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

CENTER FOR MEDICARE

Agenda

ICD-10 Coordination and Maintenance Committee Meeting
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 10, 2019

Webcast and Dial-In Information for Listen-only Participants

- Day 1: September 10, 2019: The meeting will begin promptly at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 12:30 PM to 1:30 PM. The meeting will be webcast via CMS at http://www.cms.gov/live/.
- Day 2: September 11, 2019: The meeting will begin promptly at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 12:30 PM to 1:30 PM. The meeting will be webcast via CMS at http://www.cms.gov/live/.
- Toll-free dial-in access is available for listen-only participants who cannot attend in-person:
  Day 1-September 10, 2019: Phone: 1-877-267-1577; Meeting ID: 995 481 510.
  Day 2-September 11, 2019: Phone: 1-877-267-1577; Meeting ID: 995 481 510.
  We encourage you to join early, as the number of phone lines are limited.

In-Person Attendance

- Day 1: September 10, 2019: The meeting is being held in the CMS Auditorium. The meeting time is listed above. By your attendance, you are giving consent to the use and distribution of your name, likeness and voice during the meeting. You are also giving consent to the use and distribution of any personally identifiable information that you or others may disclose about you during the meeting. Please do not disclose personal health information.

- Day 2: September 11, 2019: The meeting is being held in the CMS Auditorium. The meeting time is listed above. By your attendance, you are giving consent to the use and distribution of your name, likeness and voice during the meeting. You are also giving consent to the use and distribution of any personally identifiable information that you or others may disclose about you during the meeting. Please do not disclose personal health information.

Note: Proposals for diagnosis code topics are scheduled for September 11, 2019 and will be led by the Centers for Disease Control (CDC). Please visit CDCs website for the Diagnosis agenda located at the following address: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm

In person attendees and those participating via the phone lines may ask questions, as time permits. Remaining questions may be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov.

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

Updated Security Information for In-person Attendees:

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

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

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

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

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

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

ICD-10-PCS Topics:

1. Intraoperative Near-Infrared Fluorescence Imaging of the Hepatobiliary System Using ICG Pages 13-15	Mady Hue Brian R. Smith, M.D., FACS Associate Professor of Surgery & General Surgery Residency Program Director University of California, Irvine School of Medicine
2. Near Infrared Spectroscopy for Tissue Viability Assessment Pages 16-19	Paula Dupee Dr. Glyn Jones, MD FACS Professor of Plastic Surgery University of Illinois College of Medicine (UICOM)
3. Cesium-131 Brachytherapy Pages 20-24	Andrea Hazeley William Cavanagh Chief Research and Development Officer Isoray
4. Intravascular Ultrasound Assisted Thrombolysis Pages 25-29	Andrea Hazeley Dr. Nicolas J. Mouawad Vascular and Endovascular Surgeon, Consultant Biocompatibles Inc., a BTG International Group Company
5. Administration of Nerinitide Pages 30-31	Paula Dupee Jeffrey L Saver, MD Neurologist UCLA Medical Center
6. Administration of Eladocagene Exuparvovec Pages 32-35	Noel Manlove Brian Pfister, PhD Executive Director MSL Lead
7. Administration of Zulresso Pages 36-38	Michelle Joshua Jeremy Lutz Senior Director Commercial Operations & Analytics Sage Therapeutics, Inc.
8. Section X Updates Pages 39-43	Mady Hue

9. Addenda and Key Updates — Rhonda Butler, 3M
   Pages 44-47

10. ICD-10-PCS Structure and Principles of Maintenance — Rhonda Butler, 3M
    Pages 48-56

Registering for the meeting:
Registration for the September 10-11, 2019 ICD-10 Coordination and Maintenance Committee meeting opened on Friday, August 5, 2019 and closed on Tuesday, September 3, 2019.
Participants attending by Livestream webcast or dialing in you did not need to register online.

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

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

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

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

Contact Information

Comments on the procedure code proposals presented at the ICD-10 Coordination and Maintenance Committee meeting should be sent to the following email address: ICDProcedureCodeRequest@cms.hhs.gov

Mady Hue
(410) 786-4510
Marilu.hue@cms.hhs.gov

Noel Manlove
(410) 786-5161
Noel.manlove@cms.hhs.gov

Paula Dupee
(410) 786-0285
Paula.dupee@cms.hhs.gov

Andrea Hazeley
(410) 786-3543
Andrea.hazeley@cms.hhs.gov

Michelle Joshua
(410) 786-6050
Michelle.joshua@cms.hhs.gov

ICD-10 TIMELINE ONLY

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

September 10-11, 2019	ICD-10 Coordination and Maintenance Committee Meeting. Those who wish to attend the ICD-10 Coordination and Maintenance Committee meeting **must have registered for the meeting online by September 2, 2019.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building. 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, Maryland CMS buildings, as well as the Humphrey Building in Washington.
September 2019	Webcast of the September 10-11, 2019 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
October 1, 2019	**New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with DRG changes. Final addendum available on web pages as follows:** **Diagnosis addendum –** https://www.cdc.gov/nchs/icd/icd10cm.htm **Procedure addendum –** https://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: https://www.cdc.gov/nchs/icd/icd10cm.htm https://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.**
December 6, 2019	**Deadline for requestors: Those members of the public requesting that topics be discussed at the March 17-18, 2020 ICD-10 Coordination and Maintenance Committee meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses by this date.**
February 2020	Tentative agenda for the Procedure part of the March 17, 2020 ICD-10 Coordination and Maintenance Committee meeting posted on CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis part of the March 18, 2020 ICD-10 Coordination and Maintenance Committee meeting posted on NCHS homepage as follows: https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm Federal Register notice of March 17-18, 2020 ICD-10 Coordination and Maintenance Committee Meeting will be published.
February 7, 2020	**On-line registration opens for the March 17-18, 2020 ICD-10 Coordination and Maintenance Committee meeting at:** https://www.cms.gov/apps/events/default.asp
March 6, 2020	Because of increased security requirements, **those wishing to attend the March 17-18, 2020** 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 March 6, 2020; failure to do so may result in lack of access to the meeting**.
March 17-18, 2020	ICD-10 Coordination and Maintenance Committee Meeting.

March 2020	Webcast of the March 17-18, 2020 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
April 1, 2020	Any new ICD-10 codes to capture new diseases or technology will be implemented on April 1, 2020.
April 17, 2020	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 17-18, 2020 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2020**.
April 2020	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 2021 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: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS/list.asp
June 2020	Final addendum posted on web pages as follows: Diagnosis addendum - https://www.cdc.gov/nchs/icd/icd10cm.htm Procedure addendum - https://www.cms.gov/Medicare/Coding/ICD10/index.html
June 12, 2020	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 2020 ICD-10 Coordination and Maintenance Committee meeting, tentatively scheduled for September 8-9, 2020, must have their requests submitted to CMS for procedures and NCHS for diagnoses.**
August 1, 2020	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, 2020. This rule can be accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html

August 2020	Tentative agenda for the Procedure part of the September 2020 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage at – https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis part of the September 8-9, 2020 ICD-10 Coordination and Maintenance Committee meeting will be posted on the NCHS webpage at - https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm Federal Register notice for the September 2020 ICD-10 Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.
August 3, 2020	**On-line registration opens for the September 2020 ICD-10 Coordination and Maintenance Committee meeting at:** https://www.cms.gov/apps/events/default.asp
September 4, 2020	Because of increased security requirements, those wishing to attend the September 2020 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 4, 2020; failure to do so may result in lack of access to the meeting.**
September 8-9, 2020	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 4, 2020.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building.
September 2020	Webcast of the September 8-9, 2020 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
October 1, 2020	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 – https://www.cdc.gov/nchs/icd/icd10cm.htm **Procedure addendum –** https://www.cms.gov/Medicare/Coding/ICD10/
October 9, 2020	**Deadline for receipt of public comments on proposed new codes discussed at the September 8-9, 2020 ICD-10 Coordination and Maintenance Committee meetings for implementation on April 1, 2021.**
November 2020	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, 2021 will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/
November 9, 2020	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 8-9, 2020 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2021.**

Introductions and Overview

- ICD-10 Coordination & Maintenance (C&M) Committee meeting 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 considered for implementation on October 1, 2020
- 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 8, 2019 for codes discussed at the September 10-11, 2019 C&M meeting
- Procedure comments to CMS ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to NCHS nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2019 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2019 C&M meeting
- August 16, 2019 – Final rule with links to final codes to be implemented on October 1, 2019
  - Includes any additional codes approved from March 5-6, 2019 C&M meeting
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page.html

Addendum

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

Public Participation

- For this meeting, the public may participate in the following ways:
  - Attend meeting in person
  - Listen to proceedings through free conference lines
  - View through livestream webcast via http://www.cms.gov/live/
- CMS & CDC hope this provides greater opportunity for public participation

Written Comments

- No matter how you participate – please send written comments by
  - November 8, 2019 for codes to be implemented on October 1, 2020
  - Procedure comments to CMS ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis comments to NCHS nchsicd10cm@cdc.gov

ICD-10-PCS Codes Implementation

- ICD-10-PCS codes discussed today under consideration for October 1, 2020 implementation

March 17-18, 2020 C&M Code Requests

- December 6, 2019– Deadline for submitting topics for March 17-18, 2020 C&M meeting
  - Procedure requests to CMS ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis requests to NCHS nchsicd10cm@cdc.gov

Intraoperative Near-Infrared Fluorescence Imaging of Hepatobiliary System Using Indocyanine Green Dye

Issue: Currently there are no unique ICD-10-PCS codes to describe intraoperative near-infrared fluorescence imaging of the hepatobiliary system using indocyanine green (ICG) dye.

New Technology Application? No.

FDA Approval: The PINPOINT Endoscopic Fluorescence Imaging System is indicated for use with SPY AGENT™ GREEN and is a device and drug combination product that is FDA 510(k)-cleared and used with the intravenous administration of SPY AGENT GREEN, an ICG dye, to perform real time endoscopic visible and intraoperative fluorescence angiography, fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography.

The PINPOINT System enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct) using near-infrared imaging.

