DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
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
Virtual Meeting
ICD-10-PCS Topics
March 9, 2021

Zoom Webinar and Dial-In Information

- This meeting will be conducted via Zoom Webinar. The URL to join the Zoom Webinar, the password, and the call-in numbers are the same for both days of the meeting. Meeting details for each day are as follows.
- Day 1: March 9, 2021: 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.
- Day 2: March 10, 2021: 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.

To minimize feedback to the maximum extent possible, join the meeting using only **ONE** of the options listed below.

Option 1: Remote participants (attendees wishing to both view slides and ask questions during the Q&A portions of the meeting) must join the Zoom Webinar via the web. To join this Zoom Webinar conference from a PC, MAC, iPad, iPhone or Android device as well as, connect to the audio portion of the conference:

Click the following URL:
https://cms.zoomgov.com/j/1600784651?pwd=MEZLdWhJVGZLajV2eDF0ck4zbjBtdz09
Passcode: 798401

Option 2: Dial-in access is available for listen-only participants. Listen-only participants are participants who wish to only listen to the meeting and do not wish to comment or ask questions during the Q&A portions of the meeting.

1. From your phone, dial U.S.*: 669-254-5252 or 646-828-7666 or 833-568-8864 (Toll Free)
2. Enter the webinar ID: 160 078 4651

*If dialing in from outside of the U.S., visit https://cms.zoomgov.com/u/abTTQHnQHa for a list of Zoom International Dial-in Numbers.

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1. From your room system, dial 161.199.138.10 (US West) or 161.199.136.10 (US East)
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   Passcode: 798401

   SIP: 1600784651@sip.zoomgov.com
   Passcode: 798401

If you experience technical difficulties during the meeting, please contact Theresa Eddins for assistance at theresa.eddins@cms.hhs.gov or 212-616-2527.

Those participating in the Zoom Webinar may ask questions during the Q&A portions of the meeting using the "Raise Your Hand" feature. If time does not permit you to comment or ask a question during the Q&A session, you may submit comments and questions at any time using the "Q&A" feature. All comments and questions submitted using the "Q&A" feature, along with CMS' responses to them, will be posted as soon as possible after the meeting in the "Downloads" section of the CMS web page located at: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials. Remaining questions may be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov.

Note: Proposals for diagnosis code topics are scheduled for March 10, 2021 and will be led by the Centers for Disease Control and Prevention (CDC). Please visit CDC's website for the Diagnosis agenda located at the following address: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm.

Registration for the meeting:
Information on registering can be found at: https://www.eventbrite.com/e/icd-10-coordination-and-maintenance-committee-meeting-tickets-139023385689
***Please note that registration is not required to attend the Zoom Webinar. However, we are providing the ability to register on-line for those required to provide proof of attendance for continuing education purposes.**

Registration for the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee Meeting opened on Monday, February 1, 2021 and closed on Monday, March 1, 2021.

For questions about the registration process, please contact Mady Hue at 410-786-4510 or marilu.hue@cms.hhs.gov or Andrea Hazeley at 410-786-3543 or andrea.hazeley@cms.hhs.gov.

Introductions & Overview 9:00 AM – 9:10 AM	Mady Hue, CMS
ICD-10-PCS Topics:	
1. Administration of Trilaciclib* Pages 15-16	Mady Hue, CMS G1 Therapeutics, Inc.
2. Administration of ZEPZELCA™ (lurbinectedin)* Pages 17-19	Andrea Hazeley, CMS Jazz Pharmaceuticals
3. Administration of ENSPRYNG™ (satralizumab-mwge)* Pages 20-21	Andrea Hazeley, CMS Genentech, Inc.
4. Administration of ciltacabtagene autoleucel (cilta-cel)* Pages 22-23	Andrea Hazeley, CMS Janssen Biotech, Inc.
5. Administration of Amivantamab* Pages 24-25	Mady Hue, CMS Janssen Biotech, Inc.
6. Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC)* Pages 26-28	Mady Hue, CMS Cerus Corporation

CMS modified the approach for presenting the new technology add-on payment (NTAP) related ICD-10-PCS procedure code requests listed above that involve the administration of a therapeutic agent for the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee meeting, due to the high volume of NTAP applications and corresponding procedure code requests being considered for FY 2022. Consistent with the requirements of section 1886(d)(5)(K)(iii) of the Social Security Act, applicants submitted requests to create a unique procedure code to describe the administration of a therapeutic agent, such as the option to create a new code in Section X within the ICD-10-PCS procedure code classification. In order to accommodate all of the requests received for the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee meeting, CMS initially only displayed the Agenda and related materials associated with the above NTAP-related ICD-10-PCS procedure code requests that involve the administration of a therapeutic agent.

The slide presentations and Q&A document for these procedure code topics are available at: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.

7. Administration of OTL-103 Pages 29-31 9:10 AM – 9:25 AM	Andrea Hazeley, CMS Kent Christopherson, PHD Senior National Director, US Medical Affairs Orchard Therapeutics Milda Kaitz, CPC, CPC-I, CPMA Associate Director, Reimbursement & Policy Insights Xcenda
8. Administration of OTL-200 Pages 32-34 9:25 AM – 9:40 AM	Andrea Hazeley, CMS Kent Christopherson, PHD Senior National Director, US Medical Affairs Orchard Therapeutics Milda Kaitz, CPC, CPC-I, CPMA Associate Director, Reimbursement & Policy Insights Xcenda
9. Application of Topical Agent for Non-Excisional Eschar Removal* Pages 35-36 9:40 AM – 9:55 AM	Andrea Hazeley, CMS Brad Rubin Director, Commercial Strategy and Analytics Vericel Corporation Jon Hopper Chief Medical Officer Vericel Corporation
10. Application of Bioengineered Allogeneic Construct* Pages 37-39 9:55 AM – 10:10 AM	Andrea Hazeley, CMS Helen D. Hahn, B.S.N., M.B.A. Director Medical Affairs Regenerative Medicine Mallinckrodt Pharmaceuticals Janice Smiell, M.D. Sr. Director Medical Affairs Regenerative Medicine Mallinckrodt Pharmaceuticals

11. Computer-Aided Assessment and Characterization Software for Head CT Scan* Pages 40-42 10:10 AM – 10:25 AM	Andrea Hazeley, CMS Dr. Greg Albers Professor of Neurology Stanford University Co-Founder RapidAI Julie Nadeau Director of Reimbursement RapidAI
12. Total Artificial Heart Systems Pages 43-46 10:25 AM – 10:40 AM	Mady Hue, CMS Michael Mack, MD Medical Director Cardiothoracic Surgery Baylor Scott & White Health
13. Computer-Aided Triage and Notification Software for Computed Tomography Pulmonary Angiography (CTPA)* Pages 47-49 10:40 AM – 10:55 AM	Mady Hue, CMS Paul Radensky, MD, JD Principal McDermott+Consulting Elad Walach CEO and Co-Founder Aidoc
14. April 1 Code Implementation Pages 50-53 10:55 AM – 11:10 AM	Mady Hue, CMS
15. Transthoracic Echocardiography with Computer-Aided Image Acquisition* Pages 54-56 11:10 AM – 11:25 AM	Andrea Hazeley, CMS Deborah Godes Senior Director McDermott+Consulting Yngvil Kloster Thomas Head of Medical Affairs and Clinical Development Caption Health
16. Tissue Oxygen Saturation Imaging of GI Tract* Pages 57-59 11:25 AM – 11:40 AM	Mady Hue, CMS Paul G. Curcillo, MD, FACS Chief, Division of MIS Associate Professor, Department of Surgical Oncology Fox Chase Cancer Center, Temple University

17. Computer-Aided Mechanical Aspiration Thrombectomy*
    Pages 60-66
    11:40 AM – 11:55 AM

    Mady Hue, CMS
    Corey Teigen, MD
    Chief Technology Officer
    Penumbra

18. Transcatheter Replacement of Pulmonary Valve*
    Pages 67-70
    11:55 AM – 12:10 PM

    Mady Hue, CMS
    Matthew Gillespie, MD
    Director, Cardiac Catheterization Laboratory and Professor of Pediatrics
    The Children's Hospital of Philadelphia and Perelman School of Medicine, University of Pennsylvania

19. Combined Thoracic Aortic Arch Replacement and Descending Thoracic Aorta Restriction*
    Pages 71-73
    12:10 PM – 12:25 PM

    Mady Hue, CMS
    Joseph S. Coselli, MD
    Professor, Vice Chair, Division of Cardiothoracic Surgery
    Baylor College of Medicine
    Texas Heart Institute

    Scott A. LeMaire, MD
    Professor of Surgery and Molecular Physiology and Biophysics
    Vice Chair for Research, Michael E. DeBakey Department of Surgery
    Baylor College of Medicine
    Texas Heart Institute

LUNCH BREAK 12:30 PM to 1:30 PM

20. Coronary Intravascular Lithotripsy (IVL)*
    Pages 74-75
    1:30 PM – 1:45 PM

    Andrea Hazeley, CMS
    Rob Fletcher
    Vice President of Marketing and Reimbursement
    Shockwave Medical, Inc

21. Percutaneous Creation of an Arteriovenous Fistula (AVF)* Pages 76-77 1:45 PM – 2:00 PM	Mady Hue, CMS Thomas A. Gustafson, Ph.D. Senior Policy Advisor Arnold & Porter Gene Reu Executive Vice President Avenu Medical
22. Pharyngeal Electrical Stimulation* Pages 78-80 2:00 PM – 2:15 PM	Andrea Hazeley, CMS Cari Manypenny, M.S., CCC-SLP Manager Clinical Development Phagenesis
23. Measurement of Flow in a Cerebral Fluid Shunt Pages 81-83 2:15 PM – 2:30 PM	Andrea Hazeley, CMS Dr. Matthew Potts, M.D. Assistant Professor of Neurological Surgery Northwestern University - The Feinberg School of Medicine Dr. Adam Zysk, Ph.D. SVP Innovation & Development Rhaeos Inc.
24. Colonic Irrigation for Colonoscopy* Pages 84-85 2:30 PM – 2:45 PM	Mady Hue, CMS Mark Pomeranz, MS President and COO Motus GI
25. Mechanical Initial Specimen Diversion of Whole Blood Using Active Negative Pressure* Pages 86-88 2:45 PM – 3:00 PM	Mady Hue, CMS Greg Bullington CEO and Co-Founder Magnolia Medical Technologies
26. Concurrent Measurement of mRNA, PCR test and Detection of Antibodies* Pages 89-90 3:00 PM – 3:15 PM	Andrea Hazeley, CMS Jeff June CEO Ischemia Care Lena Chaihorsky VP, Payor Innovation Alva 10

27. Regional Anticoagulation for Renal Replacement Therapy* Pages 91-94 3:15 PM – 3:30 PM	Mady Hue, CMS Lakhmir Chawla, MD Nephrologist and Intensivist Lowell Therapeutics, Inc. James Wilkie, CEO Lowell Therapeutics, Inc.
28. Gene Expression Assay Pages 95-96 3:30 PM – 3:45 PM	Andrea Hazeley, CMS Roy F. Davis, M.D., Ph.D., M.H.A. Chief Medical Officer Immunexpress, Inc.
29. Single-use Intraluminal Closure System for Gastrointestinal Procedures Pages 97-99 3:45 PM – 4:00 PM	Andrea Hazeley, CMS Dr. Christopher Gostout Chief Medical Officer Apollo Endosurgery Tiffanie Gilbreth VP Clinical & Medical Affairs Apollo Endosurgery
30. Section X Updates Pages 100-108 4:00 PM – 4:15 PM	Mady Hue, CMS
31. Addenda and Key Updates Pages 109-115 4:15 PM – 4:30 PM	Andrea Hazeley, CMS
32. Patient Specific Intervertebral Body Fusion* Pages 116-117 4:30 PM – 4:45 PM	Mady Hue, CMS Jeffrey S. Roh, MD Orthopedic Spine Surgeon Swedish Medical Center
Closing Remarks 4:45 PM	

**Requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022.*

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

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

ICD-10 TIMELINE

A timeline of important dates in the ICD-10 process is described below: (this does not reflect April 1 discussion – See Sample Timeline provided for that topic beginning on page 50)

March 9-10, 2021	ICD-10 Coordination and Maintenance Committee Meeting.
March 2021	Recordings and slide presentations of the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
April 1, 2021	There were no ICD-10 codes finalized to capture new diagnoses or new technology for implementation on April 1, 2021. Therefore, there will be no new ICD-10 diagnosis or procedure codes implemented on April 1, 2021.
April 9, 2021	**Deadline for receipt of public comments on proposed new procedure codes and revisions discussed at the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2021**.
April 2021	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 FY 2022 ICD-10-CM diagnosis and ICD-10-PCS procedure codes finalized 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
May/June 2021	Final addendum for FY 2022 code updates 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 11, 2021	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting, must have their requests submitted to CMS for procedures and NCHS for diagnoses.**
July 2021	Federal Register notice for the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting is anticipated to be published and will include the tentative agenda.
August 2021	Hospital Inpatient Prospective Payment System final rule expected 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, 2021. This rule can be accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html
August 2021	Tentative agenda for the Procedure portion of the September 14, 2021 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 portion of the September 15, 2021 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the NCHS webpage at - https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm
August 9, 2021	**On-line registration opens for the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting at:** https://www.eventbrite.com/e/icd-10-coordination-and-maintenance-committee-meeting-tickets Please note that this meeting is anticipated to be conducted virtually and registration is not required to attend. However, we are providing the ability to register on-line for those required to provide proof of attendance for continuing education purposes. The on-line registration will be available through September 9, 2021.
September 14-15, 2021	The September 2021 ICD-10 Coordination and Maintenance Committee Meeting is anticipated to be fully virtual by zoom and dial-in.
September 2021	Recordings and slide presentations of the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages:

	Diagnosis code portion of the recording and related materials– https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
October 1, 2021	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-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 15, 2021	**Deadline for receipt of public comments on proposed new codes discussed at the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2022.**
November 2021	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, 2022 will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/
November 15, 2021	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2022.**

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, 2021
- No final decisions are made at the meeting
- CMS will describe options and recommendations to facilitate discussion
- Public can comment during the meeting and send written comments

Comments on Code Proposals

- Submit written comments by
  - April 9, 2021 for procedure codes discussed at the March 9-10, 2021 C&M meeting
  - May 10, 2021 for diagnosis codes discussed at the March 9-10, 2021 C&M meeting
- Procedure comments to CMS ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to NCHS nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2021 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2021 C&M meeting
- August 2021 – Final rule with links to final codes to be implemented October 1, 2021
  - Includes any additional codes approved from March 9-10, 2021 C&M meeting
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS

Addendum

- May/June 2021 – Final code updates and addendum posted
  - FY 2022 ICD-10-PCS (Procedures) http://www.cms.gov/Medicare/Coding/ICD10/index.html
  - FY 2022 ICD-10-CM (Diagnoses) http://www.cdc.gov/nchs/icd/icd10cm.htm

Public Participation

- For this fully virtual meeting, the public may participate in the following ways:
  - Participate via Zoom Webinar.
  - Listen to proceedings through free conference lines
  - Listen to recordings, review transcripts, and view slide presentations

- CMS & CDC hope this provides greater opportunity for public participation

Written Comments

- No matter how you participate – please send written comments by
  - April 9, 2021 for codes to be implemented on October 1, 2021
  - May 10, 2021 for diagnosis codes to be implemented on October 1, 2022
  - 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, 2021 implementation

September 14-15, 2021 C&M Code Requests

- June 11, 2021 – Deadline for submitting topics for September 14-15, 2021 C&M meeting
  - Procedure requests to CMS ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis requests to NCHS nchsicd10cm@cdc.gov

Administration of Trilaciclib

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of Trilaciclib.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food and Drug Administration (FDA) Approval? No. Marketing authorization has not yet been granted for trilaciclib but is anticipated by the Prescription Drug User Fee Act (PDUFA) target action date of February 15, 2021. Trilaciclib was granted Priority Review and Breakthrough Therapy Designation for the mitigation of clinically significant chemotherapy-induced myelosuppression in adult patients with small cell lung cancer (SCLC).

Background: Myelosuppression is a condition in which bone marrow activity is decreased resulting in fewer erythrocytes, leukocytes, and thrombocytes. Myelosuppression is one of the most common treatment-related adverse events (AE) in patients receiving systemic chemotherapy. According to the requestor, trilaciclib is a myelopreservation therapy that has the potential to mitigate chemotherapy induced myelosuppression (CIM) in SCLC patients receiving regimens containing platinum + etoposide +/- checkpoint inhibitor; or a topotecan-containing regimen.

Description of Trilaciclib
Trilaciclib is a selective, transient inhibitor of cyclin dependent kinases 4 and 6 (CDK4/6) with chemoprotective activities. The CDK4/6 enzyme pathway is a key regulator of the cell cycle.[1]

Mechanism of Action
According to the requestor, trilaciclib arrests hematopoietic stem and progenitor (HSPCs) bone marrow cells, in the G1 phase of the cell cycle during chemotherapy exposure, protecting them from chemotherapy-induced damage. Trilaciclib studies show it reduces CIM in patients with extensive-stage small-cell lung cancer (ES-SCLC).[2] The requestor also noted that in patients with CDK4/6-independent tumor cells, G1T28 may protect against multi-lineage CIM by transiently and reversibly inducing G1 cell cycle arrest in HSPCs and preventing transition to the S phase. This protects all hematopoietic lineages, including red blood cells, platelets, neutrophils and lymphocytes, from the DNA-damaging effects of certain chemotherapeutics and preserves the function of the bone marrow and the immune system.

Inpatient Administration of Trilaciclib
Trilaciclib is given via intravenous (IV) administration 30 minutes before chemotherapy on the days chemotherapy is given to reduce the treatment associated side effects which include neutropenia, anemia, thrombocytopenia, and the need for supportive care interventions and hospitalizations.[3,4] The requestor stated trilaciclib should be administered at a dose of 240 mg/m2

[1] Goel S, DeCristo MJ, McAllister SS, Zhao JJ. CDK4/6 inhibition in cancer: beyond cell cycle arrest. Trends Cell Biol. 2018;28(11):911-925.

[2] Donjerkovic D, Scott DW. Regulation of the G1 phase of the mammalian cell cycle. *Cell Res.* 2000;10(1):1-16.

[3] Weiss J, Gwaltney C, Daniel D, et al. Positive effects of trilaciclib on patient myelosuppression-related symptoms and functioning: Results from three phase 2 randomized, double-blind, placebo-controlled small cell lung cancer trials. Poster presented at: Multinational Association of Supportive Care in Cancer (MASCC)/International Society of Oral Oncology (ISOO); June21-23, 2019; San Francisco, CA.

[4] Ferrarotto R, Anderson I, Medgyasszay B, et al. Trilaciclib reduces the need for growth factors and red blood cell transfusions to manage chemotherapy-induced myelosuppression. Poster presented at: IASLC: 2020 North America Conference on Lung Cancer; October 16-17, 2020; Virtual congress

as a 30-minute IV infusion no more than 4 hours prior to chemotherapy on each day chemotherapy is administered. Patients treated with trilaciclib are generally treated with 4 cycles of 21 days each, where days 1-3 of the cycle involve chemotherapy with a dose of trilaciclib administered in conjunction with the chemotherapy. This is followed by an 18-day treatment holiday. Dosing is based on body surface area, 240 mg/m2, with an average of 2 vials per patient. Vials are 300mg.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of trilaciclib. Facilities can report the intravenous administration of trilaciclib using the following codes:

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

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of trilaciclib. Continue coding as listed in current coding.

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

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 7** Trilaciclib	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Administration of ZEPZELCA™ (lurbinectedin)

Issue: Currently, there are no unique ICD-10-PCS codes to describe the administration of ZEPZELCA™ (lurbinectedin).

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food and Drug Administration (FDA) Approval? Yes. The FDA approved the New Drug Application (NDA) for ZEPZELCA™ (lurbinectedin) on June 15, 2020, under the FDA's Accelerated Approval Program.

Background: Small cell lung cancer (SCLC) is the most aggressive form of lung cancer, characterized by rapid growth, early metastasis and rapid development of resistance to therapy. Most cases of SCLC occur in individuals aged 60-80 years. Risk factors for the development of SCLC can be patient-related or environment-related (e.g. asbestos exposure). The major patient-related risk factors include smoking, aged ≥65 years, and previous history of lung cancer. Approximately 60-70% of patients with SCLC have clinically disseminated or extensive disease at diagnosis. Many patients with SCLC have substantial comorbidities that may affect performance status and treatment options.

Although SCLC shows high sensitivity to first-line chemotherapy and radiotherapy, most patients relapse or progress within one year of treatment. The majority of SCLC treated patients relapse, however few options exist for treatment of patients with SCLC after failure of first-line therapy. Without second-line chemotherapy, the median survival time is 2 to 4 months. There have been no approved treatments for second-line treatment of SCLC since 1998, when Hycamtin (topotecan) was approved. Given that most cases of SCLC occur in individuals aged 60-80 years, this is a challenging risk-benefit profile that warrants additional second-line treatment options.

Description of ZEPZELCA™ (lurbinectedin)
ZEPZELCA™ (lurbinectedin) is indicated for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy. ZEPZELCA™ (lurbinectedin) is the first second-line treatment option for SCLC approved since 1998.

According to the requestor, ZEPZELCA™ (lurbinectedin) provides an improvement for treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy over safety results previously reported in the literature for a comparable patient population. Additionally, ZEPZELCA™ may represent a valuable clinical alternative to platinum rechallenge.[1,2] ZEPZELCA™ (lurbinectedin) safety data was reported by Trigo et al, 2020[3] as acceptable and manageable, where treatment-related SAEs occurred in 10.5% of patients; neutropenia and febrile neutropenia were most common (5%) each. Dose administration was

[1] Subbiah V, et al. Activity of lurbinectedin in second-line SCLC patients who are candidates for platinum rechallenge IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16-17, 2020.
[2] Subbiah V, et al. Activity in second-line SCLC patient candidates for platinum rechallenge. ESMO (European Society for Medical Oncology) 2020 Congress; September 19-21, 2020. Poster 1784P.
[3] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncology*. www.thelancet.com/oncology, Published online March 27, 2020. https://doi.org/10.1016/S1470-2045.

delayed in 23 (22%) patients and reduced in 28 (26%) because of treatment-related AEs; a low discontinuation rate of 2%. Trigo et al, 2020 noted that, compared with topotecan (despite the use of primary G-CSF prophylaxis in topotecan studies), ZEPZELCA™ (lurbinectedin)

- did not lead to any treatment related deaths (vs 7.9% to 11.2% for topotecan)
- had a lower rate of discontinuations due to treatment-related toxicity (2% vs 27%)
- lower grade 3/4 anemia (9% vs 26.1 to 30.5%), neutropenia (46% vs 53.8 to 78.4%), and thrombocytopenia (7% vs 45.5 to 54.3%)
- had a lower incidence of febrile neutropenia (5% vs 3 to 22.7%, in SCLC population)

Mechanism of Action
ZEPZELCA™ (lurbinectedin), a transcription inhibitor and a synthetic marine-derived agent represents an innovative approach to conventional anti-cancer drugs, with a mechanism of action based on reducing transcription-dependent replication stress and genome instability in tumor cells. ZEPZELCA™ (lurbinectedin):

- Selectively suppresses the expression oncogenic target genes and proteins
- Selectively inhibits oncogenic transcription of DNA to RNA via the dual action of RNA polymerase II degradation and the formation of DNA breaks, which leads to apoptosis
- Impacts the tumor microenvironment through multiple interactions
- Shown to induce immunogenic cell death

Inpatient Administration of ZEPZELCA™ (lurbinectedin)
ZEPZELCA™ (lurbinectedin) is administered intravenously as a 3.2 mg/m2 dose over the course of one hour, repeated every 21 days until disease progression or unacceptable toxicity. ZEPZELCA™ is expected to be primarily administered in the outpatient setting. In some cases, treatment initiation with the first infusion and possibly some additional infusions will be administered in the inpatient hospital setting. Many patients with SCLC have substantial comorbidities that may necessitate their hospitalization and initiation of SCLC treatment while in the inpatient setting.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of ZEPZELCA™ (lurbinectedin). Facilities can report the intravenous administration of ZEPZELCA™ (lurbinectedin) with one of the following ICD-10-PCS codes:

3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04305	Introduction of other antineoplastic into central vein, percutaneous approach

Coding Options
Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of ZEPZELCA™ (lurbinectedin). Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the intravenous infusion of ZEPZELCA™ (lurbinectedin).

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 8** Lurbinectedin	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Administration of ENSPRYNG™ (satralizumab-mwge)

Issue: Currently, there are no unique ICD-10-PCS codes to describe the administration of ENSPRYNG™ (satralizumab-mwge).

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food and Drug Administration (FDA) Approval? Yes. ENSPRYNG™ (satralizumab-mwge) received FDA approval for the treatment of Neuromyelitis Optica Spectrum Disorder (NMOSD) in adult patients who are AQP4-IgG positive on August 14, 2020.

Background: Neuromyelitis Optica Spectrum Disorder (NMOSD) is a rare, inflammatory, potentially life-threatening autoimmune central nervous system (CNS) disorder characterized primarily by severe, unpredictable relapses of optic neuritis and/or acute longitudinally extensive transverse myelitis (LETM). The primary disease pathology is autoimmune astrocytopathy, and astrocytic damage is a common NMOSD CNS clinical finding. About 70% of NMOSD patients are seropositive for AQP4-IgG, which is derived from peripheral plasma cells and binds to AQP4, the most abundant water channel membrane protein expressed in astrocytes and concentrated in spinal cord gray matter and the periaqueductal and periventricular regions.

