DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 04-07-06
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

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 5, 2019

Webcast and Dial-In Information for Listen-only Participants

- Day 1: March 5, 2019: The meeting will begin at 9:00 AM ET and will end promptly at 1:00 PM ET. There will not be a lunch break for this session. The meeting will be webcast via CMS at http://www.cms.gov/live/.
- Day 2: March 6, 2019: The meeting will begin at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 11:30 AM ET to 1:00 PM ET. The meeting will be webcast via CMS at http://www.cms.gov/live/.
- Toll-free dial-in access is available for listen-only participants who cannot join the webcast:
  Day 1-March 5, 2019: Phone: 1-877-267-1577; Meeting ID: 990 668 147.
  Day 2-March 6, 2019: Phone: 1-877-267-1577; Meeting ID: 990 668 147.
  We encourage you to join early, as the number of phone lines is limited.

In-Person Attendance

- Day 1: March 5, 2019: The meeting is being held in the CMS Auditorium. The meeting time is listed above. 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.

There will not be a WebEx option for this meeting. In-person attendees may ask questions, as time permits. Remaining questions, as well as questions from those attending the meeting via the webcast may be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov.

- Day 2: March 6, 2019: The meeting is being held in the CMS Media Center. The meeting time is listed above. 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 6, 2019 and will be led by the Centers for Disease Control (CDC). Please visit CDCs website for the Diagnosis agenda located at the following address: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm

Registration to attend meeting in-person:
Information on registering online to attend the meeting in-person can be found at: http://www.cms.hhs.gov/apps/events/ ***If participating via the webcast or dialing in, and not attending in-person, you do NOT need to register on-line for the meeting.** For questions about the registration process, please contact Mady Hue at 410-786-4510 or marilu.hue@cms.hhs.gov or Noel Manlove at 410-786-5161 or noel.manlove@cms.hhs.gov.

Updated Security Information for In-person Attendees:

Beginning June 1, 2018, Federal Protective Services (FPS) has implemented new security screening procedures at all CMS Baltimore locations to align with national screening standards. Please allow extra time to clear security prior to the beginning of the meeting.

Employees, contractors and visitors must place **all items** in bins for screening, including:

- Any items in your pockets
- Belts, hats, jackets & coats (not suit jackets or sport coats)
- Purses, laptop computers & cell phones
- Larger items (e.g. computer bags) can be placed directly onto the conveyer.

In the event the metal detector beeps when you walk through:

- A security guard will run a hand-held metal detector over you. If the metal detector doesn't alarm, you're cleared to enter.
- If the hand-held metal detector alarms, the guard will pat down the area of the body where the metal detector alarmed.
- If footwear alarms, it will need to be removed and placed in a bin for x-ray screening.
- Employees using a mobility aid (e.g. wheelchair, motorized scooter) will be screened using a hand-held metal detector and/or pat-down.

If you believe that you have a disability that will cause you to require reasonable accommodation to comply with the new process, please contact **reasonableaccommodationprogram@cms.hhs.gov** as soon as possible.

ICD-10-PCS Topics:

1. Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement Pages 11-13	Mady Hue Alexandra Lansky, MD Professor of Medicine, Section of Cardiology Yale School of Medicine
2. Administration of ELZONRIS™ (tagraxofusp; SL-401) Pages 14-15	Chava Sheffield, PhD Adam Soares, PharmD. MBA Medical Science Liaison, Medical Affairs Stemline Therapeutics, Inc.
3. Administration of VENCLEXTA® (venetoclax) Pages 16-17	Chava Sheffield, PhD John Hayslip, MD, MSCR Group Medical Director AbbVie
4. Brachytherapy Using Unidirectional Source Pages 18- 23	Chava Sheffield, PhD Thomas Gustafson, PhD Senior Policy Advisor Arnold & Porter Kristy Perez, PhD Vice President of Clinical Programs CivaSheet Oncology
5. Treatment of Unruptured Intracranial Aneurysm Using Flow Diverter Stent Pages 24-26	Mady Hue Alexander Coon, MD Professor of Neurosurgery Johns Hopkins
6. Renal Function Monitoring Pages 27-29	Mady Hue Stuart Goldstein, MD, FASN, FAAP, FNKP Director, Center for Acute Care Nephrology Cincinnati Children's Hospital Director of Clinical Development, MediBeacon
7. Administration of Caplacizumab Pages 30-32	Noel Manlove Jon Kendter, PharmD Associate Director of Medical Affairs Sanofi/Ablynx
8. Administration of CONTEPO® (fosfomycin) Pages 33-35	Noel Manlove Kim Sweeney, PharmD Nabriva Therapeutics

9. Administration of XOSPATA® (gilteritinib) Pages 36-37	Noel Manlove John C Hammons, PharmD, MBA Director, Field Health Economics & Outcomes Research Astellas Pharma
10. Administration of AZEDRA® (iobenguane I-131) Pages 38-40	Michelle Joshua Dr. Daniel Pryma University of Pennsylvania Vivien Wong, PhD Progenics Pharmaceuticals, Inc.
11. Angioplasty with Sustained Released Drug-Eluting Stent for Above the Knee Arteries Pages 41-45	Mady Hue Juan Diaz-Cartelle, MD Senior Medical Director Boston Scientific
12. Extracorporeal Membrane Oxygenation (ECMO) for Cardiopulmonary Support Pages 46-49	Mady Hue Joseph Cleveland, MD Surgical Director of Heart Transplantation University of Colorado School of Medicine
13. Administration of Jakafi® (ruxolitinib) Pages 50-52	Michelle Joshua Ahmad Naim, M.D. US Medical Affairs Incyte Corporation
14. Endovascular Arteriovenous Fistula (AVF) Creation Using Magnetic-guided Radiofrequency Energy and Venous Embolization Pages 53-56	Michelle Joshua Paul Kreienberg, MD Vascular Surgeon, The Vascular Group Program Director, Vascular Surgery Training Program, Albany Medical Center
15. T2Bacteria Panel Pages 57-58	Michelle Joshua Tom Lowery T2 Biosystems, Inc.
16. Administration of IMI_REL (imipenem) Pages 59-61 **Note:** This will be presented on Day 2: March 6, 2019	Noel Manlove Andrew Parker, Associate Director Dr. Eilish McCann Merck
17. Addenda and Key Updates Pages 60-69 **Note:** This will be presented on Day 2: March 6, 2019	Rhonda Butler , 3M

Registering for the meeting:
Registration for the March 5-6, 2019 ICD-10 Coordination and Maintenance Committee meeting opened on Friday, February 1, 2019 and closed on Friday, February 22, 2019. **Participants attending by Livestream webcast or dialing in you did not need to register online.**

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

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

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

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

ICD-10 TIMELINE

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

March 5-6, 2019	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 22, 2019.** 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.
March 2019	Webcast of the March 5-6, 2019 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
April 1, 2019	There were no requests for ICD-10 codes to capture new diagnoses or new technology for implementation on April 1, 2019. Therefore, there will be no new ICD-10 diagnosis or procedure codes implemented on April 1, 2019.
April 5, 2019	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 5-6, 2019 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2019**.
April 2019	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 2020 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 2019	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
June 14, 2019	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 10-11, 2019 ICD-10 Coordination and Maintenance Committee meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.**
August 1, 2019	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, 2019. 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 2019	Tentative agenda for the Procedure part of the September 10-11, 2019 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage at – https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis part of the September 10-11, 2019 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 10-11, 2019 ICD-10 Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.
August 2, 2019	**On-line registration opens for the September 10-11, 2019 ICD-10 Coordination and Maintenance Committee meeting at:** **https://www.cms.gov/apps/events/default.asp**
September 2, 2019	Because of increased security requirements, those wishing to attend the September 10-11, 2019 ICD-10 Coordination and Maintenance Committee meeting must register for the meeting online at: **https://www.cms.gov/apps/events/default.asp** **Attendees must register online by September 2, 2019; failure to do so may result in lack of access to the meeting.**
September 10-11, 2019	ICD-10 Coordination and Maintenance Committee Meeting.

	Those who wish to attend the ICD-10 Coordination and Maintenance Committee meeting **must have registered for the meeting online by September 2, 2019.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building.
September 2019	Webcast of the September 10-11, 2019 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
October 1, 2019	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 11, 2019	**Deadline for receipt of public comments on proposed new codes discussed at the September 10-11, 2019 ICD-10 Coordination and Maintenance Committee meetings for implementation on April 1, 2020.**
November 2019	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, 2020 will be posted on the following websites: http://www.cdc.gov/nchs/icd/icd10cm.htm http://www.cms.gov/Medicare/Coding/ICD10/
November 8, 2019	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 10-11, 2019 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2020.**

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 responsibility on procedure issues
  - CDC has lead responsibility on diagnosis issues
- Coding proposals requested by the public are presented and public given opportunity to comment

Code Proposals

- ICD-10-PCS code proposals being consideration for implementation on October 1, 2019
- No final decisions are 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 5, 2019 for codes discussed at the March 5-6, 2019 C&M meeting
- Procedure comments to CMS (new address) ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to Donna Pickett, CDC nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2019 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2019 C&M meeting
- August 1, 2019 – Final rule with links to final codes to be implemented on October 1, 2019
  - Includes any additional codes approved from March 5-6, 2019 C&M meeting
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page.html

Addendum

- June 2019 – Final code updates and addendum posted
  - FY 2020 ICD-10-PCS (Procedures) http://www.cms.gov/Medicare/Coding/ICD10/index.html
  - FY 2020 ICD-10-CM (Diagnoses) http://www.cdc.gov/nchs/icd/icd10cm.htm

Public Participation

- For this meeting, the public may participate in the following ways:
  - Attend meeting in person
  - Listen to proceedings through free conference lines
  - View 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 5, 2019 for codes to be implemented on October 1, 2019
  - Procedure comments to CMS ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis comments to Donna Pickett, CDC nchsicd10cm@cdc.gov

ICD-10-PCS Codes Implementation

- ICD-10-PCS codes discussed today under consideration for October 1, 2019 implementation

September 10-11, 2019 C&M Code Requests

- June 14, 2019– Deadline for submitting topics for September 10-11, 2019 C&M meeting
  - Procedure requests to CMS (new address) ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis requests to Donna Pickett, CDC nchsicd10cm@cdc.gov

Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement (TAVR)

Issue: There is not a unique ICD-10-PCS code 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), or to differentiate between a dual filter device and a deflection filter device.

New Technology Application? The requester is considering a new technology application for FY 2021.

Background: Transcatheter aortic valve replacement (TAVR) has emerged as an important alternative to surgical aortic valve replacement (SAVR) for high-risk and moderate-risk patients with aortic stenosis, offering overall less morbidity, similar mortality and significantly reduced recovery time. However, periprocedural neurological injury remains an important limitation of TAVR. In high-risk surgical candidates in the randomized PARTNER trial, TAVR was associated with an approximately two-fold increased risk of stroke or TIA (5.5% vs. 2.4%, p=0.04) compared with SAVR at 30 days. In inoperable subjects, stroke or TIA occurred in 6.7% of TAVR patients at 30 days, with 5.0% of subjects suffering a major stroke. A meta-analysis of 10,037 published TAVR patients found an overall 30-day stroke rate of 3.3±1.8%, with the majority being major strokes (2.9±1.8%) (V, add ref here). In this study, stroke was associated with a more than 3.5-fold increase in 30-day mortality (25.5±21.9% vs. 6.9±4.2%). In the more recent PARTNER 2 trial, the rates of any stroke in moderate risk patients with AS after TAVR were similar to the rates after SAVR: 5.5% vs. 6.1% at 30 days and as high as 9.5% vs. 8.9% at 2 years, for TAVR and SAVR respectively.

The timing of stroke after TAVR follows a bimodal distribution. The risk of stroke during an early high-peaking hazard phase (within 2 days of the procedure) is primarily procedure related (TAVR versus SAVR). More than 50% of strokes in TAVR patients occur during this early phase. As during other types of cardiac procedures, periprocedural stroke during TAVR is generally ischemic and embolic. TAVR patients have several high-risk features that make cerebral embolization particularly common. First, the prevalence of severe aortic atherosclerosis increases across grades of AS, which when combined with the large-caliber catheters necessary for TAVR, make dislodgement of aortic debris more likely. Second, disruption of aortic valvular and annular calcification during TAVR is an additional source of embolic material; procedural transcranial Doppler monitoring indicates that the valve itself is the primary source of cerebral emboli following TAVR, and that most emboli are composed of debris dislodged during direct manipulation of the calcified aortic valve and crushing of the leaflets and aortic annulus during implantation.

In addition to clinical stroke, there is increasing recognition of the importance of subclinical manifestations of periprocedural cerebral embolization in cardiac procedures in general and TAVR in particular. A growing body of evidence indicates that clinically, silent cerebral ischemia is common after TAVR and may have an important impact on short and long term clinical and neurocognitive outcomes. Diffusion-weighted magnetic resonance imaging (DW-MRI) is a highly sensitive and specific technique to visualize acute ischemia. Several small studies have reported DW-MRI data after unprotected TAVR. Foci of restricted cerebral perfusion on DW-MRI (cerebral ischemic lesions) are present in approximately 85% of patients (reported range 58% to 100%) after

TAVR. Most patients have multiple lesions (mean 4.6), distributed bilaterally in a pattern suggesting cerebral embolization.

Technology: The Keystone Heart TriGuard 3™ Cerebral Embolic Protection Device (CEPD) is delivered percutaneously and consists of a temporary, retrievable, sterile, single use, biocompatible filter, and is introduced transfemorally through an 8F sheath to the aortic arch. The TriGUARD 3™ CEPD filter includes a self-stabilizing frame design, a small pore size filter mesh, and a delivery system intended for ease of use. Under fluoroscopic guidance, the device is positioned in the aortic arch to cover all major cerebral arteries (covering the innominate, left carotid, and left subclavian arteries), and is held in position by the device's circumferential pressure and the support of the nitinol shaft (external communicating device) in the aortic arch.

The TriGUARD 3™ CEPD is available in a single size, and is composed of a structural nitinol frame and a polymer mesh that pushes it towards the upper wall of the aortic arch. The frame is radiopaque to increase device visualization under fluoroscopy. A nitinol connector connects the device frame to the delivery system. The CEPD filter consists of a thin and durable Polymer mesh (nominal pore size 115 X 145 μm) attached to the frame, allowing maximal blood flow while diverting emboli toward the descending aorta. The CEPD filter unit is connected to a delivery system that serves for pushing, maintaining and retrieving the filter from the aortic arch.

In addition to the filter, the TriGUARD 3™ System includes a delivery subsystem for crimping and loading the device into a commercially available 8F braided sheath. Device deployment is accomplished by pre-loading (crimping) the CEPD through the dedicated crimper into the distal end of the 8F delivery system. Under fluoroscopy, the 8F sheath is advanced over the wire already inserted through a femoral artery access site. The device is then de-sheathed and exposed to the blood stream.

Current Coding: There is no unique ICD-10-PCS code for cerebral embolic protection during TAVR procedures using a deflection filter device placed in the aortic arch. Code for 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 ICD-10-PCS codes for cerebral embolic protection during TAVR using a deflection filter device placed in the aortic arch. Continue coding the TAVR procedure as listed in current coding.

