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

Agenda

ICD-10 Coordination and Maintenance Committee
Department of Health and Human Services
Centers for Medicare & Medicaid Services
CMS Auditorium
7500 Security Boulevard
Baltimore, MD 21244-1850
ICD-10-PCS Topics
March 6, 2018

CMS – Co-Chair

Webcast and Dial-In Information

- The meeting will begin promptly at 9am ET and will be webcast.
- Toll-free dial-in access is available for participants who cannot join the webcast:
  Day 1-March 6, 2018: Phone: 1-877-267-1577; Meeting ID: 994 462 785.
  Day 2-March 7, 2018: Phone: 1-877-267-1577; Meeting ID: 990 901 683.
  We encourage you to join early, as the number of phone lines is limited.
- **If participating via the webcast or dialing in you do NOT need to register on-line for the meeting.**

This meeting is being webcast via CMS at http://www.cms.gov/live/. By your attendance, you are giving consent to the use and distribution of your name, likeness and voice during the meeting. You are also giving consent to the use and distribution of any personally identifiable information that you or others may disclose about you during the meeting. Please do not disclose personal health information.

Note: Proposals for diagnosis code topics are scheduled for March 7, 2018 and will be led by the Centers for Disease Control (CDC). Please visit CDCs website for the Diagnosis agenda located at the following address:
http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm

Registration:
Information on registering online to attend the meeting in-person can be found at:
http://www.cms.hhs.gov/apps/events/

***If participating via the webcast or dialing in, and not attending in-person, you do NOT need to register on-line for the meeting.**

For questions about the registration process, please contact Mady Hue at 410-786-4510 or marilu.hue@cms.hhs.gov or Noel Manlove at 410-786-5161 or noel.manlove@cms.hhs.gov.

Introductions and Overview	Songhai Barclift, MD

ICD-10-PCS Topics:

1. Irreversible Electroporation Pages 11-12	Noel Manlove Robert C.G. Martin, II, MD, PhD, FACS Sam & Lolita Weakley Endowed Chair, Surgical Oncology Vice-Chair of the Dept of Surgery for Research Director, Division of Surgical Oncology Professor of Surgery Director, Upper GI & HPB Multi-Disciplinary Clinic Academic Advisory Dean University of Louisville
2. Cell Suspension Autografting Pages 13-15	Noel Manlove William L. Hickerson, MD, FACS Director, Firefighters Burn Center Regional One Health, Memphis TN Professor of Plastic Surgery University of Tennessee Health Science Center
3. Insertion of the Remedē® Phrenic Nerve Stimulation System Pages 16-18	Chava Sheffield Sanjaya Gupta, MD Spencer B. Bailey, MBA, CPC
4. Endovascular Bypass of Lower Extremity Arteries Pages 19-21	Chava Sheffield David Deaton, MD, FACS Chief Medical Officer, Syntactx Vascular Surgeon, University of South Carolina
5. Implantation of Multi-function Networked Neuroprosthesis Pages 22-24	Chava Sheffield Harry Hoyen, MD Chief, Hand Service Department of Orthopedics MetroHealth Medical Center Cleveland, Ohio

6. Partial Knee Joint Replacement; Femoral Modular Head; and Articulating Spacer for Hip and Knee Joints Pages 25-29	Michelle Joshua Frank R. Voss, MD Coding Representative for AAHKS and AAOS (CPT)
7. Endovascular Thrombectomy of Intracranial and Extracranial Arteries Pages 30-32	Mady Hue Ansaar Rai, MD Vice Chairman Radiology West Virginia University Hospitals
8. Robotic Water Resection of the Prostate Pages 33-34	Michelle Joshua Eugene V. Kramolowsky, MD MSHA Urologist, Virginia Urology, Richmond, VA
9. Administration of Plazomicin Pages 35-36	Michelle Joshua Pamela Hawn, Pharm D Director, Medical Scientist
10. Percutaneous Extracorporeal Membrane Oxygenation (ECMO) for Cardiopulmonary Insufficiency Pages 37-38	Mady Hue George W. Vetrovec, MD, MACC, MSCAI Professor Emeritus, VCU Pauley Heart Center Virginia Commonwealth University Richmond, Virginia
11. Spinal Fusion with Hydroxyapatite Enhanced Interbody Fusion Device Pages 39-41	Michelle Joshua John Devine, PhD Managing Director, Invibio Biomaterial Solutions
12. Administration of GIAPREZA Pages 42-43	Michelle Joshua Terry Dettling, BSN, JD, MPH
13. Transfer of Prepuce for Reconstruction Pages 44-45	Mady Hue Amber Davidson, RHIT, CCS, CCS-P Specialist, Health Information Data Children's Hospital
14. Section X, Addenda and Key Updates Pages 46-55	Rhonda Butler , 3M

Registering for the meeting:

Registration for the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meeting opens on August 3, 2018**. If participating by Livestream webcast or dialing in you do not need to register online.**

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

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

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

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

ICD-10 TIMELINE

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

March 6-7, 2018	ICD-10 Coordination and Maintenance Committee Meeting. Those who wish to attend the ICD-10 Coordination and Maintenance Committee meeting **must have registered for the meeting online by February 23, 2018.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building. In compliance to The Real ID Act, enacted in 2005, (http://www.dhs.gov/real-id-enforcement-brief) the following states/territories: Maine, Minnesota, Missouri, Montana and Washington State **will not** gain access into any Federal Agencies using the **above states** driver's license or ID. This means CMS visitors from these states/territories will need to provide alternative proof of identification (**such as a passport**) to gain entrance into Baltimore-based and Bethesda CMS buildings, as well as the Humphrey Building in Washington. Because of increased security requirements, those wishing to attend the March 6-7, 2018 ICD-10 Coordination and Maintenance Committee meeting must register for the meeting online at: **https://www.cms.gov/apps/events/default.asp** **Attendees must register online by February 23, 2018; failure to do so may result in lack of access to the meeting.**
March 2018	Webcast of the March 6-7, 2018 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html
April 1, 2018	There were no requests for ICD-10 codes to capture new diagnoses or new technology for implementation on April 1, 2018. Therefore, there will be no new ICD-10 diagnosis or procedure codes implemented on April 1, 2018.
April 6, 2018	**Deadline for receipt of public comments on proposed new codes discussed at the March 6-7, 2018 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2018.**

April 2018	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This notice will include references to the finalized FY 2019 ICD-10-CM diagnosis and ICD-10-PCS procedure codes 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: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS/list.asp
June 2018	Final addendum posted on web pages as follows: Diagnosis addendum - http://www.cdc.gov/nchs/icd/icd10cm.htm Procedure addendum - http://cms.hhs.gov/Medicare/Coding/ICD10/index.html
July 13, 2018	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.**
August 1, 2018	Hospital Inpatient Prospective Payment System final rule to be published in the Federal Register as mandated by Public Law 99-509. This rule will also include links to all the final codes to be implemented on October 1, 2018. This rule can be accessed at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS/list.asp
August 2018	Tentative agenda for the Procedure part of the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage at – https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis part of the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meeting will be posted on the NCHS webpage at - http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm Federal Register notice for the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.

August 3, 2018	**On-line registration opens for the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meeting at: https://www.cms.gov/apps/events/default.asp**
September 3, 2018	Because of increased security requirements, those wishing to attend the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meeting must register for the meeting online at: **https://www.cms.gov/apps/events/default.asp** **Attendees must register online by September 3, 2018; failure to do so may result in lack of access to the meeting.**
September 11-12, 2018	ICD-10 Coordination and Maintenance Committee Meeting. Those who wish to attend the ICD-10 Coordination and Maintenance Committee meeting **must have registered for the meeting online by September 3, 2018.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building.
September 2018	Webcast of the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html
October 1, 2018	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with DRG changes. Final addendum available on web pages as follows: Diagnosis addendum - http://www.cdc.gov/nchs/icd/icd10cm.htm Procedure addendum – http://www.cms.gov/Medicare/Coding/ICD10/
October 12, 2018	**Deadline for receipt of public comments on proposed new codes discussed at the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meetings for implementation on April 1, 2019.**
November 2018	Any new ICD-10 codes required to capture new technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2019 will be posted on the following websites: http://www.cdc.gov/nchs/icd/icd10cm.htm http://www.cms.gov/Medicare/Coding/ICD10/
November 12, 2018	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 11-12, 2018 ICD-10**

Coordination and Maintenance Committee meetings for implementation on October 1, 2019.

Introductions and Overview

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

Code Proposals

- ICD-10-PCS code proposals being consideration for implementation on October 1, 2018
- No final decisions made at the meeting
- CMS will describe options and recommendations to facilitate discussion
- Public can comment at meeting and send written comments

Comments on Code Proposals

- Submit written comments by
  - April 6, 2018 for codes discussed at March 6-7, 2018 C&M meeting
- Procedure comments to CMS (new address) ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to Donna Pickett, CDC nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2018 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2018 C&M meeting
- August 1, 2018 – Final rule with links to final codes to be implemented on October 1, 2018
  - Includes any additional codes approved from March 6-7, 2018 C&M meeting

Addendum

- June 2018 – Final code updates and addendum posted
  - FY 2019 ICD-10-PCS (Procedures) http://www.cms.gov/Medicare/Coding/ICD10/index.html
  - FY 2019 ICD-10-CM (Diagnoses) http://www.cdc.gov/nchs/icd/icd10cm.htm

September 11-12, 2018 C&M Code Requests

- July 13, 2018– Deadline for submitting topics for September 11-12, 2018 C&M meeting
  - Procedure requests to CMS (new address) ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis requests to Donna Pickett, CDC
  - nchsicd10cm@cdc.gov

Public Participation

- For this meeting the public may participate in three ways:
  - Attend public C&M meeting
  - Listen to proceedings through free conference lines
  - Participate through a free livestream webcast
- CMS & CDC hope this provides greater opportunity for public participation

Written Comments

- No matter how you participate – please send written comments by
  - April 6, 2018 for codes to be implemented on October 1, 2018
  - Procedure comments to CMS ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis comments to Donna Pickett, CDC nchsicd9@cdc.gov

ICD-10-PCS Codes Implementation

- ICD-10-PCS codes discussed today under consideration for October 1, 2018 implementation

Irreversible Electroporation (IRE)

Issue: There is not a unique ICD-10-PCS code to describe hepatic and/or pancreatic cancer cell destruction using Irreversible Electroporation (IRE). This topic was addressed at the March 2015 ICD-10 C&M Meeting and a new code was not approved. The requestor asked that this topic be brought back for reconsideration. The requestor has also asked that detail be added to the ICD-10-PCS for procedures that use three other specific ablative techniques: radiofrequency, microwave, and cryotherapy.