NMOSD prevalence is estimated at around 0.1-10 per 100,000 individuals, affecting nearly 15,000 individuals in the United States. Individuals with NMOSD can experience recurring, successively more serious relapses. The vast majority of untreated patients (80%-90%) experience repeated relapses, and disability accumulates with each relapse. Around 60% of patients relapse within one year of diagnosis, and 90% relapse within three years. Compared with patients who experience an isolated attack, patients with relapsing disease have greater disease-related clinical burden, and upward of 83% of patients do not fully recover after subsequent relapses.

According to the requestor, there are a limited number of treatment guidelines available for NMOSD. The most recent US treatment guidelines were developed more than seven years ago, prior to any approved therapies for NMOSD. Therefore, US NMOSD treatment guidelines recommend exclusively off-label drugs such as azathioprine, with or without prednisone; mycophenolate mofetil, with or without prednisone; rituximab; or prednisone alone.

Description of ENSPRYNG™ (satralizumab-mwge)
ENSPRYNG™ (satralizumab-mwge) is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of NMOSD in adult patients who are anti-aquaporin-4 antibody (AQP4-IgG) positive. ENSPRYNG™ (satralizumab-mwge) is the first subcutaneous, the first self-administered, and the third of only three FDA-approved drugs available for NMOSD. The two other FDA-approved therapies for patients with AQP4-IgG positive NMOSD are Soliris (eculizumab) and Uplizna (inebilizumab-cdon).

The efficacy and safety of ENSPRYNG™ (satralizumab-mwge) were evaluated in SAkuraStar

and SAkuraSky[1,2] two distinct Phase 3, randomized, placebo-controlled, multicenter, double-blind studies with open-label extensions. In the SAkuraStar trial, the time to the first relapse was significantly longer in ENSPRYNG™ (satralizumab-mwge)-treated patients compared with patients who received a placebo. In addition, the time to the first relapse was significantly longer in patients treated with ENSPRYNG™ (satralizumab-mwge) plus immunosuppressive therapy (IST) compared with patients who received a placebo plus IST. In the double-blind period of the SAkuraSky trial, a lower proportion of patients in the ENSPRYNG™ (satralizumab-mwge) plus IST group had at least one adverse event compared to the placebo plus IST group (37 patients (90%) in the Enspryng plus IST group compared to 40 (95%) in the placebo plus IST group). The most common adverse reactions (incidence at least 15%) were nasopharyngitis, headache, upper respiratory tract infection, gastritis, rash, arthralgia, extremity pain, fatigue, and nausea.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of ENSPRYNG™ (satralizumab-mwge). Facilities can report the administration of ENSPRYNG™ (satralizumab-mwge) using the following code.

3E013GC Introduction of other therapeutic substance into subcutaneous tissue, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the administration of ENSPRYNG™ (satralizumab-mwge). Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the subcutaneous injection of ENSPRYNG™ (satralizumab-mwge).

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
1 Subcutaneous Tissue	**3** Percutaneous	**ADD 9** Satralizumab-mwge	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

[1] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med.. 2019;381(22)2114-2124. doi:10.1056/nejmoa1901747.

[2] Traboulsee A, Greenberg BM, Bennett JL, et al. Safety And Efficacy of Satralizumab Monotherapy In Neuromyelitis Optica Spectrum Disorder: A Randomised, Double-Blind, Multicentre, Placebo-Controlled Phase 3 Trial. Lancet Neurol. 2020;19(5):402-412. doi:10.1016/S1474-4422(20)30078-8.

Administration of ciltacabtagene autoleucel (cilta-cel)

Issue: There are no unique ICD-10-PCS codes to describe the administration of ciltacabtagene autoleucel (cilta-cel), an autologous chimeric-antigen receptor (CAR) T-cell therapy.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food and Drug Administration (FDA) Approval? Cilta-cel was granted Breakthrough Therapy designation for the treatment of relapsed or refractory multiple myeloma in December 2019. The requestor will be seeking approval for a Biologics License Application (BLA).

Background: Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells. In 2020, it is estimated that more than 32,000 people were diagnosed and nearly 13,000 died from multiple myeloma in the US. Multiple myeloma is associated with substantial morbidity and mortality and approximately 25% of patients have a median survival of two years or less. Treatment of relapsed and refractory multiple myeloma constitutes a specific unmet medical need. Patients with relapsed and refractory disease are defined as those who, having achieved a minor response or better, relapse and then progress while on therapy, or experience progression within 60 days of their last therapy.

Treatment of relapsed or refractory multiple myeloma is particularly challenging, as additional genetic mutations/alterations are continuously acquired, resulting in double-, triple-, or even multiple-refractoriness to many of the current multiple myeloma treatment options. CAR T-cell-based therapies offer potential advantages over current therapeutic strategies. In general, the growing population of patients whose multiple myeloma is refractory to current treatments provides an opportunity for novel therapies. To date, there are no currently approved CAR T-cell therapies for the treatment of multiple myeloma.

Description of Ciltacabtagene autoleucel (cilta-cel)
Ciltacabtagene autoleucel (cilta-cel) is an autologous CAR T-cell therapy directed against B-cell maturation antigen, BCMA, for the treatment of patients with relapsed or refractory multiple myeloma. BCMA plays a central role in regulating B-cell maturation and differentiation into plasma cells. Cilta-cel is designed to recognize myeloma cells and target their destruction. Its CAR T-cell technology consists of harvesting the patient's own T-cells, programming them to express a chimeric antigen receptor that identifies BCMA, a protein highly expressed on the surface of malignant multiple myeloma B-lineage cells, and reinfusing these modified cells back into the patient where they bind to the myeloma cells displaying the BCMA antigen. The T-cells become activated and proliferate resulting in the release of pro-inflammatory cytokines and cytotoxic killing of malignant myeloma cells.

Mechanism of Action
Unlike the chimeric antigen receptor design of currently approved CAR T-cell immunotherapies, which are composed of a single-domain antibody (sdAbs), ciltacabtagene autoleucel (cilta-cel) is composed of two antibody binding domains that allow for high recognition of human BCMA (CD269) and elimination of BCMA expressing myeloma cells. The two distinct BCMA-binding domains confer avidity and distinguish cilta-cel from other BCMA-targeting products. The BCMA-binding domains are linked to the receptor's interior costimulatory (4-1BB) and signaling (CD3ζ)

domains through a transmembrane linker (CD8a). These intracellular domains are critical components for T cell growth and anti-tumor activity in the body once CAR T-cells are bound to the BCMA target on multiple myeloma cells.

Inpatient Administration of Ciltacabtagene Autoleucel (cilta-cel)
Ciltacabtagene autoleucel is given as a single intravenous infusion administered through the central or peripheral vein, primarily as a standalone procedure. Once infused into the patient, CAR T-cells are able to identify BCMA, a protein highly expressed on the surface of malignant multiple myeloma B-lineage cells and target their destruction. The target dose of cilta-cel is 0.75 x 106 CAR-positive viable T-cells per kg body weight (range: 0.5-1.0 x 106 cells/kg).

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of ciltacabtagene autoleucel (cilta-cel). Facilities can report the intravenous administration of ciltacabtagene autoleucel (cilta-cel) with one of the following ICD-10-PCS codes:

XW033C3 Introduction of engineered autologous Chimeric Antigen Receptor T-cell Immunotherapy into peripheral vein, percutaneous approach, new technology group 3

XW043C3 Introduction of engineered autologous Chimeric Antigen Receptor T-cell Immunotherapy into central vein, percutaneous approach, new technology group 3

Coding Options
Option 1. Do not create new ICD-10-PCS codes for intravenous administration of ciltacabtagene autoleucel (cilta-cel). Continue using current codes as listed in current coding.

Option 2. Create new codes in section X New Technology, table XW2 Transfusion, to identify intravenous administration of ciltacabtagene autoleucel (cilta-cel).

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**2** Transfusion: Putting in blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD A** Ciltacabtagene Autoleucel	**ADD 7** New Technology Group 7

Option 3. Create new codes in section X New Technology, table XW0 Introduction, to identify intravenous administration of ciltacabtagene autoleucel (cilta-cel).

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD A** Ciltacabtagene Autoleucel	**ADD 7** New Technology Group 7

CMS Recommendation: Option 3, based on consensus of public comments received at conclusion of September 2020 C&M meeting. CMS continues to seek input.

Interim Coding Advice: Continue using current codes as listed in current coding.

Administration of Amivantamab

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of Amivantamab.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food and Drug Administration (FDA) Approval? In March 2020, amivantamab was granted Breakthrough Therapy designation by FDA for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. The requestor submitted a Biologics License Application (BLA) for amivantamab on December 3, 2020.

Background: Lung cancer is the second most common cancer in the U.S. Approximately 85 percent of all lung cancers are NSCLC. EGFR mutations are present in 10 to 15% of patients with NSCLC and are categorized as either common EGFR mutations or atypical EGFR mutations. Exon 20 insertion mutations are atypical EGFR mutations and comprise 4-10% of NSCLC patients with an EGFR mutation.

Treatment for patients with metastatic NSCLC has historically consisted of cytotoxic platinum-based chemotherapy. For patients with atypical EGFR exon 20 insertion mutations, there is no standard of care when disease has progressed on or after platinum-based chemotherapy. This form of disease has demonstrated resistance to oral tyrosine kinase inhibitors that target typical EGFR mutations.

Description and Mechanism of Action for Amivantamab
Amivantamab is a bispecific monoclonal antibody that is able to inhibit the epidermal growth factor receptor (EGFR) and c-mesenchymal epithelial transition (MET) tyrosine kinase signaling pathways known to be involved in the pathogenesis of NSCLC. It binds to the extracellular domains of the EGF and MET receptors. More specifically, research to date has identified the following components of amivantamab's mechanism of action:

- Amivantamab prevents ligand binding to the EGFR and MET receptors, thereby simultaneously inhibiting EGFR and MET receptor signaling and preventing cellular proliferation.
- Amivantamab induces degradation of EGFR and MET receptors.
- Amivantamab engages natural killer cells and macrophages to eliminate tumor cells via antibody-dependent cellular cytotoxicity (ADCC) or trogocytosis

Inpatient Administration of Amivantamab
Amivantamab is typically administered in the outpatient setting, however there are unique circumstances in which it would be administered during an inpatient stay. When provided in the inpatient hospital setting, amivantamab is administered as an intravenous infusion through the central or peripheral vein. Amivantamab is administered on a 28-day cycle. It is administered weekly for the first cycle, and every 2 weeks thereafter. It is continued until disease progression or unacceptable toxicity. A vial of amivantamab contains 350mg of the drug. The dose is 1050 mg (3 vials) for patients who weigh less than 80 kg. The dose is 1400 mg (4 vials) for patients who weigh

80 kg or more. The very first dose is split between two infusions such that one vial is administered on day one with the other vials administered on day two.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of amivantamab. Facilities can report the intravenous administration of amivantamab using the following codes:

3E0330M Introduction of monoclonal antibody into peripheral vein, percutaneous approach
3E0430M Introduction of monoclonal antibody into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of amivantamab. Continue coding as listed in current coding.

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

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD B** Amivantamab Monoclonal Antibody	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC)

Issue: There are currently no unique ICD-10-PCS codes to describe the transfusion of pathogen reduced cryoprecipitated fibrinogen complex (PRCFC).

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food and Drug Administration (FDA) Approval? Yes, FDA approval was received on November 24, 2020. The FDA also granted Breakthrough Device designation for the product.

Background: Massive hemorrhage is a serious medical condition associated with high morbidity, seen in patients with trauma, complex surgical cases, gastrointestinal bleeding, postpartum hemorrhage, and other conditions. Hemostatic efficacy during massive hemorrhage requires a strong, stable clot that persists until the wound has healed. Fibrinogen, critical for forming the fibrin matrix at the site of hemorrhage, is one of the first clotting proteins to be severely depleted during massive bleeding. Due to its central role in clot formation, early replacement of fibrinogen and associated clotting proteins is a high-priority therapeutic goal in active hemorrhage management.

According to the requestor, recent adoption of higher fibrinogen level targets for patient treatment and emphasis on early empiric or goal-directed fibrinogen replacement has put a spotlight on the current limitations of existing fibrinogen sources for treating patients today. The requestor noted that historically, cryoprecipitate antihemophilic factor (AHF) ("cryoprecipitate") has been used to treat massive hemorrhage; however, severely bleeding patients generally do not receive cryoprecipitate immediately on hospital admission in current massive transfusion protocols or during in-hospital surgical procedures because it is stored frozen and requires thawing before administration. A recent cohort study reported that for adult surgery patients receiving massive transfusion, the median time for cryoprecipitate to reach the patient in the hospital was 2.6 hours.[1] Similarly, in a recent randomized trial in adult cardiac surgery patients, the delay from recognition of major bleeding to cryoprecipitate administration was 1.7 hours.[2] If unused within four to six hours of thawing, cryoprecipitate must be discarded due to concern for bacterial contamination, leading to hospital wastage. The requestor stated that the high wastage rates due to limited post-thaw storage has limited cryoprecipitate availability at many hospitals and thus impeded use of cryoprecipitate as an effective fibrinogen source in the rapid, early treatment of massive hemorrhage.

Description and Mechanism of Action for PRCFC
PRCFC is a highly-processed, pathogen reduced product optimized to provide a concentrated source of fibrinogen to treat fibrinogen deficiency-related bleeding, including massive hemorrhage. In addition to fibrinogen, PRCFC also contains other clotting factors including factor XIII and von Willebrand factor (vWF) which are necessary to achieve stable clot formation and restore hemostasis. PRCFC is produced from plasma treated by the INTERCEPT® Blood System which uses amotosalen and UVA light to inactivate pathogens. The

[1] McQuilten Z.K. et al. (2017). Fibrinogen concentration and use of fibrinogen supplementation with cryoprecipitate in patients with critical bleeding receiving massive transfusion: a bi-national cohort study. *British Journal of Haematology*, 179(1), 131-141.
[2] Callum J. et al. (2019). Effect of fibrinogen concentrate vs cryoprecipitate on blood component transfusion after cardiac surgery: the FIBRES randomized clinical trial. *JAMA, 322*(20), 1-11.

INTERCEPT® Blood System process enables a broad spectrum transfusion-transmitted infection (TTI) risk reduction, including viruses, bacteria, and other pathogens. Due to pathogen inactivation, PRCFC has a 5-day post-thaw shelf life, while traditional cryoprecipitate has only a 4 to 6 hour shelf life. PRCFC can be stored thawed in the operating room or emergency department for immediate use.

Inpatient Administration of PRCFC
PRCFC is administered via intravenous infusion. The proposed number of PRCFC units to create the desired dose is determined by the clinician. No ABO or other pre-administration testing is required before using PRCFC.

Current Coding: There are no unique ICD-10-PCS codes to describe the transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC). Facilities can report the transfusion of PRCFC using one of the following codes:

30233T1 Transfusion of nonautologous fibrinogen into peripheral vein, percutaneous approach
30243T1 Transfusion of nonautologous fibrinogen into central vein, percutaneous approach

With one of the following codes:

30233M1 Transfusion of nonautologous plasma cryoprecipitate into peripheral vein, percutaneous approach
30243M1 Transfusion of nonautologous plasma cryoprecipitate into central vein, percutaneous approach

Reporting one code to identify the transfusion of fibrinogen in combination with one code to identify the transfusion of plasma cryoprecipitate allows the better capture of the two main components of this blood product (PRCFC), in the absence of a unique code.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC). Continue coding as listed in current coding.

Option 2. Create new codes in section 3, Administration, to identify the transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC).

Section *Body System* *Operation*	**3** Administration **0** Circulatory **2** Transfusion: Putting in blood or blood products		
Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD D** Pathogen Reduced Cryoprecipitated Fibrinogen Complex	1 Nonautologous

Option 3. Create new codes in section X, New Technology, to identify the transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC).

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**1** Transfusion: Putting in blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD D** Pathogen Reduced Cryoprecipitated Fibrinogen Complex	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Administration of OTL-103

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of OTL-103.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. Submission of OTL-103 to the FDA is expected to begin in the 4th quarter of 2021. Regenerative Medicine Advanced Therapy (RMAT) designation was granted on July 29, 2019 and Rare Pediatric Disease designation on August 18, 2019.

Background: Wiskott Aldrich Syndrome (WAS) is a rare, X-linked primary immunodeficiency disorder characterized by mutations in the WAS gene encoding the WAS protein (WASP), responsible for maintaining cellular architecture integral to intracellular and cell-substrate interactions and signaling. WAS is a spectrum disorder that may progress over time and is characterized by microthrombocytopenia, eczema, recurrent or severe life-threatening infections, and malignancy or autoimmunity. The burden of illness is profound; patients may require frequent treatment with anti-infectives and/or immunoglobulin, or platelet transfusions as well as protective head gear to prevent injuries. They may also have impaired sleep or excessive scratching due to eczema. Clinical management of WAS is based on supportive care for infections, manifestations of autoimmunity, and microthrombocytopenia. The approximate survival of WAS patients is 15 years with supportive treatment.

Allogeneic hematopoietic stem cell transplant (HSCT) is a definitive treatment that is considered for eligible WAS patients. Allogeneic HSCT-limiting complications are common, affecting up to half of all patients, and include side effects of conditioning regimens, graft-vs-host disease (GVHD), graft rejection, and autoimmune complications. The success and accompanying morbidity are largely based upon the degree of human leukocyte antigen (HLA)-matching between the donor and the patient. While overall survival associated with HLA-matched donors is high at approximately 90%, significant morbidity and mortality limits its use, particularly in patients over the age of 5 years. However, HLA-matched donors are only available for a minority of patients, meaning alternative donor sources such as mismatched donors, haploidentical donors, or umbilical cord blood must be used, which increase the risk of morbidity and are associated with lower survival rates of approximately 50%.

According to the requestor, Orchard Therapeutics has an ex vivo autologous HSC-GT approach designed to modify a patient's own HSPCs using a lentiviral vector. This gene therapy approach relies on the intrinsic ability of HSPCs to self-renew in a patient's bone marrow and produce new stem cell progeny. By doing so, patients are able to avoid the need for an allogeneic HSCT, reducing the morbidity (such as GVHD) and mortality associated with transplant, as well as eliminating the need for a donor search.

Description of OTL-103
OTL-103 is an autologous $CD34^+$ cell-enriched population that contains hematopoietic stem and progenitor cells (HSPC) transduced ex vivo using a lentiviral vector encoding the human *WAS* gene for the treatment of patients diagnosed with WAS. OTL-103 is a durable treatment that can provide comprehensive immune reconstitution across stem cell progeny in this phenotypically

heterogenous population of patients characterized by autoimmunity. As an ex vivo autologous hematopoietic stem cell gene therapy (HSC-GT) approach, OTL-103 has not exhibited the significant mortality and morbidity known to be associated with allogeneic HSCT therapy, such as GVHD. If approved by the FDA, OTL-103 would be the first ex vivo autologous HSC-GT available for use in the US intended for the treatment of patients diagnosed with WAS.

Mechanism of Action
OTL-103 is an investigational autologous HSPC-enriched cell fraction that contains CD34+ HSPCs genetically modified ex vivo using a lentiviral vector encoding the WAS complementary deoxyribonucleic acid (cDNA) sequence with expression driven by the endogenous WAS promoter, leading to physiological expression in stem cell progeny. OTL-103 was evaluated in clinical trials and expanded access programs. As of January 2020, 23 patients have been treated with OTL-103. According to the requestor, there were no reported adverse events related to OTL-103. In patients that did experience mild or moderate adverse events, investigator assessment concluded they were related to the conditioning regimen.

Inpatient Administration of OTL-103
The gene therapy approach for administration of OTL-103 includes five steps:

1. Autologous HSPCs are harvested from the patient through leukapheresis or bone marrow harvest.
2. The harvested sample is selected and purified to a CD34+ enriched cell fraction.
3. In an ex vivo process, a lentiviral vector is utilized to insert a working copy of the missing or faulty gene into the cells (the gene is disease-specific) and the product is cryopreserved, ensuring that the drug product can be released following quality control testing.
4. The patient undergoes a conditioning regimen (selected regimen is disease-dependent).
5. The genetically corrected HSPCs are transported to the treatment site, thawed, and then infused into the patient intravenously as a single, durable treatment. These cells engraft in the patient's bone marrow and begin to self-renew to produce healthy stem cell progeny containing the functional gene.

The administration details of OTL-103, including information regarding conditioning, will be described in the final prescribing information.

Current Coding: Facilities can report the administration of OTL-103 with the following ICD-10-PCS codes:

30233C0	Transfusion of autologous hematopoietic stem/progenitor cells, genetically modified into peripheral vein, percutaneous approach
30243C0	Transfusion of autologous hematopoietic stem/progenitor cells, genetically modified into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the administration of OTL-103. Continue coding as listed in current coding.

Option 2. Create new codes in section X New Technology, table XW1 Transfusion, to identify intravenous administration of OTL-103.

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**1** Transfusion: Putting in blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 4** OTL-103	**ADD 7** New Technology Group 7

Option 3. Create new codes in section X New Technology, table XW0 Introduction, to identify intravenous administration of OTL-103.

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 4** OTL-103	**ADD 7** New Technology Group 7

CMS Recommendation: CMS is interested in hearing input.

Interim Coding Advice: Continue using current codes as listed in current coding.

Administration of OTL-200

Issue: Currently, there are no unique ICD-10-PCS codes to describe the administration of OTL-200.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. Submission of OTL-200 to the FDA is expected to begin in the 4th quarter of 2021. Rare Pediatric Disease designation was granted on May 3, 2018.

Background: Metachromatic leukodystrophy (MLD) is a rare and life-threatening inherited disease of the body's metabolic system occurring in approximately one in every 100,000 live births, characterized by severe motor and cognitive impairment. MLD is caused by a mutation in the arylsulfatase A (*ARSA*) gene that results in massive accumulation of sulfatides in the brain, peripheral nervous system, causing progressive neurodegeneration of the central and peripheral nervous systems. Over time, the nervous system is damaged, leading to neurological problems such as motor, behavioral and cognitive regression, severe spasticity, and seizures. Patients with MLD gradually lose the ability to move, talk, swallow, eat, and see.

MLD is classified by the age at which symptoms first develop into early onset disease (<7 years old) or later onset disease (7 years of age or older). In the United States, the diagnostic pathway for MLD is heterogenous due to variable age onset and symptomatology, and may involve protracted workups with potential severe symptom onset prior to official diagnosis. Late infantile MLD has consistent and uniform initial presenting symptoms such as peripheral neuropathy, muscle weakness, hypotonia, and hypo- or areflexia that then advance to progressive loss of all motor functions, inability to swallow, mental regression, visual and auditory impairment, and even seizures. Disease in juvenile and adult MLD subtypes can be variable in presentation and symptomology; in juvenile MLD, symptoms include primary neurologic symptoms such as gait disturbance, loss of fine motor skills, changes in behavior, or attention difficulties, while adult MLD symptoms include primarily psychiatric symptoms such as emotional lability, personality changes, or psychotic episodes.

Currently, there are no approved treatments for MLD in the US. According to the requestor, while multiple therapies have been attempted and/or theorized, the development of treatments for MLD is limited by the inability of therapeutics to cross the blood-brain barrier, where therapy would be needed for effect, and the necessity for the timing of therapy prior to the rapidly progressive phase of the disease to prevent irreversible damage downstream from the lysosomal storage dysfunction. Because of this, most treatment efforts are restricted to palliative or supportive measures to address current symptoms and prevent or delay secondary complications.

According to the requestor, in late infantile MLD, the only treatment option is palliative care. In juvenile-onset MLD, allogeneic hematopoietic stem-cell transplant (HSCT) is a treatment approach with limited efficacy. When administered prior to symptom onset, allogeneic HSCT can provide stabilization of the cerebral demyelination process and potentially slow disease progression in later onset forms of MLD. However, allogeneic HSCT is ineffective in delaying peripheral nervous system progression, so patients post-HSCT may still experience severe, peripheral neuropathy-related motor deficits. Additionally, allogeneic HSCT is restricted by the

availability of a human-leukocyte antigen (HLA)-matched donor and the risk of morbidity and mortality.

According to the requestor, Orchard Therapeutics has an ex vivo autologous HSC-GT approach designed to modify a patient's own HSPCs using a lentiviral vector. This gene therapy approach relies on the intrinsic ability of HSPCs to self-renew in a patient's bone marrow and produce new stem cell progeny. By doing so, allogeneic HSCT-eligible patients are able to avoid the need for an HSCT, reducing the morbidity (such as graft-versus-host disease) and mortality associated with transplant, as well as eliminate the need for a donor search, and non-eligible patients are presented with a viable treatment option beyond palliative or supportive care.

Description of OTL-200
OTL-200 is an autologous $CD34^+$ cell-enriched population that contains hematopoietic stem and progenitor cells (HSPC) transduced ex vivo using a lentiviral vector encoding the *ARSA* gene for the treatment of patients diagnosed with metachromatic leukodystrophy (MLD). OTL-200 can be given in presymptomatic or early symptomatic MLD, depending on the MLD subtype. If approved by the FDA, OTL-200 would be the first ex vivo autologous hematopoietic stem cell gene therapy (HSC-GT) available for use in the US intended for the treatment of patients diagnosed with MLD.

Mechanism of Action
OTL-200 is an investigational autologous HSPC-enriched cell fraction that contains CD34+ HSPCs genetically modified ex vivo using a lentiviral vector encoding the ARSA complementary deoxyribonucleic acid (cDNA) sequence with constitutive expression driven by the human phosphoglycerate kinase (PGK) promoter leading to expression of ARSA in all stem cell progeny (Sessa 2016). As an ex vivo autologous HSC-GT approach, OTL-200 is a durable treatment that does not require the donor matching needed for allogeneic HSCT and can provide comprehensive benefit, including in infantile-onset disease. OTL-200 cells, which are able to cross the blood-brain barrier, are reinfused into patients following a conditioning regimen, which reduces defective cells and favors the engraftment of genetically modified cells expressing ARSA.