Fluorescence imaging of biliary ducts with the PINPOINT System is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Background: A laparoscopic cholecystectomy is a minimally invasive surgical procedure that removes diseased portions of the gallbladder. [1] It is estimated that over 500,000 minimally invasive cholecystectomies are performed annually in the United States for gallbladder disease.[2] Gallbladder disease may result from cholecystitis, gallstone pancreatitis and gall bladder masses/polyps, among other conditions.[3] More than 20 million Americans have gallstones.[4] The risk of developing gallstones increases annually with age, and females have a higher risk of gallstone formation than males.[3,4] Twenty-five percent of women over the age of 60 will develop gallstones.[4]

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[1] Hassler KR, Jones MW. Laparoscopic Cholecystectomy. [Updated 2019 Mar 22]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2019 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448145/

[2] McClusky D. Laparoscopic Cholecystectomy. SAGES. Accessed on May 10, 2019 at https://www.sages.org/wiki/laparoscopic-cholecystectomy/

[3] Hassler KR, Jones MW. Laparoscopic Cholecystectomy. [Updated 2019 Mar 22]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2019 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448145/

[4] Stinton LM, Shaffer EA. Epidemiology of gallbladder disease: cholelithiasis and cancer. *Gut Liver*. 2012;6(2):172–187. doi:10.5009/gnl.2012.6.2.172

ICG dye has been used for many years in ophthalmic angiography, hepatic function testing and cardiac output measurement with an adverse event rate of less than 1%. ICG dye is metabolized by the liver and has been shown to be fully recoverable in bile. It therefore is non-nephrotoxic and considered safe for use in patients with compromised kidney function, such as the elderly or diabetics. ICG dye involves no ionizing radiation and, as such, does not require the use of special safety gear that is normally required for the patient or medical staff using other modalities. ICG dye is increasingly used in laparoscopic cholecystectomy procedures to better visualize the biliary tree anatomy and avoid bile duct injuries, the most serious post-operative complication following laparoscopic cholecystectomy.[5]

According to the requester, more than 70 peer-reviewed publications confirm the clinical safety and efficacy of the PINPOINT System with ICG dye and demonstrate that together they can significantly reduce post-operative complications and improve patient outcomes.[6,7, 8,9,10,11] In addition, a recently-published analysis of patients undergoing laparoscopic cholecystectomy with and without PINPOINT using ICG dye demonstrated the use of PINPOINT with ICG dye results in better visualization and identification of the biliary tree and may increase the safety of laparoscopy.[5]

Current Coding: There are no unique ICD-10-PCS codes to describe intraoperative near-infrared fluorescence imaging of the hepatobiliary system using indocyanine green (ICG) dye. Code for the cholecystectomy procedure only, with the appropriate values from table 0FT, Resection of Hepatobiliary System and Pancreas.

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[5] Ambe PC, Plambeck J, Fernandez-Jesberg V and K Zarras. The role of indocyanine green fluoroscopy for intraoperative bile duct visualization during laparoscopic cholecystectomy: an observational cohort study in 70 patients. *Patient Safety in Surgery.* 2019; 13:2.

[6] Starker PM, Chinn B (2018) Using Outcomes Data to Justify Instituting ASC-NSQIP and New Technology. *Colorec Cancer.* Vol.4 No.1: 3.

[7] Jafari MD, et al. Perfusion Assessment in Laparoscopic Left-Sided/Anterior Resection (PILLAR II): A Multi-Institutional Study. *Journal of the American College of Surgeons.*2015;220(1):82-92.

[8] Hammond J, Lim S, Wan Y, et al. The Burden of Gastrointestinal Anastomotic Leaks: an Evaluation of Clinical and Economic Outcomes. J Gastrointest Surg. 2014;18:1176-1185.

[9] Ris F, Liot E, Kraus R, et al. Multicentre phase II trial of near-infrared imaging in elective colorectal surgery. British *Journal of Surgery.* 2018 Apr 16. doi: 10.1002/bjs.10844.

[10] Karampinis I, Ronellenfitsch U, Mertens C, Hetjens S, Post S, Kienle P, Nowak K. Indocyanine green tissue angiography affects anastomotic leakage after esophagectomy. A retrospective, case-control study. *International Journal of Surgery.* 2017.48:210-214.doi: 10.1016/j.ijsu.2017.11.001.

[11] Campbell C, Reames MK, Robinson M, et al. Conduit Vascular Evaluation is Associated with Reduction in Anastomotic Leak After Esophagectomy. *J Gastrointest Surg.* DOI10.1007/s11605-015-2794-3.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for intraoperative near-infrared fluorescence imaging of hepatobiliary system using indocyanine green (ICG) dye. Continue coding the cholecystectomy procedure as listed in current coding.

Option 2. Create new imaging type 5 Other Imaging, applied to table BF5 of section B, Imaging of Hepatobiliary System and Pancreas. In addition, create new contrast value 2 Fluorescing Agent and new contrast qualifier value 0 Indocyanine Green Dye, to identify near-infrared fluorescence imaging of the hepatobiliary system using ICG dye during cholecystectomy. A separate code is assigned for the cholecystectomy procedure, as listed in current coding.

Section	**B** Imaging
Body System	**F** Hepatobiliary System and Pancreas
Type	**ADD 5** Other Imaging: Other specified modality for visualizing a body part

Body Part	*Contrast*	*Qualifier*	*Qualifier*
0 Bile Ducts **2** Gallbladder **3** Gallbladder and Bile Ducts **5** Liver **6** Liver and Spleen **7** Pancreas **C** Hepatobiliary System, All	**0** High Osmolar **1** Low Osmolar **Y** Other Contrast	**0** Unenhanced and Enhanced **Z** None	**Z** None
0 Bile Ducts **2** Gallbladder **3** Gallbladder and Bile Ducts **5** Liver **6** Liver and Spleen **7** Pancreas **C** Hepatobiliary System, All	**ADD 2** Fluorescing Agent	**ADD 0** Indocyanine Green Dye	**Z** None

CMS Recommendation: Option 2, as described above.

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

Near Infrared Spectroscopy for Tissue Viability Assessment

Issue: There is currently no unique ICD-10-PCS code to describe the utilization of Near Infrared Spectroscopy (NIRS) tissue oxygenation imaging to measure or monitor tissue oxygen saturation levels when assessing tissue viability during surgical procedures or during the post-operative management period using an external approach that is non-invasive.

New Technology Application: No.

Food & Drug Administration (FDA) Approval? Yes. Near Infrared Spectroscopy (NIRS) using an external approach has been market cleared by the FDA. Two recent technologies that provide non-invasive NIRS are the Snapshot$_{NIR}$ (Kent Camera) device, manufactured by Kent Imaging, with 510(k) premarket approval on May 5, 2017 and the Intra Ox Handheld Tissue Oximeter, manufactured by Vioptix, with 510(k) clearance issued on November 16, 2017.

Background: Near Infrared Spectroscopy (NIRS) technology is utilized to evaluate tissue oxygen saturation levels to help surgeons and clinicians make decisions in operative procedures during repair and closure in treatment of traumatic injuries, and to assess limb preservation and tissue survival in a wide range of wounds, tissue loss, tissue repair and grafting procedures, and in ongoing post-operative monitoring.

NIRS, uses a non-invasive external approach, to assess tissue viability by measuring approximate values of tissue oxygen saturation (S_tO_2). This technology evaluates the oxygenation status in superficial tissue in order to determine tissue survival. The NIRS systems measure the S_tO_2 at a depth of 1 – 3 mm, depending on the particular device system.

S_t0_2 as measured by external NIRS is different from S_pO_2. S_pO_2 is measured through pulse oximetry and is related to arterial oxygenation. In comparison, S_tO_2 is a mixed arterial-venous value that is representative of the light sampling in the capillary bed as opposed to the arteries. S_p0_2 and S_t0_2 are used differently in a clinical setting.

Technology: The Snapshot$_{NIR}$ handheld device is a near infrared technology that utilizes six wavelengths of near infrared light to provide a measure of tissue oxygen saturation (S_tO_2). The Snapshot$_{NIR}$ device is positioned at a pre-set distance from the surface of the skin to illuminate an area of tissue with a sequence of six near infrared wavelengths and then measures the back reflected light at each wavelength, without the need to attach probes to the skin surface or puncture a vessel. The reflectance sequence measured at each pixel is processed to provide an estimate of the relative concentrations of oxyhemoglobin (HbO_2) and deoxyhemoglobin (Hb) where the ratio is used to determine oxygen saturation levels (S_tO_2) in the tissue. Quantitative S_tO_2 values across the tissue area are imaged for analysis and stored for comparison to prior and future measurements. The process can be repeated as required to evaluate tissue viability over time.

The Intra Ox Handheld Tissue Oximeter is a handheld Near Infrared Spectroscopy (NIRS) device that has a disposable sensor that provides a measure of S_tO_2. This device places the light delivery and collection optics (contained within the sensor) directly on the skin. The Intra Ox system provides a numerical S_tO_2 value for a small amount of tissue beneath. Snapshot$_{NIR}$ provides a color image approximately 4" x 6" in size with the ability for the user to observe quantitative S_tO_2

values across the tissue area, by selecting areas of interest in the image. Identifying ischemic tissue through the use of NIRS devices like Snapshot$_{NIR}$ or Intra Ox has many applications including, but not limited to, evaluating breast and skin flap repair before, during and after surgical interventions, evaluating level of tissue viability in amputation procedures, and assessing wound repair and appropriate management.

In breast reconstruction, skin flap necrosis poses many challenges in patient care including: wound repair problems, delays in adjuvant therapy, loss of implants and poor esthetic results. Mastectomy skin flap necrosis (MSFN) has been reported to have an incidence of 10-15%[1]. Higher rates (7% - 30%) of MSFN have been reported in mastectomy procedures with immediate reconstruction[2]. Both NIRS devices mentioned can be used to evaluate the viability of skin intra-operatively and monitor post-operative progression. Utilizing NIRS to monitor flaps has been shown to increase flap salvage rates and decrease flap loss rates[3].

Other approaches to assess superficial tissue intra-operatively include fluorescence angiography. This technology requires a dye to be injected that can be fluoresced with the appropriate wavelength of laser. Skin perfusion is determined by viewing the video of the transit of the fluorescent dye through the vascular bed of the tissue; areas with good perfusion appear bright due to the fluorescent dye and areas of poor perfusion remain dark.

Near Infrared Spectroscopy (NIRS) is non-invasive and can also be used to identify areas of ischemia to augment clinical judgement. Snapshot$_{NIR}$ has been compared to fluorescence angiography and was found to have strong correlation[4].

The advantages of NIRS devices over fluorescence angiography includes:

- More time efficiency (no dye injection and waiting time for uptake of the dye within the peripheral circulation is required) when obtaining readings and making clinical decisions
- The handheld and portability capability of the NIR systems (Intra-Ox and Snapshot$_{NIR}$) allow flexibility to repeatedly image or measure in any setting (ex. Operating room, recovery, clinic) thus increasing the ability to monitor post-operative progression of tissue viability.

Snapshot$_{NIR}$ is also used to assess oxygen delivery to the lower extremities. This is relevant when evaluating vascular impairment for intervention, in the assessment of vascular status and healing potential of chronic wounds, and when planning amputations and assessing the amputation flap viability. Snapshot$_{NIR}$ was shown to correlate well in a study with transcutaneous oxygen measurement (TCOM) technology (Perimed)[5]. The authors of the study noted the significant advantages of NIRS including no contact required and a much faster procedure time.

Several other studies have examined the ability of NIRS to predict healing in chronic wounds and have found that it can be predictive of wound healing[6,7]. In a case series by Landsman et. al., the author describes utilizing Snapshot$_{NIR}$ in his practice to predict surgical wound dehiscence, aid in determining level and timing of amputations, and evaluating skin graft incorporation[7].

Current Coding: External Near Infrared Spectroscopy (NIRS) tissue oxygenation imaging is not currently reported in an inpatient setting. If desired, facilities can report NIRS imaging using one of the following ICD-10-PCS codes:

4A03XR1 Measurement of arterial saturation, peripheral, external approach
4A13XR1 Monitoring of arterial saturation, peripheral, external approach

Option 1. Do not create new ICD-10-PCS code to describe the utilization of Near Infrared Spectroscopy (NIRS) tissue oxygenation imaging. Continue using current codes as listed in current coding.

Option 2. In section 8, Other Procedures, add the approach value External, applied to the body region value 2 Circulatory System and the method value D Near Infrared Spectroscopy, to identify external NIRS tissue oxygenation imaging.

