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

Agenda

ICD-10 Coordination and Maintenance Committee
Department of Health and Human Services
Centers for Medicare & Medicaid Services
CMS Auditorium
7500 Security Boulevard
Baltimore, MD 21244-1850
ICD-10-PCS Topics
March 7, 2017

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: 1-844-396-8222; Meeting ID: 909 233 082. We encourage you to join early, as the number of phone lines is limited.
- If participating via the webcast or dialing in you do NOT need to register on-line for the meeting.

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

Note: Proposals for diagnosis code topics are scheduled for March 8, 2017 and will be led by the Centers for Disease Control (CDC). Please visit CDCs website for the Diagnosis agenda located at the following address:
http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm

Introductions and Overview	Pat Brooks

ICD-10-PCS Topics:

1. Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement Pages 10-11	Michelle Joshua Alexandra Lansky, MD Professor of Medicine, Section of Cardiology Yale School of Medicine
2. Oxidized Zirconium Polyethylene Implant for Hip and Knee Replacement Pages 12-14	Pat Brooks Dr. Mark Snyder Medical Director Orthopaedic Center of Excellence
3. Administration of ZINPLAVA (Bezlotoxumab) Pages 15-17	Michelle Joshua Stephen Marcella, MD Director, Outcomes Research Merck
4. Endovascular Cardiac Implant Pages 18-19	Mady Hue Dr. Wechsler, MD, FACC Emeritus Professor of Cardiothoracic Surgery Drexel University College of Medicine
5. Combined Thoracic Arch Replacement and Thoracic Aorta Restriction Pages 20-22	Mady Hue Scott A. LeMaire, MD Professor of Surgery and Molecular Physiology and Biophysics Vice Chair for Research, Michael E. DeBakey Department of Surgery Director of Research, Division of Cardiothoracic Surgery Aortic Disease Research Laboratory Cardiovascular Research Institute; Texas Heart Institute Baylor College of Medicine
6. Renal Replacement Therapy Pages 23-24	Michelle Joshua Mary Gellens, MD Medical Director USA/ Renal Therapeutic Area Baxter Healthcare Corporation
7. Radiotherapeutic Brain Implant Pages 25-29	Pat Brooks William A. Cavanagh III Chief Operating Officer & Chief Scientific Officer

	IsoRay Medical, Inc.
8. Occlusion of Left Atrial Appendage Pages 30-31	Mady Hue Justin Noznesky, SVP Marketing and Business Development, AtriCure Michael Ferguson, PhD, Senior Director, Health Economics, AtriCure Dr. Sean Patrick Whalen, MD Department Cardiology Wake Forest Baptist Medical Center
9. Spinal Fusion with Radiolucent Interbody Fusion Device Pages 32-34	Mady Hue Ken Gall on behalf of Vertera, Inc
10. Administration of VYXEOS Pages 35-37	Michelle Joshua Margaret W. Tumas, DVM Director, Medical Affairs, Oncology Jazz Pharmaceuticals, Inc
11. Administration of KTE-C19 (axicabtagene ciloleucel) Pages 38-41	Michelle Joshua Elizabeth Faust, PhD Vice President, Medical Affairs Kite Pharma
12. Congenital Anomaly Procedures Pages 42-51 a. Resection of the Left Ventricular Outflow Tract Obstruction and/or Subaortic Membrane (Stenosis) b. Fontan Completion Procedure, Stage II c. Alfieri Stitch Valvuloplasty d. Ligation of Main Pulmonary Artery/ Pulmonary Trunk e. Fluoroscopy of Pulmonary Trunk/ Main Pulmonary Artery f. Release of Myocardial Bridge	Mady Hue Amber Davidson, RHIT, CCS, CCS-P Specialist, Health Information Data
13. Magnetically Controlled Growth Rods Pages 52-54	Michelle Joshua Dr. Suken Shah on behalf of NuVasive Specialized Orthopedics

14. Endovascular Intracranial Thrombectomy Procedures/Techniques Pages 55-58	Pat Brooks Paul R. Rao Ph.D. CCC CPHQ FACHE Retired/ Rehabilitation Consultant Medstar National Rehabilitation Hospital
15. Addenda and Key Updates Pages 59-67	Rhonda Butler , 3M

ICD-10 TIMELINE

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

March 7-8, 2017	ICD-10 Coordination and Maintenance Committee Meeting. Those who wish to attend the ICD-10 Coordination and Maintenance Committee meeting **must have registered for the meeting online by February 25, 2017.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building. In compliance to The Real ID Act, enacted in 2005, (http://www.dhs.gov/real-id-enforcement-brief) the following states/territories: Maine, Minnesota, Missouri, Montana and Washington State **will not** gain access into any Federal Agencies using the **above states** driver's license or ID. This means CMS visitors from these states/territories will need to provide alternative proof of identification (**such as a passport**) to gain entrance into Baltimore-based and Bethesda CMS buildings, as well as the Humphrey Building in Washington.
February 25, 2017	Because of increased security requirements, those wishing to attend the March 7-8, 2017 ICD-10 Coordination and Maintenance Committee meeting must register for the meeting online at: **https://www.cms.gov/apps/events/default.asp** **Attendees must register online by February 25, 2017; failure to do so may result in lack of access to the meeting.**
March 2017	Webcast of the March 7-8, 2017 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 March 8, 2017 ICD-10 Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm
April 1, 2017	There were no requests for ICD-10 codes to capture new diagnoses or new technology for implementation on April 1, 2017. Therefore, there will be no new ICD-10 diagnosis or procedure codes implemented on April 1, 2017.
April 7, 2017	**Deadline for receipt of public comments on proposed new codes discussed at the March 7-8, 2017 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2017.**
April 2017	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This notice will include references to the finalized FY 2018 ICD-10-CM diagnosis and ICD-10-PCS procedure codes to date. It will also include proposed revisions to the MS-DRG system based on ICD-10-CM/PCS codes on which the public may comment. The proposed rule can be accessed at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS/list.asp
June 2017	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 14, 2016	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 12-13, 2017 ICD-10 Coordination and Maintenance Committee meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.**
August 1, 2017	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, 2017.

	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 2017	Tentative agenda for the Procedure part of the September 12-13, 2017 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 12-13, 2017 ICD-10 Coordination and Maintenance Committee meeting will be posted on the NCHS webpage at - http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm
	Federal Register notice for the September 12-13, 2017 ICD-10 Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.
August 4, 2017	**On-line registration opens for the September 12-13, 2017 ICD-10 Coordination and Maintenance Committee meeting at: https://www.cms.gov/apps/events/default.asp**
September 1, 2017	Because of increased security requirements, those wishing to attend the September 12-13, 2017 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 1, 2017; failure to do so may result in lack of access to the meeting.**
September 12-13, 2017	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 1, 2017.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building.
October 2017	Webcast of the September 12-13, 2017 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, 2017 ICD-10 Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm
October 1, 2017	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, 2017	**Deadline for receipt of public comments on proposed new codes discussed at the September 12-13, 2017 ICD-10 Coordination and Maintenance Committee meetings for implementation on April 1, 2018.**
November 2017	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, 2018 will be posted on the following websites: http://www.cdc.gov/nchs/icd/icd10cm.htm http://www.cms.gov/Medicare/Coding/ICD10/
November 13, 2017	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 12-13, 2017 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2018.**

Introductions and Overview

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

Code Proposals

- ICD-10-PCS code proposals being consideration for implementation on October 1, 2017
- No final decisions made at the meeting
- CMS will describe options and recommendations to facilitate discussion
- Public can comment at meeting and send written comments

Comments on Code Proposals

- Submit written comments by
  - April 7, 2017 for codes discussed at March 7- 8, 2017 C&M meeting
- Procedure comments to CMS (new address) ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to Donna Pickett, CDC nchs@cdc.gov

Proposed and Final Rules

- April 2017 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2017 C&M meeting
- August 1, 2017 – Final rule with links to final codes to be implemented on October 1, 2017
  - Includes any additional codes approved from March 7- 8, 2017 C&M meeting

Addendum

- June 2017 – Final code updates and addendum posted
  - FY 2018 ICD-10-PCS (Procedures) http://www.cms.gov/Medicare/Coding/ICD10/index.html
  - FY 2018 ICD-10-CM (Diagnoses) http://www.cdc.gov/nchs/icd/icd10cm.htm

GEM Files

- FY 2018 ICD-10-CM and ICD-10-PCS GEMs posted at http://www.cms.gov/Medicare/Coding/ICD10/index.html
- Annual GEM updates will be posted in August 2017
- This will be the last GEM update

September 12-13, 2017 C&M Code Requests

- July 14, 2017– Deadline for submitting topics for September 12-13, 2017 C&M meeting
  - Procedure requests to CMS (new address) 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 7, 2017 for codes to be implemented on October 1, 2017
  - Procedure comments to CMS ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis comments to Donna Pickett, CDC nchsicd9@cdc.gov

ICD-10-PCS Codes Implementation

- ICD-10-PCS codes discussed today under consideration for October 1, 2017 implementation

MS-DRG Software on CMS Website

- CMS is now providing the MS-DRG Grouper and Medicare Code Editor (MCE) Version 34 software through download on CMS' website
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2017-IPPS-Final-Rule-Home-Page.html
  - See Related Links section at the bottom of the page
  - NTIS is no longer providing the software

Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement

Issue: Within ICD-10-PCS, there are no unique values to describe cerebral embolic protection for all three branches of the aortic arch (e.g., current coding describes only the innominate artery and left common carotid artery in the Body Part value), nor is a value provided to differentiate between filter and deflection devices.

New Technology Application? The applicant will apply for FY 2019 NTAP.

Food & Drug Administration (FDA) Approved? No

Background: Stroke remains a major complication for transcatheter aortic valve replacement (TAVR) procedures. Depending on definitions and severity and whether the strokes have been confirmed or initially diagnosed by neurologists, stroke rates vary anywhere between 1- 23% post TAVR. Major strokes occurring in at least 2-5% of procedures have also been reported to increase mortality by 3-fold.

Diffusion-weighted magnetic resonance imaging (DW-MRI) can detect and evaluate the location and volume of cerebral embolism with subsequent acute ischemic cerebral lesions. DW-MRI serves as a surrogate endpoint for clinical and subclinical ischemic stroke and has been used frequently to quantify thromboembolism associated with TAVR, showing that 80% or more of patients have new cerebral lesions post-procedure. New cerebral lesions found on DW-MRI have been shown to increase the risk of future stroke by 3-fold, as well as to increase risk of dementia more than 2-fold and other cognitive impairments including physical decline, impaired motility, depression, cognitive dysfunction, and both Parkinson's and Alzheimer's disease.

During TAVR procedures, embolic debris is released mainly due to device manipulations in the aortic arch or during valve replacement. Studies have shown that the histopathology of embolic debris captured during TAVR procedures consists of acute and organizing thrombus as well as valve and aortic wall tissue, myocardium, and calcified material derived most likely from either the native aortic valve leaflets or the aortic wall.

There are two basic types of devices: filter and retrograde flow devices. Filter designs allow continuous antegrade flow through the internal carotid artery during stent placement. Flow reversal designs promote flow of blood, including particulate matter, retrograde away from the internal carotid artery.

The Keystone Heart TriGuard™ Cerebral Embolic Protection Device is delivered percutaneously and is designed to cover all three cerebral branches of the aortic arch (the innominate artery, left common carotid artery and left subclavian artery) thus protecting the brain from embolic debris dislodged during endovascular procedures. The device is temporary and is a single wire nitinol (a metal alloy of nickel and titanium) frame with a pore size of 130μm designed to deflect cerebral emboli during cardiovascular procedures while allowing maximal blood flow to the brain. The

device is positioned across all 3-cerebral branches of the aorta and maintained by a stabilizer in the innominate artery. It is delivered through a 9-Fr sheath from the femoral artery thus avoiding any additional access sites used for TAVR procedure. The device is designed to be placed before any TAVR related devices and withdrawn after the completion of the valve replacement thus providing protection throughout the valve procedure.

The use of TriGuard™ device could be highly beneficial for patients undergoing TAVR to reduce brain damage, the likelihood of immediate and late neurological and/or cognitive impairments, and other disabling and costly events and conditions.

Current Coding: There is no unique ICD-10-PCS code for cerebral embolic protection of innominate, left common carotid and left subclavian arteries, used during TAVR procedures. Code the TAVR procedure only with the appropriate values from table 02R, Replacement of Heart and Great Vessels.

Coding Options

Option 1. Do not create new codes for cerebral embolic protection during transcatheter aortic valve replacement. Continue to code the procedure using the current coding as described.

Option 2. Create a new code in section X, New Technology, to identify a frame deployed in the aortic arch to cover the innominate, left common carotid and left subclavian arteries, and deflect debris that may be dislodged during a transcatheter aortic valve replacement (TAVR) procedure. A separate code for the valve replacement procedure would also be reported with this option.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**A** Assistance : Taking over a portion of a physiological function by extracorporeal means

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Innominate Artery and Left Common Carotid Artery	**3** Percutaneous	**1** Cerebral Embolic Filtration, Dual Filter	**2** New Technology Group 2
ADD X Aortic Arch	**ADD 3** Percutaneous	**ADD 3** Cerebral Embolic Deflection, Single	**ADD 3** New Technology Group 3

CMS recommendation: Option 2. Create a new code in section X, New Technology, to identify cerebral embolic protection of innominate, left common carotid and left subclavian arteries, used during TAVR procedures.