OTL-200 has been evaluated in prospective, non-randomized phase I/II clinical trials and expanded access programs. A phase III open label trial is currently recruiting. As of May 2020, 39 patients have been treated with OTL-200. According to the requestor, no serious adverse events or mortality related to OTL-200 have been reported to date. The most commonly reported adverse events were potentially related to busulfan conditioning and included febrile neutropenia, infections, liver disorders, stomatitis, and mucosal inflammation. During clinical development, anti-ARSA antibodies (AAA) were reported in 5 patients (antibodies against ARSA), which resolved spontaneously or after treatment with rituximab.

Inpatient Administration of OTL-200
The gene therapy approach for administration of OTL-200 includes five steps:

1. Autologous HSPCs are harvested from the patient through leukapheresis or bone marrow harvest.
2. The harvested sample is selected and purified to a CD34+ enriched cell fraction.
3. In an ex vivo process, a lentiviral vector is utilized to insert a working copy of the missing or faulty gene into the cells (the gene is disease-specific) and the product is cryopreserved, ensuring that the drug product can be released following quality-

control testing. The genetically corrected HSPCs are transported to the treatment site.

4. The patient undergoes a conditioning regimen (selected regimen is disease-dependent).
5. The genetically corrected HSPCs are, thawed and then infused into the patient intravenously as a single, durable treatment. These cells engraft in the patient's bone marrow and begin to self-renew to produce healthy stem cell progeny containing the functional gene.

The administration details of OTL-200, including information regarding conditioning, will be described in the final prescribing information.

Current Coding: Facilities can report the administration of OTL-200 with the following ICD-10-PCS codes**:**

30233C0 Transfusion of autologous hematopoietic stem/progenitor cells, genetically modified into peripheral vein, percutaneous approach

30243C0 Transfusion of autologous hematopoietic stem/progenitor cells, genetically modified into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the administration of OTL-200. Continue coding as listed in current coding.

Option 2. Create new codes in section X New Technology, table XW1 Transfusion, to identify intravenous administration of OTL-200.

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**1** Transfusion: Putting in blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD E** OTL-200	**ADD 7** New Technology Group 7

Option 3. Create new codes in section X New Technology, table XW0 Introduction, to identify intravenous administration of OTL-200.

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 E** OTL-200	**ADD 7** New Technology Group 7

CMS Recommendation: CMS is interested in hearing input.

Interim Coding Advice: Continue using current codes as listed in current coding.

Application of Topical Agent for Non-Excisional Eschar Removal

Issue: There are currently no unique ICD-10-PCS codes to describe the application of a topical agent for non-excisional eschar removal.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? No. Vericel is seeking FDA approval of a BLA for NexoBrid. Vericel is expecting FDA approval for NexoBrid on June 29, 2021 with an indication of eschar removal (debridement) in adults with deep partial thickness (DPT) and/or full thickness (FT) thermal burns.

Background: In burn patients, timely and rapid eschar removal is essential to initiate the wound healing process and prevent further complications. The dead tissue, if not removed, often becomes heavily contaminated in 2 to 3 days. The dead tissue can be the source of local and/or systemic infection, which can destroy healthy surrounding tissues and extend the original damage. To prevent these complications, it is imperative to remove eschar and evaluate the burn at the earliest possible opportunity. Once the eschar is removed, the wound bed can be revealed to observe and assess the true damage, and then the appropriate wound closure modality can be determined.

Removal of eschar may be accomplished by surgical or non-surgical means. The current standard of care (SOC) in the US relies primarily on surgical excision through use of sharp instruments such as scalpels and dermatomes to cut away/remove devitalized tissue. Non-excisional surgical procedures for the removal of eschar include Versajet™ Hydrosurgery, brushing, irrigating, and scrubbing. Non-surgical SOC includes collagenase ointment (Santyl®), with antimicrobial agents such as silver sulfadiazine (SSD), and various hydrogels.

The choice of eschar removal method depends on many variables such as burn depth, anatomical site and size (expressed as percentage of Total Body Surface Area (TBSA)) of the burn wound, the patient's general condition, available donor site for autograft harvesting, as well as the availability of surgical facilities (operating rooms) and staff.

Technology
NexoBrid is a botanical and biologic product for topical use and is comprised of two components: the NexoBrid powder that contains the active pharmaceutical ingredient (API) and a gel vehicle. The NexoBrid API is a concentrate of proteolytic enzymes enriched in Bromelain extracted from pineapple stems. According to the requestor, NexoBrid is the first enzymatic eschar removal technology to achieve rapid, consistent eschar removal. The novel mechanism of action of NexoBrid's active pharmaceutical ingredient is mediated by the proteolytic activity of the mixture of enzymes that selectively removes eschar and denatured collagen while sparing healthy tissue. NexoBrid has been shown in two phase 3 clinical trials ("DETECT" NCT02148705, NCT00324311) to have a statistically lower rate of surgical excision and lower rate of blood loss than the current SOC and an average time to complete eschar removal of 1.0 days as compared with an average to complete eschar removal of 3.8 days for the current SOC.

NexoBrid has been developed for patients with deep partial thickness and/or full thickness thermal burns. According to the requestor, NexoBrid use is not dependent on operating room facilities since it can be applied at the patient's bedside, which also eliminates the need for general anesthesia and the additional medical personnel required for surgical procedures. The Biomedical Advanced Research and Development Authority (BARDA) identified NexoBrid as a critical medical countermeasure to address the public health emergency need for an eschar removal product for the treatment of burns in adults, especially for mass casualty events, where surgical capacity is limited and rapid assessment of burn severity and intervention are imperative.

Procedure Description
Prior to use, NexoBrid powder and the gel vehicle are mixed to obtain NexoBrid Gel for topical use in a final concentration of 0.09 g/g concentrate of proteolytic enzymes enriched in bromelain. Mixed NexoBrid Gel is applied for 4 hours to the burn wound at a dose of 2 g NexoBrid powder mixed with 20 g gel vehicle per 1% TBSA, or 5 g NexoBrid powder mixed with 50 g gel vehicle per 2.5% TBSA. NexoBrid can be applied to an area of up to 15% TBSA in one session.

Current Coding: There are no unique ICD-10-PCS codes to describe the application of bromelain-enriched proteolytic enzyme for non-excisional eschar removal. Facilities can report the application of bromelain-enriched proteolytic enzyme using the following code:

> 3E00XGC Introduction of other therapeutic substance into skin and mucous membranes, external approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the application of bromelain-enriched proteolytic enzyme. Continue coding as listed in current coding.

Option 2. Create a new code in section X, New Technology, to identify the application of bromelain-enriched proteolytic enzyme.

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*
0 Skin **1** Subcutaneous Tissue	**X** External	**ADD 2** Bromelain-enriched Proteolytic Enzyme	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Application of Bioengineered Allogeneic Construct

Issue: There are currently no unique ICD-10-PCS codes to describe the application of a bioengineered allogeneic construct.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? No. Stratatech Corporation, a Mallinckrodt company, is seeking FDA approval for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated. FDA approval is anticipated by June 30, 2021.

Background: Annually, in the United States, approximately 500,000 burn injuries receive emergency medical treatment, leading to 40,000 burn injury hospitalizations with 30,000 at hospital burn centers. Vulnerable patient populations are at an increased risk of death due to the skin loss and its complications. For patients 65 years old or older, burn injury was reported as the eighth leading cause of death. Today, 96.7% of burn patients treated in burn centers will survive. According to the requestor, many of those survivors will sustain serious scarring and lifelong physical disabilities that can have a considerably negative effect on the patient's health-related quality of life, affecting physical and emotional participation, anxiety, depression, pain, heat sensitivity, and ability to return to work.

Autografting is considered to be a standard of care for severe thermal burns. Among burn patients who were hospitalized, approximately a quarter of them received autografts. An autograft procedure involves the surgical harvesting of healthy skin tissue from an uninjured site on the patient and transplanting the skin graft to the injury. While this process can be effective in providing closure of the original wound, it has significant limitations related to the donor site wounds created during surgical removal of the skin tissue for grafting. Donor site wounds are painful and can create risks of additional scarring and infection.

After patients undergo autografting, in the long term, both the grafted wound site and the donor site require continuous physical and rehabilitative therapy to maintain the range of movement, minimize scar and contracture development, and maximize functional ability. Furthermore, the amount of healthy skin available for harvesting is frequently limited in patients with burns involving 50–60% total body surface area, necessitating sequential re-harvesting of available donor sites. In addition, autografting is especially undesirable in vulnerable patient populations, such as the elderly. Geriatric skin has a thinner dermis, significant alterations in its structure due to changes in collagen production and turnover, slower angiogenesis and revascularization leading to delayed wound healing, and an increased risk of excessive scarring.

Technology
StrataGraft is an investigational, viable, bioengineered, allogeneic construct consisting of an epidermal layer of viable, fully stratified, allogeneic human Near-diploid Immortalized Keratinocytes (NIKS®) cells growing on a dermal layer composed of viable normal human dermal fibroblasts embedded in a collagen-rich matrix. According to the requestor, StrataGraft mimics the normal function of native skin, promotes the autologous healing of severe burn wounds without the

requirement to harvest healthy skin, and may be applied universally to patients (i.e., it is not a patient-specific product).

StrataGraft leverages the regenerative capacity of the patient's skin while minimizing or eliminating the complications associated with autograft harvest. In addition to providing immediate wound coverage and epidermal barrier function, the viable cells within StrataGraft express and secrete a wide variety of peptides, growth factors, and cytokines that are known to promote healing, potentially reducing the need for autograft in the management of severe thermal burns.

According to the requestor, StrataGraft is the only product granted regenerative medicine advanced therapy (RMAT) designation for the treatment of patients with acute severe thermal burns, as described in section 3033 of the 21st Century Cures Act. Upon FDA approval, StrataGraft will be the only cellular and/or tissue product for treatment of thermal burns that promotes durable wound closure and regenerative healing.

Current Coding: There are no unique ICD-10-PCS codes to describe skin replacement using a bioengineered allogeneic construct. Facilities can report skin replacement with the applicable ICD-10-PCS code(s) from table 0HR, Replacement of Skin and Breast, with device value K Nonautologous Tissue Substitute and the qualifier value 3 Full Thickness.

Section	**0** Medical and Surgical		
Body System	**H** Skin and Breast		
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part		
Body Part	*Approach*	*Device*	*Qualifier*
0 Skin, Scalp **1** Skin, Face **2** Skin, Right Ear **3** Skin, Left Ear **4** Skin, Neck **5** Skin, Chest **6** Skin, Back **7** Skin, Abdomen **8** Skin, Buttock **9** Skin, Perineum **A** Skin, Inguinal **B** Skin, Right Upper Arm **C** Skin, Left Upper Arm **D** Skin, Right Lower Arm **E** Skin, Left Lower Arm **F** Skin, Right Hand **G** Skin, Left Hand **H** Skin, Right Upper Leg **J** Skin, Left Upper Leg **K** Skin, Right Lower Leg **L** Skin, Left Lower Leg **M** Skin, Right Foot **N** Skin, Left Foot	**X** External	**K** Nonautologous Tissue Substitute	**3** Full Thickness **4** Partial Thickness

Coding Options

Option 1. Do not create new ICD-10-PCS codes for skin replacement using StrataGraft bioengineered allogeneic construct. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify skin replacement using StrataGraft bioengineered allogeneic construct.

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	**ADD F** Bioengineered Allogeneic Construct	**7** New Technology Group 7

Option 3. In table 0HR, Replacement of Skin and Breast, create new device value L Nonautologous Tissue Substitute, Bioengineered, applied to all available body parts and the approach value External to identify skin replacement using StrataGraft bioengineered allogeneic construct.

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

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

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Computer-Aided Assessment and Characterization Software for Head CT Scan

Issue: Currently there are no unique ICD-10-PCS codes that describe the utilization of software that characterizes Alberta Stroke Program Early CT Score (ASPECTS) Regions of Interest (ROIs) using computed tomography (CT) image data.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? Yes. On June 26, 2020, the FDA granted 510(k) Clearance [K200760].

Background: Approximately 800,000 primary (first-time) or secondary (recurrent) strokes occur each year in the U.S., with the majority being primary strokes (roughly 600,000). Of these strokes, approximately 87% are ischemic infarctions, 10% are primary hemorrhages, and 3% are subarachnoid hemorrhage. The most disabling strokes are those due to large vessel occlusions (LVOs), and treatment of these strokes has the largest therapeutic benefits.

The ASPECTS score is an assessment of the CT scan in a stroke patient to determine if there is evidence of irreversible injury in ten different brain regions. The Alberta Stroke Program Early CT score (ASPECTS) requires the evaluation of ten pre-defined MCA vascular territories and is calculated by subtracting one point for each involved region. Scores less than 6 typically signify patients with an irreversible large hemispheric infarction.

Typically, a patient presenting to a hospital with signs or symptoms of a suspected stroke would move through the healthcare system as follows:

1) Patients arrive at an emergency department and are rapidly triaged to the CT scanner for a non-contrast CT (NCCT) and CT Angiography (CTA). The CTA directly images large vessel occlusions and the NCCT can exclude brain hemorrhage and identify early signs of brain infarction
2) If a large vessel occlusion (LVO) is identified, a physician, typically a radiologist or neuroradiologist, determines the ASPECT score by taking a closer look for evidence of early infarct signs on the NCCT.
3) Patients within six hours of symptoms onset, with an ASPECT score between 6 and 10 that meets the clinical criteria for mechanical thrombectomy should receive thrombectomy as soon as possible. Patients who present beyond six hours of symptoms onset require a CT perfusion or MRI scan to identify if they are eligible for mechanical thrombectomy.

The requestor notes that ASPECT score determination can be difficult because early infarct signs are often very subtle and challenging to interpret correctly. Often there is disagreement between experts on the exact score and sometimes these disagreements preclude a definite answer regarding if the patient qualifies for thrombectomy or not. These interpretation challenges are manifested by limited inter-rater agreement, even among experts.

Technology
According to the requestor, Rapid ASPECTS is a unique machine learning-based, fully automated software for assessment of ASPECTS to assist frontline clinicians and radiologists to interpret CT scans and provide triage and appropriate care of stroke patients. Rapid ASPECTS extracts image data for the ROI(s) to provide analysis and computer analytics based on morphological characteristics and produces a score for each of the ten ASPECTS regions, as well as a total score in approximately two minutes. The Rapid ASPECTS processing (which takes an average of about two minutes) occurs during the time when the CTA is being performed; therefore, it is immediately available following completion of the NCCT/CTA scan.

According to the requestor, Rapid ASPECTS has several potential benefits over the current standard of care:

1. Improved accuracy of ASPECT scoring: Two studies[1,2] have shown that the automated Rapid ASPECTS score is significantly more accurate than the scores obtained by experienced clinicians.
2. Improved treatment decisions: Retrospective studies have shown the treatment decisions made by experienced clinicians would have been improved with the use of Rapid ASPECTS[12,3].
3. Reduced inter-rater variability: The analysis of the study that led to the FDA clearance of Rapid ASPECTS demonstrated a statistically significant reduction is inter-rater variability[4].
4. Improved time to treatment: As radiologists are not immediately available at the time when many LVO patients present, and obtaining a read from a neuroradiologist often takes even longer, the time to determine an ASPECT score is expected to be improved with the software. This is expected to lead to faster treatment times, which have been shown to reduce disability.

Current Coding: The interpretation of imaging procedures and characterization of Alberta Stroke Program Early CT Score (ASPECTS) Regions of Interest utilizing software is not reported separately for inpatient hospital coding. Facilities can report the CT and CT angiogram using the appropriate codes in section B, Imaging.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for software analysis of CT image data for assessment and scoring of ASPECTS in suspected stroke. Continue using current codes as listed in current coding.

Option 2. In section B Imaging table BW2, Computerized Tomography of Anatomical Regions, create new 7th character qualifier value 5 Computer-aided Assessment, applied to the Head body part and the contrast value Z No Contrast to identify the use of software that characterizes Alberta

[1] Maegerlein C, Fischer J, Mi:inch S, MD et al. Automated Calculation of the Alberta Stroke Program Early CT Score: Feasibility and Reliability. Radiology 2019; 291:141-148
[2] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. Stroke. 2019;50:3277-3279.
[3] Delio PR, Wong ML, Tsai JP, et al. Assistance from Automated ASPECTS Software Improves Reader Performance (under review 2020)
[4] Copeland K. Variability of ASPECT Scores Internal Analysis iSchemaView of data submitted to U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health, 2020a

Stroke Program Early CT Score (ASPECTS) Regions of Interest using CT image data. Continue to report the CT angiogram using the appropriate code in section B, Imaging.

Section	**B** Imaging		
Body System	**W** Anatomical Regions		
Type	**2** Computerized Tomography (CT Scan): Computer reformatted digital display of multiplanar images developed from the capture of multiple exposures of external ionizing radiation		
Body Part	*Contrast*	*Qualifier*	*Qualifier*
8 Head	**Z** None	**Z** None	**ADD 5** Computer-aided Assessment

Option 3. Create new codes in section X table XXE Measurement of Physiological Systems, to identify the use of software that characterizes Alberta Stroke Program Early CT Score (ASPECTS) Regions of Interest using CT image data. Continue to report the CT and CT angiogram using the appropriate codes in section B, Imaging.

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**E** Measurement: Determining the level of a physiological or physical function at a point in time		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 0 Central Nervous	**X** External	**ADD 0** Intracranial Vascular Activity, Computer-aided Assessment	**ADD 7** New Technology Group 7

CMS Recommendation: CMS is interested in hearing input.

Interim Coding Advice: Continue using current codes as listed in current coding.

Total Artificial Heart Systems

Issue: There are currently no unique ICD-10-PCS codes to distinguish between a pneumatic artificial heart and an autoregulated electrohydraulic artificial heart.

New Technology Application? No, not at this time. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2024 consideration.

Food & Drug Administration (FDA) Approval? No**.** The Carmat total artificial heart (TAH) is currently in an FDA approved clinical study (IDE G180184, NCT 04117295).

Background: Cardiovascular diseases are the leading cause of death in the developed world (WHO Cardiovascular diseases (CVDs) Fact sheet N°317). The prevalence of Heart Failure (HF) in Europe and the United States is approximately 12 million, of which 0.5-5% in advanced HF refractory to medical management[1,2,3]. Cardiac transplantation remains the primary option for just a select group of end-stage HF patients because of donor organ shortage. The number of heart transplant procedures reported to the International Society for Heart and Lung Transplantation registry has plateaued since 2007 between 4000 and 4200 procedures per year[4]. In parallel, the numbers of patients living with compromised cardiac function and HF is expected to rise over the next few decades because of the aging population[3]. The shortage of heart donors has fueled the development of Left Ventricular Assist Devices (LVADs) to assist the failing left ventricle, on a temporary or permanent basis[Error! Bookmark not defined.5,6,7]. The adoption of LVADs as a viable therapy for end-stage heart failure has resulted in increased referrals of patients on both sides of the spectrum, from New York Heart Association (NYHA) class 3+ to those in need of total cardiac replacement therapy[6,7,8,9,10]

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[1] Roger VL, Go AS, Lloyd-Jones DM, Adams RJ, Berry JD, Brown TM, Carnethon MR, Dai S, de Simone G, Ford ES, Fox CS, Fullerton HJ, Gillespie C, Greenlund KJ, Hailpern SM, Heit JA, Ho PM, Howard VJ, Kissela BM, Kittner SJ, Lackland DT, Lichtman JH et al.. On behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics – 2011 update: a report from the American Heart Association. Circulation 2011;123:e18–e209.

[2] M., Tendera Epidemiology, treatment, and guidelines for the treatment of heart failure in Europe; European Heart Journal Supplements (2005) 7 (Supplement J), J5–J9

[3] Ammar KA, Jacobsen SJ, Mahoney DW, Kors JA, Redfield MM, Burnett JC Jr, Rodeheffer RJ. Prevalence and prognostic significance of heart failure stages. Application of the American College of Cardiology/American Heart Association heart failure staging criteria in the community. Circulation 2007; 115:1563-1570

[4] Rose EA, Gelijns AC, Moskowitz AJ, et al. The Registry of the International Society for Heart and Lung Transplantation: Twenty-seventh official adult heart transplant report-2010. J Heart Lung Transpalant doi:10.1016/j.healun.2010.08.007.

[5] Stehlik J, Edwards LB, Kucheryavaya AY, Aurora P, Christie JD, Kirk R, Dobbels F, Rahmel AO, Hertz MI. Advanced heart failure treated with continuous-flow left ventricular assist device. N Engl J Med 2009;361:2241-51

[6] Miller LW, Pagani FD, Russell SD, et al. Use of a continuous flow device in patients awaiting heart transplantation. N Engl J Med 2007; 357:885-96.

[7] Slaughter MS, Rogers JG, Milano CA, Russell SD, Conte JV, Feldman D, Sun B, Tatooles AJ, Delgado RM, Long JW, Wozniak TC, Ghumman W, Farrar DJ, Frazier OH. Advanced heart failure treated with continuous-flow left ventricular assist device. N Engl J Med 2009;361:2241-51

[8] Miller LW Left Ventricular Assist Devices Are Underutilized. Circulation 2011;123:1552–1558.

[9] Kirklin JK, Naftel DC, Kormos RL et al. Second INTERMACS annual report: More than 1,000 primary left ventricular assist device implants. J Heart Lung Transplant 2010; 29:1-10.

[10] Kirklin JK, Naftel DC, Kormos RL et al. The Fourth INTERMACS Annual Report: 4,000 implants and counting. J Heart Lung Transplant 2012; 31:117-26.

However, for the most severe forms of cardiac dysfunction, which lead to irreversible biventricular failure, cardiac transplantation remains the only effective therapy providing longevity and quality of life. Moreover, the use of LVADs has revealed clinical events that are related to mono-ventricular support, such as right heart failure, renal failure[11].

First generation of TAHs and biventricular VADs are pneumatically-driven and have been used as a bridge to transplantation, at the cost of high morbidities related to the devices (infection, bleeding, stroke) and limited mobility for the patient[12,13,14,15]

Technology

There are currently two totally artificial heart systems: SynCardia (SynCardia Systems, LLC, Tucson, AZ), and Carmat (Carmat SA, Vélizy, France). [16]

- The SynCardia temporary TAH was FDA approved (P030011) in 2004. The SynCardia TAH is pneumatically driven pulsatile system and is indicated for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.
- The Carmat TAH is an integrated autoregulated and electrohydraulically driven biocompatible, pulsatile, system intended for full cardiac support

The following table highlights the differences between the two TAH systems:

Feature	Syncardia TAH	CARMAT TAH
Mode of actuation	External pneumatic drivers	Internal electrohydraulic pumps
Blood contact	Synthetic surfaces	Bioprosthetic surfaces
Valves	4 mechanical valves	4 biological valves
Blood flow regulation	Limited and manual	Autoregulated by the device

According to the requestor, the Carmat TAH system is comprised of 3 components:

1. The implanted prosthesis consisting of

[11] Brandler ES et al. Cardiogenic Shock in Emergency Medicine. Nov 2010. http://emedicine.medscape.com/

[12] Farrar DJ, Hill JD, Pennington DG, McBride LR, Holman WL, Kormos RL, Esmore D, Gray LA Jr, Seifert PE, Schoettle GP, Moore CH, Hendry PJ, Bhayana JN. Preoperative and postoperative comparison of patients with univentricular and biventricular support with the Thoratec ventricularassist device as a bridge to cardiac transplantation. J Thorac Cardiovasc Surg 1997;113:202–9.

[13] Copeland JG, Smith RG, Arabia FA, Nolan, PE, Sethi GK, Tsau PH, McClellan D, Slepian MJ. Cardiac replacement with a total artificial heart as a bridge to transplantation. N Engl J Med 2004; 351:859–67.

[14] Roussel JC, Senage T, Baron O, Perigaud C, Habash O, Rigal JC, Treilhaud M, Trochu JN, Despins P, Duveau D. CardioWest (Jarvik) total artificial heart: a single-center experience with 42 patients. Ann Thorac Surg 2009; 87:124–30.

[15] Cleveland JC, Naftel DC, Reece TB, Murray M, Antaki J, Pagani FD, Kirklin JK. Survival after biventricular assist device implantation: An analysis of the Interagency Registry for Mechanically Assisted Circulatory Support database. J Heart Lung Transplant 2011;30:862–9.

[16] Abiomed's Abiocor received HDE (H040006) in 2006 and is a pulsatile electrohydraulic implantable replacement heart capable of delivering up to 8 L/min pump output over a broad range of physiologic pressures. However, Abiomed discontinued this product.

- 4 biological valves at the inlet and outlet providing unidirectional pulsatile blood flow
- 2 ventricles, each separated by a membrane into two smaller cavities, one for the blood and one for the actuator fluid. The blood-contacting layer of this membrane is made of biocompatible materials
- 2 micro pumps that push the actuator fluid to the membranes and generate the systole and diastole
- Embedded electronics, microprocessors and sensors allowing autoregulated responses to changing patient physiological needs
- A flexible external bag containing the actuator fluid
- A percutaneous cable connecting the prosthesis to external components

2. The external equipment provides the mobility and autonomy needed to lead a near-normal life. It weighs <5kg and includes a controller and lithium-ion batteries providing an autonomy of about 4 hours
3. The hospital care console: The medical team must use the hospital care console (HCC) to operate the prosthesis during implantation and track how the device is functioning

Procedure Description
The Carmat TAH is implanted in the orthotopic position during standard open-heart procedure using cardiopulmonary bypass (CPB). The native ventricles are excised up to the left and right atrioventricular junctions. Bioprosthetic flanges with a circular central opening reinforced by a silicon ring are cut and sutured onto the mitral and tricuspid valve orifices. The flanges are connected to a single titanium interface device with two central openings. The Carmat TAH, with the inflow valves in place, is then positioned and secured with a click onto the interface device. Next, the pulmonary conduit with outflow valve is sutured to the distal pulmonary artery. Finally, the aortic conduit containing the outflow valve is sutured to the distal aorta. The percutaneous driveline from the device is tunneled to exit the skin at the lower right abdominal quadrant. The driveline is then connected to the controller and hospital care console. De-airing and weaning of CPB is accomplished by decreasing CPB flow while increasing the Carmat TAH output. When the device has achieved full flow, the operation mode is switched from manual to auto-regulation.