Option 2. Create new qualifier value J Deflection Filter in table 5A0 of section 5, Extracorporeal or Systemic Assistance and Performance, applied to the physiological system Circulatory, the new duration value A Temporary, and the function value Filtration, to identify cerebral embolic protection during TAVR using a deflection filter placed in the aortic arch. A separate code is assigned for the TAVR procedure, as listed in current coding.

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

Body System	*Duration*	*Function*	*Qualifier*
2 Cardiac	**1** Intermittent **2** Continuous	**1** Output	**0** Balloon Pump **5** Pulsatile Compression **6** Other Pump **D** Impeller Pump
5 Circulatory	**ADD A** Temporary	**D** Filtration	**ADD J** Deflection Filter
5 Circulatory	**1** Intermittent **2** Continuous	**2** Oxygenation	**1** Hyperbaric **C** Supersaturated
9 Respiratory	**2** Continuous	**0** Filtration	**Z** No Qualifier
9 Respiratory	**3** Less than 24 Consecutive Hours **4** 24-96 Consecutive Hours **5** Greater than 96 Consecutive Hours	**5** Ventilation	**7** Continuous Positive Airway Pressure **8** Intermittent Positive Airway Pressure **9** Continuous Negative Airway Pressure **B** Intermittent Negative Airway Pressure **Z** No Qualifier

Option 3. Create a new code in section X, New Technology, to identify cerebral embolic protection during TAVR using a deflection filter placed in the aortic arch. A separate code is assigned for the TAVR procedure, as listed in Current Coding.

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 6 Aortic Arch	**3** Percutaneous	**ADD 2** Cerebral Embolic Filtration, Single Deflection Filter	**ADD 5** New Technology Group 5

CMS Recommendation: Option 3. This option is consistent with another CEPD included in Section X that is familiar to coders and provides the requested detail to be identified in the data as a new technology that will also inform future analysis of Section X codes in the classification.

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

Administration of tagraxofusp-erzs (ELZONRIS™)

Issue: There is currently no unique ICD-10-PCS code to describe the administration of tagraxofusp-erzs injection for intravenous infusion. Tagraxofusp-erzs is an intravenously-administered antineoplastic CD123 targeted therapy that is comprised of IL-3 genetically fused to the catalytic and translocation domains of diphtheria toxin.

New Technology Application? Yes, a new technology application was submitted for tagraxofusp-erzs for FY 2020.

Food & Drug Administration (FDA) Approved? Yes. On December 21st, 2018, the FDA approved tagraxofusp-erzs for the treatment of Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) in adults and in pediatric patients 2 years and older.

Background: BPDCN is a highly aggressive hematologic cancer that is most frequently diagnosed in males between the ages of 60 and 70. Primary sites include the skin and bone marrow. According to the requestor, there is no other FDA-approved treatment or standard of care for BPDCN, and patients have a poor prognosis, with median overall survival of approximately 8 to 14 months. BPDCN that is treated with chemotherapy often results in an initial response followed by relapse and rapid disease progression. Tagraxofusp-erzs is administered intravenously; its mechanism of action involves a receptor-mediated endocytosis, inhibition of protein synthesis, and interference with IL-3 signal transduction pathways, leading to growth arrest and apoptosis in leukemia blasts and cancer stem cells.

Current Coding: Facilities can report the administration of tagraxofusp-erzs 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 administration of tagraxofusp-erzs. Continue using current codes as listed in Current Coding.

Option 2. Create new qualifier value Q Tagraxofusp-erzs in table 3E0 of section 3, Administration, applied to the fourth character values Central Vein and Peripheral Vein and the percutaneous approach, to identify intravenous administration of tagraxofusp-erzs.

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**0** Antineoplastic	**2** High-dose Interleukin-2 **3** Low-dose Interleukin-2 **5** Other Antineoplastic **ADD Q** Tagraxofusp-erzs **M** Monoclonal Antibody **P** Clofarabine

Option 3. Create new codes in section X, New Technology, to identify intravenous administration of tagraxofusp-erzs.

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 Q** Tagraxofusp-erzs Antineoplastic	**ADD 5** New Technology Group 5

CMS Recommendation: Option 3. Create new codes in section X, New Technology, to identify intravenous administration of tagraxofusp-erzs.

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

Administration of Venclexta® (venetoclax tablets)

Issue: There is currently no unique ICD-10-PCS code to describe the administration of Venclexta for the treatment of acute myeloid leukemia (AML).

New Technology Application? Yes, a new technology application was submitted for Venclexta for FY 2020.

Food & Drug Administration (FDA) Approved? Yes. On November 21st, 2018, the FDA approved Venclexta for the treatment of newly-diagnosed AML patients that are ineligible for intensive chemotherapy, either due to age greater than 75 or due to the presence of comorbidities. The FDA approved indication is for Venclexta in combination with azacitidine, decitabine or low-dose cytarabine.

Background: AML is the most common form of acute leukemia in adults, in which the bone marrow makes abnormal, immature types of red blood cells, white blood cells, or platelets. According to the requester (or requestor), AML patients who are ineligible for intensive chemotherapy currently receive lower intensity treatments that result in low complete remission rates and therefore have a median survival of 5 to 10 months.

Venclexta is an orally administered selective B-cell lymphoma 2 (BCL-2) inhibitor for the treatment of recently diagnosed AML. Venclexta works by inhibiting the anti-apoptotic BCL-2 protein, which regulates cell death and is associated with chemotherapy resistance and poor outcomes in AML patients. According to the requester, Venclexta is known to synergize with hypomethylating agents (azacitidine/decitabine) and low-dose cytarabine in AML.

Current Coding: Facilities can report the administration of Venclexta with the following ICD-10-PCS code:

3E0DX05 Introduction of Other Antineoplastic into Mouth and Pharynx, External Approach

Coding Options

Option 1. Do not create a new ICD-10-PCS code for the administration of Venclexta. Continue using current code as listed in Current Coding.

Option 2. Create new qualifier value Venetoclax in table 3E0 of section 3, Administration, applied to the fourth character value Mouth and Pharynx, external approach, to identify oral administration of Venclexta.

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
D Mouth and Pharynx	**X** External	**0** Antineoplastic	**4** Liquid Brachytherapy Radioisotope **5** Other Antineoplastic **ADD R** Venetoclax **M** Monoclonal Antibody

Option 3. Create a new code in section X, New Technology, to identify oral administration of Venclexta.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
D Mouth and Pharynx	**X** External	**ADD R** Venetoclax Antineoplastic	**ADD 5** New Technology Group 5

CMS Recommendation: Option 3. Create a new code in section X, New Technology, to identify oral administration of Venclexta.

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

Brachytherapy Using Unidirectional Source

Issue: Existing ICD-10-PCS codes that describe low-dose rate (LDR) brachytherapy do not specify application that uses a unidirectional source, and do not include all treatment sites for which brachytherapy may be used. The CivaSheet® Brachytherapy Device ("CivaSheet®") is applied intraoperatively and may be used in treatment sites beyond those described by existing ICD-10-PCS codes.

New Technology Application? Yes, a new technology application was submitted for CivaSheet® for FY 2020.

Food & Drug Administration (FDA) Approved? Yes. FDA approval was obtained on August 29, 2014.

Background: CivaSheet® is an implantable, LDR brachytherapy device that is indicated for the treatment of selected localized tumors. It is configured as an array of directional radioactive palladium-103 sources encapsulated in an organic polymer and embedded within a flexible, membrane-like bioabsorbable substrate. CivaSheet® is applied during the same operative episode as tumor resection, and can be cut and customized to the body cavity or tissue of the patient. CivaSheet® may be used concurrently with or sequentially with other treatment modalities, such as external beam radiation therapy or chemotherapy.

According to the requester, one of the unique features of the device is the use of gold shielding that is incorporated into each source, giving the sheet an active and an inactive side. The active side delivers a full dose of radiation to surgical margins, while radio-sensitive and healthy tissues on the inactive side are shielded from unnecessary and potentially harmful radiation. This configuration means that clinically effective doses of radiation can be delivered without toxicity to adjacent tissues, which provides an alternative to external beam radiation, particularly in patients that have already received maximum doses from prior radiation treatments.

Some of the localized tumors for which CivaSheet® may be used include colorectal, gynecological, head and neck, and pancreatic cancers, soft tissue sarcomas, non-small-cell lung cancer, ocular melanoma, and atypical meningioma.

Current Coding: Facilities can report CivaSheet® brachytherapy during tumor resection surgery to the appropriate Brachytherapy table in Section D Radiation Therapy, with the fifth character modality qualifier B Low Dose Rate, the sixth character isotope value B Palladium 103, and the qualifier value Z No Qualifier. Examples from the ICD-10-PCS tables are provided below.

Section **D** Radiation Therapy *Body System* **B** Respiratory System *Modality* **1** Brachytherapy			
Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Trachea **1** Bronchus **2** Lung **5** Pleura **6** Mediastinum **7** Chest Wall **8** Diaphragm	**9** High Dose Rate (HDR) **B** Low Dose Rate (LDR)	**7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

Section	**D** Radiation Therapy
Body System	**W** Anatomical Regions
Modality	**1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
1 Head and Neck **2** Chest **3** Abdomen **6** Pelvic Region	**9** High Dose Rate (HDR) **B** Low Dose Rate (LDR)	**7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

Coding Options

Option 1. Do not create new ICD-10-PCS codes for brachytherapy using CivaSheet®. Continue using current codes as described in current coding.

Option 2. In the Radiation Therapy section, create new qualifier 1 Unidirectional Source, applied to all Brachytherapy tables (D^1) for the fifth character modality value B Low Dose Rate and the sixth character Isotope value B Palladium 103, to identify CivaSheet® brachytherapy. In addition, create new fourth character treatment sites 0 Cranial Cavity, K Upper Back, L Lower Back, P Gastrointestinal Tract, Q Respiratory Tract, R Genitourinary Tract, X Upper Extremity, and Y Lower Extremity and add to table DW1, Brachytherapy of Anatomical Regions, to capture additional treatment sites specified by the requester and not currently in the Brachytherapy tables.

Section	**D** Radiation Therapy
Body System	**0** Central and Peripheral Nervous System
Modality	**1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Brain **1** Brain Stem **6** Spinal Cord **7** Peripheral Nerve	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Section	**D** Radiation Therapy
Body System	**7** Lymphatic and Hematologic System
Modality	**1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Bone Marrow **1** Thymus **2** Spleen **3** Lymphatics, Neck **4** Lymphatics, Axillary **5** Lymphatics, Thorax **6** Lymphatics, Abdomen **7** Lymphatics, Pelvis **8** Lymphatics, Inguinal	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Section	**D** Radiation Therapy
Body System	**8** Eye
Modality	**1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Eye	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Section **D** Radiation Therapy
Body System **9** Ear, Nose, Mouth and Throat
Modality **1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Ear **1** Nose **3** Hypopharynx **4** Mouth **5** Tongue **6** Salivary Glands **7** Sinuses **8** Hard Palate **9** Soft Palate **B** Larynx **D** Nasopharynx **F** Oropharynx	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Section **D** Radiation Therapy
Body System **B** Respiratory System
Modality **1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Trachea **1** Bronchus **2** Lung **5** Pleura **6** Mediastinum **7** Chest Wall **8** Diaphragm	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Section **D** Radiation Therapy
Body System **D** Gastrointestinal System
Modality **1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Esophagus **1** Stomach **2** Duodenum **3** Jejunum **4** Ileum **5** Colon **7** Rectum	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Section **D** Radiation Therapy
Body System **F** Hepatobiliary System and Pancreas
Modality **1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Liver **1** Gallbladder **2** Bile Ducts **3** Pancreas	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Section **D** Radiation Therapy
Body System **G** Endocrine System
Modality **1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Pituitary Gland **1** Pineal Body **2** Adrenal Glands	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

4 Parathyroid Glands **5** Thyroid			

Section **D** Radiation Therapy *Body System* **M** Breast *Modality* **1** Brachytherapy			
Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Breast, Left **1** Breast, Right	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Section **D** Radiation Therapy *Body System* **T** Urinary System *Modality* **1** Brachytherapy			
Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Kidney **1** Ureter **2** Bladder **3** Urethra	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Section **D** Radiation Therapy *Body System* **U** Female Reproductive System *Modality* **1** Brachytherapy			
Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Ovary **1** Cervix **2** Uterus	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Section **D** Radiation Therapy *Body System* **V** Male Reproductive System *Modality* **1** Brachytherapy			
Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Prostate **1** Testis	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Section **D** Radiation Therapy *Body System* **W** Anatomical Regions *Modality* **1** Brachytherapy			
Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
ADD 0 Cranial Cavity **1** Head and Neck **2** Chest **3** Abdomen **6** Pelvic Region **ADD K** Upper Back **ADD L** Lower Back **ADD P** Gastrointestinal Tract **ADD Q** Respiratory Tract **ADD R** Genitourinary Tract **ADD X** Upper Extremity **ADD Y** Lower Extremity	**B** Low Dose Rate (LDR)	**B** Palladium 103 (Pd-103)	**ADD 1** Unidirectional Source **Z** None

Option 3. Create new codes in section X, New Technology, to specify CivaSheet® brachytherapy during tumor resection surgery.

Section **X** New Technology *Body System* **W** Anatomical Regions *Operation* **B** Brachytherapy			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 1 Subcutaneous Tissue **ADD 2** Muscle **ADD 3** Peripheral Vein **ADD 4** Central Vein **ADD 5** Peripheral Artery **ADD 6** Central Artery **ADD C** Eye **ADD F** Respiratory Tract **ADD H** Lower GI **ADD J** Biliary and Pancreatic Tract **ADD P** Female Reproductive **ADD Q** Cranial Cavity and Brain **ADD R** Spinal Canal **ADD U** Joints **ADD V** Bones	**ADD 0** Open	**ADD B** Palladium 103 (Pd-103), Unidirectional Source	**5** New Technology Group 5

CMS Recommendation: Option 2.

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

Meeting comment: A commenter expressed concern with the coding options based on 1) the Index entry and Device Key for Brachytherapy seeds that instructs to use Radioactive Element and 2) published coding advice for the GammaTile™ collagen implant for which a new code was created effective October 1, 2017, that describes Insertion with radioactive element and for which a corresponding Index entry exists.

Response: CMS agrees that the ICD-10-PCS Index entry for Brachytherapy seeds instructs to use Radioactive Element, which is found within the Insertion tables as well as certain Removal tables of the classification and that the ICD-10-PCS procedure code 00H004Z Insertion of Radioactive Element, Cesium-131 Collagen Implant into Brain, Open Approach identifies the insertion of the GammaTile™ collagen implant. We also note that the Index entry for Brachytherapy directs users to Section D Radiation Therapy to identify the modality and specific isotope.

While we agree that, generally, it is appropriate to report an Insertion with radioactive element code to specifically identify the use of brachytherapy seeds, we also believe it does not necessarily provide additional detail beyond that captured in the proposed Brachytherapy code options for CivaSheet®. Brachytherapy, by definition, involves the placement of a locally-acting radioactive source. The CivaSheet® code proposal includes the qualifier value "Unidirectional Source" to address the unidirectional configuration and shielding that enables administration of a targeted radiation dose via seeds embedded within the CivaSheet® membrane.