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*
2 Circulatory System	**ADD X** External **3** Percutaneous	**D** Near Infrared Spectroscopy	**Z** No Qualifier

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

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

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Cesium-131 Brachytherapy

Issue: There are currently no unique ICD-10-PCS codes to describe the use of low dose rate cesium-131 brachytherapy seeds in the treatment of cancer in locations throughout the body.

New Technology Application? No

Food & Drug Administration (FDA) Approved? Yes. FDA approval was obtained in 2003.

Background: Brachytherapy with cesium-131 implants allows for a highly targeted treatment dose of radiation to be delivered to the target region while limiting the radiation dose to surrounding tissues. In general, brachytherapy minimizes the radiation exposure to critical structures that may be located near the tumor.

Low dose rate cesium-131 brachytherapy sources are radioactive implants (often referred to as brachytherapy "seeds" because of their shape) that are the size of a grain of rice. They are implanted inside or near cancer tumors and release a personalized radiation dose over a period of days. This allows for effective treatment while minimizing damage to nearby tissue, and thereby limiting side effects. Cesium-131 seeds are commonly implanted using minimally invasive techniques through the introduction of brachytherapy needles inserted under image guidance. These procedures are typically performed in an operating room under general anesthesia. Alternatively, traditional cesium- 131 seeds may be implanted intraoperatively. For example, cesium-131 seeds may be implanted intraoperatively to treat residual cancer cells that may be left behind during an open surgical procedure for tumor excision.

According to the requester, cesium-131 is one of the most common isotopes used to deliver low dose rate brachytherapy. Cesium-131 brachytherapy seeds are indicated for the treatment of malignant disease and may be used in surface, interstitial, and intracavitary applications for tumors with known radiosensitivity. The brachytherapy seeds may be used as a primary treatment or in conjunction with other treatment modalities, such as external beam radiation therapy, chemotherapy, or as a treatment for residual disease after excision of primary tumors.

Most frequently, cesium-131 brachytherapy seeds are used to treat cancer tumors of the brain, head and neck, gynecologic sites, prostate, and lungs. However, the use of cesium-131 brachytherapy seeds is not limited to these body sites, and they are used to treat other solid mass tumors located throughout the body.

Current Coding: Facilities can report implantation of low dose rate cesium-131 brachytherapy seeds to the appropriate Brachytherapy table in Section D Radiation Therapy, with the fifth character modality qualifier, B Low Dose Rate, and the sixth character isotope value, Y Other Isotope. In addition, an ICD-10 PCS code from the root operation Insertion tables in the Medical and Surgical section can be reported using the device value Radioactive Element, to identify that a radioactive element is left in the body at the end of the procedure. Where the root operation Insertion tables do not currently include the device value Radioactive Element, the device value Y Other Device can be used.

For example, for implantation of low dose rate cesium-131 brachytherapy seeds to treat central nervous system sites such as the brain, report a code from table D01, Brachytherapy of Central and

Peripheral Nervous System, with the isotope value Y Other Isotope, and a code from table 00H Insertion of Central Nervous System, with the device value Y Other Device.

Section **D** Radiation Therapy *Body System* **0** Central and Peripheral Nervous System *Modality* **1** Brachytherapy			
Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Brain **1** Brain Stem **6** Spinal Cord **7** Peripheral Nerve	**B** Low Dose Rate (LDR)	**7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

Section **0** Medical and Surgical *Body System* **0** Central Nervous System and Cranial Nerves *Operation* **H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part			
Body Part	*Approach*	*Device*	*Qualifier*
0 Brain	**0** Open	**2** Monitoring Device **3** Infusion Device **4** Radioactive Element, Cesium-131 Collagen Implant **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier
0 Brain	**3** Percutaneous **4** Percutaneous Endoscopic	**2** Monitoring Device **3** Infusion Device **M** Neurostimulator Lead **Y** Other Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for cesium-131 brachytherapy. Continue using current codes as described in current coding.

Option 2. In the Radiation Therapy section, create new isotope value 6 Cesium 131 (Cs-131), applied to all Brachytherapy tables (D^1) for the fifth character modality value B Low Dose Rate, to identify cesium-131 brachytherapy. In addition, report an ICD-10 PCS code from the root operation Insertion tables in the Medical and Surgical section using the device value Radioactive Element, to identify that a radioactive element is left in the body at the end of the procedure.

Section **D** Radiation Therapy *Body System* **0** Central and Peripheral Nervous System *Modality* **1** Brachytherapy			
Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Brain **1** Brain Stem **6** Spinal Cord **7** Peripheral Nerve	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

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

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Bone Marrow **1** Thymus **2** Spleen **3** Lymphatics, Neck **4** Lymphatics, Axillary **5** Lymphatics, Thorax **6** Lymphatics, Abdomen **7** Lymphatics, Pelvis **8** Lymphatics, Inguinal	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

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

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Eye	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

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

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Ear **1** Nose **3** Hypopharynx **4** Mouth **5** Tongue **6** Salivary Glands **7** Sinuses **8** Hard Palate **9** Soft Palate **B** Larynx **D** Nasopharynx **F** Oropharynx	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

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

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Trachea **1** Bronchus **2** Lung **5** Pleura **6** Mediastinum **7** Chest Wall **8** Diaphragm	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

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

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Esophagus **1** Stomach **2** Duodenum **3** Jejunum **4** Ileum **5** Colon **7** Rectum	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

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

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Liver **1** Gallbladder **2** Bile Ducts **3** Pancreas	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

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

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Pituitary Gland **1** Pineal Body **2** Adrenal Glands **4** Parathyroid Glands **5** Thyroid	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

Section **D** Radiation Therapy
Body System **M** Breast
Modality **1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Breast, Left **1** Breast, Right	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

Section	**D** Radiation Therapy
Body System	**T** Urinary System
Modality	**1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Kidney **1** Ureter **2** Bladder **3** Urethra	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

Section	**D** Radiation Therapy
Body System	**U** Female Reproductive System
Modality	**1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Ovary **1** Cervix **2** Uterus	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

Section	**D** Radiation Therapy
Body System	**V** Male Reproductive System
Modality	**1** Brachytherapy

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
0 Prostate **1** Testis	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

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

Treatment Site	*Modality Qualifier*	*Isotope*	*Qualifier*
1 Head and Neck **2** Chest **3** Abdomen **6** Pelvic Region	**B** Low Dose Rate (LDR)	**ADD 6** Cesium 131 (Cs-131) **7** Cesium 137 (Cs-137) **8** Iridium 192 (Ir-192) **9** Iodine 125 (I-125) **B** Palladium 103 (Pd-103) **C** Californium 252 (Cf-252) **Y** Other Isotope	**Z** None

CMS Recommendation: Option 2. Create new isotope value 6 Cesium 131 (Cs-131), applied to all Brachytherapy tables (D^1) for the fifth character modality value B Low Dose Rate, to identify cesium-131 brachytherapy. In addition, report a ICD-10 PCS code from the root operation Insertion tables in the Medical and Surgical section using the device value Radioactive Element, to identify that a radioactive element is left in the body at the end of the procedure.

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

Intravascular Ultrasound Assisted Thrombolysis

Issue: Currently, no ICD-10-PCS code or code combination is available that fully describes intravascular ultrasound assisted thrombolysis with tissue plasminogen activator (tPA).

New Technology Application? No

Food & Drug Administration (FDA) Approved? Yes. FDA approval was obtained for the EKOS™ EkoSonic® Endovascular System (EKOS™ system) for use in the peripheral vasculature in 2003. FDA approval for the EKOS™ system use in the treatment of pulmonary embolism was obtained on May 21, 2014.

Background: A pulmonary embolism (PE) is an obstruction of the pulmonary vasculature most commonly caused by a venous thrombus and less commonly by fat or tumor tissue or air bubbles. Deep vein thrombosis (DVT) is a thrombosis that forms in a vein deep in the body, usually in the lower leg or thigh. DVT and PE are variants of a disease entity referred to as venous thromboembolism (VTE), and in fact DVT if not addressed effectively can lead to PE. Peripheral arterial occlusion involves full or partial blockage of peripheral arteries. Thrombotic arterial occlusion can lead to acute limb ischemia, which can lead to amputation and can be life-threatening.

Therapeutic interventions for these indications include anticoagulation, thrombolytics, and surgical thrombectomy. Anticoagulants are standard for all PE and DVT cases (where not contraindicated by the condition of the patient); they limit additional thrombus formation but do little to remove an existing thrombus. Thrombolytics are generally used for more severe, submassive and massive cases; massive PEs, which can be immediately life-threatening, are frequently treated with surgery. For peripheral arterial occlusion, according to the requestor, reliance on anticoagulants is usually inadequate, and speedy and aggressive action is required to remove the thrombus. A thrombolytic can be effective in destruction of a thrombus, acting by binding to fibrin threads in the thrombus and activating a chemical process that leads to local fibrinolysis. All thrombolytics pose risk of serious bleeding, which precludes a significant portion of potential patients from being treated with this therapy. For those patients who are eligible, minimizing the amount of the thrombolytic to which they are exposed is desirable. While thrombolytics can be administered systemically, the risk of an adverse bleeding reaction may be minimized by delivering a lower dose of the thrombolytic directly to the clot through catheter-directed thrombolysis (CDT).

"Conventional" CDT generally relies on a multi-sidehole catheter placed adjacent to the thrombus through which thrombolytics are delivered directly to the thrombus. A newer method, such as the one utilized in the EKOS™ system, employs ultrasound to assist thrombolysis. The ultrasound does not itself dissolve the thrombus, but pulses of ultrasonic energy temporarily make the fibrin in the thrombus more porous and increase fluid flow within the thrombus. High frequency, low-intensity ultrasonic waves create a pressure gradient that drives the thrombolytic into the thrombus and keeps it in close proximity to the binding sites.

The most common indication for ultrasound assisted thrombolysis is the treatment of pulmonary embolism. However, this therapy is also indicated for use in treating DVT and peripheral arterial occlusion (PAO). The requester's internal data suggests that of the roughly 45,000 annual EKOS™ system treatments, about 68 percent are for PE, 22 percent are for DVT, and 10 percent are for PAO. For all three indications, the reasons for using the EKOS™ system and the way the system is used are very similar, allowing for anatomical differences in how the affected area is accessed.

According to the requestor, results from investigations have shown that intravascular ultrasound assisted thrombolysis using the EKOS™ system:

- Speeds time to clot dissolution, increases clot removal, and enhances clinical improvement compared to either conventional CDT or thrombectomy.
- Improves clearance of clots by comparison to conventional CDT. This is in part attributable to 48 percent greater drug absorption within 1 hour, and 84 percent greater drug absorption within 2 hours.
- Lowers the risk of bleeding and other complications.
- Requires smaller doses of thrombolytics, minimizing risk from bleeding. The EKOS™ system reduces dosage requirements by as much as 68 percent compared to conventional CDT. It requires up to four times less drug dosage than typically used in systemic delivery.

C**urrent Coding:** Facilities can report the use of intravascular ultrasound assisted thrombolysis using two codes:

6A750Z7 Ultrasound therapy of other vessels, single, and

3E06317 Introduction of other thrombolytic into central artery, percutaneous approach, or
3E05317 Introduction of other thrombolytic into peripheral artery, percutaneous approach

This is consistent with published AHA Coding Clinic advice.