Interim Coding Advice: Continue to code the transcatheter aortic valve replacement (TAVR) procedure only.

Oxidized Zirconium on Polyethylene Bearing Surface for Hip and Knee Arthroplasty

Issue: There is not a unique code for oxidized zirconium on polyethylene implants used in total joint replacements. Oxidized zirconium on polyethylene is a type of ceramic bearing surface.

New Technology application? No.

Food & Drug Administration (FDA Clearance): Yes. Oxidized zirconium implant devices were first cleared for knees and hips in 1996 and 2002, respectively. They have been on the market for over 10 years.

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.

In the U.S., 90,000 hip and knee replacement procedures are performed each year using implants with this unique bearing surface material. Additionally, there are over a dozen arthroplasty registries around the world that track oxidized zirconium implants to determine implant survivorship, clinical outcomes, and complications.

These implants are categorized in the databases of most arthroplasty registries around the world because they are recognized as a separate and distinct device type, allowing researchers to compare the clinical performance of oxidized zirconium with other material combinations. Hip prostheses made of oxidized zirconium have been described as "ceramicised metal" by some registries, including the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), while other registries categorize the bearing surface by the brand name (OXINIUM) or oxidized zirconium. Because oxidized zirconium is the more precise chemical description of the material, we ask that the term oxidized zirconium be adopted for ICD-10-PCS purposes rather than ceramicised metal. This term is also listed on the implant packaging.

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.

Ceramic vs. Oxidized Zirconium

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 requestor states that in many ways the implants are a blend that maximizes the positive attributes of both metal and ceramic while minimizing the weakness or shortfalls. 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.

Creation of distinct ICD-10-PCS codes for oxidized zirconium on polyethylene bearing surfaces would facilitate data capture and quantification of critical outcomes differences. A unique device value 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

CMS recommendation: We are interested in receiving input from the public on these options.

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.

Administration of ZINPLAVA™ (Bezlotoxumab)

Issue: There is currently no unique ICD-10-PCS code to capture the administration of bezlotuxomab, also known as ZINPLAVA.™

New Technology Application? Yes, an application has been submitted for FY 2018.

Food & Drug Administration (FDA) Approved? Yes, The Biologics License Application (BLA) for ZINPLAVA™ received regulatory approval on October 21, 2016.

Background:

CDI Overview

Clostridium difficile diarrhea, commonly referred to as *Clostridium difficile* infection (CDI) represents the most prevalent cause of antibiotic-associated gastrointestinal infections in healthcare facilities in the developed world.[1] CDI is estimated to have caused almost half a million infections in the U.S. in 2011 and was estimated to have been associated with approximately 29,000 deaths within 30 days of the initial diagnosis.[2] Those who are at high risk for CDI recurrence include patients who: are aged >65 years of age; have a previous history of CDI; are immunocompromised; have severe CDI; are infected with 027 strain; and take antibacterial drugs. [3,4]

The primary goal of CDI treatment is resolving the current CDI episode. Antibacterial drug treatment remains the cornerstone of such treatment, as recommended by the most recent treatment guidelines. These guidelines recommend antibacterial drug therapy for first-line and second-line treatment of CDI, as well as for the treatment of C. difficile infections outside of the gastrointestinal tract.[5,6,7] A major concern with CDI is that even when treatment with an antibacterial drug of a primary infection is successful, up to 25% of patients may experience a recurrence of the infection within days or weeks of the presenting episode's symptom resolution. In these patients the risk of CDI recurrence increases to

[1] Magill SS et al. Multistate Point-Prevalence Survey of Health Care–Associated Infections. NEJM 2014;370:1198-1208.

[2] Lessa et al. Burden of Clostridium difficile Infection in the United States. NEJM 2015; 372(9):825-834.

[3] Pepin et al. Emergence of Fluoroquinolones as the Predominant Risk Factor for Clostridium difficile–Associated Diarrhea: A Cohort Study during an Epidemic in Quebec. CID 205;41(9):1254-1260.

[4] Hensgens et al. Time interval of increased risk for Clostridium difficile infection after exposure to antibiotics. JAC 2012;67(3):742-748.

[5] Cohen SH, Gerding DN, Johnson S, Kelly CP, Loo VG, et al. Clinical practice guidelines for Clostridium difficile infection in adults: 2010 update by the society for healthcare epidemiology of America (SHEA) and the infectious diseases society of America (IDSA). Infect Control Hosp Epidemiol 2010; 31(5): 431-455.

[6] Surawicz CM, Brandt LJ, Binion DG, Ananthakrishnan AN, Curry SR, et al. Guidelines for diagnosis, treatment, and prevention of Clostridium difficile infections. Am J Gastroenterol 2013; 108(4): 478-498.

[7] Debast SB, Bauer MP, Kuijper EJ. European Society of Clinical Microbiology and Infectious Diseases: update of the treatment guidance document for Clostridium difficile infection. Clin Microbiol Infect 2014; 20 Suppl 2, 1-26.

45% to 65% with subsequent CDI episodes.[8,9] Disease recurrence results from continued disruption of the gut microbiota by standard of care (SOC) CDI antibiotics (or use of other antibiotics) combined with persistence of C. difficile spores (relapse) or acquisition of new spores from the environment (reinfection). Antibacterial drug use may inhibit the gut microbiota from reestablishing itself, allowing C. difficile spores potentially to germinate and colonize the gut when the antibacterial drug is discontinued. If regrowth of *C. difficile* overtakes the reestablishment of the intestinal microbiota, then spore germination and toxin production from vegetative *C. difficile* cells may restart the cycle of CDI and the need for subsequent treatment.[10] Inadequate host adaptive antibody response to toxins also increases a patient's risk for developing CDI recurrence.[11]

Bezlotuxomab Reduces Recurrence of CDI in Adult Patients Receiving Antibacterial Drug Treatment for CDI who are at High Risk for CDI Recurrence

The challenges presented in the background section highlight the need for non-antibiotic therapies, such as bezlotuxomab, that target toxin B rather than the micro-organism itself. Unlike antibacterial drugs, bezlotuxomab is a human monoclonal antibody targeting *C. difficile* toxin B and does not affect the gastrointestinal microbiota. Bezlotuxomab neutralizes toxin B, one of the toxins responsible for the symptoms of CDI, and reduces recurrence of CDI. Bezlotuxomab is given during the course of SOC antibacterial treatment of CDI. While current antibacterial therapies are used to treat the presenting CDI episode, there is an unmet need to reduce the likelihood of recurrence. Bezlotuxomab has been shown to reduce CDI recurrence in patients when compared to those who received SOC CDI antibacterial treatment alone.

Bezlotuxomab, when added to SOC CDI antibacterial treatment, has also been shown to reduce recurrence in patients at high-risk of CDI recurrence.

Bezlotuxomab will be supplied as a 1000 mg/40 mL (25 mg/mL) solution in a single-dose vial. The recommended dose is 10 mg/kg administered as an intravenous infusion over 60 minutes as a single dose. Bezlotuxomab can be infused via a central line or peripheral catheter.

Current Coding: If desired, facilities can report the administration of bezlotuxomab with the existing ICD-10-PCS codes 3E033GC Introduction of Other Therapeutic Substance into Peripheral Vein, Percutaneous Approach and 3E043GC Introduction of Other Therapeutic Substance into Central Vein, Percutaneous Approach.

[8] McFarland LV et al. A randomized placebo-controlled trial of Saccharomyces boulardii in combination with standard antibiotics for Clostridium difficile disease. JAMA 1994;271:1913-1918.

[9] McFarland LV et al. Breaking the Cycle: Treatment Strategies for 163 Cases of Recurrent Clostridium difficile Disease. Am J Gastroenterol 2002;97:1769-1775

[10] Bagdasarian N et al. Diagnosis and treatment of Clostridium difficile in adults: a systematic review. JAMA 2015;313(4):398-408.

[11] Monaghan TM. New perspectives in Clostridium difficile disease pathogenesis. Infect Dis Clin North Am 2015;29(1):1-11.

Coding Options

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

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

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 A** Bezlotoxumab Monoclonal Antibody	**3** New Technology Group 3

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

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

Endovascular Cardiac Implant

Issue: Within ICD-10-PCS there is not a unique device value to describe the use of titanium anchor implants to repair the left ventricle internally on the interventricular septum and externally on the left ventricle (LV) following ischemic damage.

New Technology Application? No.

Background: When coronary occlusion interrupts the supply of oxygen to the heart muscle, a portion of the heart wall dies (myocardial infarction) and the myocardium whose blood supply depended on that artery turns into scar. The affected part of the heart stops pumping and an extra strain is put on remaining, functional muscle causing a destructive cascade of events, known as adverse ventricular remodeling, which ultimately leaves the previously healthy portion of the heart dilated and weak. The hearts of patients with symptomatic heart failure are typically characterized by marked left ventricular dilation and reduced LV pump strength (i.e., decreased ejection fraction). As a result, a small increase in the radius of the chamber greatly increases the amount of muscle force necessary to maintain forward cardiac output, thus reducing effective pump function. Conversely, a reduction of chamber radius reduces wall tension for a given pressure so that the remaining healthy muscle in the left heart may function more efficiently. This is further exaggerated when wall tension is converted to wall stress which involves dividing the wall tension by the wall thickness. As the heart dilates and the wall tension increases, the muscle thickness decreases resulting in large increases in wall stress. Heart oxygen consumption relates directly to wall stress.

The left heart can be repaired by numerous variations of operative techniques. The most common technique is a surgical left ventricular repair (LVR) performed using an endoventricular circular patch plasty technique. This procedure is more involved and difficult than linear aneurysmectomy which excludes only the portion of the scar on the anterior wall. Surgical LVR also repairs the scarred area of the heart involving the ventricular septum. While patients with significantly enlarged LV end-systolic and end-diastolic volume index appear to benefit most from surgical intervention, surgical LVR is very invasive, requiring left ventriculotomy on an arrested heart and cardiopulmonary bypass.

Technology: The Revivent TC™ System has been developed to provide a less invasive surgical alternative to LVR to treat heart failure symptoms due to cardiomyopathy from damage to the left heart. The Revivent TC™ Device consists of permanent titanium cardiac implants (myocardial anchors) and accessory instrumentation which are used for plication of a myocardial scar in patients needing LV repair. The Revivent TC™ System utilizes titanium anchors to create full thickness plication of the target tissue that is equivalent to surgical LVR. Anchors are implanted via jugular vein access and left mini-thoracotomy, without using cardiopulmonary bypass, sternotomy or left ventriculotomy.

The implantable components consist of a series of titanium anchor pairs (one Internal and one External in each pair) covered in polyester cloth. The anchor pairs are connected to one another by an adjustable-length tether made of poly-ether-ether ketone (PEEK). Distance between the anchors is variable, and is determined by the position of the external anchor on the tether. The Internal Anchor is hinged to facilitate low profile passage through a jugular vein catheter that is positioned perpendicular to the septum, after which it can be pivoted 90° to lie flat on the septum. The External Anchor is delivered through a mini-thoracotomy and houses a cam-based reversible locking mechanism allowing apposition of the two anchors at a continuum of positions. Once the proper distance and appropriate tether force between the two are established, excess tether length is cut and removed.

Working together, an interventional cardiologist and cardiac surgeon place the Revivent TC™ Device. Guidance is provided via simultaneous fluoroscopic and echocardiographic modalities. Echocardiographic imaging is provided by an echo cardiologist. The procedure is performed in a hybrid OR suite. The interventional cardiologist works inside the heart via an endovascular approach, while the cardiac surgeon works on the epicardium through a mini-thoracotomy incision.

Current Coding: The following ICD-10-PCS codes may be used to report repair of the left ventricle.

02QM3ZZ Repair Ventricular Septum, Percutaneous Approach
02QL0ZZ Repair Left Ventricle, Open Approach.

Coding Options

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

Option 2. Create new codes in Section X, table X2Q to identify the combined internal/external technique for repairing the left ventricle. Continue to code from table 02Q for ventricular septum.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**ADD Q** Repair: Restoring, to the extent possible, a body part to its normal anatomic structure and function

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD L Ventricle, Left	**0** Open	**ADD B** Combined Internal/External Repair Technique	**3** New Technology Group 3

CMS Recommendation: CMS is interested in hearing comments from the audience.

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

Combined Thoracic Aortic Arch Replacement and Descending Thoracic Aorta Restriction

Issue: Within ICD-10-PCS there is not a unique device value to describe a dual-purpose graft that combines thoracic aortic arch replacement with descending thoracic aorta restriction. This technology has been designed for patients with complex and diverse aortic arch disease or trauma. An IDE study is currently being conducted, therefore, the request for a new ICD-10-PCS device value to identify this technology and assess clinical outcomes is being discussed.

New Technology Application? No.