The ICD-10-PCS code reported for the insertion of the GammaTile™ collagen implant identifies the specific isotope of the radioactive source used, and the specific isotope, Cesium-131, is not available in ICD-10-PCS table D01, Brachytherapy of Central and Peripheral Nervous System; therefore, no additional code is required for reporting purposes. However, the specific modality and

isotope is currently available in Section D Radiation Therapy for the CivaSheet®, and therefore we do not recommend adding specific isotope related information to the Med/Surg section.

Based on the concerns expressed, we are seeking public comments on the reporting of both an Insertion of radioactive element code from the Med/Surg section of ICD-10-PCS along with a Brachytherapy code from Section D Radiation Therapy versus a single Brachytherapy code from Section D Radiation Therapy for the CivaSheet®.

Once all comments have been received by the April 5, 2019 deadline and reviewed, we will confirm the interim coding advice for CivaSheet®.

Treatment of Unruptured Intracranial Aneurysm Using Flow Diverter Stent

Issue: There is not a unique ICD-10-PCS device value to describe the use of a Flow Diverter stent that is implanted to treat nonruptured intracranial aneurysm.

New Technology Application? No.

FDA Approval: Two Flow Diverter implant devices have been FDA approved for the endovascular treatment of adults with nonruptured intracranial aneurysms.

Stryker's Surpass Streamline™ Flow Diverter is indicated for use in the endovascular treatment of patients (18 years of age and older) with unruptured large or giant saccular wide-neck (neck width ≥ 4 mm or dome-to-neck ratio < 2) or fusiform intracranial aneurysms in the internal carotid artery from the petrous segment to the terminus arising from a parent vessel with a diameter ≥ 2.5 mm and ≤ 5.3 mm.

The Pipeline™ Flex embolization device (Medtronic) is indicated for the endovascular treatment of adults (22 years of age or older) with large or giant wide-necked intracranial aneurysms (IAs) in the internal carotid artery from the petrous to the superior hypophyseal segments. It is also indicated for use in the internal carotid artery up to the terminus for the endovascular treatment of adults (22 years of age or older) with small and medium wide-necked (neck width ≥ 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysm (IAs) arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 5.0 mm.

Background: According to the requester, Flow Diverter technology has revolutionized the treatment of wide-necked, giant, and fusiform aneurysms, where the results of microsurgery or conventional neuroendovascular strategies have traditionally been dismal.[1] The use of Flow Diverters to treat ruptured intracranial aneurysms may allow high rates of angiographic occlusion and good clinical outcome in carefully selected patients.[2]

In brief, the Flow Diverter device is implanted in the parent blood vessel (instead of placing a device inside the aneurysm sac as is done with coiling) to divert blood flow away from the aneurysm itself. While this technology may appear similar to a traditional vascular stent, Flow Diverters have a significantly higher mesh density, which prevents flow in the parent artery from entering the aneurysm, thus eliminating the need for a coil.[3] The reduction in blood flow "is designed to promote blood stasis, endothelial growth across the neck, and occlusion of the aneurysm."[4]

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[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4300059/.
[2] T.P. Madaelil et al. Flow Diversion in Ruptured Intracranial Aneurysms: A Meta-Analysis. Am Journal of Neuroradiology March 2017, 38 (3) 590-595.
[3] FDA Exec Summary, 2015 See Evaluation of Clinical Study Data for the Treatment of Aneurysm, at page 13, at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/UCM442242.pdf.
[4] *Id.*

Technology: Computational fluid dynamics analyses contributed to discovery of flow diversion treatment. In brief, the high density mesh diversionary channel (or duct) of the Flow Diverter prevents blood flow from the parent artery into the aneurysm. This intervention/mechanism of action promotes (1) blood stasis in the aneurysm, (2) endothelial growth across the neck, and (3) occlusion of the aneurysm.

The Flow Diverter has a much higher mesh density and many more uniformly-placed struts/edges than a traditional stent. A traditional stent may have 8-10 percent metal surface-area coverage whereas a Flow Diverter may have a metal surface area coverage of about 30-35 percent.

The design of the Flow Diverter is intended to disrupt blood flow going into the aneurysm. The uniform and very dense system of edges in the Flow Diverter reduces the flow of blood entering the aneurysm. In essence, everywhere that the blood flow touches an edge of the Flow Diverter, the flow velocity drops to zero. Over time, the Flow Diverter device promotes progressive thrombosis within the aneurysmal sac, and this is thought to lead to endoluminal reconstruction of the parent artery aneurysm interface.

According to the requester, because of their unique characteristics, Flow Diverters are the *only* devices capable of being a standalone therapy for aneurysm treatment without the need for other adjunctive devices. Specifically, Flow Diverters eliminate the need for coiling in the aneurysm.[5] When vascular stents are used for aneurysm therapy, they are used as adjunctive devices to the primary therapy, coil embolization. In other areas of the anatomy (e.g., abdominal aorta), stent grafts may be used for treating aneurysms, but use in neurovasculature is not appropriate because of the presence of perforator[6] vessels that could be occluded by the deployment of a stent graft.

Current Coding: Endovascular treatment of intracranial aneurysm using a flow diverter stent is coded to table 03V Restriction of Upper Arteries using the body part value Intracranial Artery, the approach value Percutaneous, and the device value Intraluminal Device.

Section **0** Medical and Surgical *Body System* **3** Upper Arteries *Operation* **V** Restriction: Partially closing an orifice or the lumen of a tubular body part			
Body Part	*Approach*	*Device*	*Qualifier*
G Intracranial Artery **H** Common Carotid Artery, Right **J** Common Carotid Artery, Left **K** Internal Carotid Artery, Right **L** Internal Carotid Artery, Left **M** External Carotid Artery, Right **N** External Carotid Artery, Left **P** Vertebral Artery, Right **Q** Vertebral Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**B** Intraluminal Device, Bioactive **C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**Z** No Qualifier

[5] Seong, Jaehoon, et al. 2007. "In Vitro Evaluation of Flow Diverters in an Elastase-Induced Saccular Aneurysm Model in Rabbit." Journal of Biomechanical Engineering 129 (6): 863–72.

[6] Perforator vessels can arise from the aneurysm.

Coding Options

Option 1. Do not create a new ICD-10-PCS code for endovascular treatment of intracranial aneurysm using a flow diverter stent. Continue coding as listed in current coding.

Option 2. Create a new device value F Intraluminal Device, Flow Diverter in table 03V Restriction of Upper Arteries, to identify a flow diverter device used in the treatment of an intracranial aneurysm.

Section **0** Medical and Surgical *Body System* **3** Upper Arteries *Operation* **V** Restriction: Partially closing an orifice or the lumen of a tubular body part			
Body Part	*Approach*	*Device*	*Qualifier*
G Intracranial Artery **H** Common Carotid Artery, Right **J** Common Carotid Artery, Left **K** Internal Carotid Artery, Right **L** Internal Carotid Artery, Left **M** External Carotid Artery, Right **N** External Carotid Artery, Left **P** Vertebral Artery, Right **Q** Vertebral Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**B** Intraluminal Device, Bioactive **C** Extraluminal Device **D** Intraluminal Device **ADD F** Intraluminal Device, Flow Diverter **Z** No Device	**Z** No Qualifier

Option 3. Create new codes in section X, New Technology to enable capture of additional detail for endovascular treatment of intracranial aneurysm using a flow diverter stent.

Section **X** New Technology *Body System* **2** Cardiovascular System *Operation* **V** Restriction: Partially closing an orifice or the lumen of a tubular body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD G Intracranial Artery	**3** Percutaneous	**ADD 0** Intraluminal Device, Flow Diverter	**ADD 5** New Technology Group 5

CMS Recommendation: Option 2. In table 03V Restriction of Upper Arteries, create new device value F Intraluminal Device, Flow Diverter, to identify a flow diverter device used in the treatment of an intracranial aneurysm. We note that if approved, corresponding changes would need to occur for the Device Key entry related to the Pipeline™ Embolization Device.

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

Renal Function Monitoring

Issue: There is not a unique ICD-10-PCS code to describe the measurement and/or monitoring of the glomerular filtration rate (GFR) in real-time for patients with impaired or normal renal function by noninvasively measuring fluorescent light emission from an exogenous tracer agent.

New Technology Application? No, not at this time.

FDA Approval: FDA approval for the Transdermal Glomerular Filtration Rate (GFR) Measurement System is anticipated in FY 2020. In October of 2018, the FDA granted Breakthrough Device Status for the Transdermal GFR Measurement System. A multi-site pivotal study is planned for 2019.

Background: Kidney disease is a hidden global epidemic with 850 million worldwide having some form of kidney disease, 10-12% of adults worldwide having chronic kidney disease, and 13.3 million patients experiencing an acute kidney injury annually, potentially leading to chronic kidney disease.[7] Current clinical practice for renal function monitoring is to calculate estimated glomerular filtration rate (eGFR), using one of the several empirically derived equations with inputs of serum creatinine concentration (requiring a blood draw) and several other parameters including height, weight, gender, and ethnicity.[8,9] The resulting eGFR suffers from several drawbacks: (1) actual GFR can decrease by as much as 50% before it is reflected as an abnormal serum creatinine concentration, resulting in a lack of sensitivity, (2) serum creatinine concentration is affected by factors other than renal clearance such as age, muscle mass, and diet, and (3) abnormal serum creatinine concentration may not manifest for up to 72 hours after a renal insult or injury, prohibiting real-time monitoring.[10,11]

According to the requester, it is this latter consequence of eGFR that renders it less than optimal, and often useless, in the intensive care unit (ICU) environment. The requester noted that dynamic changes in patient's renal function, which often occur in the ICU, cannot be observed with eGFR, hence there is an unmet medical need for point-of-care measured (not estimated) GFR. Monitoring of tracer agents that are cleared exclusively by glomerular filtration have long been used for more accurate GFR determination. However, the requester also noted that this process has routinely required numerous blood draws and subsequent laboratory analysis, and such techniques are rarely used in clinical practice, except in a few major centers for kidney treatment. Efforts to circumvent the need for blood draws and laboratory analysis were first focused on transdermal monitoring of

[7] Joint Press Release, June 27, 2018 "The hidden epidemic: Worldwide, over 850 million people suffer from kidney diseases", American Society of Nephrology – ASN (https://www.asn-online.org), ERA-EDTA (http://web.era-edta.org) and ISN (https://www.theisn.org).
[8] L. A. Inker et al., "Estimating glomerular filtration rate from serum creatinine and cystatin C," N. Engl. J. Med. 367(1), 20–29 (2012).
[9] M. A. Ferguson and S. S.Waikar, "Established and emerging markers of kidney function," Clin. Chem. 58(4), 680–689 (2012).
[10] R. A. Star, "Treatment of acute renal failure," Kidney Int. 54, 1817–1831 (1998).
[11] Z. H. Endre, J. W. Pickering, and R. J. Walker, "Clearance and beyond: the complementary roles of GFR measurement and injury biomarkers in acute kidney injury (AKI)," Am. J. Physiol. Renal Physiol. 301(4), F697–F707 (2011).

radioactive agents cleared by glomerular filtration.[12.] While technically promising, these techniques were never widely adopted, due to concerns surrounding the handling and routine patient administration of radioactive materials, especially in the ICU. More recently, efforts have focused on the transdermal monitoring of fluorescent tracer agents that are cleared by glomerular filtration.[13,14,15] This approach would result in an actual measured GFR in real-time at the point-of-care.

Technology: According to the requester, the Transdermal GFR Measurement System is a three component system consisting of (1) an optical skin sensor, (2) a monitor and (3) MB-102, which is a proprietary fluorescent tracer agent that glows in the presence of light. This innovative system is focused on real-time monitoring, ease of use, and allows cost-effective monitoring of kidney function. The noninvasive monitoring technology works in a similar fashion to pulse oximetry by using a light sensor placed on the skin. After the sensor has been placed, the proprietary biocompatible tracer is administered. The system can then monitor the patient's real-time point of care kidney function. This information will allow for earlier detection of renal issues enabling clinicians to provide earlier, and hence potentially more effective, interventions.
According to the requester, the technique is clinically applicable for real-time point of care Glomerular Filtration Rate measurement (mGFR) using their proprietary fluorescent tracer agent (MB-102) that is removed from the blood exclusively by the GFR mechanism of the kidneys. MB-102 is a pyrazine based small molecule. It is has been shown to be a GFR tracer agent in animal studies. Toxicity tests completed to date in animal studies show no adverse reactions detected for doses up to 200-300 times the estimated human dose. This agent and chemical analogs are either patented or have patents pending by MediBeacon.

The requester notes that the technology will allow for a real-time point of care measurement of GFR with the procedure performed as follows:
GFR measurement using Transdermal GFR Measurement System:

1. An external probe (similar to that of a pulse oximeter) is placed on the skin (i.e. chest wall, or sternum) and measures fluorescence as a function of time.
2. MediBeacon's patented fluorescent tracer agent is administered to the patient via IV bolus. MB-102 distributes throughout the body.
3. Measured fluorescence decreases over time as tracer agent is removed from the body via circulation through the kidneys. The removal rate of MB-102 is dependent on GFR (impaired kidney function has the lower rate of removal than normal kidney function).
4. The measured fluorescence time dependent curve is converted to an mGFR using algorithms embedded in the device monitor.
5. This non-invasive tool can be used throughout any procedure, or for as long as a patient's renal function requires monitoring. According to the requester, the system has the potential to provide

[12] C. A. Rabito et al., "Optical, real-time monitoring of the glomerular filtration rate," Appl. Opt. 44(28), 5956–5965 (2005).
[13] L. K. Chinen et al., "Fluorescence-enhanced europium-diethylenetriaminepentaacetic (DTPA)-monoamide complexes for the assessment
of renal function," J. Med. Chem. 51(4), 957–962 (2008).
[14] W. Yu, R. M. Sandoval, and B. A. Molitoris, "Rapid determination of renal filtration function using an optical ratiometric imaging approach,"
Am. J. Physiol. Renal Physiol. 292(6), F1873–F1880 (2007).
[15] D. Schock-Kusch et al., "Transcutaneous measurement of glomerular filtration rate using FITC-sinistrin in rats," Nephrol. Dial. Transplant.24 (10), 2997–3001 (2009).

early detection of problems, enable rapid intervention, and thus improve patient outcomes in a cost-effective manner.

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Current Coding: Transdermal measurement and/or monitoring of the glomerular filtration rate (GFR) in real-time is not currently coded in the inpatient setting.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for transdermal monitoring of the glomerular filtration rate (GFR) in real-time.

Option 2. In table 4A1, Monitoring of Physiological Systems, add qualifier value J Other Fluorescent Substance, applied to the body system value Urinary and the function value Rate, and add the external approach value. This change enables accurate data for noninvasive monitoring of renal function (glomerular filtration rate), such as serial optical measurements of fluorescent light emission from a previously administered fluorescent substance.

Section **4** Measurement and Monitoring *Body System* **A** Physiological Systems *Operation* **1** Monitoring: Determining the level of a physiological or physical function repetitively over a period of time			
Body System	*Approach*	*Function / Device*	*Qualifier*
D Urinary	**ADD X** External	**C** Rate	**ADD J** Other Fluorescent Substance

Option 3. Create a new code in section X, New Technology to capture the use of Fluorescent Pyrazine for noninvasive monitoring of renal function.

