CMS WILL NO LONGER BE PROVIDING PAPER COPIES OF HANDOUTS FOR THE MEETING. ELECTRONIC COPIES OF ALL MEETING MATERIALS WILL BE POSTED ON THE CMS WEBSITE PRIOR TO THE MEETING AT HTTPS://WWW.CMS.HHS.GOV/ICD9PROVIDERDIAGNOSTICCODES/03_MEETINGS.ASP

DEPARTMENT OF HEALTH & HUM
Centers for Medicare & Medicaid Serv
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Final 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 9, 2016

Pat Brooks, CMS – Co-Chairperson

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: Phone: 1-877-267-1577; Meeting ID: 993 921 961.

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: In compliance to The Real ID Act, enacted in 2005, the following states/territories: American Samoa, Louisiana, Minnesota, New Hampshire, and New York **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 CMS building.

Proposals for diagnosis code topics will be led by the Centers for Disease Control (CDC) and are scheduled to begin on March 9, 2016 following procedure code proposals. They will continue until approximately 2:00 pm on March 10, 2016. Please visit CDCs website for the Diagnosis agenda located at the following address:
http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm

6. Hematopoietic Cell Transplant Donor Type Pages 34-36	Pat Brooks Stephanie Farnia, MPH Director, Payer Policy National Marrow Donor Program Minneapolis, MN
7. Minimally Invasive Aortic Valve Replacement Pages 37-39	Michelle Joshua Sai Prasad, MD Edwards Intuity
8. Branch Endograft Repair of Common Iliac Aneurysm Pages 40-41	Mady Hue Matthew J. Sideman, MD Vascular Surgeon University of Texas Health Science Center
9. Intravenous Administration of Defitelio (defibrotide) Pages 42-44	Michelle Joshua Stan Lechpammer, MD, PhD Executive Director, Medical Affairs Oncology Lead Jazz Pharmaceuticals
10. Administration of VISTOGARD (uridine triacetate) Pages 45-47	Michelle Joshua Thomas King, MPH Director, Medical Communications
11. Insertion of Spinal Bracing and Distraction System Pages 48-51	Michelle Joshua Tenner Guillaume, MD
12. Application of Biologic Wound Matrix Pages 52-54	Michelle Joshua Jeff Ross, PhD VP Product Development, Miromatrix Medical
13. Total Anomalous Pulmonary Venous Return (TAPVR) Pages 55-56	Mady Hue Patrick Romano, MD, MPH UC Davis Center for Healthcare Policy and Research

ICD-10-PCS Updates

1. GEM Structure and Update Requests — Pat Brooks
   Pages 57-73

2. Addenda and Key Updates — Pat Brooks
   Pages 74-75

Registering for the next meeting:
Registration for the September 13-14, 2016 ICD-10 Coordination and Maintenance Committee meeting opens on August 5, 2016**. If participating by Livestream webcast or dialing in you do not need to register online.** For questions about the registration process, please contact Mady Hue at 410-786-4510 or marilu.hue@cms.hhs.gov.

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

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 9 – 10, 2016	ICD-10 Coordination and Maintenance Committee Meeting. In compliance to The Real ID Act, enacted in 2005, the following states/territories: American Samoa, Louisiana, Minnesota, New Hampshire, and New York **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.
March, 2016	Webcast of the March 9-10, 2016 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html Summary report of the Diagnosis part of the March 10, 2016 ICD-10 Coordination and Maintenance Committee meeting report will be posted on the NCHS webpage as follows: http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm
April 1, 2016	There were no requests for ICD-10 codes to capture new diseases or technology for implementation on April 1, 2016. Therefore, there will be no new ICD-10 codes implemented on April 1, 2016.
April 8, 2016	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 9–10, 2016 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2016**.
April 2016	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 complete and finalized FY 2017 ICD-10-CM diagnosis and ICD-10-PCS procedure codes. 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 2016	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 15, 2016	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 13–14, 2016 ICD-10 Coordination and Maintenance Committee meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.**
August 1, 2016	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, 2016. 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 2016	Tentative agenda for the Procedure part of the September 13–14, 2016 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 13 –14, 2016 ICD-10 Coordination and Maintenance Committee meeting will be posted on the NCHS webpage at - http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm Federal Register notice for the September 13–14, 2016 ICD-10 Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.
August 5, 2016	**On-line registration opens for the September 13-14, 2016 ICD-10 Coordination and Maintenance Committee meeting at: https://www.cms.gov/apps/events/default.asp**
September 2, 2016	Because of increased security requirements, those wishing to attend the September 13-14, 2016 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 2, 2016; failure to do so may result in lack of access to the meeting.**

September 13 –14, 2016	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 2, 2016.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building.
October 2016	Webcast of the September 13–14, 2016 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 Summary report of the Diagnosis part of the September 13–14, 2016 ICD-10 Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm
October 1, 2016	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 16, 2016	**Deadline for receipt of public comments on proposed new codes discussed at the September 13-14, 2016 ICD-10 Coordination and Maintenance Committee meetings for implementation on April 1, 2017.**
November 2016	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, 2017 will be posted on the following websites: http://www.cdc.gov/nchs/icd/icd10cm.htm http://www.cms.gov/Medicare/Coding/ICD10/
November 13, 2016	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 13-14, 2016 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2017.**

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 presented and public given opportunity to comment

Code Proposals

- 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
  - October 16, 2015 for new technology code requests for April 1, 2016 implementation (there were no such requests at this meeting)
  - November 13, 2015 for codes to be implemented on October 1, 2016
- Procedure comments to ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to Donna Pickett, CDC nchsicd10@cdc.gov

Partial Code Freeze

- We have been under a partial code freeze
  - ICD-10 will be implemented for services provided on or after October 1, 2015
  - Only ICD-10 codes for new technologies were implemented on October 1, 2015
  - The partial code freeze ends on October 1, 2016

Proposed and Final Rules

- April 2016 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2016 C&M meeting
- August 1, 2016 – Final rule with links to final codes to be implemented on October 1, 2016
  - Includes any additional codes approved from March 2016 C&M meeting

Addendum

- June 2016 – Final code updates and addendum posted
  - FY 2017 ICD-10-PCS (procedure)
    http://www.cms.gov/Medicare/Coding/ICD10/index.html
  - FY 2017 ICD-10-CM (Diagnosis)
    http://www.cdc.gov/nchs/icd/icd10cm.htm
    http://www.cms.gov/Medicare/Coding/ICD10/index.html (with links to CDC's website)

GEM and Reimbursement Files

- FY 2017 ICD-10-CM and ICD-10-PCS GEMs and Reimbursement mappings posted at http://www.cms.gov/Medicare/Coding/ICD10/index.html
- Annual GEM updates will be posted by August 2016

September 13-14, 2016 C&M Code Requests

- July 15, 2016– Deadline for submitting topics for September 13-14, 2016 C&M meeting
  - Procedure requests to ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis requests to Donna Pickett, CDC nchsicd9@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 8, 2016 for codes to be implemented on October 1, 2016
  - Procedure comments to ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis comments to Donna Pickett, CDC nchsicd9@cdc.gov

ICD-10-PCS Code Updates for October 1, 2016

Summary of New and Revised ICD-10-PCS Codes as of March 9, 2016

The October 1, 2016 update will include the backlog of all proposals for changes to the code set proposed via the ICD-10 Coordination and Maintenance Committee process during the partial code freeze, and receiving public support.

Partial Code Freeze

• The last regular, annual updates to both ICD-9-CM and ICD-10 code sets were made on October 1, 2011.

• On October 1, 2012, October 1, 2013, and October 1, 2014 there were only limited code updates to both the ICD-9-CM and ICD-10 code sets to capture new technologies and diseases as required by section 503(a) of Pub. L. 108-173.

• On October 1, 2015, ICD-10 was implemented and there were only limited code updates to ICD-10 code sets to capture new technologies and diagnoses as required by section 503(a) of Pub. L. 108-173. There were no updates to ICD-9-CM, as it will no longer be used for reporting.

• On October 1, 2016 (one year after implementation of ICD-10), regular updates to ICD-10 will begin.

Summary of ICD-10-PCS Updates from Partial Code Freeze

There are a total of 75,625 valid ICD-10-PCS codes for the FY 2017 update as of March 9, 2016. This includes 3,651 new codes which will be added, and 487 code titles which will be revised. The lists of new and revised code titles is included in the postings on CMS' website for the March 9, 2016 ICD-10 Coordination and Maintenance Committee

Of the codes added, 3,549 new codes (97% of the total update) are cardiovascular system codes. Of the new cardiovascular system codes, 3084 new codes (84% of the total update) resulted from a group of proposals to create unique device values for multiple intraluminal devices and to apply the qualifier Bifurcation to multiple root operation tables for all artery body part values. Other cardiovascular system proposals include more specific body part values for the thoracic aorta, specific table values that uniquely capture congenital cardiac procedures, and codes involving placement of an intravascular neurostimulator.

All code titles revised are in the Heart and Great Vessels body system, and result from changing coronary artery number of sites to specify number of vessels, and modifying the previously non-specific thoracic aorta body part to specify descending thoracic aorta.

Other proposals that resulted in new codes are in the lower joint body systems, for expanding the body part detail available in the root operations Removal and Revision, and adding unique codes for unicondylar knee replacement. There are also new codes for intracranial administration of

substances (such as the Gliadel chemotherapy wafer) using an open approach. There are planned new codes for face transplant, hand transplant and donor organ perfusion.

ICD-10-PCS codes discussed at the March 9 – 10, 2016 ICD-10 Coordination and Maintenance Committee meeting will also be evaluated for implementation on October 1, 2016 after the comment period closes. These additional codes are not included in the totals mentioned above. Now that the Partial Code Freeze has ended, all current and future ICD-10-PCS code proposals will be considered for implementation during the following fiscal year.

SPY Fluorescence Vascular Angiography (FVA)

Issue: Currently within ICD-10-PCS there are not unique values to describe the use of intraoperative fluorescence vascular angiography. Should new values be created?

New Technology Application? No. Novadaq's SPY® Imaging Systems received the first FDA clearance in January 2005 and are currently 510(k) cleared for use in seven surgical specialties.

Background: Novadaq's SPY (FVA) imaging technologies are used in capturing and viewing fluorescence images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro-, and reconstructive procedures. It is also intended to provide fluorescence images for the visual assessment of blood flow in vessels and related tissue perfusion during cardiovascular and gastrointestinal surgical procedures.

In plastic reconstructive surgery, use of the SPY Elite® imaging system assists surgeons to identify poorly perfused tissue following tissue resection such as in mastectomy, in order to avoid complications such as "necrosis" or death of tissue due to stricture, tension, poor blood supply or venous congestion in tissue and tissue flaps. Surgeons performing gastrointestinal (GI) surgery are able to ensure adequate blood flow in colon, gastrointestinal and esophageal tissue during resection and reconstructive procedures to identify and avoid the complication of anastomotic leak due to poor microvascular circulation in the area of the anastomosis. In laparoscopic cholecystectomy, fluorescence imaging can be used to identify two or more of the hepatobiliary ducts, particularly in abnormal anatomy with the objective of avoiding injury to the ducts and the complications associated with biliary tree injury. In non-healing wounds, fluorescence imaging is performed to assess perfusion status and as a result to determine optimal treatment strategies and evaluate treatment effectiveness over time.

Both radiography and fluoroscopy include external ionizing radiation. Fluorescence imaging involves no ionizing radiation. The Indocyanine Green (ICG) dye required to perform fluorescence imaging procedures has the unique properties of absorbing light when exposed to light in the near infrared spectrum and reflecting back that light when excited by a specific light source. ICG binds to blood plasma and acts as a type of blood surrogate as it circulates through the body. Where blood travels in the body ICG travels and where blood does not travel, neither does ICG. During procedures in which SPY FVA is utilized, ICG is excited by a near-infrared laser light source contained within the device and the reflectance fluorescent signal is captured on camera as a moving image sequence of ICG moving through the vessels and micro-vessels in the body, even those at the level of the skin. The image sequences are displayed on a monitor, and archived for medical recordkeeping. The images are reflective of the quality of blood flow within the body.

The depth of penetration of fluorescence imaging is 3-5 cm within the field of view, which allows surgeons to see macro and micro-vascular blood flow beneath the surface of tissue in the area of interest.

Adequate blood flow or "perfusion" to tissue and organs is critical to healing and proper bodily organ function. Surgeons use fluorescence imaging to assess perfusion in the context of cardiovascular surgery including, coronary artery bypass graft procedures to ensure adequate blood flow through bypass grafts and graft patency and re-perfusion to the myocardium to promote proper heart function.

ICG has been in use for more than 60 years in the U.S. and, over the course of history, has been used in ophthalmic angiography, hepatic function testing and cardiac output diagnosis with an adverse event rate of less than 1%. ICG is metabolized by the liver and has been shown to be fully recoverable in bile and is therefore non-nephrotoxic and considered safe for use in patients with compromised kidney function such as the elderly or diabetics. When combined with SPY Imaging Systems, ICG involves no ionizing radiation and as such, does not require the use of special safety gear that is normally required for the patient or medical staff. The requester notes that to date more than 175 peer- reviewed clinical publications describe the use of fluorescence imaging technology and the positive impact the use of SPY FVA systems has had on patient outcomes.

Current Coding: If desired, facilities can capture the use of ICG dye with one of the following ICD-10-PCS codes:

3E033KZ Introduction of Other Diagnostic Substance into Peripheral Vein, Percutaneous Approach

3E043KZ Introduction of Other Diagnostic Substance into Central Vein, Percutaneous Approach

Option 1. Do not assign a separate code for intraoperative use of fluorescence angiography equipment used to assess vascular perfusion during a cardiac, gastrointestinal, and skin or breast reconstruction procedure

Option 2. Create unique codes to capture intraoperative monitoring of vascular perfusion during cardiac, gastrointestinal, and skin or breast reconstruction procedures as described by the requestor. Create new function value S Vascular Perfusion in table 4A1 of the Measurement and Monitoring section. Use existing fourth character body system values Cardiac, Gastrointestinal and a new value for Skin and Breast, with the approach External and the qualifier Intraoperative.

Section **4** Measurement and Monitoring *Body System* **A** Physiological Systems *Operation* **1** Monitoring: Determining the level of a physiological or physical function repetitively over a period of time			
Body System	*Approach*	*Function / Device*	*Qualifier*
2 Cardiac **B** Gastrointestinal **G** Skin and Breast	**X** External	**ADD S** Vascular Perfusion	**G** Intraoperative

Option 3. Create new qualifier value V Indocyanine Green Dye in table 3E0 of the Administration section, applied to the sixth character substance value Other Diagnostic Substance, for the vein body part values.

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**0** Open **3** Percutaneous	**K** Other Diagnostic Substance	**ADD V** Indocyanine Green Dye **Z** No Qualifier

Option 4. Implement both options 2 and 3 as described above.