Background: Replacement of the aortic arch is technically challenging, and is associated with a high risk of perioperative death and stroke**.** According to the requester, traditionally, when disease involving the arch extends into the descending thoracic aorta, a two-stage repair is commonly necessary: the first stage entails replacement of the ascending aorta and transverse arch with what can be referred to as an Elephant Trunk (ET) graft. The second stage is generally accomplished after an interval for patient recovery and requires treatment of the descending thoracic or thoracoabdominal aorta with a separate graft.

Although the traditional ET technique has greatly facilitated the management of patients with extensive thoracic aortic disease, a second-stage operation is usually inevitable. The medical condition of the patient will dictate if and when this occurs. The objective of the second stage is to achieve exclusion of the disease and in the case of dissections promote thrombosis of the false lumen. If a second stage does not take place, then the perigraft lumen of the aorta remains perfused and thrombosis is not always achieved; this leaves the aneurysm pressurized, and often leads to fatal aortic rupture. The requester also noted that, although the ET technique creates a long, prosthetic landing zone for second-stage endovascular procedures, it is considered mobile, unsupported, and at risk of kinking.

Technology: The Thoraflex™ Hybrid is a single-use medical device, sterilized by ethylene oxide. It is preloaded into a delivery system, which is designed to offer safe delivery and accurate deployment in the patient's descending thoracic aorta. The device replaces the ascending thoracic aorta and aortic arch and restricts the descending thoracic aorta in a single procedure, performed by a cardiothoracic surgeon.

The descending thoracic aorta is restricted by placing the stented distal end of the device via an antegrade transluminal approach through the transected aorta and into the descending thoracic aorta. The device is secured by suturing an integral collar portion of the product to the distal native aortic remnant. The ascending aorta and aortic arch are then resected and replaced with the proximal, non-stented portion of the device.

The device is fully gelatin-sealed and comprises a woven polyester proximal branched arch graft pre-sewn to an anastomotic sewing collar and distal stent. The collar ensures easier anastomosis of the device to the aorta by reducing the hemodynamic traction on the anastomosis.

The product is available in a number of proximal graft sizes, distal stent diameters and currently two design configurations. The first configuration is the Thoraflex™ Hybrid Plexus Graft, a multi-branch design that enables individual aortic arch branch reconstruction. The second configuration is the Thoraflex™ Hybrid Ante-Flo™ design, allowing the island technique where the aortic arch branches and associated aortic tissue are reattached as a patch to an opening cut in the

graft. These alternative techniques offer different surgical strategies for patient treatment. Early registry data suggests implantation of the Thoraflex™ Hybrid device has resulted in excellent outcomes and beneficial aortic remodelling during follow up.

Current Coding: The following ICD-10-PCS codes are used to report replacement of the thoracic aorta, ascending/arch and restriction of the descending thoracic aorta with a graft.

02RX0JZ Replacement of Thoracic Aorta, Ascending/Arch with Synthetic Substitute, Open Approach

02VW0DZ Restriction of Thoracic Aorta, Descending with Intraluminal Device, Open Approach

Coding Options

Option 1. Do not add a new device value to table 02R, Replacement of Heart and Great Vessels or 02V, Restriction of Heart and Great Vessels. Continue to use existing codes as shown above. To identify that the patient is involved in a clinical trial, ICD-10-CM diagnosis code Z00.6, Encounter for examination for normal comparison and control in clinical research program, should also be reported.

Option 2. Create two new device values in Section X, table X2R, X Branched Synthetic Substitute with Intraluminal Device, and Y Synthetic Substitute with Intraluminal Device, to identify replacement of the thoracic aorta, ascending/arch with or without a branched synthetic substitute with intraluminal device. Continue to code from table 02V for restriction of the descending thoracic aorta.

Rationale: While the Thoraflex™ Hybrid is a single medical device intended for a single, one-stage procedure, it is clearly being utilized to achieve two distinct procedural objectives demonstrated by ICD-10-PCS root operations Replacement and Restriction. Attempts to select one root operation over another for the purposes of classifying such a device negate the intent of a procedure classification system and may impact data analyses.

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 X Thoracic Aorta, Ascending/Arch	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD X** Branched Synthetic Substitute with Intraluminal Device **ADD Y** Synthetic Substitute with Intraluminal Device	**ADD 3** New Technology Group 3

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

Body Part	*Approach*	*Device*	*Qualifier*
W Thoracic Aorta, Descending	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **E** Intraluminal device, branched or fenestrated, one or two arteries **F** Intraluminal device, branched or fenestrated, three or more arteries **Z** No Device	**Z** No Qualifier

CMS Recommendation: CMS is interested in hearing comments from the audience.

Interim Coding Advice: Continue to code 02RX0JZ Replacement of Thoracic Aorta, Ascending/Arch with Synthetic Substitute, Open Approach and 02VW0DZ Restriction of Thoracic Aorta, Descending with Intraluminal Device, Open Approach for procedures involving the Thoraflex™ Hybrid device. In addition, to identify that the patient is involved in a clinical trial, ICD-10-CM diagnosis code Z00.6, Encounter for examination for normal comparison and control in clinical research program, should also be reported.

Renal Replacement Therapy

Issue: Currently, there is no unique ICD-10-PCS code to capture the duration of a dialysis procedure. Hence it is difficult to track the prescribing patterns related to individual Renal Replacement Therapy (RRT) modalities and challenging to evaluate the efficacy of these treatment modalities.

New Technology Application? No

Food & Drug Administration (FDA) Approved? Yes

Background: Currently, the ICD-10-PCS system denotes dialysis by the use of three codes. The first code (3E1M39Z) refers to peritoneal dialysis. Peritoneal dialysis (PD) achieves the cleaning of a patient's blood through the patient's own peritoneal membrane[12] and is the dominant home dialysis therapy.[13] The second and third codes are variations of the hemodialysis procedure (5A1D00Z & 5A1D60Z). Hemodialysis cleans a patient's blood through the use of a dialysis machine and an external filter, or dialyzer.[14] However, in terms of clinical practice, "hemodialysis" includes a complex set of dialysis treatments of varying lengths of continuity. For example, Intermittent Hemodialysis (IHD) is typically prescribed for 3-5 hours per treatment and is performed 3-7 days per week. Prolonged Intermittent Renal Replacement Therapy (PIRRT) is administered between 8-12 hours per day on several or all days of the week, with breaks in therapy lasting hours to days as compared to Continuous Renal Replacement therapy (CRRT), which is administered 24 hours per day.

The current ICD-10-PCS codes requires all hemodialysis procedures to either be categorized as a "single" episode of treatment (5Al D00Z), or "multiple" treatments (5AlD60Z) *without specificity to the continuity of treatment*. As a result, if a dialysis procedure is coded as 5A1D60Z, there is no way to discern the specific duration of the therapy to determine whether it was PIRRT, IHD, or CRRT, even though these dialysis treatments differ significantly from each other.

Because the current ICD-10-PCS codes do not adequately capture the duration of a dialysis procedure, it is not possible to track the prescribing patterns relating to individual RRT modalities and evaluate the efficacy of treatment on its own terms.

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[12] "Peritoneal Dialysis," National Kidney Foundation, https://www.kidney.org/atoz/content/peritoneal, (last visited June 13, 2016).

[13] Griva, Konstadina et al. "Non-Adherence in Patients on Peritoneal Dialysis: A Systematic Review." Ed. D. William Cameron. PLoS ONE 9.2 (2014): e89001.PMC. Web. 13 June 2016.

[14] "Hemodialyis," National Kidney Foundation, https://www.kidney.org/atoz/content/hemodialysis, (last visited June 13, 2016).

Current Coding: If desired, facilities can report renal replacement therapy with one of the following ICD-10-PCS codes:

3E1M39Z Irrigation of Peritoneal Cavity using Dialysate, Percutaneous Approach
5A1D00Z Performance of Urinary Filtration, Single
5A1D60Z Performance of Urinary Filtration, Multiple

Coding Options

Option 1. Do not create new codes for RRT. Continue to use the existing ICD-10-PCS codes as described in current coding above.

Option 2. Delete existing CRRT codes 5A1D00Z Performance of Urinary Filtration, Single and 5A1D60Z Performance of Urinary Filtration, Multiple. In table 5A1, root operation Performance in the Extracorporeal Assistance and Performance section, add a new row to the table containing the body system value Urinary, the duration values Intermittent and Continuous, and the function value Filtration.

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

Body System	*Duration*	*Function*	*Qualifier*
D Urinary	**DELETE 0** Single **ADD 1** Intermittent **ADD 2** Continuous **DELETE 6** Multiple	**0** Filtration	**Z** No Qualifier

Option 3. Delete existing CRRT codes 5A1D00Z Performance of Urinary Filtration, Single and 5A1D60Z Performance of Urinary Filtration, Multiple. In table 5A1, root operation Performance in the Extracorporeal Assistance and Performance section, create new duration values Intermittent, Less than 6 Hours Per Day, Intermittent, 6-18 hours Per Day, and Continuous, Greater than 18 hours Per Day, applied to the Urinary body system and the function value Filtration.

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

Body System	*Duration*	*Function*	*Qualifier*
D Urinary	**DELETE 0** Single **DELETE 6** Multiple **ADD 7** Intermittent, Less than 6 Hours Per Day **ADD 8** Intermittent, 6-18 hours Per Day **ADD 9** Continuous, Greater than 18 hours Per Day	**0** Filtration	**Z** No Qualifier

CMS recommendation: Option 3. Delete existing CRRT codes 5A1D00Z and 5A1D60Z and create new duration values in table 5A1as described above.

Interim Coding Advice: Continue to report RRT as described in current coding.

Radiotherapeutic Brain Implant

Issue: There is currently no unique ICD-10-PCS code to capture the use of Cesium-131 collagen implants in adjuvant radiation therapy. The GammaTile™ is a technology for the treatment of brain tumors consisting of cesium-131 radioactive sources precisely embedded in collagen implants during a controlled manufacturing process.

New Technology Application? Yes, an application has been submitted for FY 2018.

Food & Drug Administration (FDA) Clearance: No. IsoRay, Inc. and GammaTile™ LLC are submitting a 510(k) to the Food and Drug Administration (FDA) in early 2017 and anticipate FDA approval before July 1, 2017. They anticipate that the GammaTile™ will be cleared by the FDA for use in the treatment of radiosensitive malignancies of the brain, including brain metastases and primary brain tumors.

Background: The GammaTile™ is designed to provide "adjuvant" radiation therapy—i.e. treatment to eliminate any remaining tumor cells—for patients who undergo surgical resection of brain tumors. Although neurosurgeons can often remove most of the tumor when performing a craniotomy with surgical excision, additional tumor cells may exist at or just beyond the margins of the resection cavity. These tumor cells, which typically are not detectable through visual inspection, significantly increase the risk of tumor recurrence if left untreated. Although chemotherapy treatments are not routinely effective in this setting, adjuvant radiation treatment (in the form of external beam radiation therapy or brachytherapy) is effective and commonly recommended for radiosensitive brain malignances.

Device

The GammaTile™ consists of cesium-131 radiation sources, which are sealed in small titanium carriers and are commonly referred to as "seeds," and embedded in a collagen matrix. These seeds are precisely positioned in a collagen matrix during a controlled manufacturing process. The ideal positioning of seeds within the collagen matrix ensures that uniform therapeutic radiation is provided to the treatment target. The GammaTile™ provides a unique and highly effective delivery modality for radiation therapy to the brain.

The GammaTile™ was designed to be used exclusively with cesium-131 sources. The spacing of seeds within the collagen matrix is specific to the inherent properties of cesium-131, including the radiation dose and fall-off of cesium-131. There is also confluence between the therapeutic emitting life of cesium-131 and the biological life of the collagen carrier, and this confluence ensures that brain tissue is never directly exposed to a high dose of radiation.

Procedure

The GammaTile™ is implanted into a patient during an inpatient craniotomy and surgical excision of brain tumors. At the conclusion of the surgical excision of a brain tumor, the neurosurgeon positions the GammaTile(s)™ within the resection cavity. Once placed in the

cavity, the GammaTile™ immediately starts to deliver radiation therapy to any tumor cells that remain in proximity to the resection cavity. The surgical closure is then completed with the GammaTile(s)™ left in place. The GammaTile™ carrier material is biocompatible and bioabsorbable, so it is left in the cavity permanently without the need for a subsequent surgical procedure to remove the implant.

Patients

GammaTile™ can provide a therapeutic option for patients with brain tumors and no other currently available effective treatment. For example, patients whose previous treatment included external beam radiation therapy are often precluded from receiving additional external beam radiation treatment because there is a lifetime limit for the amount of radiation therapy a specific area of the body can safely receive. GammaTile™ can also be used to treat recurrent tumors that are too large for treatment with external beam radiation therapy. These large tumors are not eligible for treatment with external beam radiation therapy because the radiation dose to nearby but otherwise healthy brain tissue would be too high. For example, GammaTile™ may provide the only radiation treatment option for patients with tumors close to sensitive vital brain sites (e.g., brain stem). Thus, without the option of GammaTile™, some patients with brain tumors may not be eligible for adjuvant therapy after surgical removal of a tumor.