Section **X** New Technology *Body System* **T** Urinary System *Operation* 1 Monitoring: Determining the level of a physiological or physical function repetitively over a period of time			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 5 Kidney	**X** External	**ADD E** Fluorescent Pyrazine	**5** New Technology Group 5

CMS Recommendation: Option 3. This option will allow the specific level of detail requested to be identified in the data and it will also inform future analysis of Section X codes within the classification.

Interim Coding Advice: Transdermal measurement and/or monitoring of the glomerular filtration rate (GFR) in real-time is not currently coded in the inpatient setting.

Administration of Caplacizumab

Issue: There is currently no unique ICD-10-PCS code to describe the administration of Caplacizumab.

New Technology Application? Yes, a New Technology Add-on Payment (NTAP) application for Caplacizumab for fiscal year 2020.

Food & Drug Administration (FDA) Approved? Yes. FDA approval was obtained on February 6, 2019.

Background: Caplacizumab is an intravenously administered, humanized bivalent Nanobody® which is FDA approved to treat adults with acquired thrombotic thrombocytopenic purpura (aTTP). aTTP is a life-threatening, immune-mediated thrombotic microangiopathy characterized by severe thrombocytopenia, hemolytic anemia, and organ ischemia. It is an Ultra-orphan disease with an estimated incidence of 3-11 cases per million per year in the UK and US.[16,17,18] The incidence in children (<18 years) is much lower, about 3% of that in adults.[19]

aTTP is caused by inhibitory autoantibodies to ADAMTS13, resulting in a severe deficiency in this von Willebrand factor (vWF)-cleaving protease. Decreased ADAMTS13 activity leads to an accumulation of ultra-large (or unusually large) vWF (ULvWF) multimers, which bind to platelets and induce aggregation. The consumption of platelets in these microthrombi causes severe thrombocytopenia, tissue ischemia and organ dysfunction, commonly involving the brain, heart, and kidneys, and may result in acute thromboembolic events such as stroke, myocardial infarction, venous thrombosis, and early death. The tissue and organ damage resulting from the ischemia leads to increased levels of lactate dehydrogenase (LDH; nonspecific, as this is also a marker for hemolysis), troponins (heart), and creatinine (kidney). Faster normalization of platelet counts and organ damage markers is believed to be linked with faster resolution of the ongoing microthrombotic process and the associated tissue ischemia.

Mechanism of Action Caplacizumab is a humanized bivalent Nanobody® consisting of two identical building blocks joined by a tri alanine linker. Nanobodies represent a novel therapeutic class of proteins derived from the heavy chain variable domains that occur naturally in heavy chain immunoglobulins from *Camelidae*. In terms of sequence and structure, they have a high degree of homology to human immunoglobulin heavy chain variable region domains.

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[16] Scully, M., et al. *Regional UK TTP registry: correlation with laboratory ADAMTS 13 analysis and clinical features*. Br. J. Haematol., 2008. 142(5): p. 819-26.
[17] Reese, J.A., et al. *Children and adults with thrombotic thrombocytopenic purpura associated with severe, acquired Adamts13 deficiency: comparison of incidence, demographic and clinical features.* Pediatr. Blood Cancer, 2013. 60(10): p. 1676-82.
[18] Terrell D.R., et al. *The incidence of thrombotic thrombocytopenic purpura-hemolytic uremic syndrome: all patients, idiopathic patients, and patients with severe ADAMTS-13 deficiency*. J. Thromb. Haemost., 2005. 3(7): p. 1432-6.
[19] Reese, J.A., et al. *Children and adults with thrombotic thrombocytopenic purpura associated with severe, acquired Adamts13 deficiency: comparison of incidence, demographic and clinical features.* Pediatr. Blood Cancer, 2013. 60(10): p. 1676-82.

Caplacizumab binds to the A1 domain of vWF and specifically inhibits the interaction between vWF[20] and platelets vWF, a key protein in hemostasis, is an adhesive, multimeric plasma glycoprotein with a pivotal role in the recruitment of platelets to sites of vascular injury. More than 90% of circulating vWF is expressed by endothelial cells and secreted into the systemic circulation as ULvWF multimers. ULvWF multimers exist in a globular, conformationally flexible form which unfolds under high shear stress conditions such as in arterioles and capillaries. In elongated ULvWF multimers, the platelet-binding A1 domain is constitutively active, and able to interact spontaneously with the glycoprotein (GP)Ib-IX-V receptor on platelets.

In patients with aTTP, proteolysis of ULvWF multimers by ADAMTS13 is impaired due to the presence of inhibiting or clearing anti-ADAMTS13 autoantibodies, resulting in the persistence of the constitutively active A1 domain. As a consequence, platelet spontaneously bind to ULvWF and generate microvascular blood clots in high shear blood vessels.

The interaction of caplacizumab with vWF is highly specific, and binding of the Nanobody to the vWF A1 domain does not affect the capacity of vWF to interact with coagulation factor VIII (FVIII), for which vWF has a carrier function (preventing the degradation of FVIII while in its inactive state in circulation). Similarly, the selective binding of caplacizumab does not affect the capacity of vWF to interact with fibrillar collagens or collagen type VI. The Nanobody® also does not cross-react with human blood cells or platelets and does not affect the activity of the vWF-cleaving protease ADAMTS13. Due to this high specificity, off-target effects are not expected and have not been observed in clinical trials.

Administration According to the requestor, Caplacizumab can only be administered through a bolus intravenous injection for the first dose and subcutaneous injection for all subsequent doses.
It is recommended that caplacizumab be administered immediately upon diagnosis of aTTP following the dosage and administration recommendations below:

- First day of treatment: 10 mg intravenous injection prior to a plasma exchange (PE) followed by a 10 mg subcutaneous injection after completion of PE on that day.
- Subsequent treatment during PE: daily 10 mg subcutaneous injection following PE.

Treatment after the PE period: daily 10 mg subcutaneous injection for 30 days. If the underlying immunological disease is not resolved, treatment can be extended beyond 30 days and be accompanied by optimization of immunosuppression.

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

3E013GC Introduction of Other Therapeutic Substance into Subcutaneous Tissue, Percutaneous Approach

3E033GC Introduction of Other Therapeutic Substance into Peripheral Vein, Percutaneous Approach

3E043GC Introduction of Other Therapeutic Substance into Central Vein, Percutaneous Approach

[20] Peyvandi F., et al. *Caplacizumab for Acquired Thrombotic Thrombocytopenic Purpura*. N. Engl. J. Med., 2016. 374(6): p. 511-22

Coding Options

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

Option 2. Create new qualifier value W Caplacizumab in table 3E0 of section 3, Administration, applied to the fourth character values Peripheral Vein and Central Vein, to identify subcutaneous injection or intravenous infusion of caplacizumab.

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*
1 Subcutaneous Tissue **3** Peripheral Vein **4** Central Vein	**3** Percutaneous	**G** Other Therapeutic Substance	**C** Other Substance **ADD W** Caplacizumab

Option 3. Create new codes in section X, New Technology, to identify subcutaneous injection or intravenous infusion of caplacizumab.

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*
1 Subcutaneous Tissue **3** Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD W** Caplacizumab	**5** New Technology Group 5

CMS Recommendation: Option 3. Create new codes in section X, New Technology, to identify subcutaneous injection or intravenous infusion of caplacizumab.

Interim Coding Advice: Continue to code as above under Current Coding.

Administration of CONTEPO™ (fosfomycin)

Issue: There is currently no unique ICD-10-PCS code to describe the administration of CONTEPO™ (fosfomycin).

New Technology Application? Yes, a New Technology Add-on Payment (NTAP) application was submitted for CONTEPO™ (fosfomycin) for (FY) 2020.

Food & Drug Administration (FDA) Approved? No. CONTEPO™ (fosfomycin) was designated by FDA as a Qualified Infectious Disease Product (QIDP) with Fast Track review. A New Drug Application (NDA) for CONTEPO™ (fosfomycin) was filed to the FDA on October 31, 2018. The Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2019.

Background:

Antibiotic Resistance Overview

Antibiotic resistance is a growing global crisis, described by the World Health Organization as "one of the biggest threats to global health, food security, and development today." According to the CDC, more than two million hospital infections caused by bacteria resistant to greater than one antibiotic class (known as MDR) occur every year in the US, and over 23,000 patients with an antibiotic-resistant pathogen die each year.[21] The prevalence of MDR pathogens is increasing and is considered a significant threat to global health.[22] In particular, the CDC and the World Health Organization consider antibiotic resistance to be an urgent and critical threat to human health.[23] ESBL-producing Enterobacteriaceae, carbapenem-resistant Enterobacteriaceae (CRE), and MDR *P. aeruginosa* account for ~26,000, ~9,000, and ~6,700 health care-associated infections, respectively, in the US each year.[24]

The Enterobacteriaceae, including *E. coli* and *Klebsiella pneumoniae* (*K. pneumoniae*), may acquire plasmids that encode ESBLs and confer resistance to third-generation cephalosporins and other broad-spectrum antibiotics.[25] Third-generation cephalosporins and β-lactam inhibitors (BLIs) are also commonly ineffective against Enterobacteriaceae that generate AmpC enzymes.[26]

[21] CDC. Antibiotic Use in the United States, 2017: Progress and Opportunities. Atlanta, GA: US Department of Health and Human Services, CDC; 2017. Can be found at https://www.cdc.gov/antibiotic-use/stewardship-report/outpatient.html
[22] O'Neill, The Review on Antimicrobial Resistance 2018. Can be found at: https://amrreview.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf
[23] CDC. Antibiotic Resistance Threats in the United States, 2013. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Can be found at https://www.cdc.gov/drugresistance/biggest_threats.html
[24] Id
[25] Rozwandowicz M, Brouwer M S M, Fischer J. Plasmids carrying antimicrobial resistance genes in Enterobacteriaceae. J Antimicrob Chemother. 2018 May 1;73(5):1121-1137.
[26] Jacoby GA. AmpC beta-lactamases. Clin Microbiol Rev. 2009 Jan;22(1):161-82

Increasing rates of Enterobacteriaceae resistance to fluoroquinolones and beta-lactam antibiotics have limited both classes use as first-line therapies among inpatients with infections caused by suspected or confirmed MDR pathogens. Studies have examined The Surveillance Network Database to estimate the prevalence of drug resistance among uropathogens isolated from hospitalized patients in the US. The study demonstrated more than a two-fold increase in ESBL-producing *E. coli* (from 3.3% to 8%), ESBL-producing *K. pneumoniae* (from 9.1% to 18.6%), and CRE (from 0% to 2.3%) causing UTIs in the period 2000–2009.[27] Additionally, among catheter-associated UTIs reported to the National Healthcare Safety Network in 2009–2010, 12.3% and 2.3% of *E. coli* isolates, 26.9% and 12.5% of *Klebsiella* isolates, and 25.2% and 21.3% of *P. aeruginosa* isolates were resistant to extended-resistant to extended-spectrum cephalosporins and carbapenems, respectively.

Mechanism of Action According to the requestor, CONTEPO™ (fosfomycin) is a novel, potentially first-in-class in the United States, intravenous investigational antibiotic that works at the first commitment step in cell wall synthesis, different than all other cell wall active IV antibiotics. The requestor further states CONTEPO™'s (fosfomycin) unique mechanism of action will result the following.

- broad spectrum microbiologic activity, including activity against most contemporary multi-drug resistant (MDR) pathogens with limited treatment options;
- no cross-resistance with other antibiotic classes; and
- Demonstrated in vitro synergy or additive effect in combination with other antimicrobial classes

Administration According to the requestor, in adult patients 18 years of age and older with an estimated creatinine clearance (CrCl) greater than or equal to 50 mL/min, it is anticipated that the recommended dose will be 6 g, administered via intravenous infusion over 1 hour, every 8 hours for 7 to 14 days. Dosage adjustments will be required for patients whose CrCl is 50mL/min or less.

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

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

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

Coding Options

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

[27] Shorr AF, Zilberberg MD, Micek ST, Kollef MH. Prediction of Infection Due to Antibiotic-Resistant Bacteria by Select Risk Factors for Health Care-Associated Pneumonia. *Arch Intern Med.* 2008; 168(20): 2205-10.

Option 2. Create new qualifier value Fosfomycin in table 3E0 of section 3, Administration, applied to the fourth character values Peripheral Vein and Central Vein, and the sixth character substance value Anti-infective, to identify intravenous injection of fosfomycin.

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**2** Anti-infective	**ADD K** Fosfomycin **8** Oxazolidinones **9** Other Anti-infective

Option 3. Create new codes in section X, New Technology, to identify intravenous injection of Fosfomycin.

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 K** Fosfomycin Anti-infective	**ADD 5** New Technology Group 5

CMS Recommendation: Option 3. Create new codes in section X, New Technology, to identify intravenous injection of Fosfomycin.

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

Administration of XOSPATA® (gilteritinib)

Issue: There is currently no unique ICD-10-PCS code to describe the administration of XOSPATA® (gilteritinib).

New Technology Application? Yes, a New Technology Add-on Payment (NTAP) application was submitted for XOSPATA® (gilteritinib) for (FY) 2020.

Food & Drug Administration (FDA) Approved? Yes. FDA approval was obtained on November 28, 2018.

Background: XOSPATA® (gilteritinib) is an oral, small molecule FMS-like tyrosine kinase 3 (FLT3) inhibitor that is FDA approved for the treatment of adult patients who have relapsed or refractory (R/R) Acute Myeloid Leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. AML is a heterogeneous, hematologic disease that arises from the rapid expansion of myeloid blasts in the bone marrow and peripheral blood of adult patients[28] and represents 1.1% of all new cases of cancer in the United States[29*]. FLT3 is one of the most commonly identified mutations in AML[30]. In the United States, the 5-year survival rate for AML in the United States is 26.9%[31.] The epidemiological statistics in the United States in 2018 estimated approximately 19,520 incidences of AML in mostly adult patients and 10,670 deaths. The average age was 68 years[32]. It is also estimated that approximately 57% of newly diagnosed patients will become relapsed or refractory (R/R).

XOSPATA® (gilteritinib) received FDA approval on November 28, 2018. The FDA had granted XOSPATA® (gilteritinib) Orphan Drug Designation on July 20, 2017 for treatment of adult patients who have relapsed or refractory AML with a FLT3 mutation, as detected by an agency-approved test. The FDA also granted the application for XOSPATA® (gilteritinib) Fast Track and Priority Review Designations in October 10, 2017.

Mechanism of Action Gilteritinib inhibits FLT3 receptor signaling and proliferation in cells exogenously expressing FLT3 mutations.

Administration The recommended dose of XOSPATA® (gilteritinib) is 120 mg orally administered once-daily as three 40 mg tablets and may be taken with or without food.

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[28] Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia Version 1.2018. © National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed 02-19-2018. To view the most recent and complete version of the guideline, go online to NCCN.org.

[29] 2. American Cancer Society. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf. Accessed 01-05-2018.

*Estimated new cases are based on 2000-2014 incidence data reported by the North American Association of Central Cancer Registries (NAACCR)

[30] Patel JP et al. N Engl J Med 2012;366(12):1079-89.

[31] National Cancer Institute. https://seer.cancer.gov/csr/1975_2014/results_merged/topic_survival.pdf. Accessed 03-02-2018.

[32] American Cancer Society. https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html. Accessed 03-12-2018.