Coding Options

Option 1. Do not create a new ICD-10-PCS code for intravascular ultrasound assisted thrombolysis. Continue coding as listed in current coding.

Option 2. Add the pulmonary trunk, pulmonary artery, and pulmonary vein body part values to table 02F Fragmentation of Heart and Great Vessels, to identify intravascular ultrasound assisted thrombolysis of pulmonary embolism. In addition, create new ICD-10-PCS tables 03F and 05F, Fragmentation of Upper Arteries and Fragmentation of Upper Veins and tables 04F and 06F, Fragmentation of Lower Arteries and Fragmentation of Lower Veins, applied to the upper and lower extremity body part values and the percutaneous approach, to identify intravascular ultrasound assisted thrombolysis of upper and lower extremity vessels. Facilities may choose to continue to report the administration of thrombolytic agent separately using the appropriate code as listed above in current coding. Facilities also may choose to report the imaging guidance done to assist in the performance of the procedure with a code from Section B, with the root type of Ultrasound.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device*	*Qualifier*
N Pericardium **ADD P** Pulmonary Trunk **ADD Q** Pulmonary Artery, Right **ADD R** Pulmonary Artery, Left **ADD S** Pulmonary Vein, Right **ADD T** Pulmonary Vein, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**3** Upper Arteries
Operation	**ADD F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device*	*Qualifier*
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 **Y** Upper Artery	**3** Percutaneous	**Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**ADD F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device*	*Qualifier*
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 **Y** Lower Artery	**3** Percutaneous	**Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**5** Upper Veins
Operation	**ADD F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device*	*Qualifier*
3 Innominate Vein, Right **4** Innominate Vein, Left **5** Subclavian Vein, Right **6** Subclavian Vein, Left **7** Axillary Vein, Right **8** Axillary Vein, Left **9** Brachial Vein, Right **A** Brachial Vein, Left **B** Basilic Vein, Right **C** Basilic Vein, Left **D** Cephalic Vein, Right **F** Cephalic Vein, Left **Y** Upper Vein	**3** Percutaneous	**Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**6** Lower Veins
Operation	**ADD F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device*	*Qualifier*
C Common Iliac Vein, Right **D** Common Iliac Vein, Left **F** External Iliac Vein, Right **G** External Iliac Vein, Left **H** Hypogastric Vein, Right **J** Hypogastric Vein, Left **M** Femoral Vein, Right **N** Femoral Vein, Left **P** Saphenous Vein, Right **Q** Saphenous Vein, Left **Y** Lower Vein	**3** Percutaneous	**Z** No Device	**Z** No Qualifier

Option 3. Add the pulmonary trunk, pulmonary artery, and pulmonary vein body part values to table 02F Fragmentation of Heart and Great Vessels, to identify intravascular ultrasound assisted thrombolysis of pulmonary embolism. Create new ICD-10-PCS tables 03F and 05F, Fragmentation of Upper Arteries and Fragmentation of Upper Veins and tables 04F and 06F, Fragmentation of Lower Arteries and Fragmentation of Lower Veins, applied to the upper and lower extremity body part values and the percutaneous approach, to identify intravascular ultrasound assisted thrombolysis of upper and lower extremity vessels. In addition, create new qualifier value, 0 Ultrasonic, for these five tables. Facilities may choose to continue to report the administration of thrombolytic agent separately using the appropriate code as listed above in current coding.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device*	*Qualifier*
N Pericardium **ADD P** Pulmonary Trunk **ADD Q** Pulmonary Artery, Right **ADD R** Pulmonary Artery, Left **ADD S** Pulmonary Vein, Right **ADD T** Pulmonary Vein, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**Z** No Device	**ADD 0** Ultrasonic **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**3** Upper Arteries
Operation	**ADD F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device*	*Qualifier*
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 **Y** Upper Artery	**3** Percutaneous	**Z** No Device	**ADD 0** Ultrasonic **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**ADD F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device*	*Qualifier*
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 **Y** Lower Artery	**3** Percutaneous	**Z** No Device	**ADD 0** Ultrasonic **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**5** Upper Veins
Operation	**ADD F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device*	*Qualifier*
3 Innominate Vein, Right **4** Innominate Vein, Left **5** Subclavian Vein, Right **6** Subclavian Vein, Left **7** Axillary Vein, Right **8** Axillary Vein, Left **9** Brachial Vein, Right **A** Brachial Vein, Left **B** Basilic Vein, Right **C** Basilic Vein, Left **D** Cephalic Vein, Right **F** Cephalic Vein, Left **Y** Upper Vein	**3** Percutaneous	**Z** No Device	**ADD 0** Ultrasonic **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**6** Lower Veins
Operation	**ADD F** Fragmentation: Breaking solid matter in a body part into pieces

Body Part	*Approach*	*Device*	*Qualifier*
C Common Iliac Vein, Right **D** Common Iliac Vein, Left **F** External Iliac Vein, Right **G** External Iliac Vein, Left **H** Hypogastric Vein, Right **J** Hypogastric Vein, Left **M** Femoral Vein, Right **N** Femoral Vein, Left **P** Saphenous Vein, Right **Q** Saphenous Vein, Left **Y** Lower Vein	**3** Percutaneous	**Z** No Device	**ADD 0** Ultrasonic **Z** No Qualifier

CMS Recommendation: CMS is seeking input from the audience.

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

Administration of Nerinitide

Issue: There is currently no unique ICD-10-PCS code to describe the administration of Nerinitide (NA-1).

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

Food & Drug Administration (FDA) Approval? No. The requester is planning NDA submission for FY 2021.

Background: Each year in the United States, approximately 795,000 people suffer from a stroke of which more than 140,000 of those cases are fatal. Nearly 75% of all strokes occur in people over the age of 65. Stroke is the leading cause of serious, long-term disability in the United States and reduces mobility in more than half of survivors age 65 and over.[1]

Statistical analysis of relevant animal studies suggests that irreversible focal injury begins within a few minutes and is complete within about 6 hours which presents a narrow therapeutic window.[2] Time-sensitive interventions for ischemic stroke patients include thrombolytic medications such as tissue plasminogen activator (tPA)[3] or mechanical thrombectomy/endovascular therapy but there are currently no therapies targeted for the preservation of neuronal tissue.

Nerinitide (NA-1) is a novel peptide therapeutic aimed at reducing ischemic damage when administered after the onset of acute stroke. It is also a member of a new class of neuroprotectant drugs termed "PSD-95 Inhibitors". The PSD-95 protein is an essential intermediary between glutamate receptors which trigger cell death signaling and the enzyme neuronal nitric oxide synthase, or nNOS, which generates the toxic free radical Nitric Oxide. Nerinitide inhibits the binding of PSD-95 to other molecules such as nNOS, thereby inhibiting cell death signaling.

Nerinitide (NA-1), administered independently of other recanalization therapies, is infused at a single intravenous dose of 2.6 mg/kg and has been demonstrated to be highly effective in reducing stroke size while improving the functional outcome of experimental animals subjected to acute stroke. Studies have shown that Nerinitide (NA-1) is more effective in reducing infarct size and improving functional outcome in models of ischemia-reperfusion, as compared with permanent arterial occlusion.

In November 2019, NoNO will complete its phase III trial in 1120 subjects to determine the efficacy of Nerinitide in reducing global disability in subjects with major acute ischemic stroke (AIS) undergoing endovascular thrombectomy.

There is a need to develop neuroprotectants in order to increase the proportion of patients who may benefit from recanalization therapies. These agents could improve the outcomes of those who receive endovascular recanalization.

Existing codes are either specific to other drug therapies or classes, neither of which accurately describe Nerinitide or the novel class of PSD-95 antagonists to which it belongs. A unique ICD-10-PCS code for Nerinitide ensures distinct tracking of drug utilization and corresponding patient outcomes to better inform treatment of this medical emergency.

Current Coding: There is no unique ICD-10-PCS code to describe the administration of Nerinitide (NA-1). Facilities can report the intravenous administration of Nerinitide with one the following ICD-10-PCS codes:

3E033GC Introduction of other therapeutic substance into peripheral vein, percutaneous approach
3E043GC Introduction of other therapeutic substance into central vein, percutaneous Approach

Option 1. Do not create new ICD-10-PCS codes for the administration of Nerinitide (NA-1). Continue using current codes as listed in current coding.

Option 2. Create new qualifier value T Nerinitide in table 3E0 of section 3, Administration, applied to the fourth character values Peripheral Vein and Central Vein and the sixth character value Other Therapeutic Substance, to identify intravenous infusion of Nerinitide (NA-1).

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**G** Other Therapeutic Substance	**C** Other Substance **N** Blood Brain Barrier Disruption **Q** Glucarpidase **ADD T** Nerinitide

Option 3. Create new codes in section X, New Technology, to identify intravenous infusion of Nerinitide (NA-1).

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 2** Nerinitide	**6** New Technology Group 6

CMS Recommendation: Option 3. Create new codes in section X, New Technology, to identify intravenous infusion of Nerinitide (NA-1).

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

References:

1. Stroke Fact Sheet. Center for Disease Control (CDC). Updated Sept 2017. Accessed May 2019.
2. Zivin, J. Factors determining the therapeutic window for stroke. American Academy of Neurology (AAN). Mar 1998. Accessed May 2019.
3. Powers WJ et al. 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke: A Guideline for Healthcare Professionals from the American Heart Association / American Stroke Association. Stroke 2018;49:e46-e110. Updated Apr 2018. Accessed May 2019.
4. Investigator's Brochure. NoNO Inc. Nov 2017. Accessed May 2019.

Administration of eladocagene exuparvovec

Issue: There is currently no unique ICD-10-PCS code to describe the administration of eladocagene exuparvovec for the treatment of aromatic L-amino acid decarboxylase (AADC) deficiency, a rare, inherited neurometabolic disease with life-limiting consequences.

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

Food and Drug Administration (FDA) Approval? No. An application for the approval of eladocagene exuparvovec will be submitted to the FDA for approval during Q4 of 2019, with an anticipated fast-track approval by July 2020.

Background: Eladocagene exuparvovec is a gene therapy consisting of an adeno-associated virus (AAV) vector that delivers the human dopa decarboxylase (DDC) gene to Aromatic L-amino acid decarboxylase (AADC) deficient cells in the central nervous system. Eladocagene exuparvovec was developed to address the unmet clinical needs of AADC deficient patients who commonly have no functional motor movement, never meet developmental milestones, and are at risk of an early death in the first decade of life (Hwu 2012; Hwu 2018). Caused by mutations in the DDC gene, the lack of AADC enzyme activity leads to a deficiency of dopamine, serotonin, and other catecholamines. Patients with AADC deficiency commonly have profound motor dysfunction, hypotonia, hypokinesia, oculogyric crisis, dystonia, autonomic dysfunction, extraneurologic symptoms, and failure to gain weight (Hwu 2018). Based on consensus treatment guidelines developed by the International Working Group on Neurotransmitter Related Disorders (iNTD), 99% of patients failed to achieve any motor milestones over their lifetime (Wassenberg 2017).