Significant Differences from Other Treatment Modalities

The GammaTile™ device overcomes critical shortcomings of currently available radiation treatments—both external beam radiation and brachytherapy. The GammaTile™ is readily distinguishable from all existing radiation treatment modalities on the basis of structure, function, safety, and the enhanced potential for favorable clinical outcomes.

GammaTile™ Vs. External Beam Radiation Therapy

Due to the precise positioning of the radiological sources and the use of the cesium-131 isotope, the GammaTile™ focuses therapeutic levels of radiation on an extremely small area of the brain. This radiation does not pass through healthy areas of the brain to reach the targeted tissue, and therefore may limit neurocognitive deficits seen with external beam techniques. Because of the rapid "fall off" (reduction in radiation intensity) that is characteristic of cesium-131, the GammaTile™ can target the margin of the excision with greater precision and intensity than any alternative treatment option while sparing healthy brain tissue from unnecessary and potentially damaging radiation exposure.

As compared to external beam radiation therapy, GammaTile™ uses a new and unique mechanism of action to achieve a therapeutic outcome. Radiation delivered by all types of external beam treatments deposit radiation energy within healthy areas of brain tissue as it passes through tissue from the outside inward to reach the tumor or tumors. Although the radiation dosage to healthy tissue delivered by modern external beam techniques is less than the dosage delivered by older techniques, the dose is still significant for many patients and can be injurious. In contrast to external beam radiation modalities, the GammaTile™ is a form of internal radiation termed *brachytherapy*. Brachytherapy treatments are performed using radiation sources

positioned very close to the area requiring radiation treatment and only deliver radiation to the tissues that are immediately adjacent to the margin of the surgical resection.

GammaTile™ vs. Conventional Brachytherapy

As compared to other types of brain brachytherapy, GammaTile™ uses a new and unique mechanism of action to achieve a therapeutic outcome. In traditional brain brachytherapy, radioactive seeds are glued directly on or inserted into the brain at the margins of the resected tumor cavity, coming into direct contact with brain and other vital tissues. One of the major challenges in the delivery of brachytherapy to the brain has been the likelihood of both "hot" and "cold" spots of radiation. An uneven distribution of radiation sources can result in varying levels of radiation delivered to brain tissue. Areas that receive too much radiation, or hot spots, may develop radiation necrosis. Conversely, areas that receive too little radiation to treat tumor cells, or cold spots, may not receive an effective treatment dose and tumors may recur. The GammaTile™ addresses the shortcomings present in all other forms of brachytherapy and results in radiation that is of the right dose, delivered to the right place, without complications due to hot and cold spots by combining a three-dimensional spacer function while simultaneously serving as a multi-seed carrier to facilitate rapid completion of a precise implant.

Brain brachytherapy with the GammaTile™ is fundamentally different from traditional brain brachytherapy as currently practiced in the following ways:

1. Structural Offset
2. Radiation Dose
3. Safety

Each of these differences is explained in detail below.

Structural Offset

The tissues of the central nervous system are radiation sensitive and require a tightly conformal radiation dose for therapy to be both safe and effective. In early approaches to permanent implant brain brachytherapy, surgeons inserted iodine-125 seeds directly into the substance of the brain. Although local control rates were considered reasonably good, especially in the salvage setting, clinical series of these patients consistently reported radiation necrosis with a frequency of 30 to 50 percent.

The radiation sources in the GammaTile™ are "off-set" from the brain tissue. The radiation dose emanating directly from the surface of the titanium case containing the isotope is incredibly high. A seed treatment without an off-set from the brain can emit a dose at the surface that is about 50-fold greater than therapeutically necessary. The GammaTile™ moves the sources 3 mm away from brain tissue and the high doses of radiation near the surface of the seed do not reach the brain tissue. This offset, coupled with the rapid dose fall of the cesium-131, reduces the dose to the brain surface by more than 90 percent compared to currently available techniques and still

delivers a therapeutically useful radiation dose to the operative cavity. The radiation dose reaching the brain is more uniform, stays within the prescribed dosage, and avoids the delivery of very high dose to tissue (hot spots) and the subsequent development of radiation necrosis.

Radiation Dose and Safety

GammaTile™ is unique because it achieves two simultaneous forms of radiation dose intensification. Dose intensification has been shown to be an important factor in control of aggressive brain tumors and refers to the use of radiation doses that are either higher than typical or have greater biological effectiveness. With GammaTile™ treatment, two forms of dose intensification are present, one inherent to the isotope selection and one resulting from the technique. The short half-life of cesium-131 (9.7 days) results in energy deposition—and therefore treatment—that occurs over a relatively brief period of time, and this more rapid dose delivery may significantly increase the effectiveness of the treatment compared to longer lived isotopes such as iodine-125. The second form of dose intensification stems directly from the technique itself and the ability to safely deliver high local radiation doses with the GammaTile™ implant.

Current Coding: Facilities can capture the use of Cesium-131 collagen implants in adjuvant radiation therapy with the existing ICD-10-PCS code 3E0Q005 Introduction of Other Antineoplastic into Cranial Cavity and Brain, Open Approach.

Coding Options

Option 1. Do not create new codes for the use of Cesium-131 collagen implants in adjuvant radiation therapy. Continue to use the existing ICD-10-PCS code 3E0Q005 Introduction of Other Antineoplastic into Cranial Cavity and Brain, Open Approach.

Option 2. Create a unique code to capture the use of Cesium-131 collagen implants in adjuvant radiation therapy. Create new qualifier value 6 Cesium-131 Collagen Implant in table 3E0 of the Administration section. Use existing fourth character body system value Cranial Cavity and Brain and existing sixth character substance value Antineoplastic. Add the new qualifier for the approach value Open.

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*
Q Cranial Cavity and Brain	**0** Open	**0** Antineoplastic	**4** Liquid Brachytherapy Radioisotope **5** Other Antineoplastic **ADD 6** Cesium 131 Collagen Implant **M** Monoclonal Antibody

Option 3. Create a new code in section X, New Technology, to identify adjuvant radiation therapy with Cesium-131 collagen implants.

Section **X** New Technology *Body System* **ADD 0** Nervous System *Operation* **0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 0 Brain	**0** Open	**ADD 1** Antineoplastic Cesium 131 Collagen Implant	**3** New Technology Group 3

CMS recommendation: Option 3. Create a new code in section X, New Technology, to identify adjuvant radiation therapy with Cesium-131 collagen implants.

Interim Coding Advice: Continue to code adjuvant radiation therapy with Cesium-131 collagen implants as described in current coding, with the existing ICD-10-PCS code 3E0Q005 Introduction of Other Antineoplastic into Cranial Cavity and Brain, Open Approach.

Occlusion of Left Atrial Appendage

Issue: Currently there is not a device value to identify occlusion of the left atrial appendage (LAA) specifically with the use of a clip in ICD-10-PCS table 02L, Occlusion of Heart and Great Vessels.

New Technology Application? No

Background: Atrial fibrillation (AF) has been associated with an increased risk of stroke. A high percentage of embolic strokes in patients diagnosed with AF are thought to originate from thrombi in the LAA. To decrease potential thrombi risk, cardiothoracic surgeons frequently treat the LAA (minimizing thrombi risk) during concomitant cardiac surgeries such as mitral valve replacement (MVR), aortic valve replacement (AVR), or coronary artery bypass graft (CABG). There are several surgical strategies to manage the LAA – including clipping, suture ligation, excision and suture closure, or stapling exclusion with or without excision. Some of these procedures use a permanently implanted device at the LAA site.

The requester notes that the AtriCure AtriClip® Left Atrial Appendage Management System (LAAM) is the most commonly used LAAM device available for cardiac surgeons, with over 80,000 permanently placed clips uses worldwide to date (AtriCure internal tracking). Studies have demonstrated that this FDA approved device is safe and effective and may have fewer adverse events when compared to other LAA management strategies. Long term follow-up of patients in which the AtriClip® device was implanted suggest very high LAA closure rates and very few serious device related adverse events. However, in limited situations it was found that inadequate closure may increase the risk of bleeding or the need for additional suture repair. According to the requester, given the differences in outcome associated with the AtriClip® device in comparison to other permanently implanted surgical LAA devices, it is important to allow accurate tracking between methods of treatment.

Current Coding: Occlusion of the left atrial appendage with a clip is coded to table 02L, Occlusion of Heart and Great Vessels, the body part value Left Atrium, the device value Extraluminal Device, the qualifier value Left Atrial Appendage and the appropriate approach value.

Coding Options

Option 1. Do not create new codes. Continue to code as above under current coding.
Option 2. Create new device value Extraluminal Device, Clip in table 02L, Occlusion of Heart and Great Vessels, for the body part value Left Atrium and the qualifier value Left Atrial Appendage.

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

Body Part	*Approach*	*Device*	*Qualifier*
7 Atrium, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD B** Extraluminal Device, Clip **C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**K** Left Atrial Appendage

CMS Recommendation: We would like to hear comments from the audience regarding the need and/or benefits of having the specific type of LAA extraluminal device be separately identified for inpatient reporting purposes since this request does not involve a new technology.

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

Spinal Fusion with Radiolucent lnterbody Fusion Device

Issue: There is not a unique ICD-10-PCS device value to describe spinal fusion using a radiolucent porous interbody fusion device. Additionally, there is not a unique ICD-10-PCS code to describe early post-surgical imaging assessment of fusion, which can occur with a radiolucent porous device.

New Technology Application? Yes. Vertera intends to submit a new technology application for its radiolucent porous interbody fusion devices in the fall of 2017 for FY 2019.

Food & Drug Administration (FDA) Clearance: The first radiolucent porous interbody fusion device (COHERE®) received FDA 510(k) clearance in 2015 for cervical fusion procedures. An FDA 510(k) application covering devices for lumbar fusion procedures (COALESCE®) was submitted in 2016 and FDA 510(k) clearance is anticipated in the first half of calendar year 2017.

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

Decades of research have shown that device surface structure directly affects its ability to integrate with bone. Both smooth titanium and smooth polymer (polyether-ether-ketone, PEEK) surfaces result in poor device fixation regardless of material composition. However, the same materials have been shown to exhibit strong implant-to-bone fixation when they possess a three-dimensional porous structure. As a result, porous metal networks have recently been incorporated into interbody fusion devices with promising clinical results. The requester noted that visualization of bone ingrowth within a porous interbody fusion device could provide a powerful early indicator of implant osseointegration and successful fusion outcomes without waiting the standard 6-12 months for full bone bridging of the intervertebral space. However, porous metal devices create medical imaging artifacts that prevent a surgeon from visualizing bone ingrowth within the porous network. Additionally, the biomechanical mismatch between stiff metal cages and bone may cause bone resorption due to stress shielding, or subsidence of the device into the vertebral endplates.

Vertera, Inc. has developed the first radiolucent, porous interbody fusion device made from

polyether-ether-ketone (PEEK) polymer. First introduced in the 1990's, PEEK has grown to become the most common material used for interbody fusion devices because its mechanical properties are similar to bone and it does not generate artifact on medical images. The porous PEEK architecture on Vertera devices is extruded directly from the underlying solid to provide a physical environment designed to mimic the structure and mechanical properties of trabecular bone. Extensive studies have demonstrated porous PEEK's ability to enhance bone ingrowth while retaining the mechanical properties and durability of conventional PEEK devices.
The requester asserts that Vertera's porous PEEK devices provide a unique advantage for early post-surgical assessment of fusion and patient progress. In contrast to porous metal devices that can obscure x-ray, CT and MRI images, porous PEEK's radiolucency now enables surgeons to effectively and non-invasively measure local bone ingrowth into a porous network to determine device fixation and fusion progression. The opportunity to assess implant-mediated osseous ingrowth and fusion as early as 3 months would provide a substantial clinical advantage over assessing fusion at the standard later time points of 6-12 months. Early indications of fusion progression provided by local imaging assessment of osseous ingrowth into a radiolucent, porous interbody fusion device may better inform a surgeon's management of a patient's post-operative rehabilitation and physical therapy regime to improve overall fusion outcomes.

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

Coding Options

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

Option 2. Create a new device value Interbody Fusion Device, Radiolucent Porous, for the cervical, thoracic and lumbar vertebral joint body part values in tables 0RG and 0SG, Fusion of Upper Joints and Lower Joints body systems, to identify spinal fusion procedures that use a radiolucent porous 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,	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **A** Interbody Fusion Device **ADD F** Interbody Fusion Device, Radiolucent Porous **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

Body Part	*Approach*	*Device*	*Qualifier*
2 to 7 **8** Thoracic Vertebral Joints, 8 or more **A** Thoracolumbar Vertebral Joint			

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 **ADD F** Interbody Fusion Device, Radiolucent Porous **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

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

Section **X** New Technology
Body System **R** Joints
Operation **G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
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 F** Interbody Fusion Device, Radiolucent Porous	**3** New Technology Group 3

CMS Recommendation: Option 3, as above. The requestor also indicated they would like unique codes created in tables BR0 and BR2, Plain Radiography of Axial Skeleton and Computerized Tomography of Axial Skeleton respectively, to uniquely identify follow-up assessment for local osseous ingrowth of the interbody fusion device. We are interested in hearing from the audience if this imaging procedure is frequently performed in the inpatient setting.