CMS recommendation: Option 4. Implement both options 2 and 3 as described above

Interim Coding Advice: If desired, facilities can currently capture the use of ICG dye with one of the following ICD-10-PCS codes:

3E033KZ Introduction of Other Diagnostic Substance into Peripheral Vein, Percutaneous Approach

3E043KZ Introduction of Other Diagnostic Substance into Central Vein, Percutaneous Approach

Oxidized Zirconium on Polyethylene Bearing Surface for Hip and Knee Arthroplasty

Issue: Within ICD-10-PCS, there are several synthetic substitute device types describing bearing surfaces used as hip and knee prostheses in total joint replacement. While the current device types capture most of the bearing surfaces, there is not a unique code for oxidized zirconium on polyethylene. Oxidized zirconium on polyethylene is a type of ceramic bearing surface.

New Technology application? No.

Food & Drug Administration (FDA Clearance): Oxidized zirconium implant devices were first cleared for knees and hips in 1996 and 2002, respectively. The polyethylene bearings used in conjunction with oxidized zirconium knee and hip implants were first cleared in 2007 and 2000, respectively.

Background: Oxidized zirconium is the result of a manufacturing method that provides the fracture resistance benefits of a traditional metal implant, with the reduced friction of ceramic implants in one single device. According to the manufacturers, because oxidized zirconium is a distinct bearing surface, it merits its own device type in the ICD-10-PCS classification system. ICD-9-CM had codes which captured the various types of bearing surfaces for implants used in total joint replacement procedures.

We note that devices for a hip replacement include the femoral component and the acetabular component. Generally the acetabular component is either one piece all polyethylene or two piece metal backing with bearing insert of either polyethylene, metal, ceramic, or other bearing surface. The femoral component usually has a metal stem with a modular bearing surface head of metal, ceramic or other material. Both components make up the bearing surface, so that bearing surfaces can be metal on metal, metal on polyethylene, ceramic on metal, or ceramic on polyethylene Currently, ICD-10-PCS codes identify the following combinations of bearing surfaces for hip replacement components:

- Metal on Metal;
- Metal on polyethylene;
- Ceramic on metal; and
- Ceramic on polyethylene.

For knees, there are no bearing surfaces specified in ICD-10-PCS. There is only a generic "synthetic substitute" category for knee joints.

<u>Ceramic vs. Oxidized Zirconium</u>
Oxidized zirconium on polyethylene is a ceramic. However, the requestor suggested that additional codes are needed to describe oxidized zirconium devices, as they are distinct from conventional ceramic or conventional metal. The finished oxidized zirconium retains the metallic alloy properties of strength and ductility, but improves wear performance through the ceramic surface. Oxidized zirconium contains <0.0035% of detectable nickel, the leading cause of negative reactions in patients with metal sensitivities.
In addition to having a different composition, oxidized zirconium on polyethylene bearing surfaces serve a clinical function by addressing a cause of revision, implant wear, which is the degradation

of implant surfaces from articulations. Clinically speaking, friction results in "wear" particles being shed or released into the surrounding joint cavity, which may initiate an aggressive inflammatory response. The body's reaction to wear debris may lead to osteolysis, which is unwanted destruction and loss of bone around the implant. In severe cases, osteolysis causes pain and loosening of the implant, which may result in the need for revision surgery to replace the prosthesis. An effective way to lower the risk of osteolysis and potentially increase the longevity of joint implants is to make the bearing materials more "wear resistant," hence the introduction of oxidized zirconium on polyethylene implants.

In the U.S. oxidized zirconium on polyethylene bearing surfaces are used in about 9% of hip and knee replacement procedures. Thus, with more than one million total hip and knee joint replacements performed annually, about 90,000 hip and knee replacement procedures involve implants with these unique bearing surface materials.

Creation of distinct ICD-10 codes for oxidized zirconium on polyethylene bearing surfaces would facilitate data capture and quantification of critical outcomes differences. A new category for oxidized zirconium on polyethylene devices would facilitate clinical comparisons on revision rates of various bearing surfaces. Differentiating oxidized zirconium on polyethylene bearing surfaces would also strengthen the tracking of the American Joint Replacement Registry, which now has more than 600 participating hospitals and tracks outcomes for 4,000 additional total joint arthroplasty procedures each week.

Current Coding: Code hip joint replacement procedures using the appropriate body part value in root operation table 0SR, and the device value Synthetic Substitute, Ceramic on Polyethylene as stated in the ICD-10-PCS Device Key**.** Code knee joint replacement procedures using the appropriate body part value in root operation table 0SR, and the device value Synthetic Substitute**.**

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	**0** Open	**1** Synthetic Substitute, Metal **2** Synthetic Substitute, Metal on Polyethylene **3** Synthetic Substitute, Ceramic **4** Synthetic Substitute, Ceramic on Polyethylene **J** Synthetic Substitute	**9** Cemented **A** Uncemented **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	**0** Open	**J** Synthetic Substitute	**9** Cemented **A** Uncemented **Z** No Qualifier

Coding Options:

Option 1. Do not create new codes for oxidized zirconium on polyethylene bearing surfaces. Oxidized zirconium is a ceramic. Therefore no new codes are needed. Code hip joint replacement

procedures using the appropriate body part value in root operation table 0SR, and the device value Synthetic Substitute, Ceramic on Polyethylene as stated in the ICD-10-PCS Device Key. Code knee joint replacement procedures using the appropriate body part value in root operation table 0SR, and the device value Synthetic Substitute.

Option 2. Create new device value Synthetic Substitute, Oxidized Zirconium on Polyethylene for the hip and knee joint body part values in table 0SR to identify oxidized zirconium on polyethylene bearing surfaces used as hip and knee prostheses in total joint replacement.

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 6** Synthetic Substitute, Oxidized Zirconium on Polyethylene	**9** Cemented **A** Uncemented **Z** No Qualifier

Option 3. Apply device values Synthetic Substitute, Polyethylene, Synthetic Substitute, Metal, Synthetic Substitute, Metal on Polyethylene, Synthetic Substitute, Ceramic, and Synthetic Substitute, Ceramic on Polyethylene for the related knee joint body part values that currently exist in table 0SR. Do not create new device values for oxidized zirconium on polyethylene bearing surfaces.

Note: A proposal was made at the March 2014 Coordination and Maintenance Committee meeting to add the device value Synthetic Substitute, Unicondylar to table 0SR for the knee joint body part values.

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	**0** Open	**1** Synthetic Substitute, Metal **2** Synthetic Substitute, Metal on Polyethylene **3** Synthetic Substitute, Ceramic **4** Synthetic Substitute, Ceramic on Polyethylene **J** Synthetic Substitute	**9** Cemented **A** Uncemented **Z** No Qualifier
A Hip Joint, Acetabular Surface, Right **E** Hip Joint, Acetabular Surface, Left **V** Knee Joint, Tibial Surface, Right **W** Knee Joint, Tibial Surface, Left	**0** Open	**0** Synthetic Substitute, Polyethylene **1** Synthetic Substitute, Metal **3** Synthetic Substitute, Ceramic **J** Synthetic Substitute	**9** Cemented **A** Uncemented **Z** No Qualifier
C Knee Joint, Right **D** Knee Joint, Left	**0** Open	**ADD 1** Synthetic Substitute, Metal **ADD 2** Synthetic Substitute, Metal on Polyethylene **ADD 3** Synthetic Substitute, Ceramic **ADD 4** Synthetic Substitute, Ceramic on Polyethylene **J** Synthetic Substitute **ADD L** Synthetic Substitute, Unicondylar	**9** Cemented **A** Uncemented **Z** No Qualifier
R Hip Joint, Femoral Surface, Right **S** Hip Joint, Femoral Surface, Left **T** Knee Joint, Femoral Surface, Right **U** Knee Joint, Femoral Surface, Left	**0** Open	**1** Synthetic Substitute, Metal **3** Synthetic Substitute, Ceramic **J** Synthetic Substitute	**9** Cemented **A** Uncemented **Z** No Qualifier

Option 4. Create new device value Synthetic Substitute, Oxidized Zirconium on Polyethylene for the hip and knee joint body part values in table 0SR to identify oxidized zirconium on polyethylene bearing surfaces used as hip and knee prostheses in total joint replacements. Apply device values Synthetic Substitute, Polyethylene, Synthetic Substitute, Metal, Synthetic Substitute, Metal on Polyethylene, Synthetic Substitute, Ceramic, and Synthetic Substitute, Ceramic on Polyethylene for the related knee joint body part values that currently exist in table 0SR.

Note: A proposal was made at the September 2012 Coordination and Maintenance Committee meeting to add the qualifier Bifurcation to table 03C.

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	**0** Open	**1** Synthetic Substitute, Metal **2** Synthetic Substitute, Metal on Polyethylene **3** Synthetic Substitute, Ceramic **4** Synthetic Substitute, Ceramic on Polyethylene **ADD 6** Synthetic Substitute, Oxidized Zirconium on Polyethylene **J** Synthetic Substitute	**9** Cemented **A** Uncemented **Z** No Qualifier
A Hip Joint, Acetabular Surface, Right **E** Hip Joint, Acetabular Surface, Left **V** Knee Joint, Tibial Surface, Right **W** Knee Joint, Tibial Surface, Left	**0** Open	**0** Synthetic Substitute, Polyethylene **1** Synthetic Substitute, Metal **3** Synthetic Substitute, Ceramic **J** Synthetic Substitute	**9** Cemented **A** Uncemented **Z** No Qualifier
C Knee Joint, Right **D** Knee Joint, Left	**0** Open	**ADD 1** Synthetic Substitute, Metal **ADD 2** Synthetic Substitute, Metal on Polyethylene **ADD 3** Synthetic Substitute, Ceramic **ADD 4** Synthetic Substitute, Ceramic on Polyethylene **ADD 6** Synthetic Substitute, Oxidized Zirconium on Polyethylene **J** Synthetic Substitute **ADD L** Synthetic Substitute, Unicondylar	**9** Cemented **A** Uncemented **Z** No Qualifier
R Hip Joint, Femoral Surface, Right **S** Hip Joint, Femoral Surface, Left **T** Knee Joint, Femoral Surface, Right **U** Knee Joint, Femoral Surface, Left	**0** Open	**1** Synthetic Substitute, Metal **3** Synthetic Substitute, Ceramic **J** Synthetic Substitute	**9** Cemented **A** Uncemented **Z** No Qualifier

CMS recommendation: Option 3. Apply device values Synthetic Substitute, Metal, Synthetic Substitute, Metal on Polyethylene, Synthetic Substitute, Ceramic, and Synthetic Substitute, Ceramic on Polyethylene for the related knee joint body part values that currently exist in table OSR.

Do not create new codes for oxidized zirconium on polyethylene bearing surfaces. Oxidized zirconium is a ceramic. Therefore no new codes are needed.

Interim Coding Advice: Continue to code hip joint replacement procedures using the appropriate body part value in root operation table 0SR, and the device value Synthetic Substitute, Ceramic on Polyethylene as stated in the ICD-10-PCS Device Key. Code knee joint replacement procedures using the appropriate body part value in root operation table 0SR, and the device value Synthetic Substitute.

Spinal Fusion with Nano-textured Surface

Issue: There is not a unique ICD-10-PCS device value to describe an interbody fusion device using a nano-textured surface for spinal fusion procedures. Should a new device value or new procedure code be created?

New Technology Application? Yes. Titan Spine submitted a New Technology Add-on Payment application for the Titan Spine EndoSkeleton nanoLOCK™ for FY 2017. Titan Spine received FDA clearance for intervertebral body fusion devices used for fusion: 1) with cervical bone grafts: 2) with lumbar bone grafts; 3) with lumbar integrated fixation; and 4) as a spinal vertebral body replacement in October 2014.

Background: The surgical procedure of spinal arthrodesis (i.e., surgical fixation of a joint by fusion of the joint surfaces through promotion of the proliferation of bone cells) can involve placement of a spinal interbody device which holds the two vertebra apart, while stimulating osteogenesis to complete fusion of the two vertebrae. The material or device used to hold the bone apart could either impede or contribute to the fusion process. Conventional intervertebral body fusion devices present challenges, such as debris resulting from decompensation of the device surface, inflammation, follow up epidural injections, infection, and post-surgical pain. All these can delay or slow patient recovery. Further, if conventional fusion does not achieve long term stability, patients may continue to have pain and limited function, so that revision surgery may be required.

Titan Spine's nanoLOCK™ reductive surface technology uses the proprietary manufacturing process to produce products with topographical surface features at a macro, micro and nano level. Titan Spine's proprietary nanoLOCK™ surface technology with optimized nano-surface characteristics (including cell specific kurtosis and skewedness, indicating there is consistent degree of flatness and symmetry of the surfaces created), generates a distinct cellular response necessary for both committed osteoblasts and multipotent mesenchymal stem cells (MSCs) which can discriminate surface architecture at the nano-scale.

Bone growth is related to cellular signaling from the device surface. Each layer of a nanoLOCK™ product is designed with a specific goal of stimulating an osteogenic cellular response. Macro-scale features are important for initial implant fixation (purchase, anti- migration, and anti-expulsion). Micro-scale features mimic an osteoclastic pit for bone growth (~30 microns in diameter and ~14 microns deep). Nano-scale features interface with the integrins on the outside of the cellular membrane (alpha 2 & beta 1), which generate the osteogenic and angiogenic (mRNA) responses. This promotes committed osteoblasts which build bone, occupies osteoclasts which break down bone, and promotes desired recruitment of multipotent mesenchymal stem cells (MSCs).

Conventional interbody spinal fusion cages are made from allograft bone, carbon, ceramic, metal, titanium, or plastic (Polyether ether ketone [PEEK]). Most are manufactured through additive processes such as molding, 3D printing, coating, etc. Fusion cage surfaces include

plastic, titanium, particulate spray, etc. The nanoLOCK™ device is significantly different than current interbody spinal fusion devices used for treatment of Degenerative Disk disease (DDD) in terms of materials used, methods of manufacture and the surface that is created. nanoLOCK™ uses a different mechanism of action, derived in part from a unique subtractive surface manufacturing process. Two recent studies note safety improvements for Titan Spine nanoLOCK™ interbody fusion devices, when compared to other manufacturer interbody fusion devices. Olivares-Navarrete, shows the most frequently used product, PEEK, elicits an inflammatory response, which causes an extended activation of fibroblasts, which leads to a reduction in bone matrix modeling, an increase in resolution period, and an abundance of fibrotic scar tissue. *A. Kienle et al. The Spine Journal (2015)* evaluated products using additive titanium spray/coating. The bond of the external titanium can be stressed during the impaction and in many cases produced debris (free metallic particles) in the spinal column which has tremendous potential health risks. Impaction studies on Titan Spine products, manufactured with subtractive processes from a full block of titanium, do not present this risk.

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

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	**7** Autologous Tissue Substitute **A** Interbody Fusion Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**0** Anterior Approach, Anterior Column **1** Posterior Approach, Posterior 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	**7** Autologous Tissue Substitute **A** Interbody Fusion Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**0** Anterior Approach, Anterior Column **1** Posterior Approach, Posterior Column **J** Posterior Approach, Anterior Column

Coding Options:

Option 1. Do not create new ICD-10-PCS codes for the use of Titan Spine EndoSkeleton nanoLOCK^{TM} interbody devices. Continue using codes in table as shown above in current coding.

