, Atz AM, Celermajer DS, Deal BJ, Gatzoulis MA, Gewillig MH, Hsia TY, Hsu DT, Kovacs AH, McCrindle BW, Newburger JW, Pike NA, Rodefeld M, Rosenthal DN, Schumacher KR, Marino BS, Stout K, Veldtman G, Younoszai AK, d'Udekem Y; American Heart Association Council on Cardiovascular Disease in the Young and Council on Cardiovascular and Stroke Nursing. Evaluation and Management of the Child and Adult With Fontan Circulation: A Scientific Statement From the American Heart Association. Circulation. 2019 Aug 6;140(6):e234-e284. PMID: 31256636.

[2] Hassan A, Chegondi M, Porayette P. Five decades of Fontan palliation: What have we learned? What should we expect? J Int Med Res. 2023 Oct;51(10):3000605231209156. PMID: 37910851; PMCID: PMC10621298.

[3] Monro JL, Salmon AP, Keeton BR. The outcome of antibiotic sterilized aortic homografts used in the Fontan procedure. Eur J Cardiothorac Surg. 1993;7(7):360-3; discussion 364. PMID: 8373619.

[4] Kelly JM, Hu Z, Takaesu F, Watanabe T, Storrs J, Blais B, Yuhara S, Morrison A, Nelson K, Ulziibayar A, Heuer E, Anderson C, Jimenez M, Leland J, Malbrue R, Arsuaga-Zorrilla C, Goodchild L, Naguib A, McKee C, Varner J, DeShetler C, Spiess J, Harrison A, Boe B, Armstrong AK, Salavitabar A, Hor K, Krishnamurthy R, Yates AR, Shinoka T, Carrillo SA, Davis ME, Marsden AL, Breuer CK. Investigation of a chronic single-stage sheep Fontan model. JTCVS Open. 2024 Jul 4;21:268-278. PMID: 39534321; PMCID: PMC11551305.

[5] van Brakel TJ, Schoof PH, de Roo F, Nikkels PG, Evens FC, Haas F. High incidence of Dacron conduit stenosis for extracardiac Fontan procedure. J Thorac Cardiovasc Surg. 2014 May;147(5):1568-72. PMID: 23988293.

[6] Careddu L, Petridis FD, Angeli E, Balducci A, Mariucci E, Egidy Assenza G, Donti A, Gargiulo GD. Dacron Conduit for Extracardiac Total Cavopulmonary Anastomosis: A Word of Caution. Heart Lung Circ. 2019 Dec;28(12):1872-1880. PMID: 30555011.

PTFE grafts in the Fontan circulation.[7,8] Dystrophic calcification represents a leading cause of late-term graft failure after congenital heart surgery. Furthermore, PTFE grafts are prone to somatic overgrowth and a decrease in size over time when used as Fontan conduits.[9] As a result, surgeons may need to upsize the Fontan conduits either surgically or through placement of a stent.[10] Multiple upsizing procedures can be required over a patient's lifetime.

According to the requestor, using PTFE vascular grafts in modified Fontan surgery increases the incidence of cirrhosis due to Fontan-associated liver disease (FALD) nearly 7-fold compared to surgeries without a conduit. FALD is a leading cause of late-term morbidity and mortality after Fontan surgery, due to PTFE's lack of growth capacity and compliance mismatch.[11] Thus, there is an opportunity to develop an improved vascular conduit with resistance to calcification, biological growth capacity, and compliance match. Historically, the Autologous Cell Seeded Tissue Engineered Resorbable Scaffold (ACSTERS) procedure has been referred to as Tissue-Engineered Vascular Graft (TEVG). Per the requestor, the positive results of the most recent clinical trials indicate the more accurate nomenclature is now ACSTERS, for vascular regeneration and biological growth.

Technology

The autologous cell seeding of the scaffold is a form of tissue engineering. The scaffold is resorbable, which according to the requestor results in significant improvements in vascular regeneration, enhanced biological growth capacity, and increased resistance to calcification. ACSTERS improves compliance match compared to PTFE grafts, offering several potential advantages. [1-3] ACSTERS is created by harvesting and seeding autologous bone marrow-derived mononuclear cells (BM-MNC) onto a biodegradable scaffold using vacuum seeding into the porous resorbable scaffold wall. [1,4] The scaffold size determines the dose of cells that saturates the scaffold,[5] which induces a foreign body reaction and is infiltrated by host immune cells.[6] The seeded cells, which disappear shortly after implantation, play an immunomodulatory role.[7] Host immune cells induce the ingrowth of neighboring endothelial and smooth muscle cells via paracrine signaling.[8] These cells migrate along the scaffold's luminal surface, directing neotissue formation and vascular regeneration. As the scaffold resorbs, the inflammatory response subsides, forming an autologous living vascular conduit similar to a native blood vessel, enabling biological growth as the patient grows.[1-3] Per the requestor, based on the patient's underlying congenital

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[7] Turner ME, Blum KM, Watanabe T, Schwarz EL, Nabavinia M, Leland JT, Villarreal DJ, Schwartzman WE, Chou TH, Baker PB, Matsumura G, Krishnamurthy R, Yates AR, Hor KN, Humphrey JD, Marsden AL, Stacy MR, Shinoka T, Breuer CK. Tissue engineered vascular grafts are resistant to the formation of dystrophic calcification. Nat Commun. 2024 Mar 11;15(1):2187. PMID: 38467617; PMCID: PMC10928115.

[8] Hayabuchi Y, Mori K, Kitagawa T, Sakata M, Kagami S. Polytetrafluoroethylene graft calcification in patients with surgically repaired congenital heart disease: evaluation using multidetector-row computed tomography. Am Heart J. 2007 May;153(5): 806.e1-8. PMID: 17452157.

[9] Lee J, Song MK, Lee SY, Kim GB, Bae EJ, Kwon HW, Cho S, Kwak JG, Kim WH, Lee W. Long-term outcomes of extracardiac Gore-Tex conduits in Fontan patients. Int J Cardiol Congenit Heart Dis. 2024 Mar 8;16:100505. PMID: 39712536; PMCID: PMC11657344.

[10] Puente BN, Desai M, Donofrio M, Yerebakan C, Tongut A, d'Udekem Y. Upsizing the extracardiac Fontan conduit-the fourth staged procedure for the single-ventricle palliation? JTCVS Tech. 2024 Feb 6;24:177-181. PMID: 38835567; PMCID: PMC11145377.

[11] Kisamori E, Venna A, Chaudhry HE, Desai M, Tongut A, Mehta R, Clauss S, Yerebakan C, d'Udekem Y. Alarming rate of liver cirrhosis after the small conduit extracardiac Fontan: A comparative analysis with the lateral tunnel. J Thorac Cardiovasc Surg. 2024 Oct;168(4):1221-1227.e1. PMID: 38688450.

cardiovascular anomaly, the ACSTERS can be used to connect either the inferior vena cava or hepatic vein to the right, left, or main pulmonary artery.

Procedure Description
The ACSTERS implantation procedure is a specialized open approach, cardiac vascular bypass operation that includes both preparation and implantation of the uniquely engineered scaffold. The preparation and implantation of the ACSTERS occurs during a single surgery and requires a highly coordinated effort from both the surgical and ACSTERS preparation team. Before surgery, the scaffold is selected to match the size of the intrathoracic inferior vena cava based on preoperative imaging. On the day of the surgery, after induction of general anesthesia, bone marrow is harvested from the patient and transferred to a clean room to prepare the ACSTERS. The amount of bone marrow harvested is calculated to saturate the scaffold and is determined by the size of the scaffold (i.e., 6.25 ml bone marrow/ mm diameter scaffold). Following the manufacturer's guidelines, once in the clean room, a team of three technicians prepares the ACSTERS. Using aseptic technique under a biosafety hood, the mononuclear fraction of the bone marrow is isolated using a filtration-elution method.

Cell samples are obtained before and after cell BM-MNC isolation and used to perform release testing. The BM-MNCs are then seeded onto the scaffold using a vacuum seeding method, which uses negative pressure to draw the cells into the porous wall of the scaffold. Once seeded, the proximal portion of the scaffold is resected and cut into sections for additional release testing and post-process monitoring assays. After sampling, the seeded scaffold is transferred into a sterile container and bathed in the BM-MNC isolation fluid. Release criteria include BM-MNC number and viability, seeding efficiency, endotoxin testing, and Gram stain. Post process monitoring testing includes CD45 FACS analysis, PicoGreen assay, in addition to aerobic, anaerobic, and fungal cultures. Only scaffolds meeting release criteria are transferred to the operating room for implantation.

The process of bone marrow harvest, ACSTERS preparation, completion of release testing, and transport to the OR typically takes 4 hours. While the ACSTERS is being prepared, the surgical team performs a redo sternotomy and adhesiolysis to expose the surgical field. The process is coordinated so the ACSTERS arrives and is ready for implantation at the point in the operation when the surgeon is ready for implantation. The bypass procedure connects either the inferior vena cava or hepatic vein to the right, left, or main pulmonary artery. According to the requestor, the implantation of the ACSTERS has several features in common with the implantation of a PTFE graft, with the exception that a size-matched graft is used instead of an oversized graft and handling of the seeded scaffold requires a unique surgical technique. One autologous cell seeded tissue engineered resorbable scaffold is routinely implanted. The autologous cell seeded tissue engineered resorbable scaffold is considered permanent. Post-surgery, the patient is transported to the pediatric cardiac care intensive care unit.

There are a variety of potential adverse events associated with biomaterials implanted surgically as a vascular conduit, like the use of autologous cell seeded tissue engineered resorbable scaffolds. These include bleeding, thrombo-embolic complications, aneurysmal dilation, graft stenosis, somatic overgrowth, calcification, and infection (endocarditis). Studies conducted by the requestor indicated that the most significant graft-related adverse event is stenosis. They noted early reversible graft stenosis occurs in all autologous cell-seeded tissue-engineered resorbable scaffolds

and is thought to be a part of the natural history of vascular regeneration. If the stenosis becomes clinically significant, it can be treated with angioplasty or stenting.