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

Administration of VYXEOS™

Issue: Within ICD-10-PCS, there is currently no code to describe the administration of VYXEOS™ (cytarabine and daunorubicin liposome) for injection.

New Technology Application? Yes. Celator Pharmaceuticals, Inc., a direct subsidiary of Jazz Pharmaceuticals, Inc. submitted a New Technology Add-on Payment application for VYXEOS™ for FY2018.

Food & Drug Administration (FDA) Approved? No

Background: AML is a life threatening cancer in which the bone marrow makes abnormal red blood cells, white blood cells, and platelets. These cells, called blasts, fail to differentiate properly and the growing number of the immature cells leave less room for the healthy cells. AML represents a heterogeneous group of bone marrow stem-cell disorders that vary in terms of age of onset, presence or absence of prior stem-cell dysfunction, presence or absence of exposure to potentially genotoxic agents such as chemotherapy, cytogenetic profile and mutational, microRNA and epigenetic differences.[15] Two major prognostic factors in newly diagnosed AML patients are patient age and chromosome status.[16] AML is a relatively rare disease.

The standard of care for patients with *de novo* AML, as well as secondary AML, is induction chemotherapy using two separate agents (cytarabine and an anthracycline, commonly referred to as 7+3). Most often, the 7+3 free drug dosing is where cytarabine is infused continuously days 1-7 and daunorubicin, an anthracycline, is administered intravenously on days 1, 2 and 3. Where "free drug dosing" implies cytarabine and anthracycline drug molecules are not formulated to achieve targeted tissue delivery.

Current therapies present a challenge for older AML patients because in this population, AML is associated with significant increased risk of death in those who do not respond to therapy and the risk of dying from the chemotherapy is increased in the older AML population.[2] The relatively poor treatment outcomes in older AML patients are directly attributable to the prevalence of often overlapping risk and prognostic factors, and have also led to reluctance to treat older patients with intensive chemotherapy combinations designed to induce aplasia and complete remission. .

[15] Stone RM, et al. (2015). Phase III open-label randomized study of cytarabine in combination with amonafide l-malate or daunorubicin as induction therapy for patients with secondary acute leukemia. *JCO.* April 10, 2015 vol. 33, no. 11 1252-1257.

[16] Stone RM, et al. (2004). Acute myeloid leukemia. *Hematology Am Soc Hematol Educ Program*. 2004:98-117.

Description and Mechanism of Action of VYXEOS (cytarabine and daunorubicin liposome

VYXEOS (cytarabine and daunorubicin liposome) is a novel nano-scale liposomal formulation of a fixed combination of cytarabine and daunorubicin. Through its proprietary ratiometric dosing technology platform, CombiPlex®, VYXEOS (cytarabine and daunorubicin liposome) delivers and maintains the fixed, ratiometrically synergistic 5:1 molar ratio of cytarabine: daunorubicin to cancer cells in a nano-scale delivery complex. VYXEOS (cytarabine and daunorubicin liposome) is taken up intact by the cell and releases cytarabine and daunorubicin at their synergistic ratios resulting in, according to the manufacturer, a well-coordinated pharmacology of the two drugs and the delivery of this synergistic ratio at the site of the tumor;[11,12] Per the manufacturer Liposomal encapsulation maintains the synergistic ratios, reduces degradation, and minimizes the impact of drug transporters and the effect of known resistant mechanisms;[17,18] The manufacturer asserts that VYXEOS (cytarabine and daunorubicin liposome) provides prolonged exposure of cytarabine and daunorubicin in the bone marrow. Maintenance of the synergistic drug ratio cannot be achieved with conventional forms of the two separate drugs, cytarabine and daunorubicin, regardless of how they may be dosed or scheduled.

Inpatient Administration of VYXEOS (cytarabine and daunorubicin liposome)

The following dosing information is based on the VYXEOS (cytarabine and daunorubicin liposome) clinical trials and will be submitted to the FDA in the draft proposed labeling. It is expected that induction therapy will be administered in the hospital inpatient setting and, in Study 301, 40-50% of first and second consolidation therapy was also administered in the inpatient setting.

- VYXEOS (cytarabine and daunorubicin liposome) is supplied in 50mL single-patient-use vials. Each vial contains cytarabine 100 mg and daunorubicin 44 mg in liposomes.
- Based on the patient's body surface area, the amount of reconstituted VYXEOS (cytarabine and daunorubicin liposome) which is required to be administered is:

Therapy	VYXEOS (cytarabine and daunorubicin liposome) for Injection Administered as a 90-minute infusion	
	Dose	Schedule
First Induction	cytarabine 100 mg/m^2 and daunorubicin 44 mg/m^2 (20 mL)	Days 1, 3 and 5
Second Induction	cytarabine 100 mg/m^2 and daunorubicin 44 mg/m^2 (20 mL)	Days 1 and 3
Consolidation	cytarabine 65 mg/m^2 and daunorubicin 28.6 mg/m^2 (13 mL)	Days 1 and 3

[17] Bayne W, et al. (2008). Pharmacokinetics of CPX-351 (cytarabine/daunorubicin HCl) liposome injection in the mouse. *Journal of Pharmaceutical Sciences*. DOI 10.1002/jps.

[18] Tardi P, et al. (2016). Passive and semi-active targeting of bone marrow and leukemia cells using anionic low cholesterol liposomes. *Journal of Drug Targeting.* DOI:10.1080/1061186X.2016.1184669. Published online May 16, 2016

Current Coding: If desired, facilities can report intravenous infusion of VYXEOS with one of the following ICD-10-PCS codes:

3E03305 Introduction of Other Antineoplastic into Peripheral Vein, Percutaneous Approach

3E04305 Introduction of Other Antineoplastic into Central Vein, Percutaneous Approach

Coding Options

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

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

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 B** Cytarabine and Daunorubicin Liposome Antineoplastic	**3** New Technology Group 3

CMS recommendation: Option 2. Create new codes in section X, New Technology, to identify the administration of VYXEOS.

Interim Coding Advice: Continue to report intravenous infusion of VYXEOS, as described in current coding, with one of the following ICD-10-PCS codes:

3E03305 Introduction of Other Antineoplastic into Peripheral Vein, Percutaneous Approach

3E04305 Introduction of Other Antineoplastic into Central Vein, Percutaneous Approach

Administration of KTE-C19 (axicabtagene ciloleucel)

Issue: Within ICD-10-PCS, there is currently no code to describe the administration of KTE-C19 (axicabtagene ciloleucel) for injection.

New Technology Application? Yes. Kite Pharma, Inc. submitted a New Technology Add-on Payment application for KTE-C19 (axicabtagene ciloleucel) for FY2018.

Food & Drug Administration (FDA) Approved? No

Background: KTE-C19 is indicated for the treatment of adult patients with relapsed/refractory aggressive B-cell Non-Hodgkins Lymphoma (NHL) who are ineligible for autologous stem cell transplant (ASCT). KTE-C19 is an engineered autologous cellular immunotherapy comprised of chimeric antigen receptor (CAR) construct T cells that recognizes CD19 expressing cancer cells and normal B cells.

Description and Current Treatment of Chemorefractory, Aggressive B-cell NHL

Adult NHL represents a heterogeneous group of lymphoproliferative malignancies with differing patterns of behavior and responses to treatment. The prognosis depends on the histologic type, stage, and treatment, along with other factors including the patient's age and general health, whether there are certain changes in the genes, the amount of lactate dehydrogenase (LDH) in the blood, and whether the lymphoma has been newly diagnosed or has recurred.[19,20] Diffuse large B-cell lymphoma (DLBCL) is the most common subtype of B-cell NHL, accounting for 30-40% of all cases.[21] The incidence of lymphoid neoplasm, including DLBCL, in the elderly represents a notable public health burden due to the high rates (170.6 cases per 100,000 person-years) and the aging US population.[22] DLBCL typically presents as an aggressive lymphoma, evolving over months and resulting in symptomatic disease that is imminently fatal without treatment. Importantly, in about half of all DLBCL patients immunochemotherapy presents an

[19] National Cancer Institute. Adult non-Hodgkin lymphoma treatment (PDQ®) – Professional Version. www.cancer.gov/types/lymphoma/hp/adult-nhl-treatment-pdq

[20] National Cancer Institute. Adult non-Hodgkin lymphoma treatment (PDQ®) – Patient Version. www.cancer.gov/types/lymphoma/patient/adult-nhl-treatment-pdq

[21] Chaganti S, et al. (2016). Guidelines for the management of diffuse large B-cell lymphoma. BJH Guideline, Published 2016. Available at: www.bit.do/bsh-guidelines

[22] Sehn L and Gascoyne R. (2015). Diffuse large B-cell lymphoma: optimizing outcome in the context of clinical and biologic heterogeneity. *Blood.* 2015 Jan 1;125(1):22-32

option for cure depending on the stage of the disease and the International Prognostic Index (IPI) score.[23,24]

Patients with DLBCL who have relapsed after salvage second-line therapy, by definition, are not eligible for ASCT and have a poor prognosis.[25,26] In addition, some patients who relapse and subsequently respond to second-line salvage therapy may not undergo ASCT for a variety of reasons, including being older (>65 years of age are typically ineligible), having a transient response, or failing to mobilize stem cells for ASCT. Patients who relapse and cannot undergo ASCT have no curative options. There are no available therapies that have been granted approvals for the treatment of adult patients with refractory DLBCL, primary mediastinal B-cell lymphoma (PMBCL) or follicular lymphoma (FL).

Description and Mechanism of Action of KTE-C19

Researchers have shown that T cells play a central role in the immune system and destroy diseased cells throughout the body including tumor cells. Autologous engineered T cell

[23] Morton L, et al. (2006). Lymphoma incidence patterns by WHO subtype in the United States, 1992-2001. *Blood.* 1 January 2006. Vol 107, No 1

[24] American Cancer Society. Treating B-cell non-Hodgkin lymphoma. www.cancer.org/cancer/non-hodgkinlymphoma/detailedguide/non-hodgkin-lymphoma-treating-b-cell-lymphoma

[25] Van Den Neste E, et al. (2016). Outcome of patients with relapsed diffuse large B-cell lymphoma who fail second-line salvage regimens in the International CORAL study, *Bone Marrow Transplantation* (2016) 51, 51–57

[26] National Cancer Institute. CAR T-Cell Therapy: Engineering Patients' Immune Cells to Treat Their Cancers www.cancer.gov/about-cancer/treatment/research/car-t-cells

immunotherapy or T cells engineered with CARs can redirect the specificity of T cells to tumor antigens.[27,28,29,30,31,32]

Mechanism of Action

KTE-C19 has a distinct mechanism of action directed at the antigen CD19 which is a protein expressed on the cell surface of normal B cells as well as B-cell lymphomas and leukemias. KTE-C19 is a single infusion of previously engineered autologous T cells. Engineering of a patient's own T cells begin with harvesting the cells, followed by ex vivo retroviral transduction of a CAR construct encoding an anti-CD19 CD28/CD3-zeta. The anti-CD19 CAR T cells are expanded and infused into the patient. The new CAR T cells (KTE-C19) can recognize and eliminate CD19 expressing target cells. CD19 expressing target cells include cancer cells and normal B cells. These normal B cells are considered to be non-essential tissue, as they are not required for patient survival. This binding leads to the activation and expansion of CAR T cells followed by cytotoxicity against CD19 expressing target cells. Upon recognition of CD19, KTE-C19 will target, activate, and systemically kill target cells throughout the body.

Inpatient Administration of KTE-C19

Following FDA approval, KTE-C19 is expected to be administered in the hospital inpatient setting to assure appropriate monitoring of patient adverse events.

KTE-C19 will be supplied as patient-specific cell suspension for infusion in a cryostorage bag that comprises a target dose of 2 x 10^6 anti-CD19 CAR T cells/kg subject to the patient's body weight in approximately 70mL. (10^6 = million) KTE-C19 is an autologous, single infusion immunotherapy where the whole patient-specific bag is infused. Central venous access such as a

[27] National Cancer Institute. CAR T-Cell Therapy: Engineering Patients' Immune Cells to Treat Their Cancers www.cancer.gov/about-cancer/treatment/research/car-t-cells

[28] Kochenderfer J, et al. (2010). Eradication of B-lineage cells and regression of lymphoma in a patient treated with autologous T cells genetically-engineered to recognize CD19. *Blood.* 115*29(L4099-4101, 2010.

[29] Rosenberg SA. (2011). Durable complete responses in heavily pretreated patients with metastatic melanoma using T cells transfer immunotherapy. *Clin Cancer Res*. 2011; 17(13):4550-7

[30]Magee M and Snook A. (2014). Challenges to chimeric antigen receptor (CAR)-T cell therapy for cancer. *Discovery Medicine.* Vol 18, No 100, Pages 265-271, November 2014.