Option 2. Create a new device value Interbody Fusion Device, Nanotextured Surface, for the cervical and thoracic vertebral joint body part values in tables 0RG and 0SG, to identify spinal fusion procedures that use a nanotextured 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	**7** Autologous Tissue Substitute **ADD 9** Interbody Fusion Device, Nanotextured Surface **A** Interbody Fusion Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**0** Anterior Approach, Anterior Column **1** Posterior Approach, Posterior 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	**7** Autologous Tissue Substitute **ADD 9** Interbody Fusion Device, Nanotextured Surface **A** Interbody Fusion Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**0** Anterior Approach, Anterior Column **1** Posterior Approach, Posterior Column **J** Posterior Approach, Anterior Column

Option 3. Create new codes in section X, New Technology, to identify spinal fusion procedures that use a nanotextured interbody fusion device(s). 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*	*Qualifier*
ADD 0 Occipital-cervical Joint **ADD 1** Cervical Vertebral Joint **ADD 2** Cervical Vertebral Joints, 2 or more **ADD 4** Cervicothoracic Vertebral Joint **ADD 6** Thoracic Vertebral Joint **ADD 7** Thoracic Vertebral Joints, 2 to 7 **ADD 8** Thoracic Vertebral Joints, 8 or more **ADD A** Thoracolumbar Vertebral Joint **ADD B** Lumbar Vertebral Joint **ADD C** Lumbar Vertebral Joints, 2 or more **ADD D** Lumbosacral Joint	**0** Open	**ADD 9** Interbody Fusion Device, Nanotextured Surface	**2** New Technology Group 2

Option 4. Create new codes in section X, New Technology, to identify spinal fusion procedures that use a nanotextured interbody fusion device(s). Create streamlined spinal joint body part values in the New Technology section for simplified coding and data collection for this new technology.

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*
ADD 1 Vertebral Joint, One **ADD 2** Vertebral Joints, 2 to 7 **ADD 8** Vertebral Joints, 8 or more	**0** Open	**ADD 9** Interbody Fusion Device, Nanotextured Surface	**2** New Technology Group 2

CMS recommendation: Option 4.

Interim Coding Advice: Continue to code spinal fusion procedures using the Titan Spine EndoSkeleton nanoLOCK^{TM} device with tables 0RG or 0SG, and the appropriate device value, Interbody Fusion Device**.**

Administration of Andexanet Alfa

Issue: There is no ICD-10- PCS code for the intravenous administration of Andexanet Alfa. Andexanet Alfa is a recombinant, modified and truncated human Factor Xa protein that serves as a universal antidote to direct Factor Xa inhibitors.

New Technology Application? Yes. Portola Pharmaceuticals, Inc. has submitted a New Technology Add-On Payment (NTAP) application to CMS for Andexanet Alfa for Fiscal Year 2017.

Food and Drug Administration (FDA) Approval: Portola Pharmaceuticals, Inc. initiated its submission of a rolling Biologic License Application (BLA) to the US Food and Drug Administration (FDA) in October 2016 and completed the filing in December 2015. FDA approval of Andexanet Alfa is expected in the second quarter of 2016. Andexanet Alfa has received breakthrough therapy and orphan drug designation from the FDA.

Background: Patients at high risk for thrombosis, including those with atrial fibrillation or venous thromboembolism, receive long term oral anticoagulation treatment using drugs from more than two classes of anticoagulants. An important, new class of anticoagulants is Factor Xa inhibitors indicated for the prevention of stroke and systemic embolism in patients with atrial fibrillation (AF). In addition, these oral anticoagulants are used to treat or prevent deep-vein thrombosis (DVT) and its complication, pulmonary embolism (PE). Rivaroxaban (Xarelto®), apixaban (Eliquis®) and edoxaban (Savaysa®) belong to the Factor Xa inhibitor class and are often referred to as "novel oral anticoagulants" (NOACs) or "non-vitamin K antagonist oral anticoagulants".

A serious risk associated with anticoagulation, and Factor Xa inhibition as well, is the incidence of unanticipated, serious bleeding episodes such as gastrointestinal and intracranial hemorrhage or those that may occur as a result of trauma or surgical procedures. Consequently, urgent reversal of Factor Xa inhibitor anticoagulation therapy is critical in response to these events. Although these agents have been commercially available since 2010, there is no FDA approved therapy for the urgent reversal of any Factor Xa inhibitor. Additionally, clinical evidence supporting the efficacy of off-label treatment approaches for the urgent reversal of Factor Xa inhibitor mediated anticoagulation is nominal.

Portola has developed Andexanet Alfa in response to the critical need for direct and urgent reversal of NOAC therapy.

The need for an antidote to the NOACs to rapidly reverse their effects of anticoagulation and to restore coagulation is a well-recognized, critical unmet medical need. Approximately 19,000 Medicare beneficiaries that were receiving the NOAC treatments rivaroxaban, apixaban, and the indirect Factor Xa inhibitor enoxaparin in 2014, experienced bleeding episodes and required supportive measures. Many of these patients may have benefited from a direct antidote to the NOAC treatment, which may lead to decreased costs to the healthcare system through important cost offsets. Importantly, identification of patients receiving Factor Xa reversal through Andexanet Alfa would enable tracking of this patient population for improved diagnostic, billing and reporting purposes, once the therapy is approved.

Andexanet Alfa represents a significant therapeutic advance by providing rapid reversal of anticoagulation therapy in the event of a serious bleeding episode. Additionally, the requester notes that a unique code would assist in identifying new technology add-on payments. This would lead to enhanced tracking for diagnostic, billing and reporting purposes.

Current Coding: The administration of Andexanet Alfa can be reported from table 3E0 of the Administration section of ICD-10-PCS.

Section **3** Administration *Body System* **E** Physiological Systems and Anatomical Regions *Operation* **0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products			
Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**G** Other Therapeutic Substance	**C** Other Substance

Coding Options:

Option 1: Do not create new ICD-10-PCS codes for the intravenous administration of Andexanet Alfa. Continue using codes in table 3E0 as shown above in current coding.

Option 2: To capture the intravenous administration of Andexanet Alfa create new qualifier value E in the Administration section of ICD-10-PCS.

Section **3** Administration *Body System* **E** Physiological Systems and Anatomical Regions *Operation* **0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products			
Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**G** Other Therapeutic Substance	**C** Other Substance **ADD E** Andexanet Alfa **N** Blood Brain Barrier Disruption **Q** Glucarpidase

Option 3: Create new codes in section X, New Technology section to capture the intravenous administration of Andexanet Alfa by creating new Device/Substance/Technology value Andexanet Alfa, Factor Xa Inhibitor Reversal Agent.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 7** Andexanet Alfa, Factor Xa Inhibitor Reversal Agent	**2** New Technology Group 2

CMS recommendation: Option 3. Create new ICD-10-PCS X codes for Andexanet Alfa.

Interim Coding Advice: Continue to report codes from Table 3E0 as shown above under current coding.

Insertion of Endobronchial Coils

Issue: There is no unique ICD-10-PCS code to describe the insertion of Endobronchial Coils (PneumRx Endobronchial Coil System).

New Technology Application? Yes. The requester plans to submit a new technology application in late 2016 for FY 2018.

FDA Approval: The Company will be submitting its PMA in early 2016 and anticipates FDA approval in approximately late 2016.

The device has been studied as part of an Investigational Device Exemption (IDE). In August 2012, the FDA approved a 315-subject pivotal trial at 30 sites, primarily throughout the US and including a few centers in Europe where the device has CE Mark. The pivotal study is a randomized, controlled study with a primary endpoint of improvement in 6 Minute Walk Test from baseline to 12 months, comparing Endobronchial Coil Treatment subjects to Control subjects. The trial has completed.

Background: Emphysema, a form of Chronic Obstructive Pulmonary Disease (COPD) is a chronic respiratory disease with an estimated prevalence of 1.8% and an estimated 4 million individuals diagnosed with Emphysema in the USA. Emphysema is characterized by gradual destruction and disappearance of alveolar walls. This results in reduction in the elasticity and recoil pressure of the lungs, and allows the smaller airways to collapse prematurely during exhalation, resulting in hyperinflation, air trapping, and diaphragmatic flattening with decreased diaphragmatic efficiency. This hyperinflation increases with rapid breathing associated with exercise, quickly leaving patients feeling dyspneic, which contributes to cardiac, respiratory and muscular deconditioning as patients avoid activities which trigger dyspnea. These effects are believed to be a primary contributor to the dyspnea experienced by emphysema patients. The alveolar wall damage also creates large nonfunctional air pockets or bullae that become physiologic dead space in the thorax, compressing and preventing healthier portions of the lung from expanding and contracting normally. As the disease progresses, the emphysema patient may eventually become hypoxemic due to progressive loss of alveolar capillary membrane surface area. Hypoxemia and deconditioning contribute to muscle weakness and fatigue. The effects of end-stage emphysema include severe dyspnea, severe limitation of activities, recurrent lung infections, and ultimately respiratory failure, which can result in death.

Standard medical therapy for emphysema includes smoking cessation, medications, pulmonary rehabilitation, and supplemental oxygen if necessary. There are also two surgical procedures available for treatment of severe emphysema: lung transplantation and lung volume reduction surgery (LVRS). Lung transplantation is a seldom used option because of the limited availability of donor lungs, and, since the 2005 lung allocation score (LAS) changes, low transplantation priority for emphysema patients relative to other rapidly fatal pulmonary diseases. LVRS involves resection of the most severely affected areas of emphysematous, non-bullous lung (aim is for 20-30%). LVRS is major surgery involving a thoracotomy and lengthy hospital stay.

Despite evidence that LVRS provides benefit in a small, carefully selected group of emphysema patients, very few surgeries are performed as patients and physicians await minimally-invasive therapeutic options.

Description of the Endobronchial Coil System

The Coil System is an implantable device, delivered through a fiber-optic bronchoscope. No incision is required. The Coil system consists of 1) sterile Coils and 2) a sterile, disposable, single-use (single-patient) delivery system consisting of a Guidewire, Catheter, Cartridge, and Forceps.

The Coils are composed of Nitinol, a biocompatible shape-memory material. The Coils are available in three lengths to accommodate anatomical variation in airway lengths. The Endobronchial Coils are designed to compress the areas of lung parenchyma most damaged by emphysema. This compression may redirect airflow to healthier portions of the lung, and may reduce the volume of the hyperinflated emphysematous lung, resulting in improved diaphragmatic efficiency. The Coils are designed to increase radial tension throughout the lung, helping to tether open airways, preventing airway collapse and reducing dynamic hyperinflation. Because the Coil acts by a mechanical action, these effects are not dependent on lobar fissure integrity or heterogeneity of emphysema, two common conditions of severe emphysema which restrict the utilization of endobronchial valve implants and lung volume reduction surgery. Since this therapy targets local diseased regions of the lung, multiple Coils are necessary to achieve adequate effect. In clinical trials, the majority of cases involved 10 or more Coils per treated lung, with good safety and effectiveness results.

Procedure

The Endobronchial Coils are deployed via bronchoscopic approach and under fluoroscopy, using a catheter-based delivery system.

The delivery system is used to safely deliver the Coils. The Guidewire enables the identification of suitable airways for treatment and supports the Catheter to help guide it to a delivery site. The Catheter functions as a conduit to deliver the Coil from outside the patient to the targeted treatment area. The Cartridge straightens the Coil, couples to the Catheter, and aids in the process of loading the Coil into the Catheter. The Forceps couples to the proximal end of the Coil and delivers it through the Catheter, enabling the clinician to control the placement and release of the device. The Coil can be removed by reversing the deployment procedure.

The procedure is performed by a qualified pulmonologist or surgeon trained to perform interventional procedures. The procedure employs a therapeutic bronchoscope with a 2.8mm working channel (which accommodates the delivery system) and fluoroscopy for visualization beyond the viewing range of the bronchoscope. General anesthesia or sedation is administered. The bronchoscope is inserted and navigated to the airways leading to the diseased parenchyma. The Catheter is inserted into the working channel of the bronchoscope. The Catheter is navigated to the distal airways, and positioning is verified via fluoroscopy. Each Coil is

deployed while positioning is monitored via fluoroscopy. A full treatment involves two separate procedures, for each side of the lung, typically in either the upper or lower lobe pairs. A procedure involves placing approximately 10 or more Coils throughout the treated lobe, to achieve the optimal re-tensioning effects.

Current Coding: Code the procedure with the root operation values Insertion, Removal, or Revision as appropriate from tables 0BH, 0BP, and 0BW respectively, using the body part value Tracheobronchial Tree and the device value Intraluminal Device**.**

Section	**0** Medical and Surgical
Body System	**B** Respiratory 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*	*Qualifier*
0 Tracheobronchial Tree	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**1** Radioactive Element **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device	**Z** No Qualifier

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Tracheobronchial Tree	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**0** Drainage Device **1** Radioactive Element **2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **C** Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Tracheobronchial Tree	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic **X** External	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **C** Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

Coding Options

Option 1. Do not create new codes for the insertion of endobronchial coil(s). Continue to code as above under Current Coding.

Option 2. Create new device value Intraluminal Device, Endobronchial Coil(s) for the body part values currently in table 0BH for insertion of endobronchial valve. Add the same body part values to table 0BP for removal of endobronchial coils and table 0BW for revision of endobronchial coils.

Section	**0** Medical and Surgical
Body System	**B** Respiratory 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*	*Qualifier*
3 Main Bronchus, Right **4** Upper Lobe Bronchus, Right **5** Middle Lobe Bronchus, Right **6** Lower Lobe Bronchus, Right **7** Main Bronchus, Left **8** Upper Lobe Bronchus, Left **9** Lingula Bronchus **B** Lower Lobe Bronchus, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**G** Intraluminal Device, Endobronchial Valve **ADD H** Intraluminal Device, Endobronchial Coil(s)	**Z** No Qualifier

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

Body Part	*Approach*	*Device*	*Qualifier*
ADD 3 Main Bronchus, Right **ADD 4** Upper Lobe Bronchus, Right **ADD 5** Middle Lobe Bronchus, Right **ADD 6** Lower Lobe Bronchus, Right **ADD 7** Main Bronchus, Left **ADD 8** Upper Lobe Bronchus, Left **ADD 9** Lingula Bronchus **ADD B** Lower Lobe Bronchus, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**ADD H** Intraluminal Device, Endobronchial Coil(s)	**Z** No Qualifier

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

Body Part	*Approach*	*Device*	*Qualifier*
ADD 3 Main Bronchus, Right **ADD 4** Upper Lobe Bronchus, Right **ADD 5** Middle Lobe Bronchus, Right **ADD 6** Lower Lobe Bronchus, Right **ADD 7** Main Bronchus, Left **ADD 8** Upper Lobe Bronchus, Left **ADD 9** Lingula Bronchus **ADD B** Lower Lobe Bronchus, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**ADD H** Intraluminal Device, Endobronchial Coil(s)	**Z** No Qualifier

Option 3. Create new device value Intraluminal Device, Endobronchial Coil(s) for the body part values currently in table 0BH for insertion of endobronchial valve. Use existing non-specific body part value Tracheobronchial Tree and device value Intraluminal Device in table 0BP for removal of endobronchial coils and table 0BW for revision of endobronchial coils, as shown in current coding.