Current Coding: There are no unique ICD-10-PCS codes to identify implantation of an autoregulated electrohydraulic total artificial heart. Code the procedure using both of the following ICD-10-PCS codes:

02RK0JZ Replacement of right ventricle with synthetic substitute, open approach
and
02RL0JZ Replacement of left ventricle with synthetic substitute, open approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for implantation of an autoregulated electrohydraulic total artificial heart. Continue coding as listed in current coding.

Option 2. In table 02R, Replacement of Heart and Great Vessels, create new device value L Biologic with Synthetic Substitute, Autoregulated Electrohydraulic, applied to the Heart body part and the approach value Open to identify implantation of an autoregulated electrohydraulic total

artificial heart system. In addition, create new device value M Synthetic Substitute, Pneumatic, to identify implantation of a total artificial heart that uses external pneumatic drivers.

Section	**0** Medical and Surgical		
Body System	**2** Heart and Great Vessels		
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part		
Body Part	*Approach*	*Device*	*Qualifier*
5 Atrial Septum **6** Atrium, Right **7** Atrium, Left **9** Chordae Tendineae **D** Papillary Muscle **K** Ventricle, Right **L** Ventricle, Left **M** Ventricular Septum **N** Pericardium **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava **W** Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch	**0** Open **4** Percutaneous Endoscopic	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier
ADD A Heart	**0** Open	**ADD L** Biologic with Synthetic Substitute, Autoregulated Electrohydraulic **ADD M** Synthetic Substitute, Pneumatic	**Z** No Qualifier

Option 3. Create new codes in section X table X2R, Replacement of Cardiovascular System, to identify implantation of an autoregulated electrohydraulic total artificial heart.

Section	**X** New Technology		
Body System	**2** Cardiovascular System		
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD A Heart	**0** Open	**ADD L** Biologic with Synthetic Substitute, Autoregulated Electrohydraulic	**7** New Technology Group 7

CMS Recommendation: CMS is interested in hearing input.

Interim Coding Advice: Continue using current codes as listed in current coding.

Computer-Aided Triage and Notification Software for Computed Tomography Pulmonary Angiography (CTPA)

Issue: There are currently no unique ICD-10-PCS codes to identify computed tomography pulmonary angiography (CTPA) with computer-aided triage and notification software to detect pulmonary embolism.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? Yes. The Aidoc Briefcase for pulmonary embolism was cleared by the FDA under the 510(k) pathway on April 15, 2019.

Background: In the United States it is estimated that as many as 900,000 people are affected by a venous thromboembolism (VTE), such as deep vein thrombosis (DVT) and pulmonary embolism (PE), each year[1] with VTE being the third most common cause of cardiovascular death following only myocardial infarction and cerebrovascular accidents (or stroke).[2] Across all VTEs, mortality is high with 10 to 30% of individuals dying within 30 days of diagnosis.[3] However, acute, symptomatic PE is especially life threatening as death occurs within 1 hour of onset in up to 10% of cases.[4] Options exist for treating acute, symptomatic PE, and range from anticoagulation therapy to catheter-directed thrombolysis and thrombectomy[5,6,7] and clinical studies have demonstrated a strong correlation between time to communication of PE findings, treatment and clinical outcomes.[8,9,10]

The requestor also notes that typically, patients with pulmonary embolism (PE) or suspected PE present at hospital emergency departments. Those patients that present to a hospital with signs or symptoms of PE generally move through the system as follows:

(1) Patient presents with suspected PE to the ED
(2) Patient receives CT Pulmonary Angiography (CTPA) imaging
(3) Technologist processes and reconstructs the CT images and manually routes them to the hospital PACS.
(4) The exam enters a FIFO (first-in-first-out) reading queue, where it awaits radiological

[1] https://www.cdc.gov/ncbddd/dvt/data.html
[2] Tarbox AK, Swaroop M. Pulmonary embolism. *Int J Crit Illn Inj Sci*. 2013;3(1):69-72.
[3] https://www.cdc.gov/ncbddd/dvt/data.html
[4] Naess IA, Christiansen SC, Romundstad P, Cannegieter SC, Rosendaal FR, Hammerstrøm J. Incidence and mortality of venous thrombosis: a population-based study. *J Thromb Haemost*. 2007;5(4):692-699.
[5] Kearon C, Akl EA, Ornelas J, et al. Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2016 Oct;150(4):988]. *Chest*. 2016;149(2):315-352.
[6] Konstantinides SV, Meyer G, Becattini C, et al. 2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS). *Eur Heart J*. 2020;41(4):543-603.
[7] Raja AS, Greenberg JO, Qaseem A, et al. Evaluation of Patients With Suspected Acute Pulmonary Embolism: Best Practice Advice From the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med*. 2015;163(9):701-711.
[8] Smith SB, Geske JB, Maguire JM, Zane NA, Carter RE, Morgenthaler TI. Early anticoagulation is associated with reduced mortality for acute pulmonary embolism. *Chest*. 2010;137(6):1382-1390.
[9] Soh S, Kim JM, Park JH, Koh SO, Na S. Delayed anticoagulation is associated with poor outcomes in high-risk acute pulmonary embolism. *J Crit Care*. 2016;32:21-25.
[10] Wood KE. Major pulmonary embolism: review of a pathophysiologic approach to the golden hour of hemodynamically significant pulmonary embolism. *Chest*. 2002;121(3):877-905.

interpretation
(5) Radiologist reads the CT images and make the diagnosis of PE
(6) The radiologist informs the referring physician of positive PE either verbally or through the radiologist report
(7) ED physician and/or on-call pulmonologist decide on the management strategy
(8) If appropriate, the patient proceeds to treatment

Technology
According to the requestor, Aidoc Briefcase for PE provides an artificial intelligence-based triage and notification of suspected PE cases enabling shorter time to notification. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings in CT pulmonary angiograms. The requestor states that presenting the radiologist with this notification facilitates earlier triage by prompting the user to assess the relevant original images in the picture archiving and communication system (PACS)., The requestor reports that as a result, the suspect case receives attention earlier than would have been the case in the standard of care practice alone.

The software system is based on an algorithm programmed component and is comprised of a standard off-the-shelf operating system, the Microsoft Windows server 2012 64bit, and additional applications, which include PostgreSQL, DICOM module and the BriefCase Image Processing Application. The device consists of the following three modules: (1) Aidoc Hospital Server (AHS); (2) Aidoc Cloud Server (ACS); and (3) Aidoc Worklist Application that is installed on the radiologist's desktop and provides the user interface in which notifications from the BriefCase software are received.

Current Coding: There are no unique codes to identify the use of software analysis of CTPA to detect PE and notify clinicians. Facilities can report the CTPA using the appropriate code(s) in section B, Imaging.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for software analysis of CTPA to detect pulmonary embolism and notify clinicians. Continue coding as listed in current coding.

Option 2. In section B, Imaging table B32 Computerized Tomography of Upper Arteries, create new 7th character qualifier value 6 Computer-aided Triage and Notification, applied to the body part values S Pulmonary Artery, Right and T Pulmonary Artery, Left and the contrast value 1 Low Osmolar to identify software analysis of CTPA to detect PE and notify clinicians.

Section	**B** Imaging		
Body System	**3** Upper Arteries		
Type	**2** Computerized Tomography (CT Scan): Computer reformatted digital display of multiplanar images developed from the capture of multiple exposures of external ionizing radiation		
Body Part	*Contrast*	*Qualifier*	*Qualifier*
0 Thoracic Aorta **5** Common Carotid Arteries, Bilateral **8** Internal Carotid Arteries, Bilateral **G** Vertebral Arteries,	**0** High Osmolar **1** Low Osmolar **Y** Other Contrast	**Z** None	**Z** None

Bilateral **R** Intracranial Arteries **S** Pulmonary Artery, Right **T** Pulmonary Artery, Left			
0 Thoracic Aorta **5** Common Carotid Arteries, Bilateral **8** Internal Carotid Arteries, Bilateral **G** Vertebral Arteries, Bilateral **R** Intracranial Arteries **S** Pulmonary Artery, Right **T** Pulmonary Artery, Left	**Z** None	**2** Intravascular Optical Coherence **Z** None	**Z** None
S Pulmonary Artery, Right **T** Pulmonary Artery, Left	**1** Low Osmolar	**Z** None	**ADD 6** Computer-aided Triage and Notification

Option 3. Create new codes in section X table XXE Measurement of Physiological Systems, to identify software analysis of CTPA to detect PE and notify clinicians.

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**E** Measurement: Determining the level of a physiological or physical function at a point in time		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Circulatory	**X** External	**M** Infection, Whole Blood Nucleic Acid-base Microbial Detection	**5** New Technology Group 5
5 Circulatory	**X** External	**N** Infection, Positive Blood Culture Fluorescence Hybridization for Organism Identification, Concentration and Susceptibility	**6** New Technology Group 6
B Respiratory	**X** External	**Q** Infection, Lower Respiratory Fluid Nucleic Acid-base Microbial Detection	**6** New Technology Group 6
ADD 3 Arterial	**X** External	**ADD 2** Pulmonary Artery Flow, Computer-aided Triage and Notification	**ADD 7** New Technology Group 7

CMS Recommendation: CMS is interested in hearing input.

Interim Coding Advice: Continue using current codes as listed in current coding.

April 1 Code Implementation Discussion

The Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention's National Center for Health Statistics (CDC/NCHS), are announcing our consideration of an April 1 implementation date for ICD-10-CM diagnosis and ICD-10-PCS procedure code updates, in addition to the current October 1 annual update for ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes. This April 1 code update would be in addition to the existing April 1 update under section 1886(d)(5)(K)(vii) of the Social Security Act for diagnosis or procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. Under our contemplated process, requestors would indicate if they are submitting their code request for consideration for an April 1 implementation date, if adopted, or an October 1 implementation date. The ICD-10 Coordination and Maintenance Committee would make efforts to accommodate the requested implementation date for each request submitted, however, the Committee would determine which requests would be presented for consideration for an April 1 implementation date or an October 1 implementation date.

We are interested in receiving feedback on the possible adoption of this April 1 implementation date, including how it may impact your current business processes. We are also seeking input on what factors the Committee should consider when determining which requests should be considered for either an April 1 or October 1 implementation date. The earliest date for which we would consider an April 1 code update option is April 1, 2022, as outlined below in the Sample Timeline.

We request that all comments for this topic be submitted by **May 7, 2021** to the CMS mailbox at ICDProcedureCodeRequest@cms.hhs.gov.

We would use our established process to implement an April 1 code update, which would include presenting proposals for April 1 consideration at the September ICD-10 Coordination and Maintenance Committee meeting, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments, consistent with the new Grouper release information. The code update process for an April 1 implementation date would also involve the release of new code files, coding guidelines, and coding advice on the use and reporting of new codes through AHA's *Coding Clinic for ICD-10-CM/PCS* publication.

CMS would assign the codes approved for the April 1 update to an MS-DRG(s) using its established process for Grouper assignments for new diagnosis and procedure codes. CMS would list the codes approved for an April 1 update in the annual IPPS proposed rule, along with their proposed Grouper assignments beginning October 1 of the next fiscal year. These Grouper assignments include the Major Diagnostic Category (MDC), Medicare Severity Diagnosis Related Group (MS-DRG), severity level designations for diagnosis codes of a major complication or comorbidity (MCC), a complication or comorbidity (CC) or a non-complication or comorbidity (NonCC), and the designation of procedure codes as either operating room (O.R.) procedures or non-operating room (non-O.R.) procedures. We would make these assignments available in tables 6A. – New Diagnosis Codes and 6B. – New Procedure Codes, associated with each proposed rule, at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/

Sample Timeline

June 11, 2021	Deadline for requestors: Those members of the public requesting that topics be discussed at the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting, must have their requests submitted to CMS for procedures and NCHS for diagnoses. **Requestors should indicate if they are submitting their code request for consideration for an April 1, 2022 implementation date, if adopted, or an October 1, 2022 implementation date.** The ICD-10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an April 1, 2022 implementation date or an October 1, 2022 implementation date. *We are also seeking input on what factors the Committee should consider when determining which requests should be considered for either an April 1, 2022 or October 1, 2022 implementation date.
July 2021	Federal Register notice for the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
August 2021	FY 2022 Hospital Inpatient Prospective Payment System final rule is issued. This rule will also include links to tables listing all the final codes to be implemented on October 1, 2021. This rule can be accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html
August 2021	Tentative agenda for the Procedure portion of the September 14, 2021 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 portion of the September 15, 2021 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the NCHS webpage at: https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **If adopted, topics being considered for an April 1 implementation will be identified.**

August 9, 2021	**On-line registration opens for the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting at:** https://www.eventbrite.com/e/icd-10-coordination-and-maintenance-committee-meeting-tickets Please note that this meeting will be conducted virtually and registration is not required to attend. However, we are providing the ability to register on-line for those required to provide proof of attendance for continuing education purposes. The on-line registration will be available through September 9, 2021.
September 14-15, 2021	The September 2021 ICD-10 Coordination and Maintenance Committee Meeting will be held fully virtual, with no in-person audience. Those who wish to attend must participate via Zoom Webinar or by dialing in.
September 2021	Recordings and slide presentations of the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
October 1, 2021	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-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 15, 2021	**Deadline for receipt of public comments on proposed new codes discussed at the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2022.**
November 2021	Any new ICD-10 codes that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2022 will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/
November 15, 2021	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2022.**

December 03, 2021	Deadline for requestors: Those members of the public requesting that topics be discussed at the March 8-9, 2022 ICD-10 Coordination and Maintenance Committee Meeting, must have their requests submitted to CMS for procedures and NCHS for diagnoses. **Requestors should indicate if they are submitting their code request for consideration for an October 1, 2022 implementation date, or an April 1, 2023 if adopted, implementation date.**
January 2022	The ICD-10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an October 1, 2022 implementation date or an April 1, 2023 implementation date. Federal Register notice for the March 8-9, 2022 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
February 1, 2022	ICD-10 MS-DRG Grouper software and related materials posted on CMS webpage at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software
February 1, 2022	Any updates to the ICD-10-CM and ICD-10-PCS Coding Guidelines will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/
February 1, 2022	All ICD-10-CM and ICD-10-PCS code update files (includes April 1 update and full files from prior October 1) will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/
March 8-9, 2022	ICD-10 Coordination and Maintenance Committee Meeting
March 2022	Recordings and slide presentations of the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
April 1, 2022	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes.

Transthoracic Echocardiography with Computer-Aided Image Acquisition

Issue: There are currently no unique ICD-10-PCS codes to describe transthoracic echocardiography with AI-guided image acquisition.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? Yes. Caption Guidance received breakthrough designation from the FDA in 2018 for the acquisition of cardiac ultrasound images using an AI-guided system. The FDA authorized Caption Guidance under the De Novo classification on February 7, 2020, and cleared an updated version of Caption Guidance on April 16, 2020.

Background: An echocardiogram, also called echocardiography or diagnostic cardiac ultrasound, is a non-invasive, imaging modality for quantitative and qualitative evaluation of cardiac anatomy and function. Transthoracic echocardiogram (TTE) is the most common noninvasive type of echocardiogram, and is often used as a first-line cardiac imaging modality, owing to its wide availability, noninvasiveness, and lack of radiation exposure.

During a TTE, a technician places a hand-held probe called a transducer on the patient's chest. The transducer sends high frequency sound waves that bounce off the heart and "echo" back to the probe to create pictures of the heart's chambers, valves, walls and the blood vessels (aorta, arteries, veins) attached to the heart. Two-dimensional TTE (2D-TTE) provides tomographic or "thin slice" imaging, with each tomographic view defined by the transducer position (parasternal, apical, subcostal, suprasternal) and view (long axis, short axis, four-chamber, five-chamber). Almost all imaging is performed with the patient in the left lateral decubitus position during quiet respiration or extended expiration.

Technology
According to the requestor, Caption Guidance is the only FDA-cleared AI-guided medical imaging acquisition system intended to assist medical professionals in the acquisition of cardiac ultrasound images. The Caption Guidance software functions using a deep learning algorithm, namely convolutional neural networks (CNNs) that were trained using echocardiographic clips from studies performed by trained sonographers. It gives real-time guidance to the healthcare practitioners during the acquisition of echocardiography to assist in obtaining anatomically correct images that represent standard 2D echocardiographic diagnostic views and orientations. The Caption Guidance system is software as a medical device (SaMD). To use the software, the Caption Guidance system must be installed on a compatible third-party ultrasound system.

The Caption Guidance system is indicated for use in 2D-TTE for adult patients, specifically in the acquisition of the following standard views:

- Parasternal Long-Axis (PLAX)
- Parasternal Short-Axis at the Aortic Valve (PSAX-AV)
- Parasternal Short-Axis at the Mitral Valve (PSAX-MV)
- Parasternal Short-Axis at the Papillary Muscle (PSAX-PM)
- Apical 4-Chamber (AP4)
- Apical 5-Chamber (AP5)

- Apical 2-Chamber (AP2)
- Apical 3-Chamber (AP3)
- Subcostal 4-Chamber (SubC4)
- Subcostal Inferior Vena Cava (SC-IVC)

Features of Caption Guidance
The Caption Guidance system contains the following features, which act in tandem to guide the user to acquire diagnostic quality echocardiographic images:

- Quality Meter - Real-time feedback from the Quality Meter advises the user on the expected diagnostic quality of the resulting clip, such that the user can make decisions about further optimizing the quality using the prescriptive guidance feature below.
- Prescriptive Guidance - The Prescriptive Guidance feature in Caption Guidance provides direction to the user to emulate how a sonographer would manipulate the transducer to acquire the optimal view.
- Auto-Capture - The Auto-Capture feature in Caption Guidance triggers an automatic capture of a clip when the quality is predicted to be diagnostic, emulating the way in which a sonographer knows when an image is of sufficient quality to be diagnostic and records it.
- Save Best Clip - This feature continually assesses clip quality while the user is scanning and, in the event that the user is not able to obtain a clip sufficient for auto-capture, the software allows the user to retrospectively record the highest quality clip obtained so far, mimicking the choice a sonographer might make when recording an exam.

Current Coding: Facilities can report transthoracic echocardiography using the appropriate code(s) in section B, Imaging. The utilization of software to guide TTE image acquisition is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for transthoracic echocardiography with AI-guided image acquisition. Continue coding as listed in current coding.

Option 2. In section B Imaging table B24 Ultrasonography of the Heart body system, create new 7th character qualifier value 7 Computer-aided Guidance applied to the appropriate heart body part values to identify the utilization of software to guide TTE image acquisition.

Section	**B** Imaging
Body System	**2** Heart
Type	**4** Ultrasonography: Real time display of images of anatomy or flow information developed from the capture of reflected and attenuated high frequency sound waves

Body Part	*Contrast*	*Qualifier*	*Qualifier*
4 Heart, Right **5** Heart, Left **6** Heart, Right and Left **B** Heart with Aorta **C** Pericardium	**Z** None	**Z** None	**3** Intravascular **4** Transesophageal **ADD 7** Computer-aided Guidance **Z** None

Option 3. Create new codes in section X table X2J Inspection of Cardiovascular System, to identify the utilization of software to guide TTE image acquisition.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**ADD J** Inspection: Visually and/or manually exploring a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD A Heart	**X** External	**ADD 4** Transthoracic Echocardiography**,** Computer-aided Guidance	**ADD 7** New Technology Group 7

CMS Recommendation: CMS is interested in hearing input.

Interim Coding Advice: Continue using current codes as listed in current coding.

Tissue Oxygen Saturation Imaging of GI Tract

Issue: There are currently no unique ICD-10-PCS codes to describe endoscopic tissue oxygen saturation imaging of the GI tract.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? The EP-7000X System received Breakthrough Device designation from the FDA on September 17, 2020. The 510(k) submission for the EP-7000X System was submitted on December 18, 2020 and clearance is expected between April and June 2021.

Background: Minimally invasive endoscopic procedures are typically performed through one or more small incisions, using a small video camera and surgical instruments. Physicians perform these surgical procedures using the instruments inserted in the body cavity through the incision(s) while observing images of the surgical site provided by the camera. In general, minimally invasive surgery is associated with less pain, a shorter hospital stay and fewer complications. Existing endoscopic imaging systems provide physicians with full-color video images on a monitor similar to what they would see with their naked eye during open surgeries.

According to the requestor, in addition to providing the full-color image, the EP-7000X System allows for the visualization of tissue oxygen saturation (StO_2) levels of the GI tract using a 2D endoscopic image during surgeries. The requestor states that no other endoscopic imaging system currently on the market has this capability.

Technology
The EP-7000X System is an endoscopic video imaging system that allows for the visualization of hemoglobin oxygen saturation (StO_2) levels of blood in superficial tissue using a 2D endoscopic image, which helps physicians identify tissue which is not appropriately oxygenated and thus potentially ischemic.

The EP-7000X System is comprised of the following components:

(1) the video laparoscope EL-R740M;
(2) the Processor VP-7000, which relays the image from an endoscope to a video monitor;
(3) the Light Source BL-7000X, which employs five LEDs (Violet, Sky Blue, Blue, Green, and Amber); and
(4) the Image Processing Unit EX-0, which has the Oxygen Saturation Endoscopic Imaging (OXEI) feature that receives endoscopic image data from the Processor and displays an image of StO_2 levels on a monitor using signal processing of the endoscopic image data.

The Image Processing Unit provides two OXEI display modes: OXEI-P and OXEI-F. A user selects one of the OXEI modes to use at a time. The OXEI-P mode provides a heat map image of the StO_2 level where the vivid red corresponds to higher StO_2 level and dark blue to lower StO_2 level. The intermediate StO_2 levels are indicated by colors between the spectrum of red and blue, including yellow and green. The OXEI-F mode provides an overlay image where the StO_2 level image is superimposed on the regular image. The low-StO_2 level area where the StO_2 is less than a

defined threshold level is emphasized by a blue-tinged hue, whose chromaticity becomes stronger as the StO_2 level becomes lower. The threshold can be adjusted by the user.

Procedure Description
The requestor notes that using the endoscopic imaging system in the performance of a procedure is similar to other endoscopic imaging systems and procedures, with a few additional steps (5– 7) to obtain the StO_2 images:
1. Connect the scope connector to the Light Source that is connected to the Processor.
2. Power on the Processor, Light Source and Image Processing Unit.
3. The regular image is displayed on a monitor connected to the Processor.
4. The system is ready for a physician to insert the laparoscope or endoscope in a body cavity
5. The OXEI feature is activated and deactivated by pressing the scope switch on the laparoscope or endoscope, or the Light Mode button on the light source front panel.
6. The OXEI-P and OXEI-F modes are switched back and forth by pressing the foot switch provided with the Processor as an accessory.
7. The StO_2 threshold level for the OXEI-F mode is adjusted by pressing "←" or "→" key on the keyboard also provided with the Processor as an accessory.

Current Coding: There are no unique ICD-10-PCS codes to describe adjunct endoscopic imaging of the tissue oxygen saturation levels of the GI tract during percutaneous endoscopic procedures. In these cases, only the procedure performed is reported.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the endoscopic imaging of tissue oxygen saturation levels of the GI tract. Continue coding as described in current coding.

Option 2. Create new codes in section 4, Measurement and Monitoring, for the endoscopic imaging of tissue oxygen saturation levels of the GI tract.

Section *Body System* *Operation*	**4** Measurement and Monitoring **A** Physiological Systems **1** Monitoring: Determining the level of a physiological or physical function repetitively over a period of time		
Body System	*Approach*	*Function / Device*	*Qualifier*
B Gastrointestinal	**7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**8** Motility **B** Pressure **G** Secretion	**Z** No Qualifier
B Gastrointestinal	**ADD 4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic	**ADD R** Saturation	**ADD G** Intraoperative **Z** No Qualifier
B Gastrointestinal	**X** External	**S** Vascular Perfusion	**H** Indocyanine Green Dye

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*
B Gastrointestinal	**7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**8** Motility **B** Pressure **G** Secretion	**Z** No Qualifier
B Gastrointestinal	**ADD 4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic	**ADD R** Saturation	**ADD G** Intraoperative **Z** No Qualifier

Option 3. Create new codes in section X, New Technology, for the endoscopic imaging of tissue oxygen saturation levels of the GI tract.

Section	**X** New Technology
Body System	**D** Gastrointestinal System
Operation	**2** Monitoring: Determining the level of a physiological or physical function repetitively over a period of time

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
G Upper GI **H** Lower GI	**4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic	**ADD V** Oxygen Saturation	**7** New Technology Group 7

Section	**X** New Technology
Body System	**D** Gastrointestinal System
Operation	**E** Measurement: Determining the level of a physiological or physical function at a point in time

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
G Upper GI **H** Lower GI	**4** Percutaneous Endoscopic **8** Via Natural or Artificial Opening Endoscopic	**ADD V** Oxygen Saturation	**7** New Technology Group 7

CMS Recommendation: Option 3, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Computer-Aided Mechanical Aspiration Thrombectomy

Issue: There are currently no unique ICD-10-PCS codes to describe extirpation of matter from the arterial and venous systems using computer-aided mechanical aspiration that detects thrombus and blood flow.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? Yes. FDA 510(k) clearance for the Penumbra Indigo® Aspiration System with Lightning™ Aspiration Tubing was received on March 13, 2020 (K193244) and updated on April 22, 2020 (K200771) to specify the pulmonary embolism (PE) indication.