Symptoms of AADC deficiency have been identified as early as 3 months; however, the median age of diagnosis is 3.5 years and is likely a result of misdiagnosis (Wassenberg 2017). AADC deficiency is a rare disease of primarily young children. Its prevalence ranges from 1:32,000 to 1:90,000 has been estimated for AADC deficiency in the United States. This variance is based on the limited population, early age of death, and potential delayed or misdiagnosis (Himmelreich 2019; Wassenberg 2017; Hyland 2018; Chien 2016; Pons 2004; Helman 2014).

Current treatment options are limited and yield few improvements for the majority of patients with AADC deficiency (Chien 2017). There are currently no FDA-approved therapies for AADC deficiency. First-line, off-label treatment options include dopamine agonists, monoamine oxidase inhibitors, and pyridoxine; however, the quality of evidence for these agents is rated as low or very low (Wassenberg 2017). Additional symptomatic treatments such as anticholinergics, alpha-agonists, and melatonin have been used to manage symptoms like nasal congestion, autonomic symptoms, and sleep problems, respectively (Wassenberg 2017). Eladocagene exuparvovec is the first targeted gene therapy designed to restore AADC function and dopamine synthesis in the putamen to improve patients' motor function and development.

Technology: Eladocagene exuparvovec is injected directly into the putamen bilaterally via established stereotactic surgical procedures by a neurosurgeon using commercially available guidance systems. Eladocagene exuparvovec is supplied as a single-unit dose vial and injected with a dose volume of 80 μL per injection site (4 sites, 2 per putamen, total volume of 320 μL) at a total dose of 1.8×10^{11} vector genomes per patient. The surgery is performed under general anesthesia followed by a computed tomography (CT) scan and magnetic resonance imaging (MRI)

to check for acute bleeding and any structural changes. Trajectories for intraputaminal infusion of the gene therapy product are assessed using fused MRI and CT images.

The administration of eladocagene exuparvovec will be a one-time inpatient procedure permitting time for the injection and up to 3 days to monitor patients for bleeding risk or surgical complications. The administration of eladocagene exuparvovec is expected to be initially restricted to neurosurgeons at select centers of excellence.

Description and Method of Action of eladocagene exuparvovec

Eladocagene exuparvovec is a gene therapy consisting of an adeno-associated virus (AAV) vector that delivers the human DDC gene to AADC-deficient cells in the central nervous system (CNS), resulting in increased production of the AADC enzyme and, therefore, an increase in the production of dopamine. The human DDC gene in eladocagene exuparvovec is recombinantly formed, adeno-associated virus, serotype 2 (AAV2) containing the AGIL-AADC expression cassette in place of AAV genome. The AGIL-AADC expression cassette is comprised of engineered, single-strand DNA incorporated into the AAV2 capsid.
Gene therapy with eladocagene exuparvovec provides the potential for these patients to achieve and maintain motor milestones. Two clinical trials were performed for eladocagene exuparvovec, AADC-1601 and AADC-010. The participants were 18 children from 21 months to 8.5 years of age at the time of administration with severe AADC deficiency and without full head control, ability to sit, or ability to walk. All 18 subjects were examined for 2 years following gene therapy and 8 subjects were examined for 5 years. Results for all 18 patients at 2 and 5 years following therapy will be available at the time of the FDA filing.

Combined trial data from AADC-1601 and AADC-010 demonstrated the following improvements at 2 and 5 years post-treatment:

- All patients achieved clinically and statistically significant improvement in total motor function including both gross and fine motor skills as assessed with the Peabody Developmental Motor Scale (PDMS-2) and the Alberta Infant Motor Scale (AIMS) (Chien 2019)
- All patients had clinically and statistically significant improvement in achievement of motor milestones (eg., gained head control, ability to sit unassisted, and standing with support) relative to natural history control (Chien 2018)
- All patients achieved clinically meaningful improvements in Bayley scales of infant and toddler development (Bayley-III) total score and cognitive and language subscale scores (Chien 2019)
- All patients had evidence of de novo dopamine production (visualized by F-DOPA PET imaging) consistent with successful and stable DDC gene transduction over time (Hwu 2012, Chien 2018, Chien 2019)

In clinical trials, the presence of antibodies to AAV2 does not appear to affect the efficacy of eladocagene exuparvovec. Eladocagene exuparvovec is injected directly into the brain and is not anticipated to distribute outside the CNS. Viral shedding data in children treated with eladocagene exuparvovec showed no evidence of distribution of the vector in blood or urine. The most common adverse event seen in nearly all patients was transient dyskinesia related to eladocagene exuparvovec administration and completely resolved over time with no sequelae (Hwu 2015). No

adverse events were reported during the actual surgical procedure (Hwu 2015). Adverse events, in general, were associated with the overall disease status.

Current Coding: There is currently no unique ICD-10-PCS code to describe percutaneous injection of eladocagene exuparvovec into the brain. Facilities can report the administration of eladocagene exuparvovec with the following ICD-10-PCS code:

3E0Q3GC Introduction of other therapeutic substance into cranial cavity and brain, percutaneous approach

Coding Options:

Option 1. Do not create a new ICD-10-PCS code for percutaneous injection of eladocagene exuparvovec into the brain. Continue using the code as listed in current coding.

Option 2. Create new qualifier value R Eladocagene exuparvovec in table 3E0 of section 3, Administration, applied to the body system value Q Cranial Cavity and Brain, the percutaneous approach, and the substance value G Other Therapeutic Substance, to identify the injection of eladocagene exuparvovec into the brain.

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
Q Cranial Cavity and Brain	**3** Percutaneous	**G** Other Therapeutic Substance	**C** Other Substance **ADD R** Eladocagene exuparvovec

Option 3. Create a new code in section X, New Technology, to identify the percutaneous injection of eladocagene exuparvovec into the brain.

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*
Q Cranial Cavity and Brain	**3** Percutaneous	**ADD 1** Eladocagene exuparvovec	**6** New Technology Group 6

CMS Recommendation: Option 3. Create a new code in section X, New Technology, to identify the percutaneous injection of eladocagene exuparvovec into the brain.

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

References:

1. Chien YH, Chen PW, Lee NC, et al. 3-O-methyldopa levels in newborns: result of newborn screening for aromatic l-amino-acid decarboxylase deficiency. *Mol Genet Metab.* 2016;118(4):259-263.
2. Chien YH, Lee NC, Tseng SH, et al. Efficacy and safety of AAV2 gene therapy in children with aromatic L-amino acid decarboxylase deficiency: an open-label, phase 1/2 trial. *Lancet Child Adolesc Health*. 2017;1(4):265-273.
3. Chien YH, Lee NC, Tseng SH, et al. AGIL-AADC gene therapy results in sustained improvements in motor and developmental milestones over 5 years in children with AADC deficiency. Poster presented at: American Academy of Neurology (AAN) 2019 Annual Meeting; May 4-10, 2019; Philadelphia, PA.
4. Chien Y, Lee N, Tseng S, et al. Gene therapy with AGIL-AADC in children with AADC deficiency leads to de novo dopamine production and sustained improvement in motor milestones over 5 years. Presentation at: 47th Annual Meeting of the Child Neurology Society (CNS); October 15-18, 2018; Chicago, IL.
5. Helman G, Pappa MB, Pearl PL. Widening phenotypic spectrum of AADC deficiency, a disorder of dopamine and serotonin synthesis. *JIMD Rep.* 2014;17:23-27.
6. Himmelreich N, Montioli R, Bertoldi M, et al. Aromatic amino acid decarboxylase deficiency: molecular and metabolic basis and therapeutic outlook. *Mol Genet Metab*. 2019 Mar 27. pii: S1096-7192(18)30786-8.
7. Hwu WL, Chien Y-H, Lee N-C, Li M-H. Natural history of aromatic l-amino acid decarboxylase deficiency in Taiwan. *JIMD Rep.* 2018;40:1-6.
8. Hwu WL, Muramatsu S, Tseng SH, et al. Gene therapy for aromatic L-amino acid decarboxylase deficiency. *Sci Transl Med.* 2012;4(134):134ra161.
9. Wassenberg T, Molero-Luis M, Jeltsch K, et al. Consensus guideline for the diagnosis and treatment of aromatic l- amino acid decarboxylase (AADC) deficiency. *Orphanet J Rare Dis*. 2017;12(1):1-21.

Administration of ZULRESSO™ (brexanolone)

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

New Technology Application? Yes, a New Technology Add-on Payment (NTAP) application will be submitted for ZULRESSO™ (brexanolone) for FY 2021.

Food & Drug Administration (FDA) Approved? Yes. FDA approval was obtained on March 19, 2019.

Background: PPD is a common complication of pregnancy and childbirth. It is more common than gestational diabetes, pregnancy-associated hypertension (including gestational hypertension, preeclampsia, and eclampsia), postpartum hemorrhage, and preterm delivery-related maternal complications. In the US, estimates of new mothers experiencing symptoms of PPD vary by state and range between 8-20%, with an overall average of 11.5%.

PPD is distinct from "baby blues" owing to the timing, duration, and/or severity of depressive symptoms. Women with PPD may experience a number of symptoms, including trouble bonding with and caring for their baby, thoughts of self-harm or harm to their baby, and withdrawal from friends and family. Expert opinions vary as to the timing of PPD. Onset of symptoms may occur during pregnancy or after delivery, within 4 weeks or up to 12 months postpartum.

In contrast, the symptoms of baby blues typically peak at 5 days post-delivery and resolve without treatment within 14 days. Unlike PPD, baby blues generally does not affect a mother's ability to function.

Although the precise mechanism of PPD is unknown, there are multiple hypotheses about the mechanism of disease of PPD. PPD may be triggered in susceptible women by an inability of the brain to adapt to fluctuations in allopregnanolone that occur in the peripartum period. These fluctuations in allopregnanolone have been associated with symptoms of PPD. PPD can have a significant negative effect on maternal quality of life. Furthermore, PPD may have a long-term negative effect on the development of the child, a mother's relationship with a partner, levels of the partner's own stress and depression, and the well-being of the whole family unit.

Historically, medications used to treat PPD were not specifically indicated for PPD. Patients with PPD were commonly prescribed a variety of medications typically used for major depression or other mood disorders. However, limitations exist relating to outcomes data on the use of these therapies in PPD. Non-pharmacological treatments such as psychotherapies, including cognitive behavioral therapy, psychosocial community-based intervention, and dynamic psychotherapy have also been used. Through market research conducted by Sage Therapeutics, patients have identified potential challenges with those treatment options, including long wait times for an appointment and difficulties scheduling a follow-up appointment with the provider; insurance coverage challenges; delays or interruption in treatment; changes in medications or doses (which may not be effective); and the length of treatment plan being longer than expected.

Drug Information, Dosage and Administration

ZULRESSO™ contains brexanolone, a neuroactive steroid gamma-aminobutyric acid (GABA)A receptor positive modulator that is chemically identical to endogenous allopregnanolone.