[31] Kochenderfer, J et al. (2015). Chemotherapy-refractory diffuse large B-cell lymphoma and indolent B-cell malignancies can be effectively treated with autologous T cells expressing an anti-CD19 chimeric antigen receptor *J Clin Oncol.* 2015 Feb 20;33(6):540-9.

[32] Kochenderfer J. (2016). Anti-CD19 chimeric antigen receptor T cells preceded by low-dose chemotherapy to induce remissions of advanced lymphoma. Late-breaking abstract LBA3010 and oral presentation at ASCO conference, June 2016.

port or a peripherally inserted central catheter is required for the administration of KTE-C19. KTE-C19 is infused by gravity (without an IV pump) over a period of approximately 30 minutes.

Current Coding: If desired, facilities can report intravenous infusion of KTE-C19 with one of the following ICD-10-PCS codes:

3E03305 Introduction of Other Antineoplastic into Peripheral Vein, Percutaneous Approach

3E04305 Introduction of Other Antineoplastic into Central Vein, Percutaneous Approach

Coding Options

Option 1. Do not create new codes for the administration of KTE-C19. Continue to use one of the existing ICD-10-PCS codes listed under current coding.

Option 2. Create new codes in section X, New Technology, to capture the administration of KTE-C19.

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 C** Axicabtagene Ciloleucel Cellular Immunotherapy	**3** New Technology Group 3

CMS recommendation: Option 2. Create new codes in section X, New Technology, to capture the administration of KTE-C19.

Interim Coding Advice: Continue to code intravenous infusion of KTE-C19 as described in current coding, with one of the following ICD-10-PCS codes:

3E03305 Introduction of Other Antineoplastic into Peripheral Vein, Percutaneous Approach

3E04305 Introduction of Other Antineoplastic into Central Vein, Percutaneous Approach

Resection of the Left Ventricular Outflow Tract Obstruction and/or Subaortic Membrane

Issue: Currently there is not a body part value for the left ventricle in ICD-10-PCS table 027, Dilation of Heart and Great Vessels, to accurately report resection of the left ventricular outflow tract obstruction and/or subaortic membrane.

New Technology Application? No.

Background: A subaortic membrane is a form of subaortic stenosis or obstruction in which a fibrous membrane is located below the aortic valve and causes obstruction of the flow of blood from the left ventricle into the aorta causing turbulence of the blood flow which can damage the aortic valve and increase the work of the left ventricle; it is a common cause of Left Ventricular Outflow Tract (LVOT) obstruction and requires surgical repair to excise the membrane and open up the subaortic area of the left ventricle below the aortic valve.

In this procedure the patient is placed on cardiopulmonary bypass and the aorta is opened and the aortic valve and subaortic region of the left ventricle is inspected. The subaortic membrane is removed and the left ventricle frequently requires myomectomy or myotomy to open up the subaortic area of the left ventricle outflow tract so that blood flow is unobstructed in the LVOT to the aortic valve.

Current Coding: Currently, opening up the subaortic region of the left ventricle by excision of a subaortic membrane or via a ventricular myotomy or myomectomy is coded to the root operations Excision (02B) or Repair (02Q).

Coding Options

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

Option 2. Add the body part value L, Left Ventricle to table 027, Dilation of Heart and Great Vessels, to more precisely identify procedures to correct left ventricular outflow tract (LVOT) obstruction.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**7** Dilation: Expanding an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
F Aortic Valve **G** Mitral Valve **H** Pulmonary Valve **J** Tricuspid Valve **K** Ventricle, Right **ADD L** Ventricle, Left **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Intraluminal Device, Drug-eluting **D** Intraluminal Device **Z** No Device	**Z** No Qualifier

Body Part	*Approach*	*Device*	*Qualifier*
W Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch			

CMS Recommendation: Option 2, as above.

Interim Coding Advice: Continue to use the existing ICD-10-PCS root operations excision or repair as appropriate depending on procedures performed.

Fontan Completion Procedure, Stage II

Issue: Currently there are no qualifier values for the pulmonary arteries in ICD-10-PCS table 061, Bypass of Lower Veins, to accurately report a Fontan completion procedure, stage II.

New Technology Application? No.

Background: The Fontan procedure is a palliative surgical procedure used in pediatric patients who possess only a single functional ventricle, either due to lack of a heart valve (e.g. tricuspid or mitral atresia), an abnormality of the pumping ability of the heart (e.g. hypoplastic left heart syndrome or hypoplastic right heart syndrome), or a complex congenital heart disease where a bi-ventricular repair is impossible or inadvisable. The single ventricle is doing nearly twice the expected amount of work because it has to pump blood for the body and lungs. Patients typically present as neonates with cyanosis or congestive heart failure. Fontan completion is usually carried out when the patient is 2–5 years of age, but is also performed before 2 years of age in children with univentricular hearts. It involves diverting the venous blood from the IVC and SVC to the pulmonary arteries without passing through the right ventricle.

In this procedure, the patient is placed on cardiopulmonary bypass. The inferior vena cava is divided from the entrance to the right atrium and usually a synthetic graft is cut to appropriate length for use as the conduit and anastomosed from the inferior vena cava to the pulmonary artery (usually the right PA); often, the conduit has a fenestration (intentional opening) allowing for the conduit to be sutured to an opening in the right atrium in addition to the pulmonary artery anastomosis site (fenestrated conduit).

Current Coding: Bypass procedures from the IVC to the pulmonary arteries are currently coded in table 021, Bypass of Heart and Great Vessels, with the body part value Right Atrium and the applicable pulmonary artery qualifier.

Coding Options

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

Option 2. Create a new row in table 061, Bypass of Lower Veins, to more precisely identify bypass procedures from the IVC to the pulmonary arteries. Create new qualifier values Pulmonary Trunk, Pulmonary Artery, Right, and Pulmonary Artery, Left, to apply to the body part value Inferior Vena Cava.

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

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

CMS Recommendation: Option 2, as above.

Interim Coding Advice: Continue to use table 021, Bypass of Heart and Great Vessels, with the body part value Right Atrium and the applicable pulmonary artery qualifier.

Alfieri Stitch Valvuloplasty

Issue: Currently there is not a body part value for the mitral valve in ICD-10-PCS table 02V, Restriction of Heart and Great Vessels, to accurately report a stitch valvuloplasty.

New Technology Application? No.

Background: The Alfieri stitch (a.k.a. "Bow-Tie" Procedure or edge-to-edge mitral valve repair) is a surgical technique used to treat severe mitral regurgitation during which a suture is placed between two segments of the mitral valve. This results in two mitral valve orifices and is shown to significantly reduce the degree of mitral regurgitation. The intent of this procedure is to restrict the blood flow through the valve.

Current Coding: Stitch valvuloplasty of the mitral valve is currently coded to table 02Q, Repair of Heart and Great Vessels, with the body part value G, Mitral Valve.

Coding Options

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

Option 2. Create a new row in table 02V, Restriction of Heart and Great Vessels, for coding stitch valvuloplasty of the mitral valve performed to restrict blood flow in cases of severe mitral regurgitation. Add the body part value G, Mitral Valve to table 02V, with all available approach values and device value Z No Device.

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

Body Part	*Approach*	*Device*	*Qualifier*
ADD G Mitral Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

CMS Recommendation: Option 2, as above.

Interim Coding Advice: Continue to use table 02Q, Repair of Heart and Great Vessels, with the body part value G, Mitral Valve.

Ligation of Main Pulmonary Artery/Pulmonary Trunk

Issue: Currently there is not a body part value for the pulmonary trunk in ICD-10-PCS table 02L, Occlusion of Heart and Great Vessels, to accurately report a pulmonary trunk ligation.

New Technology Application? No.

Background: Many palliative or corrective heart procedures, such as the Fontan Completion procedure, require the pulmonary valve or the main pulmonary artery (pulmonary trunk) to be ligated or occluded to stop central blood flow, since the newly place conduit provides the new blood flow route.

Current Coding: Ligation of the pulmonary artery is currently coded to table 02Q, Repair of Heart and Great Vessels, with the appropriate body part value.

Coding Options

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

Option 2. In table 02L, Occlusion of Heart and Great Vessels, add the body part values Pulmonary Trunk and Right Pulmonary Artery, and add the qualifier value No Qualifier to the table row containing Left Pulmonary Artery, to more precisely identify palliative or corrective procedures where ligation of a pulmonary artery is performed.

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

Body Part	*Approach*	*Device*	*Qualifier*
7 Atrium, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**K** Left Atrial Appendage
H Pulmonary Valve **ADD P** Pulmonary Trunk **ADD Q** Pulmonary Artery, Right **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**Z** No Qualifier
R Pulmonary Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**T** Ductus Arteriosus **ADD Z** No Qualifier

CMS Recommendation: Option 2, as above.

Interim Coding Advice: Continue to use table 02Q, Repair of Heart and Great Vessels, with the appropriate body part value.

Fluoroscopy of Pulmonary Trunk

Issue: Currently there is not a body part value for the pulmonary trunk in ICD-10-PCS table B31, Fluoroscopy of Upper Arteries, to accurately report a fluoroscopic assessment of the patency of the pulmonary trunk.

New Technology Application? No.

Current Coding: If desired, facilities can report fluoroscopic assessment of the pulmonary trunk using the right or left pulmonary artery body part value in table B31, Fluoroscopy of Upper Arteries.

Coding Options

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

Option 2. Create new body part value U Pulmonary Trunk and add to table B31, Fluoroscopy of Upper Arteries for fluoroscopic assessment of the pulmonary trunk.

Section	**B** Imaging
Body System	**3** Upper Arteries
Type	**1** Fluoroscopy: Single plane or bi-plane real time display of an image developed from the capture of external ionizing radiation on a fluorescent screen. The image may also be stored by either digital or analog means

Body Part	*Contrast*	*Qualifier*	*Qualifier*
0 Thoracic Aorta **1** Brachiocephalic-Subclavian Artery, Right **2** Subclavian Artery, Left **3** Common Carotid Artery, Right **4** Common Carotid Artery, Left **5** Common Carotid Arteries, Bilateral **6** Internal Carotid Artery, Right **7** Internal Carotid Artery, Left **8** Internal Carotid Arteries, Bilateral **9** External Carotid Artery, Right **B** External Carotid Artery, Left **C** External Carotid Arteries, Bilateral **D** Vertebral Artery, Right **F** Vertebral Artery, Left **G** Vertebral Arteries, Bilateral **H** Upper Extremity Arteries, Right **J** Upper Extremity Arteries, Left **K** Upper Extremity Arteries, Bilateral **L** Intercostal and Bronchial Arteries **M** Spinal Arteries **N** Upper Arteries, Other **P** Thoraco-Abdominal Aorta **Q** Cervico-Cerebral Arch **R** Intracranial Arteries **S** Pulmonary Artery, Right **T** Pulmonary Artery, Left **ADD U** Pulmonary Trunk	**0** High Osmolar **1** Low Osmolar **Y** Other Contrast	**1** Laser	**0** Intraoperative
0 Thoracic Aorta **1** Brachiocephalic-Subclavian Artery, Right **2** Subclavian Artery, Left **3** Common Carotid Artery, Right	**0** High Osmolar **1** Low Osmolar **Y** Other Contrast	**Z** None	**Z** None

Body Part	*Contrast*	*Qualifier*	*Qualifier*
4 Common Carotid Artery, Left **5** Common Carotid Arteries, Bilateral **6** Internal Carotid Artery, Right **7** Internal Carotid Artery, Left **8** Internal Carotid Arteries, Bilateral **9** External Carotid Artery, Right **B** External Carotid Artery, Left **C** External Carotid Arteries, Bilateral **D** Vertebral Artery, Right **F** Vertebral Artery, Left **G** Vertebral Arteries, Bilateral **H** Upper Extremity Arteries, Right **J** Upper Extremity Arteries, Left **K** Upper Extremity Arteries, Bilateral **L** Intercostal and Bronchial Arteries **M** Spinal Arteries **N** Upper Arteries, Other **P** Thoraco-Abdominal Aorta **Q** Cervico-Cerebral Arch **R** Intracranial Arteries **S** Pulmonary Artery, Right **T** Pulmonary Artery, Left **ADD U** Pulmonary Trunk			
0 Thoracic Aorta **1** Brachiocephalic-Subclavian Artery, Right **2** Subclavian Artery, Left **3** Common Carotid Artery, Right **4** Common Carotid Artery, Left **5** Common Carotid Arteries, Bilateral **6** Internal Carotid Artery, Right **7** Internal Carotid Artery, Left **8** Internal Carotid Arteries, Bilateral **9** External Carotid Artery, Right **B** External Carotid Artery, Left **C** External Carotid Arteries, Bilateral **D** Vertebral Artery, Right **F** Vertebral Artery, Left **G** Vertebral Arteries, Bilateral **H** Upper Extremity Arteries, Right **J** Upper Extremity Arteries, Left **K** Upper Extremity Arteries, Bilateral **L** Intercostal and Bronchial Arteries **M** Spinal Arteries **N** Upper Arteries, Other **P** Thoraco-Abdominal Aorta **Q** Cervico-Cerebral Arch **R** Intracranial Arteries **S** Pulmonary Artery, Right **T** Pulmonary Artery, Left **ADD U** Pulmonary Trunk	**Z** None	**Z** None	**Z** None

CMS Recommendation: We are interested in hearing from the audience if this imaging procedure is frequently performed in the inpatient setting.