Background: Acute massive PE, defined as hemodynamic instability from acute PE, and acute submassive PE, defined by right ventricular strain without hypotension, are common life-threatening conditions that represent the serious manifestations of venous thromboembolic disease. The physiologic effect of massive PE is right ventricular failure, which reduces left ventricular preload and can lead to systemic hypotension and sudden death. Although submassive PE has a lower mortality than massive PE, it is associated with a higher mortality and higher rate of clinical deterioration than low-risk PE.[1]

Therapeutic anticoagulation is the standard of care first-line treatment; the 2016 American College of Chest Physicians (ACCP), 2019 European Society of Cardiology (ESC), and 2011 American Heart Association (AHA) guidelines all recommend the prompt use of anticoagulant therapy (Grade 1b, Class Ia, and Class 1a respectively).[2] However, according to the requestor, several studies have shown higher rates of in-hospital adverse events and pulmonary hypertension and poor functional status at follow-up in high risk submassive PE patients given anticoagulants alone[3].

In addition to medical therapy, surgical thrombectomy and endovascular treatments may also be used for PE. Given the incomplete efficacy of anticoagulation alone and the potential bleeding complications of thrombolytics, endovascular catheter-directed therapy provides alternative options in treating PE. According to the requestor, although there are other endovascular clot removal products indicated for use in PE on the market, none of these products uses a

[1] Giri J, Sista AK, Weinberg I, et al. Interventional Therapies for Acute Pulmonary Embolism: Current Status and Principles for the Development of Novel Evidence: A Scientific Statement From the American Heart Association. Circulation. 2019;140(20) (Giri, 2019).

[2] Jaff MR, McMurtry MS, Archer SL, et al. Management of Massive and Submassive Pulmonary Embolism, Iliofemoral Deep Vein Thrombosis, and Chronic Thromboembolic Pulmonary Hypertension. Circulation. 2011;123(16):1788-1830 (Jaff, 2011); Kearon C, Akl EA, Ornelas J, et al. Antithrombotic Therapy for VTE Disease. Chest. 2016;149(2):315-352 (Kearon, 2016); Konstantinides SV, Meyer

[3] Chatterjee S, Chakraborty A, Weinberg I, et al. Thrombolysis for Pulmonary Embolism and Risk of All-Cause Mortality, Major Bleeding, and Intracranial Hemorrhage. JAMA. 2014;311(23):2414 (Chatterjee, 2014); Kline JA, Nordenholz KE, Courtney DM, et al. Treatment of submassive pulmonary embolism with tenecteplase or placebo: cardiopulmonary outcomes at 3 months: multicenter double-blind, placebo-controlled randomized trial. Journal of Thrombosis and Haemostasis. 2014;12(4):459-468 (Kline, 2014); Meyer G, Vicaut E, Danays T, et al. Fibrinolysis for Patients with Intermediate-Risk Pulmonary Embolism. New England Journal of Medicine. 2014;370(15):1402-1411 (Meyer, 2014).

mechanical thrombectomy aspiration device that can detect when the catheter is in thrombus or patent flow in order to reduce blood loss.

Deep venous thrombosis (DVT), which is frequently the predecessor to PE, occurs when thrombus forms in the deep veins of the body, most often in the legs. As with PE, anticoagulation has been established as the standard treatment option for DVT to prevent PE and recurrent DVT[4]. Studies of anticoagulation in DVT suggested that presence of residual thrombus at 6 months doubled the risk of recurrent venous thromboembolism (VTE)[5], leading to future research into additional thrombo-reductive strategies.

Treatment options for DVT have expanded to include surgical thrombectomy and endovascular treatments[6]. Surgical intervention is invasive, requires general anesthesia, and may carry a small additional risk of PE[5]. Endovascular treatments include catheter-directed thrombolysis (CDT) and pharmacomechanical catheter-directed thrombolysis (PCDT). CDT allows a thrombolytic agent to be infused directly into the thrombus by using a catheter with multiple side-holes. PCDT combines catheter-directed thrombolysis and percutaneous mechanical thrombectomy and reduces thrombolytic drug exposure. The use of endovascular thrombolysis as an adjunct to anticoagulant therapy is considered reasonable in several acute DVT scenarios; however, the potential benefit must be weighed carefully against the increased risk of bleeding[5].

Given the incomplete efficacy of anticoagulation alone and the potential bleeding complications of thrombolytics, endovascular catheter-directed therapy provides alternative options in treating VTE. Percutaneous mechanical thrombectomy devices provide alternative treatment options that may address the concerns with anticoagulation and thrombolytics in patients with VTE. According to the requestor, as with PE, the Indigo® System is the only mechanical thrombectomy aspiration device that can detect when the catheter is in thrombus or patent flow in order to reduce blood loss when used for treatment of DVT.

In acute limb ischemia (ALI), the rapid onset of perfusion limitation (<14 days) threatens limb viability because of insufficient time for adequate collateral recruitment[7]. Uncertainty remains regarding interventional outcomes for ALI patients, and despite recent improvements in therapeutic technique and declines in 1-year amputation rate, there have been no significant improvements in 1-year amputation-free survival, which remains unchanged at 52.3%[8]. Clinical practice recommendations for the diagnosis and management of ALI classify patients using the Rutherford classification scale[9]. Patients falling into Rutherford category II (a and b)

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[4] Streiff MB, Agnelli G, Connors JM, et al. Guidance for the treatment of deep vein thrombosis and pulmonary embolism. J Thromb Thrombolysis. 2016;41(1):32-67 (Streiff, 2016).

[5] Jaff, 2011.

[6] Goktay AY, Senturk C. Endovascular Treatment of Thrombosis and Embolism. Advances in experimental medicine and biology. 2017;906:195-213 (Goktay, 2017)

[7] Acar, R.D., Sahin, M., and Kirma, C. (2013). One of the most urgent vascular circumstances: Acute limb ischemia. SAGE Open Med. 1: p. 2050312113516110 (Acar, 2013).

[8] Gilliland, C., Shah, J., Martin, J.G., and Miller, M.J., Jr. (2017). Acute limb ischemia. Tech Vasc Interv Radiol. 20(4): p. 274-280 (Gilliland, 2017); Baril, D.T., Ghosh, K., and Rosen, A.B. (2014). Trends in the incidence, treatment, and outcomes of acute lower extremity ischemia in the united states medicare population. J Vasc Surg. 60(3): p. 669-77 e2 (Baril, 2014).

[9] Gerhard-Herman, et al. (2017). 2016 aha/acc guideline on the management of patients with lower extremity peripheral artery disease: A report of the american college of cardiology/american heart association task force on clinical practice guidelines. J Am Coll Cardiol. 69(11): p. e71-e126 (Gerhard-Herman, 2017); Aboyans, V. et al. (2018). Editor's choice - 2017 esc guidelines on the diagnosis and treatment of peripheral arterial diseases, in collaboration with the european society for vascular surgery (esvs). Eur J

are at risk of limb loss, with prompt treatment and revascularization urgently indicated for limb salvage.

Contemporary revascularization guidelines for ALI include, but are not limited to, CDT and surgical thromboembolectomy[10]. Over the past decades, the surgical management of ALI has evolved to include endovascular approaches[11], especially following the publication of three randomized, multicenter trials that established the efficacy of CDT as compared with surgical revascularization[12]. Catheter-directed thrombolysis[13], along with newer endovascular approaches, have become routine for restoring perfusion in ALI patients[14]. Nevertheless, the cost of ALI-related complications and mortality remains high, leading to strong interest in assessing the efficacy of different revascularization devices and procedures[15]. The requestor stated the Indigo® System is the only mechanical thrombectomy aspiration device that can detect when the catheter is in thrombus or patent flow in order to reduce blood loss when used for treatment of ALI.

Technology

According to the requestor, unlike the other endovascular clot removal products discussed above, the Indigo® System uses a mechanical pump (the Penumbra Engine®) to generate a vacuum for aspiration. Additionally, the Lightning™ tubing is the technology aspect of the Indigo® System that detects when the catheter is in patent flow (and therefore removing blood) or in thrombus (and removing clot). This technology automatically stops and starts the Penumbra Engine® to reduce blood loss (e.g., stopping the pump when the catheter is in patent flow, and starting when the physician moves the catheter back into thrombus). The Lightning™ tubing provides audio and visual signals to the physician when the Indigo® System is in each of these states to help the physician know when to move the catheter for better clot removal. The requestor stated no other system on the market has this capability.

Procedure Description

In this procedure, the provider treats an occlusion in a noncoronary or non–intracranial artery, vein or in an arterial bypass graft by using a technique of mechanical aspiration thrombectomy. The procedure includes vascular access (typically via the femoral vein) and manipulating the catheter to the clot under imaging guidance, including through the heart to the pulmonary arteries for treatment of PE. Once to the clot, the Lightning™ component of the Indigo® System is turned on and the physician uses auditory and visual clues to engage and remove the thrombus with the assistance of imaging. The Lightning™ component also has sensors that detect whether the device

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Vasc Endovasc Surg. 55(3): p. 305-368 (Aboyans, 2018); Rutherford, R.B., Baker, J.D., Ernst, C., Johnston, K.W., Porter, J.M., Ahn, S., and Jones, D.N. (1997). Recommended standards for reports dealing with lower extremity ischemia: Revised version. J Vasc Surg. 26(3): p. 517-38 (Rutherford, 1997).

[10] Gerhard-Herman, 2017; Aboyans, 2018

[11] Baril, 2014; Leung, D.A., et al. (2015). Rheolytic pharmacomechanical thrombectomy for the management of acute limb ischemia: Results from the pearl registry. J Endovasc Ther. 22(4): p. 546-57 (Leung, 2015).

[12] Investigators, T.S. (1994). Results of a prospective randomized trial evaluating surgery versus thrombolysis for ischemia of the lower extremity. The stile trial. Ann Surg. 220(3): p. 251-66; discussion 266-8 (Investigators, 1994); Ouriel, K., et al. (1994). A comparison of thrombolytic therapy with operative revascularization in the initial treatment of acute peripheral arterial ischemia. J Vasc Surg. 19(6): p. 1021-30 (Ouriel, 1994); Ouriel, K., Veith, F.J., and Sasahara, A.A. (1996). Thrombolysis or peripheral arterial surgery: Phase i results. Topas investigators. J Vasc Surg. 23(1): p. 64-73; discussion 74-5 (Ouriel, 1996).

[13]Morrison, H.L. (2006). Catheter-directed thrombolysis for acute limb ischemia. Semin Intervent Radiol. 23(3): p. 258-69 (Morrison, 2006).

[14] Aboyans, 2018; Baril, 2014.

[15] Shishehbor, M.H. (2014). Acute and critical limb ischemia: When time is limb. Cleve Clin J Med. 81(4): p. 209-16 (Shishehbor, 2014).

is in thrombus or blood and only turns on suction when in thrombus. The requestor noted that aspiration is used to remove the thrombus rather than mechanical force, therefore it does not rely on a large intravascular device to capture the clot and does not need to be repeatedly placed into and removed from the body for adequate thrombus removal.

Current Coding: There are no unique ICD-10-PCS codes to describe the extirpation of matter from peripheral vessels using a computer-aided mechanical thrombectomy aspiration device. Facilities can report this procedure with the applicable ICD-10-PCS code(s) from the table(s) listed below.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

Body Part	*Approach*	*Device*	*Qualifier*
P Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava	**3** Percutaneous	**Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta 5 Superior Mesenteric Artery **9** Renal Artery, Right **A** Renal Artery, Left **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	**3** Percutaneous	**Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**5** Upper Veins
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

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 **M** Internal Jugular Vein, Right **N** Internal Jugular Vein, Left	**3** Percutaneous	**Z** No Device	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**6** Lower Veins
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Inferior Vena Cava **1** Splenic Vein **8** Portal Vein **C** Common Iliac Vein, Right **D** Common Iliac Vein, Left **F** External Iliac Vein, Right **G** External Iliac Vein, Left **M** Femoral Vein, Right **N** Femoral Vein, Left	**3** Percutaneous	**Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the extirpation of matter from peripheral vessels using a computer-aided mechanical thrombectomy aspiration device. Continue coding as listed in current coding.

Option 2. Create new codes in tables 02C Extirpation of Heart and Great Vessels, 04C Extirpation of Lower Arteries, 05C Extirpation of Upper Veins and 06C Extirpation of Lower Veins, to identify extirpation of matter from peripheral vessels using a computer-aided mechanical aspiration thrombectomy device.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

Body Part	*Approach*	*Device*	*Qualifier*
P Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava	**3** Percutaneous	**Z** No Device	**ADD B** Computer-aided Mechanical Aspiration **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**4** Lower Arteries
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta 5 Superior Mesenteric Artery **9** Renal Artery, Right **A** Renal Artery, Left **C** Common Iliac Artery, Right **D** Common Iliac Artery, Left **E** Internal Iliac Artery, Right **F** Internal Iliac Artery, Left	**3** Percutaneous	**Z** No Device	**ADD B** Computer-aided Mechanical Aspiration **Z** No Qualifier

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			

Section	**0** Medical and Surgical
Body System	**5** Upper Veins
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

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 **M** Internal Jugular Vein, Right **N** Internal Jugular Vein, Left	**3** Percutaneous	**Z** No Device	**ADD B** Computer-aided Mechanical Aspiration **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**6** Lower Veins
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Inferior Vena Cava **1** Splenic Vein **8** Portal Vein **C** Common Iliac Vein, Right **D** Common Iliac Vein, Left **F** External Iliac Vein, Right **G** External Iliac Vein, Left **M** Femoral Vein, Right **N** Femoral Vein, Left	**3** Percutaneous	**Z** No Device	**ADD B** Computer-aided Mechanical Aspiration **Z** No Qualifier

Option 3. Create new codes in section X, New Technology, to identify the extirpation of matter from peripheral vessels using a computer-aided mechanical thrombectomy aspiration device.

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*
ADD Q Upper Extremity Vein, Right **ADD R** Upper Extremity Vein, Left **ADD S** Lower Extremity Artery, Right	**3** Percutaneous	**ADD T** Computer-aided Mechanical Aspiration	**7** New Technology Group 7

ADD T Lower Extremity Artery, Left **ADD U** Lower Extremity Vein, Right **ADD V** Lower Extremity Vein, Left **ADD W** Abdominal Aorta **ADD Y** Great Vessel			

CMS Recommendation: CMS is interested in hearing input.

Interim Coding Advice: Continue using current codes as listed in current coding.

Transcatheter Replacement of Pulmonary Valve

Issue: There are currently no unique ICD-10-PCS codes to describe transcatheter replacement of the pulmonary valve at its native site.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? The Harmony™ transcatheter pulmonary valve (TPV) received the FDA Breakthrough Device designation on May 01, 2019. As an FDA-designated Breakthrough Technology device, the Harmony™ TPV is the first transcatheter pulmonary valve that is designed to treat the patient's condition at the native site of the pulmonary valve without a pre-existing valved conduit or pre-existing bioprosthetic valve. FDA approval is expected first quarter 2021.

Background: The pulmonary valve is located between the right ventricle and the main pulmonary artery. Normally, deoxygenated blood is pumped from the right ventricle through the pulmonary valve and into the main pulmonary artery on its way to the lungs to become reoxygenated. The pulmonary valve functions to prevent backflow of blood into the right ventricle.

Anatomically, the upper extension of the right ventricle through the pulmonary valve and into the main pulmonary artery comprises the right ventricular outflow tract (RVOT). Disorders of the pulmonary valve, such as pulmonary valve stenosis and atresia, cause obstruction of the RVOT, hindering the flow of blood to the lungs for reoxygenation.

Most pulmonary valve disorders are congenital. Patients with congenital pulmonary valve defects require early intervention to relieve the RVOT obstruction. This typically takes place in infancy, with many patients undergoing multiple procedures throughout their childhood.

Early intervention for pulmonary valve disorders can take multiple forms:
- Creation of a Blalock-Thomas-Taussig (BTT) shunt from the subclavian or innominate artery to the right or left pulmonary artery
- Percutaneous balloon valvuloplasty of the existing anomalous pulmonary valve
- Reconstruction of the RVOT via incision and patch graft
- Surgical placement of a right ventricular-pulmonary artery (RV-PA) valved conduit

The procedures performed early in life are mostly palliative in that they are not intended as permanent correction. Instead, these procedures allow the patient to develop while delaying surgical replacement of the pulmonary valve until the patient has completed growing.

Some of the early interventions to relieve obstruction and stenosis later lead the patient to develop pulmonary valve insufficiency (regurgitation). The BTT shunt, balloon valvuloplasty, and RVOT patch graft primarily focus on the immediate need to improve blood flow to the lungs, without addressing the backflow of blood into the right ventricle. Although pulmonary valve insufficiency (regurgitation) can be tolerated for varying periods, there are long-term consequences. Backflow eventually leads to chronic volume overload, right ventricular hypertrophy, and right-sided heart failure as well as development of significant arrhythmias.

Eventual replacement of the pulmonary valve, typically performed when the patient is a young adult, is necessary as a permanent correction and to address the consequences of backflow. Pulmonary valve replacement is currently an open surgical procedure. Recently, a new procedure has been developed for transcatheter pulmonary valve replacement at its native site between the right ventricle and the main pulmonary artery.

Technology and Procedure
The transcatheter procedure at the valve's native site is typically performed for Tetralogy of Fallot with either pulmonary valve stenosis or pulmonary atresia. Less commonly, it may be performed for truncus arteriosus, double-outlet right ventricle, and other congenital conditions which affect blood flow to the lungs. According to the requestor, patients who undergo the new transcatheter pulmonary valve replacement procedure at the native site had previously been palliatively treated with either a BTT shunt, balloon valvuloplasty, or RVOT patch graft. This procedure at the native site is not performed on patients who had previously received a valved RV-PA conduit.

The transcatheter pulmonary valve replacement procedure uses a unique bioprosthetic valve. Zooplastic valve tissue is mounted onto an hourglass-shaped nitinol frame for delivery and proper seating at the native site. The procedure begins with access to the central venous system, typically the femoral vein at the groin or the internal jugular vein, and placement of a venous sheath. After a catheter is introduced into the right side of the heart, angiography of the right ventricular outflow tract is performed, noting the bifurcation of the right and left pulmonary arteries. The valve is loaded onto a delivery system. The delivery system is placed into the venous sheath and maneuvered over a guidewire into the superior vena cava. It is then advanced into the right atrium, through the tricuspid valve, and into the right ventricle. From the right ventricle, the delivery system is maneuvered into the main pulmonary artery and advanced to the bifurcation, with its distal component directed into either the left or right pulmonary artery. Under fluoroscopy, the sheath enclosing the valve is sequentially withdrawn. The valve expands into position and is then released. The valve's position between the right ventricle and the pulmonary artery is confirmed using angiography. Intracoronary echocardiography may also be performed to assess the function of the new valve leaflets and identify any valve leakage. Following removal of the delivery system and other instruments, the venous access is closed.

The requestor noted this new transcatheter procedure replaces the pulmonary valve at its native site between the right ventricle and the main pulmonary artery. The requestor also noted that there is another type of transcatheter pulmonary valve replacement which has been performed for approximately 10 years, but it does not take place at the native site. Instead, this type of transcatheter pulmonary replacement is performed within a previously placed RV-PA conduit. The RV-PA conduit is designed with a bioprosthetic valve inside the conduit which takes over the function of the pulmonary valve, albeit at a different location. As the patient grows, if the valve within the conduit develops dysfunction, the valve can be replaced by implanting another valve within the conduit via a transcatheter "valve-in-valve" technique.

Current Coding: There are no unique ICD-10-PCS codes to uniquely identify transcatheter replacement of the pulmonary valve at the native site. Facilities can report the procedure using the appropriate code in table 02R, Replacement of Heart and Great Vessels.

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

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for transcatheter replacement of the pulmonary valve at the native site. Continue coding as listed in current coding.

Option 2. In table 02R, Replacement of Heart and Great Vessels, create new 7th character qualifier value M Native Site, applied to the Pulmonary Valve body part, the approach value Percutaneous and the device value Zooplastic Tissue to identify transcatheter replacement of the pulmonary valve at the native site.

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

Body Part	*Approach*	*Device*	*Qualifier*
F Aortic Valve **G** Mitral Valve **H** Pulmonary Valve **J** Tricuspid Valve	**3** Percutaneous	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**H** Transapical **Z** No Qualifier
H Pulmonary Valve	**3** Percutaneous	**8** Zooplastic Tissue	**ADD M** Native Site

Option 3. Create new codes in section X table X2R, Replacement of Cardiovascular System, to identify transcatheter replacement of the pulmonary valve at the native site.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD H Pulmonary Valve	**3** Percutaneous	**ADD M** Zooplastic Tissue, Native Site	**7** New Technology Group 7

Option 4. In table 02R, Replacement of Heart and Great Vessels, create new 7th character qualifier values L In Existing Conduit and M Native Site, applied to the Pulmonary Valve body part, the approach value Percutaneous and the device value Zooplastic Tissue to identify transcatheter replacement of the pulmonary valve at a native site versus at an existing conduit site.

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

Body Part	*Approach*	*Device*	*Qualifier*
F Aortic Valve **G** Mitral Valve **H** Pulmonary Valve **J** Tricuspid Valve	**3** Percutaneous	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**H** Transapical **Z** No Qualifier
H Pulmonary Valve	**3** Percutaneous	**8** Zooplastic Tissue	**ADD L** In Existing Conduit **ADD M** Native Site

CMS Recommendation: Option 3, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Combined Thoracic Aortic Arch Replacement and Descending Thoracic Aorta Restriction

Issue: There are currently no unique ICD-10-PCS codes to describe thoracic aortic arch replacement combined with restriction of the descending thoracic aorta.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? No. This device is currently seeking Premarket Approval (PMA) from the FDA. The device received Breakthrough Device designation on March 20, 2020.

Background: Replacement of the aortic arch is technically challenging, and is associated with a high risk of perioperative death and stroke. When disease involving the arch extends into the descending thoracic aorta, a two-stage repair is commonly necessary. The first stage entails replacement of the ascending aorta and transverse arch with an elephant trunk (ET) graft. The second stage is generally accomplished after an interval for patient recovery and requires treatment of the descending thoracic or thoracoabdominal aorta with a separate endograft.

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

Technology and Procedure
The Thoraflex™ Hybrid device is a dual purpose medical device that replaces the ascending aorta and aortic arch while also stabilizing and repairing the descending thoracic aorta in a single procedure, performed by a cardiothoracic surgeon. It is preloaded into a delivery system, which is designed to offer safe delivery and accurate deployment.

The descending thoracic aorta is repaired by placing the stented distal end of the device via an antegrade transluminal approach through the transected aorta and into the descending thoracic aorta. The device is secured by suturing an integral collar portion of the product to the distal native aortic remnant. The ascending aorta and aortic arch are then resected and replaced with the proximal, non-stented portion of the device. The device is fully gelatin-sealed and comprises a woven polyester proximal branched arch graft pre-sewn to an anastomotic sewing collar and distal stent. According to the requestor, the collar ensures easier anastomosis of the device to the aorta by reducing the hemodynamic traction on the anastomosis.

The device is available in a number of proximal graft sizes, distal stent diameters and currently two design configurations. The first configuration is the Thoraflex™ Hybrid Plexus Graft, a multi-branch design that enables individual aortic arch branch reconstruction. The second configuration,

the Thoraflex™ Hybrid Ante-Flo™ design, allows the island technique where the aortic arch branches and associated aortic tissue are reattached as a patch to an opening cut in the graft. These alternative techniques offer different surgical strategies for patient treatment.

Current Coding: There are no unique ICD-10-PCS codes to identify thoracic aortic arch replacement combined with restriction of the descending thoracic aorta. Facilities can report the thoracic aortic arch replacement using the appropriate code in table 02R, Replacement of Heart and Great Vessels, and the restriction of the descending thoracic aorta using the appropriate code in table 02V, Restriction of Heart and Great Vessels.

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

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

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

Body Part	*Approach*	*Device*	*Qualifier*
W Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **E** Intraluminal Device, Branched or Fenestrated, One or Two Arteries **F** Intraluminal Device, Branched or Fenestrated, Three or More Arteries **Z** No Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for thoracic aortic arch replacement combined with restriction of the descending thoracic aorta. Continue coding as listed in current coding.

Option 2. Create new codes in section X table X2R, Replacement of Cardiovascular System and 02V, Restriction of Cardiovascular System, to identify thoracic aortic arch replacement combined with restriction of the descending thoracic aorta. Both codes would be reported for this procedure.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD X Thoracic Aorta, Ascending/Arch	**0** Open	**ADD N** Branched Synthetic Substitute with Intraluminal Device	**7** New Technology Group 7

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD W Thoracic Aorta, Descending	**0** Open	**ADD P** Intraluminal Device with Branched Synthetic Substitute	**7** New Technology Group 7

Option 3a. Create new codes in section X table X2Q, Repair of Cardiovascular System, to identify thoracic aortic arch replacement combined with restriction of the descending thoracic aorta in a single procedure code.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD Y Aortic Arch with Descending Thoracic Aorta	**0** Open	**ADD N** Branched Synthetic Substitute with Intraluminal Device	**7** New Technology Group 7

Option 3b. Create new codes in section X table X2Q, Repair of Cardiovascular System, to identify thoracic aortic arch replacement combined with restriction of the descending thoracic aorta using separate body part values, resulting in 2 codes to report.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD W Thoracic Aorta, Descending **ADD X** Thoracic Aorta, Ascending/Arch	**0** Open	**ADD N** Branched Synthetic Substitute with Intraluminal Device	**7** New Technology Group 7

CMS Recommendation: CMS is interested in hearing input.

Interim Coding Advice: Continue using current codes as listed in current coding.

Coronary Intravascular Lithotripsy (IVL)

Issue: Currently, there is no unique ICD-10-PCS code to identify the use of intravascular lithotripsy (IVL) to treat calcified lesions in the coronary arteries.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? No. FDA approval for the coronary IVL is expected in early 2021. The coronary IVL system has received Breakthrough Device Designation from the FDA.