ZULRESSO™ is a clear, colorless solution supplied in single dose vials. ZULRESSO™ is also a sterile and preservative-free solution intended for dilution. It is supplied as 100 mg brexanolone in a 20 mL single dose vial (5 mg/mL). The recommended target dosage for ZULRESSO™ is 90 mcg/kg/h administered as a continuous intravenous solution over 60 hours (2.5 days) as follows:

• 0 to 4 hours: Initiate with a dosage of 30 mcg/kg/hour

• 4 to 24 hours: Increase dosage to 60 mcg/kg/hour

• 24 to 52 hours: Increase dosage to 90 mcg/kg/hour (a reduction in dosage to 60 mcg/kg/hour may be considered during this time period for patients who do not tolerate 90 mcg/kg/hour)

• 52 to 56 hours: Decrease dosage to 60 mcg/kg/hour

• 56 to 60 hours: Decrease dosage to 30 mcg/kg/hour

Outcomes, Complications and Supervision of ZULRESSO™ Administration

Patient's receiving ZULRESSO™ must be carefully monitored and supervised by a healthcare professional. ZULRESSO™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ZULRESSO™ REMS because excessive sedation or sudden loss of consciousness can result in serious harm. In clinical studies, ZULRESSO™ caused sedation and somnolence that required dose interruption or reduction in some patients during the infusion (5% of ZULRESSO™-treated patients compared to 0% of placebo-treated patients). Some patients were also reported to have loss of consciousness or altered state of consciousness during the ZULRESSO™ infusion (4% of the ZULRESSO™-treated patients compared with 0% of the placebo-treated patients). Time to full recovery from loss or altered state of consciousness, after dose interruption, ranged from 15 to 60 minutes.

A healthcare provider must be available on site to continuously monitor the patient, and intervene as necessary, for the duration of the ZULRESSO™ infusion. Patients should be monitored for hypoxia using continuous pulse oximetry equipped with an alarm. ZULRESSO™ treatment should be initiated early enough during the day to allow for recognition of excessive sedation. During the infusion, patients must be monitored for sedative effects every 2 hours during planned, non-sleep periods. The infusion should be immediately stopped if there are signs or symptoms of excessive sedation. After symptoms resolve, the infusion may be resumed at the same or lower dose as clinically appropriate. The infusion should also be immediately stopped if pulse oximetry reveals hypoxia. After hypoxia, the infusion should not be resumed.

Current Coding: There is no unique ICD-10-PCS code to describe the administration of ZULRESSO™ (brexanolone). Facilities can report the intravenous administration of ZULRESSO™ (brexanolone) with one of the following ICD-10-PCS codes:

3E033GC Introduction of other therapeutic substance into peripheral vein, percutaneous approach
3E043GC Introduction of other therapeutic substance into central vein, percutaneous approach

Option 1. Do not create new ICD-10-PCS codes for intravenous administration of ZULRESSO™ (brexanolone). Continue using current codes as listed in current coding.

Option 2. Create new qualifier value R Brexanolone in table 3E0 of section 3, Administration, applied to the fourth character values Peripheral Vein and Central Vein and the sixth character value Other Therapeutic Substance, to identify intravenous infusion of ZULRESSO™ (brexanolone).

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

Option 3. Create new codes in section X, New Technology, to identify intravenous infusion of ZULRESSO™ (brexanolone).

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 0** Brexanolone	**6** New Technology Group 6

CMS Recommendation: Option 3. Create new codes in section X, New Technology, to identify intravenous infusion of ZULRESSO™ (brexanolone).

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

Using the ICD-10-PCS New Technology Section X Codes

The information that follows is provided in response to requests for more detail about the ICD-10-PCS section X, New Technology, as well as specific coding instruction for the section.

General Information

Section X, New Technology, is a section added to ICD-10-PCS beginning October 1, 2015. The section provides a place for codes that uniquely identify procedures that capture new technologies not currently classified in ICD-10-PCS, or procedures that generally would not be captured in the inpatient setting.

New Technology section X was created in response to public comments received regarding proposals presented at ICD-10 Coordination and Maintenance Committee Meetings, and general issues facing classification of procedures utilizing a new technology. The public had opposed requests to add new codes to the existing ICD-10-PCS sections for the reporting of specific drugs, devices, or supplies in an inpatient setting, even when the code was related to an application for Medicare's New Technology Add-On Payment (NTAP) program. More information on the NTAP program can be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-payment/AcuteInpatientPPS/newtech.html.

The New Technology section is intended as a separate place for certain procedures utilizing new technology, such as infusion of newly developed drugs, new treatment modalities, or new adjunct procedures. The request for a new procedure code does not have to be associated with an application in the NTAP program to have codes proposed and subsequently finalized in the New Technology section.

New Technology section X does not introduce new coding concepts or unusual guidelines for correct coding. To the extent possible within the structure of the section X and taking into account data collection needs, section X codes generally maintain continuity with the other sections in ICD-10-PCS by using the same root operation and body part values as their closest counterparts in other sections of ICD-10-PCS. For example, the two codes for infusion of ceftazidime-avibactam, a new technology antibiotic that required unique procedure codes effective October 1, 2015, use the same root operation (Introduction) and body part values (Central Vein and Peripheral Vein) in section X as the infusion codes in section 3 Administration, which are their closest counterparts in the other sections of ICD-10-PCS. However, the two codes for monitoring of knee joint, a new technology intraoperative knee replacement monitoring procedure that required unique codes effective October 1, 2015, use fourth character body part values (Knee Joint, Right and Knee Joint, Left) that do not have counterparts in section 4, Measurement and Monitoring. This differing level of specificity was included in the New Technology section X code to satisfy data collection needs.

In ICD-10-PCS, the information specified in the seventh character is called the qualifier, and the type of information specified depends on the section. In section X, New Technology, the seventh character is used exclusively to specify the New Technology Group. The New Technology Group is a number or letter that changes each year that new codes are added to the tables in section X, New Technology. For example, section X codes added for the first year have the seventh character value 1, New Technology Group 1, and the next year that section X codes were added have the seventh character value 2 New Technology Group 2, and so on. This is a simpler use of the qualifier than in many other sections of ICD-10-PCS, such as the Medical and Surgical section.

Because the section X qualifier value is only used to indicate the update year the code was created, there are no special coding instructions or requirements for the use of the qualifier, because all codes for a particular procedure added to the section X tables in the same year will all have the same New Technology Group qualifier. Its function is to allow the New Technology section to evolve over time according to data collection needs, as medical technology evolves.

Coding Instruction
Section X codes can be reported alone or with other ICD-10-PCS codes, depending on whether multiple procedures are performed. Section X codes fully represent the specific new technology described in the procedure code title, and do not require an additional code from another section of ICD-10-PCS to capture the new technology.

For example, code XW04321 Introduction of Ceftazidime-Avibactam Anti-infective into Central Vein, Percutaneous Approach, New Technology Group 1, would be reported to indicate that Ceftazidime-Avibactam Anti-infective was administered via the central vein. A separate code from table 3E0 in the Administration section of ICD-10-PCS would not be reported in addition to this code. The section X code fully identifies the administration of the ceftazidime-avibactam antibiotic, and no additional code is needed.

However, this does not mean that a procedure described by a New Technology section X code must be reported alone. When it comes to coding multiple procedures during an inpatient hospital stay episode, New Technology section X codes are no different from other ICD-10-PCS codes. If additional procedures are performed, then multiple procedures are reported.

For example, code X2A5312 Cerebral Embolic Filtration, Dual Filter in Innominate Artery and Left Common Carotid Artery, Percutaneous Approach, New Technology Group 2, would be reported to indicate that a dual filter cerebral embolic filtration device was utilized in a transcatheter aortic valve replacement (TAVR) procedure. A separate code is reported for the TAVR procedure from table 02R, Replacement of Heart and Great Vessels.

Another example would be to report a code from table XNS, Reposition of the Bones, from the New Technology section, to indicate that a magnetically controlled growth rod (MCGR) was utilized in a spinal fusion procedure. A separate code is reported for the concomitant spinal fusion procedure from table 0RG, Fusion of Upper Joints or table 0SG, Fusion of Lower Joints.

The New Technology section X codes are found by looking in the ICD-10-PCS Index or the Tables. In the Index, the name of the new technology device, substance or technology for a section X code is included as a main term. In addition, all codes in section X are listed under the main term New Technology. Index entries for the New Technology section X code describing ceftazidime-avibactam are shown below.

Ceftazidime-Avibactam Anti-infective XW0

New Technology
Ceftazidime-Avibactam Anti-infective **XW0**

Where applicable, entries are also added to the Device Key or Substance Key to further assist coders in finding procedures classified to the New Technology section. Below are examples of Device Key entries for procedures that have been classified to the New Technology section.

Term	ICD-10-PCS Value
MAGEC(R) Spinal Bracing and Distraction System	**Use:** Magnetically Controlled Growth Rod(s) in New Technology
MIRODERM(tm) Biologic Wound Matrix	**Use:** Skin Substitute, Porcine Liver Derived in New Technology
nanoLOCK(tm) interbody fusion device	**Use:** Interbody Fusion Device, Nanotextured Surface in New Technology
Perceval sutureless valve	**Use:** Zooplastic Tissue, Rapid Deployment Technique in New Technology

In the ICD-10-PCS Tables, New Technology section X codes are displayed like the other ICD-10-PCS tables, with a separate table for each root operation and body system. The section X codes for the root operation Introduction in New Technology Group 1 (valid beginning October 1, 2015) are shown in the table below.

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	**2** Ceftazidime-Avibactam Anti-infective **3** Idarucizumab, Dabigatran Reversal Agent **4** Isavuconazole Anti-infective **5** Blinatumomab Antineoplastic Immunotherapy	**1** New Technology Group 1

Section X Update

At the September 11-12, 2018 ICD-10 Coordination and Maintenance (C&M) Committee Meeting we announced our plans to begin analyzing the frequency of the New Technology Group 1 codes within Section X as it has been 3 years since the implementation of these codes. We stated that we planned to share the results of our initial analysis at the March 5-6, 2019 ICD-10 C&M meeting, and that we would consider the following during our review.

- Was the procedure code related to a new technology add-on payment application (NTAP)?
- If yes, was the technology approved for the NTAP?
- What is the frequency (total number of cases) of this procedure code as reported in the data for FYs 2016, 2017 and 2018?
- Based on review of the data and the clinical aspects of each procedure code, we will propose one of the options below
    1. Leave the code in Section X (e.g. procedure codes related to the administration of a specific medication)
    2. Reassign the code to the Med/Surg section of ICD-10-PCS and delete from Section X (e.g. NTAP has expired, data analysis and clinical review, justifies incorporating this technology/procedure into the main Med/Surg section)
    3. Delete the Section X code (e.g. the procedure is not reported as anticipated in the data, therefore the absence of a unique code for this technology/procedure in the classification has minimal impact)

Due to our restricted time allotment for the March 2019 ICD-10 C&M meeting we were unable to have the full discussion regarding the Section X codes as we had initially planned. However, we presented the findings from our initial analysis with regard to the frequency in which they have been reported in the data.

We analyzed the following 14 ICD-10-PCS procedure codes.