Interim Coding Advice: If desired, facilities can report fluoroscopic assessment of the pulmonary trunk using the right or left pulmonary artery body part value in table B31, Fluoroscopy of Upper Arteries.

Release of Myocardial Bridge

Issue: Currently there is not a body part value for the coronary artery (or arteries) in ICD-10-PCS table 02N, Release of Heart and Great Vessels, to accurately report procedures performed to treat various cardiovascular conditions, such as myocardial bridging.

New Technology Application? No.

Background: Myocardial bridging is a congenital anomaly in which a segment of a coronary artery takes a tunneled intramuscular course under a "bridge" of overlying myocardium. This causes vessel compression in systole, resulting in hemodynamic changes that may be associated with angina, myocardial ischemia, acute coronary syndrome, left ventricular dysfunction, arrhythmias, and even sudden cardiac death. Some patients require surgery to correct the condition by removing the "bridge" of myocardial tissue that is covering and compressing the anomalous coronary artery by myotomy or myomectomy of the overlying myocardial tissue.

Current Coding: Correction of myocardial bridging is currently coded to table 02Q, Repair of Heart and Great Vessels, with the applicable coronary artery body part value.

Coding Options

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

Option 2. In table 02N, Release of Heart and Great Vessels, add all coronary artery body part values to more precisely identify procedures performed to release abnormal constraint on the coronary arteries, such as correction of myocardial bridging.

Section **0** Medical and Surgical *Body System* **2** Heart and Great Vessels *Operation* **N** Release: Freeing a body part from an abnormal physical constraint by cutting or by the use of force			
Body Part	*Approach*	*Device*	*Qualifier*
ADD 0 Coronary Artery, One Artery **ADD 1** Coronary Artery, Two Arteries **ADD 2** Coronary Artery, Three Arteries **ADD 3** Coronary Artery, Four or More Arteries **4** Coronary Vein **5** Atrial Septum **6** Atrium, Right **7** Atrium, Left **8** Conduction Mechanism **9** Chordae Tendineae **D** Papillary Muscle **F** Aortic Valve **G** Mitral Valve **H** Pulmonary Valve **J** Tricuspid Valve **K** Ventricle, Right **L** Ventricle, Left **M** Ventricular Septum **N** Pericardium **P** Pulmonary Trunk **Q** Pulmonary Artery, Right	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

Body Part	*Approach*	*Device*	*Qualifier*
R Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava **W** Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch			

CMS Recommendation: Option 2, as above.

Interim Coding Advice: Continue to code correction of myocardial bridging using table 02Q, Repair of Heart and Great Vessels, with the applicable coronary artery body part value.

Magnetically Controlled Growth Rods

Issue: Within ICD-10-PCS, the current section X codes for Magnetically Controlled Growth Rods (MCGR) do not include the various body parts to which the MCGR construct could be fixed. These codes do not describe each of the surgical approaches that could be selected. The current section X codes do not adequately describe the Early Onset Scoliosis (EOS) surgery utilizing MCGR. Lastly the current codes do not describe MCGR replacement (for example, in the event of rod breakage) nor do they describe MCGR removal.

New Technology Application? The applicant was approved for FY 2017 NTAP.

Food & Drug Administration (FDA) Approved? Yes

Background: MCGR was granted both the New Technology Add-on Payment (NTAP) and six section X codes to describe its use, effective October 1, 2016. The codes currently associated with MCGR are as follows:

XNS0032 Reposition of Lumbar Vertebra using Magnetically Controlled Growth Rod(s), Open Approach, New Technology Group 2

XNS0432 Reposition of Lumbar Vertebra using Magnetically Controlled Growth Rod(s), Percutaneous Endoscopic Approach, New Technology Group 2

XNS3032 Reposition of Cervical Vertebra using Magnetically Controlled Growth Rod(s), Open Approach, New Technology Group 2

XNS3432 Reposition of Cervical Vertebra using Magnetically Controlled Growth Rod(s), Percutaneous Endoscopic Approach, New Technology Group 2

XNS4032 Reposition of Thoracic Vertebra using Magnetically Controlled Growth Rod(s), Open Approach, New Technology Group 2

XNS4432 Reposition of Thoracic Vertebra using Magnetically Controlled Growth Rod(s), Percutaneous Endoscopic Approach, New Technology Group 2

While these codes begin to describe the procedures associated with this technology, the requestor believes that EOS surgery utilizing MCGR is more comprehensively and more precisely described by codes with a root operation of Fusion, which is fundamental to the use of MCGR according to the requestor. Per the requestor, surgical fusion with autografts or allografts is a fundamental part of virtually all MCGR surgeries. For EOS surgery to be successful, it is imperative for the construct's anchor sites to be stabilized via fusion. Surgical fusion is performed to create a solid bridge of new bone between two vertebral segments in the spine in order to provide stability. Bone graft or bone substitutes are used to provide the foundation and environment the body requires to stimulate enough new bone growth for this stabilizing bridge to form in the vertebral joints. If the vertebra don't fuse, distraction (lengthening) of the MCG

rod(s) isn't possible and the bone/screw interface (where the construct is affixed) may be compromised. For these reasons, the requestor feels fusion codes are more accurate and appropriate to describe MCGR surgery for EOS.

The requestor asserts that fusion codes would better reflect the initial MCGR implant surgery, which has a number of variables depending on the severity of the case. In addition, the requestor believes new codes are necessary to describe MCGR replacement (in the event of rod breakage) and to describe MCGR removal by creating additional codes with root operations of Insertion and Removal which would result in the creation of 76 new codes to adequately describe the entire surgical case from device implantation to removal.

The requestor also asks that the three section X codes described above containing the "Percutaneous Endoscopic" approach be deleted and replaced with codes that contain the "Percutaneous" approach as the percutaneous and open approaches are the approaches utilized in EOS surgery. (Percutaneous Endoscopy is not used with MCGR surgery.) Lastly the requestor asks for the creation of separate codes for cases when one MCGR is used, even though that occurs in a minority of cases (currently ~20%), as well as codes that address the implantation of replacement MCGR and the removal of MCGR at the completion of a case.

Current Coding: Report the initial surgery to place MCGR using the codes in table XNS of the New Technology section. Code the concomitant fusion procedure separately using the appropriate code(s) in tables 0RG or 0SG, Fusion of Upper and Lower Joints.

Coding Options

Option 1. Do not create additional new codes for MCGR surgery. Continue to use the existing ICD-10-PCS codes as described in current coding.

Option 2.

2a. In table XNS, Reposition in the Bones body system of the New Technology section, delete three codes specifying the percutaneous endoscopic approach and add three codes specifying the percutaneous approach, to enable more precise reporting of Reposition procedures performed using magnetically controlled growth rods (MCGR).

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*
0 Lumbar Vertebra **3** Cervical Vertebra **4** Thoracic Vertebra	**0** Open **ADD 3** Percutaneous **DELETE 4** Percutaneous Endoscopic	**3** Magnetically Controlled Growth Rod(s)	**2** New Technology Group 2

2b. Create new codes in Section X, table XRG to identify spinal fusion performed in conjunction with the initial reposition procedure to place magnetically controlled growth rods.

Section **X** New Technology *Body System* **ADD R** Joints *Operation* **ADD G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 6 Thoracic Vertebral Joint **ADD 7** Thoracic Vertebral Joints, 2 to 7 **ADD B** Lumbar Vertebral Joint **ADD C** Lumbar Vertebral Joints, 2 or more **ADD D** Lumbosacral Joint	**ADD 0** Open **ADD 3** Percutaneous	**ADD 3** Magnetically Controlled Growth Rod(s)	**ADD 2** New Technology Group 2

2c. Create new codes in section X to identify replacement of magnetically controlled growth rods using the root operations Removal and Insertion, applied to the vertebra and rib body part values.

Section **X** New Technology *Body System* **N** Bones *Operation* **ADD H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 0 Lumbar Vertebra **ADD 1** Ribs, 1 to 2 **ADD 2** Ribs, 3 or More **ADD 3** Cervical Vertebra **ADD 4** Thoracic Vertebra	**ADD 0** Open **ADD 3** Percutaneous	**ADD 3** Magnetically Controlled Growth Rod(s)	**ADD 2** New Technology Group 2

Section **X** New Technology *Body System* **N** Bones *Operation* **ADD P** Removal: Taking out or off a device from a body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 0 Lumbar Vertebra **ADD 1** Ribs, 1 to 2 **ADD 2** Ribs, 3 or More **ADD 3** Cervical Vertebra **ADD 4** Thoracic Vertebra	**ADD 0** Open **ADD 3** Percutaneous	**ADD 3** Magnetically Controlled Growth Rod(s)	**ADD 2** New Technology Group 2

CMS recommendation: Option 2a. In table XNS, Reposition in the Bones body system of the New Technology section, delete three codes specifying the percutaneous endoscopic approach and add three codes specifying the percutaneous approach, to enable more precise reporting of Reposition procedures performed using magnetically controlled growth rods (MCGR).

Interim Coding Advice: Continue to use the existing ICD-10-PCS codes for placement of MCGR and separate coding of concomitant spinal fusion as described in current coding.

Endovascular Intracranial Thrombectomy Procedures

Issue: ICD-10-PCS codes do not distinguish the major techniques used in percutaneous intracranial extirpation procedures such as mechanical embolectomy using stent retriever, aspiration, or a combination of procedures.

New Technology Application? No.

FDA Approval: The Trevo® Pro Retriever and the Trevo® ProVue Retriever received FDA clearance in 2012.

Background: During an acute ischemic stroke (AIS), the blood supply to part of the brain is cut off because atherosclerosis or a blood clot has blocked a blood vessel. The incidence of AIS is approximately 700,000 per year, with about 61,000 deaths, according to the American College of Emergency Physicians. In recent years, tissue plasminogen activator given intravenously (IV-tPA) has been the preferred treatment for AIS for patients presenting within 4.5 hours of symptom onset. However, more than half of the patients treated with IV-tPA do not recover completely or die and statistics indicate that fewer than 5% of acute ischemic strokes patients are eligible to receive IV-tPA for treatment. Furthermore, IV-tPA efficacy significantly decreases after the first hour of symptom onset and has little effect on large-vessel occlusions and hyper-dense thrombi.

In light of these challenges for successful stroke treatment, clinical experts looked to other options for patients with large-vessel occlusions, including mechanical thrombectomy (also referred to as endovascular therapy or mechanical embolectomy), which reopens occluded vessels by directly extracting an occlusive embolus from the cerebral vasculature. There are various FDA approved/cleared devices that have been approved for mechanical thrombectomy. It is particularly important to be able to distinguish between thrombectomy via stent retriever devices and other mechanical techniques (e.g., aspiration) given that clot removal via retriever devices is distinctly supported by the American Heart Association/American Stroke Association, and results published in peer-reviewed scientific literature confirm the effectiveness of the clot removal via a stent retriever technique.

In 2012, the FDA cleared the Trevo® Pro Retriever, which utilizes proprietary Stentriever® Technology for optimized clot retrieval in patients experiencing acute ischemic stroke and the Trevo® ProVue Retriever, the first clot removal device fully visible during the procedure for precise positioning within the clot and optimized clot retrieval in patients experiencing acute ischemic stroke.

These devices are intended to restore blood flow by removing clot in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV- tPA or who fail IV- tPA therapy are candidates for mechanical thrombectomy via stent retriever. Other stent retrieval systems include the Merci® Retrieval System and the Solitaire® FR Retriever.

A stent retriever used to treat an ischemic stroke differs from an implantable stent since it is inserted to actually remove the clot and then is withdrawn, in contrast to a stent that is used to maintain an anatomical opening/passage. Because the stent is used to help remove the clot and

is not left in the body at the end of the procedure, it is considered a surgical technique rather than a device in the ICD-10-PCS classification, and is not assigned a device value in ICD-10-PCS.

Current clinical literature on ischemic stroke treatment supports the effectiveness of mechanical thrombectomy via stent retriever. In large-vessel occlusions specifically, there are significantly higher odds of a favorable outcome with endovascular therapy compared to intravenous therapy.

Suction/Aspiration Thrombectomy

Good recovery and improved outcomes in acute ischemic stroke (AIS) patients are highly dependent on the time taken to restore blood flow to the brain. The IV administration of tPA to break up the clot is widely used, but this technique is not effective in patients with occlusion of large intra-cerebral arteries such as in the basilar artery or proximal middle cerebral artery There are several alternative endovascular treatments that are more effective than tPA. For example, suction/aspiration thrombectomy is associated with considerably higher recanalization rates than intravenous tPA.

Suction/aspiration thrombectomy devices employ vacuum aspiration to remove the occlusive clot in acute ischemic stroke. Manual aspiration of thrombi can be performed through any microcatheter, but these catheters have a tendency to clog. Thus, development of a suction thrombectomy system required a solution to the problem of clogging of aspiration tips. Today's suction/aspiration thrombectomy systems (e.g., Penumbra) address this problem by including a bore separator wire with a bulbous tip that the operator continually advances and retracts, disrupting the attached clot and pulling in the thrombus ahead of the catheter.