Background: Percutaneous coronary intervention (PCI) with drug-eluting stent (DES) implantation is the most frequent mode of coronary revascularization. Advanced age and an increasing frequency of diabetes mellitus, hypertension, and renal insufficiency contribute to an increasing prevalence and severity of vascular calcification. Despite the use of high pressure noncompliant balloon catheters, cutting/scoring balloons and atheroablative technologies to modify calcium, PCI of heavily calcified lesions may be associated with early complications (e.g., dissection, perforation, myocardial infarction [MI]) and/or late adverse events (e.g., restenosis, stent fracture, thrombosis and need for repeat revascularization).

Coronary calcification may impede stent delivery and deployment, leading to under expansion, malposition, or direct damage to the stent surface, potentially impairing drug delivery. Suboptimal stent expansion is the strongest predictor of subsequent stent thrombosis and restenosis. Although atherectomy facilitates stent expansion, the extent of calcium modification is limited by guidewire bias and may be associated with peri-procedural complications including slow-flow, no-reflow, coronary dissection, perforation, and MI.

Coronary intravascular lithotripsy (IVL) is a new treatment option for treating calcified lesions in the coronary arteries. Coronary IVL utilizes controlled sound waves in short pulses to selectively crack intimal and medial calcium within the vessel wall without affecting soft tissue. Once fractured, the calcium's resistance to balloon dilatation is reduced, thereby allowing the blood vessel to be dilated using a low-pressure angioplasty balloon prior to coronary stenting.

Procedure Description
The primary mechanism of action of coronary IVL therapy is lithotripsy, which is generated from multiple lithotripsy emitters that are integrated into a semi-compliant balloon-catheter platform. The coronary IVL catheter is advanced to the target lesion and the integrated balloon is inflated with fluid at a low pressure to contact the arterial wall. Coronary IVL is then activated, creating a small bubble within the catheter balloon that rapidly expands and collapses. The rapid expansion and collapse of the bubble creates sonic pressure waves that travel through the innermost layer of the vessel wall and crack the calcium within the vessel wall.

Current Coding: Currently, facilities report balloon angioplasty with or without stent insertion to treat calcified lesions in the coronary arteries with codes in table 027. The performance of coronary intravascular lithotripsy is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for coronary intravascular lithotripsy. Continue coding as listed in current coding.

Option 2. Add the following body part values to table 02F Fragmentation of Heart and Great Vessels, to identify coronary intravascular lithotripsy: 0 Coronary Artery, One Artery, 1 Coronary Artery, Two Arteries, 2 Coronary Artery, Three Arteries and 3 Coronary Artery, Four or More Arteries. Separately assign the applicable ICD-10-PCS code(s) for angioplasty or stent insertion if performed.

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*
ADD 0 Coronary Artery, One Artery **ADD 1** Coronary Artery, Two Arteries **ADD 2** Coronary Artery, Three Arteries **ADD 3** Coronary Artery, Four or More Arteries	**3** Percutaneous	**Z** No Device	**Z** No Qualifier

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Percutaneous Creation of an Arteriovenous Fistula (AVF)

Issue: There are currently no unique ICD-10-PCS codes to describe the percutaneous creation of an arteriovenous fistula (AVF) using thermal resistance energy.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? Yes. The Ellipsys® Vascular Access System received a De Novo Reclassification Order (DEN170004) on June 18, 2018. A subsequent 510(k) approval, which included balloon angioplasty as a procedural step to immediately follow anastomosis creation during percutaneous AVF, was received on August 19, 2019.

Background: Access to the bloodstream is necessary for hemodialysis in the treatment of end-stage renal disease. This access can be provided by a catheter, graft, or AVF; the latter is generally preferred for patients whose vascular anatomy and condition permits it. Until recently, the only method for creating an AVF was through an open surgical approach. Today, an AVF can be created percutaneously using the Ellipsys® Vascular Access System or an alternative technology, the WavelinQ™ EndoAVF System.

Technology
The Ellipsys® Vascular Access System is a device that enables percutaneous creation of an AVF using thermal resistance energy. According to the requestor, a percutaneous AVF, or pAVF, provides an alternative option to traditional surgically-created AVFs and offers a number of advantages. The pAVF created by the Ellipsys® Vascular Access System is between a vein and an artery that remain side-by-side and is distinct from the surgical "end-to-side" approach used for most surgical AVFs, where one vessel is truncated and the end is attached to the side of another vessel. The requestor notes that the pAVF side-by-side approach contributes to improvements in the performance of the procedure such as successful fistula creation, time to two-needle cannulation, and cumulative patency over several years. In addition, the requestor notes that pAVFs created using the Ellipsys® Vascular Access System have demonstrated better outcomes compared to those procedures performed using the currently available alternative pAVF technology, including having a higher fraction of cases with clinically functional AVFs, speedier maturation, more durable AVFs and a lower failure rate.

Procedure Description
During the creation of a pAVF using the Ellipsys® Vascular Access System, the cubital vein is cannulated under ultrasound guidance. The physician inserts a needle through the vein, punctures the lumen of the adjacent proximal radial artery, and advances a guidewire into the artery. A sheath is tracked over the guidewire and advanced into the artery. A single Ellipsys® catheter is then inserted through the sheath and positioned so its distal tip is in the artery. The sheath is withdrawn, and the catheter is used to mechanically capture and compress the walls of artery and vein. The power source is activated and thermal resistance energy (*i.e.*, direct heat) is precisely applied to fuse the artery and vein adventitia together and cut an elliptical anastomosis, permanently connecting the artery and vein. The catheter is removed, allowing blood to flow through the anastomosis, creating an AVF. The flow through the fistula is assessed using Doppler ultrasound; it is immediately increased by balloon angioplasty of the anastomosis. The

percutaneous AVF created using the Ellipsys® Vascular Access System differs from the alternative technology (WavelinQ™) for creating a pAVF in the following ways:

- Source of energy − thermal resistance for Ellipsys®, radiofrequency for WavelinQ™;
- Number of specialized catheters employed −one for Ellipsys®, two for WavelinQ™; and
- Additional procedural steps – balloon angioplasty for Ellipsys®, embolization for WavelinQ™; and
- Form of imaging involved − ultrasound for Ellipsys®, fluoroscopy and ultrasound for WavelinQ™.

Current Coding: There are no unique ICD-10-PCS codes to identify percutaneous creation of an arteriovenous fistula using thermal resistance energy. Facilities can report the procedure using one of the following code(s):

031B3ZF Bypass right radial artery to lower arm vein, percutaneous approach
031C3ZF Bypass left radial artery to lower arm vein, percutaneous approach

A code for the angioplasty from table 037, Dilation of Upper Arteries, would be reported separately.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the percutaneous creation of an arteriovenous fistula using thermal resistance energy. Continue coding as listed in current coding.

Option 2. Create new codes in section X table X2K, Bypass of Cardiovascular System, to identify the percutaneous creation of an arteriovenous fistula using thermal resistance energy.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**ADD K** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD B Radial Artery, Right **ADD C** Radial Artery, Left	**3** Percutaneous	**ADD 1** Thermal Resistance Energy	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Pharyngeal Electrical Stimulation

Issue: There are currently no unique ICD-10-PCS codes to describe pharyngeal electrical stimulation.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? No, the Phagenyx® System has not yet received FDA Approval. The Phagenyx® System received Breakthrough Device Designation for the treatment of neurogenic dysphagia in adult tracheotomized patients weaned from mechanical ventilation in 2019. In 2021, the FDA expanded Breakthrough Device Designation to include the treatment of non-progressive neurogenic dysphagia.

Background: Neurogenic dysphagia is dysphagia arising from the disruption of any of the neurological systems or processes involved in the execution of a coordinated safe swallow. A broad range of different underlying diseases (neurological or non-neurological) or care management interventions, like mechanical ventilation, can give rise to this form of neurological disruption, which can manifest as desensitization or dysfunction of local neurological sensory systems, a disruption of control systems in the swallow motor cortex, or both.

Neurogenic dysphagia is commonly seen after stroke, traumatic brain injury or prolonged mechanical ventilation. It can also be complicated by a combination of those factors, e.g., dysphagia arising from an initial insult to the brain (stroke, trauma or inflammation) is further complicated following extended mechanical ventilation due to local desensitization/disuse atrophy of swallow-related nerves and muscles.

Dysphagia routinely results in an unsafe airway due to the inability of the patient to manage or clear pooled secretions in the hypopharynx. These secretions can enter the lower airways and can make their way to the lower respiratory spaces and act as a locus for infection (aspiration pneumonia). Dysphagic patients also routinely lack an effective cough. In the case of ventilated patients with tracheostomy tubes, poor secretion management and an ineffective cough can prevent the tube from being safely removed (decannulated) after respiratory function has recovered. Delayed decannulation increases length of stay, significantly increases burden of care, limits discharge options, increases risk of tissue damage, prevents oral and speech rehabilitation, and increases risk of pneumonia. Dysphagia also gives rise to an ineffective swallow, which affects nutritional intake and quality of life. Patients with an ineffective swallow must be fed via tube or via modified oral intake. This creates a substantial burden of care, extends hospital length of stay, reduces discharge rates to a home setting, reduces quality of life, and increases risk of infection and re-hospitalization.

A US-specific dysphagia impact study published in 2017 by Patel et al[1] showed that after adjusting for patient characteristics, comorbidity and hospital related factors, the absolute in-hospital mortality is 2.9% higher per year in patients with dysphagia. This translates into up to 19,000 additional deaths per year among US patients specifically due to dysphagia.

[1] Patel D. A., Krishnaswami S., Steger E., Conover E., Vaezi M. F., Ciucci M. R., Francis D. O. Economic and survival burden of dysphagia among inpatients in the United States. Diseases of the Esophagus (2018) 31, 1–7

Technology
The Phagenyx® System is designed to treat neurogenic dysphagia. Phagenyx® uses electrical pulses to stimulate sensory nerves in the oropharynx. According to the requestor, once stimulated, these nerves send signals to the motor cortex in the brain, increasing cortical activity, promoting neuroplasticity and restoring swallowing control through functional cortical reorganization. In addition, Phagenyx® treatment results in beneficial changes in the local sensory mechanisms of the pharyngeal mucosa linked to swallow and cough reflex through an increase in the swallow-related neurotransmitter Substance P. The requestor notes that Phagenyx® System does not treat the underlying diseases that give rise to dysphagia; it treats the common neurological symptoms and swallowing deficits that these diseases cause (i.e., neurogenic dysphagia).

The Phagenyx® System is comprised of a sterile single patient use catheter and a Base Station. The catheter is a two-part fine bore flexible tube that is introduced intranasally and extends to the patients' stomach. It incorporates two bipolar ring electrodes on its outer surface to deliver the electrical stimulation. The catheter design also incorporates an optional feeding lumen, which can be used to administer nutrition and fluids if required, meaning that only one tube is required for both treatment and feeding. The Base Station is a touch-screen user interface that facilitates the optimization of stimulation levels and stores patient and treatment information.

Procedure Description
1. Prior to insertion, the Phagenyx® catheter is adjusted to fit the patient's anatomy. Using integrated guides to help confirm position, the catheter is inserted intranasally and passed through the pharynx and esophagus, until the tip is located in the stomach, and the electrodes are in the oropharynx. Pharyngeal Electrical Stimulation (PES) electrical fields act on the pharyngeal mucosa, base of the tongue, epiglottis, and the area above the larynx (primarily the oropharynx and part of the laryngopharynx), with peripheral sensory nerves IX and X targeted.
2. The catheter is connected to the Base Station and stimulation is incrementally increased to establish the Threshold Level (lowest current the patient can detect) and Tolerance Level (highest level they can tolerate). A Stimulation Level is derived from these two values. This must be done for each treatment.
3. 10 minutes of treatment are delivered once per day for three consecutive days. For the minority of patients that do not respond to three treatments, up to a maximum of three more treatments are permitted.
4. Only one catheter is used per patient for the whole treatment regimen (i.e., it stays in place between treatment sessions). Once all treatments are completed, the catheter is removed and disposed of in clinical waste. Alternatively, if required, the catheter can be left in place for up to 30 days to facilitate feeding.
5. Following treatment, medical records are updated to denote PES was performed with the Phagenyx® System.

Current Coding: Facilities can report the placement of electrodes in the oropharynx to stimulate sensory nerves using electrical pulses with the following code:

0CHY7YZ Insertion of other device into mouth and throat, via natural or artificial opening

Facilities can also report the insertion of a feeding tube using the appropriate code in table 0DH, Insertion of Gastrointestinal System.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the use of electrical pulses to stimulate sensory nerves in the oropharynx. Continue using current codes as listed in current coding.

Option 2. Create new codes in section 0, Medical and Surgical, to identify the use of electrical pulses to stimulate sensory nerves in the oropharynx. Continue to report the insertion of a feeding tube using the appropriate code in table 0DH, Insertion of Gastrointestional System, as listed in current coding.

Section	**0** Medical and Surgical
Body System	**C** Mouth and Throat
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*
Y Mouth and Throat	**7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**1** Radioactive Element **B** Intraluminal Device, Airway **ADD** M Neurostimulator Lead **Y** Other Device	**Z** No Qualifier

Option 3. Create a new code in section X, New Technology, to identify the use of electrical pulses to stimulate sensory nerves in the oropharynx. Continue to report the insertion of a feeding tube using the appropriate code in table 0DH, Insertion of Gastrointestional System, as listed in current coding.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
D Mouth and Pharynx	**7** Via Natural or Artificial Opening	**ADD** M Neurostimulator Lead	**7** New Technology Group 7

CMS Recommendation: Option 3, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Measurement of Flow in a Cerebral Fluid Shunt

Issue: There are currently no unique ICD-10-PCS codes to describe the noninvasive measurement of flow through a cerebrospinal fluid (CSF) shunt.

New Technology Application? No. However, the requestor intends to submit a New Technology Add-on Payment (NTAP) application in October 2021 for FY 2023 consideration.

Food & Drug Administration (FDA) Approval? No. The FlowSense Noninvasive Thermal Sensor received Breakthrough Device Designation from the FDA in June 2020.

Background: Hydrocephalus is a debilitating neurological disorder that results from the overproduction and/or impaired reabsorption of cerebrospinal fluid (CSF) in the ventricles of the brain. Causes include congenital malformations, intracerebral hemorrhage, infection, trauma, and tumors. The condition can occur in nearly all age groups from infants to elderly patients, with the latter group particularly susceptible to idiopathic normal pressure hydrocephalus (iNPH). Hydrocephalus affects over 1 million people in the United States alone. In nearly all cases, the treatment involves surgical implantation of a pressure-regulated silicone tube assembly, known as a 'shunt'. Ventricular shunt assemblies typically involve two silicone catheters, connected upstream and downstream of a regulating valve, to drain excess fluid away from the cerebral ventricles to a distal absorptive site, such as the peritoneum, pleural cavity, or right atrium. Unfortunately, shunts suffer from high failure rates, which results in an impaired quality of life for both patients and their caregivers due to the uncertainty associated with the potential for shunt failure.

The symptoms of shunt failure are identical to those of hydrocephalus and are non-specific, including headaches, nausea, dizziness, and drowsiness. Catheter occlusion or malfunction can be difficult to diagnose without medical imaging or surgery. As a result, patients commonly undergo a range of diagnostic procedures for these vague symptoms, including evaluating the size of the cerebral ventricles with computed tomography (CT) scans or magnetic resonance imaging (MRI), and evaluating for disconnection or fracture of the shunt tubing with X-ray imaging, known as a 'shunt-series'. According to the requestor, such procedures represent indirect measures and they suffer from a combination of low accuracy, radiation exposure, and in the case of MRIs in pediatric patients, the need for anesthesia. More direct measures of shunt patency include nuclear medicine "shunt function" studies where a radionucleotide tracer is directly injected into the shunt system. However, the requestor notes this procedure can be painful, can introduce infection into the shunt, and it is poorly suited to pediatric populations. Similarly, lumbar puncture tests also rely on hollow needles to collect spinal CSF for the assessment of pressure and viral infections. In some cases, patients are admitted to the hospital for long-term observation or to undergo exploratory surgeries to definitively rule out shunt malfunction.

Technology

FlowSense is a wireless, noninvasive thermal flow sensor that can be mounted on a patient's neck overlying the shunt to detect the presence and magnitude of CSF. FlowSense enables monitoring of CSF flow, which can potentially eliminate delays with diagnostic testing and expedite appropriate triage and treatment for patients. FlowSense uses measurements of temperature and heat transfer to non-invasively tell if and how much fluid is flowing through a shunt in a hydrocephalus patient.

Similar in size to a bandage, it is composed of soft silicone with no hard edges. Data is wirelessly transmitted to a custom designed mobile app.

Procedure Description
FlowSense assesses the flow of CSF through an existing implanted CSF shunt non-invasively via the following steps:

1) The CSF shunt tube is localized in a skin region where the tube is superficial (within about 4 mm of the surface). The most superficial region is typically on or near the clavicle, where the shunt tube must pass over the bone. Localization is typically performed via visual inspection and palpation, but may also include the use of ultrasound in rare cases.
2) The FlowSense device is adhered to the skin over the localized shunt tubing. The device, which is about the size of an adhesive bandage, must be aligned with the tubing for successful measurement.
3) The device is powered on and wirelessly paired to a receiver via Bluetooth. A flashing LED on the device indicates the device status and assists with pairing.
4) A device measurement is initiated by following the prompts on a mobile app, which guides the provider through the measurement process. The device automatically applies heat and measures the temperature on the skin. The mobile app may also indicate an error or warning in the event that a measurement issue occurs, for example if the device is not adhered properly to the patient's skin. The measurement itself takes about five minutes to complete.
5) The device measurement results, which are displayed on the receiver, are recorded in the patient's medical record.
6) The provider interprets the results of the measurement by applying their knowledge of and experience with a) shunt function and malfunction, b) the dynamics of normal and abnormal CSF flow, c) the patient's history, symptoms, and level of shunt dependence, and d) any additional tests that have been performed (for example, a radiology scan).

These steps, which are performed sequentially, typically take about 20 minutes. The procedure gives important spot check information on the presence of flow in the CSF shunt to a physician in order to assist in the determination of shunt function or malfunction. The procedure can be performed in the emergency department for patients showing symptoms of shunt malfunction, in a pre-operative setting for patients undergoing a CSF shunt revision surgery (to validate shunt malfunction), and in a post-operative setting after shunt placement surgery (to confirm functionality of a newly-implanted shunt). According to the requestor, the only known complication associated with this procedure is the potential for skin irritation due to the device adhesive.

Current Coding: The non-invasive assessment of the flow of cerebrospinal fluid (CSF) through an existing implanted CSF shunt is not reported separately for inpatient hospital coding. Facilities can report the CT scan, if performed, using the appropriate code(s) in section B, Imaging.

Coding Options
Option 1. Do not create new ICD-10-PCS codes for the non-invasive assessment of the flow of cerebrospinal fluid (CSF) through an existing implanted CSF shunt. Continue coding as listed in current coding.

Option 2. Create a new code in section X table XXE Measurement of Physiological Systems, to identify the non-invasive assessment of the flow of cerebrospinal fluid (CSF) through an existing implanted CSF shunt.

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**E** Measurement: Determining the level of a physiological or physical function at a point in time		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 0 Central Nervous	**X** External	**ADD W** Flow, Cerebrospinal Fluid Shunt Wireless Sensor	**7** New Technology Group 7

Option 3. Create a new code in section 4 table 4B0 Measurement of Physiological Devices, to identify the non-invasive assessment of the flow of cerebrospinal fluid (CSF) through an existing implanted CSF shunt.

Section	**4** Measurement and Monitoring		
Body System	**B** Physiological Devices		
Operation	**0** Measurement: Determining the level of a physiological or physical function at a point in time		
Body System	*Approach*	*Function / Device*	*Qualifier*
0 Central Nervous	**X** External	**ADD W** Cerebrospinal Fluid Shunt	**ADD 0** Wireless Sensor

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Colonic Irrigation for Colonoscopy

Issue: There are currently no unique ICD-10-PCS codes to describe colonic irrigation performed intraoperatively with a disposable oversleeve for colonoscopy procedures.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? Yes. The Pure-Vu® System received 510(k) clearance May 4, 2019.

Background: Indications for colonoscopy can be for diagnostic or therapeutic purposes and may be performed on patients with conditions such as acute lower GI bleeding, hematochezia, incessant diarrhea, constipation, unknown abdominal pain, Irritable Bowel Syndrome, Inflammatory Bowel Disease (Crohns, colitis), or a mass found on computed tomography (CT). Achieving hemostasis as quickly as possible in patients that require an urgent colonoscopy most commonly due to GI bleeding can be critical to the patient, reduce the need for transfusions and the hospital length of stay. In addition, inadequate preparation of the bowel may result in delayed or repeat colonoscopies, thereby extending the hospital length of stay for these patients and potentially creates a significant burden with extended preparation time and increased risks. The Pure-Vu® System is targeted for patients that need to undergo a colonoscopy and are unable to have an adequate preparation due to comorbidities or motility issues, have contraindications for traditional bowel prep, or have an emergent issue such as a significant lower GI bleed for which there is not sufficient time for preprocedural preparation.

Technology
According to the requestor, the Pure-Vu® System is an oversleeve based, high intensity intra-procedural cleansing device for colonoscopy procedures. It is designed to connect to currently marketed colonoscopes to avoid aborted and delayed procedures due to poor visualization of the colon mucosa by providing high intensity intra-procedural cleansing of the colon during a colonoscopy. The requestor states this is achieved by the device creating a unique High Intensity, Pulsed Vortex Irrigation Jet that consists of a mixture of air and water to break-up fecal matter, blood clots and other debris and scrub the walls of the colon while simultaneously removing the debris through two suction channels. The suction channels have a sensor to detect the formation of a clog in the channels. If the sensor detects a clog forming, it then triggers the system to automatically purge the material out of the channel and back into the colon where it can be further emulsified by the Pulsed Vortex Irrigation Jet and then automatically reverts back into suction mode once the channel is cleared.

The Pure-Vu® System is comprised of a Workstation (WS) that controls the function of the system, a disposable Oversleeve that is mounted on a colonoscope and inserted into the patient and a disposable connector with tubing (Umbilical tubing with Main Connector) that provides the interface between the WS, the Oversleeve and off the shelf waste containers. The Pure-Vu® System also contains additional ancillary components required for mounting the disposable sleeve on a colonoscope.

Procedure Description
The Pure-Vu® System is loaded over a colonoscope and is controlled by foot pedals that allow the physician to activate the system as desired while navigating through the colon. The colonoscopy with the Pure-Vu® Oversleeve is advanced through the colon in the same manner as a standard colonoscopy. The system gives the physician the control to cleanse the colon as needed based on visual feedback from the colonoscope to make sure they have an unobstructed view of the colon mucosa to detect and treat any pathology. The requestor states it is important to note that since the Pure-Vu® system does not interfere with the working channel of the colonoscope, the physician is able to perform all diagnostic or therapeutic interventions in a standard fashion with an unobstructed field of view.

Current Coding: There are no unique ICD-10-PCS codes to describe colonic irrigation performed intraoperatively with a disposable oversleeve for colonoscopy procedures. Facilities can report colonic irrigation for colonoscopy procedures using the following code:

3E1H88Z Irrigation of lower GI using irrigating substance, via natural or artificial opening endoscopic

Coding Options

Option 1. Do not create new ICD-10-PCS codes for colonic irrigation performed intraoperatively with a disposable oversleeve for colonoscopy procedures. Continue coding as listed in current coding.

Option 2. Create a new code in section 3, Administration, to identify colonic irrigation performed intraoperatively with a disposable oversleeve for colonoscopy procedures.

Section	**3** Administration		
Body System	**E** Physiological Systems and Anatomical Regions		
Operation	**1** Irrigation: Putting in or on a cleansing substance		
Body System / Region	*Approach*	*Substance*	*Qualifier*
H Lower GI	**8** Via Natural or Artificial Opening Endoscopic	**8** Irrigating Substance	**ADD E** Intraoperative

Option 3. Create a new code in section X, New Technology, to identify colonic irrigation performed intraoperatively with a disposable oversleeve for colonoscopy procedures.

Section	**X** New Technology		
Body System	**D** Gastrointestinal System		
Operation	**P** Irrigation: Putting in or on a cleansing substance		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
H Lower GI	**8** Via Natural or Artificial Opening Endoscopic	**ADD K** Intraoperative Single-use Oversleeve	**7** New Technology Group 7

CMS Recommendation: Option 3, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Mechanical Initial Specimen Diversion of Whole Blood Using Active Negative Pressure

Issue: There are currently no unique ICD-10-PCS codes to describe the mechanical initial specimen diversion of whole blood using active negative pressure.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? Yes. The Steripath® Micro™ Blood Collection System received 510(k) clearance from the FDA on October 8, 2020.

Background: A large number of patients who present symptomatic for sepsis are compromised, hypotensive (low blood pressure) and hypovolemic (low blood volume), have difficult intravenous access (DIVA) or are small in stature with lower blood volume. Clinicians typically utilize a syringe technique to collect blood from this patient population to enable management of negative pressure (attempting to avoid vein collapse) while improving the opportunity to collect a sufficient volume of blood to culture which is critical for sensitivity.

Sources of contamination exist that techniques presently embodied in the standard of care pertaining to blood culture do not address including skin flora embedded too deeply to be affected by topical antiseptics. It has been proven that venipuncture dislodges fragments of skin that will (through the needle cannula) enter a blood culture bottle with the initial aliquot of a specimen[1]. There is no antiseptic that can perfectly sterilize skin and penetrate to reach deeply embedded organisms, which is why manual diversion of the initial aliquot of a blood specimen was originally proposed and subsequently proven to reduce blood culture contamination rates[2]. According to the requestor, manual diversion as a process improvement technique, though successful at reducing blood culture contamination, has shown only modest reduction in contamination. Therefore, the requestor states it remains self-limiting as a practical option for standard practice in that it adds approximately 6-steps to an already complex procedure, introduces an additional opportunity for touch-based contamination to occur, requires additional time from the operator to perform and is not an engineered approach to ensure healthcare worker compliance and ensuing sustainable results.