Current Coding: There is no unique ICD-10-PCS code to describe the administration of XOSPATA® (gilteritinib). Facilities can report the oral administration of XOSPATA® (gilteritinib) with the following ICD-10-PCS code:

3E0DX05 Introduction of Other Antineoplastic into Mouth and Pharynx, External Approach.

Option 1. Do not create new ICD-10-PCS codes for oral administration of XOSPATA® (gilteritinib). Continue using current codes as listed in Current Coding.

Option 2. Create new qualifier value V Gilteritinib in table 3E0 of section 3, Administration, applied to the fourth character value Mouth and Pharynx and the sixth character value Antineoplastic, to identify oral administration of XOSPATA® (gilteritinib).

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
D Mouth and Pharynx	**X** External	**0** Antineoplastic	**5** Other Antineoplastic **M** Monoclonal Antibody **ADD V** Gilteritinib

Option 3. Create new codes in section X, New Technology, to identify oral administration of XOSPATA® (gilteritinib).

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
D Mouth and Pharynx	**X** External	**ADD V** Gilteritinib Antineoplastic	**5** New Technology Group 5

CMS Recommendation: Option 3. Create new codes in section X, New Technology, to identify oral administration of XOSPATA® (gilteritinib).

Interim Coding Advice: Continue to code as above under Current Coding.

Administration of AZEDRA® (iobenguane I-131)

Issue: There is currently no unique ICD-10-PCS code to describe the administration of AZEDRA® (iobenguane I-131).

New Technology Application? Yes, a New Technology Add-on Payment (NTAP) application was submitted for AZEDRA® (iobenguane I-131) for federal fiscal year (FY) 2020.

Food & Drug Administration (FDA) Approved? Yes, AZEDRA® was approved by the U.S. Food and Drug Administration (FDA) on July 30, 2018.

Background: AZEDRA®, a very high specific activity radiopharmaceutical, is the first and only drug approved for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma (collectively referred to as PPGL) who require systemic anticancer therapy.[33] PPGL are ultra-rare neuroendocrine tumors, affecting only 2 to 8 people per million in the United States. PPGL lead to life-threatening cardiovascular complications that deprive a person of their health and peace of mind; PPGL often strike during the prime of life, but can occur at any age, and can run in families.[34] People with PPGL face life-long risk of tumor progression, dangerous hypertension, cardiovascular complications, and death. Specifically, cardiovascular complications can lead to death in 30% of metastatic cases,[35] and a five-year survival rate for people with PPGL has been reported to be as low as 12%.[36]

AZEDRA® received FDA approval on July 30, 2018. The FDA granted AZEDRA® Orphan Drug Designation for the treatment of neuroendocrine tumors on January 18, 2006, and Fast Track designation on March 8, 2006. AZEDRA® also received Breakthrough Therapy designation from the FDA on July 26, 2015.

Before AZEDRA®, patients in the U.S. had no approved treatment option for advanced PPGL disease. With the FDA approval of AZEDRA®, for the first time, physicians have an FDA-approved treatment option that is proven to control the symptomatic high blood pressure in people with PPGL, shrink and control tumor growth, and reduce dangerous cardiovascular complications, all contributing to improved outcomes.[37]

Mechanism of Action. AZEDRA® (iobenguane I-131) is a novel radiotherapy product containing a small molecule ligand that specifically targets neuroendocrine tumors (such as PPGL) and labeled with a radioisotope, which can be used as an imaging agent as well as for therapy. AZEDRA® is manufactured using a novel, proprietary platform called Ultratrace®, which prevents unlabeled or "cold" iobenguane from being carried through the manufacturing process to the final formulation. The unprecedented use of Ultratrace® in the production of iobenguane I-131 radiotherapy yielded a new drug, i.e., AZEDRA®, with exceptionally high specific activity that can efficiently, effectively, and safely deliver therapy to patients who, if left untreated, experience debilitating clinical symptoms and high mortality rates.

Administration. Patients are first imaged with a "dosimetric" dose of AZEDRA® to ensure the patients' avidity to iobenguane, i.e., to determine that the patient has the potential to respond to the

[33] AZEDRA® Prescribing Information. New York, NY. Progenics Pharmaceuticals, Inc. 08 2018.
[34] Fishbein, et al., Ann. Surg. Oncol. 2013; 20:1444–1450.
[35] Baudin, et al., European Journal of Endocrinology 2014; 171, R111–R122.
[36] Park, et al., Korean Journal of Urology 2011; 42:241–246.
[37] See AZEDRA® Prescribing Information. New York, NY. Progenics Pharmaceuticals, Inc. 08 2018.

therapy. Dosimetric results are also used to determine a therapeutic dose that is safe to normal organs and effective in destroying cancer cells. This imaging step is designed to enable the delivery of an individualized therapeutic dose that is optimized for each patient.

The recommended dosimetric dosage of AZEDRA® is 5 to 6 mCi (185 to 222 MBq) for patients weighing more than 50 kg and 0.1 mCi/kg (3.7 MBq/kg) for patients weighing l50 kg or less. Dosimetric doses are administered as an intravenous (IV) injection.

The recommended therapeutic dose of AZEDRA® is based on body weight and is reduced, if necessary, based on the dosimetry data. The recommended weight-based dose per therapeutic cycle is 500 mCi (18,500 MBq) for patients weighing more than 62.5 kg and 8 mCi/kg (296 MBq/kg) for patients weighing 62.5 kg or less. Therapeutic doses are administered intravenously, in ~50 mL over a period of ~30 minutes (100 mL/hour). A total of 2 therapeutic doses can be administered a minimum of 90 days apart.[38]

Current Coding: If desired, facilities can report the administration of AZEDRA® (Iobenguane I-131) 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

Facilities may also choose to report CW7NGZZ Systemic Nuclear Medicine Therapy of Whole Body using Iodine 131 (I-131) to capture additional information about the procedure.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the administration of AZEDRA® (Iobenguane I-131). Continue using current codes as listed in Current Coding.

Option 2. Create new qualifier value S Iobenguane I-131 in table 3E0 of section 3, Administration, applied to the fourth character values Peripheral Vein and Central Vein, to identify intravenous infusion of AZEDRA® (Iobenguane I-131).

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**0** Antineoplastic	**2** High-dose Interleukin-2 **3** Low-dose Interleukin-2 **5** Other Antineoplastic **M** Monoclonal Antibody **P** Clofarabine **ADD S** Iobenguane I-131

[38] AZEDRA® Prescribing Information. New York, NY. Progenics Pharmaceuticals, Inc. 08 2018.

Option 3. Create new codes in section X, New Technology, to identify intravenous infusion of AZEDRA® (Iobenguane I-131).

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 S** Iobenguane I-131 Antineoplastic	**5** New Technology Group 5

CMS Recommendation: Option 3. Create New Codes in section X, New Technology, to identify intravenous infusion of AZEDRA® (Iobenguane I-131).

Interim Coding Advice: Continue to code as above under Current Coding.

Meeting Comment: A commenter inquired as to why this technology is being proposed as an antineoplastic versus radioactive substance.

CMS Response: **S**ince radiopharmaceuticals can be also be used for diagnostic purposes, and the specific chemical element I-131 is included in the substance value, we know it is a radioactive substance, therefore, classifying it as an antineoplastic gives us additional information that classifying it as a radiopharmaceutical does not.

Angioplasty with Sustained Release Drug-Eluting Stent for Above the Knee Arteries

Issue: There is not a unique ICD-10-PCS device value to identify the insertion of a sustained release drug-eluting stent for peripheral arteries above the knee, specifically the superficial femoral artery (SFA) and the proximal popliteal artery (PPA).

New Technology Application? Yes, an NTAP application has been submitted for FY 2020.

FDA Approval: Yes. A premarket approval application (PMA) for the Eluvia™ Drug-Eluting Vascular Stent System (Eluvia) was approved by the FDA on September 18, 2018.

Background: Peripheral artery disease (PAD) of the lower extremities occurs when fatty or calcified material (plaque) builds up in the walls of the arteries and makes them narrower, thus restricting blood flow. When this occurs, the muscles in the legs cannot get enough blood and oxygen, especially during exertion such as exercise or walking. The main symptoms of PAD include pain, burning sensations, or general discomfort in muscles of the feet, calves or thighs. As the disease progresses, plaque accumulation may significantly reduce blood flow through the arteries resulting in claudication and increasing disability, with severe cases often leading to amputation of the affected limb. PAD affects over 8.5 million Americans[39], with a prevalence among Medicare beneficiaries of 10-14%[40], and 53,600 inpatient Medicare PAD principal or secondary diagnosis discharges[41]. Patients with claudication are often treated with endovascular procedures, including stenting, with 11,086 Inpatient Medicare PAD revascularization femoral/popliteal stent procedure discharges in FY 2017[42].

Two of the most common endovascular approaches used in the treatment of symptomatic PAD are angioplasty and stenting. Angioplasty is a procedure in which a balloon is inserted into an artery via a catheter and inflated to expand the artery and reduce the blockage. The balloon is then deflated and removed. Some procedures use drug coated balloons, in which a drug is applied to the lesion at the time of balloon inflation. Stenting occurs via a procedure in which a stent is placed in the artery to keep the artery open and prevent it from re-narrowing, and can be done with a bare metal stent, drug-coated stent and now with a sustained release drug-eluting stent.

Peripheral arterial disease can occur in the superficial femoral arteries and/or the proximal popliteal arteries, which present unique challenges with respect to maintaining long term patency. Following an intervention within the SFA or PPA, these arteries elicit a healing response that often results in restenosis or re-narrowing of the arterial lumen. This cascade of events leading to restenosis starts with inflammation, followed by smooth muscle cell proliferation and matrix formation.[43]

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[39] American Heart Association, Peripheral Artery Disease (PAD) Resources
[40] Kalbaugh CA et al. J Am Heart Assoc. 2017 May 3;6(5).
[41] Definitive Healthcare (2018). 2017 Centers for Medicare and Medicaid Services (CMS) Medicare Standard Analytical Files (SAF). Retrieved from https://www.definitivehc.com/
[42] FY2017 Medicare Provider Analysis and Review files.
[43] Forrester JS, Fishbein M, Helfant R, Fagin J. A paradigm for restenosis based on cell biology: clues for the development of new preventive therapies. J Am Coll Cardiol. 1991 Mar 1;17(3):758-69.

Technology: According to the requester, the Eluvia™ Drug-Eluting Vascular Stent System aims to address current treatment gaps and support clinical outcomes not adequately associated with the use of existing endovascular technologies: it is the first and only polymer-based, sustained release drug-eluting stent designed to treat and restore blood flow in the peripheral arteries above the knee, specifically the SFA and PPA, and elutes medication that helps to prevent tissue regrowth during the entire period most commonly associated with restenosis. The Eluvia™ Drug-Eluting Vascular Stent System is indicated for improving luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native SFA and/or PPA with reference vessel diameters (RVD) ranging from 4.0-6.0 mm and total lesion lengths up to 190 mm. The sustained release of the anti-restenotic drug paclitaxel is intentionally designed to elute beyond twelve months delivering drug when restenosis is most likely to occur, a significantly longer period than the two-month duration of drug deposited from drug-coated balloons and drug-coated stents.

Note: The requester would also like to reference its request discussed at the September 2018 ICD-10 Coordination and Maintenance Committee meeting for new ICD-10-PCS procedure codes to describe the placement of the Saval sustained release drug eluting stent *below* the knee. The Saval pivotal Investigational Device Exemption (IDE) trial began enrollment in August 2018 under the FDA's first peripheral Expedited Access Pathway (EAP) Program. The Saval Stent System is intended to improve luminal diameter in critical limb ischemia (CLI) subjects with lesions of the infrapopliteal arteries with reference vessel diameters (RVD) ranging from 2.50 – 3.75 mm and total lesion lengths up to 140 mm.

The requester refers to the portion of the popliteal artery that is above the knee (and part of the indication for the Eluvia™ Drug-Eluting Vascular Stent System) as the proximal popliteal artery (PPA). They refer to the portion of the popliteal artery that is below the knee (and the indication for the Saval Stent System) as the infrapopliteal artery. The infrapopliteal are all vessels distal to the 3rd portion of the popliteal artery (i.e., from where the anterior tibial arises all the way to the foot) and are all below the knee.

They are addressing PAD in the distinct anatomy of above and below the knee through two different purpose built sustained release drug-eluting stent systems: Eluvia for disease above the knee (proximal SFA and PPA) and Saval for disease below the knee (infrapopliteal, tibial and peroneal). The anatomical, vessel diameter and disease differences above and below the knee have yielded the development of these devices. Patients treated endovascularly with devices including Eluvia above the knee are at an earlier stage of PAD, claudication, while those treated with endovascular devices, such as Saval, below the knee, are at a later stage of PAD, critical limb ischemia. Arteries below the knee are smaller diameter than above the knee, requiring smaller diameter stents. Below the knee patients are more likely to be diabetic and have longer, occlusive and calcified lesions.

According to the requester, distinct procedure codes are required to differentiate between the insertion of a sustained release drug eluting stent and the insertion of non-sustained release drug eluting stent. Specifically, with this request, a unique ICD-10 procedure coding to describe

placement of a sustained release drug eluting stent system above the knee. However, to avoid any potential confusion the requester suggests delineation of above and below the knee procedures for the popliteal artery.

Current Coding: Angioplasty procedures of the lower extremity arteries that utilize placement of a sustained-release drug-eluting stent can be reported using the device value 4 Intraluminal Device, Drug-Eluting in table 047, Dilation of Lower Arteries, with the applicable body part and approach. A procedure in which multiple sustained-release drug-eluting stents are placed at the angioplasty site can be reported using one of the device values below:

- 5 Intraluminal Device, Drug-eluting, Two
- 6 Intraluminal Device, Drug-eluting, Three
- 7 Intraluminal Device, Drug-eluting, Four or More

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

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

Coding Options

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

Option 2. In table 047, Dilation of Lower Arteries, create device value Intraluminal Device, Sustained-Release Drug-Eluting applied to the femoral and popliteal body part values.

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*
K Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left	**3** Percutaneous	**ADD 3** Intraluminal Device, Sustained Release Drug-eluting	**Z** No Qualifier

		4 Intraluminal Device, Drug-eluting **D** Intraluminal Device **Z** No Device	

Option 3. In section X table X27, Dilation of Cardiovascular System, create new device values to capture the use of a sustained release drug-eluting stent in dilation procedures, applied to the femoral, proximal and distal popliteal, tibial and peroneal artery body part values.

Section **X** New Technology *Body System* **2** Cardiovascular System *Operation* **7** Dilation: Expanding an orifice or the lumen of a tubular body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD H Femoral Artery, Right **ADD J** Femoral Artery, Left **ADD K** Popliteal Artery, Proximal Right **ADD L** Popliteal Artery, Proximal Left **ADD M** Popliteal Artery, Distal Right **ADD N** Popliteal Artery, Distal 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	**3** Percutaneous	**ADD 8** Intraluminal Device, Sustained Release Drug-eluting **ADD 9** Intraluminal Device, Sustained Release Drug-eluting, Two **ADD B** Intraluminal Device, Sustained Release Drug-eluting, Three **ADD C** Intraluminal Device, Sustained Release Drug-eluting, Four or More	**5** New Technology Group 5

CMS Recommendation: Option 3. To allow the specific level of detail requested to be identified in the data as a new technology that will also inform future analysis of Section X codes in the classification.