Current Coding: There are no unique ICD-10-PCS codes to describe cardiovascular bypass using an autologous cell seeded resorbable scaffold. The only body part option is Inferior Vena Cava. Table 061 does not have an option to bypass from the hepatic vein to one of the pulmonary arteries. According to the PCS Coding Guidelines, the body part value assigned is the next proximal vessel with an entry in the table, in cases where a specific vessel is not available in the applicable PCS Table. In the case of the hepatic vein, the IVC is the proximal vessel. Code the procedure in table 061, Bypass of Lower Veins, with the body part value 0 Inferior Vena Cava, the device value 7 Autologous Tissue Substitute, the open approach, and the applicable pulmonary artery qualifier.

Section	**0** Medical and Surgical
Body System	**6** Lower Veins
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Inferior Vena Cava	**0** Open **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**5** Superior Mesenteric Vein **6** Inferior Mesenteric Vein **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **Y** Lower Vein

Coding Options

Option 1. Do not create new ICD-10-PCS codes for cardiovascular bypass using an autologous cell seeded resorbable scaffold. Continue coding as described in current coding.

Option 2. In section X New Technology table X2K, Bypass of Cardiovascular System, create new device value F Autologous Cell Seeded Tissue Engineered Resorbable Scaffold to Pulmonary Artery, applied to the body part values 0 Inferior Vena Cava and G Hepatic Vein, and the open approach, to identify cardiovascular bypass using an autologous cell seeded resorbable scaffold.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**K** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
A Atrium, Left	**3** Percutaneous	**0** Conduit through Coronary Sinus to Right Atrium	**A** New Technology Group 10
B Radial Artery, Right **C** Radial Artery, Left	**3** Percutaneous	**1** Thermal Resistance Energy	**7** New Technology Group 7
H Femoral Artery, Right **J** Femoral Artery, Left	**3** Percutaneous	**D** Conduit through Femoral Vein to Superficial Femoral Artery **E** Conduit through Femoral Vein to Popliteal Artery	**9** New Technology Group 9
ADD 0 Inferior Vena Cava **ADD G** Hepatic Vein	**0** Open	**ADD F** Autologous Cell Seeded Tissue Engineered Resorbable Scaffold to Pulmonary Artery	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 08 - Section X Updates
Fall 2025 ICD-10 Coordination and Maintenance Committee Update

For this Fall 2025 code update we are sharing our analysis results for the Group 7 section X Codes from FYs 2022, 2023, and 2024. For the March 2026 code update we will share an updated analysis to include the results for the Group 7 section X codes for FY 2025, along with the CMS recommendation.

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

- Was the procedure code related to 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 Medicare Provider Analysis and Review (MedPAR) data for the relevant FYs?

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

1. Leave the code in section X (e.g., procedure codes related to the administration of a specific medication)
2. Delete the section X code. Revise Index and/or Reference key entries to direct the user to an existing code in the Medical and Surgical or other section of ICD-10-PCS (e.g., NTAP has expired, data analysis and clinical review justifies incorporating this technology/procedure into the main Medical and Surgical section)
3. Delete the section X code, corresponding Index entries, and any Reference Key entries from the classification (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(s) 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 Medical and Surgical section). The corresponding Index entries for the section X code(s) will also be deleted, and new Index entries, along with any Reference Key entries will be created to reflect the newly established code(s).

Section X – Fall 2025 Update
Group 7

ICD-10-PCS Code	Code Description	FY 2022		FY 2023		FY 2024		FY 2025		Total Freq	CMS Recommendation	Technology Brand Name
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP			
X2CP3T7	Extirpation of matter from abdominal aorta using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	37	NO	31	NO	41	NO		NO	109	TBA at Spring update	Penumbra Indigo® Aspiration System with Lightning™ Aspiration Tubing
X2CQ3T7	Extirpation of matter from right upper extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	59	NO	50	NO	55	NO		NO	164	TBA at Spring update	Penumbra Indigo® Aspiration System with Lightning™ Aspiration Tubing
X2CR3T7	Extirpation of matter from left upper extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	115	NO	61	NO	107	NO		NO	283	TBA at Spring update	Penumbra Indigo® Aspiration System with Lightning™ Aspiration Tubing
X2CS3T7	Extirpation of matter from right lower extremity artery using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	390	NO	342	NO	361	NO		NO	1093	TBA at Spring update	Penumbra Indigo® Aspiration System with Lightning™ Aspiration Tubing
X2CT3T7	Extirpation of matter from left lower extremity artery using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	416	NO	285	NO	377	NO		NO	1078	TBA at Spring update	Penumbra Indigo® Aspiration System with Lightning™ Aspiration Tubing
X2CU3T7	Extirpation of matter from right lower extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	101	NO	142	NO	231	NO		NO	474	TBA at Spring update	Penumbra Indigo® Aspiration System with Lightning™ Aspiration Tubing
X2CV3T7	Extirpation of matter from left lower extremity vein using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	179	NO	230	NO	370	NO		NO	779	TBA at Spring update	Penumbra Indigo® Aspiration System with Lightning™ Aspiration Tubing

ICD-10-PCS Code	Code Description	FY 2022		FY 2023		FY 2024		FY 2025				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
X2CY3T7	Extirpation of matter from great vessel using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	583	NO	575	NO	683	NO		NO	1841	TBA at Spring update	Penumbra Indigo® Aspiration System with Lightning™ Aspiration Tubing
X2JAX47	Inspection of heart using transthoracic echocardiography, computer-aided guidance, new technology group 7	398	YES	1127	YES	693	NO		NO	2218	TBA at Spring update	Caption Guidance
X2KB317	Bypass right radial artery using thermal resistance energy, percutaneous approach, new technology group 7	3	NO	1	NO	2	NO		NO	6	TBA at Spring update	Ellipsys® Vascular Access System
X2KC317	Bypass left radial artery using thermal resistance energy, percutaneous approach, new technology group 7	5	NO	2	NO	5	NO		NO	12	TBA at Spring update	Ellipsys® Vascular Access System
X2RX0N7	Replacement of thoracic aorta, arch using branched synthetic substitute with intraluminal device, open approach, new technology group 7	103	NO	76	YES	123	YES		YES	302	TBA at Spring update	Thoraflex™ Hybrid device
X2VW0N7	Restriction of thoracic aorta, descending using branched synthetic substitute with intraluminal device, open approach, new technology group 7	91	NO	79	YES	119	YES		YES	289	TBA at Spring update	Thoraflex™ Hybrid device
X2V73Q7	Restriction of coronary sinus with reduction device, percutaneous approach, new technology group 7	3	NO	2	NO	0	NO		NO	5	TBA at Spring update	Neovasc Reducer System
XD2G4V7	Monitoring of upper GI oxygen saturation, percutaneous endoscopic approach, new technology group 7	0	NO	1	NO	2	NO		NO	3	TBA at Spring update	FUJIFILM EP-7000X System
XD2G8V7	Monitoring of upper GI oxygen saturation, via natural or artificial opening endoscopic, new technology group 7	1	NO	2	NO	3	NO		NO	6	TBA at Spring update	FUJIFILM EP-7000X System
XD2H4V7	Monitoring of lower GI oxygen saturation, percutaneous endoscopic approach, new technology group 7	0	NO	0	NO	0	NO		NO	0	TBA at Spring update	FUJIFILM EP-7000X System

ICD-10-PCS Code	Code Description	FY 2022		FY 2023		FY 2024		FY 2025				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XD2H8V7	Monitoring of lower GI oxygen saturation, via natural or artificial opening endoscopic, new technology group 7	1	NO	0	NO	2	NO		NO	3	TBA at Spring update	FUJIFILM EP-7000X System
XDPH8K7	Irrigation of lower GI using intraoperative single-use oversleeve, via natural or artificial opening endoscopic, new technology group 7	115	NO	125	NO	114	NO		NO	354	TBA at Spring update	Pure-Vu® System
XFJB8A7	Inspection of hepatobiliary duct using single-use duodenoscope, new technology group 7	692	YES	824	YES	789	NO		NO	2305	TBA at Spring update	aScope™ Duodeno/EXALT™ Model D Single-Use Duodenoscope
XFJD8A7	Inspection of pancreatic duct using single-use duodenoscope, new technology group 7	175	YES	151	YES	145	NO		NO	471	TBA at Spring update	aScope™ Duodeno/EXALT™ Model D Single-Use Duodenoscope
XHRPXF7	Replacement of skin with bioengineered allogeneic construct, external approach, new technology group 7	353	YES	344	YES	479	YES		YES	1176	TBA at Spring update	StrataGraft
XNS00C7	Reposition of lumbar vertebra using posterior (dynamic) distraction device, open approach, new technology group 7	5	NO	6	NO	6	NO		NO	17	TBA at Spring update	ApiFix Minimally Invasive Deformity Correction (MID-C) System
XNS03C7	Reposition of lumbar vertebra using posterior (dynamic) distraction device, percutaneous approach, new technology group 7	0	NO	0	NO	1	NO		NO	1	TBA at Spring update	ApiFix Minimally Invasive Deformity Correction (MID-C) System
XNS40C7	Reposition of thoracic vertebra using posterior (dynamic) distraction device, open approach, new technology group 7	4	NO	3	NO	2	NO		NO	9	TBA at Spring update	ApiFix Minimally Invasive Deformity Correction (MID-C) System
XNS43C7	Reposition of thoracic vertebra using posterior (dynamic) distraction device, percutaneous approach, new technology group 7	0	NO	0	NO	0	NO		NO	0	TBA at Spring update	ApiFix Minimally Invasive Deformity Correction (MID-C) System

ICD-10-PCS Code	Code Description	FY 2022		FY 2023		FY 2024		FY 2025				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XRGA0R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7[1]	4	YES	5	YES	7	YES		YES	16	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device
XRGA3R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7[1]	0	YES	2	YES	0	YES		YES	2	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device
XRGA4R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7[1]	0	YES	0	YES	0	YES		YES	0	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device
XRGB0R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7[1]	126	YES	176	YES	131	YES		YES	433	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device
XRGB3R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7[1]	2	YES	2	YES	2	YES		YES	6	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device
XRGB4R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7[1]	1	YES	1	YES	0	YES		YES	2	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device
XRGC0R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, open approach, new technology group 7[1]	67	YES	82	YES	101	YES		YES	250	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device
XRGC3R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7[1]	0	YES	4	YES	1	YES		YES	5	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device
XRGC4R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7[1]	0	YES	0	YES	0	YES		YES	0	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device

