DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 00-00-00
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
September 11, 2018

Webcast and Dial-In Information

- The meeting will begin promptly at 9am ET and will be webcast via CMS at http://www.cms.gov/live/. By your attendance, you are giving consent to the use and distribution of your name, likeness and voice during the meeting. You are also giving consent to the use and distribution of any personally identifiable information that you or others may disclose about you during the meeting. Please do not disclose personal health information.
- Toll-free dial-in access is available for listen-only participants who cannot join the webcast:
  Day 1-September 11, 2018: Phone: 1-877-267-1577; Meeting ID: 908 381 636.
  Day 2-September 12, 2018: Phone: 1-877-267-1577; Meeting ID: 909 444 644.
  We encourage you to join early, as the number of phone lines is limited.

NEW: Instructions for Remote Meeting Participants

- Remote presenters (referred to as "panelists" in WebEx) and participants wishing to ask questions during the Q&A portions of the meeting must join the meeting by WebEx.
- Toll-free WebEx log in information: **Day 1-September 11, 2018**:
  1. Event address for **participants**: https://events-cms.webex.com/events-cms/onstage/g.php?MTID=e15de5ab6e1d20cf9fa7c02829f13f4bf
  2. Event address for **remote presenters (panelists)**: https://events-cms.webex.com/events-cms/onstage/g.php?MTID=eefc517ca9f0ec858ea4b1877b90034b5
  3. Event number: 908 381 636
  4. Event password: This event does not require a password for attendees or panelists.

- Toll-free WebEx log in information: **Day 2-September 12, 2018**:
    1. Event address for **participants**: https://events-cms.webex.com/events-cms/onstage/g.php?MTID=e3bf010920f178df3eab041e70e1093da
    2. Event address for **remote presenters (panelists)**: https://events-cms.webex.com/events-cms/onstage/g.php?MTID=e258aa3de637e69f8f67f5b13dcf17b87
    3. Event number: 909 444 644
    4. Event password: This event does not require a password for attendees or panelists.

Note: Proposals for diagnosis code topics are scheduled for September 12, 2018 and will be led by the Centers for Disease Control (CDC). Please visit CDCs website for the Diagnosis agenda located at the following address: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm

Registration to Attend the 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, WebEx 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.

Introductions and Overview	Songhai Barclift, MD

ICD-10-PCS Topics:

1. Lymphatic Mapping in Gynecological Cancers Pages 12-15	Mady Hue Michael Frumovitz, MD, MPH, FACOG Department of Gynecologic Oncology and Reproductive Medicine, Division of Surgery MD Anderson Cancer Center
2. Administration of Vabomere Pages 16-18	Michelle Joshua Michael Gavigan Vice President Melinta Therapeutics, Inc
3. Cell Suspension Autografting Pages 19-22	Noel Manlove Jeremiah Sparks Sr. Director of Commercialization Avita Medical
4. Intramedullary Limb Lengthening System Pages 23-25	Mady Hue Claire Shannon, MD Orthopedic Surgeon Johns Hopkins Hospital
5. Subcutaneous Implantable Cardioverter Defibrillator Pages 26-31	Mady Hue Olaf Hedrich, MD, FACC, FHRS Senior Medical Director Boston Scientific
6. Administration of Erdafitinib Pages 32-33	Noel Manlove Waleed Shalaby, MD, PhD, Medical Director, Oncology Medical Affairs
7. Administration of Esketamine Pages 34-35	Noel Manlove H. Lynn Starr, MD Director Clinical Development, Medical Affairs
8. Administration of ERLEADA™ Apalutamide Pages 36-39	Michelle Joshua Denise D'Andrea, MD, Director, Medical Affairs-Oncology
9. Angioplasty with Sustained Release Drug Eluting Stent Pages 40-45	Mady Hue Juan Diaz-Cartelle, MD Sr. Medical Director Boston Scientific Corporation

10. T-Cell Depleted Stem Cell Transplantation Pages 46-47	Michelle Joshua Grace S. Kao, MD and Jugna Shah, MPH American Society for Blood and Marrow Transplantation
11. Fluorescence-guided brain tumor surgery using Gleolan™ (ALA) Pages 48-50	Michelle Joshua Gary Grossman Senior Director NX Development Corp
12. Addenda and Key Updates Pages 51-67	Rhonda Butler , 3M

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:

September 11-12, 2018	ICD-10 Coordination and Maintenance Committee Meeting. Those who wish to attend the ICD-10 Coordination and Maintenance Committee meeting **must have registered for the meeting online by September 3, 2018.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building. 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.
September 2018	Webcast of the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html
October 1, 2018	**New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with DRG changes. Final addendum available on web pages as follows:** **Diagnosis addendum – http://www.cdc.gov/nchs/icd/ic d10cm.htm** **Procedure addendum – http://www.cms.gov/Medicare/Coding/ICD10/**
October 12, 2018	**Deadline for receipt of public comments on proposed new codes discussed at the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meetings for implementation on April 1, 2019.**
November 2018	Any new ICD-10 codes required to capture new technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2019 will be posted on the following websites: http://www.cdc.gov/nchs/icd/icd10cm.htm http://www.cms.gov/Medicare/Coding/ICD10/

November 13, 2018	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 11-12, 2018 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2019.**
December 7, 2018	**Deadline for requestors: Those members of the public requesting that topics be discussed at the March 5-6, 2019 ICD-10 Coordination and Maintenance Committee meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses by this date.**
February 2019	Tentative agenda for the Procedure part of the March 5, 2019 ICD-10 Coordination and Maintenance Committee meeting posted on CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis part of the March 6, 2019 ICD-10 Coordination and Maintenance Committee meeting posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm Federal Register notice of March 5-6, 2019 ICD-10 Coordination and Maintenance Committee Meeting will be published.
February 1, 2019	**On-line registration opens for the March 5-6, 2019 ICD-10 Coordination and Maintenance Committee meeting at: https://www.cms.gov/apps/events/default.asp**
March 2019	Because of increased security requirements, **those wishing to attend the March 5-6, 2019** ICD-10 Coordination and Maintenance Committee meeting are required to register for the meeting online at: **https://www.cms.gov/apps/events/default.asp** **Attendees must register online by February 22, 2019; failure to do so may result in lack of access to the meeting**.
March 5-6, 2019	ICD-10 Coordination and Maintenance Committee Meeting.
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/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html

April 1, 2019	Any new ICD-10 codes to capture new diseases or technology will be 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/ICD9ProviderDiagnosticCodes/ICD-9-CM-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 3, 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 3, 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 3, 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/ICD9ProviderDiagnosticCodes/meetings.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
  - November 13, 2018 for codes discussed at the September 11-12, 2018 C&M meeting
- Procedure comments to CMS (new address) ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to Donna Pickett, CDC nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2018 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2018 C&M meeting
- August 1, 2018 – Final rule with links to final codes to be implemented on October 1, 2018
  - Includes any additional codes approved from March 6-7, 2018 C&M meeting
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Final-Rule-Home-Page.html

Addendum

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

March 5-6, 2019 C&M Code Requests

- December 7, 2018– Deadline for submitting topics for March 5-6, 2019 C&M meeting
  - Procedure requests to CMS (new address) ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis requests to Donna Pickett, CDC nchsicd10cm@cdc.gov

Public Participation

- For this meeting, the public may participate in the following ways:
  - Attend meeting in-person
  - Listen to proceedings through free conference lines
  - View through a free livestream webcast
  - Participate via WebEx (new)
- CMS & CDC hope this provides greater opportunity for public participation

Written Comments

- No matter how you participate – please send written comments by
  - November 13, 2018 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

Intraoperative Fluorescence Lymphatic Mapping in Gynecological Cancers Using Indocyanine Green (ICG) Dye

Issue: Currently there are no unique codes to describe the use of intraoperative fluorescence lymphatic mapping for cervical and uterine cancer.

New Technology Application? Yes. The requestor intends to apply for FY 2020 consideration.

Food & Drug Administration (FDA) Approval? An FDA submission has been made for the on-label use of PINPOINT as an intraoperative fluorescence visualization system for the identification of lymph nodes during lymphatic mapping in cervical and uterine cancers. FDA approval is anticipated by Q1 2019.

Background: Uterine cancer, also known as endometrial cancer, is the most prevalent gynecologic cancer with 61,380 estimated new cases in 2017 and mortality rates rising an average of 1.4% year over year.[1] Cervical cancer also affects thousands of women annually, with 12,820 estimated new cases last year.[1]

The International Federation of Gynecology and Obstetrics (FIGO) and National Cancer Center Network (NCCN) developed guidelines for surgical staging as a technique to treat gynecological cancers.[2, 3, 4] Surgical staging and its pathological assessment provides information on the primary tumor and lymph node status. A patient's lymph node status is critical for predicting the severity or likely outcome of one's cancer and is key for assessing the need for adjuvant treatment.[5]

Lymphadenectomy (i.e., the removal of one or more groups of lymph nodes) is the standard surgical cancer management technique in many practices.[6] Traditionally, it was suggested that the more nodes removed, the better the chance of detecting metastasis, but also the more likely the patient will develop side effects. As a result, patients had unnecessary comprehensive lymphadenectomy for staging even when their disease may be confined to the uterus.[6] It is important to note that a complete lymphadenectomy may result in unwarranted excess costs due to prolonged operating room time, prolonged anesthesia, increased blood loss, vascular and nerve damage, and an increased conversion rate from laparoscopy to laparotomy to complete the operation successfully.[6]

---

[1] Surveillance, Epidemiology, and End Results (SEER) Program Cancer Stat Facts: Uterine Cancer. National Cancer Institute. Bethesda, MD. Available from: http://seer.cancer.gov/statfacts/html/corp.html . Accessed on April 11, 2018.

[2] Pecorelli S, Zigliani L, Odicino F. Revised FIGO staging for carcinoma of the cervix. Int J Gynaecol Obstet. 2009 May. 105(2):107-8. [Medline].

[3] Pecorelli S. Revised FIGO staging for carcinoma of the vulva, cervix, and endometrium. Int J Gynaecol Obstet. 2009 May. 105(2):103-4. [Medline].

[4] NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer. V 3.2013. Available at http://www.nccn.org/professionals/physician_gls /pdf/cervical.pdf. Accessed: September 5, 2013.

[5] Sullivan SA. Sentinel Lymph Node Biopsy in Endometrial Cancer: a New Standard of Care? Curr Treat Options Oncol. 2017; 18(10):62.

[6] Abu-Rustum NR. Sentinel Lymph Node Mapping for Endometrial Cancer: A Modern Approach to Surgical Staging. Journal of the National Comprehensive Cancer Network. 2014; 12(2):288-297.

Furthermore, a comprehensive systematic review of RCTs and quasi-RCTs comparing lymphadenectomy versus no lymphadenectomy in adult women diagnosed with endometrial cancer found that women who undergo lymphadenectomy experienced serious adverse events and have an increased risk of surgery-related morbidity or lymphoedema/lymphocyst formation which can negatively impact a patient's quality of life.[7]

Consequently, surgeons have begun doing lymphatic mapping because it is an accurate, safe[7] and more cost-effective approach[8,9,10] as compared to undergoing a lymphadenectomy for staging. Lymphatic mapping is an image-guided procedure that uses various dyes and/or tracers to optimize selective lymph node removal, thereby minimizing the morbidity and costs associated with lymphadenectomy. Lymphatic mapping is centered on the fact that the lymph drains in an orderly pattern away from the tumor through the lymphatic system to what is commonly called the sentinel LNs or SLNs.[11] Lymphatic mapping is defined as the injection of a dye/tracer and observing the lymphatic flow through the channels as it incorporates into a LN. Lymphatic mapping therefore enables the accurate identification of the SLN to be excised for a more focused pathological examination.[6]

Currently, blue dyes (e.g., IB, patent blue, methylene blue etc.), radiotracers (e.g., technetium 99m), or a combination of both are utilized for the identification of LNs during lymphatic mapping in gynecological cancers.[12]

SPY PINPOINT Endoscopic Fluorescence Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. More than 300 peer-reviewed publications confirm the clinical safety and efficacy of SPY fluorescence imaging technology and ICG and demonstrate that they can significantly reduce post-operative complications and improve patient outcomes.[13,14,15,16,17,18,19,20] Furthermore, the results of FILM, a randomized, prospective, open label, multi-center study designed to demonstrate the effectiveness of ICG and PINPOINT as an intraoperative visualization tool in the identification of lymph nodes during lymphatic mapping showed the use of PINPOINT and ICG highly effective and superior to blue dye in identifying lymph nodes.

---

[7] Frost JA. Lymphadenectomy for the management of endometrial cancer. Cochrane Database Syst Rev. 2017.