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

Extracorporeal Membrane Oxygenation (ECMO) for Cardiopulmonary Support

Issue: There is not a unique ICD-10-PCS procedure code to differentiate Extracorporeal Membrane Oxygenation (ECMO) that is utilized for intraprocedural support from ECMO that is utilized as life support. ICD-10-PCS also does not differentiate between peripheral vessel percutaneous and peripheral vessel open cutdown veno-venous (VV) and veno-arterial (VA) ECMO.

New Technology Application? No.

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

Background: ECMO is an advanced life support technique used in critically ill patients who are felt to have severe cardiopulmonary insufficiency that has not responded to conventional management. While on ECMO, a patient's blood is continuously circulated from the body through the ECMO machine where it is oxygenated and then returned back into the patient, thus temporarily replacing lung function (e.g., Veno-venous ECMO) or both heart and lung functions (e.g., Veno-arterial ECMO). ECMO is a modification of the cardiopulmonary bypass system used for open heart surgery and is used to support patients who are at imminent risk of death from severe heart, lung or heart-lung failure. ECMO is typically utilized for days or weeks, until the damaged heart or lungs recover or until the patient can be transitioned to long-term organ replacement such as heart transplant or implantable ventricular assist devices (VAD). All of this is true regardless of cannulation approach.

Less frequent but important to note is that ECMO may be utilized as temporary support during a procedure such as a lung transplant or a high risk percutaneous coronary intervention (PCI). As in the cases described above, ECMO used concurrently with a high-risk procedure is initiated using one of three cannulation approaches. However, the patient is only on ECMO for the duration of the procedure.

Initiation of ECMO requires vascular access, which can be accomplished via insertion of cannulae directly into the cardiac chambers or great vessels (open-chest or central access) or by insertion of cannulae via the femoral, cervical, or axillary vessels either by open surgical cutdown or percutaneously. According to the requester, patient specific anatomic considerations, and not surgeon preference, determine whether vessel cannulation is accomplished centrally or peripherally. For peripheral cannulation, patient specific circumstances as well as anatomic considerations determine whether cannulation is percutaneous or via open cutdown. The following outlines the differences in technique for percutaneous and open cutdown peripheral vessel cannulation for VA and VV ECMO:

- VA peripheral vessel percutaneous ECMO cannulation involves two percutaneous insertions; arterial and venous. This type of ECMO support provides respiratory and circulatory support.

- VV peripheral vessel percutaneous ECMO cannulation involves two percutaneous venous insertions, one in an upper vein and one in a lower vein. Alternatively, this may be accomplished with percutaneous insertion of a specially designed two-stage or double lumen cannula into a single vein. VV ECMO provides respiratory support only.

• VA peripheral vessel open cutdown ECMO requires arterial and venous cannulation and involves separate open surgical cutdowns of the femoral, cervical or axillary artery and vein. This type of ECMO support provides respiratory and circulatory support.

• VV peripheral vessel open cutdown ECMO requires venous cannulation via an open surgical cutdown in an upper vein and an open surgical cutdown in a lower vein. Alternatively, after open surgical exposure of a large single vein a specially designed two-stage or double lumen cannula is placed under direct visualization. VV ECMO provides respiratory support only.

Current Coding: ECMO support during a procedure is coded to table 5A1 Extracorporeal Performance using the physiological system value Circulation, the function value Oxygenation, and the appropriate qualifier specifying the method of cannulation.

Section **5** Extracorporeal or Systemic Assistance and Performance *Body System* **A** Physiological Systems *Operation* **1** Performance: Completely taking over a physiological function by extracorporeal means			
Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**2** Continuous	**2** Oxygenation	**F** Membrane, Central **G** Membrane, Peripheral Veno-arterial **H** Membrane, Peripheral Veno-venous

Coding Options

Option 1. Do not create new ICD-10-PCS codes for intraprocedural ECMO support during a procedure. Continue coding ECMO as listed in current coding.

Option 2. Create new duration value A Intraprocedural in table 5A1 Extracorporeal Performance, applied to the physiological system Circulatory and the function value Oxygenation, to identify ECMO support during a procedure that is discontinued at the end of the procedure.

Section **5** Extracorporeal or Systemic Assistance and Performance *Body System* **A** Physiological Systems *Operation* **1** Performance: Completely taking over a physiological function by extracorporeal means			
Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**2** Continuous **ADD A** Intraprocedural	**2** Oxygenation	**F** Membrane, Central **G** Membrane, Peripheral Veno-arterial **H** Membrane, Peripheral Veno-venous

Option 3. Create new duration value A Intraprocedural in table 5A1 Extracorporeal Performance, applied to the physiological system Circulatory and the function value Oxygenation, to identify ECMO support during a procedure that is discontinued at the end of the procedure. Revise existing qualifier so they specify the approach used for cannulation, and create two new qualifier values J Membrane, Open Peripheral Veno-arterial Cannulation, and K Membrane, Open Peripheral Veno-venous Cannulation.

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

Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**2** Continuous **ADD A** Intraprocedural	**2** Oxygenation	**REVISE F** Membrane, Open Central Cannulation **REVISE G** Membrane, Percutaneous Peripheral Veno-arterial Cannulation **REVISE H** Membrane, Percutaneous Peripheral Veno-venous Cannulation **ADD J** Membrane, Open Peripheral Veno-arterial Cannulation **ADD K** Membrane, Open Peripheral Veno-venous Cannulation

CMS Recommendation: Option 3. The ability to differentiate intraprocedural ECMO support from ECMO that is utilized as advanced life support and to identify the method of cannulation is important for data collection purposes. We note that assignment of an ICD-10-PCS approach value within the Med/Surg section of the classification requires attention to the site of the procedure versus how vascular access was achieved. For ECMO, the site of the procedure is the patient's vasculature, and there is not a separately implanted "device". The method of cannulation in the qualifier value is unique to ECMO as it identifies how the circulatory support is being accomplished.

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

Meeting Comment: A commenter asked if consideration had been given to proposing a coding option that included duration values to identify how long a patient utilized ECMO treatment.

Response: CMS did draft a coding option that included duration values however, the requester indicated they were not interested in that option so we removed it from the proposal and did not present it at the meeting. Below we provide 2 additional coding options that include duration values for which we are also seeking public comment.

Option 4. Delete duration value 2 Continuous. Create new duration value A Intraprocedural in table 5A1 Extracorporeal Performance, applied to the physiological system Circulatory and the function value Oxygenation, to identify ECMO support during a procedure that is discontinued at the end of the procedure. Add duration values 3 Less than 24 Consecutive Hours and 4 24-96 Consecutive Hours; create new duration values B 5-8 Days and C Greater than 8 Days to enable capture of additional detail for ECMO.

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

Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**DELETE 2** Continuous **ADD 3** Less than 24 Consecutive Hours **ADD 4** 24-96 Consecutive Hours **ADD A** Intraprocedural **ADD B** 5-8 Days **ADD C** Greater than 8 Days	**2** Oxygenation	**F** Membrane, Central **G** Membrane, Peripheral Veno-arterial **H** Membrane, Peripheral Veno-venous

Option 5. Delete duration value 2 Continuous. Create new duration value A Intraprocedural in table 5A1 Extracorporeal Performance, applied to the physiological system Circulatory and the function value Oxygenation, to identify ECMO support during a procedure that is discontinued at the end of the procedure. Add duration values 3 Less than 24 Consecutive Hours and 4 24-96 Consecutive Hours; create new duration values B 5-8 Days and C Greater than 8 Days to enable capture of additional detail for ECMO. Revise existing qualifier so they specify the approach used for cannulation, and create two new qualifier values J Membrane, Open Peripheral Veno-arterial Cannulation, and K Membrane, Open Peripheral Veno-venous Cannulation.

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

Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**DELETE 2** Continuous **ADD 3** Less than 24 Consecutive Hours **ADD 4** 24-96 Consecutive Hours **ADD A** Intraprocedural **ADD B** 5-8 Days **ADD C** Greater than 8 Days	**2** Oxygenation	**REVISE F** Membrane, Open Central Cannulation **REVISE G** Membrane, Percutaneous Peripheral Veno-arterial Cannulation **REVISE H** Membrane, Percutaneous Peripheral Veno-venous Cannulation **ADD J** Membrane, Open Peripheral Veno-arterial Cannulation **ADD K** Membrane, Open Peripheral Veno-venous Cannulation

Comments were also made regarding the terminology for intraprocedural versus intraoperative for which we also encourage public comments.

Administration of Jakafi® (ruxolitinib)

Issue: There is currently no unique ICD-10-PCS code to describe the administration of (ruxolitinib)

New Technology Application: Yes. Incyte Corporation submitted a New Technology Add-on Payment (NTAP) application for Jakafi® for fiscal year 2020.
Food and Drug Administration (FDA) Approval: Jakafi® was first approved in November 2011 for the treatment of patients with intermediate or high-risk myelofibrosis (MF). Jakafi® was also approved in December 2014 for the treatment of patients with polycythemia vera (PV) who have had an inadequate response to hydroxyurea.

A supplemental new drug application (sNDA) for Jakafi® for the treatment of patients with acute graft versus host disease (GVHD) who have had an inadequate response to corticosteroids, submitted with Orphan Drug and Breakthrough Therapy designations, was accepted by the FDA for Priority Review.

Background:
Allogeneic hematopoietic stem cell transplantation (allo-HSCT) represents a potentially curative treatment option for several high-risk or relapsed hematologic malignancies, as well as for certain non-malignant hematologic disorders[44,45,46,47]. Despite the increasing use of allo-HSCT and advances in methodology, outcomes remain suboptimal. Major barriers to successful outcomes include relapse of the underlying malignancy and transplant-related complications. Acute GVHD, a serious complication of allo-HSCT that results when activated donor T cells attack host tissues, occurs in 30-70% of patients and represents a significant source of morbidity and mortality, accounting for up to one-third of the deaths in these patients[35,48,49,50,51]. Many acute GVHD diagnoses occur in the first few months post-transplant, sometimes while the patient is still hospitalized from the allo-HSCT and often after initial discharge. Approximately 40% of patients with acute GVHD are readmitted to the hospital[52].

[44] Blazar BR, Murphy WJ, Abedi M. Advances in graft-versus-host disease biology and therapy. Nat Rev Immunol. 2012;12(6):443-458.
[45] D'Souza A, Lee S, Zhu X, Pasquini M. Current use and trends in hematopoietic cell transplantation in the United States. Biol Blood Marrow Transplant. 2017;23(9):1417-1421.
[46] Gratwohl A, Baldomero H, Aljurf M, et al. Hematopoietic stem cell transplantation: a global perspective. JAMA. 2010;303(16):1617-1624.
[47] Magenau J, Runaas L, Reddy P. Advances in understanding the pathogenesis of graft-versus-host disease. Br J Haematol. 2016;173(2):190-205.
[48] Ferrara JL, Levine JE, Reddy P, Holler E. Graft-versus-host disease. Lancet. 2009;373(9674):1550-1561.
[49] Jagasia M, Arora M, Flowers ME, et al. Risk factors for acute GVHD and survival after hematopoietic cell transplantation. Blood. 2012;119(1):296-307.
[50] McDonald GB, Tabellini L, Storer BE, Lawler RL, Martin PJ, Hansen JA. Plasma biomarkers of acute GVHD and nonrelapse mortality: predictive value of measurements before GVHD onset and treatment. Blood. 2015;126(1):113-120.
[51] Gooley TA, Chien JW, Pergam SA, et al. Reduced mortality after allogeneic hematopoietic-cell transplantation. N Engl J Med. 2010;363(22):2091-2101.
[52] Data on file. Incyte Corporation.

Currently, there are no FDA-approved options for first-line treatment of acute GVHD. Systemic corticosteroids are used as conventional first-line therapy for grade II to IV GVHD, and response rates between 40% and 60% have been previously reported[53,54,55] however, responses are not often durable[56]. Second-line treatment is indicated following failure of corticosteroid treatment. There are no FDA-approved treatments for patients with steroid-refractory acute GVHD, and despite available treatment options, patients do not always respond, underscoring the need for new and innovative treatments for these patients. Patients who develop steroid-refractory acute GVHD can progress to severe disease, with 1-year mortality rates of 70-80%[57,58,59,60.]

Patients with an inadequate response to corticosteroids include those that are steroid-refractory (i.e., patients who progress or fail to improve following steroid treatment), or steroid-dependent (patients who cannot taper without flaring) are eligible for treatment with Jakafi®. Jakafi® is expected to often be initiated in the inpatient setting (60-80% of the time[9]), during either hospital admission for allo-HSCT, or upon need for hospital re-admission for treating patients with acute GVHD who have had an inadequate response to corticosteroids.

Jakafi® is dosed orally and can be administered with or without food. No other formulations are available. The recommended starting dose for Jakafi® for the treatment of patients with acute GVHD who have had an inadequate response to corticosteroids is 5mg twice daily. A dose increase to 10 mg twice daily should be considered after at least 3 days of treatment if the hematologic parameters are stable.

Current Coding: If desired, facilities can report the administration of Jakafi® (ruxolitinib) with the following ICD-10-PCS code:

3E0DXGC Introduction of Other Therapeutic Substance into Mouth and Pharynx, External Approach

Coding Options

[53] Martin PJ, Rizzo JD, Wingard JR, et al. First and second-line systemic treatment of acute graft-versus-host disease: recommendations of the American Society of Blood and Marrow Transplantation. Biol Blood Marrow Transplant. 2012;18(8):1150-1163

[54] MacMillan ML, Robin M, Harris AC, et al. A refined risk score for acute graft-versus-host disease that predicts response to initial therapy, survival and transplant-related mortality. Biol Blood Marrow Transplant. 2015;21(4):761-767.

[55] Westin JR, Saliba RM, De Lima M, et al. Steroid-refractory acute GVHD: predictors and outcomes. Adv Hematol. 2011;2011:601953.

[56] Garnett C, Apperley JF, Pavlu J. Treatment and management of graft-versus-host disease: improving response and survival. Ther Adv Hematol. 2013;4(6):366-378.

[57] Shapira MY, Klimov A, Vipul S, et al. Regional intra-arterial steroid treatment in 120 patients with steroid-resistant or -dependent GvHD. Bone Marrow Transplant. 2017;52(10):1416-1422.

[58] Nadeau M, Perreault S, Seropian S, Foss F, Isufi I, Cooper DL. The use of basiliximab-infliximab combination for the treatment of severe gastrointestinal acute GvHD. Bone Marrow Transplant. 2016;51(2):273-276.

[59] von Dalowski F, Kramer M, Wermke M, Wehner R, Rollig C, Alakel N, et al. Mesenchymal stromal cells for treatment of acute steroid-refractory graft versus host disease: clinical responses and long-term outcome. Stem Cells. 2016;34(2):357-366.

[60] Dotoli GM, De Santis GC, Orellana MD, et al. Mesenchymal stromal cell infusion to treat steroid-refractory acute GvHD III/IV after hematopoietic stem cell transplantation. Bone Marrow Transplant. 2017;52(6):859-862.

Option 1. Do not create new ICD-10-PCS codes for the administration of Jakafi® (ruxolitinib). Continue using current codes as listed in Current Coding.