[1] *Code Description revised effective FY 2024*

ICD-10-PCS Code	Code Description	FY 2022		FY 2023		FY 2024		FY 2025				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XRGD0R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7[1]	53	YES	132	YES	121	YES		YES	306	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device
XRGD3R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7[1]	1	YES	1	YES	3	YES		YES	5	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device
XRGD4R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7[1]	0	YES	0	YES	0	YES		YES	0	TBA at Spring update	Aprevo™ Intervertebral Body Fusion Device
XW00X27	Introduction of anacaulase-bcdb into skin, external approach, new technology group 7[1]	29	NO	41	NO	45	NO		NO	115	TBA at Spring update	NexoBrid
XW01X27	Introduction of anacaulase-bcdb into subcutaneous tissue, external approach, new technology group 7[1]	0	NO	0	NO	0	NO		NO	0	TBA at Spring update	NexoBrid
XW01397	Introduction of satralizumab-mwge into subcutaneous tissue, percutaneous approach, new technology group 7	2	NO	0	NO	0	NO		NO	2	TBA at Spring update	ENSPRYNG™
XW013V7	Introduction of covid-19 vaccine dose 3 into subcutaneous tissue, percutaneous approach, new technology group 7	7	NO	2	NO	1	NO		NO	10	TBA at Spring update	COMIRNATY®/ SPIKEVAX™
XW013W7	Introduction of covid-19 vaccine booster into subcutaneous tissue, percutaneous approach, new technology group 7	90	NO	38	NO	1	NO		NO	129	TBA at Spring update	COMIRNATY®/ SPIKEVAX™
XW023V7	Introduction of covid-19 vaccine dose 3 into muscle, percutaneous approach, new technology group 7	502	NO	61	NO	12	NO		NO	575	TBA at Spring update	COMIRNATY®/ SPIKEVAX™

ICD-10-PCS Code	Code Description	FY 2022		FY 2023		FY 2024		FY 2025				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW023W7	Introduction of covid-19 vaccine booster into muscle, percutaneous approach, new technology group 7	4518	NO	3016	NO	178	NO		NO	7712	TBA at Spring update	COMIRNATY®/ SPIKEVAX™
XW023X7	Introduction of tixagevimab and cilgavimab monoclonal antibody into muscle, percutaneous approach, new technology group 7	438	NO	363	NO	0	NO		NO	801	TBA at Spring update	EVUSHELD™
XW023Y7	Introduction of other new technology monoclonal antibody into muscle, percutaneous approach, new technology group 7	112	NO	27	NO	6	NO		NO	145	TBA at Spring update	
XW03357	Introduction of narsoplimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 7	2	NO	0	NO	0	NO		NO	2	TBA at Spring update	Narsoplimab
XW04357	Introduction of narsoplimab monoclonal antibody into central vein, percutaneous approach, new technology group 7	0	NO	0	NO	2	NO		NO	2	TBA at Spring update	Narsoplimab
XW03367	Introduction of terlipressin into peripheral vein, percutaneous approach, new technology group 7	1	NO	6	NO	104	YES		YES	111	TBA at Spring update	TERLIVAZ®
XW04367	Introduction of terlipressin into central vein, percutaneous approach, new technology group 7	0	NO	1	NO	16	YES		YES	17	TBA at Spring update	TERLIVAZ®
XW03377	Introduction of trilaciclib into peripheral vein, percutaneous approach, new technology group 7	6	YES	1	YES	2	NO		NO	9	TBA at Spring update	COSELA™
XW04377	Introduction of trilaciclib into central vein, percutaneous approach, new technology group 7	1	YES	1	YES	0	NO		NO	2	TBA at Spring update	COSELA™
XW03387	Introduction of lurbinectedin into peripheral vein, percutaneous approach, new technology group 7	7	YES	12	YES	7	NO		NO	26	TBA at Spring update	ZEPZELCA™

ICD-10-PCS Code	Code Description	FY 2022		FY 2023		FY 2024		FY 2025				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW04387	Introduction of lurbinectedin into central vein, percutaneous approach, new technology group 7	6	YES	8	YES	3	NO		NO	17	TBA at Spring update	ZEPZELCA™
XW033A7	Introduction of ciltacabtagene autoleucel into peripheral vein, percutaneous approach, new technology group 7	1	NO	23	YES	29	NO		NO	53	TBA at Spring update	CARVYKTI™
XW043A7	Introduction of ciltacabtagene autoleucel into central vein, percutaneous approach, new technology group 7	36	NO	159	YES	289	NO		NO	484	TBA at Spring update	CARVYKTI™
XW033B7	Introduction of amivantamab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 7	7	YES	6	YES	8	YES		YES	21	TBA at Spring update	RYBREVANT™
XW043B7	Introduction of amivantamab monoclonal antibody into central vein, percutaneous approach, new technology group 7	0	YES	0	YES	2	YES		YES	2	TBA at Spring update	RYBREVANT™
XW033C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	20	NO	30	NO	14	NO		NO	64	TBA at Spring update	
XW043C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	94	NO	105	NO	97	NO		NO	296	TBA at Spring update	
XW033G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	10	NO	8	NO	7	NO		NO	25	TBA at Spring update	
XW043G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	26	NO	66	NO	64	NO		NO	156	TBA at Spring update	
XW033H7	Introduction of axicabtagene ciloleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	27	NO	41	NO	33	NO		NO	101	TBA at Spring update	Yescarta®

ICD-10-PCS Code	Code Description	FY 2022		FY 2023		FY 2024		FY 2025				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW043H7	Introduction of axicabtagene ciloleucel immunotherapy into central vein, percutaneous approach, new technology group 7	177	NO	250	NO	226	NO		NO	653	TBA at Spring update	Yescarta®
XW033J7	Introduction of tisagenlecleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	9	NO	9	NO	6	NO		NO	24	TBA at Spring update	KYMRIAH®
XW043J7	Introduction of tisagenlecleucel immunotherapy into central vein, percutaneous approach, new technology group 7	43	NO	44	NO	21	NO		NO	108	TBA at Spring update	KYMRIAH®
XW033K7	Introduction of idecabtagene vicleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	27	YES	35	YES	14	NO		NO	76	TBA at Spring update	ABECMA®
XW043K7	Introduction of idecabtagene vicleucel immunotherapy into central vein, percutaneous approach, new technology group 7	174	YES	271	YES	111	NO		NO	556	TBA at Spring update	ABECMA®
XW033L7	Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	0	NO	0	NO	0	NO		NO	0	TBA at Spring update	AMTAGVI™
XW043L7	Introduction of lifileucel immunotherapy into central vein, percutaneous approach, new technology group 7	1	NO	3	NO	8	NO		NO	12	TBA at Spring update	AMTAGVI™
XW033M7	Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	6	YES	11	YES	13	NO		NO	30	TBA at Spring update	Tecartus™
XW043M7	Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7	83	YES	94	YES	86	NO		NO	263	TBA at Spring update	Tecartus™
XW033N7	Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	14	NO	19	NO	30	NO		NO	63	TBA at Spring update	Breyanzi®
XW043N7	Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7	87	NO	133	NO	193	NO		NO	413	TBA at Spring update	Breyanzi®

ICD-10-PCS Code	Code Description	FY 2022		FY 2023		FY 2024		FY 2025				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW0DXR7	Introduction of fostamatinib into mouth and pharynx, external approach, new technology group 7	10	NO	19	NO	18	NO		NO	47	TBA at Spring update	TAVALISSE
XW0G7R7	Introduction of fostamatinib into upper GI, via natural or artificial opening, new technology group 7	0	NO	0	NO	1	NO		NO	1	TBA at Spring update	TAVALISSE
XW0H7R7	Introduction of fostamatinib into lower GI, via natural or artificial opening, new technology group 7	0	NO	0	NO	0	NO		NO	0	TBA at Spring update	TAVALISSE
XW0V0P7	Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7	269	NO	541	YES	859	YES		YES	1669	TBA at Spring update	CERAMENT® G
XW133D7	Transfusion of high-dose intravenous immune globulin into peripheral vein, percutaneous approach, new technology group 7	64	NO	94	NO	145	NO		NO	303	TBA at Spring update	GAMUNEX-C
XW143D7	Transfusion of high-dose intravenous immune globulin into central vein, percutaneous approach, new technology group 7	8	NO	13	NO	11	NO		NO	32	TBA at Spring update	GAMUNEX-C
XW133E7	Transfusion of hyperimmune globulin into peripheral vein, percutaneous approach, new technology group 7	15	NO	14	NO	16	NO		NO	45	TBA at Spring update	Anti-SARS-CoV-2 hyperimmune globulin/IGIV-C
XW143E7	Transfusion of hyperimmune globulin into central vein, percutaneous approach, new technology group 7	2	NO	3	NO	1	NO		NO	6	TBA at Spring update	Anti-SARS-CoV-2 hyperimmune globulin/IGIV-C
XWHD7Q7	Insertion of neurostimulator lead into mouth and pharynx, via natural or artificial opening, new technology group 7	3	NO	1	NO	8	YES		YES	12	TBA at Spring update	Phagenyx® System
XXE0X07	Measurement of intracranial vascular activity, computer-aided assessment, new technology group 7	433	NO	428	NO	419	NO		NO	1280	TBA at Spring update	Rapid ASPECTS

ICD-10-PCS Code	Code Description	FY 2022		FY 2023		FY 2024		FY 2025				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XXE3X27	Measurement of pulmonary artery flow, computer-aided triage and notification, new technology group 7	69	NO	97	NO	34	NO		NO	200	TBA at Spring update	Aidoc Briefcase for PE
XXE5XR7	Measurement of infection, mechanical initial specimen diversion technique using active negative pressure, new technology group 7	0	NO	0	NO	0	NO		NO	0	TBA at Spring update	Steripath® Initial Specimen Diversion Device®
XXE5XT7	Measurement of intracranial arterial flow, whole blood mrna, new technology group 7	0	NO	5	NO	2	NO		NO	7	TBA at Spring update	ISC-REST kit – ISCDx
XXE5XV7	Measurement of infection, serum/plasma nanoparticle fluorescence sars-cov-2 antibody detection, new technology group 7	1	NO	94	NO	1	NO		NO	96	TBA at Spring update	ISC-REST kit – QIAGEN Access Anti-SARS-CoV-2 Total Test
XXE97U7	Measurement of infection, nasopharyngeal fluid sars-cov-2 polymerase chain reaction, new technology group 7	711	NO	1664	NO	2391	NO		NO	4766	TBA at Spring update	ISC-REST kit – QIAstat-Dx Respiratory SARS-CoV-2 Panel
XY0YX37	Extracorporeal introduction of nafamostat anticoagulant, new technology group 7	4	NO	0	NO	1	NO		NO	5	TBA at Spring update	Niyad™