[8] Suidan RS. A cost-utility analysis of sentinel lymph node mapping, selective lymphadenectomy, and routing lymphadenectomy in the management of low-risk endometrial cancer. Journal of Clinical Oncology. 2017; 35(8): 10-10.

[9] McCann G. Lymphatic mapping and sentinel lymph node dissection compared to complete lymphadenectomy in the management of early-stage vulvar cancer: A cost-utility analysis. Gynecologic Oncology. 2015; 136(2): 300-304.

[10] Erickson BK. Cost-effectiveness analysis of sentinel lymph node biopsy in the treatment of early-stage vulvar cancer. Int J Gynecol Cancer. 2014; 24(8): 1480-1485.

[11] National Cancer Institute. Sentinel Lymph Node Biopsy. https://www.cancer.gov/about -cancer/diagnosis-staging/staging/sentinel-node-bio psy-fact-sheet. Accessed May 4, 2018.

[12] How, J. et al. Comparing indocyanine green, technetium, and blue dye for sentinel lymph node mapping in endometrial cancer. Gynecol Oncol. 2015; 137(3):436-442.

Current Coding: Lymphatic mapping performed using injection of a dye/tracer and observing the lymphatic flow through the channels as it incorporates into a lymph node is coded to table 4A1, Monitoring of Physiological Systems, using the body system value Lymphatic and the function value Flow.

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*
6 Lymphatic	**0** Open **3** Percutaneous **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**5** Flow **B** Pressure	**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. In table 4A1, Monitoring of Physiological Systems, add qualifier value H Indocyanine Green Dye for the body system value Lymphatic and the function value Flow, to enable capture of additional detail for lymphatic mapping procedures using Indocyanine Green dye.

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*
6 Lymphatic	**ADD X** External	**5** Flow	**ADD H** Indocyanine Green Dye **Z** No Qualifier

[13] Harless CA. Tailoring through Technology: A Retrospective Review of a Single Surgeon's Experience with Implant -Based Breast Reconstruction before and after Implementation of Laser-Assisted Indocyanine Green Angiography. The Breast Journal. 2016; 22(3):274-81.

[14] Harless CA. The Clinical Efficacy and Financial Impact of Laser-assisted Indocyanine Green Angiography on Implant-based Breast Reconstruction at a Large Academic Medical Center. Plastic & Reconstructive Surgery. 2015; 135 (5S): 53.

[15] Duggal CS. An Outcome Analysis of Intraoperative Angiography for Postmastectomy Breast Reconstruction. Aesthetic Surgery Journal. 2014; 34(1):61-5.

[16] Sood M. Potential of the SPY intraoperative perfusion assessment system to reduce ischemic complications in immediate postmastectomy breast reconstruction. Annals of surgical intervention and research. 2013; 7(1):1 -9.

[17] Chatterjee A. A Comparison of Free Autologous Breast Reconstruction with and without the Use of Laser-Assisted Indocyanine Green Angiography: A Cost-Effectiveness Analysis. Plastic and Reconstructive Surgery. 2013; 131(5): 693e-701e.

[18] Komorowska-Timek E. Intraoperative Perfusion Mapping with Laser-Assisted Indocyanine Green Imaging Can Predict and Prevent Complications in Immediate Breast Reconstruction. Plastic and Reconstructive Surgery. 2010; 125(4):1065 - 73.

[19] Starker PM, Chinn B. Using outcomes data to justify instituting new technology: a single institution's experience. Surgical Endoscopy. 2017; 32: 1586-1592.

[20] Jafari MD, Wexner SD, Martz JE, McLemore EC, Margolin DA, et al. Perfusion Assessment in Laparoscopic Left Sided/ Anterior Resection (PILLAR II): A Multi-Institutional Study. J Am Coll Surg. 2015; 220: 82-92.

Option 3. In section 8, Other Procedures, create new method value Fluorescence Guided Procedure and new qualifier value Indocyanine Green Dye, applied to all fourth character body region values and applicable approaches. These changes will enable capture of additional detail for fluorescence-guided procedures that use indocyanine green dye (ICG). Note: Additional detail can be added to Axis 4 to specify the body region.

Section **8** Other Procedures *Body System* **E** Physiological Systems and Anatomical Regions *Operation* **0** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease			
Body Region	*Approach*	*Method*	*Qualifier*
9 Head and Neck Region **W** Trunk Region	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**C** Robotic Assisted Procedure	**Z** No Qualifier
9 Head and Neck Region **W** Trunk Region	**X** External	**B** Computer Assisted Procedure	**F** With Fluoroscopy **G** With Computerized Tomography **H** With Magnetic Resonance Imaging **Z** No Qualifier
9 Head and Neck Region **W** Trunk Region	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**ADD E** Fluorescence Guided Procedure	**ADD N** Indocyanine Green Dye **Z** No Qualifier
X Upper Extremity **Y** Lower Extremity	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Robotic Assisted Procedure	**Z** No Qualifier
X Upper Extremity **Y** Lower Extremity	**X** External	**B** Computer Assisted Procedure	**F** With Fluoroscopy **G** With Computerized Tomography **H** With Magnetic Resonance Imaging **Z** No Qualifier
X Upper Extremity **Y** Lower Extremity	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD E** Fluorescence Guided Procedure	**ADD N** Indocyanine Green Dye **Z** No Qualifier

CMS Recommendation: Option 2. In table 4A1, Monitoring of Physiological Systems, add qualifier value H Indocyanine Green Dye for the body system value Lymphatic and the function value Flow, to enable capture of additional detail for lymphatic mapping procedures using Indocyanine Green Dye.

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

Administration of Vabomere™ (meropenem-vaborbactam)

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

New Technology Application? Yes, a New Technology Add-on Payment (NTAP) application was submitted and has been approved for Vabomere™ (meropenem-vaborbactam) for FY 2019.

Food & Drug Administration (FDA) Approval? Yes, Vabomere™ received FDA approval on August 29, 2017.

Background: Vabomere™ was developed to address certain gram-negative bacteria, widely considered to be one of the largest current areas of unmet medical need, as these pathogens are growing increasingly resistant to existing therapies with few antibiotics in development. Vabomere™ is FDA-approved for the treatment of patients 18 years of age and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli (E. coli)*, *Klebsiella pnemoniae*, and *Enterobacter cloacae species* complex. As reflected in the FDA-approved labeling, Vabomere™ in vitro data also show susceptibility for the following gram-negative bacteria: *Citrobacter freundii, Citrobacter koseri, Enterobacter aerogenes, Klebsiella oxytoca, Morganella morganii, Proteus mirabilis, Providencia spp., Pseudomonas aeruginosa,* and *Serratia marcescens.* See Prescribing Information (PI) § 12.4.

As further outlined in the FDA-approved labeling, Vabomere™ demonstrated in vitro activity against Enterobacteriaceae in the presence of some beta-lactamases and extended-spectrum beta-lactamases (ESBLs) of the following groups: KPC, SME, TEM, SHV, CTX-M, CMY, and ACT. In addition, in the Phase 3 cUTI trial with Vabomere™, some isolates of *E. Coli*, *K. pneumoniae*, *E. cloacae*, *C. freundii*, *P. mirabilis*, and *P. stuartii* that produced beta-lactamases were susceptible to Vabomere™. These isolates produced one or more beta-lactamases of the following enzyme groups: OXA (non-carbapenemases), KPC, CTX-M, TEM, SHV, CMY, and ACT. PI § 12.4.

Vabomere™ was developed specifically in response to the urgent and growing threat of CRE. Vabomere™ has been shown, as noted in the FDA-approved labeling, to be active against a number of different gram-negative bacteria, including carbapenem-resistant Enterobacteriaceae (CRE).

Antibiotic resistance in gram-negative bacteria has increased markedly in the last decade, leaving clinicians and critically-ill patients few choices for treatment. The designation of CRE as an urgent antimicrobial resistance threat by the Centers for Disease Control and Prevention (CDC) has created an urgent need for new agents—a need that has been recognized worldwide by health authorities.[1] The World Health Organization (WHO) also declared the research and development of new drugs for CRE as a "CRITICAL PRIORITY".[2] Similarly, the White House Counsel on Combating Antibiotic Resistant Bacteria issued a draft report in September 2017 stating that "the

[1] CDC, Antibiotic Resistance Threats in the United States, 2013. Atlanta: CDC; 2013.
[2] WHO, Global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics. February 27, 2017.

existence and availability of a diverse array of antibiotics acts as insurance against future epidemics" and "this availability should be considered as a metric when the [U.S. government], other governments, payers, and other potential investors consider the value of these drugs."[3] As noted, Vabomere™ was developed specifically to help meet this currently unmet need.
In January 2014, the FDA designated Vabomere™ (formerly known as Carbavance) as a qualified infectious disease product (QIDP) under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act in recognition of Vabomere™'s promise in treating serious or life-threatening antimicrobial resistant infections. Vabomere™ also received significant support through two contracts[4] awarded by the Biomedical Advanced Research and Development Authority (BARDA) that include financial commitments, non-clinical development activities, clinical studies, manufacturing, and associated regulatory activities designed to gain U.S. approval of Vabomere™ for treatment of serious gram-negative infections.

Description and Method of Action. Vabomere™ uses the first-in-class beta lactamase inhibitor vaborbactam to treat new patient populations by causing carbapenem-resistant infections to be sensitive to meropenem. Vabomere™ protects meropenem from degradation by certain carbapenem-resistant enterobacteriaceae (CRE) strains producing the *Klebsiella pneumoniae* carbapenemase (KPC) enzyme, thereby providing a therapeutic effect where bacteria would otherwise be resistant and unresponsive to treatment.

The vaborbactam component of Vabomere™ is a non-suicidal beta-lactamase inhibitor that protects meropenem from degradation by certain serine beta-lactamases such as KPC. Vaborbactam, as noted, is a novel, first-in-class beta-lactamase inhibitor. Vaborbactam, while it alone does not have any antibacterial activity, allows for the treatment of resistant infections by disarming the resistant properties of the bacteria so that they are sensitive to meropenem. Vaborbactam does not decrease the activity of meropenem against meropenem-sensitive organisms, but it facilitates and is essential to the novel approach to fighting resistant infections by causing resistant infections to be sensitive to meropenem.

The meropenem component of Vabomere™ is a penem antibacterial drug. The bactericidal action of meropenem results from the inhibition of cell wall synthesis. Meropenem penetrates the cell wall of most gram-positive and gram-negative bacteria to bind penicillin-binding protein (PBP) targets. Meropenem is stable to hydrolysis by most beta-lactamases, including penicillinases and cephalosporinases produced by gram-negative and gram-positive bacteria, with the exception of carbapenem hydrolyzing beta-lactamases.

The FDA-approved labeling (see PI §§ 1.1, 1.2, 12.4) discusses Vabomere™'s activity against bacteria that produce beta-lactamases, including KPC. Accordingly, Vabomere™ is a new antibiotic that has demonstrated activity against KPC-producing CRE and that is approved by FDA to treat cUTI including pyelonephritis caused by these specific and potentially highly resistant bacteria.

Inpatient Administration of Vabomere™. The recommended dosage of Vabomere™ is 4 grams (meropenem 2 grams and vaborbactam 2 grams) administered every 8 hours by intravenous (IV)

[3] White House Counsel on Combating Antibiotic Resistant Bacteria. Recommendations for Incentivizing the Development of Therapeutics Diagnostics and Vaccines to Combat Antibiotic Resistance. September 2017.
[4] BARDA Contract Nos. HHSO100201400002 and HHSO100201600026C.

infusion over 3 hours in patients 18 years of age and older with an estimated glomerular filtration rate (eGFR) greater than or equal to 50 mL/min/1.73m2. The duration of treatment is for up to 14 days. Per the FDA-approved labeling, dosage adjustment is recommended in patients with renal impairment who have an eGFR less than 50 mL/min/1.73m2.

Current Coding: Facilities can report the administration of Vabomere™ (meropenem-vaborbactam) 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 for the administration of meropenem-vaborbactam. Continue using current codes as listed in Current Coding.

Option 2. Create new qualifier value Meropenem-vaborbactam Anti-infective in table 3E0 of section 3, Administration, applied to the fourth character values Peripheral Vein and Central Vein, to identify intravenous infusion of meropenem-vaborbactam.

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 2** Meropenem-vaborbactam Anti-infective **8** Oxazolidinones **9** Other Anti-infective

Option 3. Create new codes in section X, New Technology, to identify intravenous infusion of meropenem-vaborbactam.

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 N** Meropenem-vaborbactam Anti-infective	**5** New Technology Group 5

CMS Recommendation: Option 3. Create new codes in section X, New Technology, to identify intravenous infusion of meropenem-vaborbactam.