New Technology Application? No

Background: Irreversible electroporation (IRE) is a new tissue ablation technique in which micro to millisecond electrical pulses are delivered to undesirable tissue to produce cell death through irreversible cell membrane permeabilization. IRE affects only the cell membrane and no other structure in the tissue. The current ICD-10-PCS codes do not identify the specific technique that induces tumor cell membrane porosity thereby causing cancer cell death (via apoptosis).

Locally advanced hepatic and pancreatic cancer patients have limited options for long term durable disease control. Ablation techniques such as cryoablation and radiofrequency ablation are current treatment options. However, these procedures have been associated with destruction of adjacent healthy tissue. In contrast, IRE therapy can be well tolerated with rapid resolution of hepatic and/or pancreatic inflammation and preservation of healthy tissue and vascular structures.

Current Coding: The IRE tissue ablation technique used for hepatic and/or pancreatic cancer cell destruction can be reported using the codes in table 0F5, Destruction of Hepatobiliary System and Pancreas. Under ICD-10-PCS, ablation is a term included in the root operation Destruction as, "physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent".

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Liver **1** Liver, Right Lobe **2** Liver, Left Lobe **G** Pancreas	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new codes for Irreversible Electroporation. Continue using codes in section 0F5 as indicated above.

Option 2. Create new qualifier value F (Irreversible Electroporation) in table 0F5 Destruction of Hepatobiliary System and Pancreas, to identify IRE versus other destruction techniques.

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Liver **1** Liver, Right Lobe **2** Liver, Left Lobe **G** Pancreas	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**ADD F** Irreversible Electroporation **Z** No Qualifier

Option 3. Create new qualifier value Irreversible Electroporation in table 0F5 Destruction of Hepatobiliary System and Pancreas, to identify IRE versus other destruction techniques. In addition, create new qualifier values Radiofrequency, Microwave, and Cryotherapy in table of section 0F5 Destruction of Hepatobiliary System and Pancreas, to identify other specific destruction techniques.

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Liver **1** Liver, Right Lobe **2** Liver, Left Lobe **G** Pancreas	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**ADD F** Irreversible Electroporation **ADD G** Radiofrequency **ADD H** Microwave **ADD J** Cryotherapy **Z** No Qualifier

CMS Recommendation: We are interested in receiving input from the public on these options. As stated earlier, this topic was initially presented in the March 2015 ICD-10 Coordination & Maintenance Committee meeting. Following the March 2015 meeting, CMS received public comments opposing the creation of new codes. The commenters stated that the current ICD-10-PCS root operation Destruction correctly captures this procedure. The commenters also noted that physician documentation of this procedure will not clearly distinguish the specific technique of irreversible electroporation from other techniques used for tumor ablation. Therefore, if a unique code were created, it would be difficult for coders to determine when to assign the code for this technology.

Interim Coding Advice: In the interim, continue to assign codes from table 0F5 as described in current coding.

Cell Suspension Autografting

Issue: There currently is no unique ICD-10-PCS code to capture cell suspension epithelial autografts.

New Technology Application? No.

Food & Drug Administration (FDA) Approved? No. An application for Pre-Market Approval was submitted to the FDA in September 2017.

Background: ReCell is a type of epithelial autograft that can be used for large wounds such as major burns. It is also currently being considered for additional acute and chronic types of wounds. The procedure involves harvesting a split-thickness skin sample from a healthy donor site on the patient. This sample is then placed into a warm enzyme-containing incubator where it biochemically separates the epidermis from the dermis. After about 15 to 20 minutes, the sample is removed and its surface is scraped to separate the cells from the tissue. This creates a mixed population of cells, primarily keratinocytes and fibroblasts but also including melanocytes, Langerhans cells, and epidermal basal cells. The cells are then suspended in a buffer solution and filtered to remove debris. The result is a regenerative epithelial cell suspension that can be immediately applied to the prepared wound via a spray technique or a drip technique.

Depending on the extent of the injury, the cell suspension autograft can be applied alone or in conjunction with another skin graft. The entire process takes place in the operating room. It is performed by the surgeon, sometimes with assistance by a nurse or technician under the surgeon's supervision. According to the requester, the surgeon is present and exclusively engaged throughout.

Current Coding: Report the split-thickness skin harvest using the appropriate body part in table 0HB, Excision of Skin and Breast body system and the qualifier Z, to indicate that the skin excision is therapeutic, not diagnostic.

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Skin, Scalp **1** Skin, Face **2** Skin, Right Ear **3** Skin, Left Ear **4** Skin, Neck **5** Skin, Chest **6** Skin, Back **7** Skin, Abdomen	**X** External	**Z** No Device	**X** Diagnostic **Z** No Qualifier

8 Skin, Buttock **9** Skin, Perineum **A** Skin, Inguinal **B** Skin, Right Upper Arm **C** Skin, Left Upper Arm **D** Skin, Right Lower Arm **E** Skin, Left Lower Arm **F** Skin, Right Hand **G** Skin, Left Hand **H** Skin, Right Upper Leg **J** Skin, Left Upper Leg **K** Skin, Right Lower Leg **L** Skin, Left Lower Leg **M** Skin, Right Foot **N** Skin, Left Foot **Q** Finger Nail **R** Toe Nail			

Facilities can report the application of cell suspension autografting using the following ICD-10-PCS code:

3E00XGC Introduction of Other Therapeutic Substance into Skin and Mucous Membranes, External Approach

Coding Options

Option 1. Do not create new codes for the application of cell suspension autografting. Continue to use the current codes as described above.

Option 2. Create new qualifier Partial Thickness, Cell Suspension in table 0HR, Replacement of Skin and Breast body system, applied to the skin body part values and the device value Autologous Tissue Substitute, to identify cell suspension autografting.

Section **0** Medical and Surgical *Body System* **H** Skin and Breast *Operation* **R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part			
Body Part	*Approach*	*Device*	*Qualifier*
0 Skin, Scalp **1** Skin, Face **2** Skin, Right Ear **3** Skin, Left Ear **4** Skin, Neck **5** Skin, Chest **6** Skin, Back **7** Skin, Abdomen **8** Skin, Buttock **9** Skin, Perineum **A** Skin, Inguinal	**X** External	**7** Autologous Tissue Substitute	**ADD 2** Partial Thickness, Cell Suspension **3** Full Thickness **4** Partial Thickness

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

Option 3. Create a new code in Section X to identify cell suspension autografting. Create new Device/Substance/Technology value Autologous Epithelial Cell Suspension in table XH0 for the body part value Skin.

Section	**X** New Technology		
Body System	**H** Skin, Subcutaneous Tissue, Fascia and Breast		
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*
P Skin	**X** External	**L** Autologous Epithelial Cell Suspension	**4** New Technology Group 4

Option 4. Create a new code in the Administration section to identify cell suspension autografting. Create new qualifier value Autologous Epithelial Cell Suspension in table 3E0 for the body part value Skin and Mucous Membranes, applied to the substance value Other Therapeutic Substance and the approach value External Approach.

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*
0 Skin and Mucous Membranes	**X** External	**G** Other Therapeutic Substance	**C** Other Substance **ADD L** Autologous Epithelial Cell Suspension

CMS recommendation: CMS seeks public input on these options.

Interim Coding Advice: Continue to report autograft harvest and application of cell suspension autografting as shown in current coding above.

Insertion of the Remedē® Phrenic Nerve Stimulation System

Issue: The Remedē® System is an implantable nerve stimulator used to treat moderate to severe central sleep apnea (CSA) in adults. The device consists of an implantable pulse generator (IPG), sensing lead, stimulation lead, and patient programmer. Existing ICD-10-PCS codes describe the insertion of all of the system elements except insertion of the stimulating lead when placed into the left pericardiophrenic vein.

New Technology Application? Yes, an application has been submitted for FY 2019.

Food & Drug Administration (FDA) Approved? Yes. The Remedē® System received premarket approval on October 6, 2017.

Background: Central sleep apnea (CSA) is a chronic form of sleep disordered breathing characterized by the temporary withdrawal of brainstem-driven respiratory drive that results in cessation of breathing, hypoxia, and sympathetic surges which can lead to cardiovascular complications and is associated with poor outcomes. There are currently no effective alternative treatments available for moderate to severe CSA. It is increasingly recognized as a comorbidity in a number of disorders, including heart failure (HF), valvular disease, and atrial fibrillation.

It is estimated that CSA affects nearly 40% of patients with heart failure and can lead to excessive daytime drowsiness, impaired cognitive function, and reduced exercise capacity. Studies have shown that CSA can lead to the worsening of heart failure and is associated with an increased risk of death.

Respicardia, Inc. has developed the Remedē® System, which is used to treat adult patients with moderate to severe CSA. The Remedē® System is designed to improve cardiovascular health by restoring a more normal breathing pattern during sleep in patients with CSA.

The Remedē® System implantable pulse generator (IPG) is implanted via a submuscular or subcutaneous approach in the pectoral region. The sensing lead is inserted into the azygos vein. The stimulation lead is inserted unilaterally, either into the right innominate (brachiocephalic) or into the left pericardiophrenic veins, which are anatomically adjacent to the right and left phrenic nerve, respectively.

Current Coding: The following ICD-10-PCS codes are used to report insertion of the components of the Remedē® System:

0JH60DZ Insertion of Multiple Array Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach, for insertion of the implantable pulse generator in the pectoral region
AND
05H03MZ Insertion of Neurostimulator Lead into Azygos Vein, Percutaneous Approach, for transvenous insertion of sensing lead in the azygos vein
AND
05H33MZ Insertion of Neurostimulator Lead into Right Innominate Vein, Percutaneous Approach, for transvenous insertion of the stimulator lead in the right innominate (brachiocephalic) vein
OR

05H43MZ Insertion of Neurostimulator Lead into Left Innominate Vein, Percutaneous Approach, for transvenous insertion of the stimulator lead in the left pericardiophrenic vein.