Option 2. Create new qualifier value T Ruxolitinib in table 3E0 of section 3, Administration, applied to the fourth character value Mouth and Pharynx and the external approach, to identify oral administration of Jakafi® (ruxolitinib).

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
D Mouth and Pharynx	**X** External	**G** Other Therapeutic Substance	**C** Other Substance **ADD T** Ruxolitinib

Option 3. Create a new code in section X, New Technology, to identify oral administration of Jakafi® (ruxolitinib).

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
D Mouth and Pharynx	**X** External	**ADD T** Ruxolitinib	**ADD 5** New Technology Group 5

CMS Recommendation: Option 3. Create a new code in section X, New Technology, to identify oral administration of Jakafi® (ruxolitinib).

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

Endovascular Arteriovenous Fistula (endoAVF) Creation Using Magnetic-Guided Radiofrequency Energy and Venous Embolization

Issue: There is currently no unique ICD-10-PCS code to describe Endovascular Arteriovenous Fistula (endoAVF) Creation Using Magnetic-Guided Radiofrequency Energy and Venous Embolization.

New Technology Application? No

Food & Drug Administration (FDA) Approved? Yes, the WavelinQ endoAVF system received FDA De Novo marketing authorization on June 22, 2018.

Background: 30 million American adults have chronic kidney disease (CKD)[61]. Seniors, African Americans and Hispanics are at increased risk for CKD. Individuals with diabetes and hypertension are included in the high risk groups. The WavelinQ (formerly named everlinQ) system has demonstrated that it can create endovascular endoAVFs that mature faster and require fewer post-creation interventions than standard surgically created Arteriovenous Fistulas.[62],[63]

Arteriovenous Fistulae (AVF)

Arteriovenous fistulae (AVF) are the recommended type of vascular access for hemodialysis.[61] Despite initiatives to increase AVF use, fistulas are still underutilized with only 17% of patients initiating dialysis with an AVF and 67% of patients still using a central venous catheter (CVC) at 3 months after dialysis initiation[61]. Failure rates (fail to mature and become usable) for surgical AVF range from 20-60%[61],[64],[65],[66] Surgical AVFs also take a long time to mature – approximately 132 days[61]. Further, >83% of AVF patients need at least one intervention in the first year[66], typically receiving 1.5 to 3.3 additional interventions per year to mature and maintain patency[67],[68],[69],[70],[71]. The endovascular AV fistula is created using magnetic-guided arterial and venous catheters that utilize radiofrequency energy and includes vascular embolization of the brachial vein, fistulogram, angiography (to fluoroscopically guide placement of the arterial magnetic catheter), venography (to

[61] USRDS Annual Report, 2017.
[62] Yang et al. Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation. J Vasc Access. 2017; 18: 8-14.
[63] Arnold et al. Evaluation of Hemodialysis Arteriovenous Fistula Interventions and Associated Costs: Comparison between Surgical and Endovascular AV Fistula. J Vasc Interv Radiol 2018: 1-9. (in press)
[64] Dember, et al. Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: a randomized controlled trial. JAMA. 2008; 299: 2164-71.
[65] Al-Jaishi et al. Patency rates of the arteriovenous fistula for hemodialysis: a systematic review and meta-analysis. Am J Kidney Dis. 2014; 63: 464-78.
[66] Thamer, et al. Medicare Costs Associated with Arteriovenous Fistulas. Am J Kidney Dis. 72(1): 10-18. published online March 28, 2018.
[67] Lee et al. Tradeoffs in Vascular Access Selection in Elderly Patients Initiating Hemodialysis with a Catheter. Am J Kidney Dis. 2018.
[68] Yang et al. Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation. J Vasc Access. 2017; 18: 8-14.
[69] Arnold et al. Evaluation of Hemodialysis Arteriovenous Fistula Interventions and Associated Costs: Comparison between Surgical and Endovascular AV Fistula. J Vasc Interv Radiol 2018: 1-9. (in press)
[70] Buickians et al. The natural history of autologous fistulas as first-time dialysis access in the KDOQI era. J Vasc Surg. 2008; 47: 415-21; discussion 20-1.
[71] Falk et al. Maintenance and salvage of arteriovenous fistulas. J Vasc Interv Radiol. 2006; 17: 807-13.

fluoroscopically guide placement and alignment of the venous magnetic radiofrequency (RF) catheter, ultrasound and final fistulogram to document AV fistula creation.

Procedure Description Using the wavelinQ endoAVF System

The patient is positioned supine on the angiography table with arm extended, prepped and draped. Intravenous sedation and local anesthesia is administered. Ultrasound guidance is used to localize primary target vein access site. Ultrasound-guided venipuncture of a vein in the arm is then performed using a micropuncture set and a 0.018" guidewire is inserted. Venous access is verified via ultrasound or venogram. Next, a 7Fr dilator and vascular sheath is introduced and a venogram of the central veins is performed. Under ultrasound guidance, the target artery is then accessed using a micropuncture set. Next, a 0.018" guidewire is inserted and heparin is administered intravenously. An arteriogram of the entire arm is then performed. A 4Fr guide catheter is used in the artery to advance the 0.018" guidewire to the target creation site using fluoroscopy. Then the 4Fr micropuncture sheath is replaced with a 6Fr vascular sheath. Using the arterial guidewire as a roadmap, the venous guidewire is advanced into the vein with the aid of a selective catheter, Tuohy borst valve and fluoroscopy. Then a venogram is performed to confirm superficial communication via the presence of a perforator vein at the intended fistula site. Under fluoroscopic guidance the arterial magnetic endoAVF catheter is inserted into the 6Fr sheath and advanced over the 0.018" guidewire to the target fistula creation site making sure proper orientation to the venous guide catheter is maintained. The guide catheter is then removed from the venous anatomy. The venous magnetic endoAVF catheter is then inserted into the 7Fr sheath and advanced over the 0.018" guidewire using fluoroscopy. The WavelinQ catheters are then rotated to bring the magnets into correct orientation and alignment. Correct orientation and alignment is confirmed via fluoroscopy. Then both the arterial and venous 0.018" guidewires are removed. The electrode is deployed, and correct alignment and orientation are reconfirmed fluoroscopically. RF cutting current is delivered to the electrode for approximately 1.3 seconds. The electrode on the venous catheter is retracted, and both endoAVF catheters are removed. An angiogram of the newly created fistula is then obtained through the 6Fr arterial sheath to verify successful endoAVF creation with outflow in cephalic and/or basilic veins. The brachial vein in the mid-upper arm is then occluded by coil embolization to direct more flow to the cephalic and/or basilic veins, and the venous and arterial sheaths are removed. Finally, hemostasis is obtained at the arterial and venous access sites using manual compression for a minimum of 20 minutes. The patient is seen post-operatively to evaluate healing and fistula development.

Current Coding: There are no unique ICD-10-PCS codes to report percutaneous endovascular bypass of upper extremity arteries for AV fistula creation using a magnetic-guided radio-frequency technique (the WavelinQ system).

To report these procedures, facilities may use the open approach, which is the only approach currently in Table 031 Bypass of Upper Arteries, the appropriate body part value, and the device value Z No Device.

Section **0** Medical and Surgical *Body System* **3** Upper Arteries *Operation* **1** Bypass: Altering the route of passage of the contents of a tubular body part			
Body Part	*Approach*	*Device*	*Qualifier*
9 Ulnar Artery, Right **B** Radial Artery, Right	**0** Open	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**3** Lower Arm Artery, Right **F** Lower Arm Vein
A Ulnar Artery, Left **C** Radial Artery, Left	**0** Open	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**4** Lower Arm Artery, Left **F** Lower Arm Vein

In addition, report coil embolization of the brachial vein using Table 05L Occlusion of Upper Veins, with the appropriate body part value, the percutaneous approach, and the device value D Intraluminal Device.

Section **0** Medical and Surgical *Body System* **5** Upper Veins *Operation* **L** Occlusion: Completely closing an orifice or the lumen of a tubular body part			
Body Part	*Approach*	*Device*	*Qualifier*
0 Azygos Vein **1** Hemiazygos Vein **3** Innominate Vein, Right **4** Innominate Vein, Left **5** Subclavian Vein, Right **6** Subclavian Vein, Left **7** Axillary Vein, Right **8** Axillary Vein, Left **9** Brachial Vein, Right **A** Brachial Vein, Left **B** Basilic Vein, Right **C** Basilic Vein, Left **D** Cephalic Vein, Right **F** Cephalic Vein, Left **G** Hand Vein, Right **H** Hand Vein, Left **L** Intracranial Vein **M** Internal Jugular Vein, Right **N** Internal Jugular Vein, Left **P** External Jugular Vein, Right **Q** External Jugular Vein, Left **R** Vertebral Vein, Right **S** Vertebral Vein, Left **T** Face Vein, Right **V** Face Vein, Left **Y** Upper Vein	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**Z** No Qualifier

Coding Options

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

Option 2. Add the approach value Percutaneous to table 031, Bypass of Upper Arteries, for the ulnar and radial artery body part values, the device value No Device, and the qualifier Lower Arm Vein, to identify percutaneous endovascular AV fistula creation using magnetic-guided radio-frequency technique (the WavelinQ system).

Section **0** Medical and Surgical *Body System* **3** Upper Arteries *Operation* **1** Bypass: Altering the route of passage of the contents of a tubular body part			
Body Part	*Approach*	*Device*	*Qualifier*
9 Ulnar Artery, Right **A** Ulnar Artery, Left **B** Radial Artery, Right **C** Radial Artery, Left	**0** Open **ADD 3** Percutaneous	**Z** No Device	**F** Lower Arm Vein

CMS Recommendation: Option 2. Add the approach value Percutaneous to table 031, Bypass of Upper Arteries, for the ulnar and radial artery body part values, the device value No Device, and the qualifier Lower Arm Vein, to identify percutaneous endovascular AV fistula creation using magnetic-guided radio-frequency technique (the WavelinQ system).

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

T2Bacteria® Panel (Whole Blood Nucleic Acid-base Microbial Detection)

Issue: There is currently no unique ICD-10-PCS code to describe the T2Bacteria® Panel.

New Technology Application? Yes, a New Technology Add-on Payment (NTAP) application was submitted for the T2Bacteria® Panel (Whole Blood Nucleic Acid-base Microbial Detection) for federal fiscal year (FY) 2020.

Food & Drug Administration (FDA) Approved? Yes, the T2Bactera® Panel was approved by the U.S. Food and Drug Administration (FDA) on May 24, 2018.

Background: The T2Bacteria® Panel is a new diagnostic technology that can detect five major bacterial pathogens directly from whole blood and provide a result within three to five hours, with an overall sensitivity of 90% and overall specificity of 98%. More rapid effective antimicrobial therapy has been shown to reduce the odds of death by over 50% and reduce the length of stay by an average of 8 days.

T2 Biosystems has commercialized the FDA-cleared assay for direct-from-blood detection of bacteremia – the T2Bacteria assay. This assay is culture-independent and circumvents the speed limitations of cell growth during the standard of care, blood culture. Specifically, it returns a bacteria species identification in three to five hours, with limits of detection (defined as 95% sensitivity) ranging from 2 to 11 CFU/mL. The detected species are five of the most common and virulent sepsis-causing organisms, including *E. coli*, *E. faecium*, *K. pneumoniae*, *P. aeruginosa*, and *S. aureus*. The T2Bacteria® Panel detects and identifies ~90% of the infections caused by pathogens that commonly "escape" antimicrobial therapy, known as the ESKAPE pathogens. The T2Bacteria® Panel is indicated as an aid in the diagnosis of bacteremia and results should be used in conjunction with other clinical and laboratory data. Concomitant blood cultures are necessary to recover organisms for susceptibility testing or further identification and for organisms not detected by the T2Bacteria® Panel.

New Technology Differentiating Qualities
The T2Bacteria® Panel relies on developments in magnetic resonance and nanotechnology to determine the presence of bacterial pathogens in a patient's blood in three to five hours. The T2 magnetic resonance (T2MR) detection principle exploits the physics of magnetic resonance. The T2Dx Instrument, which runs the T2Bacteria® Panel, is a fully automated sample-to-results system.

To administer a T2Bacteria diagnostic test, a healthcare professional will collect a blood sample via venipuncture or intravenous catheter. Once a sample is extracted, the operator loads a K_2EDTA blood sample onto the cartridge and inserts it into the T2Dx benchtop diagnostic system. Subsequently the T2Dx pipettes 2 mL of the blood sample and treats it with a detergent to selectively lyse the red blood cells. Then pathogen cells are concentrated via centrifugation and supernatant removal. After concentration, the pathogen cells and other cellular debris are subjected to bead beating to release target DNA. This lysate is then amplified with a whole blood multiplexed asymmetric PCR method. After amplification, target amplicon is aliquoted into separate tubes for hybridization with unique capture probe functionalized superparamagnetic particles, which causes particle aggregation and a change in the T2 relaxation time that is detectable by T2MR.

Although T2Bacteria is diagnostic technology having no therapeutic benefit by itself, it is most closely described as a minimally invasive medical procedure in that administration requires patient's skin to be broken via venipuncture or indwelling device.

Current Coding: If desired, facilities can report the collection of blood from an indwelling vascular catheter for microbial testing using the T2Bacteria Panel with the following ICD-10-PCS code:

8C02X6K Collection of Blood from Indwelling Device in Circulatory System

Coding Options

Option 1. Do not create new ICD-10-PCS codes for nucleic acid-base microbial testing of whole blood using the T2Bacteria panel. Continue using current codes as listed in Current Coding.

Option 2. Create new sixth character function value J Infection and new qualifier value M Whole Blood Nucleic Acid-base Microbial Detection in table 4A0, Measurement of Physiological Systems, to identify testing of whole blood for bacterial infection using the T2Bacteria panel's nucleic acid-base detection method.

Section	**4** Measurement and Monitoring		
Body System	**A** Physiological Systems		
Operation	**0** Measurement: Determining the level of a physiological or physical function at a point in time		
Body System	*Approach*	*Function / Device*	*Qualifier*
5 Circulatory	**X** External	**ADD J** Infection	**ADD M** Whole Blood Nucleic Acid-base Microbial Detection
5 Circulatory	**X** External	**L** Volume	**Z** No Qualifier

Option 3. Create new codes in section X, New Technology, for microbial testing of whole blood using the T2Bacteria panel's nucleic acid-base detection method.

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**E** Measurement: Determining the level of a physiological or physical function at a point in time		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Circulatory	**X** External	**ADD M** Infection, Whole Blood Nucleic Acid-base Microbial Detection	**5** New Technology Group 5

CMS Recommendation: Option 3. Create new codes in section X, New Technology, for microbial testing of whole blood using the T2Bacteria panel's nucleic acid-base detection method.

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

Administration of IMI/REL (imipenem/cilastatin/relebactam)

Issue: There is currently no unique ICD-10-PCS code to describe the administration of IMI/REL.

New Technology Application? Yes, a New Technology Add-on Payment (NTAP) application for IMI/REL for fiscal year 2020.

Food & Drug Administration (FDA) Approved? No. A New Drug Application (NDA) for IMI/REL was filed to the FDA on November 16, 2018. An FDA acknowledgement of the filing was received. The Prescription Drug User Fee Act (PDUFA) target action date for IMI/REL is July 16, 2019.