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

Cell Suspension Autografting

Issue: Currently there is not a unique ICD-10-PCS code to identify cell suspension epithelial autografts. This topic was presented at the March 2018 C&M Meeting and because agreement could not be reached on whether to classify cell suspension epithelial autografts as a device or a substance, a code was not approved at that time. The requestor asked that this topic be brought back for reconsideration.

New Technology Application? No

Food & Drug Administration (FDA) Approval? No. In September 2017, AVITA submitted to the FDA a Pre-Market Approval (PMA) application for RECELL® for the treatment of burn injuries. Since that time, the FDA has approved several increases in the number of patients who may be treated in the United States with RECELL® Autologous Cell Harvesting Device under an FDA Compassionate Use Investigational Device Exemption (IDE) program. FDA approval of RECELL® is expected during Q3 of 2018.

Background: RECELL® is a type of epithelial autograft that can be used for large wounds such as major burns. It is also currently being considered for additional acute and chronic types of wounds. The procedure involves harvesting a small split-thickness skin sample from a healthy donor site on the patient. This sample is then placed into a warm enzyme-containing incubator where it biochemically separates the epidermis from the dermis. After about 15 to 20 minutes, the sample is removed and its surface is scraped to separate the cells from the tissue. This creates a mixed population of cells, primarily keratinocytes and fibroblasts but also including melanocytes, Langerhans cells, and epidermal basal cells. The cells are then suspended in a buffer solution and filtered to remove debris. The result is a regenerative epithelial cell suspension that can be immediately applied to the prepared wound via a spray technique or a drip technique. Depending on the extent of the injury, the cell suspension autograft can be applied alone or in conjunction with another skin graft. The entire process takes place in the operating room. It is performed by the surgeon, sometimes with assistance by a nurse or technician under the surgeon's supervision. The surgeon is present and exclusively engaged throughout.

According to the requester, cell suspension autografting and conventional skin grafts are similar in that a cell suspension autograft is biological material composed of keratinocytes and other key cells harvested directly from skin, and it physically takes the place and the function of the patient's skin.

Cell suspension autografting differs from conventional skin grafts as follows.

- Cell suspension autografts, as named, are solutions containing skin cells and do not take the form of a sheet of tissue.
- Cell suspension autografts adhere to the recipient site without use of fixation (e.g. by sutures).
- Cell suspension autografts are applied to the wound site as a liquid which then becomes a permanent layer of skin.

The pivotal trial for RECELL® cell suspension autografts was supported by the Armed Forces Institute of Regenerative Medicine with a priority in treating burns in military personnel returning from deployment. The HHS Biomedical Advanced Research and Development Authority (BARDA) has also provided ongoing support for cell suspension autograft trials as a countermeasure against public health emergencies and mass burn casualty events.

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

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Skin, Scalp **1** Skin, Face **2** Skin, Right Ear **3** Skin, Left Ear **4** Skin, Neck **5** Skin, Chest **6** Skin, Back **7** Skin, Abdomen **8** Skin, Buttock **9** Skin, Perineum **A** Skin, Inguinal **B** Skin, Right Upper Arm **C** Skin, Left Upper Arm **D** Skin, Right Lower Arm **E** Skin, Left Lower Arm **F** Skin, Right Hand **G** Skin, Left Hand **H** Skin, Right Upper Leg **J** Skin, Left Upper Leg **K** Skin, Right Lower Leg **L** Skin, Left Lower Leg **M** Skin, Right Foot **N** Skin, Left Foot **Q** Finger Nail **R** Toe Nail	**X** External	**Z** No Device	**X** Diagnostic **Z** No Qualifier

Facilities can report the application of cell suspension autografting using the following ICD-10-PCS code:
3E00XGC Introduction of Other Therapeutic Substance into Skin and Mucous Membranes, External Approach

Coding Options

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

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

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Skin, Scalp **1** Skin, Face **2** Skin, Right Ear **3** Skin, Left Ear **4** Skin, Neck **5** Skin, Chest **6** Skin, Back **7** Skin, Abdomen **8** Skin, Buttock **9** Skin, Perineum **A** Skin, Inguinal **B** Skin, Right Upper Arm **C** Skin, Left Upper Arm **D** Skin, Right Lower Arm **E** Skin, Left Lower Arm **F** Skin, Right Hand **G** Skin, Left Hand **H** Skin, Right Upper Leg **J** Skin, Left Upper Leg **K** Skin, Right Lower Leg **L** Skin, Left Lower Leg **M** Skin, Right Foot **N** Skin, Left Foot	**X** External	**7** Autologous Tissue Substitute	**ADD 2** Cell Suspension Technique **3** Full Thickness **4** Partial Thickness

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

Section	**X** New Technology
Body System	**H** Skin, Subcutaneous Tissue, Fascia and Breast
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
P Skin	**X** External	**ADD 1** Autologous Epithelial Cell Suspension	**5** New Technology Group 5

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

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
0 Skin and Mucous Membranes	**X** External	**G** Other Therapeutic Substance	**ADD 1** Autologous Epithelial Cell Suspension **C** Other Substance

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

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

Intramedullary Limb Lengthening System

Issue: Currently, there is not a unique ICD-10-PCS device value to describe a limb lengthening intramedullary internal fixation device.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The FDA granted 510(k) premarket approval on February 27, 2017 for the Lower PRECICE Intramedullary Limb Lengthening System indicated for limb lengthening of the tibia and femur. On July 12, 2011 the FDA granted 510(k) premarket approval (K101997) for the long bones which included the humerus.

Background: Limb length discrepancy may be diagnosed as an infant, in childhood, or later in life, depending on the cause. The PRECICE system can be used for patients of all ages, as limb discrepancy may be congenital, developmental, or result from trauma or bone diseases. The use of the PRECICE system in Medicare beneficiaries would typically be due to trauma or a bone disease. According to the requestor, published studies have shown the PRECICE system to have a lower risk of infections when compared to external fixation, which offers an additional clinical benefit for Medicare patients.

It is recommended that if a leg length discrepancy is greater than 1.5 to 2.0 cm (5/8 inch) it should be treated. The concern is that walking with the pelvis out of alignment can start to cause low back pain, hip pain, or knee pain over time. Walking or running, relies on constant shifting from one base of support to the other. Limb length discrepancy can increase the amount of energy needed to walk and reduce muscular efficiency, making movement more difficult. If the difference between limbs is greater than 2.0 cm (5/8 inch), the limp is worse, which can cause back pain and significant curve of the spine. Limping causes abnormal pressure on the joints and can lead to painful arthritis of the hip, knee, or ankle, if left untreated. Back, hip, and knee problems often occur if the condition is left untreated.

The PRECICE System was developed to lengthen the limb gradually without the use of external fixation. Laubscher[1] compared patients implanted with PRECICE to patients treated with external fixation and found that there was a statistically significant reduction in healing time between the two procedures. Healing time for the PRECICE group was 31.3 days/cm vs. 47.1 days/cm for the external fixation group ($p<0.001$). In addition seven out of thirteen of the external fixation patient had pin site infections (no infections with the PRECICE device. And the pain scores during the distraction phase, consolidation phase and cosmetic scar rating were significantly better in the PRECICE group.

Szymczuk[2] reviewed 32 external fixation and 30 PRECICE intramedullary limb lengthening patient results and found the intramedullary nail had superior range of motion during the lengthening phase and at consolidation. In addition, the PRECICE patients had an overall lower

[1] Laubscher M., Mitchell C., Timms A., Outcomes following femoral lengthening An Initial Comparison of the PRECICE Intramedullary Lengthening Nail and the LRS External Fixator Monorail System. Bone Joint J 2016;98-B
[2] Szymczuk V., Hammouda, A.,*Gesheff, M., Lengthening With Monolateral External Fixation Versus Magnetically Motorized Intramedullary Nail in Congenital Femoral Deficiency. J Pediatr Orthop 2017;00:000–000)

complication rate, while maintaining similar distraction (length) and healing indices to monolateral external fixation.

Technology: The PRECICE Intramedullary Limb Lengthening (IMLL) System is composed of the PRECICE Nail, locking screws, end cap, surgical instruments, and an External Remote Controller (ERC or ERC 2P). The nail is available in tibial and femoral models; with various diameters, lengths and screw hole configurations to accommodate a variety of patient anatomies. The locking screws are also available in a variety of diameters, lengths, and thread styles.

Procedure: The procedure involving a PRECICE implant is similar to implanting an intramedullary nail in the femur, tibia or humerus. Traditional intramedullary surgical techniques are used to implant and secure the proximal and distal sections of the PRECICE nail to the target bone. The difference between with the PRECICE implant is that it has a small magnet that allows the implant to get shorter or longer when the magnet is turned by the External Remote Controller (ERC). The ERC is a hand held device with two large magnets. The magnet in the implant turns when the ERC is placed on the arm or leg and turned on. As with other intramedullary implants the PRECICE implant can be removed when the patient's limb is healed.

Current Coding: Code limb lengthening procedures that utilize the intramedullary limb lengthening system to the appropriate body part value in tables 0PH and 0QH, Insertion of Upper Bones and Insertion of Lower Bones, using the device value 6 Internal Fixation Device, Intramedullary and the applicable approach.

Section **0** Medical and Surgical *Body System* **P** Upper Bones *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*
C Humeral Head, Right **D** Humeral Head, Left **F** Humeral Shaft, Right **G** Humeral Shaft, Left **H** Radius, Right **J** Radius, Left **K** Ulna, Right **L** Ulna, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **5** External Fixation Device **6** Internal Fixation Device, Intramedullary **8** External Fixation Device, Limb Lengthening **B** External Fixation Device, Monoplanar **C** External Fixation Device, Ring **D** External Fixation Device, Hybrid	**Z** No Qualifier

Section **0** Medical and Surgical *Body System* **Q** Lower Bones *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*
6 Upper Femur, Right **7** Upper Femur, Left **8** Femoral Shaft, Right **9** Femoral Shaft, Left **B** Lower Femur, Right **C** Lower Femur, Left **G** Tibia, Right **H** Tibia, Left **J** Fibula, Right **K** Fibula, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **5** External Fixation Device **6** Internal Fixation Device, Intramedullary **8** External Fixation Device, Limb Lengthening **B** External Fixation Device, Monoplanar **C** External Fixation Device, Ring **D** External Fixation Device, Hybrid	**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. In tables 0PH and 0QH, Insertion of Upper Bones and Insertion of Lower Bones, create device value 7 Internal Fixation Device, Intramedullary Limb Lengthening applied to the humerus, femur and tibia body part values respectively.

Section	**0** Medical and Surgical
Body System	**P** Upper Bones
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*
F Humeral Shaft, Right **G** Humeral Shaft, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **5** External Fixation Device **6** Internal Fixation Device, Intramedullary **ADD 7** Internal Fixation Device, Intramedullary Limb Lengthening **8** External Fixation Device, Limb Lengthening **B** External Fixation Device, Monoplanar **C** External Fixation Device, Ring **D** External Fixation Device, Hybrid	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**Q** Lower Bones
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*
8 Femoral Shaft, Right **9** Femoral Shaft, Left **G** Tibia, Right **H** Tibia, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD 7** Internal Fixation Device, Intramedullary Limb Lengthening	**Z** No Qualifier

CMS Recommendation: Option 2. In tables 0PH and 0QH, Insertion of Upper Bones and Insertion of Lower Bones, create device value 7 Internal Fixation Device, Intramedullary Limb Lengthening applied to the humerus, femur and tibia body part values respectively.

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

Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) Lead

Issue: Currently, there is not a unique ICD-10-PCS device value in table 0JH to describe a subcutaneous implantable cardioverter defibrillator (S-ICD) lead.

New Technology Application? No.

Food and Drug Administration (FDA) Approval? The Subcutaneous Implantable Cardioverter Defibrillator (S-ICD™) System received premarket approval on September 28, 2012 and is indicated to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrythmias.

Background: The use of implantable cardioverter defibrillators (ICDs) is an established therapy for the prevention of death from ventricular arrhythmia. Existing conventional ICDs rely on transvenous leads for cardiac sensing and defibrillation. Complications of defibrillator implantation have been associated mainly with transvenous lead insertion and have included pneumothorax, hemothorax and cardiac tamponade. Difficulties in achieving venous access can prolong the procedure and occasionally result in failed ICD implantation. In the long term, lead failure remains a major limitation in the use of ICDs, despite decades of innovations in lead design. Lead failure either generates inappropriate shocks or impedes appropriate therapy. Moreover, failed leads often require removal, a procedure that is associated with substantial morbidity and mortality. If cardiac pacing is not necessary, there may be a clinical advantage of the subcutaneous implantable defibrillator system in that it avoids complications related to transvenous electrodes.