The gentle negative pressure created by the Steripath® Micro™ Blood Collection System's unique bladder-driven mechanism of action is designed to achieve initial specimen diversion while avoiding collapsing of the veins (losing venous access) of this susceptible patient population.

Technology and Procedure
According to the requestor, Magnolia Medical Technologies, Inc., developed the Steripath® Initial Specimen Diversion Device® (ISDD®) as an active diversion vein-to-bottle closed system designed to augment standard blood culture practice. The Steripath® Micro Blood Collection System ™ is a new single-use disposable ISDD® used for blood culture collection to reduce blood culture contamination and false positive diagnostic test results for sepsis. The Steripath® ISDD® product

[1] Buchta, C., N. Nedorost, H. Regele, M. Egerbacher, G. Körmöczi, P. Höcker, and M. Dettke. 2005. Skin plugs in phlebotomy puncture for blood donation. Wien Klin. Wochenschr. 117:141-144
[2] Patton RG, Schmitt T. Innovation for reducing blood culture contamination: initial specimen diversion technique. J Clin Microbiol. 2010 Dec;48(12):4501-3

portfolio, including the Steripath® Micro™ ISDD®, is the only FDA 510(k)-cleared family of devices indicated to reduce blood culture contamination.

Unlike manual diversion, Steripath® is by design a closed-system so as not to introduce opportunities for touch contamination beyond that which occurs with conventional methods of blood culture sample acquisition, and is provided as a preassembled and packaged sterile kit so as to not require set-up touch point contamination or additional time from the operator. The requestor reported that irrespective of a healthcare system's use of nursing staff or dedicated phlebotomists to acquire blood culture samples, of whether a given facility was a teaching institution, government military or veterans administration hospital or large or small community hospital or emergency department there within, irrespective of sample size, and location, Steripath® implementation has resulted in a 73% to 100% reduction in blood culture contamination across a broad array of large scale clinical datasets.

The requestor states it uses a novel architecture that utilizes initial negative pressure driven by a syringe or blood culture bottle to invert an internal bladder. The inversion of the bladder in turn creates gentle negative pressure to divert and sequester the initial 0.6 to 0.9 mL of blood collected from the patient, the portion known to most likely contain contaminants. Once diversion is complete, the user presses a side button to isolate the diverted blood and automatically a second independent blood flow pathway opens to collect the blood specimen into the syringe (or blood culture bottle) for culture testing.

Current Coding: There is no unique ICD-10-PCS code to identify the mechanical initial specimen diversion of whole blood by a single-use blood collection device using active negative pressure.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for a single-use blood collection device that diverts the initial specimen from the portion used for blood culture. Continue coding as listed in current coding.

Option 2. Create a new code in section X table XXE, Measurement of Physiological Systems, to identify a single-use blood collection device that diverts the initial specimen from the portion used for blood culture.

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**E** Measurement: Determining the level of a physiological or physical function at a point in time		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Circulatory	**X** External	**M** Infection, Whole Blood Nucleic Acid-base Microbial Detection	**5** New Technology Group 5
5 Circulatory	**X** External	**N** Infection, Positive Blood Culture Fluorescence Hybridization for Organism Identification, Concentration and Susceptibility	**6** New Technology Group 6
B Respiratory	**X** External	**Q** Infection, Lower Respiratory Fluid Nucleic Acid-base Microbial Detection	**6** New Technology Group 6
5 Circulatory	**X** External	**ADD R** Infection, Mechanical Initial Specimen Diversion Technique Using Active Negative Pressure	**7** New Technology Group 7

Option 3. Create new codes in section 8, Other Procedures, to identify the mechanical initial specimen diversion of whole blood by a single-use blood collection device using active negative pressure.

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	**3** Percutaneous	**6** Collection	**ADD A** Blood, Initial Specimen Diversion Technique

CMS Recommendation: Option 2, as described above.

Concurrent Measurement of mRNA, PCR test and Detection of Antibodies

Issue: There are currently no unique ICD-10-PCS codes to describe the concurrent measurement of mRNA, PCR test and detection of antibodies from blood and nasal specimens.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? No.

Background: There are 695,000 ischemic strokes each year in the US, with 185,000 of these events being recurrent strokes. Up to 40% (250,000) of ischemic strokes are diagnosed as "cryptogenic" or unknown cause. Cryptogenic strokes have limited treatment available leading to high recurrence risk. When the cause of a stroke is identified, guideline-directed effective secondary prevention protocols may be adopted to prevent a more massive, costly, and severe recurrent stroke. When the cause is unknown, recurrent stroke risk is five times greater than when the cause is determined, such as stroke due to undiagnosed atrial fibrillation.

The key to secondary prevention (i.e. preventing another stroke through medical management) is identifying stroke etiology. For example, anticoagulant therapy is indicated for cardioembolic stroke. This is in distinction to large artery atherosclerotic strokes where antiplatelet agents are recommended. The diagnostic workup to determine the cause of stroke can be complex and inconsistent across hospitals, may require invasive procedures (implantable cardiac monitoring or transesophageal echocardiogram), may be lengthy, and is often inconclusive (cryptogenic).

The requestor notes that since the COVID-19 public health emergency, the cryptogenic stroke rate is calculated at 65% in COVID-19 populations, including patients presenting without traditional stroke comorbidities, making secondary stroke prevention difficult. The cause of stroke in COVID-19 patients is still not well understood. Clinical information is needed to determine stroke etiology, specifically, cardioembolic or large artery atherosclerosis causes of stroke that have clear treatment and risk reduction guidelines. Respiratory screening that includes COVID-19, influenza, and other respiratory viral and bacterial organisms, and the identification of COVID-19 antibodies to determine if the patient previously may have had COVID-19, is also needed.

Technology
According to the requestor, the Ischemia Care Respiratory and Stroke Test (ISC-REST) blood and swab collection kit is the first clinically available laboratory testing for ischemic stroke to assist with determining the cause of stroke based on mRNA expression and respiratory status (including COVID-19) using blood and nasal specimens. ISC- REST is indicated when a patient presents within 30 hours of symptom onset with a NIH Stroke Scale/Score (NIHSS) greater than or equal to five. ISC-REST combines (i) a blood test for cause of stroke (ISCDx), (ii) plus a respiratory panel that includes COVID-19 screening, (iii) plus a COVID-19 antibody test. The primary purpose of ISC-REST is to stratify ischemic stroke patients by cause, including COVID-19 status, to simplify care pathways to prevent a secondary stroke which is often more severe, costly, and debilitating. The technology is based upon prior clinical research that has suggested whole blood mRNA expression may help differentiate ischemic stroke mechanisms.

Procedure Description
The ISC-REST kit reports three test results to provide information related to cause of ischemic stroke and COVID-19 status:

- First, ISCDx, a test result based upon a whole blood sample as a source of mRNA, to aid in the diagnosis of cardioembolic and large artery atherosclerotic stroke (two major leading stroke causes and affecting treatment decisions). The testing results indicate whether the gene expression in the sample was consistent with cardioembolic stroke or large artery atherosclerosis stroke. The test (ISCDx) is the result of the Biomarkers of Acute Stroke Etiology (BASE) clinical trial NCT02014896. The validated testing performance has a sensitivity of 89.66%, specificity of 70.00%, positive likelihood ratio of 2.99, negative likelihood ratio of 0.15, and accuracy of 84.62%.
- Second, the QIAstat-Dx Respiratory SARS-CoV-2 Panel is a multiplexed nucleic acid real-time PCR test intended for the qualitative detection and differentiation of nucleic acid from multiple respiratory viral and bacterial organisms, including the SARS-CoV-2 virus, in nasopharyngeal swabs (NPS) eluted in universal transport media collected from patients suspected of COVID-19 by their healthcare provider.
- Third, the QIAGEN Access Anti-SARS-CoV-2 Total Test is a rapid, digital lateral flow serological test, using nanoparticle fluorescence, intended for qualitative detection of total antibodies to SARS-CoV-2 in human serum and plasma (heparin, EDTA). The Access Anti-SARS-CoV-2 Total Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2.

Current Coding: The concurrent measurement of mRNA, PCR test and detection of antibodies from blood and nasal specimens is not reported separately for inpatient hospital coding. The specimen collection by nasopharyngeal swab is also not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the concurrent measurement of mRNA, PCR test and detection of antibodies from blood and nasal specimens. Continue coding as listed in current coding.

Option 2. Create new codes in section X table XXE Measurement of Physiological Systems, to identify each component of the concurrent measurement of mRNA, PCR test and detection of antibodies to detect the cause of ischemic stroke and COVID-19 infection status from blood and nasal specimens.

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**E** Measurement: Determining the level of a physiological or physical function at a point in time		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Circulatory	**X** External	**ADD T** Intracranial Arterial Flow, Whole Blood mRNA **ADD V** Infection, Serum/Plasma Nanoparticle Fluorescence SARS-CoV-2 Antibody Detection	**7** New Technology Group 7
9 Nose	**7** Via Natural or Artificial Opening	**ADD U** Infection, Nasopharyngeal Fluid SARS-CoV-2 Polymerase Chain Reaction	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Regional Anticoagulation for Renal Replacement Therapy

Issue: There are currently no unique ICD-10-PCS codes to describe regional anticoagulation in an extracorporeal dialysis circuit with nafamostat.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment application for FY 2023.

Food & Drug Administration (FDA) Approval? FDA Breakthrough Device Designation for Niyad™ as a regional anticoagulation device was granted for renal replacement therapy (RRT) on April 9, 2020. It is regulated as a device because it anticoagulates blood outside the patient.

Background: The kidneys are responsible for filtering and cleaning blood, producing the urine that carries liquid waste out of the body, and regulating the fluid balance of the body. When the kidneys begin to lose their ability to filter water and waste from the blood, kidney failure may result. Acute kidney failure (or acute kidney injury (AKI)) can be categorized as prerenal, postrenal, or renal. Prerenal failure accounts for approximately 60-70% of all cases and occurs when the kidneys are not receiving enough blood to filter. This can happen for a number of reasons, including a significant drop in blood pressure due to blood loss from surgery, burns, severe injuries, infections (E.g. sepsis), occlusion or restriction of a blood vessel carrying blood to the kidneys, heart failure or liver failure. If treated promptly, the condition can be reversed. Postrenal failure, also known as obstructive renal failure, occurs when a blockage or obstruction is present in the ureters or bladder, such as with kidney stones, bladder stones, or cancer. The kidneys often recover within a couple weeks once the obstruction is removed. Renal failure accounts for approximately 25-40% of all cases and is considered the most complex. It may occur when conditions such as glomerulonephritis, acute interstitial nephritis, acute tubular necrosis, or polycystic kidney disease are present.

Patients with acute kidney failure that is unresponsive to medications, intravenous fluids, or other medical treatment options to improve kidney function will generally need to receive dialysis through an artificial kidney machine. The machine circulates blood outside the patient, through a dialysis filter, and then returns blood to the patient. According to the requestor, exposure of blood to the dialysis filter may cause clotting that results in frequent filter changes, increased blood loss, increased transfusions, and delayed or prolonged treatment time.

The requestor reported that acute renal replacement therapy (RRT), which is performed over long periods of time (i.e., 24/7),with lower blood flow rates and slower ultrafiltration rates, is favored over standard intermittent hemodialysis (IHD) in critically ill patients who are unable to tolerate rapid solute removal, such as those suffering from AKI.

During RRT, blood flows from the patient into a dialysis filter driven by a peristaltic pump. This procedure allows for blood purification and enables fluid removal. The requestor stated that anticoagulation of the extracorporeal circuit is a desired feature of RRT because interaction of blood with the plastic materials in the extracorporeal circuit is thrombogenic and development of blood clots undermines performance of the hemodialyzer. If the entire circuit clots, the procedure is compromised; the process must be stopped, and the filter must be changed. According to the requestor, when this occurs the filter is discarded and, more significantly, the patient loses the clotted blood in the filter, which increases blood loss and the need for transfusions. As such, an

international consensus guideline known as the Kidney Disease Improving Global Outcome (KDIGO) Clinical Practice Guidelines for Acute Kidney Injury (KDIGO 2012) recommends "using anticoagulation during RRT in AKI if a patient does not have an increased bleeding risk or impaired coagulation and is not already receiving anticoagulation." (Level 1B, strong recommendation, moderate quality evidence). In addition, for patients with an increased risk of bleeding, the KDIGO guideline suggests using off-label citrate anticoagulation, rather than no anticoagulation, during RRT in a patient without contraindications for citrate. There are currently no approved regional anticoagulants in the US.

Since there are no FDA-approved agents for regional anticoagulation, approximately 60% of acute RRT is initiated without the use of any anticoagulant.[1] Some centers utilize citrate anticoagulation in an off-label fashion, though there are documented dangers such as life-threatening hypocalcemia or alkalosis.

Technology

Niyad™ is an anticoagulant for the dialysis filter that reduces blood clots. Nafamostat, the active ingredient of Niyad™, is a small molecule, broad spectrum, protease inhibitor that inhibits thrombin at the platelet thrombin receptor, PAR1.[2] It also inhibits various enzyme systems, such as coagulation and fibrinolytic systems (Xa and XIIa), the kallikrein–kinin system, the complement system, and pancreatic proteases.[3,4,5]

According to the requestor, nafamostat has a small molecular weight of 539.59 Da and a short systemic circulation half-life (~8 minutes), making it ideally suited as a regional anticoagulant in extracorporeal circuits. When nafamostat is administered into the afferent limb of the RRT circuit, the blood becomes anticoagulated because of nafamostat's rapid action on thrombin. As blood is transported into the hemodialyzer, nafamostat's small molecular weight allows a significant proportion to be removed via filtration. Therefore, the amount of nafamostat that is returned to the patient via the efferent limb is limited and is rapidly metabolized. Thus, the anticoagulation effect of nafamostat is primarily limited to the RRT circuit.

The requestor reported that nafamostat is approved and marketed as Futhan® in Japan and South Korea for regional anticoagulation; it has no contraindications as an anticoagulant in RRT nor does it have any limitation on the treatment/administration period. Nafamostat can be used in

[1] Bellomo R, Cass A, Cole L, Finfer S, Gallagher M, Lo S, McArthur C, McGuinness S, Myburgh J, Norton R, Scheinkestel C, Su S. Intensity of Continuous Renal-Replacement Therapy in Critically Ill Patients. N Engl J Med. 2009;361(17):1627–1638.
[2] Fuse I, Higuchi W, Toba K, Aizawa Y. Inhibitory Mechanism of Human Platelet Aggregation by Nafamostat Mesilate. Platelets. 1999;10:212-218.
[3] Hitomi Y, Ikari N, Fujii S. Inhibitory Effect of a New Synthetic Protease Inhibitor (FUT-175) on the Coagulation System. Haemostasis. 1984;15(3):164-168.
[4] Fujii S, Hitomi Y. New Synthetic Inhibitors of C1r, C1 Esterase, Thrombin, Plasmin, Kallikrein and Trypsin Biochim. Biophys. Acta, 1981;661:342-345.
[5] Aoyama T, Ino Y, Ozeki M, Oda M, Sato T, Koshiyama T, Suzuki S, Fujita M. Pharmacological Studies of FUT-175, Nafamostat Mesilate I. Inhibition of Protease Activity in in Vitro and in Vivo Experiments. Japan. J. Pharmacol. 1984;35:203-227.

patients at risk of bleeding and in patients for whom the use of heparin is contraindicated.[6,7,8]

Procedure
Prepare the dialysis circuit by priming the dialysis filter according to the manufacturer's instructions with Niyad™.

- Prepare a solution of Niyad™
  –Add WFI or 5 % dextrose for injection to the Niyad™ vial.
  –Repeat above step for a second vial.
- Add the contents of the two reconstituted vials to 0.9 % saline for injection.
- Measure the activated clotting time (ACT) using a celite system. Titrate the dose up or down to achieve the desired the level of anticoagulation.

Current Coding: There are no unique ICD-10-PCS codes to describe regional anticoagulation in an extracorporeal dialysis circuit with nafamostat. Facilities can continue to report the RRT procedure using the appropriate code from the table below.

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*
D Urinary	**7** Intermittent, Less than 6 Hours Per Day **8** Prolonged Intermittent, 6-18 hours Per Day **9** Continuous, Greater than 18 hours Per Day	**0** Filtration	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for regional anticoagulation in an extracorporeal dialysis circuit with nafamostat. Continue coding as listed in current coding.

Option 2. Create a new code in table 5A1, Extracorporeal or Systemic Assistance and Performance, to identify regional anticoagulation in an extracorporeal dialysis circuit with nafamostat.

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*
D Urinary	**7** Intermittent, Less than 6 Hours Per Day **8** Prolonged Intermittent, 6-18 hours Per Day **9** Continuous, Greater than 18 hours Per Day	**0** Filtration	**ADD J** Extracorporeal Anticoagulation **Z** No Qualifier

[6] Ohtake Y, Hirasawa H, Sugai T, Oda S, Shiga H, Matsuda K, Kitamura N. Nafamostat Mesylate as Anticoagulant in Continuous Hemofiltration and Continuous Hemodiafiltration. Contrib Nephrol. 1991;93:215-217.
[7] Lee YK, Lee HW, Choi KH, Kim BS. Ability of Nafamostat Mesilate to Prolong Filter Patency during Continuous Renal Replacement Therapy in Patients at High Risk of Bleeding: A Randomized Controlled Study. PLoS ONE 9(10): e108737.
[8] Maruyama Y, Yoshida H, Uchino S, Yokoyama K, Yamamoto H, Takinami M, Hosoya T. Nafamostat Mesilate as an Anticoagulant During Continuous Veno-venous Hemodialysis: A Three-year Retrospective Cohort Study. Int J Artif Organs. 2011;34(7):571-576.

Option 3. Create a new code in section X, New Technology, to identify regional anticoagulation in an extracorporeal dialysis circuit with nafamostat. A separate code would continue to be reported for the RRT.

Section	**X** New Technology		
Body System	**Y** Extracorporeal		
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*
Y Extracorporeal	**X** Externa**l**	**ADD 3** Nafamostat Anticoagulant	**7** New Technology Group 7

CMS Recommendation: CMS is interested in hearing input.

Interim Coding Advice: Continue using current codes as listed in current coding.

Gene Expression Assay

Issue: There are currently no unique ICD-10-PCS codes to describe a gene expression assay of a blood specimen.

New Technology Application? No. However, the requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2023 consideration.

Food & Drug Administration (FDA) Approval? No. Immunexpress is expecting FDA clearance for SeptiCyte® RAPID in the second quarter of 2021. Additionally, Immunexpress is expecting to supplement their 510K for use of SeptiCyte with EDTA tubes shortly after initial FDA clearance.

Background: Sepsis, until recently, has been clinically defined as "the presence (probable or documented) of infection together with systemic manifestations of infection."[1,2] Sepsis is a complex, poorly understood immuno-pathological disorder characterized by a pro-inflammatory response that may be followed by an anti-inflammatory, immunosuppressive state, or may cycle between states over several weeks. An early, uncontrollable excessive or hyper-inflammatory response can be associated with septic shock, then cardiovascular collapse, metabolic derangements, multiple organ dysfunction, and finally death within days of onset.

The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3), published in 2016, changed the definitions and clinical criteria of sepsis and septic shock. Sepsis-3 now defines sepsis as "a life-threatening organ dysfunction caused by a dysregulated host response to infection." Therefore, the key to diagnosing sepsis according to the new definition lies in determining whether the host has a dysregulated immune response, and whether that response is due to an infection.

Technology
SeptiCyte® RAPID is a gene expression assay that can assist in the discrimination between the presence of sepsis (i.e. infection positive systemic inflammation) and infection negative systemic inflammation (SIRS). SeptiCyte® RAPID uses a reverse transcription polymerase chain reaction to measure the relative expression levels of host response genes isolated from whole blood collected in either general EDTA tubes or PAXgene® Blood RNA Tubes. SeptiCyte® RAPID generates a score (SeptiScore™) that falls within one of three discrete interpretation bands based on the increasing likelihood of infection-positive systemic inflammation.

SeptiCyte® RAPID molecular analysis is used in conjunction with clinical assessments, vital signs and laboratory findings as an aid to differentiate infection-positive sepsis from systemic inflammatory response syndrome or infection negative systemic inflammation (SIRS or INSI) in critically ill adults. SeptiCyte® RAPID has been shown to have clinical validity and reliability in banked samples from two observational clinical trials that supported the 510K clearance of SeptiCyte LAB: the VENUS trial (NCT02127502) and the MARS trial (NCT01905033).

[1] Dellinger R P, et al. (2013). Surviving Sepsis Campaign: international guidelines for management of severe sepsis and septic shock, 2012. Intensive care medicine, 39(2), 165–228.
[2] Dellinger R P, et al. (2013). Surviving sepsis campaign: international guidelines for management of severe sepsis and septic shock: 2012. Critical care medicine, 41(2), 580–637.

SeptiCyte® RAPID is intended for diagnostic use and will be used in the inpatient setting to facilitate the diagnosis of sepsis to improve medical treatment and patient recovery.

Procedure Description
SeptiCyte® RAPID consists of collection of blood in an EDTA tube or PAXgene® blood RNA tube followed by pipetting 900µl directly from PAXgene blood tube or 240 ul from EDTA tube to the lysis chamber of the test cartridge. The test cartridge is used with the Idylla™ platform, which is a fully automated RT-PCR based molecular testing system.

Inside the cartridge, a combination of chemical reagents, lytic enzymes, heat, and High Intensity Focused Ultrasound (HIFU) induces lysis of the cells within the cartridge. The nucleic acids are liberated for subsequent reverse transcription quantitative real-time PCR (RT-qPCR) amplification. All necessary reagents for RT-qPCR are present in a stable formulation and are used to amplify specific biomarkers indicative for probability of sepsis. Detection and relative quantification of these specific targets is achieved through 5'-exonucleolytic release of fluorophores from labeled nucleic acid probes bound to amplification targets. The fluorescence is detected by the Idylla™ Instrument in real time.

At the end of the roughly one-hour processing, a SeptiScore™ is calculated that the requestor states clearly links probability of sepsis and validity of the analytical process with a spectrum of three distinct results or 'bands' displayed on a console screen.

Current Coding: The performance of gene expression assay of a blood specimen is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify SeptiCyte® RAPID molecular analysis of a blood specimen. Continue coding as listed in current coding.

Option 2. Create new codes in section X table XXE, Measurement of Physiological Systems, to identify SeptiCyte® RAPID molecular analysis of a blood specimen.

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**E** Measurement: Determining the level of a physiological or physical function at a point in time		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
5 Circulatory	**X** External	**ADD S** Infection, Whole Blood Reverse Transcription and Quantitative Real-time Polymerase Chain Reaction	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Single-use Intraluminal Closure System for Gastrointestinal Procedures

Issue: There are currently no unique ICD-10-PCS codes to describe the use of a single-use intraluminal closure system during incisionless endoscopic gastrointestinal tract procedures.

New Technology Application? No.

Food and Drug Administration (FDA) Approval? The original OverStitch™ Endoscopic Suturing System received FDA clearance on June 30, 2008 for exclusive use with a double channel therapeutic endoscope. In 2017, the FDA approved the OverStitch SX™ Endoscopic Suturing System, which can be used on a variety of single channel scopes. The Apollo ESG™ System is under an FDA IDE clinical trial for expanded use in Endoscopic Sleeve Gastroplasty (ESG). A DeNovo 510k Application for ESG will be submitted in 2021.

Background
The OverStitch™ and the OverStitch SX™ Endoscopic Suturing Systems are disposable, single-use, mechanical end-cap catheter devices, mounted onto either a standard diagnostic endoscope or a double-channel gastroscope. They are intended for endoscopic placement of sutures and approximation of soft tissue within the gastrointestinal tract. The systems allow the endoscopist to 'reload' the suture without removing the endoscope.

The OverStitch™ and the OverStitch SX™ Endoscopic Suturing Systems have been used in a variety of applications including closure of fistula, perforation or other defects, closure after surgical excision, and stent fixation. The requestor states that currently, the OverStitch™ and the OverStitch SX™ are the only systems that perform incisionless endoscopic surgical closure using a mechanical catheter system. This technique differs from traditional techniques, which require either a laparoscopic or an open incision for the physician to perform the surgical closure.

The Apollo ESG™ System is also a disposable, single-use device, intended for endoscopic approximation of stomach tissue to reduce the volume of the stomach, resulting in sleeve gastroplasty. Unlike the OverStitch™ devices, used for a variety of gastrointestinal procedures, the Apollo ESG™ System was designed and is seeking approval as a specific use device for Endoscopic Sleeve Gastroplasty (ESG). The Apollo ESG™ can be used with dual channel or single channel endoscopes.

Procedure Description
The OverStitch™ and the OverStitch SX™ systems enable incisionless endolumenal surgical closure by allowing physicians to use hand controls, which operate the catheter system in the gastrointestinal tract, to perform a tissue anchor and cinch closure. The catheter advances the anchor, which is integral for securing and stabilizing the closure. A cinch is passed down the scope's principal channel and deployed while applying the desired amount of suture tension to secure each suture. The implanted cinch fixation devices remain permanently within the gastrointestinal tract lumen securing the tissue closure.

The Apollo ESG™ utilizes a single-use OverStitch™ handle and cable to perform tissue approximation using the same anchor and cinch technique described above. The Apollo ESG™ system effects volumetric reduction of the stomach with the anchor and cinch closure system. The significant difference between the Apollo ESG™ technique and the laparoscopic sleeve

gastrectomy (LSG) technique is that the Apollo ESG™ draws the intact stomach in on itself while the LSG technique partitions the stomach into a sleeve from the outside with removal of the excluded stomach. The number of full thickness plications along the length of the stomach can range from six to eight, each with a cinch retention device.