Topic # 09 - Addenda and Key Updates*

ICD-10-PCS Index Addenda

Lttr		A
Main	Add	Acellular Tissue Engineered Vessel (ATEV(tm)) use Bioengineered Human Acellular Vessel in New Technology
Lttr		G
Main	Add	Gallbladder fossa
Main	Add	use Peritoneal Cavity
Main	Add	GRAFAPEX(tm) use Treosulfan
Lttr		H
Main	Delete	Hemolung(R) Respiratory Assist System (RAS) 5A0920Z
Lttr		S
Main	Add	SYMVESS(tm) use Bioengineered Human Acellular Vessel in New Technology
Lttr		Z
Main	Add	ZEVASKYN (tm) use Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy in New Technology
Main	Add	ZIIHERA(R) use Zanidatamab Antineoplastic

ICD-10-PCS Body Part Key Addenda

Section 0		Medical and Surgical
Axis 4		Body Part
Term		Peritoneal Cavity
Includes	Add	Gallbladder fossa

ICD-10-PCS Device Key Addenda

Axis 6		Device
Row		
Term		Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy in New Technology
Includes	Add	ZEVASKYN (tm)
Row		
Term		Bioengineered Human Acellular Vessel in New Technology
Includes	Add	Acellular Tissue Engineered Vessel (ATEV(tm))
Includes	Add	SYMVESS(tm)

**All proposed addenda updates are being considered for implementation on April 1, 2026.*

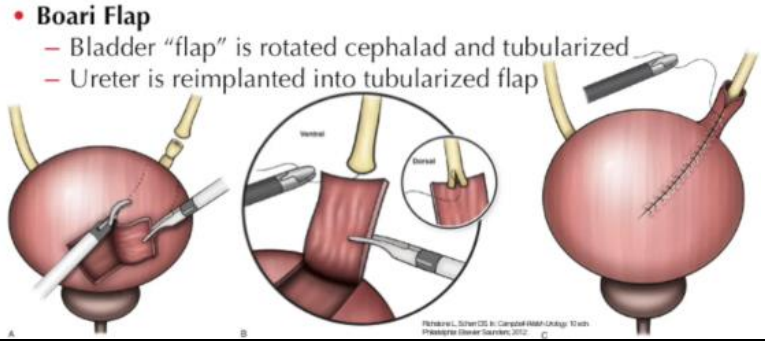
ICD-10-PCS Substance Key Addenda

Section X		New Technology
Axis 6		Device / Substance / Technology
Row	Add	
Term	Add	Treosulfan
Includes	Add	GRAFAPEX(tm)
Row	Add	
Term	Add	Zanidatamab Antineoplastic
Includes	Add	ZIIHERA(R)

ICD-10-PCS Table Addenda

Medical and Surgical Section

Axis 3 Root Operation
Ureteral Reimplantation with Boari Bladder Flap

Source	Description	Code specification
2025, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section, create new table 0TX Transfer of Urinary System. Add qualifier values 6 Ureter, Right and 7 Ureter, Left, applied to the body part value B Bladder and the open and percutaneous endoscopic approaches, to identify procedures such as ureteral reimplantation with a Boari bladder flap. Ureteral Reimplantation with a Boari bladder flap involves incising a section of bladder, rotating it toward the affected ureter and tubularizing it for anastomosis with the remaining healthy ureter. The primary goal of the Boari flap is to reconstruct the ureter, restoring the normal flow of urine from the kidney to the bladder. 	Add: 0TXB[04]Z[67] (4 codes)

**All proposed addenda updates are being considered for implementation on April 1, 2026.*

EXAMPLE

Section	**0** Medical and Surgical
Body System	**T** Urinary System
Operation	**ADD X** Transfer: Moving, without taking out, all or a portion of a body part to another location to take over the function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
B Bladder	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**6** Ureter, Right **7** Ureter, Left

Axis 4 Body Part
Omental or Mesenteric Surgical Aspiration

Source	Description	Code specification
2025, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0DD, Extraction of Gastrointestinal System, add the body part values U Omentum and V Mesentery, and qualifier value Z No Qualifier, applied to the open and percutaneous endoscopic approaches to identify procedures such as the debulking, or cytoreduction, of mesenteric or omental tumors by surgical aspiration. Omental or mesenteric tumor debulking using devices such as the Cavitron Ultrasonic Surgical Aspirator (CUSA) is a surgical approach for treating tumors, especially when complete resection is challenging or when it's necessary to reduce tumor bulk for symptom relief or to prepare for further treatments. CUSA can be used to aspirate tissue precisely. It's a common strategy when complete tumor removal isn't feasible, particularly with locally advanced or extensive mesenteric involvement. The goal is to alleviate symptoms like abdominal pain or obstruction and potentially improve the effectiveness of subsequent therapies like chemotherapy or radiation therapy.	Add: 0DD[UV][04]ZZ (4 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**D** Gastrointestinal System
Operation	**D** Extraction: Pulling or stripping out or off all or a portion of a body part by the use of force

Body Part	*Approach*	*Device*	*Qualifier*
1 Esophagus, Upper **2** Esophagus, Middle **3** Esophagus, Lower **4** Esophagogastric Junction **5** Esophagus **6** Stomach **7** Stomach, Pylorus **8** Small Intestine **9** Duodenum	**3** Percutaneous **4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**X** Diagnostic

A Jejunum **B** Ileum **C** Ileocecal Valve **E** Large Intestine **F** Large Intestine, Right **G** Large Intestine, Left **H** Cecum **J** Appendix **K** Ascending Colon **L** Transverse Colon **M** Descending Colon **N** Sigmoid Colon **P** Rectum			
Q Anus	**3** Percutaneous **4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic **X** External	**Z** No Device	**X** Diagnostic
ADD U Omentum **ADD V** Mesentery	**ADD 0** Open **4** Percutaneous Endoscopic	**Z** No Device	**ADD Z** No Qualifier

Ventricular Septum Pacing

Source	Description	Code specification
2025, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 02H, Insertion of Heart and Great Vessels, add the body part value M Ventricular Septum, applied to the percutaneous approach, device values J Cardiac Lead, Pacemaker, K Cardiac Lead, Defibrillator, M Cardiac Lead, N Intracardiac Pacemaker, and Y Other Device and qualifier value Z No Qualifier to identify procedures such as ventricular septum pacing. Ventricular septal pacing refers to the implantation of a pacing lead into the ventricular septum, which is the muscular wall that divides the heart's right and left ventricles. This placement is an alternative to the more traditional right ventricular (RV) apex placement.[1] While the RV apex has been the standard location, septal placement is gaining traction due to potential benefits in terms of pacing thresholds (the amount of electrical energy needed to stimulate the heart) and shock impedance (the resistance to the flow of electrical current during a defibrillation shock). Septal placement offers an alternative for patients who may not be ideal candidates for RV apex placement or for those where septal placement offers certain advantages.	Add: 02HM3[JKMNY]Z (5 codes)

[1] Das A, Kahali D. Ventricular septal pacing: Optimum method to position the lead. Indian Heart J. 2018 Sep-Oct;70(5):713-720. doi: 10.1016/j.ihj.2018.01.023. Epub 2018 Jan 11. PMID: 30392512; PMCID: PMC6204444.

EXAMPLE

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*
4 Coronary Vein **6** Atrium, Right **7** Atrium, Left **K** Ventricle, Right **L** Ventricle, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Monitoring Device, Pressure Sensor **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **J** Cardiac Lead, Pacemaker **K** Cardiac Lead, Defibrillator **M** Cardiac Lead **N** Intracardiac Pacemaker **Y** Other Device	**Z** No Qualifier
ADD M Ventricular Septum	**3** Percutaneous	**J** Cardiac Lead, Pacemaker **K** Cardiac Lead, Defibrillator **M** Cardiac Lead **N** Intracardiac Pacemaker **Y** Other Device	**Z** No Qualifier

Axis 7 Qualifier
Endoscopic Drainage of the Hepatobiliary System and Pancreas

Source	Description	Code specification
2025, public request with CMS internal review	In the Medical and Surgical section table 0F9, Drainage of Hepatobiliary System and Pancreas, add the qualifier values D Transmural and E Transpapillary, applied to body part values 4 Gallbladder, G Pancreas, 5 Right Hepatic Duct, 6 Left Hepatic Duct, 7 Common Hepatic Duct, 8 Cystic Duct, 9 Common Bile Duct, C Ampulla of Vater, D Pancreatic Duct, and F Accessory Pancreatic Duct, the approach value 8 Via Natural or Artificial Opening Endoscopic, and device value 0 Drainage Device. This change will enable the differentiation between the endoscopic techniques utilized to drain hepatobiliary and pancreatic fluid collections for better tracking and reporting. Endoscopic drainage methods are becoming the preferred treatment approach for diagnoses such as acute cholecystitis, pancreatic pseudocysts, and walled-off necrosis, because they are less invasive than surgery and yield high long-term success rates. The aim is to create a canal that helps to drain the fluid into the gastrointestinal tract, avoiding the need to place an external drain. Construction of the canal can be done either directly across the stomach or duodenal wall for	Add: 0F9[4G56789CDF]80[DE] (20 codes)

	transmural (TSM) drainage or through transpapillary drainage (TPD).[2] TPD involves cannulating the pancreatic duct using endoscopic retrograde cholangiopancreatography (ERCP) and placing a stent to drain the fluid collection. TSM drainage involves creating a pathway (with lumen-apposing metal stents (LAMS), plastic stents, or self-expanding metal stents (SEMS) between the fluid collection and the stomach or duodenum, using endoscopic ultrasound (EUS). Determining which method of endoscopic drainage is most suitable requires consideration of comorbidities, the patient's anatomy (gallbladder position, cystic duct characteristics, in-dwelling metal biliary stent), presence of ascites, potential future surgical candidacy, and available local expertise (endoscopic, radiographic, and surgical).[3]	

EXAMPLE

Section	**0** Medical and Surgical
Body System	**F** Hepatobiliary System and Pancreas
Operation	**9** Drainage: Taking or letting out fluids and/or gases from a body part