Procedure: The procedure is performed under ECG, intra-arterial blood pressure, and pulse oximetry monitoring. The patient is prepped, given IV antibiotic prophylaxis, and placed under conscious sedation or general anesthesia. Local anesthetic is injected into the region where the incision is made (unless the patient is under general anesthesia). An incision is then made over the sixth rib between the midaxillary line and the anterior axillary line. If an existing generator is present, subcutaneous dissection of the pulse generator is performed. The insertion of the subcutaneous electrode is guided by anatomical landmarks.

The subcutaneous electrode is positioned parallel to and 1 to 2 cm to the left of the sterna midline. The electrode has an 8-cm shocking coil, flanked by two sensing electrodes. The distal sensing electrode is positioned adjacent to the manubriosternal junction and the proximal sensing electrode is positioned adjacent to the xiphoid process. The electrodes may require repositioning to ensure adequate sensing and defibrillation threshold. Upon final positioning the electrode is connected to an electrically active pulse generator. Cardiac rhythm is detected by the two sensing electrodes or by either of the sensing electrodes and the pulse generator.

The subcutaneous implantable defibrillator system automatically selects an appropriate sense vector for rhythm detection and for avoiding double QRS counting and T-wave oversensing. Once signals have been validated as free of noise and double detection, discrimination feature analysis and rate detection are used to sort rhythm type and determine the need for the procedure. A conditional discrimination zone incorporating a feature extraction technique can be programmed between rates of 170 and 240 beats per minute to distinguish supraventricular

tachycardia from ventricular tachycardia and avoid inappropriate treatment of the former. Reconfirmation of ventricular tachyarrhythmia follows capacitor charging to avoid the delivery of shocks for nonsustained ventricular tachyarrhythmias. Defibrillator threshold testing of the device during implantation, when performed, is done with the use of 65-J shocks to ensure an energy margin of safety. The incision is then closed, and the wound is dressed. The physician documents the procedure, generates a report, and communicates with the referring physician, patient, and family.

After monitoring the vital signs, obtaining and reviewing a chest x-ray and electrocardiogram prior to discharge, the wound is assessed and instruction for postoperative care is given. The patient returns to the clinic post-implant at 7 days, 30 days and 90 days where the subcutaneous implantable defibrillator is interrogated, and appropriate device settings assessed. The wound is assessed at the 7-day clinic visit with respect to appropriate healing and the dressing is subsequently removed. Any required antibiotics or analgesic medications are prescribed.

Current Coding: Procedures involving the insertion, removal, or revision of a subcutaneous implantable cardioverter defibrillator lead are captured using the device value P Cardiac Rhythm Related Device with the appropriate subcutaneous tissue and fascia body part value and the applicable approach value in tables 0JH, 0JP and 0JW, root operations Insertion, Removal, and Revision respectively. Procedures involving the insertion, removal, or revision of a defibrillator generator are coded separately using the device value 8 Defibrillator Generator.

Section	**0** Medical and Surgical
Body System	**J** Subcutaneous Tissue and Fascia
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*
6 Subcutaneous Tissue and Fascia, Chest	**0** Open **3** Percutaneous	**0** Monitoring Device, Hemodynamic **2** Monitoring Device **4** Pacemaker, Single Chamber **5** Pacemaker, Single Chamber Rate Responsive **6** Pacemaker, Dual Chamber **7** Cardiac Resynchronization Pacemaker Pulse Generator **8** Defibrillator Generator **9** Cardiac Resynchronization Defibrillator Pulse Generator **A** Contractility Modulation Device **B** Stimulator Generator, Single Array **C** Stimulator Generator, Single Array Rechargeable **D** Stimulator Generator, Multiple Array **E** Stimulator Generator, Multiple Array Rechargeable **H** Contraceptive Device **M** Stimulator Generator **N** Tissue Expander **P** Cardiac Rhythm Related Device **V** Infusion Device, Pump **W** Vascular Access Device, Totally Implantable **X** Vascular Access Device, Tunneled	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**J** Subcutaneous Tissue and Fascia
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device*	*Qualifier*
T Subcutaneous Tissue and Fascia, Trunk	**0** Open **3** Percutaneous	**0** Drainage Device **1** Radioactive Element **2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **H** Contraceptive Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Stimulator Generator **N** Tissue Expander **P** Cardiac Rhythm Related Device **V** Infusion Device, Pump **W** Vascular Access Device, Totally Implantable **X** Vascular Access Device, Tunneled **Y** Other Device	**Z** No Qualifier

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

Body Part	*Approach*	*Device*	*Qualifier*
T Subcutaneous Tissue and Fascia, Trunk	**0** Open **3** Percutaneous	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **H** Contraceptive Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Stimulator Generator **N** Tissue Expander **P** Cardiac Rhythm Related Device **V** Infusion Device, Pump **W** Vascular Access Device, Totally Implantable **X** Vascular Access Device, Tunneled **Y** Other 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. In tables 0JH, 0JP and 0JW, root operations Insertion, Removal, and Revision, create device value F Subcutaneous Defibrillator Lead, applied to the corresponding chest/trunk body part value and approach values in the table.

Section	**0** Medical and Surgical
Body System	**J** Subcutaneous Tissue and Fascia
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*
6 Subcutaneous Tissue and Fascia, Chest	**0** Open **3** Percutaneous	**0** Monitoring Device, Hemodynamic **2** Monitoring Device **4** Pacemaker, Single Chamber **5** Pacemaker, Single Chamber Rate Responsive **6** Pacemaker, Dual Chamber **7** Cardiac Resynchronization Pacemaker Pulse Generator **8** Defibrillator Generator **9** Cardiac Resynchronization Defibrillator Pulse Generator **A** Contractility Modulation Device **B** Stimulator Generator, Single Array **C** Stimulator Generator, Single Array Rechargeable **D** Stimulator Generator, Multiple Array **E** Stimulator Generator, Multiple Array Rechargeable **ADD F** Subcutaneous Defibrillator Lead **H** Contraceptive Device **M** Stimulator Generator **N** Tissue Expander **P** Cardiac Rhythm Related Device **V** Infusion Device, Pump **W** Vascular Access Device, Totally Implantable **X** Vascular Access Device, Tunneled	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**J** Subcutaneous Tissue and Fascia
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device*	*Qualifier*
T Subcutaneous Tissue and Fascia, Trunk	**0** Open **3** Percutaneous	**0** Drainage Device **1** Radioactive Element **2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **ADD F** Subcutaneous Defibrillator Lead **H** Contraceptive Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Stimulator Generator **N** Tissue Expander **P** Cardiac Rhythm Related Device **V** Infusion Device, Pump **W** Vascular Access Device, Totally Implantable **X** Vascular Access Device, Tunneled **Y** Other Device	**Z** No Qualifier

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

Body Part	*Approach*	*Device*	*Qualifier*
T Subcutaneous Tissue and Fascia, Trunk	**0** Open **3** Percutaneous	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **ADD F** Subcutaneous Defibrillator Lead **H** Contraceptive Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Stimulator Generator **N** Tissue Expander **P** Cardiac Rhythm Related Device **V** Infusion Device, Pump **W** Vascular Access Device, Totally Implantable **X** Vascular Access Device, Tunneled **Y** Other Device	**Z** No Qualifier
T Subcutaneous Tissue and Fascia, Trunk	**X** External	**0** Drainage Device **2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **ADD F** Subcutaneous Defibrillator Lead **H** Contraceptive Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Stimulator Generator **N** Tissue Expander **P** Cardiac Rhythm Related Device **V** Infusion Device, Pump **W** Vascular Access Device, Totally Implantable **X** Vascular Access Device, Tunneled	**Z** No Qualifier

Option 3. In table 0JH, root operation Insertion, create device value F Subcutaneous Defibrillator Lead, applied to the chest body part value and approach values in the table. For procedures involving removal or adjusting a malfunctioning or displaced subcutaneous defibrillator lead, continue to code to the device value P Cardiac Rhythm Related Device in tables 0HP and 0JW as shown in current coding above.

Section	**0** Medical and Surgical		
Body System	**J** Subcutaneous Tissue and Fascia		
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*
6 Subcutaneous Tissue and Fascia, Chest	**0** Open **3** Percutaneous	**0** Monitoring Device, Hemodynamic **2** Monitoring Device **4** Pacemaker, Single Chamber **5** Pacemaker, Single Chamber Rate Responsive **6** Pacemaker, Dual Chamber **7** Cardiac Resynchronization Pacemaker Pulse Generator **8** Defibrillator Generator **9** Cardiac Resynchronization Defibrillator Pulse Generator **A** Contractility Modulation Device **B** Stimulator Generator, Single Array **C** Stimulator Generator, Single Array Rechargeable **D** Stimulator Generator, Multiple Array **E** Stimulator Generator, Multiple Array Rechargeable **ADD F** Subcutaneous Defibrillator Lead **H** Contraceptive Device **M** Stimulator Generator **N** Tissue Expander **P** Cardiac Rhythm Related Device **V** Infusion Device, Pump **W** Vascular Access Device, Totally Implantable **X** Vascular Access Device, Tunneled	**Z** No Qualifier

CMS Recommendation: Option 3. In table 0JH, root operation Insertion, create device value F Subcutaneous Defibrillator Lead, applied to the chest body part value and approach values in the table. For procedures involving removal or adjusting a malfunctioning or displaced subcutaneous defibrillator lead, continue to code to the device value P Cardiac Rhythm Related Device in tables 0HP and 0JW as shown in current coding above.

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

Administration of Erdafitinib

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

New Technology Application? Yes, a new technology application will be submitted for erdafitinib for FY 2020.

Food & Drug Administration (FDA) Approval? No. On March 15, 2018, the FDA granted breakthrough therapy designation for Erdafitinib in the treatment of urothelial cancer in adult patients whose tumors have certain FGFR genetic alterations and who have had disease progression during or following at least one line of prior chemotherapy including within 12 months of chemotherapy. The New Drug Application (NDA) submission is planned for September 2018.

Background: Erdafitinib is an orally-administered fibroblast grown factor receptor (FGFR) tyrosine kinase inhibitor that is a targeted treatment for patients with metastatic or surgically unresectable urothelial cancer. Urothelial cancer is also known as transitional cell cancer. It is most frequently found in the bladder and is a common cancer in both men and women in the U.S. These cancers start in the urothelial cells that line the inside of the bladder. For patients with metastatic disease, outcomes can be dire because the tumors often progress rapidly and there is a lack of efficacious treatments, especially in relapsed or refractory disease[1]. Patients with locally advanced or metastatic urothelial cancer have low survival rates. In 2018, an estimated 81,190 new cases of urothelial cancer in the bladder will be diagnosed and an estimated 17,240 deaths will occur as a result of urothelial cancer[2]. According to the requestor, first-line treatments are limited to mainly combination chemotherapies, while second-line treatments are limited to anti-PD-L1/PD-1 therapy. A subset of patients, who have a FGFR genetic alteration in the tumor, and who have had disease progression during or following at least one line of prior chemotherapy including within 12 months of chemotherapy, may benefit from erdafitinib.

Current Coding: Facilities can report the oral administration of erdafitinib 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 new ICD-10-PCS codes for the administration of erdafitinib. Continue using current codes as listed in Current Coding.

Option 2. Create new qualifier value7 Erdafitinib 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 erdafitinib.

[1]National Cancer Institute. Bladder Cancer Treatment (PDQ®)—Health Professional Version. Available at: https://www.cancer.gov/types/bladder/hp/bladder-treatment-pdq

[2] National Cancer Institute. Cancer Stat Facts: Bladder Cancer. Available at: https://seer.cancer.gov/statfacts/html/urinb.html. Accessed February 2018

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 7** Erdafitinib **M** Monoclonal Antibody

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

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 L** Erdafitinib Antineoplastic	**ADD 5** New Technology Group 5

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

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

Administration of Esketamine HCl

Issue: Currently, there is not a unique ICD-10-PCS code to describe the administration of Esketamine.

New Technology Application? A new technology application will be submitted for Esketamine for FY 2020.

Food and Drug Administration (FDA) Approval? No. The FDA granted breakthrough therapy designations for esketamine nasal spray for treatment-resistant depression (2013) and for a second indication, major depressive disorder (MDD) in adult patients with imminent risk of suicide (2016). The Food and Drug Administration has not approved the use of esketamine for treatment of MDD. The New Drug Application (NDA) for Esketamine nasal spray in the treatment of treatment-resistant depression was submitted September 4, 2018.