Section	**0** Medical and Surgical
Body System	**B** Respiratory 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*	*Qualifier*
3 Main Bronchus, Right **4** Upper Lobe Bronchus, Right **5** Middle Lobe Bronchus, Right **6** Lower Lobe Bronchus, Right **7** Main Bronchus, Left **8** Upper Lobe Bronchus, Left **9** Lingula Bronchus **B** Lower Lobe Bronchus, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**G** Intraluminal Device, Endobronchial Valve **ADD H** Intraluminal Device, Endobronchial Coil(s)	**Z** No Qualifier

Option 4. Create new codes in section X, New Technology, to identify endoscopic insertion, removal and revision of endobronchial coils. Use the same bronchus body part values as in the body system Respiratory System of the Med/Surg section.

Section	**X** New Technology
Body System	**B** Respiratory 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 3 Main Bronchus, Right **ADD 4** Upper Lobe Bronchus, Right **ADD 5** Middle Lobe Bronchus, Right **ADD 6** Lower Lobe Bronchus, Right **ADD 7** Main Bronchus, Left **ADD 8** Upper Lobe Bronchus, Left **ADD 9** Lingula Bronchus **ADD B** Lower Lobe Bronchus, Left	**8** Via Natural or Artificial Opening Endoscopic	**ADD H** Intraluminal Device, Endobronchial Coil(s)	**2** New Technology Group 2

Section	**X** New Technology
Body System	**B** Respiratory System
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 3 Main Bronchus, Right **ADD 4** Upper Lobe Bronchus, Right **ADD 5** Middle Lobe Bronchus, Right **ADD 6** Lower Lobe Bronchus,	**8** Via Natural or Artificial Opening Endoscopic	**ADD H** Intraluminal Device, Endobronchial Coil(s)	**2** New Technology Group 2

Right **ADD** **7** Main Bronchus, Left **ADD** **8** Upper Lobe Bronchus, Left **ADD** **9** Lingula Bronchus **ADD** **B** Lower Lobe Bronchus, Left			

Section	**X** New Technology
Body System	**B** Respiratory System
Operation	**W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD **3** Main Bronchus, Right **ADD** **4** Upper Lobe Bronchus, Right **ADD** **5** Middle Lobe Bronchus, Right **ADD** **6** Lower Lobe Bronchus, Right **ADD** **7** Main Bronchus, Left **ADD** **8** Upper Lobe Bronchus, Left **ADD** **9** Lingula Bronchus **ADD** **B** Lower Lobe Bronchus, Left	**8** Via Natural or Artificial Opening Endoscopic	**ADD** **H** Intraluminal Device, Endobronchial Coil(s)	**2** New Technology Group 2

Option 5. Create new codes in section X, New Technology, to identify endoscopic insertion, removal and revision of endobronchial coils. Create streamlined body part values Bronchus, Right and Bronchus, Left in the New Technology section for simplified coding and data collection for this new technology.

Section	**X** New Technology
Body System	**B** Respiratory 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 **V** Bronchus, Right **ADD** **W** Bronchus, Left	**8** Via Natural or Artificial Opening Endoscopic	**ADD** **H** Intraluminal Device, Endobronchial Coil(s)	**2** New Technology Group 2

Section	**X** New Technology
Body System	**B** Respiratory System
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD **V** Bronchus, Right **ADD** **W** Bronchus, Left	**8** Via Natural or Artificial Opening Endoscopic	**ADD** **H** Intraluminal Device, Endobronchial Coil(s)	**2** New Technology Group 2

Section	**X** New Technology
Body System	**B** Respiratory System
Operation	**W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD **V** Bronchus, Right **ADD** **W** Bronchus, Left	**8** Via Natural or Artificial Opening Endoscopic	**ADD** **H** Intraluminal Device, Endobronchial Coil(s)	**2** New Technology Group 2

CMS Recommendation: Option 5. Create new codes in section X, New Technology, to identify endoscopic insertion, removal and revision of endobronchial coils. Create streamlined body part values Bronchus, Right and Bronchus, Left in the New Technology section for simplified coding and data collection for this new technology.

Interim Coding Advice: Continue to code the procedure with the root operation values Insertion, Removal, or Revision as appropriate from tables 0BH, 0BP, and 0BW respectively, using the body part value Tracheobronchial Tree and the device value Intraluminal Device.

Hematopoietic Cell Transplant Donor Type

Issue: ICD-10-PCS does not have codes which differentiate between related and unrelated donors in allogeneic hematopoietic cell transplant.

New Technology Application? No

Background: Hematopoietic Cell Transplant (HCT), also known as Bone Marrow Transplant or Stem Cell Transplant, is a curative therapy utilized for hematologic malignancies and other life-threatening conditions. Approximately 20,000 transplants are performed annually in the United States. There are two main categories of HCT – autologous and allogeneic. In autologous transplant, an individual's own cells are reinfused into his/her body after the conditioning regimen. In allogeneic transplant, a donor's cells are utilized for immune reconstitution and graft vs. tumor effect. Within allogeneic transplant, two types of donors are possible– related donors (siblings or other family members) and unrelated donors (adult donors or cryopreserved cord blood units). There are significant clinical process differences based on the donor type utilized, as well as resultant resource differences.

Under ICD-9-CM, there was an ability to differentiate between cells that came from a related vs. an unrelated donor, but detailed donor source codes are not currently available in ICD-10-PCS. Researchers and payer stakeholders are interested in understanding the clinical outcomes and cost differences between allogeneic related vs. allogeneic unrelated transplants. In order to retrospectively understand the type of transplant performed, facilities need to be able to identify donor source information from the coding of the transplant procedure on an inpatient claim. In the FY2013 CMS IPPS MedPar data file, approximately 75% of providers were reporting the ICD-9-CM donor source procedure code on their transplant claims.

It appears that the differentiation of a related vs. unrelated donor was overlooked during the development of the ICD-10-PCS coding set. We request that the ICD-10-PCS codes be updated so that the donor source can be captured in ICD-10-PCS. This coding change would also be useful in the solid organ transplant setting, particularly for identifying the type of live kidney donor used.

Current Coding: Code the procedure with the appropriate values from table 302, Transfusion. Code HCT using the qualifier value 1, Nonautologous and the body part and substance values as documented**.**

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**0** Open **3** Percutaneous	**G** Bone Marrow **H** Whole Blood **J** Serum Albumin **K** Frozen Plasma **L** Fresh Plasma	**0** Autologous **1** Nonautologous

		M Plasma Cryoprecipitate **N** Red Blood Cells **P** Frozen Red Cells **Q** White Cells **R** Platelets **S** Globulin **T** Fibrinogen **V** Antihemophilic Factors **W** Factor IX **X** Stem Cells, Cord Blood **Y** Stem Cells, Hematopoietic	

Coding Options:

Option 1. Do not create new codes for related and unrelated donors in allogeneic hematopoietic cell transplants. Continue to use existing codes as shown above.

Option 2. Create new qualifier values 2 Allogeneic, Related or 3 Allogeneic, Unrelated/Unknown for the central and peripheral vein body part values and the substance values Bone Marrow, Stem Cells, Cord Blood and Stem Cells, Hematopoietic in table 302. Delete qualifier value 1 Nonautologous *for only this subset of table 302*, and use new qualifier value Allogeneic, Unrelated/Unknown for coding procedures where the bone marrow transplant donor genetic match is either unrelated or the genetic relationship is not documented.

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**0** Open **3** Percutaneous	**G** Bone Marrow **X** Stem Cells, Cord Blood **Y** Stem Cells, Hematopoietic	**0** Autologous **DELETE 1** Nonautologous **ADD 2** Allogeneic, Related **ADD 3** Allogeneic, Unrelated/Unknown

Option 3. Create new qualifier values 2 Allogeneic, Related or 3 Allogeneic, Unrelated for the central and peripheral vein body part values and the substance values Bone Marrow, Stem Cells, Cord Blood and Stem Cells, Hematopoietic in table 302. Delete qualifier value 1 Nonautologous *for only this subset of table 302*, and use the qualifier value Z No Qualifier for coding procedures where the bone marrow transplant donor relationship is not documented.

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**0** Open **3** Percutaneous	**G** Bone Marrow **X** Stem Cells, Cord Blood **Y** Stem Cells, Hematopoietic	**0** Autologous **DELETE 1** Nonautologous **ADD 2** Allogeneic, Related **ADD 3** Allogeneic, Unrelated **ADD Z** No Qualifier

Option 4. Create new qualifier values 2 Allogeneic, Related or 3 Allogeneic, Unrelated for the central and peripheral vein body part values and the substance values Bone Marrow, Stem Cells, Cord Blood and Stem Cells, Hematopoietic in table 302. Use qualifier value 1 Nonautologous for coding procedures where the bone marrow transplant donor relationship is not documented.

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**0** Open **3** Percutaneous	**G** Bone Marrow **X** Stem Cells, Cord Blood **Y** Stem Cells, Hematopoietic	**0** Autologous **1** Nonautologous **ADD 2** Allogeneic, Related **ADD 3** Allogeneic, Unrelated

CMS recommendation: Option 3. Create new qualifier values 2 Allogeneic, Related or 3 Allogeneic, Unrelated for the central and peripheral vein body part values and the substance values Bone Marrow, Stem Cells, Cord Blood and Stem Cells, Hematopoietic in table 302. Delete qualifier value 1 Nonautologous *for only this subset of table 302*, and use the qualifier value Z No Qualifier for coding procedures where the bone marrow transplant donor relationship is not documented.

Interim Coding Advice: Continue to code the procedure with the appropriate values from table 302, Tranfusion. Code HCT using the qualifier value 1, Nonautologous and the body part and substance values as documented.

Minimally Invasive Aortic Valve Replacement

Issue: Currently there are not any ICD-10-PCS procedure codes to distinguish aortic valve replacement devices that are used in a minimally invasive surgical approach. Should a new ICD-10-PCS code be created?

New Technology Application? Yes. Edwards Lifesciences submitted a New Technology Add-on Payment application for the EDWARDS INTUITY Elite™ Valve System for FY 2017.

Food and Drug Administration (FDA) Approval: Edwards Lifesciences anticipates approval of the Pre-Market Approval (PMA) in the first half of calendar year (CY) 2016, and availability on the market shortly thereafter.

Background: Aortic valve disease manifests primarily in the form of aortic stenosis, or calcification of the aortic valve. Aortic stenosis leads to critical narrowing of the aortic valve. When this happens, a significant pressure gradient develops across the aortic valve, causing the heart to work harder to overcome the obstruction. Over time, this leads to myocardial hypertophy. This disease can go undiagnosed for years existing in an asymptomatic state. However, once symptoms occur – angina, syncope, and heart failure – the interval between the onset of symptoms and death without treatment is 2 and 5 years. Occurrence of symptoms is an indication for surgical aortic valve replacement (SAVR). Aortic valve disease occurs in 2.3% of patients between 65- and 75-years old, and 4.8% of patients 75 years and older.

Current treatment options for patients with aortic valve disease include medical management for earlier stage disease and surgical aortic valve replacement if the patient's disease state merits surgical treatment. Aortic valve replacement is the standard of care if the patient's disease state merits surgical treatment for the treatment of symptomatic aortic stenosis. In this case, the patient undergoes a surgical procedure to replace the valve, through which the surgeon completely divides the sternum (full sternotomy), accesses the heart and aortic valve, excises the diseased valve, meticulously places between 12 and 15 sutures through the aortic annulus and sewing ring of the valve, seats the valve, and ties all sutures. If appropriate, the surgeon can use variations of this approach and access the heart using a minimally invasive surgical (MIS) approach. MIS procedures access the aortic valve through a small incision between the right 3rd and 4th intercostal space, called a right anterior thoracotomy, or make a partial incision of the sternum, called an upper hemi- or mini-sternotomy. According to the requester, despite the clinical advantages associated with MIS aortic valve replacement, the proportion of patients undergoing this technique remains low.

The EDWARDS INTUITY Elite™ valve system is an aortic valve prosthesis, which replaces the diseased valve during an aortic valve replacement procedure. The device is a bovine pericardial aortic bioprosthetic valve with a balloon expandable stainless steel frame and a textured sealing cloth. The device can be implanted via traditional approaches, such as full-sternotomy, as well as in minimally invasive approaches including a right anterior thoracotomy and hemi-sternotomy. It can also be inserted during concomitant valve procedures, for example, with coronary artery bypass graft (CABG). The requester reported that studies have shown substantial improvement

in key clinical, safety, and utilization outcomes such as reoperation, length of stay (LOS), mortality, and cross-clamp times (XCT).

The requester also noted that clinical trials have shown that the EDWARDS INITUITY Elite™ valve system and MIS approach may be used for patients who would otherwise be unable to undergo traditional full-sternotomy replacement valve procedures that require large incisions and more sutures. This subset of patients may now benefit from the new system which can be performed using a minimally invasive approach, increasing their chance for survival. Additionally, the new mechanism of action for the rapid deployment device has dramatically altered the ease and speed at which a diseased aortic valve can be removed and a new valve implanted, thereby allowing the patient to recover sooner and decreasing the length of stay.

The EDWARDS INITUITY Elite™ valve system technology consists of a new delivery system design that allows rapid deployment of the valve. The delivery system is comprised of a balloon expandable stent that permits the new valve to be precisely positioned in the correct location, necessitating only 3 sutures to secure it. The requester asserts that the technique enables the surgeon to utilize only 3 sutures as opposed to the 12 to 18 sutures typically required in traditional aortic valve replacement procedures. The technology also employs a flexible deployment arm enabling the surgeon optimal access to anatomy for valve deployment and suturing. Lastly, the construct of the delivery system is such that only the proper sized valve can be placed into it. This ensures optimal balloon inflation and assists in the prevention of device migration which can lead to paravalvular leaks.

The requester suggests that this new technology creates the need to ensure that the rapid deployment aspect of the MIS AVR procedure is appropriately tracked and monitored. By appropriately delineating between the traditional and rapid deployment procedures, researchers can adequately examine what are expected to be improved real-world health outcomes associated with rapid deployment procedures, in addition to other outcomes such as healthcare resource use. Both clinical and resource use outcomes can be examined both over the short and long term which may help to inform decisions best practices for AVR procedures and aortic valve disease patients.

Current Coding: Code aortic valve replacement procedures using bovine pericardial derived prosthetic valve with the Aortic Valve body part value in root operation table 02R, and the device value Zooplastic Tissue.

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

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

Coding Options:

Option 1. Do not create new ICD-10-PCS codes for the EDWARDS INTUITY Elite™ valve system. Continue using codes in table 02R as shown above in current coding.

Option 2. Create new qualifier value Rapid Deployment System for procedures that use a rapid deployment system in table 02R applied to body part value Aortic Valve and the device value Zooplastic Tissue.

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

Body Part	*Approach*	*Device*	*Qualifier*
F Aortic Valve	**0** Open **4** Percutaneous Endoscopic	**8** Zooplastic Tissue	**ADD 3** Rapid Deployment System **Z** No Qualifier
F Aortic Valve	**3** Percutaneous	**8** Zooplastic Tissue	**ADD 3** Rapid Deployment System **H** Transapical **Z** No Qualifier

Option 3. Create new codes in section X, New Technology, to identify procedures that use a rapid deployment system for aortic valve replacement procedures that use a zooplastic derived prosthetic valve.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD F Aortic Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD 3** Zooplastic Tissue, Rapid Deployment System	**2** New Technology Group 2

CMS recommendation: Option 3.