Note: According to the ICD-10-PCS coding guideline B4.2, "Where a specific branch of a body part does not have its own body part value in PCS, the body part is typically coded to the closest proximal branch that has a specific body part value." The left innominate vein is the closest proximal branch of the left pericardiophrenic vein.

Coding Options

Option 1. Do not create new codes for the insertion of the Remedē® System stimulating lead into the left pericardiophrenic vein. Continue to code as above in current coding.

Option 2. In table 05H, Insertion of the Upper Veins body system, create new qualifier value Pericardiophrenic Vein, for the body part value Innominate Vein, Left and the device value Neurostimulator Lead.

Section	**0** Medical and Surgical
Body System	**5** Upper Veins
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device*	*Qualifier*
4 Innominate Vein, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**M** Neurostimulator Lead	**ADD 0** Pericardiophrenic Vein **Z** No Qualifier

Option 3. Create new codes in section X, New Technology, to identify the two major components of the Remedē® phrenic nerve stimulation system. In table XHH, Insertion of Skin, Subcutaneous Tissue, Fascia and Breast, create new device value Implantable Phrenic Nerve Stimulation Device, Generator for the body part value Subcutaneous Tissue and Fascia, Chest, to capture insertion of the implantable pulse generator.

Section	**X** New Technology
Body System	**H** Skin, Subcutaneous Tissue, Fascia and Breast
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*
ADD 6 Subcutaneous Tissue and Fascia, Chest	**0** Open **3** Percutaneous	**ADD M** Implantable Phrenic Nerve Stimulation Device, Generator	**4** New Technology Group 4

In table X2H, Insertion of Cardiovascular System, create new device value Implantable Phrenic Nerve Stimulation Device, Leads for the body part value Azygos Vein and Right Innominate Vein or Left Pericardiophrenic Vein, to specify insertion the sensing lead in the azygos vein, and the neurostimulator lead in the right innominate vein or the left pericardiophrenic vein.

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*
ADD 4 Azygos Vein and Right Innominate Vein or Left Pericardiophrenic Vein	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD Q** Implantable Phrenic Nerve Stimulation Device, Sensing and Stimulation Leads	**4** New Technology Group 4

CMS Recommendation: CMS is interested in input from the audience on these options.

Interim Coding Advice: Continue to report insertion of the phrenic nerve stimulation system as shown in current coding above.

Endovascular Bypass of Lower Extremity Arteries

Issue: There is currently no unique ICD-10-PCS code to describe percutaneous lower extremity artery bypass using adjacent veins.

New Technology Application? No, a NTAP application may be submitted for FY 2020.

Food & Drug Administration (FDA) Approved? No – the LimFlow was accepted into the FDA's Breakthrough Device Program and received approval of its investigational device exemption (IDE); the DETOUR system received conditional approval of its IDE application.

Background: Atherosclerotic arterial occlusion can result in severe and critical limb ischemia. Occlusions of lower extremity arteries may involve the superficial femoral artery, popliteal artery, anterior tibial artery, posterior tibial artery, and peroneal artery. First-line treatments include angioplasty, stenting, and atherectomy, but some complex lesions are not responsive to these procedures. Bypass of the occluded portion of the artery is the next available treatment option, after which amputation of the limb is the only remaining option.

While bypass of lower extremity arteries has traditionally been performed using an open approach, endovascular approaches are currently being studied in clinical trials. Two such technologies used in these endovascular procedures include the LimFlow and DETOUR system. In both of these technologies, the procedures involve the creation of a connection above the occlusion between the blocked artery and an adjacent vein. This is followed by insertion of a balloon catheter which dilates the connection and allows for the passage of additional instruments and the positioning of endovascular stents.

In procedures using the LimFlow technology, a valvutome is passed along the entire length of the vein and the vein is dilated. Overlapping stents are then positioned throughout the vein from the ankle through the artery-vein connection. The vein is thereby relined and reinforced to enable the vein to withstand the arterial blood flow. In this procedure, the occluded anterior or posterior tibial artery is re-routed into the corresponding tibial vein. Another type of procedure, which is used less commonly, involves re-routing blood from an occluded peroneal artery into the corresponding peroneal vein. In both of these cases, the vein takes over the function of the occluded artery in perfusing the foot.

In procedures using the DETOUR technology, a second connection is created below the occlusion between the artery and adjacent vein. Overlapping stents are positioned through the second artery-vein connection along the vein and through the first artery-vein connection back into the artery above the occlusion. The blood is thereby rerouted from the superficial femoral artery into the femoral vein and then back into the popliteal artery.

Current Coding: There are no unique ICD-10-PCS code to report percutaneous peripheral bypass of the lower extremities. To report these procedures, facilities may use the percutaneous endoscopic approach, which is the closest approach available in Table 041, the appropriate body part value, and the device value Synthetic Substitute.

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
K Femoral Artery, Right **L** Femoral Artery, Left	**0** Open **4** Percutaneous Endoscopic	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**H** Femoral Artery, Right **J** Femoral Artery, Left **K** Femoral Arteries, Bilateral **L** Popliteal Artery **M** Peroneal Artery **N** Posterior Tibial Artery **P** Foot Artery **Q** Lower Extremity Artery **S** Lower Extremity Vein
M Popliteal Artery, Right **N** Popliteal Artery, Left	**0** Open **4** Percutaneous Endoscopic	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**L** Popliteal Artery **M** Peroneal Artery **P** Foot Artery **Q** Lower Extremity Artery **S** Lower Extremity Vein
T Peroneal Artery, Right **U** Peroneal Artery, Left **V** Foot Artery, Right **W** Foot Artery, Left	**0** Open **4** Percutaneous Endoscopic	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**P** Foot Artery **Q** Lower Extremity Artery **S** Lower Extremity Vein

Coding Options

Option 1. Do not create a new code for percutaneous lower extremity artery bypass using adjacent veins. Utilize the current codes as described in current coding.

Option 2. Create new codes in Section X, New Technology, to identify percutaneous bypass of lower extremity arteries using adjacent veins.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
ADD K Femoral Artery, Right **ADD L** Femoral Artery, Left **ADD M** Popliteal Artery, Right **ADD N** Popliteal Artery, Left **ADD P** Anterior Tibial Artery, Right **ADD Q** Anterior Tibial Artery, Left **ADD R** Posterior Tibial Artery, Right	**3** Percutaneous	**ADD 9** Intraluminal Device to Lower Vein	**4** New Technology Group 4

ADD S Posterior Tibial Artery, Left **ADD T** Peroneal Artery, Right **ADD U** Peroneal Artery, Left			

Option 3. Add the approach value Percutaneous to table 041, Bypass of the Lower Arteries body system, for the lower extremity body part values, the device value Synthetic Substitute, and the qualifier Lower Extremity Vein, to identify percutaneous bypass of lower extremity arteries using adjacent veins.

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
K Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **ADD P** Anterior Tibial Artery, Right **ADD Q** Anterior Tibial Artery, Left **ADD R** Posterior Tibial Artery, Right **ADD S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left **V** Foot Artery, Right **W** Foot Artery, Left	**0** Open **ADD 3** Percutaneous **4** Percutaneous Endoscopic	**J** Synthetic Substitute	**S** Lower Extremity Vein

CMS Recommendation: Option 1. Do not create a new code for percutaneous lower extremity artery bypass using adjacent veins. Utilize the current codes as described in current coding.

Interim Coding Advice: Continue to code as shown in current coding.

Implantation of Multi-function Networked Neuroprosthesis

Issue: There are no ICD-10-PCS codes to describe the implantation of a multi-function networked neuroprosthetic system to restore functional movement in the upper limb and/or trunk for patients with cervical and/or thoracic level spinal cord injury (SCI). The applicant is seeking separate codes for two configurations of the multi-function networked neuroprosthetic system: the Upper Extremity configuration and the Trunk configuration.

New Technology Application? No. The applicant has indicated that it would be applying for NTAP in the future.

Food & Drug Administration (FDA Clearance): No. An early feasibility clinical trial of the multi-function networked neuroprosthetic system is currently underway for FDA approval.

Background: Individuals with SCI typically have a range of permanent neurological deficits and disability. A networked neuroprosthesis is an implanted device with several components that activates peripheral neural pathways in a coordinated manner in order to provide one or more functions to people with paralysis. The multi-function networked neuroprosthetic system is designed for SCI patients that still have sufficient intact innervation of paralyzed muscles. Using low level pulsatile electrical current, the multi-function networked neuroprosthetic system attempts to restore hand/arm functional movement and/or provide trunk stability in patients with cervical and/or thoracic level SCI. The intent to move is sensed through the electrodes placed in muscles that are still under voluntary control of the individual, such as the platysma, trapezius, or wrist extensors.

The device consists of multiple pulse generators, a power source, multiple tissue-contracting electrodes, and at least one recording module connected to one or more recording electrodes. The pulse generators are networked to each other inside the body via implanted network cables. Depending on how these components are configured and connected determines the configuration, and the configuration determines resulting functional capabilities of the upper extremity and/or the trunk.

In contrast to earlier generation hand function neuroprostheses which have been found to produce increased pinch force and the ability to move objects of various size and weight[1,2] the multi-function networked neuroprosthesis differs due to having greater flexibility in that it is more customizable and can lead to more than one functional outcome. More than one functional

[1] Wuolle KS, Van Doren CL, Thrope GB, et al. Development of a quantitative hand grasp and release test for patients with tetraplegia using a hand neuroprosthesis. J Hand Surg [Am] 1994; 19:209-218.
[2] Peckham, P. H., Keith, M. W., Kilgore, K. L., Grill, J. H., Wuolle, K. S., Thrope, G. B., Gorman, P., Hobby, J., Mulcahey, M. J., Carroll, S., Hentz, V., and Wiegner, A., "Efficacy of an Implanted Neuroprosthesis for Restoring Hand Grasp in Tetraplegia: A Multicenter Study," Arch. Physical Medicine and Rehabilitation, vol. 82, pp. 1380-8, 2001.

outcome is possible through the connection of implantable connections into configurations. Another difference is the lack of externally placed components, which may facilitate the individual's ability to use the device without assistance. Finally, because the implanted electrodes do not cross major joints, individuals do not have to wear a cast, facilitating enhanced post-operative recovery.