Background: Esketamine HCl has been studied in the treatment of adult patients with treatment-resistant depression (Major Depressive Disorder in adults who have not responded adequately to at least two different antidepressants of adequate dose and duration to treat a depressive episode). An estimated 16.2 million patients had at least one major depressive episode in 2016[1] and approximately one-third of those patients are estimated to have treatment resistant depression[2]. Medicare patients comprise approximately 21% of the patients diagnosed with treatment resistant depression—many having multiple hospital admissions for severe, recurrent depression[3]. Esketamine (the S-isomer of racemic ketamine) is being investigated as an antidepressant with a novel mechanism of action and it is a non-competitive, subtype non-selective, activity-dependent glutamate receptor modulator. It is delivered as a nasal spray in a device intended for self-administration by the patient under the supervision of a healthcare professional.

According to applicant, the issuance of a new ICD-10-PCS code will support program efficiency and patient access.

Current Coding: Facilities can report the administration of esketamine hydrochloride nasal spray with the following ICD-10-PCS code:

3E097GC Introduction of Other Therapeutic Substance into Nose, Via Natural or Artificial Opening

Coding Options

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

---

[1]National Institute of Mental Health. Major depression among adults. https://www.nimh.nih.gov/health/statistics/major-depression.shtml. Accessed April 12, 2018.

[2] Rush AJ et al. Am J Psychiatry. 2006;163(11):1905-1917. **3.** Agency for Healthcare Research and Quality. Definition of treatment-resistant depression in the Medicare population. https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id105TA.pdf. Accessed April 12, 2018.

[3] *Data sourced from IQVIA (IMS) patient claims database.

Option 2. Create new qualifier value Esketamine Hydrochloride in table 3E0 of section 3, Administration, applied to the fourth character value Nose and the sixth character substance value Other Therapeutic Substance, to identify administration of esketamine hydrochloride nasal spray.

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*
9 Nose	**7** Via Natural or Artificial Opening	**G** Other Therapeutic Substance	**ADD 3** Esketamine Hydrochloride **C** Other Substance

Option 3. Create a new code in section X, New Technology, to identify administration of esketamine hydrochloride nasal spray.

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*
9 Nose	**7** Via Natural or Artificial Opening	**ADD M** Esketamine Hydrochloride	**ADD 5** New Technology Group 5

CMS Recommendation: Option 3. Create a new code in section X, New Technology, to identify administration of esketamine hydrochloride nasal spray.

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

Administration of ERLEADA™ (apalutamide), for oral use

Issue: There is no ICD-10-PCS code for the use of ERLEADA™. ERLEADA™ (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (NM-CRPC).

New Technology Application? Yes. Johnson & Johnson Healthcare Systems Inc., on behalf of Janssen Pharmaceuticals, Inc. will be submitting a New Technology Add-On Payment (NTAP) application to CMS for ERLEADA™ (apalutamide) for Fiscal Year 2020.

Food and Drug Administration (FDA) Approval? On February 14, 2018, ERLEADA™ received FDA approval for treatment of patients with non-metastatic castration-resistant prostate cancer.

Background: ERLEADA™ is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (NM-CRPC). ERLEADA™ represents a new treatment option, fulfilling a longstanding unmet need in the treatment of this patient population, because it is the first FDA-approved treatment for NM-CRPC.
In the US, an estimated 1 in 9 men will be diagnosed with prostate cancer during his lifetime, and 1 in 41 men will die of the disease (American Cancer Society 2018). Prostate cancer is the most frequently diagnosed cancer in men, excluding basal and squamous cell skin cancers, and the second most common cause of cancer death among men in the US. An estimated 164,690 men will be newly diagnosed with prostate cancer, and 29,430 men will die from the disease in 2018 (American Cancer Society 2018). Assessing the prevalence of NM-CRPC using currently available epidemiologic data presents several challenges. The accuracy of epidemiological data in NM-CRPC is strongly dependent on the sensitivity of the diagnostic tools used to detect metastases (Rozet 2016).

Prostate cancer is an androgen-driven disease (Locke 2008). Androgen-sensitive cancer responds to treatment that decreases androgen levels. Androgen deprivation therapy (ADT), such as treatment with GnRH agonists/antagonists or bilateral orchiectomy, decrease androgen production in the testes but do not affect androgen production by the adrenals or in the tumor tissue itself (Attard 2008). Castration resistance can develop through several different molecular events, which can include: oncogene activation, tumor suppressor gene inactivation, apoptosis evasion, intratumoral androgen production and aberrant androgen receptor (AR) activation (Kahn 2014, Logothetis 2013). ARs in tumor cells exposed to ADT undergo selective alterations that result in aberrant AR reactivation, which result in the AR pathway remaining active despite decreased amounts of androgenic ligands (Kahn 2014, Crona 2017). These mechanisms allow cancer cells to evade apoptosis, promoting tumor cell growth and ultimately result in progression to the castration-resistant disease state termed CRPC (Kahn 2014).It is recommended to follow the standard of care by utilizing ADT to maintain castrate levels of serum testosterone (<50 ng/dL) even in patients with castration-resistant disease (NCCN 2018, Cookson 2018, Lowrance 2018, Merseburger 2015).

Patients with NM-CRPC generally present with prostate-specific antigen (PSA) levels that continue to rise after medical or surgical castration despite castrate serum testosterone levels (<50 ng/dL). These patients do not have radiographically detectable metastases and are usually asymptomatic (Cookson 2018, Lowrance 2018, Scher 2008). Often patients with NM-CRPC progress to metastatic CRPC (mCRPC), with studies reporting 33% to 46% of patients developing metastases within 2 years of NM-CRPC diagnosis (Moreira 2016, Smith 2011, Smith 2005).

Apalutamide is an androgen receptor (AR) inhibitor that binds directly to the ligand-binding domain of the AR. Apalutamide inhibits AR nuclear translocation, inhibits DNA binding, and impedes AR-mediated transcription.

ERLEADA™ is administered orally once daily with or without food, with a recommended dose of 240mg (four 60mg tablets). Patients receiving ERLEADA™ should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

Current Coding: Facilities can report the administration of ERLEADA™ (apalutamide) 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 new ICD-10-PCS codes for the administration of ERLEADA™ (apalutamide). Continue using current codes as listed in Current Coding.

Option 2. Create new qualifier value Apalutimide in table 3E0 of section 3, Adminstration, applied to the fourth character value Mouth and Pharynx and the external approach, to identify oral administration of ERLEADA™ (apalutamide).

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 6** Apalutimide **M** Monoclonal Antibody

Option 3. Create a new code in section X, New Technology, to identify oral administration of ERLEADA™ (apalutamide).

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 J** Apalutamide 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 ERLEADA™ (apalutamide).

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

References

American Cancer Society. Key statistics for prostate cancer. https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html. Accessed August 22, 2018.

Attard G, Reid AH, Yap TA, et al. Phase I clinical trial of a selective inhibitor of CYP17, abiraterone acetate, confirms that castration-resistant prostate cancer commonly remains hormone driven. *J Clin Oncol*. 2008;26(28):4563-4571.

Cookson MS, Roth BJ, Dahm P, et al. Castration-resistant prostate cancer: AUA guideline. Available from: www.auanet.org. Accessed August 22, 2018.
Crona DJ, Whang YE. Androgen receptor-dependent and -independent mechanisms involved in prostate cancer therapy resistance. *Cancers*. 2017;9(6):67.

ERLEADA™ (apalutamide) [Prescribing Information]. Horsham, PA: Janssen Products, LP. February 2018. https://www.janssenmd.com/pdf/erleada/erleada_pi.pdf

FDA approves new treatment for a certain type of prostate cancer using novel clinical trial endpoint [press release]. Silver Springs, MD: U.S. Food and Drug Administration; February 14, 2018. Available from: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm596768.htm**.** Accessed August 22, 2018.

Hernandez RK, Cetin K, Pirolli M, et al. Estimating high-risk castration resistant prostate cancer (CRPC) using electronic health records. *Can J Urolog*. 2015;22(4):7858-7864.

Howard LE, Moreira DM, De Hoedt A, et al. Thresholds for PSA doubling time in men with nonmetastatic castration-resistant prostate cancer. *BJU Int.* 2017;120(5B):E80-E86.

Kahn B, Collazo J, Kyprianou N. Androgen receptor as a driver of therapeutic resistance in advanced prostate cancer. *Int J Biol Sci*. 2014;10(6):588-595.

Liede A, Arellano J, Hechmati G, et al. Prevalence of non-metastatic castration-resistant prostate cancer (CRPC) at high risk of bone metastases in 19 countries in 2013 [abstract]. *Eur J Cancer*. 2013;49(suppl):S710.Abstract 2938.

Lin JH, Macomson B, Tunceli O, et al. Association of prostate specific-antigen doubling time (PSADT) with metastasis-free survival (MFS) and overall survival (OS) in non-metastatic castration-resistant prostate cancer (nmCRPC) [abstract]. *J Clin Oncol*. 2017;35(15 suppl). Abstract e16525.

Locke JA, Guns ES, Lubik AA, et al. Androgen levels increase by intratumoral de novo steroidogenesis during progression of castration-resistant prostate cancer. *Cancer Res*. 2008;68(15):6407-6415.

Logothetis CJ, Gallick GE, Maity SN, et al. Molecular classification of prostate cancer progression: foundation for marker-driven treatment of prostate cancer. *Cancer Discov*. 2013;3(8):849-861.

Lowrance WT, Murad MH, Oh WK, et al. Castration-Resistant Prostate Cancer: AUA Guideline Amendment 2018. In press. *J Urol* 2018.

Merseburger AS, Hammerer P, Rozet F, et al. Androgen deprivation therapy in castrate-resistant prostate cancer: how important is GnRH agonist backbone therapy? *World J Urol*. 2015;33(8):1079-1085.

Moreira DM, Howard LE, Sourbeer KN, et al. Predictors of time to metastasis in castration-resistant prostate cancer. *Urology*. 2016;96:171-176.

Rozet F, Roumeguère T, Spahn M, Beyersdorff D, Hammerer P. Non-metastatic castrate-resistant prostate cancer: a call for improved guidance on clinical management. *World J Urol*. 2016;34(11):1505-1513.

Scher HI, Halabi S, Tannock I, et al. Design and end points of clinical trials for patients with progressive prostate cancer and castrate levels of testosterone: recommendations of the prostate cancer clinical trials working group. *J Clin Oncol*. 2008;26(7):1148-1159.

Smith MR, Cook R, Lee KA, Nelson JB. Disease and host characteristics as predictors of time to first bone metastasis and death in men with progressive castration-resistant nonmetastatic prostate cancer. *Cancer*. 2011;117(10):2077-2085.

Smith MR, Kabbinavar F, Saad F, et al. Natural history of rising serum prostate-specific antigen in men with castrate nonmetastatic prostate cancer. *J Clin Oncol*. 2005;23(13):2918-2925.

Virgo KS, Basch E, Loblaw DA, et al. Second-line hormonal therapy for men with chemotherapy-naïve, castration-resistant prostate cancer: American Society of Clinical Oncology provisional clinical opinion. *J Clin Oncol*. 2017;35(17):1952-1964.

Angioplasty with Sustained Release Drug-Eluting Stent

Issue: Currently, there is not a unique device value to identify a sustained release drug-eluting stent for arteries below the knee (BTK) in ICD-10-PCS. Additionally, there is not a unique body part value for the tibio-peroneal trunk in the Lower Arteries body system.

New Technology Application? No, not at this time.

Food and Drug Administration (FDA) Approval? Food and Drug Administration (FDA) submission for the SAVAL™ Drug-Eluting Vascular Stent System is expected to take place in June 2021, with FDA approval anticipated in December 2021.

Background: Critical Limb Ischemia (CLI) is a progression of peripheral artery disease (PAD), characterized by severe obstruction of arteries (especially in lower limbs) which reduces blood flow to the extremities and places patient tissue viability at risk. CLI patients experience severely debilitating clinical outcomes, including severe pain in the impacted limb even at rest, risk of open ulceration, gangrene and, if not treated properly, amputation of limb, all of which reduces patient mobility and quality of life[1]. In addition, CLI patients experience increased risk of mortality, increasing further for patients undergoing limb amputations. Diabetics with CLI are at particularly high risk for advanced complications; studies indicate that within one year of CLI diagnosis, 40% to 50% of diabetics will experience an amputation[2].

The standard of care for CLI patients has historically utilized one of two methods for revascularization of diseased infra-popliteal vessels: surgical bypass or percutaneous transluminal angioplasty (PTA). While bypass has shown to be a potential avenue for revascularization of BTK arteries and was considered the front-line therapy for CLI patients, the surgery is invasive and technically challenging, especially considering the fragile health state of the affected population. Considering these challenges, this procedure continues to experience significant variability in outcomes, patient healing, and costs[3]. There are important limitations and risks associated with bypass surgery, including significant postoperative morbidity, up to 20%, and frequent wound complications in 10% to 20% of patients. Additionally, new stenosis within the vein graft conduit occurs in 30% to 40% of patients within the first two years.