ICD-10-PCS Code	Description
X2C0361	Extirpation of Matter From Coronary Artery, One Artery Using Orbital Atherectomy Technology, Percutaneous Approach, New Technology Group 1
X2C1361	Extirpation of Matter From Coronary Artery, Two Arteries Using Orbital Atherectomy Technology, Percutaneous Approach, New Technology Group 1
X2C2361	Extirpation of Matter From Coronary Artery, Three Arteries Using Orbital Atherectomy Technology, Percutaneous Approach, New Technology Group 1
X2C3361	Extirpation of Matter From Coronary Artery, Four Or More Arteries Using Orbital Atherectomy Technology, Percutaneous Approach, New Technology Group 1
XR2G021	Monitoring of Right Knee Joint Using Intraoperative Knee Replacement Sensor, Open Approach, New Technology Group 1
XR2H021	Monitoring of Left Knee Joint Using Intraoperative Knee Replacement Sensor, Open Approach, New Technology Group 1
XW03321	Introduction of Ceftazidime-Avibactam Anti-infective into Peripheral Vein, Percutaneous Approach, New Technology Group 1
XW03331	Introduction of Idarucizumab, Dabigatran Reversal Agent into Peripheral Vein, Percutaneous Approach, New Technology Group 1

ICD-10-PCS Code	Description
XW03341	Introduction of Isavuconazole Anti-infective into Peripheral Vein, Percutaneous Approach, New Technology Group 1
XW03351	Introduction of Blinatumomab Antineoplastic Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 1
XW04321	Introduction of Ceftazidime-Avibactam Anti-infective into Central Vein, Percutaneous Approach, New Technology Group 1
XW04331	Introduction of Idarucizumab, Dabigatran Reversal Agent into Central Vein, Percutaneous Approach, New Technology Group 1
XW04341	Introduction of Isavuconazole Anti-infective into Central Vein, Percutaneous Approach, New Technology Group 1
XW04351	Introduction of Blinatumomab Antineoplastic Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 1

ICD-10-PCS Code	Frequency FY 2016	Frequency FY 2017	Frequency FY 2018	Total Frequency Procedure Code Reported	Approved as a New Technology?
X2C0361	1,086	1,574	1,787	4,444	No
X2C1361	258	264	272	794	No
X2C2361	41	33	44	118	No
X2C3361	9	0	1	10	No
XR2G021	858	1,135	886	2,879	No
XR2H021	796	1,093	864	2,753	No
XW03321	48	47	62	157	No
XW03331	13	102	102	217	No
XW03341	5	8	14	27	No
XW03351	45	43	46	134	Yes
XW04321	6	7	9	22	No
XW04331	0	9	12	21	No
XW04341	2	3	10	15	No
XW04351	73	104	100	277	Yes

ICD-10-PCS Index Addenda

Lttr	B	
Main	Add	Barricaid(R) Annular Closure Device (ACD) use Synthetic Substitute
Lttr	C	
Main	Revise from	Cook Zenith AAA Endovascular Graft
	Revise to	Cook Zenith AAA Endovascular Graft use Intraluminal Device
	Delete	use Intraluminal Device, Branched or Fenestrated, One or Two Arteries in 04V
	Delete	use Intraluminal Device, Branched or Fenestrated, Three or More Arteries in 04V
	Delete	use Intraluminal Device
Main	Add	Cook Zenith(R) Fenestrated AAA Endovascular Graft
	Add	use Intraluminal Device, Branched or Fenestrated, One or Two Arteries in 04V
	Add	use Intraluminal Device, Branched or Fenestrated, Three or More Arteries in 04V
Lttr	S	
Main		Scapholunate ligament
	Delete	use Hand Bursa and Ligament, Right
	Delete	use Hand Bursa and Ligament, Left
	Add	use Wrist Bursa and Ligament, Right
	Add	use Wrist Bursa and Ligament, Left
Lttr	Z	
Main	Revise from	Zenith AAA Endovascular Graft
	Revise to	Zenith AAA Endovascular Graft use Intraluminal Device
	Delete	use Intraluminal Device, Branched or Fenestrated, One or Two Arteries in 04V

	Delete	use Intraluminal Device, Branched or Fenestrated, Three or More Arteries in 04V
	Delete	use Intraluminal Device
Main	Add	Zenith(R) Fenestrated AAA Endovascular Graft
	Add	use Intraluminal Device, Branched or Fenestrated, One or Two Arteries in 04V
	Add	use Intraluminal Device, Branched or Fenestrated, Three or More Arteries in 04V

ICD-10-PCS Body Part Key Addenda

Axis 4		Body Part
Row		
Term		Hand Bursa and Ligament, Left
Term		Hand Bursa and Ligament, Right
Includes	Delete	Scapholunate ligament
Row		
Term		Wrist Bursa and Ligament, Left
Term		Wrist Bursa and Ligament, Right
Includes	Add	Scapholunate ligament

ICD-10-PCS Device Key Addenda

Axis 6		Device
Row		
Term		Intraluminal Device, Branched or Fenestrated, One or Two Arteries for Restriction in Lower Arteries
Includes	Delete	Cook Zenith AAA Endovascular Graft
Includes	Delete	Zenith AAA Endovascular Graft
Includes	Add	Cook Zenith(R) Fenestrated AAA Endovascular Graft
Includes	Add	Zenith(R) Fenestrated AAA Endovascular Graft
Row		

Term		Intraluminal Device, Branched or Fenestrated, Three or More Arteries for Restriction in Lower Arteries
Includes	Delete	Cook Zenith AAA Endovascular Graft
Includes	Delete	Zenith AAA Endovascular Graft
Includes	Add	Cook Zenith(R) Fenestrated AAA Endovascular Graft
Includes	Add	Zenith(R) Fenestrated AAA Endovascular Graft

Row

Term		Synthetic Substitute
Includes	Add	Barricaid(R) Annular Closure Device (ACD)

ICD-10-PCS Table Addenda

Medical and Surgical Section
Axis 5 Approach

Transvaginal Drainage of Pelvis

Source	Description	Code specification
2019, public comment & CMS internal review	In table 0W9 Drainage of General Anatomical Regions, add approach values 7, Via Natural or Artificial Opening and 8, Via Natural or Artificial Opening Endoscopic, applied to the body part value J, Pelvic Cavity, to identify when pelvic drainage is performed using a transvaginal approach.	0W9J[78][0Z][XZ] (6 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**W** Anatomical Regions, General
Operation	**9** Drainage: Taking or letting out fluids and/or gases from a body part

Body Part	*Approach*	*Device*	*Qualifier*
J Pelvic Cavity	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **ADD 7** Via Natural or Artificial Opening **ADD 8** Via Natural or Artificial Opening Endoscopic	**0** Drainage Device	**Z** No Qualifier
J Pelvic Cavity	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **ADD 7** Via Natural or Artificial Opening **ADD 8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**X** Diagnostic **Z** No Qualifier

Measurement and Monitoring Section
Axis 7 Qualifier

Intercompartmental Pressure Measurement

Source	Description	Code specification
2019, Coding Clinic Editorial Advisory Board & CMS internal review	In table 4A0 Measurement of Physiological Systems, create new qualifier E Compartment, applied to the body system value F, Musculoskeletal, the percutaneous approach, and the function value B Pressure, to identify percutaneous intercompartmental pressure measurement.	4A0F3BE (1 code)

EXAMPLE

Section **4** Measurement and Monitoring *Body System* **A** Physiological Systems *Operation* **0** Measurement: Determining the level of a physiological or physical function at a point in time			
Body System	*Approach*	*Function / Device*	*Qualifier*
F Musculoskeletal	**3** Percutaneous	**3** Contractility	**Z** No Qualifier
F Musculoskeletal	**3** Percutaneous	**ADD B** Pressure	**ADD E** Compartment
F Musculoskeletal	**X** External	**3** Contractility	**Z** No Qualifier

ICD-10-PCS Structure and Principles of Maintenance

ICD-10-PCS (PCS) Structure

- Multi-axial structure and hierarchy are attributes of PCS
- These attributes support coded data that is
    - more consistent in its definitions
    - easier to aggregate across areas of the classification

Multi-axial Attribute and the Meaning of "Character"

- Each axis in the 7-axis classification system (often referred to as "character") captures one type of information
- Limited to 34 possible values—the numbers 0 through 9 and all letters except I and O

PCS Table Excerpt: 021 Bypass of Heart and Great Vessels, first row

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Coronary Artery, One Artery **1** Coronary Artery, Two Arteries **2** Coronary Artery, Three Arteries **3** Coronary Artery, Four or More Arteries	**0** Open	**8** Zooplastic Tissue **9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**3** Coronary Artery **8** Internal Mammary, Right **9** Internal Mammary, Left **C** Thoracic Artery **F** Abdominal Artery **W** Aorta

Hierarchy and the Meaning of "Value"

- The term "value" refers to a specific instance of the type of information captured by a character/axis of classification
    - Value refers to both the letter or number **and** its accompanying text descriptor
    - In the Med/Surg section, the 4th character is *body part*, the value of the 4th character is a specific body part **Example: 6 Stomach**

PCS Table Excerpt: 0D16^^^ Bypass of Stomach

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*
6 Stomach	**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 **9** Duodenum **A** Jejunum **B** Ileum **L** Transverse Colon

The database that houses the ICD-10-PCS allows the 34 numbers and letters to mean different things in different tables. Body part value is the most common example where a number or letter means something different in a different table.

PCS Table Excerpt: 0016^^^ Bypass of Cerebral Ventricle

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 **A** Subgaleal Space **B** Cerebral Cisterns

PCS Table Excerpt: 0316^^^ Bypass of Left Axillary Artery

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*
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

Values in Context

- The fact that individual letters and numbers mean different things in different contexts is well known to PCS users
- Less well known is that, for the 6th and 7th characters, the "dependencies" are at the level of the PCS tables (first 3 letters/numbers, e.g. 031, 3E0, 4A1)
    - A value can only have one meaning—*one text description*—within a PCS table

Where 6th and 7th Character Detail is Most Frequently Requested

- PCS tables where new detail is most frequently requested
    - Section 0 Med/Surg—device values and qualifier values
    - Section 3, Administration—substance values and qualifier values
    - Section 5, Extracorporeal or Systemic Assistance and Performance—qualifier values

ICD-10-PCS Structure and Device Value

- Device value (6th character)—used to specify appliance/other material that is
  - Classified as a device within ICD-10-PCS
  - Left in the patient at the end of the procedure
- In each PCS table, the structure allows 34 unique device values
  - PCS tables were initially populated with general device values, and new device values typically identify and describe a more specific example of a general device value in the same table

Device Value History: Replacement of Lower Joints

- PCS table 0SR, Replacement of Lower Joints is used for joint replacement procedures such as hip and knee
- ICD-10-PCS' initial draft release was in 1998, and table 0SR contained three general device values
- Device value detail has been added three times since the initial draft:

1. Prior to ICD-10 implementation, four device values were added to further specify the joint prosthesis material (specific subtypes of Synthetic Substitute device value).
2. One device value was added October 1, 2017 for hip/knee prosthesis made of oxidized zirconium on polyethylene.
3. Four new device values were added for October 1, 2018: three device values for partial knee joint replacement, and one device value for hip/knee joint replacement using articulating spacer.

Device Value History: Table 0SR Replacement of Lower Joints

Year Introduced	Device Value
1998	0SR^^7 Autologous Tissue Substitute
1998	0SR^^J Synthetic Substitute
1998	0SR^^K Nonautologous Tissue Substitute
2014	0SR^^0 Synthetic Substitute, Polyethylene
2014	0SR^^1 Synthetic Substitute, Metal
2014	0SR^^2 Synthetic Substitute, Metal on Polyethylene
2014	0SR^^3 Synthetic Substitute, Ceramic
2014	0SR^^4 Synthetic Substitute, Ceramic on Polyethylene
2017	0SR^^6 Synthetic Substitute, Oxidized Zirconium on Polyethylene
2018	0SR^^E Articulating Spacer
2018	0SR^^L Synthetic Substitute, Unicondylar Medial
2018	0SR^^M Synthetic Substitute, Unicondylar Lateral
2018	0SR^^N Synthetic Substitute, Patellofemoral
????	0SR???