Interim Coding Advice: Continue using codes in table 02R as shown above in current coding.

Branched Endograft Repair of Common Iliac Aneurysm

Issue: ICD-10-PCS does not currently identify the endovascular repair of common iliac aneurysm involving both the internal and external iliac arteries with a branched endograft. Should a new device value be created to specifically identify these repairs?

New Technology Application? Yes. Submission date November 18, 2015 for FY 2017.

Food and Drug Administration (FDA) Status: Approval for the first endograft intended for this repair was granted February 29, 2016; GORE® EXCLUDER® Iliac Branch Endoprosthesis; IDE clinical study G130038, original approval date May 16, 2013.

Background: Of the estimated 39,000 Abdominal Aortic Aneurysms (AAA) repaired by the endovascular technique commonly known as "EVAR", an estimated 15-44% involve concurrent common iliac artery aneurysm (CIA). In about 25% of these concurrent AAA/CIA cases, the extent of the iliac aneurysm complicates endovascular repair either because of an inadequate anatomic landing or "sealing" zone above the iliac bifurcation, or because the aneurysm extends into one or both of the iliac branches (internal and external iliac arteries). Currently, aneurysm exclusion alternatives in this situation involve either the sacrifice of blood flow to the internal iliac, an additional surgical bypass graft to restore flow, or the use of endografts using various physician developed techniques to preserve flow in both branch vessels.

Exclusion or "restriction" of extensive iliac aneurysms with a branching endograft is similar to that for aorto-bi-iliac repair (e.g., EVAR), with which this repair is commonly associated. Bilateral vessel access is usually gained via the femoral artery, wire and catheter placement is done under radiologic guidance, and the branched endograft is delivered and deployed. The proximal extent of the repair (i.e., into the abdominal aorta) is carried out as required to assure complete, secure exclusion/restriction of the aneurysm.

The goal of branching endograft repair of the CIA is to preserve blood flow (perfusion) to pelvic organs and musculature in a safe, efficient and standardized manner. Patients avoid the risks associated with reduced perfusion including buttock claudication, sexual dysfunction, and other ischemia related complications. Branched endograft technique reduces variability and increases efficiency versus current alternatives while preserving flow into all vessels.

Current Coding: Branched endograft repair of the common iliac arteries would currently be reported in Table 04V, Restriction of the Lower Arteries.

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

Body Part	*Approach*	*Device*	*Qualifier*
C Common Iliac Artery, Right D Common Iliac Artery, Left	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	Z No Qualifier

Coding Options:

Option 1. Do not add a new device value to table 04V, Restriction of the Lower Arteries. Continue to use existing codes as shown above.

Option 2. Add the device value E, Intraluminal Device, Branched or Fenestrated, to the root operation Restriction, in Table 04V for the Common Iliac Artery body part values.

Note: The following proposal is based on CMS' recommended option 2 for the joint industry proposal *Branching and Fenestrated Endograft Repair of Aortic Aneurysms* that was presented at the September 2015 ICD-10 C&M meeting.

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

Body Part	*Approach*	*Device*	*Qualifier*
C Common Iliac Artery, Right D Common Iliac Artery, Left	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device ADD E Intraluminal Device, Branched or Fenestrated Z No Device	Z No Qualifier

Option 3. Create new codes in section X, New Technology to identify endovascular repair of common iliac aneurysm involving both the internal and external iliac arteries with a branched endograft. Use the same body part values as in the body system Lower Arteries of the Med/Surg section.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD C Common Iliac Artery, Right **ADD D** Common Iliac Artery, Left	**3** Percutaneous	**ADD E** Intraluminal Device, Branched or Fenestrated	**2** New Technology Group 2

CMS Recommendation: CMS recommends Option 3, effective October 1, 2016.

Interim Coding Advice: Continue to code endovascular repair of aneurysms occurring in the common iliac arteries that use a branched device with the appropriate ICD-10-PCS codes from table 04V, Restriction of Lower Arteries.

Administration of Defibrotide

Issue: There is no ICD-10-PCS code for the intravenous administration of Defitelio (Defibrotide) injection for treatment of patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with evidence of multi-organ dysfunction following hematopoietic stem-cell transplantation (HSCT).

New Technology Application? Yes. Jazz Pharmaceuticals submitted a FY 2017 New Technology Add-on Payment (NTAP) application for Defibrotide on November 17, 2015.

Food and Drug Administration (FDA) Approval: The rolling submission of the New Drug Application (NDA) for Defibrotide was completed on July 31, 2015. On September 29, 2015, the FDA accepted the NDA for filing with Priority Review under the Prescription Drug User Fee Act (PDUFA), and the User Fee goal date is March 31, 2016.

Background:

Description and Current Treatment of VOD.

HSCT is a potentially curative intervention used to treat many different malignant diseases and non-malignant disorders. HSCT is a process in which stem cells are harvested from a patient's (autologous), donor's (allogeneic) bone marrow or peripheral blood for intravenous infusion. VOD is a potentially life-threatening complication of HSCT. VOD is believed to be the result of endothelial cell damage and hepatocellular injury from high-dose conditioning regimens prior to HSCT. VOD is more common in allogeneic HSCT recipients than in autologous HSCT recipients.

VOD develops in 8% - 15% of patients after HSCT, and ranges in severity from what has been classically defined as disease limited to the liver (mild) and reversible, to a severe syndrome associated with multi-organ dysfunction or failure, and death. Temporally, VOD is an early complication of transplant (typically occurs within the first 21 Days post HSCT.), but late onset VOD (up to Day+50 post-HSCT) has also been observed.[11] Incidence of VOD depends on the type of transplant, type of pre-transplant conditioning regimen, type of GvHD prophylaxis regimen used prior to the HSCT, diagnostic criteria used for VOD and pre-existing risk factors, including older patient age, pre-existing hepatic dysfunction, poor performance status, prior radiation in abdominal area, and prior myeloblative stem cell transplant.

HSCT patients with VOD characterized with evidence of multi-organ dysfunction face an immediate risk of death, with a mortality rate of more than 80% when only supportive care is applied.

There are no FDA-approved treatments for VOD. A number of prophylactic medications have been evaluated for VOD with varying degrees of success. Current treatment for VOD consists largely of supportive care, with the goal of maintaining intravascular volume and renal perfusion while avoiding extra-vascular fluid accumulation.[16] Pharmacological treatment options for VOD are solely experimental uses of medications not FDA-approved for treatment of VOD.

Description and Mechanism of Action of Defibrotide.
Defibrotide is the sodium salt of a highly complex, polydisperse mixture of predominantly single-stranded polydeoxyribonucleotides, having a mean molecular weight of 13-20 kDa. Defibrotide is prepared by controlled depolymerization of DNA isolated from swine intestinal mucosa using a particular combination of physico-chemical conditions. While the mechanism of action has not been fully elucidated, preclinical data suggest that Defibrotide stabilizes endothelial cells by reducing endothelial cell activation and by protecting endothelial cells from further damage, resulting in the restoration of thrombo-fibrinoloytic balance.

Summary of Substantial Clinical Improvement Shown in Defibrotide Clinical Studies.
In clinical studies, the defibrotide treated population showed significantly improved survival at Day+100 over a Historical Control not treated with defibrotide. Survival at Day+100 post-HSCT, widely accepted by the transplant community as a standard endpoint for assessing survival status following HSCT, was the primary efficacy endpoint in the defibrotide pivotal, historically-controlled study. In addition, consistent day +100 survival among defibrotide patients was observed across other defibrotide clinical studies. The pivotal study also demonstrated statistically significant improved efficacy results in favor of defibrotide as measured by the secondary efficacy endpoint – Complete Response (CR) by Day+100, achievement of which represents a resolution of the clinical signs and symptoms of VOD and associated organ failure. This clinically relevant and meaningful efficacy endpoint supports defibrotide as an effective treatment of the early onset cause of mortality and demonstrates that defibrotide can alleviate at least one barrier to successful post-HSCT survival to afford the transplant patient the opportunity for engraftment and (hopefully) a cure for the underlying disease that required HSCT.

Defibrotide can offer an effective treatment to benefit even for those patients with prognostic factors associated with worse outcomes post-HSCT. When compared to Historical Control patients, improvements in survival outcomes were observed with defibrotide treatment even among subgroups of patients with baseline prognostic factors associated with worse outcomes, such as ventilator dependent and dialysis dependent patients. Overall, data from across the defibrotide clinical studies provide positive and consistent evidence for the risk-benefit and the manageable safety profile of defibrotide for the treatment of VOD with evidence of multi-organ dysfunction following HSCT. A manageable safety profile for defibrotide at its recommended dose and schedule was demonstrated in both pediatric and adult patients. The overall incidence of TEAEs (treatment-emergent adverse events defined as any adverse event [AE] starting after initiation of defibrotide treatment; related and unrelated; nonserious and serious), as well as fatal TEAEs and AEs of special interest (i.e. hemorrhage and hypotension) are well characterized and manageable by transplant physicians. The Numbers Needed to Treat (NNT) for defibrotide is comparable to or lower than other therapeutic medical interventions in critical care.

Current Coding: The intravenous administration of defibrotide can be reported using codes from table 3E0 of the Administration section of ICD-10-PCS.

Section **3** Administration *Body System* **E** Physiological Systems and Anatomical Regions *Operation* **0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products			
Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**G** Other Therapeutic Substance	**C** Other Substance

Coding Options:

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of defibdrotide. Continue using codes in table 3E0 as shown above in current coding.

Option 2. To capture the intravenous administration of defibrotide, create new qualifier value Defibrotide for the sixth character substance value injection in table 3E0 of the Administration section of ICD-10-PCS.

Section **3** Administration *Body System* **E** Physiological Systems and Anatomical Regions *Operation* **0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products			
Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 8** Injection	**ADD 0** Defibrotide

Option 3. Create new codes in section X, New Technology to capture the intravenous administration of defibrotide by creating new Device/Substance/Technology value Defibrotide Injection.

Section **X** New Technology *Body System* **W** Anatomical Regions *Operation* **0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 9** Defibrotide Injection	**ADD 2** New Technology Group 2

CMS recommendation: Option 3.

Interim Coding Advice: Continue to code the intravenous administration of defibrotide using codes from table 3E0 of the Administration section of ICD-10-PCS

Administration of Uridine triacetate

Issue: There is no ICD-10-PCS code for the administration of VISTOGARD (uridine triacetate) oral granules, a pyrimidine analog indicated for the emergency treatment of fluorouracil or capecitabine overexposure in adult and pediatric patients. Should a new code be created?

New Technology Application? Yes. BTG International submitted a FY 2017 New Technology Add-on Payment (NTAP) application for uridine triacetate.

Food and Drug Administration (FDA) Approval: The FDA accepted the uridine triacetate New Drug Application (NDA) filing for Priority Review on September 8, 2015 and was approved on December 11, 2015 in advance of the Prescription Drug User Fee Act (PDUFA) User Fee goal date of March 10, 2016. Uridine triacetate has been granted Orphan Drug Designation from the FDA as an antidote in the treatment of 5-fluorouracil (5-FU) poisoning and from the European Medicines Agency (EMA) as a treatment for 5-FU overdose. The NDA for uridine triacetate is held by Wellstat Therapeutics, its developer. The trade name for uridine triacetate oral granules is VISTOGARD®. BTG International acquired US market rights to VISTOGARD® from Wellstat.

Background: VISTOGARD is the first and only antidote indicated for the emergency treatment of adult and pediatric patients following a fluorouracil or capecitabine overdose regardless of the presence of symptoms, or who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac or central nervous system, and/or early-onset, unusually severe adverse reactions (e.g., gastrointestinal toxicity and/or neutropenia) within 96 hours following the end of fluorouracil or capecitabine administration.

Overdoses due to infusion pump misadventure (malfunctions and programming errors, as well as due to pharmacy transcription errors) can lead to excessive 5-FU exposures, at least 10% higher than the maximum tolerated dose, or at a higher than intended infusion rate (>1.25x the intended rate of infusion). Additionally in a subset of approximately 10% - 20% of patients treated with a therapeutic dose of 5-FU, clearance defects can cause impaired ability to catabolize and/or eliminate the drug, leading to severe treatment-related toxicity, which is lethal in 1,300 patients per year (frequency of 0.5% treated patients), with treatment-related mortality of up to 5% reported in elderly patients.

The most common cause for impaired clearance of 5-FU is DPD deficiency. Approximately 85% of a standard dose of 5-FU is initially degraded by the action of DPD. It is estimated that 3% - 5% of the Caucasian population and 8% of the African-American population are DPD deficient. Nearly half of all severe toxicities with 5-FU are thought to result from a deficiency in the enzyme DPD.

In clinical studies, despite age, gender, race, or tumor type, survival was almost universal if the patient received uridine triacetate within 96 hours post-cessation of 5-FU. Uridine triacetate reduced the incidence, severity and virulence of toxicities associated with 5-FU toxicity whether due to overdose or rapid onset. More patients were able to resume chemotherapy after severe toxicities of a 5-FU overdose after treatment with uridine triacetate than would be the case after supportive care alone, if the patient survived. The safety and tolerability profile of uridine triacetate is consistent with what would be expected for patients with cancer and following 5-FU treatment but is generally less in severity and incidence with what would be expected with 5-FU overdose.

Inpatient Administration of Uridine Triacetate.
Uridine triacetate should be administered within 96 hours of 5-FU administration to treat patients at risk of serious toxicity following an overdose of 5-FU and patients exhibiting symptoms of serious toxicity.

Current Coding: The administration of VISTOGARD® can be reported using table 3E0.

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*
D Mouth and Pharynx	**X** External	**G** Other Therapeutic Substance	**C** Other Substance

Coding Options:

Option 1. Do not create new ICD-10-PCS codes for the oral administration of VISTOGARD®. Continue using table 3E0 as shown above in current coding.

Option 2. To capture the oral administration of VISTOGARD®, create new qualifier value Uridine Triacetate in table 3E0 of the Administration section of ICD-10-PCS.

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*
D Mouth and Pharynx	**X** External	**G** Other Therapeutic Substance	**C** Other Substance **ADD R** Uridine Triacetate

Option 3. Create a new code in section X, New Technology section to capture the oral administration of VISTOGARD® by creating the value Uridine Triacetate for the sixth character to describe the Device/Substance/Technology.

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
D Mouth and Pharynx	**X** External	**ADD 8** Uridine Triacetate	**2** New Technology Group 2

CMS recommendation: Option 3.

Interim Coding Advice: Continue using table 3E0 as shown above in current coding.

Insertion of Spinal Bracing and Distraction System

Issue: Within ICD-10-PCS there are no unique device values to describe the insertion of magnetically controlled spinal growth rods. Should new ICD-10-PCS device values be created to identify these types of growth rods?

New Technology Application? Yes. Ellipse technologies submitted a New Technology Add-on Payment application for the MAGEC® Spinal Bracing and Distraction System for FY 2017.

Food and Drug Administration (FDA) Approval: Ellipse technologies has received 510(k) approvals for the MAGEC® system, a system used to treat scoliosis.