Current Coding: There is no unique ICD-10-PCS procedure code available for the implantation of a multi-function networked neuroprosthesis. The following codes could be used to describe the implantation of the various components.

0KHX0MZ	Insertion of Stimulator Lead into Upper Muscle, Open Approach
0KHX0YZ	Insertion of Other Device into Upper Muscle, Open Approach
0KHY0MZ	Insertion of Stimulator Lead into Lower Muscle, Open Approach
0KHY3MZ	Insertion of Other Device into Lower Muscle, Open Approach
0JH60EZ	Insertion of Multiple Array Rechargeable Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
0JH80EZ	Insertion of Multiple Array Rechargeable Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach

Coding Options

Option 1. Do not create new codes for the implantation of the upper extremity and trunk configurations of the multi-function networked neuroprosthesis. Continue to use one or more of the existing ICD-10-PCS codes listed under current coding.

Option 2. Create new codes in section X, New Technology, to capture the implantation of the multi-function networked neuroprosthesis. Two or more codes are required to fully capture the implantation of the device.

Create new codes in Section X, root operation Insertion table XHH to identify implantation of the power module component of the device.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
6 Subcutaneous Tissue and Fascia, Chest **8** Subcutaneous Tissue and Fascia, Abdomen	**0** Open	**P** Totally Implantable Networked Neuroprosthesis, Power Module	**4** New Technology Group 4

Create new codes in Section X, root operation Insertion table XWH to identify implantation of the muscle activation component of the device.

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
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*
T Trunk **V** Upper Extremity	**0** Open	**M** Totally Implantable Networked Neuroprosthesis, Muscle Activation Component	**4** New Technology Group 4

CMS Recommendation: Option 1. Do not create new codes for the implantation of the upper extremity and trunk configurations of the multi-function networked neuroprosthesis. Continue to use one or more of the existing ICD-10-PCS codes listed under current coding.

Interim Coding Advice: Continue to code as shown in current coding.

Partial Knee Joint Replacement; Femoral Modular Head;
and Articulating Spacer for Hip and Knee Joint

Issue: There is currently no unique ICD-10-PCS device value in table 0SR to describe lateral or medial unicompartmental/unicondylar or patellofemoral components utilized for a knee replacement procedure. There is also currently no unique ICD-10-PCS device value in table 0SP to describe which portion of a knee or hip joint implant is removed during joint replacement revision surgery. Lastly, it is also not possible to report that an articulating spacer was placed into a knee or hip joint with currently available ICD-10-PCS device values.

New Technology Application? No.

Background:

Partial Knee Joint Replacement

Hospitals use ICD-10-PCS codes to track and record the procedures performed, and it is critical for hospitals to know how many of each type of knee arthroplasty procedures are performed. The requester notes that ultimately, separating the outcomes of medial unicompartmental, lateral unicompartmental, and patellofemoral arthroplasty will allow for improved tracking of outcomes for hospitals, surgeons, and joint registries.

Knee or Hip Joint Replacement Revision Surgery

The removal of lower joint prostheses as a component of joint replacement revision surgery is currently coded using codes from table 0SP. As these implant removals are all classified using the device value Synthetic Substitute in ICD-10-PCS, the requester states it is critical that they describe which portion of the implant is removed. According to the requester it is also critical that they accurately differentiate which portion of the prosthesis is involved when a new component of a previously placed prosthesis is implanted using ICD-10-PCS table 0SR. By adding detail to the ICD-10-PCS tables 0SP and 0SR, the requester asserts it will be possible to more specifically identify the devices that were removed and ultimately replaced as part of a joint replacement revision procedure, thus enhancing research possibilities and providing more accurate statistics for joint registries. For example, these additions should allow easier identification of whether an implant failure is due to the liner, the modular head, the partial joint implant, the antibiotic spacer, or a total joint implant.

Articulating Spacer for Hip and Knee Joint

Currently, the treatment of a periprosthetic joint infection is treated by implant removal and placement of an antibiotic spacer for a period of months to allow the more effective eradication of the infection. These antibiotic spacers can be classified into static spacers not designed to allow joint movement, and articulating spacers that are designed to allow joint movement. The procedure

for implanting an articulating spacer requires greater work to allow the joint to function more normally.

Current Coding: Code the removal of a knee joint prosthesis, or the replacement of all or part of the knee joint with a prosthetic component, using the device value Synthetic Substitute, and the most specific available knee joint body part values for the procedure performed, as shown in tables 0SP and 0SR below.

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

Body Part	*Approach*	*Device*	*Qualifier*
C Knee Joint, Right **D** Knee Joint, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**J** Synthetic Substitute	**C** Patellar Surface **Z** No Qualifier
T Knee Joint, Femoral Surface, Right **U** Knee Joint, Femoral Surface, Left **V** Knee Joint, Tibial Surface, Right **W** Knee Joint, Tibial Surface, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**J** Synthetic Substitute	**Z** No Qualifier

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

Body Part	*Approach*	*Device*	*Qualifier*
C Knee Joint, Right **D** Knee Joint, Left **T** Knee Joint, Femoral Surface, Right **U** Knee Joint, Femoral Surface, Left **V** Knee Joint, Tibial Surface, Right **W** Knee Joint, Tibial Surface, Left	**0** Open	**J** Synthetic Substitute	**9** Cemented **A** Uncemented **Z** No Qualifier

Code the removal of a spacer from the hip or knee joint, or the insertion of a spacer in the hip or knee joint, using the device value Spacer, and the most specific available knee or hip joint body part values for the procedure performed, as shown in tables 0SP and 0SH below.

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebral Joint **3** Lumbosacral Joint **5** Sacrococcygeal Joint **6** Coccygeal Joint **7** Sacroiliac Joint, Right **8** Sacroiliac Joint, Left **9** Hip Joint, Right **B** Hip Joint, Left **C** Knee Joint, Right **D** Knee Joint, Left **F** Ankle Joint, Right	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**8** Spacer	**Z** No Qualifier

G Ankle Joint, Left **H** Tarsal Joint, Right **J** Tarsal Joint, Left **K** Tarsometatarsal Joint, Right **L** Tarsometatarsal Joint, Left **M** Metatarsal-Phalangeal Joint, Right **N** Metatarsal-Phalangeal Joint, Left **P** Toe Phalangeal Joint, Right **Q** Toe Phalangeal Joint, Left			

Section **0** Medical and Surgical *Body System* **S** Lower Joints *Operation* **H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part			
Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebral Joint **2** Lumbar Vertebral Disc **3** Lumbosacral Joint **4** Lumbosacral Disc **5** Sacrococcygeal Joint **6** Coccygeal Joint **7** Sacroiliac Joint, Right **8** Sacroiliac Joint, Left **9** Hip Joint, Right **B** Hip Joint, Left **C** Knee Joint, Right **D** Knee Joint, Left **F** Ankle Joint, Right **G** Ankle Joint, Left **H** Tarsal Joint, Right **J** Tarsal Joint, Left **K** Tarsometatarsal Joint, Right **L** Tarsometatarsal Joint, Left **M** Metatarsal-Phalangeal Joint, Right **N** Metatarsal-Phalangeal Joint, Left **P** Toe Phalangeal Joint, Right **Q** Toe Phalangeal Joint, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**8** Spacer	**Z** No Qualifier

Coding Options

Option 1. Do not create new codes specifying additional detail for procedures involving lateral or medial unicompartmental/unicondylar knee replacement, patellofemoral knee replacement, or articulating spacers.

Option 2. Partial Knee Joint Replacement

In the Lower Joints body system, revise the device value Synthetic Substitute, Unicondylar to Synthetic Substitute, Unicondylar Lateral. Add new device values Synthetic Substitute, Unicondylar Medial and Synthetic Substitute, Patellofemoral to the root operation Replacement table 0SR and the root operation Removal table 0SP, for the knee joint body part values. These changes enable capture of additional detail for partial knee arthroplasty procedures.

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

Body Part	*Approach*	*Device*	*Qualifier*
C Knee Joint, Right **D** Knee Joint, Left	**0** Open	**J** Synthetic Substitute **REVISE from L** Synthetic Substitute, Unicondylar **REVISE to L** Synthetic Substitute, Unicondylar Lateral **ADD M** Synthetic Substitute, Unicondylar Medial **ADD N** Synthetic Substitute, Patellofemoral	**9** Cemented **A** Uncemented **Z** No Qualifier

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

Body Part	*Approach*	*Device*	*Qualifier*
C Knee Joint, Right **D** Knee Joint, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD L** Synthetic Substitute, Unicondylar Lateral **ADD M** Synthetic Substitute, Unicondylar Medial **ADD N** Synthetic Substitute, Patellofemoral	**Z** No Qualifier

Option 3. Modular Femoral Head Exchange

In the Lower Joints body system, add new device value Modular Head to the root operation Supplement table 0SU and the root operation Removal table 0SP, for the hip joint femoral surface body part values. These changes enable capture of additional detail for subsequent hip arthroplasty procedures in which the modular head is exchanged.

Section	**0** Medical and Surgical
Body System	**S** Lower Joints
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*
R Hip Joint, Femoral Surface, Right **S** Hip Joint, Femoral Surface, Left	**0** Open	**9** Liner **B** Resurfacing Device **ADD G** Modular Head	**Z** No Qualifier

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

Body Part	*Approach*	*Device*	*Qualifier*
R Hip Joint, Femoral Surface, Right **S** Hip Joint, Femoral Surface, Left	**0** Open	**ADD G** Modular Head **J** Synthetic Substitute	**Z** No Qualifier

Option 4. Articulating Spacer for Hip and Knee Joint

In the Lower Joints body system of the Medical and Surgical section, add new device value Spacer, Articulating to the root operation Replacement table 0SR and the root operation Removal table 0SP, for the hip joint and knee joint body part values. These changes enable capture of additional detail for placement and removal of articulating antibiotic spacers in the hip and knee joints.