Limits on Use of a PCS Value

- Reminder: In each PCS table, 34 total letters/numbers are available for a value such as device value
- Each device value can only be used once in a PCS table
    - The fact that a device value in a PCS table applies to one body part in the table does not mean it can be reused for another body part in that table
    - **Example**: table 0SR, the device value specific to **knee** replacement (N Synthetic Substitute, Patellofemoral) cannot be re-used for a new device value specific to **ankle** replacement

Deleted PCS Values and Codes

- A PCS value (and all codes that use it) may be deleted from the classification to eliminate options that would/should never be used
    - Simplifies the classification
    - Eliminates the maintenance burden for vendors
- Stakeholders support eliminating options that would/should never be used
    - Value is clinically inappropriate in a particular PCS table
    - Device/substance did not get approved for use in the U.S. (investigational only)
- Stakeholders **do not** support re-using a previously deleted value
    - Can create problems with coded data for longitudinal analysis

PCS Structure and Qualifier Value

- Qualifier is used to specify additional detail about the procedure
    - A specific surgical technique
    - More detail about procedure site
- Like the device value, within a PCS table a qualifier value (letter/number) can only be used once, regardless of how narrowly or broadly applied in the table

Qualifier Value in Root Operation Bypass

- In the excerpt below, table 031 Bypass of Upper Arteries, qualifier values specify **a single type of information**
    - Target of a bypass procedure (the body part bypassed "to").
- Many of the 34 numbers/letters are already used
- As surgical advances enable vascular bypass to more distant sites, the remaining qualifiers are being used to capture **significant distinctions** among target vessels
    - Goal is for all upper artery bypass procedures—current and future—to be able to be captured accurately using available qualifiers
    - New qualifier values added in the last two update cycles have been less detailed values, to maximize their applicability and conserve remaining values

PCS Table Excerpts: 031 Bypass of Upper Arteries

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*
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 **FY 2019 T** Abdominal Artery **V** Superior Vena Cava **FY 2020 W** Lower Extremity Vein
H Common Carotid Artery, Right **J** Common Carotid Artery, Left	**0** Open	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**G** Intracranial Artery **J** Extracranial Artery, Right **K** Extracranial Artery, Left **FY 2019 Y** Upper Artery

Qualifier Values and Potential Coding Conflicts

- In other tables, qualifier values present a more complex challenge
- Qualifier values are used to specify more than one type of information, such as
  - More detail about the body part/site of the procedure
  - Further specify the surgical technique used
  - Specify some other aspect of the procedure, e.g. Temporary, Intraoperative, Diagnostic
- Because the qualifier can be used to specify more than one type of information there is potential for creating coding conflicts
  - Two qualifiers specify different aspects of the same procedure
  - Result: there is the potential for two codes to describe the same procedure equally accurately, but differ in the type of qualifier detail provided

Combination Qualifiers in PCS

- Qualifier conflicts can be avoided in the PCS tables by creating "combination qualifiers"
  - Where two qualifiers could apply to the same procedure a qualifier is created that specifies two aspects of a procedure
- **Example**: Combination qualifiers created in table 5A1 for ECMO procedures
- Three new combination qualifier values added for October 1, 2018
- New qualifiers enable capture of two types of detail in one code, thereby avoiding coding conflicts
  - Type of oxygenation support (membrane)
  - AND site of vascular access (central, peripheral VA, peripheral VV)
- Original, non-combination qualifier value was deleted

PCS Table Excerpt: 5A1 Performance

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

Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**2** Continuous	**2** Oxygenation	**FY 2019 DELETE 3** Membrane **FY 2019 ADD F** Membrane, Central **FY 2019 ADD G** Membrane, Peripheral Veno-arterial **FY 2019 ADD H** Membrane, Peripheral Veno-venous

Section 5 Qualifier Usage

- To date, 17 of 34 qualifiers in table 5A1 have been used
- All qualifiers so far (except Z No Qualifier) are specific to one 4th character body system value and one 6th character function value
    - Cardiac and Output
    - Circulatory and Oxygenation
    - Respiratory and Ventilation

Section 5 Qualifier Use to Date

Qualifier Value	Applicable Body System (4th character)	Applicable Body Function (6th character)
5^^^^^0 Balloon Pump	Cardiac	Output
5^^^^^2 Manual	Cardiac	Output
5^^^^^5 Pulsatile Compression	Cardiac	Output
5^^^^^6 Other Pump	Cardiac	Output
5^^^^^D Impeller Pump	Cardiac	Output
5^^^^^1 Hyperbaric	Circulatory	Oxygenation
DELETED 5^^^^^3 Membrane	Circulatory	Oxygenation
5^^^^^C Supersaturated	Circulatory	Oxygenation
5^^^^^F Membrane, Central	Circulatory	Oxygenation
5^^^^^G Membrane, Peripheral Veno-arterial	Circulatory	Oxygenation
5^^^^^H Membrane, Peripheral Veno-venous	Circulatory	Oxygenation
5^^^^^4 Nonmechanical	Respiratory	Ventilation
5^^^^^7 Continuous Positive Airway Pressure	Respiratory	Ventilation
5^^^^^8 Intermittent Positive Airway Pressure	Respiratory	Ventilation
5^^^^^9 Continuous Negative Airway Pressure	Respiratory	Ventilation
5^^^^^B Intermittent Negative Airway Pressure	Respiratory	Ventilation
5^^^^^Z No Qualifier	Multiple body systems	Multiple functions

A Role for Section X: Extending Longevity for ICD-10-PCS Tables

- In some PCS tables, many of the 34 letters/numbers have been used
- The challenge is to use the remaining letters and numbers in ways that produce useful distinctions in the coded data for a significant period of time
- It is often difficult to predict whether a proposed new PCS value will be useful in the data
- Where there is doubt about using a remaining letter or number for a proposed new PCS value, section X can maximize the usefulness of the values used in the other PCS tables

Section X History

- Section X was added to the ICD-10-PCS effective FY 2016
- At the time it was introduced, CMS stated that section X could be used to support the NTAP program as well other new procedures and technologies
- Intentionally designed with structure that differs from other PCS tables
    - More flexible because of the New Technology Group # in the 7th character
    - Virtually unlimited capacity for new values/codes

Section X Uses

- Section X value can be used to capture desired specificity in the data without permanently using letters/numbers in other PCS tables
- Codes can be created in section X to gather very specific data about a new procedure/technology
- This data can be used to more confidently assess the usefulness of adding new values/codes permanently to one of the other PCS sections. For example:
    - Has the device, surgical technique or other distinction been approved/adopted for use in the U.S.?
    - Would a new PCS value be a meaningful distinction to capture for inpatient hospital data?
    - Is this level of procedure detail adequately documented so the distinction specified in the new PCS value can be coded?

PCS Table Examples: Section X

Section **X** New Technology *Body System* **2** Cardiovascular System *Operation* **C** Extirpation: Taking or cutting out solid matter from a body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Coronary Artery, One Artery **1** Coronary Artery, Two Arteries **2** Coronary Artery, Three Arteries **3** Coronary Artery, Four or More Arteries	**3** Percutaneous	**6** Orbital Atherectomy Technology	**1** New Technology Group 1

Section **X** New Technology *Body System* **2** Cardiovascular System *Operation* **R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
F Aortic Valve	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**3** Zooplastic Tissue, Rapid Deployment Technique	**2** New Technology Group 2

Section	**X** New Technology
Body System	**H** Skin, Subcutaneous Tissue, Fascia and Breast
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
P Skin	**X** External	**L** Skin Substitute, Porcine Liver Derived	**2** New Technology Group 2

Section	**X** New Technology
Body System	**N** Bones
Operation	**S** Reposition: Moving to its normal location, or other suitable location, all or a portion of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Lumbar Vertebra **3** Cervical Vertebra **4** Thoracic Vertebra	**0** Open **3** Percutaneous	**3** Magnetically Controlled Growth Rod(s)	**2** New Technology Group 2

A Possible Role for Section 8: Future Needs of ICD-10-PCS

- It is difficult to predict if/when a new procedure coding system (or a new version of the current system) will be adopted for use in the U.S.
- Meanwhile, medical technology and technique continues to evolve
- Section 8 is a section that is essentially unused
    - Contains one root operation, "Other Procedures"
    - Currently, this one root operation classifies "replicated" ICD-9 codes and assorted ancillary procedures

Section	**8** Other Procedures
Body System	**C** Indwelling Device
Operation	**0** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease

Body Region	*Approach*	*Method*	*Qualifier*
1 Nervous System	**X** External	**6** Collection	**J** Cerebrospinal Fluid **L** Other Fluid
2 Circulatory System	**X** External	**6** Collection	**K** Blood **L** Other Fluid

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*
1 Nervous System **U** Female Reproductive System	**X** External	**Y** Other Method	**7** Examination
2 Circulatory System	**3** Percutaneous	**D** Near Infrared Spectroscopy	**Z** No Qualifier
9 Head and Neck Region	**0** Open	**C** Robotic Assisted Procedure	**Z** No Qualifier
9 Head and Neck Region	**0** Open	**E** Fluorescence Guided Procedure	**M** Aminolevulinic Acid **Z** No Qualifier
9 Head and Neck Region	**3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**C** Robotic Assisted Procedure **E** Fluorescence Guided Procedure	**Z** No Qualifier
9 Head and Neck 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	**X** External	**C** Robotic Assisted Procedure	**Z** No Qualifier
9 Head and Neck Region	**X** External	**Y** Other Method	**8** Suture Removal
H Integumentary System and Breast	**3** Percutaneous	**0** Acupuncture	**0** Anesthesia **Z** No Qualifier
H Integumentary System and Breast	**X** External	**6** Collection	**2** Breast Milk
H Integumentary System and Breast	**X** External	**Y** Other Method	**9** Piercing
K Musculoskeletal System	**X** External	**1** Therapeutic Massage	**Z** No Qualifier
K Musculoskeletal System	**X** External	**Y** Other Method	**7** Examination
V Male Reproductive System	**X** External	**1** Therapeutic Massage	**C** Prostate **D** Rectum
V Male Reproductive System	**X** External	**6** Collection	**3** Sperm
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 **E** Fluorescence Guided Procedure	**Z** No Qualifier
W Trunk Region	**X** External	**B** Computer Assisted Procedure	**F** With Fluoroscopy **G** With Computerized Tomography **H** With Magnetic Resonance Imaging **Z** No Qualifier
W Trunk Region	**X** External	**C** Robotic Assisted Procedure	**Z** No Qualifier
W Trunk Region	**X** External	**Y** Other Method	**8** Suture Removal
X Upper Extremity **Y** Lower Extremity	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Robotic Assisted Procedure **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
X Upper Extremity **Y** Lower Extremity	**X** External	**C** Robotic Assisted Procedure	**Z** No Qualifier
X Upper Extremity **Y** Lower Extremity	**X** External	**Y** Other Method	**8** Suture Removal
Z None	**X** External	**Y** Other Method	**1** In Vitro Fertilization **4** Yoga Therapy **5** Meditation **6** Isolation