In recent years, the arrival of endovascular treatment of CLI has been driven by the continued evolution of catheter-based technologies, as well as the benefits of a less invasive approach in treating this fragile population[4]. It is well established that recovery from PTA is significantly faster than open surgery. Patients treated with PTA do not experience common surgical

[1] Kinlay S. Management of critical limb ischemia. *Circ. Cardiovasc. Interv.* 2016;9:2 Article Number: e001946.
[2] Elsayed S, Clavijo LC. Critical limb ischemia. *Cardiol. Clin.* 2015;33(1):37-47.
[3] Conte MS. Critical appraisal of surgical revascularization for critical limb ischemia. *J. Vasc. Surg.* 2013;57(2 Suppl):8S-13S.
[4] Gray BH, Diaz-Sandoval LJ, Dieter RS, Jaff MR, White CJ. SCAI expert consensus statement for infrapopliteal arterial intervention appropriate use. Catheter. Cardiovasc. Interv. 2014;84(4):539-545.

complications associated with bypass, such as wound morbidity. PTA has been shown to have similar outcomes to that of surgical bypass[5, 6].

Standard PTA as a first line treatment of infrapopliteal vessel therapy has three significant limitations in CLI treatment. First is the very high presence of chronic total occlusions in CLI patients. Chronic occlusions, often significantly calcified, are associated with an increased risk of complications, (i.e., distal embolization, dissection, poor response to PTA, and restenosis) which impact success rates negatively for traditional PTA in CLI lesions. The second limitation is restenosis. The common clinical endpoints of freedom from restenosis, reintervention, and amputation after PTA in infrapopliteal lesions has been reported to be as low as 39% at 1 year in CLI patients[7]; these outcomes decrease in long tibial lesions[8]. Third, BTK arteries are prone to recoil (immediate re-narrowing after PTA) without the presence of a scaffold in place making the need for a self-expanding stent like the SAVAL DES Vascular Stent System highly important for vessel patency. The benefits of using paclitaxel eluting nitinol stents, bare metal nitinol stents, and limus-eluting balloon expandable stents has been well-studied in infrapopliteal lesions as evaluated in several meta-analyses[9,10,11,12,13,14,15].

Technology: The SAVAL DES Vascular Stent System is a medical device containing a drug/polymer coating, that provides a mechanical scaffold for vascular lumen support (the stent component) and a pharmacological agent (paclitaxel) targeted towards reducing the injury response that leads to restenosis after stent implantation. Paclitaxel is an antiproliferative drug that induces irreversible polymerization of cell microtubules, thus inhibiting mitosis. It is widely used in antineoplastic chemotherapy of cancers; however, doses required in chemotherapeutic treatment are significantly higher per treatment cycle in cancer patients than in peripheral artery disease patients[16].

---

[5] Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. *Lancet*. 2005;366(9501):1925-1934.

[6] Popplewell MA, Davies HOB, Narayanswami J, et al. A Comparison of Outcomes in Patients with Infrapopliteal Disease Randomised to Vein Bypass or Plain Balloon Angioplasty in the Bypass vs. Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial. Eur. J. Vasc. Endovasc. Surg. 2017;54(2):195-201.

[7] Giles KA, Pomposelli FB, Spence TL, et al. Infrapopliteal angioplasty for critical limb ischemia: relation of TransAtlantic InterSociety Consensus class to outcome in 176 limbs. *J. Vasc. Surg.* 2008;48(1):128-136.

[8] Sadaghianloo N, Jean-Baptiste E, Declemy S, Mousnier A, Brizzi S, Hassen-Khodja R. Percutaneous angioplasty of long tibial occlusions in critical limb ischemia. *Ann. Vasc. Surg.* 2013;27(7):894-903.

[9] Zhang J, Xu X, Kong J, et al. Systematic Review and Meta-Analysis of Drug-Eluting Balloon and Stent for Infrapopliteal Artery Revascularization. Vasc. Endovascular Surg. 2017;51(2):72-83.

[10] Xiao Y, Chen Z, Yang Y, Kou L. Network meta-analysis of balloon angioplasty, nondrug metal stent, drug-eluting balloon, and drug-eluting stent for treatment of infrapopliteal artery occlusive disease. Diagnostic and Interventional Radiology. 2016;22(5):436-443.

[11] Katsanos K, Kitrou P, Spiliopoulos S, Diamantopoulos A, Karnabatidis D. Comparative Effectiveness of Plain Balloon Angioplasty, Bare Metal Stents, Drug-Coated Balloons, and Drug-Eluting Stents for the Treatment of Infrapopliteal Artery Disease: Systematic Review and Bayesian Network Meta-analysis of Randomized Controlled Trials. J. Endovasc. Ther. 2016;23(6):851-863.

[12] Mosquera Arochena NJ. Drug-eluting stents remain the golden standard for below-the-knee occlusive disease. J. Cardiovasc. Surg. (Torino). 2016;57(5):677-682.

[13] Caradu C, Trombert D, Midy D, Ducasse E. The management of below-the-knee arterial critical ischemia: Update, systematic review and meta-analysis. Italian Journal of Vascular and Endovascular Surgery. 2016;23(3):148-159.

[14] Baerlocher MO, Kennedy SA, Rajebi MR, et al. Meta-analysis of drug-eluting balloon angioplasty and drug-eluting stent placement for infrainguinal peripheral arterial disease. J. Vasc. Interv. Radiol. 2015;26(4):459-473.e454.

[15] Liu X, Zheng G, Wen S. Drug-eluting stents versus control therapy in the infrapopliteal disease: A meta-analysis of eight randomized controlled trials and two cohort studies. International Journal of Surgery. 2017;44:166-175.

[16] Ng VG, Mena C, Pietras C, Lansky AJ. Local delivery of paclitaxel in the treatment of peripheral arterial disease. *Eur. J. Clin. Invest.* 2015;45(3):333-345.

Paclitaxel has been shown to inhibit proliferation and migration of smooth muscle cells, effectively suppressing neointimal hyperplasia after vessel injury[17]. The SAVAL DES Vascular Stent System with a drug/polymer formulation provides matrix-controlled drug delivery to the stented vessel segment with an early burst in the first 72 hours post-implant, followed by a controlled slower, sustained release phase that is designed to deliver paclitaxel for 15-18 months when restenosis is most likely to occur in the peripheral vasculature.

The SAVAL DES Vascular Stent System is about to start enrolling in an IDE clinical trial: The SAVAL Pivotal Trial is a Randomized Trial comparing the Drug-Eluting Stent (DES) Below the Knee (BTK) Vascular Stent System vs Percutaneous Transluminal Angioplasty (PTA) Treating Infrapopliteal Lesions in Subjects With Critical Limb Ischemia conducted in the United States, Europe, and Japan at up to 50 investigational centers, with up to 35 centers located in the US. Enrollment is expected to be distributed approximately equally across regions.

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

[17] Dake MD, Van Alstine WG, Zhou Q, Ragheb AO. Polymer-free paclitaxel-coated zilver PTX stents evaluation of pharmacokinetics and comparative safety in porcine arteries. *Journal of Vascular and Interventional Radiology.* 2011;22(5):603-610.

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 **W** Foot Artery, Left **Y** Lower Artery	**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
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	**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

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			

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 popliteal, tibial, and peroneal body part values.

Note: A request to add the anatomical term Tibioperoneal Trunk to the ICD-10-PCS Body Part Key/Definitions and refer to the popliteal artery body part values is included in the proposed addenda of this meeting's agenda.

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*
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 **Y** Lower Artery	**3** Percutaneous	**ADD 3** Intraluminal Device, Sustained Release Drug-eluting **4** Intraluminal Device, Drug-eluting **D** Intraluminal Device **Z** No Device	**Z** No Qualifier

Option 3. In Section X table X27, Dilation of Lower Arteries, create new device values to capture the use of a sustained release drug-eluting stent in dilation procedures, applied to the popliteal, tibial, and peroneal 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 par

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
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	**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. In Section X table X27, Dilation of Lower Arteries, create new device values to capture the use of a sustained release drug-eluting stent in dilation procedures, applied to the popliteal, tibial, and peroneal body part values.

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

T-Cell Depleted Hematopoietic Stem Cells for Transplantation

Issue: There is currently no unique ICD-10-PCS code to identify a stem cell transplant that uses a T-cell depleted graft. T-cell depletion is a technique utilized with cells from unrelated donors or related donors other than human leukocyte antigens (HLA)-identical sibling donors to reduce the incidence of Graft versus Host Disease (GVHD).

New Technology Application? No.

Food and Drug Administration (FDA) Approval? Yes. January 23, 2014.

Background: Allogeneic hematopoietic stem cell (HSC) transplants are used in the treatment of certain blood cancers, such as leukemia, multiple myeloma, and some types of lymphoma. Several sources of allogeneic donors are used for HSC transplantation, including HLA-identical sibling donors, unrelated donors, and other relative donors. According to the Center for International Blood & Marrow Transplant Research (CIBMTR), the number of 'other relatives' has increased to 11% of all allogeneic transplants performed in the United States. The risk of GVHD is increased when cells from unrelated donors or other relative donors are used compared to HLA-identical sibling donors. One method for reducing the risk of GVHD is to use a T-cell depleted graft.

The T-cell depletion procedure occurs following apheresis and prior to the infusion of the cells. There is no separate ICD-10-PCS code to describe a stem cell transplant conducted utilizing a T-cell depleted (TCD) graft. TCD HCT has resulted in improved time to engraftment, reduction in the incidence of GVHD, and lower rates of transplant-related complications. With the exception of chronic myeloid leukemia, TCD is not associated with adverse relapse or survival outcomes compared to conventional GVHD prophylaxis.
According to the applicant, the medical record indicates both the order for T-cell depletion and documentation in the procedure note that the cells were T-cell depleted.

Current Coding: T-cell depleted HSC transplant procedures are coded using the substance value Stem Cells, Hematopoietic in section 3, Administration, table 302 Transfusion, with the appropriate qualifier value specifying the donor source.

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

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for transfusion of T-cell depleted hematopoietic stem cells. Continue using current codes as described in current coding.

Option 2. Create new substance value Stem Cells, T-cell Depleted Hematopoietic in table 302 of section 3, Administration, applied to the qualifier values specifying an Allogeneic donor source.

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	**ADD U** Stem Cells, T-cell Depleted Hematopoietic	**2** Allogeneic, Related **3** Allogeneic, Unrelated **4** Allogeneic, Unspecified

CMS Recommendation: Option 2. Create new substance value Stem Cells, T-cell Depleted Hematopoietic in table 302 of section 3, Administration, applied to the qualifier values specifying an Allogeneic donor source.

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

Fluorescence-guided brain tumor surgery (FGS) using Gleolan™ (ALA, aminolevulinic acid)

Issue: There is currently no unique ICD-10-PCS code to describe the use of Gleolan™ **(**ALA**,** aminolevulinic acid), an optical imaging agent intended for oral administration indicated in patients with glioma, as an adjunct for the visualization of malignant tissue during surgery.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes, on June 6, 2017, Gleolan™ was approved as an optical imaging agent indicated in patients with glioma (suspected World Health Organization (WHO) Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery.

Background: Glioma is a rare disease affecting fewer than 50,000 people annually in the United States, with survival ranging from 24 weeks to 1 year. Gliomas are the most common type of brain tumor, typically impacting individuals between the ages of 40 and 85, and accounting for approximately 78% of malignant brain tumors. The WHO categorizes brain tumors using grades I through IV, ranging from the least advanced disease (Grade I) to the worst prognosis (Grade IV). Patients with Grades III or IV gliomas have a poor prognosis, and surgery is the most common treatment and typically the first line of treatment. The applicant stated that using standard microsurgical techniques and operating room white light, it is difficult to obtain discernable tumor margins to achieve complete resection.

Currently, the brain tumor and margin are assessed prior to surgery using CT and MRI, with and without contrast agents. The applicant explained that due to brain shift that occurs during the surgery, these images are of limited use. In addition, small tumors may be missed or shifted during surgery, making other techniques such as intraoperative MRI and neurosurgical mapping less effective. Finally, malignant glioma cells are often found beyond the area of the margins signaled on the MRI. As a result of these limitations presented by current imaging techniques, the applicant stated that there is an unmet need for a safe and effective tool that provides neurosurgeons with directly visible, highly accurate predictive correlation of the fluorescent tissue with confirmed malignant histopathology, unambiguous information about the location and extent of the tumor in real time, with a high resolution to enable microsurgery of confirmed malignant tissue while differentiating from normal brain tissue.