Section **0** Medical and Surgical *Body System* **S** Lower Joints *Operation* **R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part			
Body Part	*Approach*	*Device*	*Qualifier*
9 Hip Joint, Right **B** Hip Joint, Left **C** Knee Joint, Right **D** Knee Joint, Left	**0** Open	**ADD E** Synthetic Substitute, Articulating Spacer	**Z** No Qualifier

Section **0** Medical and Surgical *Body System* **S** Lower Joints *Operation* **P** Removal: Taking out or off a device from a body part			
Body Part	*Approach*	*Device*	*Qualifier*
9 Hip Joint, Right **B** Hip Joint, Left **C** Knee Joint, Right **D** Knee Joint, Left	**0** Open	**NO CHANGE 8** Spacer **ADD E** Synthetic Substitute, Articulating Spacer	**Z** No Qualifier

Note: Continue to code insertion of a static spacer using the existing device value Spacer in table 0SH, Insertion of Lower Joints.

Section **0** Medical and Surgical *Body System* **S** Lower Joints *Operation* **H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part			
Body Part	*Approach*	*Device*	*Qualifier*
9 Hip Joint, Right **B** Hip Joint, Left **C** Knee Joint, Right **D** Knee Joint, Left	**0** Open	**NO CHANGE 8** Spacer	**Z** No Qualifier

CMS Recommendation: Options 2, 3 and 4.

Interim Coding Advice: Continue to code as shown in current coding.

Endovascular Thrombectomy of Intracranial and Extracranial Arteries

Issue: ICD-10-PCS codes do not distinguish the major techniques used in endovascular thrombectomy for acute ischemic stroke. This proposal was previously presented at the March 7, 2017 ICD-10 Coordination and Maintenance Committee meeting. As a result of comments raised at the meeting, the proposal has been revised to reflect a more streamlined and practicable method for differentiating the techniques.

New Technology Application: No.

FDA Approval: Two FDA-approved stent retrievers are used in the United States, the Trevo® by Stryker and the Solitaire™ by Medtronic. Two aspiration catheters are FDA-approved in the United States, the Penumbra System® by Penumbra Inc. and the Riptide® by Medtronic.

Background: Ischemic stroke results from thrombus lodging in the precerebral or cerebral arteries and preventing blood flow to the brain. Intravenous infusion of thrombolytics, such as tPA, is effective in dissolving some clots, but must be performed within 4.5 hours of symptom onset, although effectiveness drops off sharply after the first hour. However, tPA is not effective for some types of occlusions, such as large-vessel occlusion (e.g., the M1 segment of the middle cerebral artery) and hyper-dense thrombus. For patients outside the time window and those for whom thrombolytic infusion has failed or is otherwise ineffective, several interventional techniques are available to physically capture and remove the clot.

According to the requester, differentiating these interventional techniques in the encoded data is valuable to identifying and analyzing the most effective treatments in stroke. The requester noted that the most recent AHA/ASA Guidelines for the Early Management of Patients With Acute Ischemic Stroke Regarding Endovascular Treatment reviews the published literature on endovascular thrombectomy techniques including the usefulness of stent retrievers while citing the need to compare the relative effectiveness of the devices and techniques for optimal management.

<u>Stent Retriever Thrombectomy</u>

In stent retriever thrombectomy, a specialized catheter is advanced through the vasculature into and through the thrombus. The stent component expands to engage the clot. The stent, trapped thrombus, and catheter are slowly withdrawn together, while local aspiration is applied to help retain the clot within the stent. These procedural steps can be repeated as necessary to ensure the artery has been sufficiently reopened and revascularized. The entire procedure is performed under angiographic guidance with periodic assessment and completion angiography. Although the thrombectomy instrument is referred to as a "stent" because of its appearance, no device remains in the body after the procedure is completed.

<u>Direct Aspiration Thrombectomy</u>

Aspiration thrombectomy is also known as suction thrombectomy. In contrast to the local aspiration that is integral to the stent retriever thrombectomy technique, primary aspiration thrombectomy uses a large-bore catheter to directly engage and remove the clot. Aspiration can be repeated as necessary and the entire procedure is performed under angiographic guidance and assessment. No device remains within the body after the procedure is completed.

Combined Stent Retriever/Aspiration Thrombectomy Techniques

In some scenarios, stent retriever thrombectomy and direct aspiration thrombectomy are used together to remove the clot and enhance rapid revascularization. Combining a stent retriever with a distal aspiration catheter, for example by placing the stent retriever adjacent to the aspiration catheter or by passing the stent retriever through the aspiration catheter, is one technique that is currently being used. The combination is felt to reduce fragmentation of the clot, which can lead to distal embolic complications.

In another scenario, if direct aspiration thrombectomy is not deemed sufficiently effective in revascularizing the vessel as the first approach, it is immediately followed by a stent retriever thrombectomy during the same operative episode. Other combinations may also be used depending on the specific clinical scenario and physician preference.

Current Coding: Endovascular thrombectomy of intracranial and extracranial arteries is coded to table 03C, Extirpation of Upper Arteries.

Section	**0** Medical and Surgical
Body System	**3** Upper Arteries
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

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

T Temporal Artery, Left **U** Thyroid Artery, Right **V** Thyroid Artery, Left **Y** Upper Artery			

Coding Options

The previous proposal attempted to identify the three endovascular thrombectomy techniques of stent retriever, direct aspiration, and combined. However, it was felt that it would be difficult to consistently and reliably differentiate local aspiration integral to stent retriever thrombectomy from combined techniques that use direct aspiration and stent retriever together.

Option 1. Do not create new codes for intracranial and extracranial thrombectomy using stent retriever. Continue to code endovascular mechanical thrombectomy procedures using the root operation Extirpation in the body system Upper Arteries, with the appropriate body part value and the approach value Percutaneous.

Option 2. In table 03C, Extirpation of Upper Arteries, create qualifier value 7 Stent Retriever to distinguish endovascular thrombectomy of intracranial and extracranial arteries using stent retriever from other extirpation procedures. Add the new qualifier value, for the fourth character intracranial and extracranial artery body part values, and the approach value Percutaneous.

Section	**0** Medical and Surgical		
Body System	**3** Upper Arteries		
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part		
Body Part	*Approach*	*Device*	*Qualifier*
G Intracranial Artery **H** Common Carotid Artery, Right **J** Common Carotid Artery, Left **K** Internal Carotid Artery, Right **L** Internal Carotid Artery, Left **M** External Carotid Artery, Right **N** External Carotid Artery, Left **P** Vertebral Artery, Right **Q** Vertebral Artery, Left	**3** Percutaneous	**Z** No Device	**6** Bifurcation **ADD 7** Stent Retriever **Z** No Qualifier

This new value would be assigned whenever a stent retriever is used for thrombectomy, either with local aspiration as an adjunctive part of the technique or when a stent retriever is used together with direct aspiration. The existing qualifier Z, No Qualifier, would be assigned whenever direct aspiration alone is performed as the primary technique.

CMS Recommendation: Option 2. In table 03C, Extirpation of Upper Arteries, create qualifier value 7 Stent Retriever to distinguish endovascular thrombectomy of intracranial and extracranial arteries using stent retriever from other extirpation procedures.

Interim Coding Advice: Continue to code endovascular thrombectomy of the intracranial and extracranial arteries to table 03C, Extirpation of Upper Arteries.

Robotic Water Resection of the Prostate

Issue: There is currently no unique ICD-10-PCS code to describe the use of a robotic waterjet to resect the prostate in treating benign prostatic hyperplasia (BPH).

New Technology Application? Yes, a new technology application has been submitted for FY 2019.

Food & Drug Administration (FDA) Approved? Yes. The FDA granted FDA 510(k) De Novo clearance on December 21, 2017.

Background: Benign prostatic hyperplasia (BPH) is a condition in men in which the prostate gland is enlarged and not cancerous. The condition can result in several lower urinary tract symptoms (LUTS), including urinary frequency and urgency, trouble starting a urine stream, nocturia, urinary retention and urinary incontinence. Primary treatments for BPH include medical therapies, such as alpha blockers and 5-alpha reductase inhibitors. If medical therapies are unsuccessful, several minimally-invasive procedures are available, which involve the use of heat for resection or destruction of prostate tissue, or clipping of the prostate tissue without destruction. These procedures carry some risk of unwanted side effects resulting from thermal injury or other complications.

Aquablation therapy, delivered using the AQUABEAM System, uses a robotically controlled high-velocity saline stream to resect the obstructive prostate tissue without the use of heat for the resection[3]. Aquablation therapy is an autonomous waterjet ablation therapy that enables targeted, controlled, heat-free and immediate removal of prostate tissue for the treatment of LUTS caused by BPH. Aquablation therapy requires the use of external ultrasound image guidance and incorporates endoscopic visualization to identify the prostatic adenoma and plan the surgical resection treatment area. The system's robot then uses the planning inputs from the surgeon to deliver Aquablation therapy. The combination of surgical mapping and robotically-controlled resection of the prostate is designed to offer predictable and reproducible outcomes, independent of prostate size, prostate shape or surgeon experience.

Current Coding: Facilities can report Aquablation therapy used to resect the prostate with the following ICD-10-PCS code:

0V508ZZ Destruction of Prostate, Via Natural or Artificial Opening Endoscopic

If desired, facilities can also assign the following ICD-10-PCS code for the robotic assistance:

8E0W8CZ Robotic Assisted Procedure of Trunk Region, Via Natural or Artificial Opening Endoscopic

Coding Options

Option 1. Do not create a new code for the Aquablation therapy used to resect the prostate. Utilize the current code as described in current coding.

Option 2. Create a new code in Section X, New Technology, to identify Aquablation therapy used to resect the prostate.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Prostate	**8** Via Natural or Artificial Opening Endoscopic	**ADD** A Robotic Waterjet Ablation	**4** New Technology Group 4

CMS Recommendation: Option 2. Create a new code in Section X, New Technology, to identify the Aquablation procedure used to resect the prostate.

Interim Coding Advice: Continue to code the Aquablation procedure for resection of the prostate as described above in current coding.

Administration of Plazomicin

Issue: There currently is no unique ICD-10-PCS code to capture administration of plazomicin.

New Technology Application? Yes, an application has been submitted for FY 2019.

Food & Drug Administration (FDA) Approved? No. A New Drug Application (NDA) was submitted to the FDA on October 26, 2017. FDA has granted the NDA Priority Review and set a target action date under the Prescription Drug User Fee Act of June 25, 2018.