Body Part	*Approach*	*Device*	*Qualifier*
4 Gallbladder **G** Pancreas	**8** Via Natural or Artificial Opening Endoscopic	**0** Drainage Device	**ADD D** Transmural **ADD E** Transpapillary **Z** No Qualifier
5 Hepatic Duct, Right **6** Hepatic Duct, Left **7** Hepatic Duct, Common **8** Cystic Duct **9** Common Bile Duct **C** Ampulla of Vater **D** Pancreatic Duct **F** Pancreatic Duct, Accessory	**8** Via Natural or Artificial Opening Endoscopic	**0** Drainage Device	**ADD D** Transmural **ADD E** Transpapillary **Z** No Qualifier

Simple Prostatectomy

Source	Description	Code specification
2025, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0VT Resection of Male Reproductive System, create new qualifier value E Capsule Intact, applied to body part value 0 Prostate, device value Z No device and all available approach values to identify procedures such as simple prostatectomies.	Add: 0VT0[0478]ZE (4 codes)

[2] Misra D, Sood T. Pancreatic Pseudocyst. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK557594/

[3] AGA Clinical Practice Update on Role of EUS-Guided Gallbladder Drainage in Acute Cholecystitis: Commentary Irani, Shayan S. et al. Clinical Gastroenterology and Hepatology, Volume 21, Issue 5, 1141 - 1147

	The prostate is a gland surrounded by thin, fibrous layer called the capsule. It's not a true capsule in the sense of a distinct, separate structure, but rather a band of fibromuscular tissue and does not contain prostate tissue.[4] In a simple prostatectomy the inside tissue of the prostate gland is removed while leaving the capsule intact. By leaving the capsule intact, the nerves next to the seminal vesicles are preserved to help decrease the risk of erectile dysfunction and urinary incontinence. This technique is said to be analogous to taking the fruit from an orange while leaving the peel behind.[5] A simple prostatectomy is typically performed to relieve urinary symptoms caused by an enlarged prostate (benign prostatic hyperplasia, or BPH) and is not performed for malignancies of the prostate.	

EXAMPLE

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

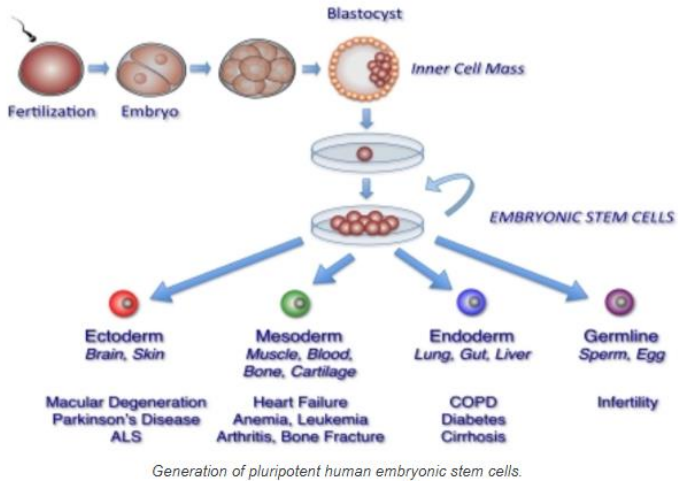
Body Part	*Approach*	*Device*	*Qualifier*
0 Prostate	**0** Open **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**ADD E Capsule Intact** **Z** No Qualifier

Administration Section
Axis 6 Substance

Embryonic Stem Cell Transplantation

Source	Description	Code specification
2025, CMS internal review	In the Administration section, in Physiological Systems and Anatomical Regions table 3E0 Introduction, add the substance value A Stem Cells, Embryonic, applied to body part values 3 Peripheral Vein and 4 Central Vein, the approach value 3 Percutaneous, and qualifier value Z No Qualifier, to describe venous embryonic stem cell transplantation.	Delete: 302[34]3AZ (2 codes) Add: 3E0[34]3AZ (2 codes)

[4] Ayala AG, Ro JY, Babaian R, Troncoso P, Grignon DJ. The prostatic capsule: does it exist? Its importance in the staging and treatment of prostatic carcinoma. Am J Surg Pathol. 1989 Jan;13(1):21-7. PMID: 2909195.
[5] Mohit Khera, MD, MBA, MPH (2023, December 19). Simple Prostatectomy. Medscape. Retrieved from https://emedicine.medscape.com/article/445996-overview

	Under this proposal, the ICD-10-PCS codes that currently exist in table 302 Transfusion of Circulatory System to describe venous embryonic stem cell transplantation would be deleted, as the definition of the root operation Transfusion is "Putting in blood or blood products". Embryonic stem cells are a type of pluripotent (capable of giving rise to several different cell types) stem cell found in the inner cell mass of a blastocyst, a very early-stage embryo. These cells can be cultured in the laboratory and under the right conditions will proliferate indefinitely. They have the remarkable ability to develop into any cell type in the body. They are not harvested from cord blood and are not considered a blood product.[6]  *Generation of pluripotent human embryonic stem cells.*	

EXAMPLES

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein	**3** Percutaneous	**3** Anti-inflammatory **4** Serum, Toxoid and Vaccine **6** Nutritional Substance **7** Electrolytic and Water Balance Substance **ADD A** Stem Cells, Embryonic **F** Intracirculatory Anesthetic **H** Radioactive Substance	**Z** No Qualifier

[6] NIH Stem Cell Information Home Page. In Stem Cell Information [https://stemcells.nih.gov/info/basics/stc-basics]. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2016 [cited February 1, 2021]

		K Other Diagnostic Substance **N** Analgesics, Hypnotics, Sedatives **P** Platelet Inhibitor **R** Antiarrhythmic **T** Destructive Agent **X** Vasopressor	
4 Central Vein	**3** Percutaneous	**3** Anti-inflammatory **4** Serum, Toxoid and Vaccine **6** Nutritional Substance **7** Electrolytic and Water Balance Substance **ADD A** Stem Cells, Embryonic **F** Intracirculatory Anesthetic **H** Radioactive Substance **K** Other Diagnostic Substance **N** Analgesics, Hypnotics, Sedatives **P** Platelet Inhibitor **R** Antiarrhythmic **T** Destructive Agent **X** Vasopressor	**Z** No Qualifier

Section	**3**	Administration	
Body System	**0**	Circulatory	
Operation	**2**	Transfusion: Putting in blood or blood products	
Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**DELETE A** Stem Cells, Embryonic	**Z** No Qualifier
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**C** Hematopoietic Stem/Progenitor Cells, Genetically Modified	**0** Autologous
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**D** Pathogen Reduced Cryoprecipitated Fibrinogen Complex	**1** Nonautologous
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**G** Bone Marrow **X** Stem Cells, Cord Blood **Y** Stem Cells, Hematopoietic	**0** Autologous **2** Allogeneic, Related **3** Allogeneic, Unrelated **4** Allogeneic, Unspecified
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**H** Whole Blood **J** Serum Albumin **K** Frozen Plasma **L** Fresh Plasma **M** Plasma Cryoprecipitate **N** Red Blood Cells **P** Frozen Red Cells **Q** White Cells **R** Platelets **S** Globulin **T** Fibrinogen **V** Antihemophilic Factors **W** Factor IX	**0** Autologous **1** Nonautologous
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**U** Stem Cells, T-cell Depleted Hematopoietic	**2** Allogeneic, Related **3** Allogeneic, Unrelated **4** Allogeneic, Unspecified

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

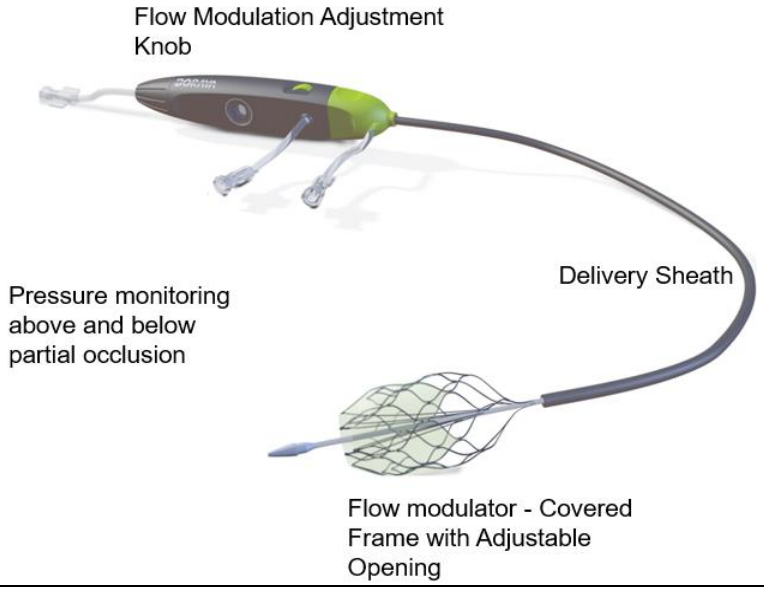
Lttr I
Main Introduction of substance in or on
Vein
Central 3E04
Add Embryonic Stem Cells 3E04
Peripheral 3E03
Add Embryonic Stem Cells 3E03

Lttr T
Main Transfusion
Vein
Central
Stem Cells
Delete Embryonic 30243AZ
Peripheral
Stem Cells
Delete Embryonic 30233AZ

Extracorporeal or Systemic Assistance and Performance Section
Axis 7 Qualifier

Venous Flow Modulation

Source	Description	Code specification
2025, public request with CMS internal review	In the Extracorporeal or Systemic Assistance and Performance section table 5A0, add the qualifier value E Blood Flow Modulator, applied to body system value 2 Cardiac, duration value 2 Continuous, and function value 1 Output to describe continuous cardiac output assistance with a blood flow modulating device. The Doraya™ device is a short-term intravenous flow regulator that received Breakthrough Device Designation from the FDA on May 29, 2020. The Doraya™ device is percutaneously deployed in the inferior vena cava (IVC) below the level of the renal veins and is designed to treat patients with acute decompensated heart failure (ADHF), who suffer from symptoms of congestion and shortness of breath due to elevated cardiac filling pressure and fluid backup into the lungs. When in place, the Doraya™ device partially occludes the IVC, which modulates or limits blood flow from the body to the heart, in turn reducing pressure on the heart.	Add: 5A0221E (1 code)