Background: The Ellipse Technologies, Inc. MAGEC® Spinal Bracing and Distraction system is comprised of one or two sterile, single use spinal rods that are surgically implanted using appropriate commercially available fixation components (i.e., pedicle screws, hooks and/or connectors). The implanted spinal rod is used to brace the spine during growth to minimize the progression of scoliosis. The system includes a non-sterile hand held External Remote Controller. Each rod includes a small internal magnet, which allows the rod to be lengthened by use of the non-sterile hand held External Remote controller. At various times after rod implantation, the remote controller is used to non-invasively lengthen or shorten the implanted rod. The External Remote controller is electrically powered and placed over the patient's spine and then manually activated, which causes the implanted magnet to rotate and either lengthen or shorten the rod.

Periodic lengthening of the rod is performed to distract the spine and to provide adequate bracing during growth to minimize the progression of scoliosis. Once the physician determines that the implant has achieved its intended use and is no longer required, the implant is extracted.

The Ellipse MAGEC® Spinal Bracing and Distraction system is intended for skeletally immature patients less than 10 years of age, with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) associated with, or at risk of Thoracic Insufficiency syndrome (TIS).

Current Coding: The use of magnetically controlled growth rods can be reported using one of the following ICD-10-PCS codes currently used for the insertion of traditional growth rods.

Code the procedure with the root operation values Reposition for the initial implantation of magnetically controlled growth rods and Revision for subsequent adjustment of magnetically controlled growth rods from tables 0PS, 0QS, 0PW and 0QW respectively, using the vertebra body part values and the device value Internal Fixation Device.

Section **0** Medical and Surgical
Body System **P** Upper Bones
Operation **S** Reposition: Moving to its normal location, or other suitable location, all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
1 Rib, Right **2** Rib, Left **3** Cervical Vertebra **4** Thoracic Vertebra **5** Scapula, Right **6** Scapula, Left **7** Glenoid Cavity, Right **8** Glenoid Cavity, Left **9** Clavicle, Right **B** Clavicle, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **Z** No Device	**Z** No Qualifier

Section **0** Medical and Surgical
Body System **Q** Lower Bones
Operation **S** Reposition: Moving to its normal location, or other suitable location, all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebra **1** Sacrum **2** Pelvic Bone, Right **3** Pelvic Bone, Left **4** Acetabulum, Right **5** Acetabulum, Left **6** Upper Femur, Right **7** Upper Femur, Left **8** Femoral Shaft, Right **9** Femoral Shaft, Left **B** Lower Femur, Right **C** Lower Femur, Left **D** Patella, Right **F** Patella, Left **G** Tibia, Right **H** Tibia, Left **J** Fibula, Right **K** Fibula, Left **L** Tarsal, Right **M** Tarsal, Left **N** Metatarsal, Right **P** Metatarsal, Left **Q** Toe Phalanx, Right **R** Toe Phalanx, Left **S** Coccyx	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device	**Z** No Qualifier

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Sternum **1** Rib, Right **2** Rib, Left **3** Cervical Vertebra **4** Thoracic Vertebra **5** Scapula, Right	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**4** Internal Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

6 Scapula, Left **7** Glenoid Cavity, Right **8** Glenoid Cavity, Left **9** Clavicle, Right **B** Clavicle, Left			

Section **0** Medical and Surgical *Body System* **Q** Lower Bones *Operation* **W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device			
Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebra **1** Sacrum 4 Acetabulum, Right **5** Acetabulum, Left **S** Coccyx	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**4** Internal Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

Coding Options:

Option 1. Do not create new ICD-10-PCS codes for the implantation of magnetically controlled spinal growth rods. Continue using codes in tables 0PS, 0QS, 0PW and 0QW as shown above in current coding.

Option 2. Create new device value Internal Fixation Device, Magnetically Controlled for the vertebra body part values in tables 0PS and 0QS for implantation of magnetically controlled spinal growth rods.

Section **0** Medical and Surgical *Body System* **P** Upper Bones *Operation* **S** Reposition: Moving to its normal location, or other suitable location, all or a portion of a body part			
Body Part	*Approach*	*Device*	*Qualifier*
3 Cervical Vertebra **4** Thoracic Vertebra	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD 3** Internal Fixation Device, Magnetically Controlled **4** Internal Fixation Device **Z** No Device	**Z** No Qualifier

Option 3. Create new codes in section X, New Technology, to identify implantation of magnetically controlled growth rods. Use the same vertebra body part values as in the body systems Upper Bones and Lower Bones of the Med/Surg section.

Section **X** New Technology *Body System* **N** Bones *Operation* **S** Reposition: Moving to its normal location, or other suitable location, all or a portion of a body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 0 Lumbar Vertebra **ADD 3** Cervical Vertebra **ADD 4** Thoracic Vertebra	**0** Open **4** Percutaneous Endoscopic	**ADD 3** Magnetically Controlled Growth Rod(s)	**2** New Technology Group 2

CMS recommendation: Option 3. Create new ICD-10-PCS X codes for implantation of magnetically controlled growth rod(s).

Interim Coding Advice: Continue to report for the implantation of magnetically controlled growth rod(s) as shown above under current coding.

Application of Biologic Wound Matrix (MIRODERM™)

Issue: There is no ICD-10- PCS code to describe the application of MIRODERM™ biologic wound matrix.

New Technology Application? Yes. Miromatrix Medical, Inc., submitted a New Technology Add-on Payment application for MIRODERM™ Biologic Wound Matrix for fiscal year 2017.

Food and Drug Administration (FDA) Approval:
MIRODERM™ Wound Matrix TF K143426 was approved by the FDA on January 27, 2015 via 510(k) premarket notification.

Background: MIRODERM™, a new non-crosslinked acellular wound matrix that is derived from the porcine liver and, processed and stored in a phosphate buffered aqueous solution, is the only acellular skin substitute product that is derived from liver, keeping intact the high vascular density of the native liver. Other acellular biologic wound substitute products are derived from dermis, urinary bladder, or small intestine submucosa, all of which are thin, dense and relatively avascular tissue compared to the open and highly vascularized substrate present in the liver. Miromatrix' perfusion decellularization technology has enabled the decellularization of whole organs previously unobtainable by traditional immersion decellularization methods. Traditional decellularization involves immersing tissues in a decellularization solution which is diffusion based. This method limits the ability to fully decellularize thick, complex tissue such as the liver. Miromatrix perfusion decellularization overcomes these hurdles by facilitating rapid access to the whole organ through the native vasculature by cannulating the vasculature and perfusing a mild detergent solution through the native capillaries. Most cells are located in close proximity to a capillary, resulting in an exponential increase in the effective surface area of the detergent and decreased time to dissolve the cellular materials as it is expelled through the venous system (as opposed to through the organ wall or capsule). MIRODERM™ is the result of a patented Perfusion Decellularization process that rapidly removes cellular material while maintaining the native architecture, vasculature and tissue structure.

MIRODERM™ is clinically indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds (abrasions, lacerations, second-degree burns, skin tears), drainage wounds, and surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence).

MIRODERM™ is positioned to completely contact the entire surface of the wound bed and extend slightly beyond all wound margins. As required, it is securely anchored to the wound site with a physician's preferred fixation method. An appropriate, primary non-adherent wound dressing is then applied over the MIRODERM matrix. A secondary dressing (multi-layer compression bandage system), total contact cast, or other appropriate dressing that will manage

the wound exudate should be applied in order to keep the MIRODERM™ matrix moist and keep all layers securely in place. Additional applications of MIRODERM™ are applied as needed until the wound closes.

Current Coding: Code skin graft procedures using biologically derived skin substitute with the appropriate body part value in root operation table 0HR, and the device value Nonautologous Tissue Substitute.

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

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

Coding Options:

Option 1. Do not create new ICD-10-PCS codes for the application of MIRODERM™ Biologic Wound Matrix. Continue using codes in table 0HR as shown above in current coding.

Option 2. Create new codes in section X, New Technology, to identify procedures that use a porcine liver derived skin substitute. Create streamlined skin body part values as shown in the

body system Skin, Subcutaneous Tissue, Fascia and Breast for simplified coding and data collection for this new technology.

Section	**X** New Technology		
Body System	**H** Skin, Subcutaneous Tissue, Fascia and Breast		
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD S Skin, Head and Neck **ADD T** Skin, Trunk **ADD V** Skin, Upper Extremity **ADD W** Skin, Lower Extremity	**X** External	**ADD L** Skin Substitute, Porcine Liver Derived	**2** New Technology Group 2

Option 3. Create new codes in section X, New Technology, to identify procedures that use a porcine liver derived skin substitute. Report the single skin body part value P Skin used in streamlined tables in the body system Skin and Breast of the Med/Surg section, (e.g., table 0SP), for simplified coding and data collection for this new technology.

Section	**X** New Technology		
Body System	**H** Skin, Subcutaneous Tissue, Fascia and Breast		
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD P Skin	**X** External	**ADD L** Skin Substitute, Porcine Liver Derived	**2** New Technology Group 2

CMS recommendation: Option 3

Interim Coding Advice: Continue to code skin graft procedures using biologically derived skin substitute with the appropriate body part value in root operation table 0HR, and the device value Nonautologous Tissue Substitute.

Repair of Total Anomalous Pulmonary Venous Return

Issue: The surgical procedure to repair total anomalous pulmonary venous return (TAPVR) can vary depending upon the anatomy of the pulmonary venous connections. The anatomic location of the anomalous pulmonary venous connection can be supracardiac (46%), cardiac (20%), infracardiac (23%), or mixed (11%). In a supra- and infracardiac total anomalous pulmonary venous connection, a normal pulmonary venous pathway is created by opening and forming an anastomosis between the pulmonary venous confluence or common vein and the left atrium. Currently, ICD-10-PCS does not provide qualifier values for pulmonary veins in table 021, Bypass of Heart and Great Vessels. Should new qualifier values be created?

New Technology? No.

Background: Total anomalous pulmonary venous return (TAPVR) is a type of congenital heart disease in which the four pulmonary veins that normally take oxygenated blood from the lungs to the left side of the heart do not attach normally to the left atrium. Instead, they attach to other vascular structures that prevent oxygenated blood from reaching the left side of the heart and subsequent pumping of oxygenated blood to the systemic circulation. Initial stabilization of the affected neonate may involve creation or enlargement of an atrial septal defect (ASD) to allow oxygenated blood to flow to the left side of the heart.

The most common anatomic variants of TAPVR are as follows:

1. Supracardiac: Individual pulmonary veins form a horizontal pulmonary venous confluence (HVC) that is located behind the left atrium, and most often connects to the left innominate vein by way of a vertical vein.
2. Infracardiac: Pulmonary veins form a vertical confluence that descends below the diaphragm and most often joins the portal vein (PV). Pulmonary venous blood then drains into the inferior vena cava (IVC) via the ductus venosus or the hepatic sinusoids.
3. Cardiac: Pulmonary veins connect to the posterior aspect of the coronary sinus (CS) or to the back wall of the right atrium.
4. Mixed: Pulmonary veins have multiple connections that enter at two or more of the above levels. For example, the left pulmonary veins (LPV) may connect to the left innominate vein (LIV), while the right pulmonary veins (RPV) may connect with the CS.

Current Coding: The repair of TAPVR would currently be coded to the root operation Repair in table 02Q, Repair of Heart and Great Vessels with body part values S and T for pulmonary veins.

Section **0** Medical and Surgical *Body System* **2** Heart and Great Vessels *Operation* **Q** Repair: Restoring, to the extent possible, a body part to its normal anatomic structure and function			
Body Part	*Approach*	*Device*	*Qualifier*
S Pulmonary Vein, Right **T** Pulmonary Vein, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

Coding Options:

Option 1. Do not create new qualifier values. Continue to use the root operation Repair as shown above.

Option 2. Add new qualifier values S Pulmonary Vein, Right, T Pulmonary Vein, Left, and U Pulmonary Vein, Confluence to table 021, Bypass of Heart and Great Vessels to enable the ability to correctly describe a bypass from the appropriate pulmonary vein qualifier value to the appropriate body part value.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
7 Atrium, Left **V** Superior Vena Cava	**0** Open **4** Percutaneous Endoscopic	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **ADD S** Pulmonary Vein, Right **ADD T** Pulmonary Vein, Left **ADD U** Pulmonary Vein, Confluence

CMS Recommendation: Option 2.

Interim Coding Advice: Continue to code with the root operation Repair as shown in current coding.

ICD-10 GEMs FY2017 Version Update

Update Summary

The updated FY2017 General Equivalence Mappings (GEMs) are posted for public comment. All changes to date resulting from public comment and internal review have been incorporated into the FY2017 GEMs. The types of changes made include

- Cluster translations expanded for completeness
- Single entries expanded to better meet inclusion criteria
- Entries revised to better meet inclusion criteria

All changes meeting inclusion criteria were included in the updated files. Documentation for general and technical users of the GEMs is posted with the GEMs files.

In particular, the GEMs Documentation for Technical Users

- Specifies GEMs entry inclusion criteria and provides examples
- Discusses GEMs flags in detail and provides examples
- Answers other frequently asked technical questions
- Discusses translation rules for obstetrics and angioplasty

Examples of updated GEMs entries are provided in the following pages. Diagnosis GEMs entries are first, followed by procedure GEMs entries.

DIAGNOSIS GEMs

Public comment:

ICD-10-CM to ICD-9-CM GEM entry for "Postsurgical lymphedema"

2016 entry	Updated 2017 entry	Comment
I97.89 Other postprocedural complications and disorders of the circulatory system, not elsewhere classified To/From **997.1** Cardiac complications, not elsewhere classified	**I97.89** Other postprocedural complications and disorders of the circulatory system, not elsewhere classified To/From **997.1** Cardiac complications, not elsewhere classified **OR** **997.99** Complications affecting other specified body systems, not elsewhere classified	The complete meaning of the ICD-10-CM code per the index includes postsurgical lymphedema (elephantiasis). Per the ICD-9-CM index, postsurgical lymphedema and postsurgical elephantiasis are included in 997.99. The entry will also be updated in the ICD-9-CM to ICD-10-CM GEM.

Public comment:

ICD-10-CM to ICD-9-CM GEM entry for "Osteopenia"

2016 entry	Updated 2017 entry	Comment
Example **M85.8[0-9]** (24 codes) Other specified disorders of bone density and structure, unspecified site To **733.99** Other disorders of bone and cartilage	**Example** **M85.8[0-9]** (24 codes) Other specified disorders of bone density and structure, unspecified site To **733.90** Disorder of bone and cartilage, unspecified **OR** **733.99** Other disorders of bone and cartilage	The updated entry is a more complete translation of the condition specified in the ICD-10-CM codes. Per the ICD-10-CM index, both osteopenia and osteosclerosis are included in this subcategory. Per the ICD-9-CM index, code 73390 includes osteopenia and code 73399 includes Sclerosis>> Bone. The entry will also be updated in the ICD-9-CM to ICD-10-CM GEM.

Internal review:

ICD-9-CM to ICD-10-CM GEM entry for "unspecified bone/cartilage disorder"

2016 entry	Updated 2017 entry	Comment
733.90 Disorder of bone and cartilage, unspecified To **M89.9** Disorder of bone, unspecified **OR** **M94.9** Disorder of cartilage, unspecified	**733.90** Disorder of bone and cartilage, unspecified To **M85.9** Disorder of bone density and structure, unspecified **OR** **M89.9** Disorder of bone, unspecified **OR** **M94.9** Disorder of cartilage, unspecified	The updated entry is a more complete entry for this "unspecified" ICD-9-CM code, which includes unspecified disorders of bone density and structure.