Background: Infections due to multidrug-resistant (MDR) gram-negative pathogens are a major public health concern and are increasing in the U.S. and worldwide. These infections are associated with increased morbidity and mortality compared to infections caused by susceptible organisms often due to limited therapeutic options.[4,5] As a result**,** there is an urgent need for new antibiotics to treat infections due to MDR gram-negative organisms.[6,7] In 2013 and again in 2017, the Centers for Disease Control and Prevention identified Carbapenem-Resistant *Enterobacteriaceae* (CRE) as "nightmare bacteria" and an immediate public health threat requiring "urgent and aggressive action".

Plazomicin is a next-generation aminoglycoside developed to treat serious bacterial infections due to MDR Enterobacteriaceae that commonly occur in the hospital setting. Plazomicin's unique chemical structure was specifically designed to target resistant bacteria including aminoglycoside-resistant strains, which are also often resistant to other key classes of antibiotics, including ß-lactams and carbapenems. Two indications are being sought for plazomicin: complicated urinary tract infection (cUTI), including pyelonephritis, and bloodstream infections (BSI) due to certain MDR Enterobacteriaceae; both indications are for patients with limited treatment options.

Because the plazomicin label has not yet been approved by the FDA, the dosage information for plazomicin is not yet known. However, based on phase 3 clinical trials, the expected recommended dose of plazomicin is 15 mg/kg administered every 24 hours by intravenous (IV) infusion over 30 minutes in patients 18 years of age or older and with normal renal function or mild renal impairment (creatinine clearance [CLcr] greater than 60 mL/min). Reduction in dose is expected in those with moderate or severe renal impairment (CLcr less than 60 mL/min).

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[4] Falagas ME, et al., Deaths Attributable to Carbapenem-Resistant *Enterobacteriaceae* Infections, Emerg Infect Dis. 2014 Jul; 20(7): 1170–1175

[5] Lee C-C, et al., Propensity-matched analysis of the impact of extended-spectrum b-lactamase production on adults with community-onset Escherichia coli, Klebsiella species, and Proteus mirabilis bacteremia, Journal of Microbiology, Immunology and Infection (2017), http://dx.doi.org/10.1016/j.jmii.2017.05.006

[6] Gelband H, et al., The State of the World's Antibiotic, 2015, The Center for Disease Dynamics, Economics & Policy, https://cddep.org/publications/state_worlds_antibiotics_2015/, accessed November 30, 2017

[7] Antimicrobial Resistance Global Report on Surveillance 2014, World Health Organization, http://www.who.int/drugresistance/documents/surveillancereport/en/, accessed November 30, 2017

Current Coding: If desired, facilities can report the administration of plazomicin with one of the following ICD-10-PCS codes:

3E03329 Introduction of Other Anti-infective into Peripheral Vein, Percutaneous Approach
3E04329 Introduction of Other Anti-infective into Central Vein, Percutaneous Approach

Coding Options

Option 1. Do not create new codes for the administration of plazomicin. Continue to use the current codes as described above.

Option 2. Create new codes in Section X, New Technology, to identify intravenous infusion of plazomicin.

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/Therapeutic*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD G** Plazomicin Anti-infective	**4** New Technology Group 4

CMS recommendation: Option 2. Create new codes in section X, New Technology, to identify intravenous infusion of plazomicin.

Interim Coding Advice: Continue to report administration of plazomicin if desired as shown in current coding above.

Percutaneous Extracorporeal Membrane Oxygenation (ECMO) for Cardiopulmonary Insufficiency

Issue: Currently, there is no unique ICD-10-PCS code to capture percutaneous Extracorporeal Membrane Oxygenation (ECMO).

New Technology Application: No.

Food & Drug Administration (FDA) Approval Status: The FDA has approved specific components and accessories that may be used in conjunction with ECMO. However, currently there is no known integrated ECMO system with FDA-approved labeling demonstrating safety and efficacy.

Background: Extracorporeal Membrane Oxygenation (ECMO) is a bypass technique that offers support to patients who have reversible cardiopulmonary insufficiency that has not responded to conventional management. It involves passing a patient's blood through an extracorporeal membrane oxygenator that adds oxygen and removes carbon dioxide. The goal of ECMO is to provide organ and tissue oxygenation during cessation of cardiac activity.

While the ECMO procedure has existed for the past four decades, the indications, technical details, and equipment designs have grown during this time. In recent years, providers are also increasingly performing short-term, percutaneous ECMO procedures in addition to open-chest ECMO. ECMO was originally only used for respiratory support, but today, ECMO is commonly used for respiratory and cardiac support.

Percutaneous ECMO can be used to treat refractory cardiogenic shock (myocardial infarction, failure to wean from cardiopulmonary bypass after cardiac surgery, fulminant myocarditis, decompensated chronic heart failure, peripartum cardiomyopathy), as a bridge to durable LVAD or transplantation, as a part of resuscitation in certain circumstances, as a bridge to recovery following lung transplantation for pulmonary hypertension.[1] ECMO is predominantly used on newborns and pediatric cases, but over the past several years there has been an increase in the number of hospitals using ECMO on adults.

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[1] The terms "Percutaneous ECMO" and "Peripheral ECMO" describe the same procedures. "Percutaneous" is typically used in coding, while "Peripheral" is generally used in a clinical setting.

Hospitals use ECMO procedures to provide different targeted support to patients.

Central ECMO cannulation involves sternotomy and direct surgical cannulation of the right atrium and aorta. This involves two open insertions; arterial and venous and provides cardiorespiratory support.

VA Peripheral ECMO cannulation involves two femoral percutaneous insertions; arterial and venous. This type of ECMO support provides respiratory and circulatory support.

VV ECMO requires two venous insertions, one in the upper veins and one in the lower veins. This provides respiratory support only.

The requester notes that the recent growth in reporting of surgical ECMO for adults and the implementation of ICD-10 increases the need for more specific coding for these procedures. New codes for ECMO that distinguish the type of support provided are necessary so that providers can correctly code for these less resource intensive cases.

Current Coding: The following ICD-10-PCS code may be used to report percutaneous ECMO.

5A15223 Extracorporeal Membrane Oxygenation, Continuous

Coding Options

Option 1. Do not create new codes. Continue to code as above under current coding.

Option 2. In table 5A1, create new qualifier value F Membrane, Peripheral, for application to the Circulatory, Cardiac and Respiratory fourth character physiological system values, with the duration value Continuous, and the function value Oxygenation. In addition, revise the existing qualifier 3 Membrane to specify Membrane, Central. These changes will enable capture of additional detail that distinguishes ECMO procedures requiring central cannulation using a sternotomy and open direct cannulation of the heart and aorta from less invasive ECMO procedures that use peripheral vascular access and a percutaneous approach.

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

Body System	*Duration*	*Function*	*Qualifier*
ADD 2 Cardiac **ADD 9** Respiratory	**2** Continuous	**2** Oxygenation	**ADD F** Membrane, Peripheral
5 Circulatory	**2** Continuous	**2** Oxygenation	**REVISE from 3** Membrane **REVISE to 3** Membrane, Central **ADD F** Membrane, Peripheral

CMS Recommendation: Option 2.

Interim Coding Advice: Continue to code as stated in current coding above.

Spinal Fusion with Hydroxyapatite Enhanced Interbody Fusion Device

Issue: There is currently no unique ICD-10-PCS device value to describe spinal fusion using a radiolucent hydroxyapatite enhanced PEEK interbody fusion device.

New Technology Application? No.

Food & Drug Administration (FDA) Approved? Yes. The following devices have been granted FDA 510(k) clearance.

Device Manufacturer	Indication	510(k) Number
Spine Frontier	Cervical	K142026
Meditech Spine	Cervical	K142345
Reliance Medical Systems	Cervical and Cervical Stand Alone	K142269
Cutting Edge Spine	PLIF, TLIF and Rotating TLIF	K150321
Innovasis	PLIF	K151785
Degen	Cervical	K151496
Choice Spine	Cervical Stand Alone	K152515
HT Medical	PLIF and TLIF w/Ti Graft Plug	K153615
Keos	TLIF and PLIF	K160631
LinkSpine	TLIF and PLIF	K162693
Innovasis	ALIF	K162236
Spineology	ALIF Stand Alone	K163670
Meditech spine	PLIF, ALIF, TLIF and Lateral	K170395

Background: Spinal fusion procedures utilize neural decompression and arthrodesis to reduce pain and vertebral segment motion associated with spinal degeneration, deformity and trauma. Fusion procedures often involve placement of an interbody fusion device to facilitate fusion of adjacent vertebrae, maintain disc height and restore spinal alignment. The structure of the interbody fusion device may impact successful clinical outcomes. According to the requester, effective device designs provide a biomechanically favorable fusion environment; prevent implant migration, collapsing and micro-motion; and do not obscure medical images during post-operative assessment. Conventional device designs that fail to meet these criteria may lead to continued post-operative pain, necessitate revision procedures and limit a surgeon's ability to assess a patient's fusion progress.

Invibio Biomaterial Solutions has developed a polymer utilized in interbody fusion devices that incorporates hydroxyapatite into the PEEK. Both hydroxyapatite and PEEK have been used in spinal surgeries for years, but this is the first time they are being used together to promote bone apposition to the implant. Hydroxyapatite has a physical and chemical structure similar to the mineral component of bone and is both osteoconductive and biocompatible.

The Invibio polymer is manufactured in a way that allows the hydroxyapatite to be available on all surfaces and not just on the endplates of the implant. This allows for maximum contact area of bone to hydroxyapatite to promote earlier and better bone growth. With the addition of hydroxyapatite to PEEK, the device has the same mechanical properties as PEEK alone, such as radiolucency and bone-like modulus of elasticity.

Current Coding: Code spinal fusion procedures using the appropriate body part value in tables 0RG and 0SG, Fusion of Upper Joints and Fusion of Lower Joints, with the device value Interbody Fusion Device.

Coding Options

Option 1. Do not create new ICD-10-PCS codes. Continue using codes as above in current coding.

Option 2. Create a new device value PEEK Interbody Fusion Device, Radiolucent with Hydroxyapatite, for the cervical, thoracic and lumbar vertebral joint body part values in tables 0RG and 0SG, Fusion of Upper Joints and Lower Joints body systems, to identify spinal fusion procedures that use a radiolucent hydroxyapatite interbody fusion device(s).