	Insertion of the Doraya™ device is performed in the cardiac catheterization lab under conscious sedation. Vascular access is gained using standard techniques to allow for advancement of the introducer sheath and guidewire, continuing to the IVC. Using fluoroscopic guidance, the device is advanced through the introducer sheath and over a guidewire until the device is below the lower renal vein, according to a venogram roadmap. The handle is then fixed to the patient's body to prevent migration. The nitinol frame is deployed by pulling back and locking the delivery sheath. Once in place, the frame location within the vessel is not changed. The guidewire is retrieved, the pressure ports on the device are connected to the monitor and pressures above and below the flow restriction are verified. Once the device is implanted and the flow modulator is deployed, the physician adjusts the opening in the flow modulator in order to achieve the desired reduction in cardiac pressure. Hemodynamic monitoring is done through the duration of the device dwell. The patient is placed on anticoagulation therapy while the device is implanted to prevent thrombus formation, and the flow modulator is adjusted as needed to maintain a pressure gradient and reduce central venous pressure. The Doraya™ device remains in the patient for up to 24 hours and can be removed sooner if the physician believes that the desired therapeutic results have been achieved. Removal of the Doraya™ device is performed while the patient is conscious. Doraya: A Blood Flow Modulator  	

EXAMPLE

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

Body System	*Duration*	*Function*	*Qualifier*
2 Cardiac	**1** Intermittent	**1** Output	**0** Balloon Pump **5** Pulsatile Compression **6** Other Pump **D** Impeller Pump
2 Cardiac	**2** Continuous	**1** Output	**0** Balloon Pump **5** Pulsatile Compression **6** Other Pump **D** Impeller Pump **ADD E** Blood Flow Modulator
2 Cardiac	**2** Continuous	**2** Oxygenation	**C** Supersaturated

Physical Rehabilitation and Diagnostic Audiology Section
Axis 4 Body System/Region

Negative Pressure Wound Therapy

Source	Description	Code specification
2025, public request with CMS internal review	In Physical Rehabilitation and Diagnostic Audiology section table F08, add the body system/region values E Integumentary System -Thorax/Abdomen and P Musculoskeletal System - Thorax/Abdomen, applied to type qualifier value 5 Wound Management, for all equipment values and qualifier Z None. This proposed change would enable the capture of adjunctive management of acute and chronic wounds of the thorax or abdomen.	Add: F08[EP]5[BCDEFUAYZ]Z (18 codes)

EXAMPLE

Section	**F** Physical Rehabilitation and Diagnostic Audiology
Body System	**0** Rehabilitation
Operation	**8** Activities of Daily Living Treatment: Exercise or activities to facilitate functional competence for activities of daily living

Body System/Region	*Type Qualifier*	*Equipment*	*Qualifier*
D Integumentary System -Head and Neck **ADD E** Integumentary System -Thorax/Abdomen **F** Integumentary System -Upper Back / Upper Extremity **G** Integumentary System -Lower Back / Lower Extremity **H** Integumentary System -Whole Body **J** Musculoskeletal System -Head and Neck **K** Musculoskeletal System -Upper Back / Upper Extremity **L** Musculoskeletal System -Lower Back / Lower Extremity **M** Musculoskeletal System -Whole Body **ADD P** Musculoskeletal System - Thorax/Abdomen	**5** Wound Management	**B** Physical Agents **C** Mechanical **D** Electrotherapeutic **E** Orthosis **F** Assistive, Adaptive, Supportive or Protective **U** Prosthesis **A** Negative Pressure Therapy **Y** Other Equipment **Z** None	**Z** None

Physical Rehabilitation and Diagnostic Audiology Section
Axis 5 Body System/Region

Microcurrent Therapy

Source	Description	Code specification
2025, public request with CMS internal review	In Physical Rehabilitation and Diagnostic Audiology section table F07, add the type qualifier value Y Other Therapy Techniques, the equipment value D Electrotherapeutic and the qualifier value 0 Microcurrent Stimulation, applied to body system/region values D Integumentary System - Head and Neck, E Integumentary System -Thorax/Abdomen, F Integumentary System - Upper Back / Upper Extremity, G Integumentary System - Lower Back / Lower Extremity, and H Integumentary System - Whole Body. This proposed change would enable capture of the utilization of adjunctive therapies such as microcurrent electrical neuromuscular stimulation (MENS) and frequency-specific microcurrent (FSM). MENS and FSM are both forms of microcurrent therapy that use low-level electrical currents to promote healing and reduce pain. MENS involves series of stimuli delivered superficially, in the microampere range, through special transducer gloves or through electrodes placed on the skin, that send electrical impulses in the microampere range to stimulate tissue healing, reduce pain, and potentially improve muscle function. It is a key component for many medical and sport applications, and it is largely used for rehabilitation, training, and recovery purposes. FSM is an emerging technique for addressing many health conditions including fibromyalgia, chronic fatigue, and myofascial and neuropathic pain. Pairs of frequencies of microampere-level electrical stimulation are applied to identified places on the skin of a patient via combinations of conductive graphite gloves, moistened towels, or gel electrode patches. In studies, consistent findings are profound and palpable tissue softening and warming within seconds of applying frequencies appropriate for treating particular conditions. The softening is not superficial, as in the	Add: F07[DEFGH]YD0 (5 codes)

	epidermal layer, but is in the deeper skeletal muscles.[7] FSM is not the primary treatment for any condition but may offer additional relief, especially for conditions that are difficult to treat or resist healing.	

EXAMPLE

Section	**F** Physical Rehabilitation and Diagnostic Audiology
Body System	**0** Rehabilitation
Operation	**7** Motor Treatment: Exercise or activities to increase or facilitate motor function

Body System/Region	*Type Qualifier*	*Equipment*	*Qualifier*
D Integumentary System - Head and Neck **ADD E** Integumentary System -Thorax/Abdomen **F** Integumentary System - Upper Back / Upper Extremity **G** Integumentary System - Lower Back / Lower Extremity **H** Integumentary System - Whole Body	**ADD Y** Other Therapy Techniques	**ADD D** Electrotherapeutic	**ADD 0** Microcurrent Stimulation

New Technology Section
Axis 6 Device / Substance / Technology

Intra-Arterial Stem Cell Infusion

Source	Description	Code specification
2025, Coding Clinic Editorial Advisory Board & CMS internal review	In the New Technology section table XW0, Anatomical Regions, add substance value 4 Stem Cells, Somatic, applied to the body part value 5 Peripheral Artery and the approach value 3 Percutaneous. This proposed change would enable the capture of procedures such as intra-arterial stem cell infusion. Intra-arterial stem cell infusion, a minimally invasive technique, involves delivering stem cells directly into the arteries supplying the affected tissue. Recently, delivering stem cells directly into the arteries supplying the affected portion of the brain has been investigated as an adjunct to thrombolysis or mechanical thrombectomy in conditions like ischemic stroke to potentially improve cell engraftment and therapeutic outcomes.[8,9] Preclinical data suggest that intra-arterial stem cell infusion leads	XW0534B (1 code)

[7] McMakin CR, Oschman JL. Visceral and somatic disorders: tissue softening with frequency-specific microcurrent. J Altern Complement Med. 2013 Feb;19(2):170-7. doi: 10.1089/acm.2012.0384. Epub 2012 Jul 9. PMID: 22775307; PMCID: PMC3576917.
[8] Bhatia V, Gupta V, Khurana D, Sharma RR, Khandelwal N. Randomized Assessment of the Safety and Efficacy of Intra-Arterial Infusion of Autologous Stem Cells in Subacute Ischemic Stroke. AJNR Am J Neuroradiol. 2018 May;39(5):899-904. doi: 10.3174/ajnr.A5586. Epub 2018 Mar 15. PMID: 29545253; PMCID: PMC7410650.
[9] Guzman R, Janowski M, Walczak P. Intra-Arterial Delivery of Cell Therapies for Stroke. Stroke. 2018 May;49(5):1075-1082. doi: 10.1161/STROKEAHA.117.018288. Epub 2018 Apr 18. PMID: 29669876; PMCID: PMC6027638.

	to a greater number of cells targeting the ischemia. The main reason for this is believed to be because the stem cells bypass filtering organs, such as the lung, the spleen, and the liver.[10] Somatic stem cells, also known as adult stem cells, are undifferentiated cells found in various tissues throughout the body that can self-renew and differentiate into specialized cell types to maintain and repair tissues. They can develop into specialized cell types within their tissue of origin, such as blood cells in bone marrow or skin cells in the skin. The following types of somatic stem cells have been studied in intra-arterial infusions: • Mesenchymal Stem Cells (MSCs) - isolated from a variety of tissues, such as umbilical cord, endometrial polyps, menses blood, bone marrow, and adipose tissue[11] • Bone Marrow Mononuclear Cells (BMMNCs) - found in bone marrow • Neural Stem Cells (NSCs) – found in the brain • Umbilical Cord Mesenchymal Stem Cells (UCMSCs) - found in the umbilical cord tissue • Hematopoietic Stem Cells (HSCs) - found in the peripheral blood and the bone marrow • Induced Pluripotent Stem Cells (iPSCs) - derived from skin or blood cells that have been reprogrammed back into an embryonic-like state. In most cases, mesenchymal stem cells, bone marrow mononuclear cells or hematopoietic stem cells are used as the cellular component of the therapy in	

[10] Pendharkar AV, Chua JY, Andres RH, Wang N, Gaeta X, Wang H, et al. Biodistribution of neural stem cells after intravascular therapy for hypoxic-ischemia. Stroke. 2010;41:2064–2070. doi: 10.1161/STROKEAHA.109.575993.
[11] Ding DC, Shyu WC, Lin SZ. Mesenchymal stem cells. Cell Transplant. 2011;20(1):5-14. doi: 10.3727/096368910X. PMID: 21396235.

	clinical trials of stem cell-based therapies for stroke, while neural stem cells are used less often.[12]	

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 System / Region	*Approach*	*Substance*	*Qualifier*
ADD 5 Peripheral Artery	**3** Percutaneous	**ADD 4** Stem Cells, Somatic	**B** New Technology Group 11

[12] Sukhinich K.K., Namestnikova D.D., Gubskii I.L., Gabashvili A.N., Mel'nikov P.A., Vitushev E.Y., Vishnevskii D.A., Revkova V.A., Solov'eva A.A., Voitkovskaya K.S., et al. Distribution and Migration of Human Placental Mesenchymal Stromal Cells in the Brain of Healthy Rats after Stereotaxic or Intra-Arterial Transplantation. Bull. Exp. Biol. Med. 2020;168:542–551. doi: 10.1007/s10517-020-04750-8.