Public comment:

ICD-9-CM to ICD-10-CM GEM entry for "Common variable immunodeficiency"

2016 entry	Updated 2017 entry	Comment
279.06 Common variable immunodeficiency To **D83.8** Other common variable immunodeficiencies **OR** **D83.9** Common variable immunodeficiency, unspecified	**279.06** Common variable immunodeficiency To **D83.1** Common variable immunodeficiency with predominant immunoregulatory T-cell disorders	The updated entry is a more accurate translation of the condition specified in the ICD-9-CM code. The entry will also be changed in the ICD-10-CM to ICD-9-CM GEM.

Internal review:

ICD-9-CM to ICD-10-CM GEM entry for "T-cell defect immunodeficiency"

2016 entry	Updated 2017 entry	Comment
279.10 Immunodeficiency with predominant T-cell defect, unspecified To **D83.1** Common variable immunodeficiency with predominant immunoregulatory T-cell disorders	**279.06** Common variable immunodeficiency To **D84.8** Other specified immunodeficiencies	The updated entry is a more accurate translation of the condition specified in the ICD-9-CM code. The entry will also be changed in the ICD-10-CM to ICD-9-CM GEM.

Internal review:

ICD-9-CM to ICD-10-CM GEM entry for "other cell-mediated immunodeficiency"

2016 entry	Updated 2017 entry	Comment
279.19 Other deficiency of cell-mediated immunity To **D80.8** Other immunodeficiencies with predominantly antibody defects	**279.19** Other deficiency of cell-mediated immunity To **D84.8** Other specified immunodeficiencies	The updated entry is a more accurate translation of the condition specified in the ICD-9-CM code. The entry will also be changed in the ICD-10-CM to ICD-9-CM GEM.

Internal review:

ICD-10-CM to ICD-9-CM GEM entry for "Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia"

2016 entry	Updated 2017 entry	Comment
D80.6 Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia To **279.19** Other deficiency of cell-mediated immunity	**D80.6** Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia To **279.09** Other deficiency of humoral immunity	The updated entry is a more accurate translation of the condition specified in the ICD-10-CM codes. The entry will also be updated in the ICD-9-CM to ICD-10-CM GEM.

Internal review:

ICD-10-CM to ICD-9-CM GEM entry for "unspecified immunodeficiency with predominantly antibody defects"

2016 entry	Updated 2017 entry	Comment
D80.9 Immunodeficiency with predominantly antibody defects, unspecified To	**D80.9** Immunodeficiency with predominantly antibody defects, unspecified To	The updated entry is a more accurate translation of the condition specified in the ICD-10-CM codes. The entry will

2016 entry	Updated 2017 entry	Comment
279.19 Other deficiency of cell-mediated immunity	**279.09** Other deficiency of humoral immunity	also be updated in the ICD-9-CM to ICD-10-CM GEM.

Public comment:

ICD-9-CM to ICD-10-CM GEM entry for "Dermatophytosis of the body"

2016 entry	Updated 2017 entry	Comment
110.5 Dermatophytosis of the body To **B35.5** Tinea imbricata	**110.5** Dermatophytosis of the body To **B35.4** Tinea corporis **OR** **B35.5** Tinea imbricata	The updated entry is a more complete translation of the condition specified in the ICD-9-CM code, per the ICD-9-CM index.

Internal review:

ICD-10-CM to ICD-9-CM GEM entry for "Unspecified obstructive/reflex uropathy"

2016 entry	Updated 2017 entry	Comment
N13.9 Obstructive and reflux uropathy, unspecified To **59.29** Urinary calculus, unspecified	**N13.9** Obstructive and reflux uropathy, unspecified To **59.29** Urinary calculus, unspecified	Flagging error only. The entry was marked as a combination entry (10112) and should be marked as a single entry (10000).

Internal review:

ICD-9-CM to ICD-10-CM GEM entry for "Cortex contusion/laceration w/o LOC"

2016 entry	Updated 2017 entry	Comment
Example **851.[0,2]1** Cortex (cerebral) contusion without mention of open intracranial wound, with no loss of consciousness (2 codes) To **S06.339A** Contusion and laceration of cerebrum, unspecified, with loss of consciousness of unspecified duration, initial encounter	**Example** **851.[0,2]1** Cortex (cerebral) contusion without mention of open intracranial wound, with no loss of consciousness (2 codes) To **S06.330A** Contusion and laceration of cerebrum, unspecified, without loss of consciousness, initial encounter	Typographical error.

Internal review:

ICD-9-CM to ICD-10-CM GEM entry for "intracranial contusion/laceration w/ concussion"

2016 entry	Updated 2017 entry	Comment
Example **851.[0-3,8,9]9** Cortex (cerebral) contusion without mention of open intracranial wound, with concussion, unspecified (6 codes) To **S06.330A** Contusion and laceration of cerebrum, unspecified, without loss of consciousness, initial encounter **OR** **S06.339A** Contusion and laceration of cerebrum, unspecified, with loss of consciousness of unspecified duration, initial encounter	**Example** **851.[0,1,2,3,8,9]9** Cortex (cerebral) contusion without mention of open intracranial wound, with concussion, unspecified (6 codes) To **S06.330A** Contusion and laceration of cerebrum, unspecified, without loss of consciousness, initial encounter	Typographical error.

Internal review:

ICD-9-CM to ICD-10-CM GEM entry for "Cerebellar/brain stem contusion w/ concussion"

2016 entry	Updated 2017 entry	Comment
851.49 Cerebellar or brain stem contusion without mention of open intracranial wound, with concussion, unspecified To **S06.380A** Contusion, laceration, and hemorrhage of brainstem without loss of consciousness, initial encounter **OR** **S06.389A** Contusion, laceration, and hemorrhage of brainstem with loss of consciousness of unspecified duration, initial encounter	**851.49** Cerebellar or brain stem contusion without mention of open intracranial wound, with concussion, unspecified To **S06.370A** Contusion, laceration, and hemorrhage of cerebellum without loss of consciousness, initial encounter **OR** **S06.380A** Contusion, laceration, and hemorrhage of brainstem without loss of consciousness, initial encounter	Typographical error.

Public comment:

ICD-9-CM to ICD-10-CM GEM entry for "Dermatophytosis of the body"

2016 entry	Updated 2017 entry	Comment
270.6 Disorders of urea cycle metabolism From/to **E72.20** Disorder of urea cycle metabolism, unspecified **OR** **E72.22** Arginosuccinic aciduria **OR** **E72.23** Citrullinemia **OR** **E72.29** Other disorders of urea cycle metabolism	**110.5** Dermatophytosis of the body To **B35.4** Tinea corporis **OR** **B35.5** Tinea imbricata	The updated entry is a more complete translation of the condition specified in the ICD-9-CM code, per the ICD-9-CM index.

Internal review:

ICD-9-CM to ICD-10-CM GEM entry for "Cerebellar/brain stem laceration w/ concussion"

2016 entry	Updated 2017 entry	Comment
Example **851.[567]9** Cerebellar or brain stem laceration without mention of open intracranial wound, with concussion, unspecified To **S06.370A** Contusion, laceration, and hemorrhage of cerebellum without loss of consciousness, initial encounter **OR** **S06.379A** Contusion, laceration, and hemorrhage of cerebellum with loss of consciousness of unspecified duration, initial encounter **OR** **S06.380A** Contusion, laceration, and hemorrhage of brainstem without loss of consciousness, initial encounter **OR** **S06.389A** Contusion, laceration, and hemorrhage of brainstem with loss of consciousness of unspecified duration, initial encounter	**Example** **851.[567]9** Cerebellar or brain stem laceration without mention of open intracranial wound, with concussion, unspecified To **S06.370A** Contusion, laceration, and hemorrhage of cerebellum without loss of consciousness, initial encounter **OR** **S06.380A** Contusion, laceration, and hemorrhage of brainstem without loss of consciousness, initial encounter	Typographical error.

Public comment:

ICD-9-CM to ICD-10-CM GEM entry for "Open fracture of fibula with tibia"

2016 entry	Updated 2017 entry	Comment
Example **823.32** Open fracture of shaft of fibula with tibia To **S82.201B** Unspecified fracture of shaft of right tibia, initial encounter for open fracture type I or II **AND** **S82.402B** Unspecified fracture of shaft of left fibula, initial encounter for open fracture type I or II **OR** **S82.401B** Unspecified fracture of shaft of right fibula, initial encounter for open fracture type I or II **AND** **S82.202B** Unspecified fracture of shaft of left tibia, initial encounter for open fracture type I or II	**Example** **823.32** Open fracture of shaft of fibula with tibia To **S82.201B** Unspecified fracture of shaft of right tibia, initial encounter for open fracture type I or II **AND** **S82.401B** Unspecified fracture of shaft of right fibula, initial encounter for open fracture type I or II **OR** **S82.202B** Unspecified fracture of shaft of left tibia, initial encounter for open fracture type I or II **AND** **S82.402B** Unspecified fracture of shaft of left fibula, initial encounter for open fracture type I or II	Typographical error. The combination flags were set incorrectly.

Public comment:

ICD-9-CM to ICD-10-CM GEM entry for "Osteoradionecrosis"

2016 entry	Updated 2017 entry	Comment
526.89 Other specified diseases of the jaws To **M27.8** Other specified diseases of jaws	**526.89** Other specified diseases of the jaws To **M27.8** Other specified diseases of jaws **OR** **M27.2** Inflammatory conditions of jaws	The updated entry is a more complete translation of the condition specified in the ICD-9-CM code. Osteoradionecrosis is included in ICD-9-CM code 526.89 and included in ICD-10-CM code M.27.2. The entry will also be changed in the ICD-10-CM to ICD-9-CM GEM.

Internal review:

ICD-10-CM to ICD-9-CM GEM entry for "Tuberculosis of spine"

2016 entry	Updated 2017 entry	Comment
Example **A18.01** Tuberculosis of spine To **015.00** Tuberculosis of vertebral column, unspecified **AND** **737.40** Curvature of spine, unspecified, associated with other conditions	**Example** **A18.01** Tuberculosis of spine To **015.00** Tuberculosis of vertebral column, unspecified **AND** **737.40** Curvature of spine, unspecified, associated with other conditions **OR** **015.00** Tuberculosis of vertebral column, unspecified **AND** **737.42** Lordosis associated with other conditions	The updated entry is a more complete translation of the condition specified in the ICD-9-CM code. As specified in the ICD-10-CM index, tuberculosis of the spine includes tuberculous lordosis.

PROCEDURE GEMs

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "Removal of cervical cerclage"

2016 entry	Updated 2017 entry	Comment
Example **69.96** Removal of cerclage material from cervix To **0UPD[03478]CZ** Removal of Extraluminal Device from Uterus and Cervix, Via Natural or Artificial Opening (5 codes)	**Example** **69.96** Removal of cerclage material from cervix To **0UPD7CZ** Removal of Extraluminal Device from Uterus and Cervix, Via Natural or Artificial Opening	The updated entry is a more accurate translation of the procedure specified in the ICD-9-CM code. The entry will also be changed in the ICD-10-PCS to ICD-9-CM GEM.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "implantable pressure sensor insertion"

2016 entry	Updated 2017 entry	Comment
Example **38.26** Insertion of implantable pressure sensor without lead for intracardiac or great vessel hemodynamic monitoring To/From **02H[467LSTV][034]0Z** Insertion of Pressure Sensor Monitoring Device into Coronary Vein, Open Approach (5 codes)	**Example** **38.26** Insertion of implantable pressure sensor without lead for intracardiac or great vessel hemodynamic monitoring To **02H[PQ][034]0Z** Insertion of Pressure Sensor Monitoring Device into Right Pulmonary Artery, Percutaneous Approach (6 codes)	Change request is from the manufacturer of an implantable pressure sensor, for purposes of correct coding in ICD-10-PCS. Currently ICD-9 code 38.26 does not capture any other procedure besides the insertion of the manufacturer's device (CardioMEMS pressure sensor monitor). The entry will also be changed in the ICD-10-PCS to ICD-9-CM GEM.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "pulmonary artery pressure monitoring"

2016 entry	Updated 2017 entry	Comment
Example **89.63** Pulmonary artery pressure monitoring To/From **4A133[5BJ]3** Monitoring of Arterial Flow, Pulmonary, Percutaneous Approach (3 codes)	**Example** **89.63** Pulmonary artery pressure monitoring To/From **02HP[034]2Z** Insertion of Monitoring Device into Pulmonary Trunk, Percutaneous Approach (3 codes)	The updated entry is consistent with ICD-9-CM index entries, with ICD-10-PCS Reference Manual FY2016 version, p. 67, exercise 6, and Coding Clinic 3Q 2015 p. 35. Index entries referring to 89.63: Catheterization > Swan-Ganz (pulmonary) Insertion > catheter > Swan-Ganz (pulmonary) Insertion > Swan-Ganz catheter (pulmonary) Monitoring > pulmonary artery > wedge. The entry will also be changed in the ICD-10-PCS to ICD-9-CM GEM.

Internal review:

ICD-10-PCS to ICD-9-CM GEM entry for "pulmonary artery measurement/monitoring"

2016 entry	Updated 2017 entry	Comment
Example **4A[01]3[034][5BJ]3** Monitoring of Arterial Flow, Pulmonary, Percutaneous Approach (12 codes) To	**4A[01]3[034][5BJ]3** Monitoring of Arterial Flow, Pulmonary, Percutaneous Approach (12 codes) To	The updated entry is a more accurate translation of the procedure specified in the ICD-10-PCS codes. The entry will also be updated in the ICD-9-CM to ICD-10-CM GEM.

2016 entry	Updated 2017 entry	Comment
89.63 Pulmonary artery pressure monitoring	**89.59** Other nonoperative cardiac and vascular measurements	

Public comment:

ICD-10-PCS to ICD-9-CM GEM entry for "Intraoperative knee joint monitoring"

2016 entry	Updated 2017 entry	Comment
Example **XR2[GH]021** Monitoring of Right Knee Joint using Intraoperative Knee Replacement Sensor, Open Approach, New Technology Group 1 (2 codes) To **NoI9**	**Example** **XR2[GH]021** Monitoring of Right Knee Joint using Intraoperative Knee Replacement Sensor, Open Approach, New Technology Group 1 (2 codes) To **NoI9**	Flagging error only. The "No Map" flag was 0 and it should have been 1.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "Insertion of intercostal drainage catheter"

2016 entry	Updated 2017 entry	Comment
Example **34.04** Insertion of intercostal catheter for drainage To **0W9[9B][04]ZZ** Drainage of Right Pleural Cavity, Percutaneous Endoscopic Approach (4 codes)	**Example** **34.04** Insertion of intercostal catheter for drainage To **0W9[9B]3ZZ** Drainage of Right Pleural Cavity, Percutaneous Endoscopic Approach (4 codes)	The updated entry is a more accurate translation of the procedure specified in the ICD-9-CM code. The entry will also be changed in the ICD-10-PCS to ICD-9-CM GEM.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "Thoracoscopic pleural cavity drainage"

2016 entry	Updated 2017 entry	Comment
Example **34.06** Thoracoscopic drainage of pleural cavity To **0W9[9B][34]0Z** Drainage of Right Pleural Cavity with Drainage Device, Percutaneous Endoscopic Approach (4 codes)	**Example** **34.06** Thoracoscopic drainage of pleural cavity To **0W9[9B]30Z** Drainage of Right Pleural Cavity with Drainage Device, Percutaneous Endoscopic Approach (2 codes)	The updated entry is a more accurate translation of the procedure specified in the ICD-9-CM code. The entry will also be changed in the ICD-10-PCS to ICD-9-CM GEM.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "Other incision of pleura"

2016 entry	Updated 2017 entry	Comment
Example **34.09** Other incision of pleura To **0W9[9B][04]ZZ** Drainage of Right Pleural Cavity, Percutaneous Endoscopic Approach (4 codes)	**Example** **34.09** Other incision of pleura To **0B9[NP][04]ZZ** Drainage of Right Pleura, Percutaneous Endoscopic Approach (4 codes)	The updated entry is a more accurate translation of the procedure specified in the ICD-9-CM code. The entry will also be changed in the ICD-10-PCS to ICD-9-CM GEM.