Section **0** Medical and Surgical *Body System* **R** Upper Joints *Operation* **G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile			
Body Part	*Approach*	*Device*	*Qualifier*
0 Occipital-cervical Joint **1** Cervical Vertebral Joint **2** Cervical Vertebral Joints, 2 or more **4** Cervicothoracic Vertebral Joint **6** Thoracic Vertebral Joint **7** Thoracic Vertebral Joints, 2 to 7 **8** Thoracic Vertebral Joints, 8 or more **A** Thoracolumbar Vertebral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**A** Interbody Fusion Device **ADD B** PEEK Interbody Fusion Device, Radiolucent With Hydroxyapatite	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

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

0 Lumbar Vertebral Joint **1** Lumbar Vertebral Joints, 2 or more **3** Lumbosacral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**A** Interbody Fusion Device **ADD B** PEEK Interbody Fusion Device, Radiolucent With Hydroxyapatite	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

Option 3. Create new codes in section X, New Technology, to identify spinal fusion procedures that use a radiolucent PEEK interbody fusion device. Use the same spinal joint body part values as in the body system Upper Joints and Lower Joints of the Med/Surg section.

Section **X** New Technology *Body System* **R** Joints *Operation* **G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Occipital-cervical Joint **1** Cervical Vertebral Joint **2** Cervical Vertebral Joints, 2 or more **4** Cervicothoracic Vertebral Joint **6** Thoracic Vertebral Joint **7** Thoracic Vertebral Joints, 2 to 7 **8** Thoracic Vertebral Joints, 8 or more **A** Thoracolumbar Vertebral Joint **B** Lumbar Vertebral Joint **C** Lumbar Vertebral Joints, 2 or more **D** Lumbosacral Joint	**0** Open	**ADD G** PEEK Interbody Fusion Device, Radiolucent With Hydroxyapatite	**4** New Technology Group 4

CMS Recommendation: Option 3.

Interim Coding Advice: Continue to code spinal fusion procedures using the appropriate body part value in tables 0RG and 0SG, Fusion of Upper Joints and Fusion of Lower Joints, with the device value Interbody Fusion Device.

Administration of GIAPREZA™

Issue: There is currently no unique ICD-10-PCS code to describe the administration of GIAPREZA, a human angiotensin vasoconstrictor for use in septic or other distributive shock.

New Technology Application? Yes, an application has been submitted for FY 2019.

Food & Drug Administration (FDA) Approved? Yes. The FDA granted approval on December 21, 2017.

Background: Individuals with septic or other distributive shock experience critically low blood pressure which can lead to organ damage. The body leverages three major counter-regulatory systems in blood pressure homeostasis; the sympathetic nervous system, which utilizes catecholamines, the arginine-vasopressin system, which utilizes vasopressins, and the renin-angiotensin-aldosterone system (RAAS), which utilizes angiotensin II. Current medical treatment of septic or other distributive shock involves adequate hydration and high doses of vasopressor therapy. If this medical treatment fails, treatment options are limited and are associated with adverse events.

GIAPREZA™, developed by La Jolla Pharmaceuticals, is a synthetic human angiotensin II vasoconstrictor administered through IV infusion. This drug complements existing therapy by leveraging the RAAS to help raise blood pressure in patients where the current standard of medical treatment has failed.

Current Coding: There is no unique ICD-10-PCS code to describe the administration of GIAPREZA™. If desired, facilities can report intravenous infusion of GIAPREZA™ with the following ICD-10-PCS codes:

3E033XZ	Introduction of Vasopressor into Peripheral Vein, Percutaneous Approach
3E043XZ	Introduction of Vasopressor into Central Vein, Percutaneous Approach

Coding Options

Option 1. Do not create new codes for administration of GIAPREZA™ into a peripheral or central vein. Continue to use one of the ICD-10-PCS codes listed under current coding.

Option 2. Add new substance value Synthetic Human Angiotensin II to table XW0 in the New Technology section, to capture the administration of GIAPREZA™.

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*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD H** Synthetic Human Angiotensin II	**4** New Technology Group 4

CMS Recommendation: Option 2. Add new substance value Synthetic Human Angiotensin II to table XW0 in the New Technology section, to capture the administration of GIAPREZA™.

Interim Coding Advice: Continue to code as shown in current coding.

Transfer of Prepuce for Reconstruction

Issue: In table 0HX, Transfer, Skin and Breast, the title of body part value A was revised from Skin, Genitalia to Skin, Inguinal in the FY 2018 ICD-10-PCS code update. Prior to that update, procedure code 0HXAXZZ, Transfer genitalia skin, external approach, was reported for the transfer of skin and prepuce for patients undergoing complex repairs for urogenital anomalies. Currently, the root operation Transfer is not an available option in the Male Reproductive System section of ICD-10-PCS to enable accurate coding for this type of repair.

New Technology Application? No.

Background: There are many types of male urogenital congenital malformations that require extensive reconstruction and repair utilizing the foreskin (prepuce) to accomplish a complete repair. The most common is hypospadias, a birth defect in which the opening of the urethra develops abnormally on the underside of the penis. The opening can occur anywhere from just below its normal location at the end of the penis to the perineum behind the scrotum. Distal and mid-shaft hypospadias is the most common and is usually repaired in a one-stage procedure. Proximal and perineal hypospadias is less common and may require two-stage repair.

Other types of defects include: Chordee, a ventral curvature of the penis that is common with hypospadias or other scrotal anomalies; Penile Torsion, an abnormal rotation of the penile shaft; and other anomalies such as Penoscrotal Transposition, Buried/Hidden Penis and Penoscrotal Webbing. Patients born with these types of anomalies do not have the foreskin removed by circumcision after they are born so this tissue can be available for the reconstructive surgeries these patients can undergo as they grow older.

The foreskin can be transferred to reconstruct the penile urethra (urethroplasty) in these patients and can also be formed into flap grafts (Byars' flaps) that will be arranged to reconstruct and cover defects of the penile shaft skin.

Current Coding: Code reconstruction procedures that utilize the foreskin to repair the penile shaft to table 0VQ, Repair, Male Reproductive System, with the body part value S Penis and the appropriate approach. Code reconstruction procedures that utilize the foreskin to repair the urethra to table 0TQ, Repair, Urinary System, with the body part value D Urethra and the appropriate approach value.

Coding Options

Option 1. Do not create new ICD-10-PCS codes. Continue using current codes as listed in Current Coding.

Option 2. Add root operation Transfer, creating new table 0VX, for the Male Reproductive body system. Add qualifier values Urethra and Penis for the body part value Prepuce, to capture procedures utilizing the prepuce (foreskin) for reconstruction procedures to correct congenital malformations such as hypospadias, chordee, and hidden penis.

Section **0** Medical and Surgical *Body System* **V** Male Reproductive 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*
ADD T Prepuce	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**Z** No Device	**ADD D** Urethra **ADD S** Penis

CMS Recommendation: Option 2. Add root operation Transfer, creating new table 0VX, for the Male Reproductive body system. Add qualifier values Urethra and Penis for the body part value Prepuce, to capture procedures utilizing the prepuce (foreskin) to correct genital malformations.

Interim Coding Advice: Continue to code as above under current coding.

Section X New Technology

Reminder: the purpose of Section X New Technology

- Two types of codes typically classified in Section X
    - New technologies that are not usually captured by coders for inpatient coding
    - New technologies for which ICD-10-PCS does not usually have the desired specificity required to uniquely identify the procedure for CMS' New Technology Add-on Payment (NTAP)

Example: Interbody Fusion Device (IFD)

- Med/Surg section has a single device value specifying Interbody Fusion Device
- At present three specific subtypes have either applied for the NTAP or are applying for the NTAP for FY 2019
    - Nanotextured Surface Interbody Fusion Device (codes valid beginning 10/1/2016)
    - Radiolucent Porous Interbody Fusion Device (codes valid beginning 10/1/2017)
    - PEEK Interbody Fusion Device, Radiolucent (proposed at this March 2018 C&M meeting)
- Creating unique device values for each of these subtypes in the Med/Surg section would lead to an unsustainable proliferation of interbody fusion device values

Section X Code Life Cycle

- After section X codes have served their purpose, proposals to delete X codes and create new codes in the Med/Surg or other sections of ICD-10-PCS would be addressed at subsequent C&M meetings
- This allows the necessary time to evaluate the desirable level of specificity for data collection after the new code has been in use or after the NTAP has expired for a specific technology in which a code was created
- For example, creating section X codes for the various subtypes of IFD allows the industry time to determine the long-term data collection requirements for IFDs

Section X Resources for Coding

- In early June, the ICD-10-PCS annual update posted on the CMS ICD-10 web site provides Addenda files containing multiple Index, Definitions and PCS Table entries for all section X codes in the update
- The addenda file posted in June show all section X codes, and their corresponding resource entries, that go into effect October 1
- Coding advice for new codes, including section X codes, are typically published in 4th quarter Coding Clinic

ICD-10-PCS Index/Body Part Key/Device Key Addenda

Lttr A

Main Revise from Abdominohysterectomy
Revise to Abdominohysterectomy see Resection, Uterus 0UT9
Delete see Resection, Uterus 0UT9
Delete see Resection, Cervix 0UTC

Lttr B

Main Delete Bililite therapy see Ultraviolet Light Therapy, Skin 6A80
Main Add Bili light therapy see Phototherapy, Skin 6A60

Lttr C

Main Revise from Costotransverse ligament
Revise to Costotransverse ligament use Rib(s) Bursa and Ligament
Delete use Sternum Bursa and Ligament
Delete use Rib(s) Bursa and Ligament
Main Revise from Costoxiphoid ligament
Revise to Costoxiphoid ligament use Sternum Bursa and Ligament
Delete use Sternum Bursa and Ligament
Delete use Rib(s) Bursa and Ligament

Lttr D

Main Delete Drotrecogin alfa see Introduction of Recombinant Human-activated Protein C
Main Add DownStream(R) System
Add 5A0512C
Add 5A0522C
Main Add Drotrecogin alfa, infusion see Introduction of Recombinant Human-activated Protein C

Lttr H

Main Humeroradial joint
Delete use Elbow Joint, Right
Delete use Elbow Joint, Left
Add use Humeral Shaft, Right
Add use Humeral Shaft, Left
Add use Radius, Right
Add use Radius, Left