Topic # 10 – Intracochlear Administration of DB-OTO

Issue: There are no unique ICD-10-PCS codes to describe the intracochlear administration of DB-OTO. An April 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. DB-OTO received Rare Pediatric Disease (July 28, 2021), Orphan Drug (August 11, 2021), and Fast Track (August 22, 2023) designations from the FDA for the treatment of patients with congenital hearing loss due to biallelic variants of the otoferlin (OTOF) gene. DB-OTO also received a Regenerative Medicine Advanced Therapy (July 5, 2024) designation from the FDA for the treatment of congenital auditory neuropathy secondary to biallelic mutations of the OTOF gene. The requestor indicated they are seeking accelerated approval for a Biologics License Application.

Background: Otoferlin-related hearing loss is an ultra-rare condition (~20 to 50 new patients per year in the US) caused by variants in the OTOF gene that result in non-functional otoferlin protein, leading to disrupted communication between the sensory inner hair cells and the auditory nerve. Biallelic pathogenic variants of the OTOF gene cause congenital severe-to-profound hearing loss.

There are no approved medicines for otoferlin-related hearing loss at this time. Currently, management options for these patients is limited to prostheses, such as hearing aids or cochlear implants (CIs). Patients with otoferlin-related hearing loss typically do not benefit from hearing aids and require surgically placed CIs. CI electrodes facilitate the transmission of sound information to the brain by directly stimulating the spiral ganglion neurons, effectively bypassing inner hair cells responsible for sensing sound vibrations in a functional cochlea.

According to the requestor, CI prostheses have notable limitations compared to physiological hearing. These devices provide abnormal, low-resolution hearing. Accordingly, children who use these prostheses to hear have persistent challenges hearing speech in social environments (e.g., classrooms), have compromised receptive and expressive language development, experience listening-related fatigue, are at higher risk of significant impairments in executive function, show relatively poorer academic performance, and have poorer sound localization ability.

Because these prostheses must be removed at night (to prevent skin deterioration and recharge) or in certain scenarios (e.g., swimming or sports requiring a helmet), patients with otoferlin-related hearing loss experience prolonged periods without hearing, raising safety concerns and limiting participation in activities. Importantly, the surgical insertion of the electrodes of the CI prosthetic damages the structures of the inner ear and likely precludes the patient from receipt of future, potentially curative treatments that require intact cellular structures.

Per the requestor, while cochlear implants are impactful for a patient who would have otherwise been deaf, there is a high unmet need for an improved therapy that can address the pathophysiology of congenital hearing loss to modify the disease process. DB-OTO is designed to provide durable, physiological hearing to individuals with profound, congenital hearing loss caused by variants of the OTOF gene.

Mechanism of Action
DB-OTO is an investigational cell-selective, dual adeno-associated virus (AAV) vector gene therapy. The treatment aims to deliver a working copy to replace the faulty OTOF gene using a modified, non-pathogenic virus that is delivered via an infusion into the cochlea (inner ear of hearing) as part of a surgical procedure under general anesthesia. In this gene therapy, the newly introduced OTOF gene is under the control of a proprietary cell-specific Myo15 promoter, which is intended to restrict expression only to hair cells that normally express otoferlin. Expression of functional otoferlin in the inner hair cells is critical to enable neurotransmission between the inner ear and the auditory nerve, enabling hearing.

Inpatient Administration of DB-OTO
DB-OTO is administered under general anesthesia as a single drug product in a single intracochlear infusion into the perilymph of each inner ear through the round window membrane (RWM) using the same mastoidectomy and facial recess surgical approach that is used to access the round window for cochlear implantation. However, after the round window is visualized, the procedures for DB-OTO infusion differ from those employed for cochlear implantation. For DB-OTO infusion, a fenestration (opening) is made in the lateral semicircular canal (part of the inner ear of balance) in order to provide an egress path for displaced perilymph by the vector suspension. A small opening is then made in the RWM to enable the insertion of the catheter approximately 4 mm through the membrane. The vector suspension is then infused over 16 minutes at a fixed rate and volume using a syringe and syringe pump. After delivery of DB-OTO, the catheter is slowly removed, and the RWM and fenestration are gently repaired using grafts harvested from the surgical site (fascia, bone or muscle).

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of DB-OTO via intracochlear infusion. Facilities can report the surgical insertion of the catheter and the intracochlear administration of DB-OTO using the following codes:

09HH0YZ Insertion of other device into right ear, open approach
09HJ0YZ Insertion of other device into left ear, open approach
3E0B3GC Introduction of other therapeutic substance into ear, percutaneous approach

In addition, assign a code from table 09P, Removal of Ear, Nose, Sinus using the applicable ear body part value(s), the device value Y Other Device and the open approach to identify the procedure to remove the catheter and a code from table 09U, Supplement of Ear, Nose, Sinus, using the applicable inner ear body part value(s), the device value 7 Autologous Tissue Substitute and the open approach to identify the procedure to augment the round window membrane using locally harvested tissue (fascia, bone, or muscle) following the intracochlear infusion.

Section	**0** Medical and Surgical		
Body System	**9** Ear, Nose, Sinus		
Operation	**P** Removal: Taking out or off a device from a body part		
Body Part	*Approach*	*Device*	*Qualifier*
H Ear, Right **J** Ear, Left **K** Nasal Mucosa and Soft Tissue	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**0** Drainage Device **7** Autologous Tissue Substitute **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Y** Other Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**9** Ear, Nose, Sinus
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*
5 Middle Ear, Right **6** Middle Ear, Left **9** Auditory Ossicle, Right **A** Auditory Ossicle, Left **D** Inner Ear, Right **E** Inner Ear, Left	**0** Open **8** Via Natural or Artificial Opening 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 for the intracochlear administration of DB-OTO. Continue coding as described in current coding.

Option 2. In section X New Technology create new table X9H, Insertion of Ear, Nose, Sinus, with new device value 1 Infusion Device, Temporary, applied to the body part values D Inner Ear, Right, E Inner Ear, Left, and F Inner Ear, Bilateral, and the open approach, to identify surgical insertion of the catheter.

Section	**X** New Technology
Body System	**ADD 9** Ear, Nose, Sinus
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 D Inner Ear, Right **ADD E** Inner Ear, Left **ADD F** Inner Ear, Bilateral	**0** Open	**ADD 1** Infusion Device, Temporary	**B** New Technology Group 11

In section X table XW0, Introduction of Anatomical Regions, create new substance value 3 DB-OTO via Intracochlear Infusion, applied to the body part value E Ear(s) and the percutaneous approach, to identify the intracochlear administration of DB-OTO. Continue to separately report the appropriate code from table 09U, Supplement of Ear, Nose, Sinus using the applicable Inner Ear body part value for the augmentation of the round window membrane using locally harvested tissue (fascia, bone, or muscle), as described in current coding.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD E Ear(s)	**3** Percutaneous	**ADD 3** DB-OTO via Intracochlear Infusion	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 11 – Administration of CPI-601

Issue: There are no unique ICD-10-PCS codes to describe the administration of CPI-601 enzyme replacement therapy for the treatment of infantile Batten disease. An April 1, 2026 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The requestor received Orphan Drug Designation on February 7, 2018, for the treatment of neuronal ceroid lipofuscinosis type 1 (CLN1).

Background: Neuronal ceroid-lipofuscinoses (NCLs) are lysosomal storage diseases (LSDs) and collectively are the most common hereditary progressive neuro-visceral degenerative disease in children, with a prevalence of approximately 1.5 to 9 per million population (1.3 to 7 per 100,000 live births). Deficiency of the lysosomal enzyme palmitoyl protein thioesterase-1 (PPT1; EC 3.1.2.22) causes the human lysosomal storage disorder, designated CLN1, characterized by progressive blindness, motor disturbances, loss of speech, seizures, regression of motor development, ataxia, and early death. Disease onset varies from infancy to adulthood in males and females of diverse ethnic backgrounds. The requestor maintains that over 90 mutations in the PPT1/CLN1 gene have been described in NCL individuals, with no current treatment available for the fatal disease.

The requestor has collected data on 23 patients globally with the disease through their registry. Data analysis facilitated the development of human recombinant PPT1 for delivery via the intracerebroventricular (ICV) route. The ICV dose recovered 64% of the wild-type PPT1 enzyme activity in the brain of PPT1 knockout mice. According to the requestor, the data confirmed the histological findings that the animals are responding statistically significantly to the treatment. ICV treatment also decreased the loss of neurons in all regions of the brain and spinal cord assessed. CatwalkXT data analysis of 17 measures showed more statistically significant differences for the ICV treatment, with 13/17 showing differences with treatment. Notably, it appears treatment returns average stride length, average swing speed, and step cycle to near normal levels. Per the requestor, in combination, the results illustrate that the delivery of rhPPT1 enzyme ICV can statistically significantly impact the phenotype. Currently, the requestor is conducting large animal toxicology studies for this protein.

Mechanism of Action
CPI-601 is an investigational CLN1 enzyme replacement therapy. Per the requestor, the therapy delivers the human recombinant PPT1 protein via ICV by entering the cells through the mannose 6 phosphate receptor. Then the receptor's function would include clearing stored material from the cells.

Inpatient Administration of CPI-601
According to the requestor, the human recombinant PPT1 protein would be administered in an inpatient setting biweekly. Dosage requirements for CPI-601 have not been finalized by the requestor to date.

Current Coding: There is no unique ICD-10-PCS code to describe the administration of CPI-601. Facilities can report the intraventricular administration of CPI-601 using the following code:

> 3E0Q3GC Introduction of other therapeutic substance into cranial cavity and brain, percutaneous approach

Coding Options

Option 1. Do not create a new ICD-10-PCS code for the intraventricular administration of CPI-601. Continue coding as described in current coding.

Option 2. In section X table XW0, Introduction of Anatomical Regions, create new substance value 2 CPI-601 Enzyme Replacement Therapy, applied to the new body part value 6 Cerebral Ventricle and the percutaneous approach, to identify the intraventricular administration of CPI-601.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 6 Cerebral Ventricle	**3** Percutaneous	**ADD 2** CPI-601 Enzyme Replacement Therapy	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above

Interim Coding Advice: Continue as described in current coding.