Stent Retriever Thrombectomy with Aspiration

The American Hospital Association/American Stroke Association (AHA/ASA) Guidelines discuss the advantages of a combined stent retriever-aspiration technique, noting the combination of balloon guide catheters or distal access/aspiration catheters with stent retrievers provides rapid, effective and safe recanalization. The thrombus is retracted into the aspiration catheter with continuous suction. Embolization into new territory (such as the anterior cerebral artery) is minimized and debris from the thrombectomy, if any, may be aspirated (instead of embolizing distally to branches of the MCA). The distal access provided by the aspiration catheter also simplifies subsequent thrombectomy attempts, if required.

The combination of two different techniques for recanalization (distal aspiration together with stent retriever thrombectomy) provides physicians with a technique that offers:

(1) rapid recanalization and
(2) low risk for distal embolic complications.

The distal location of the aspiration catheter also enables rapid replacement of a stent-retriever if a second thrombectomy attempt is required. There is an additional cost of using both a distal access catheter and a stent retriever catheter and increased time required to set up the three-tiered catheter system.

Current Coding: Code endovascular mechanical embolectomy procedures using the root operation Extirpation in the body system Upper Arteries, the body part value Intracranial Artery, and the approach Percutaneous**.**

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

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

Coding Options

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

Option 2. Create unique codes in table 03C, Extirpation of Upper Arteries, to distinguish endovascular intracranial thrombectomy using stent retriever from other intracranial extirpation procedures. Add qualifier values 2 Stent Retriever Technique, 3 Aspiration Technique and 4 Both Stent Retriever and Aspiration Techniques for the fourth character body part value G Intracranial Artery, with the approach value Percutaneous.

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

Body Part	*Approach*	*Device*	*Qualifier*
G Intracranial Artery	**3** Percutaneous	**Z** No Device	**ADD 2** Stent Retriever Technique **ADD 3** Aspiration Technique **ADD 4** Both Stent Retriever and Aspiration Technique **6** Bifurcation **Z** No Qualifier

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

Interim Coding Advice: Continue to code endovascular mechanical embolectomy procedures using the root operation Extirpation in the body system Upper Arteries, the body part value Intracranial Artery, and the approach Percutaneous.

ICD-10-PCS Definitions Addenda

Section 1 Obstetrics
Axis 3 Operation

Row		
Term		Change
Explanation	Delete	All CHANGE procedures are coded using the approach EXTERNAL
Row		
Term		Drainage
Explanation	Delete	The qualifier DIAGNOSTIC is used to identify drainage procedures that are biopsies
Row		
Term		Extraction
Explanation	Delete	The qualifier DIAGNOSTIC is used to identify extraction procedures that are biopsies

Section F Physical Rehabilitation and Diagnostic Audiology
Axis 5 Type Qualifier

Row	Delete	
Term	Delete	Neurophysiologic Intraoperative
Definition	Delete	Monitors neural status during surgery
Row		
Term		Prosthesis
Explanation	Delete	Artificial substitutes for missing body parts that augment performance or function
Definition	Add	Artificial substitutes for missing body parts that augment performance or function
Includes	Add	Limb prosthesis, ocular prosthesis

Section X New Technology
Axis 3 Operation

Row	Delete	
Term	Delete	Insertion
Definition	Delete	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
Includes	Delete	Insertion of radioactive implant, insertion of central venous catheter
Row	Delete	

Term	Delete	Removal
Definition	Delete	Taking out or off a device from a body part
Explanation	Delete	If a device is taken out and a similar device put in without cutting or puncturing the skin or mucous membrane, the procedure is coded to the root operation CHANGE. Otherwise, the procedure for taking out a device is coded to the root operation REMOVAL
Includes	Delete	Drainage tube removal, cardiac pacemaker removal

Row	Delete	
Term	Delete	Revision
Definition	Delete	Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device
Explanation	Delete	Revision can include correcting a malfunctioning or displaced device by taking out or putting in components of the device such as a screw or pin
Includes	Delete	Adjustment of position of pacemaker lead, recementing of hip prosthesis

Axis 5 Approach

Row	Delete	
Term	Delete	Via Natural or Artificial Opening
Definition	Delete	Entry of instrumentation through a natural or artificial external opening to reach the site of the procedure

Row	Delete	
Term	Delete	Via Natural or Artificial Opening Endoscopic
Definition	Delete	Entry of instrumentation through a natural or artificial external opening to reach and visualize the site of the procedure

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

Lttr	A	
Main	Add	Antigen-free air conditioning see Atmospheric Control, Physiological Systems 6A0

Lttr	D	
Main	Revise from	Decortication, lung see Extraction, Respiratory System 0BD
	Revise to	Decortication, lung
	Add	see Extirpation, Respiratory System 0BC
	Add	see Release, Respiratory System 0BN

Lttr H

Main Add HeartMate 3(tm) LVAS use Implantable Heart Assist System in Heart and Great Vessels

Main Revise from Hepatic flexure use Ascending Colon
Revise to Hepatic flexure use Transverse Colon

Lttr L

Main Revise from Lingual tonsil use Tongue
Revise to Lingual tonsil use Pharynx

Lttr P

Main Phototherapy
Add Ultraviolet light see Ultraviolet Light Therapy, Physiological Systems 6A8

Main Revise from Plasmapheresis, therapeutic 6A550Z3
Revise to Plasmapheresis, therapeutic see Pheresis, Physiological Systems 6A5

Main Revise from Plateletpheresis, therapeutic 6A550Z2
Revise to Plateletpheresis, therapeutic see Pheresis, Physiological Systems 6A5

Lttr T

Main Takedown
Revise from Stoma see Repair
Revise to Stoma
Add see Excision
Add see Reposition

Main Transposition
Add see Bypass

ICD-10-PCS Table Addenda

Medical and Surgical Section

Axis 4 Body Part

Excision/Resection of Thyroid Isthmus

Source	Description	Code specification
2016, AHIMA & CMS internal review	In tables 0GB and 0GT, Excision and Resection of the Endocrine body system, add the body part value Thyroid Gland Isthmus, for procedures in which part or all of the thyroid isthmus is cut out.	0GBJ[034]Z[XZ] (6 codes) 0GTJ[04]ZZ (2 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Pituitary Gland **1** Pineal Body **2** Adrenal Gland, Left **3** Adrenal Gland, Right **4** Adrenal Glands, Bilateral **6** Carotid Body, Left **7** Carotid Body, Right **8** Carotid Bodies, Bilateral **9** Para-aortic Body **B** Coccygeal Glomus **C** Glomus Jugulare **D** Aortic Body **F** Paraganglion Extremity **G** Thyroid Gland Lobe, Left **H** Thyroid Gland Lobe, Right **ADD J** Thyroid Gland Isthmus **L** Superior Parathyroid Gland, Right **M** Superior Parathyroid Gland, Left **N** Inferior Parathyroid Gland, Right **P** Inferior Parathyroid Gland, Left **Q** Parathyroid Glands, Multiple **R** Parathyroid Gland	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**X** Diagnostic **Z** No Qualifier

Reposition of Sesamoid Bones in the Foot

Source	Description	Code specification
2016, AHIMA & CMS internal review	In table 0QS, Reposition of Lower Bones, create new qualifier Sesamoid Bone(s) 1st Toe, applied to the body part values Metatarsal, Right and Metatarsal, Left, to enable precise reporting of procedures to reposition the sesamoid bone(s) of the foot.	0QS[NP][034][45Z]2 (18 codes) 0QS[NP]XZ2 (2 codes)

EXAMPLE

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*
N Metatarsal, Right **P** Metatarsal, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **5** External Fixation Device **Z** No Device	**ADD 2** Sesamoid Bone(s) 1st Toe **Z** No Qualifier
N Metatarsal, Right **P** Metatarsal, Left	**X** External	**Z** No Device	**ADD 2** Sesamoid Bone(s) 1st Toe **Z** No Qualifier

Excision/Repair of Oral Cavity and Throat

Source	Description	Code specification
2016, Coding Clinic EAB & CMS internal review	In the Anatomical Regions body system of the Med/Surg section, add the body part value Oral Cavity and Throat to tables 0WB Excision, and 0WQ Repair, to enable reporting of procedures on structures in the oral cavity or throat that span multiple tissue layers, such as excision of floor of mouth.	0WB3[034X]Z[XZ] (8 codes) 0WQ3[034X]ZZ (4 codes)

EXAMPLE

Section **0** Medical and Surgical
Body System **W** Anatomical Regions, General
Operation **B** Excision: Cutting out or off, without replacement, a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Head **2** Face **ADD 3** Oral Cavity and Throat **4** Upper Jaw **5** Lower Jaw **8** Chest Wall **K** Upper Back **L** Lower Back	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**Z** No Device	**X** Diagnostic **Z** No Qualifier

Body Part	*Approach*	*Device*	*Qualifier*
M Perineum, Male **N** Perineum, Female			

Extirpation of Solid Matter from Retroperitoneum

Source	Description	Code specification
2016, public comment & CMS internal review	In table 0WC, Extirpation of the Anatomical Regions, add the body part value Retroperitoneum to enable precise reporting of procedures such as removal of foreign body from the retroperitoneal space.	0WCH[034X]ZZ (4 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**W** Anatomical Regions, General
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

Body Part	*Approach*	*Device*	*Qualifier*
1 Cranial Cavity **3** Oral Cavity and Throat **9** Pleural Cavity, Right **B** Pleural Cavity, Left **C** Mediastinum **D** Pericardial Cavity **G** Peritoneal Cavity **ADD H** Retroperitoneum **J** Pelvic Cavity	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**Z** No Device	**Z** No Qualifier

Medical and Surgical Section
Axis 7 Qualifier

Insertion of External Heart Assist Devices

Source	Description	Code specification
2017, Coding Clinic Editorial Advisory Board & CMS internal review	In the Heart and Great Vessels body system, revise the device value External Heart Assist System to Short-term External Heart Assist System, and add the qualifier Intraoperative to table 02H, Insertion to clarify that these are short-term devices and to distinguish between procedures in which the device is used intraoperatively only, and procedures where the device remains in the patient at the conclusion of the procedure, and is removed anywhere from several hours to several days later. In addition, add the qualifier Biventricular to tables 02P and 02W, Removal and Revision in the Heart and Great Vessels body system, for the device value External Heart Assist System, to enable precise reporting of these procedures to remove or revise a biventricular external heart assist device.	02HA[034]RJ (3 codes) 02PA[034]RS (3 codes) 02WA[034]RS (3 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Q** Implantable Heart Assist System	**Z** No Qualifier
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**REVISE from R** External Heart Assist System **REVISE to R** Short-term External Heart Assist System	**ADD J** Intraoperative **S** Biventricular **Z** No Qualifier

Drug-coated Balloon Dilation of Lower Arteries

Source	Description	Code specification
2017, Coding Clinic Editorial Advisory Board & CMS internal review	In table 047, Dilation of Lower Arteries, apply qualifier Drug-Coated Balloon to the remaining body part values in the table, applied to the device values Drug-Eluting Intraluminal Device, Intraluminal Device, and Z No Device, to enable precise reporting of dilation procedures that use the drug-coated balloon technique.	047[0-J,P-Y]^^1 (243 codes)

EXAMPLE

Section **0** Medical and Surgical
Body System **4** Lower Arteries
Operation **7** Dilation: Expanding an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
ADD 0 Abdominal Aorta **ADD 1** Celiac Artery **ADD 2** Gastric Artery **ADD 3** Hepatic Artery **ADD 4** Splenic Artery **ADD 5** Superior Mesenteric Artery **ADD 6** Colic Artery, Right **ADD 7** Colic Artery, Left **ADD 8** Colic Artery, Middle **ADD 9** Renal Artery, Right **ADD A** Renal Artery, Left **ADD B** Inferior Mesenteric Artery **ADD C** Common Iliac Artery, Right **ADD D** Common Iliac Artery, Left **ADD E** Internal Iliac Artery, Right **ADD F** Internal Iliac Artery, Left **ADD H** External Iliac Artery, Right **ADD J** External Iliac Artery, Left **K** Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **ADD P** Anterior Tibial Artery, Right **ADD Q** Anterior Tibial Artery, Left **ADD R** Posterior Tibial Artery, Right **ADD S** Posterior Tibial Artery, Left **ADD T** Peroneal Artery, Right **ADD U** Peroneal Artery, Left **ADD V** Foot Artery, Right **ADD W** Foot Artery, Left **ADD Y** Lower Artery	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Intraluminal Device, Drug-eluting **D** Intraluminal Device **Z** No Device	**ADD 1** Drug-Coated Balloon **6** Bifurcation **Z** No Qualifier

New Technology Section
Axis 6 Substance

Other Therapeutic Substance

Source	Description	Code specification
CMS internal review	In table XW0 of the New Technology section, add substance value G Other Therapeutic Substance for the central and peripheral vein body part values, to identify new technology drugs for which there is no unique code.	XW0[34]3G3 (2 codes)

EXAMPLE

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