Lttr I

Main Delete Interspinous ligament
Delete use Head and Neck Bursa and Ligament
Delete use Upper Spine Bursa and Ligament
Delete use Lower Spine Bursa and Ligament
Main Delete Intertransverse ligament
Delete use Upper Spine Bursa and Ligament
Delete use Lower Spine Bursa and Ligament
Main Add Interspinous ligament, cervical use Head and Neck Bursa and Ligament
Main Add Interspinous ligament, lumbar use Lower Spine Bursa and Ligament
Main Add Interspinous ligament, thoracic use Upper Spine Bursa and Ligament
Main Add Intertransverse ligament, cervical use Head and Neck Bursa and Ligament
Main Add Intertransverse ligament, lumbar use Lower Spine Bursa and Ligament
Main Add Intertransverse ligament, thoracic use Upper Spine Bursa and Ligament

Lttr K

Main Add KYMRIAH use Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy

Lttr L

Main Delete Ligamentum flavum
Delete use Upper Spine Bursa and Ligament
Delete use Lower Spine Bursa and Ligament
Main Add Ligamentum flavum, cervical use Head and Neck Bursa and Ligament
Main Add Ligamentum flavum, lumbar use Lower Spine Bursa and Ligament
Main Add Ligamentum flavum, thoracic use Upper Spine Bursa and Ligament

Lttr M

Main Add Mediastinal cavity use Mediastinum
Main Add Mediastinal space use Mediastinum

Lttr P

Main Revise from Patch, blood, spinal 3E0S3GC
Revise to Patch, blood, spinal 3E0R3GC
Main Proximal radioulnar joint
Delete use Elbow Joint, Right
Delete use Elbow Joint, Left
Add use Radius, Right
Add use Radius, Left
Add use Ulna, Right
Add use Ulna, Left

Lttr R

Main Add Radial head
Add use Radius, Right
Add use Radius, Left
Main Add Radioulnar joint
Add use Radius, Right
Add use Radius, Left
Add use Ulna, Right
Add use Ulna, Left
Main Add Retroperitoneal cavity use Retroperitoneum
Main Revise from Rhytidectomy see Face lift
Revise to Rhytidectomy see Alteration, Face 0W02

Lttr S

Main Delete Sclerotherapy, mechanical see Destruction
Main Add Sclerotherapy see Destruction
Main Revise from Sternocostal ligament
Revise to Sternocostal ligament use Sternum Bursa and Ligament
Delete use Sternum Bursa and Ligament
Delete use Rib(s) Bursa and Ligament
Main Add Supersaturated Oxygen therapy
Add 5A0512C
Add 5A0522C

Lttr T

Main Add Tisagenlecleucel use Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy

ICD-10-PCS Table Addenda

Medical and Surgical Section
Axis 3 Operation

Drug-coated Balloon Angioplasty of Additional Sites

Source	Description	Code specification
2017, public & CMS internal review	In the Upper Arteries and Upper Veins body systems of the Medical and Surgical section, add qualifier value Drug Coated Balloon, for the root operation Dilation table 037 and 057 respectively, applied to all upper extremity body part values except the hand, and the device values D Intraluminal Device and Z No Device. These changes enable capture of additional detail for procedures such as drug-coated balloon angioplasty of an arteriovenous dialysis fistula.	037[0123456789ABC][034][DZ]1 (78 codes) 057[3456789ABCDF][034][DZ]1 (72 codes)

EXAMPLES

Section	**0** Medical and Surgical
Body System	**3** Upper Arteries
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Internal Mammary Artery, Right **1** Internal Mammary Artery, Left **2** Innominate Artery **3** Subclavian Artery, Right **4** Subclavian Artery, Left **5** Axillary Artery, Right **6** Axillary Artery, Left **7** Brachial Artery, Right **8** Brachial Artery, Left **9** Ulnar Artery, Right **A** Ulnar Artery, Left **B** Radial Artery, Right **C** Radial Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device **D** Intraluminal Device	**ADD 1** Drug-Coated Balloon

Section	**0** Medical and Surgical
Body System	**5** Upper Veins
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
3 Innominate Vein, Right **4** Innominate Vein, Left **5** Subclavian Vein, Right **6** Subclavian Vein, Left **7** Axillary Vein, Right	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device **D** Intraluminal Device	**ADD 1** Drug-Coated Balloon

8 Axillary Vein, Left **9** Brachial Vein, Right **A** Brachial Vein, Left **B** Basilic Vein, Right **C** Basilic Vein, Left **D** Cephalic Vein, Right **F** Cephalic Vein, Left			

Extraction of Hepatobiliary and Pancreas Sites

Source	Description	Code specification
2017, public & CMS internal review	Add the root operation Extraction to the hepatobiliary and pancreas body system to capture additional detail, including percutaneous aspiration biopsies and brush biopsies.	0FD[012][34]ZX (6 codes) 0FD[456789CDFG][348]ZX (30 codes)

EXAMPLE

Section **0** Medical and Surgical
Body System **F** Hepatobiliary System and Pancreas
Operation **ADD** **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*
0 Liver **1** Liver, Right Lobe **2** Liver, Left Lobe	**3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**X** Diagnostic
4 Gallbladder **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 **G** Pancreas	**3** Percutaneous **4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**X** Diagnostic

Medical and Surgical Section
Axis 6 Device

Creation without Using a Device

Source	Description	Code specification

2016, public comment & CMS internal review	In the Heart and Great Vessels body system of the Medical and Surgical section, add the device value Z No Device to the root operation Creation table 024, for all body part values in the table. These changes enable capture of detail for procedures that do not use additional material (graft or synthetic) to perform the procedure. In addition, revise the root operation definition so that it correctly states that a device or material does not have to be used in this root operation. The root operation Creation table 0W4 has always included the device value Z No Device.	024F0ZJ (one code) 024[GJ]0Z2 (2 codes)

EXAMPLE

Section **0** Medical and Surgical
Body System **2** Heart and Great Vessels
Operation **REVISE from 4** Creation: Putting in or on biological or synthetic material to form a new body part that to the extent possible replicates the anatomic structure or function of an absent body part
REVISE to 4 Creation: Forming a new body part that to the extent possible replicates the anatomic structure or function of an absent body part

Body Part	*Approach*	*Device*	*Qualifier*
F Aortic Valve	**0** Open	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **ADD Z** No Device	**J** Truncal Valve
G Mitral Valve **J** Tricuspid Valve	**0** Open	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **ADD Z** No Device	**2** Common Atrioventricular Valve

Fusion using Nanoscale Rough Surface Interbody Fusion Device

Source	Description	Code specification
2017, public request with CMS internal review	In the Upper Joints and Lower Joints body systems of the Medical and Surgical section, create a new device character value Interbody Fusion Device, Nanoscale Rough Surface for the cervical, thoracic and lumbar joint body part values in root operation Fusion tables 0RG and 0SG, to identify spinal fusion	0RG[0124678A][034]C[0J] (48 codes) 0SG[013][034]C[0J] (18 codes)

	procedures that utilize a Nanoscale Rough Surface interbody fusion device(s).	

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Occipital-cervical Joint **1** Cervical Vertebral Joint **2** Cervical Vertebral Joints, 2 or more **4** Cervicothoracic Vertebral Joint **6** Thoracic Vertebral Joint **7** Thoracic Vertebral Joints, 2 to 7 **8** Thoracic Vertebral Joints, 8 or more **A** Thoracolumbar Vertebral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**A** Interbody Fusion Device **ADD C** Interbody Fusion Device, Nanoscale Rough Surface	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebral Joint **1** Lumbar Vertebral Joints, 2 or more **3** Lumbosacral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**A** Interbody Fusion Device **ADD C** Interbody Fusion Device, Nanoscale Rough Surface	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

Medical and Surgical Section
Axis 7 Qualifier

Spinal Canal Bypass Qualifiers

Source	Description	Code specification
2017, Coding Clinic Editorial Advisory Board & CMS internal review	In the Central Nervous and Cranial Nervous body system of the Medical and Surgical section, add the qualifier values Atrium and Blood Vessel, to the root operation Bypass table 001 for the body part value Spinal Canal. These changes enable capture of detail for bypass procedures from the spinal canal to additional sites, such as the lumboatrial shunt procedure.	001U[03][7JK]2 (9 codes) 001U4[7JK][24679] (15 codes)

	In addition, add the approach value Percutaneous Endoscopic for the body part value Spinal Canal, for completeness.	

EXAMPLE

Section	**0** Medical and Surgical
Body System	**0** Central Nervous System and Cranial Nerves
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
U Spinal Canal	**0** Open **3** Percutaneous **ADD 4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**ADD 2** Atrium **4** Pleural Cavity **6** Peritoneal Cavity **7** Urinary Tract **9** Fallopian Tube

Anatomical Regions Bypass Qualifiers

Source	Description	Code specification
2017, Coding Clinic Editorial Advisory Board & CMS internal review	In the Anatomical Regions body system of the Medical and Surgical section, add the qualifier value Upper Vein, to the root operation Bypass table 0W1 for the pleural cavity, peritoneal cavity and pelvic cavity body part values. These changes enable capture of detail for bypass procedures from various anatomical regions to upper vein vascular sites such as the Superior Vena Cava. In addition, add the approach value Percutaneous to all applicable rows in table 0W1, for completeness.	0W1[9BGJ][034]JW (12 codes) 0W1[9BGJ]3J[9BGJY] (20 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
9 Pleural Cavity, Right **B** Pleural Cavity, Left **G** Peritoneal Cavity **J** Pelvic Cavity	**0** Open **ADD 3** Percutaneous **4** Percutaneous Endoscopic	**J** Synthetic Substitute	**4** Cutaneous **9** Pleural Cavity, Right **B** Pleural Cavity, Left **G** Peritoneal Cavity **J** Pelvic Cavity **ADD W** Upper Vein **Y** Lower Vein

Administration Section
Axis 4 Anatomical Region

Influenza Vaccine in Muscle

Source	Description	Code specification
2017, public & CMS internal review	In the Administration section, add the axis 4 body system/region value Muscle, to the root operation Introduction table 3E0 for the Influenza Vaccine qualifier value. These changes enable capture of detail for intramuscular injection of influenza vaccine.	3E02340 (one code)

EXAMPLE

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
2 Muscle	**3** Percutaneous	**4** Serum, Toxoid and Vaccine	**ADD 0** Influenza Vaccine **Z** No Qualifier