Public comment:

ICD-10-PCS to ICD-9-CM GEM entry for "Percutaneous upper artery monitoring device"

2016 entry	Updated 2017 entry	Comment
03HY33Z Insertion of Monitoring Device into Upper Artery, Percutaneous Approach To **38.03** Incision of upper limb vessels	**03HY33Z** Insertion of Monitoring Device into Upper Artery, Percutaneous Approach To **38.91** Arterial catheterization	The updated entry is a more accurate translation of the procedure specified in the ICD-10-PCS code. The entry will also be changed in the ICD-10-CM to ICD-9-CM GEM.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "insertion of loop recorder"

2016 entry	Updated 2017 entry	Comment
Example **37.79** Revision or relocation of cardiac device pocket To **0JWT[03]PZ** Revision of Cardiac Rhythm Related Device in Trunk Subcutaneous Tissue and Fascia, Open Approach (2 codes)	**Example** **37.79** Revision or relocation of cardiac device pocket To **0JWT[03]2Z** Revision of Monitoring Device in Trunk Subcutaneous Tissue and Fascia, Open Approach (2 codes) **OR** To **0JH6[03]2Z** Insertion of Monitoring Device into Chest Subcutaneous Tissue and Fascia, Open Approach (2 codes)	The updated entry is a more complete translation of the procedure specified in the ICD-9-CM code, per the ICD-9-CM index and instructional notes for the source system code. According to the requester, the ICD-10-PCS code represents correct coding for the insertion of this device.

Public comment:

ICD-10-PCS to ICD-9-PCS GEM entry for "endovascular extirpation"

2016 entry	Updated 2017 entry	Comment
Example **03C53ZZ** Extirpation of Matter from Right Axillary Artery, Percutaneous Approach (138 codes) To **38.03** Incision of vessel, upper limb vessels	**Example** **03C53ZZ** Extirpation of Matter from Right Axillary Artery, Percutaneous Approach (138 codes) To **39.79** Other endovascular procedures on other vessels	The updated entry is a more accurate translation of the percutaneous approach specified in the ICD-PCS-CM code. The entry will also be changed in the ICD-9-CM to ICD-10-PCS GEM. In addition, GEMs entries for percutaneous extirpation of vessel codes translating to open incision codes in ICD-9-CM codes 38.00 and 38.03-38.09 will be similarly updated.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "transcatheter embolization for GI hemorrhage"

2016 entry	Updated 2017 entry	Comment
44.44 Transcatheter embolization for gastric or duodenal bleeding To **04L23DZ** Occlusion of Gastric Artery with Intraluminal Device, Percutaneous Approach	**Example** **44.44** Transcatheter embolization for gastric or duodenal bleeding To **04L[2345]3DZ** Occlusion of Gastric Artery with Intraluminal Device, Percutaneous Approach (4 codes) **OR** **06L[145]3DZ** Occlusion of Splenic Vein with Intraluminal Device, Percutaneous Approach (3 codes)	The updated entry is a more complete translation of the procedure specified in the ICD-9-CM code per the entries in the ICD-9-CM index. The entry will also be changed in the ICD-10-PCS to ICD-9-CM GEM.

Public comment:

ICD-10-PCS to ICD-9-CM GEM entry for "ligation of esophageal varices"

2016 entry	Updated 2017 entry	Comment
Example **06L3[034][CD]Z** Occlusion of Esophageal Vein with Extraluminal Device, Open Approach (6 codes) To	**Example** **06L3[034][CD]Z** Occlusion of Esophageal Vein with Extraluminal Device, Open Approach (6 codes) To	The updated entry is a more complete translation of the procedure specified in the ICD-10-PCS code. The entry will also be changed in the ICD-9-CM to ICD-10-PCS GEM.

2016 entry	Updated 2017 entry	Comment
38.87 Other surgical occlusion of vessels, abdominal veins	**38.87** Other surgical occlusion of vessels, abdominal veins OR **42.91** Ligation of esophageal varices	

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "endoscopic biliary duct dilation"

2016 entry	Updated 2017 entry	Comment
Example **51.84** Endoscopic dilation of ampulla and biliary duct To **0F7[5689C]8ZZ** Dilation of Right Hepatic Duct, Via Natural or Artificial Opening Endoscopic (5 codes)	**Example** **51.84** Endoscopic dilation of ampulla and biliary duct To **0F7[5689CDF]8ZZ** Dilation of Right Hepatic Duct, Via Natural or Artificial Opening Endoscopic (7 codes) **OR** To **0F9[5689CDF]8ZZ** Drainage of Right Hepatic Duct, Via Natural or Artificial Opening Endoscopic (7 codes)	The updated entry is a more complete translation of the procedure specified in the ICD-9-CM code, per the ICD-9-CM index and instructional notes for the source system code. The entry will also be changed in the ICD-10-PCS to ICD-9-CM GEM.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "endoscopic control of esophageal bleeding"

2016 entry	Updated 2017 entry	Comment
Example **42.33** Endoscopic excision or destruction of lesion or tissue of esophagus To **0D[B5]5[48]ZZ** Destruction of Esophagus, Via Natural or Artificial Opening Endoscopic (4 codes) **OR** **0W3P8ZZ** Control Bleeding in Gastrointestinal Tract, Via Natural or Artificial Opening Endoscopic **OR** **3E0G8TZ** Introduction of Destructive Agent into Upper GI,	**Example** **42.33** Endoscopic excision or destruction of lesion or tissue of esophagus To **0D[B5]5[48]ZZ** Destruction of Esophagus, Via Natural or Artificial Opening Endoscopic (4 codes) **OR** **06L[34]3[CDZ]Z** Occlusion of Esophageal Vein with Extraluminal Device, Percutaneous Approach (6 codes) **OR** **0W3P8ZZ** Control Bleeding in Gastrointestinal Tract, Via	The updated entry is a more complete translation of the procedure specified in the ICD-9-CM code, per the ICD-9-CM index and instructional notes for the source system code. The entry will also be changed in the ICD-10-PCS to ICD-9-CM GEM.

2016 entry	Updated 2017 entry	Comment
Via Natural or Artificial Opening Endoscopic	Natural or Artificial Opening Endoscopic **OR** **3E0G8TZ** Introduction of Destructive Agent into Upper GI, Via Natural or Artificial Opening Endoscopic	

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "excision of retroperitoneum"

2016 entry	Updated 2017 entry	Comment
Example **54.4** Excision or destruction of peritoneal tissue To **0D[B5][STVW][034]ZZ** Destruction of Greater Omentum, Open Approach (28 codes)	**Example** **54.4** Excision or destruction of peritoneal tissue To **0D[B5][STVW][034]ZZ** Destruction of Greater Omentum, Open Approach (28 codes) **OR** **0WBH[034]ZZ** Excision of Retroperitoneum, Open Approach (3 codes)	The updated entry is a more complete translation of the procedure specified in the ICD-9-CM code, per the ICD-9-CM index and instructional notes for the source system code. The entry will also be changed in the ICD-10-PCS to ICD-9-CM GEM.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "obstetric laceration repair of anus"

2016 entry	Updated 2017 entry	Comment
Example **75.62** Repair of current obstetric laceration of rectum and sphincter ani To **0DQ[PR]^ZZ** Repair Rectum, Open Approach (8 codes)	**Example** **75.62** Repair of current obstetric laceration of rectum and sphincter ani To **0DQ[PR]^ZZ** Repair Anal Sphincter, Open Approach (8 codes) **OR** **0DQQ[03478]ZZ** Repair Anus, Open Approach (5 codes)	The updated entry is a more complete translation of the procedure specified in the ICD-9-CM code, per the ICD-9-CM index for the source system code.

Public comment:

ICD-10-PCS to ICD-9-CM GEM entry for "laparoscopic excision of stomach"

2016 entry	Updated 2017 entry	Comment
0DB64ZZ Excision of Stomach, Percutaneous Endoscopic Approach To **43.41** Endoscopic excision or destruction of lesion or tissue of stomach	**0DB64ZZ** Excision of Stomach, Percutaneous Endoscopic Approach To **43.41** Endoscopic excision or destruction of lesion or tissue of stomach **OR** To **43.89** Open and other partial gastrectomy	The updated entry is a more complete translation of the procedure specified in the ICD-10-PCS code. The entry will also be changed in the ICD-9-CM to ICD-10-PCS GEM.

Public comment:

ICD-10-PCS to ICD-9-CM GEM entry for "burr hole intracranial drainage"

2016 entry	Updated 2017 entry	Comment
Example To **009[1246][34][0Z]Z** Drainage of Cerebral Ventricle, Percutaneous Approach (16 codes) **OR** **0W91[34][0Z]Z** Drainage of Cranial Cavity, Percutaneous Approach (4 codes) To **01.09** Other cranial puncture	**Example** To **009[1246][34][0Z]Z** Drainage of Cerebral Ventricle, Percutaneous Approach (16 codes) **OR** **0W91[34][0Z]Z** Drainage of Cranial Cavity, Percutaneous Approach (4 codes) To **01.09** Other cranial puncture **OR** **01.24** Other craniotomy	The updated entry is a more complete translation of the procedure specified in the ICD-10-PCS code. ICD-9-CM code 01.24 includes burr hole drainage per the ICD-9-CM index. The entry will also be changed in the ICD-9-CM to ICD-10-PCS GEM.

Public comment:

ICD-10-PCS to ICD-9-CM GEM entry for "burr hole intracranial drainage, cont."

2016 entry	Updated 2017 entry	Comment
Example To **0095[34][0Z]Z** Drainage of Subarachnoid Space, Percutaneous Approach (4 codes) To **01.01** Cisternal puncture	**Example** To **0095[34][0Z]Z** Drainage of Subarachnoid Space, Percutaneous Approach (4 codes) To **01.01** Cisternal puncture	The updated entry is a more complete translation of the procedure specified in the ICD-10-PCS code. ICD-9-CM code 01.24 includes burr hole drainage per the ICD-9-CM index. The entry will also be

2016 entry	Updated 2017 entry	Comment
	OR **01.24** Other craniotomy	changed in the ICD-9-CM to ICD-10-PCS GEM.

Public comment:

ICD-10-PCS to ICD-9-CM GEM entry for "Percutaneous extirpation, intracranial artery"

2016 entry	Updated 2017 entry	Comment
03CG3ZZ Extirpation of Matter from Intracranial Artery, Percutaneous Approach To **00.62** Percutaneous angioplasty of intracranial vessel(s) **OR** **17.54** Percutaneous atherectomy of intracranial vessel(s) **OR** **39.74** Endovascular removal of obstruction from head and neck vessel(s) **AND** **00.40** Procedure on single vessel	**03CG3ZZ** Extirpation of Matter from Intracranial Artery, Percutaneous Approach To **39.74** Endovascular removal of obstruction from head and neck vessel(s) **AND** **00.40** Procedure on single vessel	The updated entry is a more accurate mapping of the procedure specified in the ICD-10-PCS code per the root operation definition. Per the requester, the only clinically correct translation of Extirpation for the intracranial artery is 39.74. The entry will also be changed in the ICD-9-CM to ICD-10-PCS GEM.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "implantation of heart replacement system"

2016 entry	Updated 2017 entry	Comment
Example **37.52** Implantation of total internal biventricular heart replacement system To **02HA[034]QZ** Insertion of Implantable Heart Assist System into Heart, Open Approach (3 codes)	**Example** **37.52** Implantation of total internal biventricular heart replacement system To **02RK0JZ** Replacement of Right Ventricle with Synthetic Substitute, Open Approach **AND** **02RL0JZ** Replacement of Left Ventricle with Synthetic Substitute, Open Approach	According to the requester, the updated entry is a more accurate translation of the procedure specified in the ICD-9-CM code, where heart replacement system is clearly distinguished from implantable heart assist system per the ICD-9-CM index and instructional notes.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "revision of heart replacement system"

2016 entry	Updated 2017 entry	Comment
Example **37.54** Replacement or repair of other implantable component of (total) replacement heart system To **02WA[034]QZ** Revision of Implantable Heart Assist System in Heart, Open Approach (3 codes)	**Example** **37.54** Replacement or repair of other implantable component of (total) replacement heart system To **02WA0JZ** Revision of Synthetic Substitute in Heart, Open Approach	According to the requester, the updated entry is a more accurate translation of the procedure specified in the ICD-9-CM code, where heart replacement system is clearly distinguished from implantable heart assist system per the ICD-9-CM index and instructional notes.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "removal of heart replacement system"

2016 entry	Updated 2017 entry	Comment
Example **37.55** Removal of internal biventricular heart replacement system To **02PA[034]QZ** Removal of Implantable Heart Assist System from Heart, Open Approach (3 codes)	**Example** **37.55** Removal of internal biventricular heart replacement system To **02PA0JZ** Revision of Synthetic Substitute from Heart, Open Approach	According to the requester, the updated entry is a more accurate translation of the procedure specified in the ICD-9-CM code, where heart replacement system is clearly distinguished from implantable heart assist system per the ICD-9-CM index and instructional notes.

Addenda

Body Part Definitions (Body Part Key) Addenda

Axis 4 Body Part

Row

Term Auditory Ossicle, Left

Term Auditory Ossicle, Right

Includes Delete Ossicular chain

Row

Term Internal Carotid Artery, Left

Term Internal Carotid Artery, Right

Includes Delete Ophthalmic artery

Row

Term Intracranial Artery

Includes Add Internal carotid artery, intracranial portion

Includes Add Ophthalmic artery

Row Add

Term Add Main Bronchus, Right

Includes Add Bronchus Intermedius

Includes Add Intermediate bronchus

Row

Term Perineum Muscle

Includes Add Levator ani muscle

Row

Term Spinal Meninges

Includes Add Filum terminale

Row

Term Thoracic Aorta

Includes Delete Bronchial artery

Row

Term Trunk Muscle, Left

Term Trunk Muscle, Right

Includes Delete Levator ani muscle

Row Add

Term Add Upper Artery

Includes Add Bronchial artery