Gleolan™ is provided as a lyophilized powdered form in 50mL glass vials that is reconstituted for oral ingestion prior to administration between 2 and 4 hours prior to surgery. The active substance in Gleolan™, aminolevulinic acid, is a naturally occurring amino acid, which when taken orally, is converted by the body into protoporphyrin IX (PPIX). PPIX has a unique fluorescence profile and is well tolerated as a natural endogenous metabolite. When illuminated under blue light with ancillary excitation and emission filters to visualize fluorescence excitation in the wavelength of 375 to 440 nm and for observation from 620 to 710 nm, the PPIX in the tumor glows an intense red, while the normal brain tissue appears blue. This enables the neurosurgeon to see the red-violet glow of malignant glioma tissue more clearly during surgery and helps to facilitate resection of the glioma while sparing normal tissue.

Current Coding: Do not code fluorescence guided surgery separately in ICD-10-PCS. The oral administration of Gleolan™ (aminolevulinic acid) can be reported using the following ICD-10-PCS code:

3E0DXKZ Introduction of Other Diagnostic Substance into Mouth and Pharynx, External Approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes. Continue to code fluorescence-guided brain tumor Surgery (FGS) using Gleolan™ as listed in Current Coding.

Option 2. In section 8, Other Procedures, create new method value Fluorescence Guided Procedure, applied to all fourth character body region values and applicable approaches. These changes will enable capture of additional detail where a fluorescing substance is used as guidance during the procedure.

Section	**8** Other Procedures
Body System	**E** Physiological Systems and Anatomical Regions
Operation	**0** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease

Body Region	*Approach*	*Method*	*Qualifier*
9 Head and Neck Region **W** Trunk Region	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**C** Robotic Assisted Procedure **ADD E** Fluorescence Guided Procedure	**Z** No Qualifier
9 Head and Neck Region **W** Trunk Region	**X** External	**B** Computer Assisted Procedure	**F** With Fluoroscopy **G** With Computerized Tomography **H** With Magnetic Resonance Imaging **Z** No Qualifier
X Upper Extremity **Y** Lower Extremity	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Robotic Assisted Procedure **ADD E** Fluorescence Guided Procedure	**Z** No Qualifier
X Upper Extremity **Y** Lower Extremity	**X** External	**B** Computer Assisted Procedure	**F** With Fluoroscopy **G** With Computerized Tomography **H** With Magnetic Resonance Imaging **Z** No Qualifier

In addition, create new codes in table 3E0 of Section 3, Administration, to identify oral administration of aminolevulinic acid (ALA).

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	**K** Other Diagnostic Substance	**ADD** Aminolevulinic Acid **Z** No Qualifier

Option 3. In section 8, Other Procedures, create new method value Fluorescence Guided Procedure and new qualifier value Aminolevulinic Acid, applied to all fourth character body region values and applicable approaches. These changes will enable capture of additional detail for fluorescence-guided procedures that use aminolevulinic acid.

Section	**8** Other Procedures		
Body System	**E** Physiological Systems and Anatomical Regions		
Operation	**0** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Region	*Approach*	*Method*	*Qualifier*
9 Head and Neck Region **W** Trunk Region	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**C** Robotic Assisted Procedure	**Z** No Qualifier
9 Head and Neck Region **W** Trunk Region	**X** External	**B** Computer Assisted Procedure	**F** With Fluoroscopy **G** With Computerized Tomography **H** With Magnetic Resonance Imaging **Z** No Qualifier
9 Head and Neck Region **W** Trunk Region	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**ADD E** Fluorescence Guided Procedure	**ADD M** Aminolevulinic Acid **Z** No Qualifier
X Upper Extremity **Y** Lower Extremity	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Robotic Assisted Procedure	**Z** No Qualifier
X Upper Extremity **Y** Lower Extremity	**X** External	**B** Computer Assisted Procedure	**F** With Fluoroscopy **G** With Computerized Tomography **H** With Magnetic Resonance Imaging **Z** No Qualifier
X Upper Extremity **Y** Lower Extremity	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD E** Fluorescence Guided Procedure	**ADD M** Aminolevulinic Acid **Z** No Qualifier

CMS Recommendation: Option 3. In section 8, Other Procedures, create new method value Fluorescence Guided Procedure and new qualifier value Aminolevulinic Acid, applied to all fourth character body region values and applicable approaches. These changes will enable capture of additional detail for fluorescence-guided procedures that use aminolevulinic acid.

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

ICD-10-PCS Index Addenda

Lttr A
Main Revise from Ablation see Destruction
Revise to Ablation
Add see Control bleeding in
Add see Destruction
Main Add Antibacterial Envelope (TYRX) (AIGISRx) use Anti-Infective Envelope

Lttr B
Main Revise from Block, Nerve, anesthetic injection 3E0T3CZ
Revise to Block, Nerve, anesthetic injection 3E0T3BZ

Lttr D
Main Add Dismembered pyeloplasty see Repair, Kidney Pelvis

Lttr P
Main Panniculectomy
Delete see Excision, Abdominal Wall 0WBF
Add see Excision, Subcutaneous Tissue and Fascia, Abdomen 0JB8
Main Add Pyeloplasty, dismembered see Repair, Kidney Pelvis

Lttr R
Main Delete Reveal (DX)(XT) use Monitoring Device
Main Add Reveal (LINQ)(DX)(XT) use Monitoring Device

Lttr T
Main Add Tibioperoneal trunk
Add use Popliteal Artery, Right
Add use Popliteal Artery, Left
Main Add TYRX Antibacterial Envelope use Anti-Infective Envelope

ICD-10-PCS Body Part Key Addenda

Section 0 Medical and Surgical
Axis 4 Body Part
Term Popliteal Artery, Left
Term Popliteal Artery, Right
Includes Add Tibioperoneal trunk

ICD-10-PCS Device Key Addenda

Axis 6	Device	
Term	Monitoring Device	
Includes	Delete	Reveal (DX)(XT)
Includes	Add	Reveal (LINQ)(DX)(XT)

ICD-10-PCS Substance Key Addenda

Section 3	Administration	
Axis 6	Substance	
Term	Anti-Infective Envelope	
Includes	Add	Antibacterial Envelope (TYRX) (AIGISRx)
Includes	Add	TYRX Antibacterial Envelope

ICD-10-PCS Table Addenda

Medical and Surgical Section
Axis 4 Body Part

Intestinal Bypass

Source	Description	Code specification
2018, public comment & CMS internal review	In the Gastrointestinal body system of the Medical and Surgical section, add general body part values 8 Small Intestine and E Large Intestine to Bypass table 0D1, with applicable qualifier values including new general qualifier Small Intestine and new general qualifier Large Intestine, to enable accurate data for bypass procedures where the physician cannot determine the specific anatomical site on the intestine, such as colostomy in patient with previous colon resection.	0D18[048][7JKZ][48HKLMNPQ] (108 codes) 0D1E[048][7JKZ][4EP] (36 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
ADD 8 Small Intestine	**0** Open **4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**4** Cutaneous **ADD 8** Small Intestine **H** Cecum **K** Ascending Colon **L** Transverse Colon **M** Descending Colon **N** Sigmoid Colon **P** Rectum **Q** Anus
ADD E Large Intestine	**0** Open **4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**4** Cutaneous **ADD E** Large Intestine **P** Rectum

Extraction of breast tissue

Source	Description	Code specification
2018, public comment & CMS internal review	In the Skin and Breast body system of the Medical and Surgical section, add the breast body part values and the approach value Open, to enable accurate data for non-excisional debridement of breast tissue, beneath the level of the skin.	0HD[TUVY]0ZZ (4 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
ADD T Breast, Right **ADD U** Breast, Left **ADD V** Breast, Bilateral **ADD Y** Supernumerary Breast	**ADD 0** Open	**Z** No Device	**Z** No Qualifier

Medical and Surgical Section
Axis 5 Approach

Transorifice Occlusion of Gastric Varices

Source	Description	Code specification
2018, public comment & CMS internal review	In the Lower Veins body system of the Medical and Surgical section, add the transorifice approach values 7 Via Natural or Artificial Opening and 8 Via Natural or Artificial Opening Endoscopic to Occlusion table 06L, for the body part value Gastric Vein. This change enables accurate data for transorifice and transorifice endoscopic procedures where occlusion of the gastric vein is performed, such as EGD with ligation of gastric varices. This change is consistent with previous changes made to table for the body part value Esophageal Vein.	06L2[78][CDZ]Z (6 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**6** Lower Veins
Operation	**L** Occlusion: Completely closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
ADD 2 Gastric Vein **3** Esophageal Vein	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**Z** No Qualifier

Breast Procedures and External Approach

Source	Description	Code specification
2017, public comment & CMS internal review	In the Skin and Breast body system of the Medical and Surgical section, delete the approach value X External Approach for the breast body part values, for all root operations except the root operations 2 Change and M Reattachment. This change facilitates a clear distinction in the classification, between procedures on the breast and procedures on the skin of the chest. All procedures performed on the skin of the breast will be classified to the body part value 5 Skin, Chest, and will use the External approach.	Delete: 0H^[TUVY]X^^ (83 codes)

EXAMPLES

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Skin, Scalp **1** Skin, Face **2** Skin, Right Ear **3** Skin, Left Ear **4** Skin, Neck **5** Skin, Chest **6** Skin, Back **7** Skin, Abdomen **8** Skin, Buttock **9** Skin, Perineum **A** Skin, Inguinal **B** Skin, Right Upper Arm **C** Skin, Left Upper Arm **D** Skin, Right Lower Arm **E** Skin, Left Lower Arm **F** Skin, Right Hand **G** Skin, Left Hand **H** Skin, Right Upper Leg **J** Skin, Left Upper Leg **K** Skin, Right Lower Leg **L** Skin, Left Lower Leg **M** Skin, Right Foot **N** Skin, Left Foot **Q** Finger Nail **R** Toe Nail	**X** External	**Z** No Device	**X** Diagnostic **Z** No Qualifier
T Breast, Right **U** Breast, Left **V** Breast, Bilateral **Y** Supernumerary Breast	**0** Open **3** Percutaneous **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic **DELETE X** External	**Z** No Device	**X** Diagnostic **Z** No Qualifier
W Nipple, Right **X** Nipple, Left	**0** Open **3** Percutaneous **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic **X** External	**Z** No Device	**X** Diagnostic **Z** No Qualifier

Section **0** Medical and Surgical
Body System **H** Skin and Breast
Operation **Q** Repair: Restoring, to the extent possible, a body part to its normal anatomic structure and function

Body Part	*Approach*	*Device*	*Qualifier*
0 Skin, Scalp **1** Skin, Face **2** Skin, Right Ear **3** Skin, Left Ear **4** Skin, Neck **5** Skin, Chest **6** Skin, Back **7** Skin, Abdomen **8** Skin, Buttock **9** Skin, Perineum **A** Skin, Inguinal **B** Skin, Right Upper Arm **C** Skin, Left Upper Arm **D** Skin, Right Lower Arm **E** Skin, Left Lower Arm **F** Skin, Right Hand **G** Skin, Left Hand **H** Skin, Right Upper Leg **J** Skin, Left Upper Leg **K** Skin, Right Lower Leg **L** Skin, Left Lower Leg **M** Skin, Right Foot **N** Skin, Left Foot **Q** Finger Nail **R** Toe Nail	**X** External	**Z** No Device	**Z** No Qualifier
T Breast, Right **U** Breast, Left **V** Breast, Bilateral **Y** Supernumerary Breast	**0** Open **3** Percutaneous **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic **DELETE X** External	**Z** No Device	**Z** No Qualifier
W Nipple, Right **X** Nipple, Left	**0** Open **3** Percutaneous **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic **X** External	**Z** No Device	**Z** No Qualifier

Medical and Surgical Section
Axis 7 Qualifier

Possible Qualifier Detail for root operation Revision

Source	Description	Code specification
CMS internal	**Note**: This topic is a preliminary proposal. CMS wishes to solicit public comment and suggestions for a possible proposal on this topic. In the Medical and Surgical section, add new qualifier values to Revision tables 0^W that specify that an additional substance or device was used to perform the Revision procedure. Revision is defined as, "Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device." **Option 1**—Example of general qualifier values **0** Additional Substance **1** Additional Device **Option 2**—Example of more detailed qualifier values **0** Additional Substance **1** Additional Device, Intraluminal **2** Additional Device, Extraluminal **3** Additional Device, Autologous Tissue Substitute **4** Additional Device, Nonautologous Tissue Substitute **5** Additional Device, Synthetic Substitute	N/A The options and examples are for public comment and suggestions.