Background: IMI/REL is a fixed dose combination of imipenem/cilastatin (IMI), a β-lactam (BL) antibacterial (specifically, a carbapenem), and relebactam (REL), a novel β-lactamase inhibitor (BLI). It is anticipated that when approved, IMI/REL will be indicated in patients 18 years of age and older with (a) complicated intra-abdominal infections (cIAI) caused by susceptible gram-negative microorganisms where limited or no alternative therapies are available and (b) complicated urinary tract infections (cUTI), including pyelonephritis, caused by susceptible gram-negative microorganisms where limited or no alternative therapies are available.

<u>B-lactam antibacterials and B-lactamase inhibitors</u>
IMI was the first marketed carbapenem when approved by the FDA in 1985. It is a sterile formulation of imipenem (a thienamycin antibacterial) and cilastatin sodium (inhibitor of the renal dipeptidase, dehydropeptidase-l). IMI is stable against hydrolysis by many extended spectrum β-lactamases (ESBLs) and is frequently used for the treatment of serious bacterial infections in which gram-negative bacteria and/or anaerobes play a significant role. In the US, IMI (Primaxin®) is indicated for the treatment of the following infections:

- Lower respiratory tract infections
- Urinary tract infections
- Intra-abdominal infections
- Gynecologic infections
- Bacterial septicemia
- Bone and joint infections
- Skin and skin structure infections
- Endocarditis

The development of resistance to BL antibacterials can occur through the production of β-lactamases; this is one of the most important resistance mechanisms among gram-negative bacteria. β-lactamases inactivate BL antibiotics by hydrolyzing the β-lactam amide bond to produce a ring-opened structure that no longer has antibacterial activity. Resistance can also develop through over-expression of efflux pumps (thus removing the antibacterial from the periplasmic space) or down-regulation of porin expression (thus preventing the antibacterial from entering the periplasmic space). Resistance to BL antibacterials mediated by β-lactamases can be mitigated by the addition of a BLI, thereby restoring the activity of the BL.

REL is a non-β-lactam, small molecule diazabicyclooctane (DABCO) BLI with inhibitory activity against various β-lactamases: Class A carbapenemases (such as KPC), Class C cephalosporinases

(including AmpC), and ESBLs. REL has been shown, in in vitro susceptibility and hollow fiber time-kill studies, to restore the activity of sub-inhibitory concentrations of IMI in imipenem-resistant isolates (Pseudomonas aeruginosa and Enterobacteriaceae expressing the aforementioned β-lactamases). Additional in vivo animal efficacy studies further confirm the activity of REL, and integrated in vivo and in vitro pharmacokinetic (PK)/pharmacodynamic (PD) modeling and joint probability of target attainment (PTA) analyses indicate that the combination of REL and IMI would be active in most imipenem-resistant strains at clinically achievable doses and concentrations. Furthermore, both IMI and REL are not subject to efflux pumps in P. aeruginosa. Many hospitalized patients at risk for multidrug-resistant (MDR) infections and at risk for poor outcomes from these infections have multiple underlying comorbidities, and the IMI/REL clinical program has included these patients. IMI/REL has also been evaluated in subjects with varying degrees of renal insufficiency, and dosing in these patients is well-supported by PK and clinical data.

Mechanism of Action Relebactam is an investigational, intravenous, class A and C beta-lactam/beta-lactamase inhibitor, currently being evaluated in combination with imipenem/cilastatin for the treatment of certain Gram-negative bacterial infections. According to the requestor, in contrast to other available agents, IMI/REL addresses both CR *Pseudomonas* spp. and KPC-producing Enterobacteriaceae/CRE, two of the three most critical antimicrobial-resistant bacteria according to the World Health Organization (WHO) global priority list to guide research, discovery, and development of new antimicrobials and the Centers for Disease Control and Prevention (CDC) list of antibiotic resistance threats.[72,73] The FDA has designated the combination of relebactam with imipenem/cilastatin for intravenous use as a Qualified Infectious Disease Product (QIDP) with Fast Track status for the treatment of complicated urinary tract infections (cUTI), complicated intra-abdominal infections (cIAI) and hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP).

Administration According to the requestor, it is anticipated that the recommended dose will be 500 mg imipenem/500 mg cilastatin/250 mg relebactam, administered via intravenous infusion over 30 minutes every 6 hours. The dosage will be adjusted for decreased renal function, with dosage of the fixed-dose combination decreasing proportionally with decreases in renal creatinine clearance category.

Current Coding: If desired, facilities can report the administration of IMI/REL (imipenem/cilastatin/relebactam) with one of the following ICD-10-PCS codes:

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

[72] World Health Organization. Global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics. Accessed at https://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en/ on 10/9/2018

[73] Centers for Disease Control and Prevention. Antibiotic resistance threats in the United States, 2013. Accessed at https://www.cdc.gov/drugresistance/biggest_threats.html on 10/09/2018

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the IMI/REL (imipenem/cilastatin/relebactam). Continue using current codes as listed in Current Coding.

Option 2. Create new qualifier value U Imipenem/cilastatin/relebactam in table 3E0 of section 3, Adminstration, applied to the fourth character values Peripheral Vein and Central Vein, to identify intravenous infusion of IMI/REL (imipenem/cilastatin/relebactam).

Section **3** Administration *Body System* **E** Physiological Systems and Anatomical Regions *Operation* **0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products			
Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**2** Anti-infective	**ADD U** Imipenem/cilastatin/relebactam **8** Oxazolidinones **9** Other Anti-infective

Option 3. Create new codes in section X, New Technology, to identify intravenous infusion of IMI/REL (imipenem/cilastatin/relebactam).

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 U** Imipenem/cilastatin/relebactam Anti-infective	**5** New Technology Group 5

CMS Recommendation: Create new codes in section X, New Technology, to identify intravenous infusion of IMI/REL (imipenem/cilastatin/relebactam).

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

ICD-10-PCS Index Addenda

Lttr S
Main Add Submandibular space use Subcutaneous Tissue and Fascia, Face

ICD-10-PCS Body Part Key Addenda

Axis 4 Body Part
Row
Term Subcutaneous Tissue and Fascia, Face
Includes Add Submandibular space

ICD-10-PCS Definitions Addenda

Section 0 Medical and Surgical
Axis 3 Operation
Row
Term Control
Explanation Delete The site of the bleeding is coded as an anatomical region and not to a specific body part

ICD-10-PCS Table Addenda

Medical and Surgical Section
Axis 4 Body Part

Extirpation of Upper and Lower Jaw

Source	Description	Code specification
2018, public comment & CMS internal review	In the General Anatomical Region body system of the Medical and Surgical section, add upper and lower jaw body part values to root operation Extirpation. This will allow the capture of an extirpation procedure of the upper and lower jaw such as evacuation of a semi-solid hematoma from mandibular and maxillary spaces.	0WC[45][034]ZZ (6 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 **ADD 4** Upper Jaw **ADD 5** Lower Jaw **9** Pleural Cavity, Right **B** Pleural Cavity, Left **C** Mediastinum **D** Pericardial Cavity **G** Peritoneal Cavity **H** Retroperitoneum **J** Pelvic Cavity **P** Gastrointestinal Tract **Q** Respiratory Tract **R** Genitourinary Tract	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

Coronary Artery to Root Operation Supplement

Source	Description	Code specification
2018, Coding Clinic Editorial Advisory Board & CMS internal review	In the Heart and Great Vessels body system of the Medical and Surgical section, add the coronary artery body part values to root operation Supplement table 02U, to enable capture of specific detail for a procedure to reinforce or augment coronary arteries, such as a stent graft placed to seal and reinforce a perforated coronary artery status post atherectomy.	02U[0123][034][78JK]Z (48 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**U** Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
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 **5** Atrial Septum **6** Atrium, Right **7** Atrium, Left **9** Chordae Tendineae **A** Heart **D** Papillary Muscle **H** Pulmonary Valve **K** Ventricle, Right **L** Ventricle, Left **M** Ventricular Septum **N** Pericardium **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

W Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch			

Coronary Artery body part to Root Operation Insertion

Source	Description	Code specification
2018, Coding Clinic Editorial Advisory Board & CMS internal review	In the Heart and Great Vessels body system of the Medical and Surgical section, add the coronary artery body part values to Insertion table 02H. This change allows the capture of detail for procedures on the coronary arteries such as insertion of a stent into the coronary artery to prevent the risk of coronary obstruction following a prosthetic valve deployment.	02H[0123][034][DY]Z (24 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*
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	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**D** Intraluminal Device **Y** Other Device	**Z** No Qualifier
4 Coronary Vein **6** Atrium, Right **7** Atrium, Left **K** Ventricle, Right **L** Ventricle, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Monitoring Device, Pressure Sensor **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **J** Cardiac Lead, Pacemaker **K** Cardiac Lead, Defibrillator **M** Cardiac Lead **N** Intracardiac Pacemaker **Y** Other Device	**Z** No Qualifier
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Q** Implantable Heart Assist System **Y** Other Device	**Z** No Qualifier
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**R** Short-term External Heart Assist System	**J** Intraoperative **S** Biventricular **Z** No Qualifier

Sinus body part to Root Operation Supplement

Source	Description	Code specification
2018, public comment & CMS internal review	In the Ear, Nose and Sinus body system of the Medical and Surgical section, add the sinus body part values to Supplement table 09U. This change allows the capture of more detail for procedures where additional material is used to reinforce or augment the sinus.	09U[BCPQRSTUVWX][03478][7JK]Z (165 codes)

EXAMPLE

Section **0** Medical and Surgical
Body System **9** Ear, Nose, Sinus
Operation **U** Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 External Ear, Right **1** External Ear, Left **2** External Ear, Bilateral	**0** Open **X** External	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier
5 Middle Ear, Right **6** Middle Ear, Left **9** Auditory Ossicle, Right **A** Auditory Ossicle, Left **D** Inner Ear, Right **E** Inner Ear, Left	**0** Open **8** Via Natural or Artificial Opening Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier
7 Tympanic Membrane, Right **8** Tympanic Membrane, Left **N** Nasopharynx	**0** Open **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier
ADD B Mastoid Sinus, Right **ADD C** Mastoid Sinus, Left **L** Nasal Turbinate **ADD P** Accessory Sinus **ADD Q** Maxillary Sinus, Right **ADD R** Maxillary Sinus, Left **ADD S** Frontal Sinus, Right **ADD T** Frontal Sinus, Left **ADD U** Ethmoid Sinus, Right **ADD V** Ethmoid Sinus, Left **ADD W** Sphenoid Sinus, Right **ADD X** Sphenoid Sinus, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier
K Nasal Mucosa and Soft Tissue	**0** Open **8** Via Natural or Artificial Opening Endoscopic **X** External	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier
M Nasal Septum	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

Medical and Surgical Section
Axis 7 Qualifier

Bypass Thoracic Aorta to Innominate Artery

Source	Description	Code specification
2018, Coding Clinic Editorial Advisory Board & CMS internal review	In the Heart and Great Vessels body system of the Medical and Surgical section, add the qualifier value Innominate Artery to Bypass table 021 for the thoracic aorta body part values. This change enables the capture of a bypass procedure from the thoracic aorta to the innominate artery.	021[WX][04][89AJKZ] A (24 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
W Thoracic Aorta, Descending	**0** Open	**8** Zooplastic Tissue **9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**ADD A** Innominate Artery **B** Subclavian **D** Carotid **F** Abdominal Artery **G** Axillary Artery **H** Brachial Artery **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **V** Lower Extremity Artery
W Thoracic Aorta, Descending	**0** Open	**Z** No Device	**ADD A** Innominate Artery **B** Subclavian **D** Carotid **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left
W Thoracic Aorta, Descending	**4** Percutaneous Endoscopic	**8** Zooplastic Tissue **9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**ADD A** Innominate Artery **B** Subclavian **D** Carotid **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left
X Thoracic Aorta, Ascending/Arch	**0** Open **4** Percutaneous Endoscopic	**8** Zooplastic Tissue **9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**ADD A** Innominate Artery **B** Subclavian **D** Carotid **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left

Transfer Large Intestine to Vagina

Source	Description	Code specification
2018, Coding Clinic Editorial Advisory Board & CMS internal review	In the Gastrointestinal body system of the Medical and Surgical section, add the qualifier value Vagina to Transfer table 0DX for the large intestine body part value. This change enables the capture of vaginal construction procedures using the large intestine.	0DXE[04]Z7

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
E Large Intestine	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**5** Esophagus **ADD 7** Vagina

Administration Section
Axis 4 Body Part

Delete Peripheral Artery and Central Artery from Transfusion

Source	Description	Code specification
2018, CMS internal review & IPPS proposed rule	In the Administration section, in the Circulatory body system, delete body part values 5, Peripheral Artery and 6, Central Artery from Transfusion table, 302. This deletion removes clinically invalid codes involving transfusion of substances in the peripheral and central arteries.	302[56][03][GHJKLMNPQRSTVWXY][01] (128 codes)

EXAMPLE

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

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

			Unrelated **4** Allogeneic, Unspecified
3 Peripheral Vein **4** Central Vein	**0** Open **3** Percutaneous	**H** Whole Blood **J** Serum Albumin **K** Frozen Plasma **L** Fresh Plasma **M** Plasma Cryoprecipitate **N** Red Blood Cells **P** Frozen Red Cells **Q** White Cells **R** Platelets **S** Globulin **T** Fibrinogen **V** Antihemophilic Factors **W** Factor IX	**0** Autologous **1** Nonautologous
DELETE 5 Peripheral Artery **DELETE 6** Central Artery	**0** Open **3** Percutaneous	**G** Bone Marrow **H** Whole Blood **J** Serum Albumin **K** Frozen Plasma **L** Fresh Plasma **M** Plasma Cryoprecipitate **N** Red Blood Cells **P** Frozen Red Cells **Q** White Cells **R** Platelets **S** Globulin **T** Fibrinogen **V** Antihemophilic Factors **W** Factor IX **X** Stem Cells, Cord Blood **Y** Stem Cells, Hematopoietic	**0** Autologous **1** Nonautologous
7 Products of Conception, Circulatory	**3** Percutaneous **7** Via Natural or Artificial Opening	**H** Whole Blood **J** Serum Albumin **K** Frozen Plasma **L** Fresh Plasma **M** Plasma Cryoprecipitate **N** Red Blood Cells **P** Frozen Red Cells **Q** White Cells **R** Platelets **S** Globulin **T** Fibrinogen **V** Antihemophilic Factors **W** Factor IX	**1** Nonautologous
8 Vein	**0** Open **3** Percutaneous	**B** 4-Factor Prothrombin Complex Concentrate	**1** Nonautologous

Axis 7 Qualifier

Hyperthermia Antineoplastic Chemotherapy

Source	Description	Code specification
2018, Coding Clinic Editorial Advisory	In the Administration section, create new qualifier value Y, Hyperthermia to Introduction table 3E0, for the body part value M, Peritoneal Cavity for the antineoplastic substance. This change enables the	3E0M30Y (one code)

Board & CMS internal review	capture of administering hyperthermic intraperitoneal chemotherapy (HIPEC)	

EXAMPLE

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
M Peritoneal Cavity	**3** Percutaneous	**0** Antineoplastic	**4** Liquid Brachytherapy Radioisotope **5** Other Antineoplastic **M** Monoclonal Antibody **ADD Y** Hyperthermic