Topic # 12 – Administration of ZEMAIRA®

Issue: There are no unique ICD-10-PCS codes to describe the administration of an alpha1-proteinase inhibitor for treatment of acute graft versus host disease (aGVHD) in adults.
An April 1, 2026 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No.

Background: Acute graft versus host disease (aGVHD) is a rare and life-threatening condition occurring in patients undergoing allogeneic hematopoietic stem cell transplantation (alloHCT) caused by immune-competent donor T cells, developing in approximately 50% of patients. According to the requestor, in 2024, there were 1,008 Medicare Fee-For-Service inpatient allogeneic transplants reported in claims data (100% Inpatient Research Identifiable Files). aGVHD is one of the leading causes of death within 100 days after allogeneic HCT. Patients with aGVHD predominantly experience the condition impacting their skin, gastrointestinal tract, and liver. There is a clinically relevant risk of infectious disease complications due to underlying malignancy, immunosuppressive cancer therapies, and aGVHD itself. There is no FDA-approved first-line treatment available. The current standard of care is high-dose corticosteroids, which are ineffective in roughly 50% of patients.

According to the requestor, ZEMAIRA® is an alpha1-proteinase inhibitor (A1-PI) used in combination with corticosteroids for first-line treatment of acute graft versus host disease (aGVHD) in adults. ZEMAIRA® is designed to impact the aGVHD disease pathology, e.g., reduction of pro-inflammatory cytokine secretion and activity; exertion of potential tissue protective effects via serine protease inhibition; and impact on immune cell populations to attenuate aGVHD pathophysiology, including T-regulatory (Tregs) to T-effector (Teff) cell ratio increase and inhibition of neutrophil migration to sites of inflammation.

Mechanism of Action
Per the requestor, the primary A1-PI mechanism of action as a serine protease inhibitor involves pleiotropic anti-inflammatory and non-immunosuppressive effects. The exact A1-PI biological mechanism of action in aGVHD is not yet fully elucidated but there are several putative pathways implicated for A1-PI that are relevant to aGVHD disease pathology, e.g., reduction of pro-inflammatory cytokine secretion and activity; exertion of potential tissue protective effects via serine protease inhibition; and impact on immune cell populations to attenuate aGVHD pathophysiology, including T-regulatory (Tregs) to T-effector (Teff) cell ratio increase and inhibition of neutrophil migration to sites of inflammation.

A1-PI irreversibly binds and inhibits multiple serine proteases, with a preferential binding affinity to neutrophil elastase, proteinase 3, and cathepsin G. These serine proteases, if not inhibited, interact and cleave members of the protease activated receptors (PAR) and cytokines (e.g., IL-1β, IL-33), involved in several biological signaling pathways, and promote immune responses and inflammation. They are also found in neutrophil granulocytes, shown to enhance aGVHD via intestinal tissue damage, allogenic antigen presentation to T cells, and T cell activation.

In a mouse model of allogenic hematopoietic stem cell transplant (allo-HCT), A1-PI appeared to have a number of downstream effects, including inhibition of pro-inflammatory cytokine release and promoting graft versus host tolerance by inducing an increase of Tregs to Teff cell ratio.

Inpatient Administration of ZEMAIRA®
ZEMAIRA® is administered intravenously through a separate dedicated infusion line and cannot be mixed with other medicinal products. Providers should perform a visual inspection of the solution before administering the treatment. The solution should be clear, colorless to slightly yellow, and free from visible particles. ZEMAIRA® should be kept at room temperature and administered within 3 hours of reconstitution. During administration, the solution is filtered using a 5-micron infusion filter. The administration infusion rate is approximately 0.08 mL/kg/min as determined by the response and comfort of the patient. For the treatment of aGVHD, the recommended dosage of 120 mg/kg body weight takes approximately 30 minutes to infuse.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of an alpha1-proteinase inhibitor. Facilities can report the intravenous administration of an alpha1-proteinase inhibitor using one of the following codes:

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of an alpha1-proteinase inhibitor. Continue coding as described in current coding.

Option 2. In section X table XW0, Introduction of Anatomical Regions, create new substance value 0 Alpha1-proteinase Inhibitor, applied to the body part values 3 Peripheral Vein and 4 Central Vein, and the percutaneous approach, to identify the intravenous administration of alpha1-proteinase inhibitor.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 0** Alpha1-proteinase Inhibitor	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.

Topic # 13 – Administration of anitocabtagene autoleucel

Issue: There are no unique ICD-10-PCS procedure codes to describe the administration of anitocabtagene autoleucel (anito-cel). An April 1, 2026 implementation date is being requested.

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

Food & Drug Administration (FDA) Approval? No. Anito-cel has been granted Fast Track, Orphan Drug, and Regenerative Medicine Advanced Therapy designations. The requestor will be seeking approval for a Biologics License Application (BLA) and is targeting approval in 2026.

Background: Multiple Myeloma (MM) is an incurable cancer of plasma cells, marked by clinical features such as renal failure, bone lesions, hypercalcemia, and bone marrow suppression, which arise from the overproduction of monoclonal proteins and the direct effects of tumor cells. In 2025, it is estimated that 36,110 patients were diagnosed with MM and that nearly 12,030 patients died from MM in the U.S. The requestor reported that while the 5-year survival rate has significantly improved since the 2000s in the U.S., the rate of improvement in 5-year survival rate has been plateauing in recent years, indicating the need for novel, effective therapies.

Relapsed or refractory multiple myeloma (RRMM) is characterized by progressively worse outcomes and increased refractoriness with each line of therapy. Prognosis for patients with fourth line (4L+) RRMM who are triple-class exposed is very poor with median progression-free survival (mPFS) and overall survival (mOS) of 4.1 and 15.4 months, respectively.

While there are commercially available CAR T-cell therapies and bispecific monoclonal antibodies for treatment of 4L+ RRMM, not all produce deep or durable responses. Moreover, currently available bispecific monoclonal antibodies and CAR T-cell therapies have been associated with serious adverse events, including cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity (ICANS), immune effector cell-associated enterocolitis, delayed neurotoxicities, prolonged cytopenias, and infections. Anito-cel has been shown to provide durable results (mPFS of 30.2 months & mOS not reached at a median follow-up of 38.1 months) in the Phase 1 trial in 4L+ patients, including those with high-risk features (Bishop 2024). Further, no delayed or non-ICANS neurotoxicities, including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome, have been reported with anito-cel in the Phase 1 trial (N=38, median follow-up of 38.1 months with minimum follow-up of 25 months) and the iMMagine-1 trial (N=98 patients with at least one month of follow-up from anito-cel infusion).

Mechanism of Action
Anito-cel is a novel autologous BCMA-directed CAR T-cell therapy. Anito-cel features a BCMA-specific D-Domain binder instead of a traditional antibody-derived binder.

D-Domain proteins are small and structurally compact. The 8 kDa D-Domain binder is approximately one-third the size of traditional antibody-derived binders such as the single chain variable fragment (scFv) (28 kDa) and the combination of two distinct camelid VH domains (VHH) (30 kDa) binders used in currently approved BCMA-directed CAR T-cell therapies (Freeman 2024).

In addition to being small and structurally compact, D-Domain proteins are also devoid of disulfide bonds and N-linked glycosylation. The size and compactness of the D-domain along with the lack of disulfide bonds and N-linked glycosylation facilitates efficient and stable protein folding. These attributes contribute to reduced inter-patient variability in CAR+ T-cell composition, increased production efficiency and scalability, and high transduction efficiency (high CAR+) resulting in a low total cell dose. Moreover, the anti-BCMA D-Domain binder exhibits a fast off-rate and enhanced cell surface T-cell expression with the absence of tonic signaling. Faster dissociation rate and shorter interaction with target cells may mimic physiological T-cell activation and may result in reduced cytokine release and immunotoxicity, while preserving anti-tumor activity. Combined, the unique properties of the D-Domain lead to the efficacy, safety and manufacturability profile observed in clinical trials.

Inpatient Administration of anitocabtagene autoleucel
Anito-cel is given as a single intravenous infusion administered through the central or peripheral vein, primarily as a standalone procedure. Following infusion, anito-cel recognizes and binds to BCMA, a protein highly expressed on malignant B-lineage cells in MM, triggering T-cell activation, expansion, and the targeted elimination of BCMA-expressing cells (Freeman 2024). The target dose of anito-cel is $115 \pm 10 \times 10^6$ CAR-positive viable T-cells.

In the iMMagine-1 trial, the safety evaluable population (N=98 patients with at least one month of follow-up from anito-cel infusion) had the following adverse events (AEs). 86% (84/98) of patients had CRS Grade 1 or less, including 17% (17/98) with no CRS. The percentage of patients with either no CRS or CRS that resolved by ≤7 or ≤14 days after anito-cel infusion were 63% and 98%, respectively. There were no Grade 3 or Grade 4 CRS events. There was one Grade 5 event in a 76-year-old patient who had rapidly progressive disease between screening and baseline and did not receive bridging therapy. 91% (91/98) of patients did not have ICANS. Of the 9% (9/98) of patients who had ICANS of any grade, only 1 patient experienced Grade 3 ICANS; no patients had Grade >3 ICANS. All ICANS cases resolved. No delayed or non-ICANS neurotoxicities were observed including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome. Similarly, no delayed or non-ICANS neurotoxicities have been observed in the Phase 1 trial (N=38, median follow-up of 38.1 months with minimum follow-up of 25 months) (Bishop 2024). In iMMagine-1, the most common Grade 3 and higher treatment-emergent adverse events (TEAEs) were cytopenias. No replication competent lentivirus was detected, and no secondary primary malignancies of T-cell origin or hematologic malignancies were reported. Three deaths occurred due to TEAEs (related and unrelated to anito-cel): retroperitoneal hemorrhage secondary to biopsy, CRS and fungal infection (Freeman 2024).

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

XW033C7 Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW043C7 Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7

Coding Options

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

Option 2. In section X table XW0, Introduction of Anatomical Regions, create new substance value 1 Anitocabtagene Autoleucel Immunotherapy, applied to the body part values 3 Peripheral Vein and 4 Central Vein and the percutaneous approach, to identify the intravenous administration of anitocabtagene autoleucel (anito-cel).

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 1** Anitocabtagene Autoleucel Immunotherapy	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue as described in current coding.