EXAMPLE Option 1

Section **0** Medical and Surgical *Body System* **2** Heart and Great Vessels *Operation* **W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device			
Body Part	*Approach*	*Device*	*Qualifier*
5 Atrial Septum **M** Ventricular Septum	**0** Open **4** Percutaneous Endoscopic	**J** Synthetic Substitute	**Z** No Qualifier
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue **C** Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Cardiac Lead **N** Intracardiac Pacemaker **Q** Implantable Heart Assist System **Y** Other Device	**ADD 0** Additional Substance **ADD 1** Additional Device **Z** No Qualifier
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**R** Short-term External Heart Assist System	**S** Biventricular **Z** No Qualifier
A Heart	**X** External	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue **C** Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Cardiac Lead **N** Intracardiac Pacemaker **Q** Implantable Heart Assist System	**ADD 0** Additional Substance **ADD 1** Additional Device **Z** No Qualifier
A Heart	**X** External	**R** Short-term External Heart Assist System	**S** Biventricular **Z** No Qualifier
F Aortic Valve **G** Mitral Valve **H** Pulmonary Valve **J** Tricuspid Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**ADD 0** Additional Substance **ADD 1** Additional Device **Z** No Qualifier
Y Great Vessel	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue **C** Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Y** Other Device	**ADD 0** Additional Substance **ADD 1** Additional Device **Z** No Qualifier
Y Great Vessel	**X** External	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue **C** Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**ADD 0** Additional Substance **ADD 1** Additional Device **Z** No Qualifier

EXAMPLE Option 2

Section **0** Medical and Surgical
Body System **2** Heart and Great Vessels
Operation **W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	*Approach*	*Device*	*Qualifier*
5 Atrial Septum **M** Ventricular Septum	**0** Open **4** Percutaneous Endoscopic	**J** Synthetic Substitute	**ADD 0** Additional Substance **ADD 1** Additional Device, Intraluminal **ADD 2** Additional Device, Extraluminal **ADD 3** Additional Device, Autologous Tissue Substitute **ADD 4** Additional Device, Nonautologous Tissue Substitute **ADD 5** Additional Device, Synthetic Substitute **Z** No Qualifier
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue **C** Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Cardiac Lead **N** Intracardiac Pacemaker **Q** Implantable Heart Assist System **Y** Other Device	**ADD 0** Additional Substance **ADD 1** Additional Device, Intraluminal **ADD 2** Additional Device, Extraluminal **ADD 3** Additional Device, Autologous Tissue Substitute **ADD 4** Additional Device, Nonautologous Tissue Substitute **ADD 5** Additional Device, Synthetic Substitute **Z** No Qualifier
A Heart	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**R** Short-term External Heart Assist System	**S** Biventricular **Z** No Qualifier
A Heart	**X** External	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue **C** Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Cardiac Lead **N** Intracardiac Pacemaker **Q** Implantable Heart Assist System	**ADD 0** Additional Substance **ADD 1** Additional Device, Intraluminal **ADD 2** Additional Device, Extraluminal **ADD 3** Additional Device, Autologous Tissue Substitute **ADD 4** Additional Device, Nonautologous Tissue Substitute **ADD 5** Additional Device, Synthetic Substitute **Z** No Qualifier
A Heart	**X** External	**R** Short-term External Heart Assist System	**S** Biventricular **Z** No Qualifier
F Aortic Valve **G** Mitral Valve **H** Pulmonary Valve **J** Tricuspid Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**ADD 0** Additional Substance **ADD 1** Additional Device, Intraluminal **ADD 2** Additional Device, Extraluminal **ADD 3** Additional Device, Autologous Tissue Substitute **ADD 4** Additional Device, Nonautologous Tissue Substitute **ADD 5** Additional Device, Synthetic Substitute **Z** No Qualifier
Y Great Vessel	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue	**ADD 0** Additional Substance **ADD 1** Additional Device, Intraluminal **ADD 2** Additional Device, Extraluminal

		C Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Y** Other Device	**ADD 3** Additional Device, Autologous Tissue Substitute **ADD 4** Additional Device, Nonautologous Tissue Substitute **ADD 5** Additional Device, Synthetic Substitute **Z** No Qualifier
Y Great Vessel	**X** External	**2** Monitoring Device **3** Infusion Device **7** Autologous Tissue Substitute **8** Zooplastic Tissue **C** Extraluminal Device **D** Intraluminal Device **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**ADD 0** Additional Substance **ADD 1** Additional Device, Intraluminal **ADD 2** Additional Device, Extraluminal **ADD 3** Additional Device, Autologous Tissue Substitute **ADD 4** Additional Device, Nonautologous Tissue Substitute **ADD 5** Additional Device, Synthetic Substitute **Z** No Qualifier

Upper Artery Bypass Qualifier

Source	Description	Code specification
2017, Coding Clinic Editorial Advisory Board & CMS internal review	In the Upper Arteries body system of the Medical and Surgical section, add new qualifier value Lower Extremity Vein to the root operation Bypass table 031 for the upper extremity artery body part values. This change enables capture of detail for arteriovenous bypass (fistula) from an upper extremity to a lower extremity vein such as the femoral vein.	031^0[9AJKZ]W (55 codes)

EXAMPLE

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*
2 Innominate Artery	**0** Open	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**0** Upper Arm Artery, Right **1** Upper Arm Artery, Left **2** Upper Arm Artery, Bilateral **3** Lower Arm Artery, Right **4** Lower Arm Artery, Left **5** Lower Arm Artery, Bilateral **6** Upper Leg Artery, Right **7** Upper Leg Artery, Left **8** Upper Leg Artery, Bilateral **9** Lower Leg Artery, Right **B** Lower Leg Artery, Left **C** Lower Leg Artery, Bilateral **D** Upper Arm Vein **F** Lower Arm Vein **J** Extracranial Artery, Right **K** Extracranial Artery, Left **ADD W** Lower Extremity Vein
3 Subclavian Artery, Right **4** Subclavian Artery, Left	**0** Open	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue	**0** Upper Arm Artery, Right **1** Upper Arm Artery, Left

		J Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**2** Upper Arm Artery, Bilateral **3** Lower Arm Artery, Right **4** Lower Arm Artery, Left **5** Lower Arm Artery, Bilateral **6** Upper Leg Artery, Right **7** Upper Leg Artery, Left **8** Upper Leg Artery, Bilateral **9** Lower Leg Artery, Right **B** Lower Leg Artery, Left **C** Lower Leg Artery, Bilateral **D** Upper Arm Vein **F** Lower Arm Vein **J** Extracranial Artery, Right **K** Extracranial Artery, Left **M** Pulmonary Artery, Right **N** Pulmonary Artery, Left **ADD W** Lower Extremity Vein
5 Axillary Artery, Right **6** Axillary Artery, Left	**0** Open	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**0** Upper Arm Artery, Right **1** Upper Arm Artery, Left **2** Upper Arm Artery, Bilateral **3** Lower Arm Artery, Right **4** Lower Arm Artery, Left **5** Lower Arm Artery, Bilateral **6** Upper Leg Artery, Right **7** Upper Leg Artery, Left **8** Upper Leg Artery, Bilateral **9** Lower Leg Artery, Right **B** Lower Leg Artery, Left **C** Lower Leg Artery, Bilateral **D** Upper Arm Vein **F** Lower Arm Vein **J** Extracranial Artery, Right **K** Extracranial Artery, Left **T** Abdominal Artery **V** Superior Vena Cava **ADD W** Lower Extremity Vein
7 Brachial Artery, Right	**0** Open	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**0** Upper Arm Artery, Right **3** Lower Arm Artery, Right **D** Upper Arm Vein **F** Lower Arm Vein **V** Superior Vena Cava **ADD W** Lower Extremity Vein
8 Brachial Artery, Left	**0** Open	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**1** Upper Arm Artery, Left **4** Lower Arm Artery, Left **D** Upper Arm Vein **F** Lower Arm Vein **V** Superior Vena Cava **ADD W** Lower Extremity Vein
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 **ADD W** Lower Extremity 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 **ADD W** Lower Extremity Vein

Bifurcation Qualifier

Source	Description	Code specification
2018, Coding Clinic Editorial Advisory Board & CMS internal review	In the peripheral artery body systems Upper Arteries and Lower Arteries of the Medical and Surgical section, delete the qualifier value Bifurcation from all tables—037 Dilation of Upper Arteries, 04C, Extirpation of Upper Arteries, 047 Dilation of Lower Arteries, 04C Extirpation of Lower Arteries, and 04V Restriction of Lower Arteries. The original proposal for the qualifier Bifurcation was intended to capture data regarding procedures on the coronary arteries. Keep the qualifier Bifurcation as is for the PCS tables in the body system Heart and Great Vessels.	037^[034][4567DEFGZ]6 (810 codes) 03C^[034]Z6 (90 codes) 047^[034][4567DEFGZ]6 (837 codes) 04C^[034]Z6 (93 codes) 04V0[034][CDEFZ]6 (15 codes)

EXAMPLE

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

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

Cerebral Ventricle Bypass Qualifier

Source	Description	Code specification
2018, Coding Clinic Editorial Advisory Board & CMS internal review	In the Central Nervous System and Cranial Nerves body system of the Medical and Surgical section, add new qualifier value Subgaleal Space to the root operation Bypass table 001 for the Cerebral Ventricle body part value. This change enables capture of detail for procedures from the cerebral ventricle to the subgaleal space, such as subgaleal shunt placement.	0016[034][7JK]A (9 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
6 Cerebral Ventricle	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**0** Nasopharynx **1** Mastoid Sinus **2** Atrium **3** Blood Vessel **4** Pleural Cavity **5** Intestine **6** Peritoneal Cavity **7** Urinary Tract **8** Bone Marrow **ADD A** Subgaleal Space **B** Cerebral Cisterns

Section 3 Administration
Axis 4 Anatomical Region

Epidural Space

Source	Description	Code specification
2018, public & CMS internal review	In the Administration section, revise the axis 4 body system/region value from Epidural Space to Epidural Space, Intracranial. This change clarifies code assignment for procedures on the intracranial epidural space versus the spinal epidural space (assigned to anatomical region value Spinal Canal), and increases consistency between the Administration section and the Medical and Surgical section.	3E[01]S^^^ (20 codes)

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*
REVISE from S Epidural Space **REVISE to S** Epidural Space, Intracranial	**3** Percutaneous	**0** Antineoplastic	**2** High-dose Interleukin-2 **3** Low-dose Interleukin-2 **4** Liquid Brachytherapy Radioisotope **5** Other Antineoplastic **M** Monoclonal Antibody

Section 3 Administration
Axis 5 Approach

Arthroscopic Irrigation of Joints

Source	Description	Code specification
2018, public & CMS internal review	In the Administration section, add the approach value 4 Percutaneous Endoscopic to Irrigation table 3E1, for the axis 4 body system/region value Joints. This change enables accurate data for procedures where arthroscopic irrigation of a joint is the definitive procedure performed.	3E1U48[XZ] (2 codes)

EXAMPLE

Section	**3** Administration
Body System	**E** Physiological Systems and Anatomical Regions
Operation	**1** Irrigation: Putting in or on a cleansing substance

Body System / Region	*Approach*	*Substance*	*Qualifier*
U Joints	**3** Percutaneous **ADD 4** Percutaneous Endoscopic	**8** Irrigating Substance	**X** Diagnostic **Z** No Qualifier

Section 4 Measurement and Monitoring
Axis 6 Function

External Monitoring of Renal Function

Source	Description	Code specification
2018, public & CMS internal review	In Monitoring table 4A1, new qualifier value Other Fluorescent Substance, applied to the axis 4 physiological system value Urinary, axis 6 function value Rate, and 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. One application of this technology (in clinical trials) uses Fluorescent Pyrazine as the tracer agent. Alternatively, create a new code in section X to capture the use of Fluorescent Pyrazine for noninvasive monitoring of renal function.	4A1DXCJ (one code) OR XT25XE5 (one code)

EXAMPLE

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

EXAMPLE, ALTERNATIVE PROPOSAL

Section **X** New Technology
Body System **T** Urinary System
Operation **2** 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

New Technology Section
Axis 6 Device/Substance/Technology

Andexanet Alfa name revised

Source	Description	Code specification
2018, public & CMS internal review	In the New Technology section, revise the axis 6 device/substance/technology value from Andexanet Alfa to Coagulation Factor Xa, Inactivated. This change request is from the manufacturer and reflects the final generic name of the drug. In addition, the manufacturer Portola requests the addition of the brand name Andexxa to the Substance Key.	XW0[34]372 (2 codes)

EXAMPLE

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

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

Section X New Technology

Axis 6 Device / Substance / Technology
Term Delete Andexanet Alfa, Factor Xa Inhibitor Reversal Agent
Includes Delete Factor Xa Inhibitor Reversal Agent, Andexanet Alfa

Term Add Coagulation Factor Xa, Inactivated
Includes Add Andexxa
Includes Add Coagulation Factor Xa, (Recombinant) Inactivated