Technology
According to the requestor, the key technology that distinguishes the OverStitch™, OverStitch SX™, and the Apollo ESG™ systems is the deployment of the cinch device. The cinch device is an implant comprised of thermoplastic and stainless steel materials, and an implantable PEEK cinch component, that press-fit onto the tail end of the suture to maintain suture position in situ, and maintain the tension to allow tissue apposition. Once deployed, the cinch lies within the gastrointestinal tract lumen indefinitely. The knotless fixation design provides fast, secure closure without the need to tie complex surgical knots.

Gys et al (2019)[1] performed a systematic review and meta-analysis of safety and efficacy of endoscopic gastric plication for morbid obesity. Twenty-two clinical trials with a baseline total of 2,475 patients were included in the review. Mean age at the moment of surgery was 41.2 years old (range 31.5–47.6). Mean baseline BMI was 37.8 ± 4.1 kg/m2 (range 28.0–60.2; median 37.9).Seven different techniques including transoral endoluminal stapling (or suction based), full thickness suturing and/or anchor devices were used to obtain gastric volume reduction. A meta-analysis of the OverStitch™ device was performed, which included eight of the clinical trials (1,721 patients) with 6-24 month follow up. Percentage of excess weight loss (%EWL) at 6 and 12 months was 57.9 ± 3.8% (50.5–65.5, $I^2 = 0.0$) and 68.3± 3.8% (60.9–75.7, $I^2 = 5.8$). An average total of six (range 4–9) sutures with eight (range 3–14) "plications" or "bites" were used. Serious adverse events were described in 18 patients (1.05% of patients): pneumothorax (n = 2), perigastric collection (n = 8), pulmonary embolism (n = 2), intraluminal bleeding (n = 5), and leakage (n = 1).

Cinch device malfunction, although infrequent, can be a challenging complication to manage[2]. The cinching and suture cutting involves three processes—(1) locking the suture using the cinch plug, (2) engaging the suture cutter, and (3) activating the cutter and slicing the suture. When excessive suture tension is applied during cinching, the spring inside the handle of the cinch device may fracture and malfunction and may fail to engage and activate the suture cutter. The cinch with the trapped and uncut suture cannot be removed from the endoscope channel. In such situations, the cinch handle is dismantled, and the central stiff metallic wire leading to the cutting system is captured and pulled manually to activate it and sever the suture.
To avoid encountering such technical difficulties, suture tension is slightly released just before squeezing the cinch handle.

Current Coding: There are no unique ICD-10-PCS codes to identify the utilization of a single-use intraluminal closure system in gastrointestinal procedures. Report the applicable ICD-10-PCS gastrointestinal system code(s) using the approach value 8 Via Natural or Artificial Opening Endoscopic.

[1] Gys, B., Plaeke, P., Lamme, B. *et al.* Endoscopic Gastric Plication for Morbid Obesity: a Systematic Review and Meta-analysis of Published Data over Time. *OBES SURG* **29,** 3021–3029 (2019). https://doi.org/10.1007/s11695-019-04010-3
[2] Asokkumar, Ravishankar & Babu, Mohan & Bautista-Castaño, Inmaculada & Lopez-Nava, Gontrand. (2020). The Use of the OverStitch for Bariatric Weight Loss in Europe. Gastrointestinal endoscopy clinics of North America. 30. 129-145. 10.1016/j.giec.2019.08.007.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify the utilization of a single-use intraluminal closure system in gastrointestinal procedures. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the utilization of a single-use intraluminal closure system in gastrointestinal procedures. Also report the applicable ICD-10-PCS gastrointestinal system code(s) using the approach value 8 Via Natural or Artificial Opening Endoscopic.

Section	**X** New Technology
Body System	**D** Gastrointestinal System
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Upper Intestinal Tract **6** Stomach **D** Lower Intestinal Tract	**8** Via Natural or Artificial Opening Endoscopic	**ADD S** Intraluminal Device, Cinch	**7** New Technology Group 7

Option 3. Create a new code in section X, New Technology, to identify the utilization of a single-use intraluminal closure system in gastrointestinal procedures. Also report the applicable ICD-10-PCS gastrointestinal system code(s) using the approach value 8 Via Natural or Artificial Opening Endoscopic.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Upper Intestinal Tract **6** Stomach **D** Lower Intestinal Tract	**8** Via Natural or Artificial Opening Endoscopic	**ADD S** Cinch Deployment Technique	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Section X Update
March 2021 ICD-10 Coordination and Maintenance Committee Meeting

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 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 or other 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)

For the March 2019 ICD-10 C&M meeting we provided the findings from our initial analysis with regard to the frequency with which the New Technology Group 1 codes had been reported in the data.

At the September 2019 meeting we did not propose any changes to the New Technology Group 1 codes and stated we would continue to monitor the data.

For the March 2020 ICD-10 C&M meeting we shared the results of our analysis for the New Technology Group 2 codes within Section X as it has been 3 years since the implementation of those codes. We provided the frequency (total number of cases) of the New Technology Group 2 procedure codes as reported in the data for FYs 2017, 2018, and 2019. We also updated the data for the New Technology Group 1 codes to include the frequency of the codes for FY 2019.

We revised the format in which we display the findings from our analyses. We created an Excel spreadsheet with 2 specific tabs labeled accordingly as Group 1 Codes and Group 2 Codes. On each tab is the list of ICD-10-PCS codes, code description, frequency by fiscal year and if the technology was approved for the NTAP.

At the September 2020 ICD-10 C&M meeting we reviewied the updated analysis results in more detail and encouraged participants to consider the options listed above while reviewing the data for discussion. Commenters suggested adding another option for consideration.

For this March 2021 ICD-10 C&M meeting we are proposing changes based on the public comments received and will also discuss a new approach to consider for future proposals.

1. Fourth option issue - During the September 2020 virtual meeting and expressed in comments following the meeting that were submitted by the November 9, 2020 deadline, commenters recommended CMS consider a fourth option for the Section X codes which was described as creating a unique code in another section of ICD-10-PCS and deleting the existing section X code. Upon further review and consideration of the public comments, we understand the delineation commenters were expressing and why it differs from the description provided in option 2. **We agree with the recommendation and are formally proposing to add a fourth option for consideration. Example provided below.**

    4. Create a new code in Med/Surg or other section of ICD-10-PCS and delete the code from Section X. (e.g. NTAP has expired, data analysis and clinical review justify uniquely identifying the technology in the Med/Surg section)

So, continuing with the orbital atherectomy example, based on public comments from the September meeting, in applying this proposed option 4, for Table 02C, Extirpation of Heart and Great Vessels, we would propose to create a new qualifier value 7, Orbital Atherectomy Technique, for the coronary artery body part values.

PCS Table Example: 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

PCS Table Example: Med/Surg

Section **0** Medical and Surgical *Body System* **2** Heart and Great Vessels *Operation* **C** Extirpation: Taking or cutting out solid matter from a 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 **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**6** Bifurcation **ADD 7 Orbital Atherectomy Technique** **Z** No Qualifier

2. Guiding Principles - A commenter recommended that CMS establish guiding principles in consideration of the 4th option that was discussed at the September 2020 meeting.

For example, the commenter suggested that section X codes be deleted when the technology is no longer eligible for NTAP, determine further action with regards to new

codes or Index entries based on the type of the technology (e.g. drug versus surgical procedure), a volume threshold to help identify whether the technology has gained acceptance and/or become mainstream medicine or standard of care, and public comments. **We are requesting public comments on this recommendation and have also provided additional details submitted by the commenter in this updated posting.**

Additional Details submitted by commenter for consideration with the 4th option:

For drug administration procedures, regardless of the volume of ICD-10-PCS codes reported, the commenter recommended the following:

- Delete the Section X code
- Delete the Alphabetic Index entry(ies) instructing users to look in Section X.
- Add new Alphabetic Index entry(ies) for the specific drug, referring to the general drug class or category (e.g. anti-infective) to assist users in assigning the correct value in table 3E0, Administration, Physiological Systems and Anatomical Regions, Introduction, if they are interested in continuing to report these optional codes.
- Add the drug name (brand name and generic name) to the Substance Key with the appropriate substance/qualifier value in table 3E0

For surgical procedures with high volume (threshold to be determined), the commenter recommended the following:

- Delete the Section X code.
- Consider creating unique values in the appropriate section (e.g. Medical Surgical) and in the corresponding root operation as the Section X code, to allow identification and tracking of the technology.
- Creating new codes should not require a new code request from the public.

For surgical procedures with low volume, the commenter recommended the following:

- Delete the Section X code.
- Delete the Alphabetic Index entry(ies) instructing users to look in Section X.
- Create Alphabetic Index entry(ies) directing users to the appropriate existing PCS table or root operation. No new code would be created.
- Allow interested parties to submit requests to create unique values to uniquely identify the technology outside of section X.

3. Format of data – During the September meeting CMS also requested feedback on the format and content of the data analysis presented for the Section X codes. We received very few comments but those that did comment expressed support. We also received a recommendation to add another column to the far right to identify the CMS recommendation for each code using the existing options 1-3, and if finalized, the addition of the option 4. **We are proposing to add this column as the commenter suggested.**

4. Notification to Original Requestors – Concerns were expressed regarding how requestors may be notified that the Section X code(s) finalized at the time of their request would one day be considered eligible for deletion once the 3-year timeframe had passed. During the September meeting we noted that there is currently not a set or standard communication

process; however, we could consider adding information to clarify from the beginning that the Section X codes were intended to be temporary codes and explain the options that the Section X code(s) would be subject to. **We are proposing to include this information in our communications with requestors starting with the September 2021 meeting.**

5. Public Comments – As discussed during the September meeting, we stated we were providing a couple of examples to illustrate our proposed actions for the Section X New Technology Group 1 codes, based on the existing options 1-3. We also stated that the purpose of the discussion was more of an informational, informal dialogue because this is the first time we were actually proposing to delete any of the Section X codes and we were seeking input and feedback for the process. While we continue to move forward with specific proposals and requesting public comments based on the discussions to date, we also wanted participants to consider a new or different approach for future proposals related to Section X codes in response to public comments we received. Commenters noted that the frequency of the data CMS shares is helpful; however, it should not be a driving factor in determining whether or not a Section X code should be deleted, since the CMS data is limited specifically to the Medicare population and may not fully represent other patient populations utilizing the technology or product. The commenters stated that data collection for clinical outcomes research and tracking for certain technologies warrants maintaining certain Section X codes and the indication for which the technology is utilized should also be factored in the proposals and decisions. We agree with those comments and therefore, similar to standard code proposals, including Addenda items, we believe that future proposals pertaining to Section X codes should be submitted by the public. This approach would continue to include the current data according to fiscal year, by the frequency in which they've been reported in the Medicare claims data, and whether or not the procedure or product described by the code was approved as a technology with respect to the NTAP policy. However, we believe that it would be beneficial to have requests submitted by the public since those additional factors raised by the commenters could also be considered further. **We are seeking input on this alternative approach for future Section X proposals.**

6. Root operation definition - We received comments recommending that CMS consider broadening the definition of the root operation Assistance. The commenters noted that some procedures now being captured in ICD-10-PCS, such as embolic protection, do not fall neatly into the existing root operation or another root operation. The commenter stated that some embolic protection systems, including the Sentinel® device, are not extracorporeal, and since embolic protection devices perform a filtration function, they do not clearly "take over a portion of a physiological function." To accommodate these and other future "assistance" procedures, the commenters suggested a broader definition such as "Taking over a portion of, or providing intraoperative support for, a physiological function" would be useful**. As a result of these comments, we are tabling the proposal for the Embolic Protection Codes until we can review public comments for this suggested root operation revision and consider this recommendation further. We did receive several comments in support of creating new codes for Embolic Protection in Table 5A0, and some commenters got very creative in offering up additional options so we are sharing those in more detail in this updated posting.**

Additional Details

A. Some commenters supported Option 2 from the September 2020 meeting as outlined below

Option 2. Create a new code in table 5A0, Extracorporeal or Systemic Assistance and Performance, to identify when intraoperative embolic protection is performed during a procedure.

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

Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**ADD A** Intraoperative	**ADD 0** Filtration	**Z** No Qualifier

However, commenters also recommended that if this option were to be finalized, CMS should delete the two codes in section X table X2A that may currently be reported to identify cerebral embolic protection was performed:

- X2A5312 Cerebral embolic filtration, dual filter in innominate artery and left common carotid artery, percutaneous approach, new technology group 2, (created for cerebral embolic protection using the SENTINEL™ Cerebral Protection System)

- X2A6325 Cerebral embolic filtration, single deflection filter in aortic arch, percutaneous approach, new technology group 5, (created to describe cerebral embolic protection using the TriGUARD 3™ Cerebral Embolic Protection Device)

Commenters also stated that since intraoperative embolic filtration would be performed in conjunction with another procedure, the definitive surgical procedure would be able to identify the site.

B. Other commenters supported Option 3 from the September 2020 meeting as outlined below

Option 3. Create new codes in table 5A0, Extracorporeal or Systemic Assistance and Performance, to identify when intraoperative embolic protection is performed during cerebral or peripheral artery procedures.

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

Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**ADD A** Intraoperative	**ADD 0** Filtration	**ADD E** Head and Neck Arteries **ADD J** Extremity Arteries **Z** No Qualifier

Similar to other comments submitted for option 2, the recommendation is to delete section X table X2A, incorporate all three codes from section X table X2A to table 5A0 and have the function values match the current names in the section X table X2A, such as:

Character 4 – 5, Circulatory
Character 5 – A, Intraoperative
Character 6 – 0, Filtration
? Filtration, Dual Filter
? Filtration, Single Deflection Filter
? Filtration, Extracorporeal Flow Reversal Circuit
Character 7 – E, Head and Neck Arteries
J, Extremity Arteries

Two new rows would be needed, one for the existing filters and the qualifier value of E, Head and Neck Arteries, and one for 0, Filtration and both qualifiers of E and J. According to the commenters, by keeping the existing names, the specific body part(s) are then known because each of these filters is used in their specific location in the body. If the generic value of 0, Filtration is used, the arteries would be captured in the qualifier value.

C. Another commenter recommended a modified Option 3, to capture options for intravascular filtration, and extracorporeal filtration, to identify the location of the two types of filters. The commenter stated that if the function value Filtration, is modified to identify the location of the filter, CMS should adjust the numbering scheme, as 0-Filtration is used with respiratory procedures in table 5A0.

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

Body System	*Duration*	*Function*	*Qualifier*
5 Circulatory	**ADD A** Intraoperative	**ADD 6** Filtration, intravascular **ADD 7** Filtration, extracorporeal	**ADD E** Head and Neck Arteries **ADD J** Extremity Arteries **Z** No Qualifier

We will provide additional updates at the September 2021 meeting for the topics where we requested consideration versus an actual proposal.

Group 1 codes Recap – similar to what was discussed at the September 2020 meeting
Orbital atherectomy codes – CMS proposing 4th option, if supported by public comments
Monitoring of knee joint using intraoperative knee replacement sensor – CMS proposing option 3
Introduction of drug codes – CMS proposing to delete – option 2

Group 2 codes Recap -
Cerebral embolic protection – tabled
Replacement of aortic valve – tabled for consideration of the 4th option, though public comments supported deleting – CMS proposing option 3
Reposition of magnetically controlled growth rods – propose option 2
Fusion nanotextured surface IFD– CMS proposing option 2
Introduction of drugs – CMS proposing option 1 at this time based on public comments

Section X_March 8, 2020 Update
Group 1

ICD-10-PCS Code	Code Description	FY 2016		FY 2017		FY 2018		FY 2019		
		Frequency	Approved as a New Technology?	Frequency	Approved as a New Technology?	Frequency	Approved as a New Technology?	Frequency	Approved as a New Technology?	Total Frequency Procedure Code Reported
X2C0361	Extirpation of matter from coronary artery, one artery using orbital atherectomy technology, percutaneous approach, new technology group 1	1,086	NO	1574	NO	1787	NO	2002	NO	6,446
X2C1361	Extirpation of matter from coronary artery, two arteries using orbital atherectomy technology, percutaneous approach, new technology group 1	258	NO	264	NO	272	NO	272	NO	1,066
X2C2361	Extirpation of matter from coronary artery, three arteries using orbital atherectomy technology, percutaneous approach, new technology group 1	41	NO	33	NO	44	NO	36	NO	154
X2C3361	Extirpation of matter from coronary artery, four or more arteries using orbital atherectomy technology, percutaneous approach, new technology group 1	9	NO	0	NO	1	NO	2	NO	12
XR2G021	Monitoring of right knee joint using intraoperative knee replacement sensor, open approach, new technology group 1	858	NO	1135	NO	886	NO	887	NO	3,766
XR2H021	Monitoring of left knee joint using intraoperative knee replacement sensor, open approach, new technology group 1	796	NO	1093	NO	864	NO	818	NO	3,571
XW03321	Introduction of ceftazidime-avibactam anti-infective into peripheral vein, percutaneous approach, new technology group 1	48	NO	47	NO	62	NO	55	NO	212
XW03331	Introduction of idarucizumab, dabigatran reversal agent into peripheral vein, percutaneous approach, new technology group 1	13	NO	102	YES	102	YES	103	NO	320
XW03341	Introduction of isavuconazole anti-infective into peripheral vein, percutaneous approach, new technology group 1	5	NO	8	NO	14	NO	23	NO	50
XW03351	Introduction of blinatumomab antineoplastic immunotherapy into peripheral vein, percutaneous approach, new technology group 1	45	YES	43	YES	46	NO	61	NO	195
XW04321	Introduction of ceftazidime-avibactam anti-infective into central vein, percutaneous approach, new technology group 1	6	NO	7	NO	9	NO	12	NO	34
XW04331	Introduction of idarucizumab, dabigatran reversal agent into central vein, percutaneous approach, new technology group 1	0	NO	9	YES	12	YES	13	NO	34
XW04341	Introduction of isavuconazole anti-infective into central vein, percutaneous approach, new technology group 1	2	NO	3	NO	10	NO	9	NO	24
XW04351	Introduction of blinatumomab antineoplastic immunotherapy into central vein, percutaneous approach, new technology group 1	73	YES	104	YES	100	NO	114	NO	391

ICD-10-PCS Index Addenda Example

Lttr		C	
Main	Delete		Ceftazidime-Avibactam Anti-infective XW0
Main	Add		Ceftazidime-Avibactam use Anti-infective
Lttr		E	
Main		Extirpation	
	Delete		Orbital Atherectomy Technology X2C
Lttr		I	
Main	Delete		Intraoperative Knee Replacement Sensor XR2
Lttr		M	
Main		Monitoring	
	Delete		Intraoperative Knee Replacement Sensor XR2
Lttr		N	
Main		New Technology	
	Delete		Ceftazidime-Avibactam Anti-infective XW0
	Delete		Intraoperative Knee Replacement Sensor XR2
	Delete		Orbital Atherectomy Technology X2C
Lttr		O	
Main	Delete		Orbital Atherectomy Technology X2C
Main	Add		Orbital Atherectomy see Extirpation, Heart and Great Vessels 02C

ICD-10-PCS Substance Key Addenda Example

Section 3	Administration	
Axis 6		Substance
Row	Add	
Term	Add	Anti-infective
Includes	Add	Ceftazidime-Avibactam

Section X_March 8, 2020
Update-Group 2

ICD-10-PCS Code	Code Description	FY 2017		FY 2018		FY 2019		FY 2020		
		Frequency	Approved as a New Technology?	Frequency	Approved as a New Technology?	Frequency	Approved as a New Technology?	Frequency	Approved as a New Technology?	Total Frequency Procedure Code Reported
X2A5312	Cerebral embolic filtration, dual filter in innominate artery and left common carotid artery, percutaneous approach, new technology group 2	142	NO	1,957	NO	4,598	YES	N/A	YES	6,697
X2RF032	Replacement of aortic valve using zooplastic tissue, rapid deployment technique, open approach, new technology group 2	541	NO	1400	YES	1066	NO	N/A	NO	3,007
X2RF332	Replacement of aortic valve using zooplastic tissue, rapid deployment technique, percutaneous approach, new technology group 2	892	NO	1022	NO	1562	NO	N/A	NO	3,476
X2RF432	Replacement of aortic valve using zooplastic tissue, rapid deployment technique, percutaneous endoscopic approach, new technology group 2	2	NO	5	NO	10	NO	N/A	NO	17
XHRPXL2	Replacement of skin using porcine liver derived skin substitute, external approach, new technology group 2	158	NO	200	NO	201	NO	N/A	NO	559
XNS0032	Reposition of lumbar vertebra using magnetically controlled growth rod(s), open approach, new technology group 2	0	YES	21	NO	31	NO	N/A	NO	52
XNS0332	Reposition of lumbar vertebra using magnetically controlled growth rod(s), percutaneous approach, new technology group 2	0	YES	1	NO	0	NO	N/A	NO	1
XNS3032	Reposition of cervical vertebra using magnetically controlled growth rod(s), open approach, new technology group 2	0	YES	12	NO	16	NO	N/A	NO	28
XNS3332	Reposition of cervical vertebra using magnetically controlled growth rod(s), percutaneous approach, new technology group 2	0	YES	0	NO	0	NO	N/A	NO	0
XNS4032	Reposition of thoracic vertebra using magnetically controlled growth rod(s), open approach, new technology group 2	0	YES	11	NO	23	NO	N/A	NO	34
XNS4332	Reposition of thoracic vertebra using magnetically controlled growth rod(s), percutaneous approach, new technology group 2	0	YES	0	NO	0	NO	N/A	NO	0
XRG0092	Fusion of occipital-cervical joint using nanotextured surface interbody fusion device, open approach, new technology group 2	1	NO	1	NO	0	NO	N/A	NO	2
XRG1092	Fusion of cervical vertebral joint using nanotextured surface interbody fusion device, open approach, new technology group 2	43	NO	34	NO	21	NO	N/A	NO	98
XRG2092	Fusion of 2 or more cervical vertebral joints using nanotextured surface interbody fusion device, open approach, new technology group 2	137	NO	77	NO	61	NO	N/A	NO	275
XRG4092	Fusion of cervicothoracic vertebral joint using nanotextured surface interbody fusion device, open approach, new technology group 2	6	NO	3	NO	3	NO	N/A	NO	12
XRG6092	Fusion of thoracic vertebral joint using nanotextured surface interbody fusion device, open approach, new technology group 2	2	NO	3	NO	2	NO	N/A	NO	7
XRG7092	Fusion of 2 to 7 thoracic vertebral joints using nanotextured surface interbody fusion device, open approach, new technology group 2	3	NO	4	NO	1	NO	N/A	NO	8
XRG8092	Fusion of 8 or more thoracic vertebral joints using nanotextured surface interbody fusion device, open approach, new technology group 2	0	NO	0	NO	0	NO	N/A	NO	0
XRGA092	Fusion of thoracolumbar vertebral joint using nanotextured surface interbody fusion device, open approach, new technology group 2	6	NO	4	NO	2	NO	N/A	NO	12
XRGB092	Fusion of lumbar vertebral joint using nanotextured surface interbody fusion device, open approach, new technology group 2	75	NO	127	NO	146	NO	N/A	NO	348
XRGC092	Fusion of 2 or more lumbar vertebral joints using nanotextured surface interbody fusion device, open approach, new technology group 2	52	NO	68	NO	59	NO	N/A	NO	179
XRGD092	Fusion of lumbosacral joint using nanotextured surface interbody fusion device, open approach, new technology group 2	55	NO	70	NO	104	NO	N/A	NO	229
XW03372	Introduction of inactivated coagulation factor xa into peripheral vein, percutaneous approach, new technology group 2	8	NO	4	NO	337	YES	N/A	YES	349
XW03392	Introduction of defibrotide sodium anticoagulant into peripheral vein, percutaneous approach, new technology group 2	8	YES	3	YES	6	YES	N/A	NO	17
XW04372	Introduction of inactivated coagulation factor xa into central vein, percutaneous approach, new technology group 2	2	NO	0	NO	35	YES	N/A	YES	37
XW04392	Introduction of defibrotide sodium anticoagulant into central vein, percutaneous approach, new technology group 2	1	YES	1	YES	6	YES	N/A	NO	8
XW0DX82	Introduction of uridine triacetate into mouth and pharynx, external approach, new technology group 2	5	YES	4	YES	1	NO	N/A	NO	10

ICD-10-PCS Index Addenda

Lttr A
Main Angiography
Delete see Plain Radiography, Heart B20
Delete see Fluoroscopy, Heart B21
Add see Computerized Tomography (CT Scan), Artery
Add see Fluoroscopy, Artery
Add see Magnetic Resonance Imaging (MRI), Artery
Add see Plain Radiography, Artery

Lttr C
Main Add Casirivimab (REGN10933) and Imdevimab (REGN10987) use REGN-COV2 Monoclonal Antibody

Main Add Control bleeding using Tourniquet, External
Add see Compression, Anatomical Regions 2W1

Lttr I
Main Delete InterStim(R) Therapy neurostimulator use Stimulator Generator, Single Array in 0JH
Main Add Imdevimab (REGN10987) and Casirivimab (REGN10933) use REGN-COV2 Monoclonal Antibody
Main Add InterStim(tm) II Therapy neurostimulator use Stimulator Generator, Single Array in 0JH
Main Add InterStim(tm) Micro Therapy neurostimulator use Stimulator Generator, Single Array Rechargeable in 0JH

Lttr P
Main Add PERCEPT(tm) PC neurostimulator use Stimulator Generator, Multiple Array in 0JH

Lttr T
Main Add Tourniquet, External see Compression, Anatomical Regions 2W1

ICD-10-PCS Device Key Addenda

Axis 6 Device
Row
Term Stimulator Generator, Multiple Array for Insertion in Subcutaneous Tissue and Fascia
Includes Add PERCEPT(tm) PC neurostimulator

Row		
Term		Stimulator Generator, Single Array for Insertion in Subcutaneous Tissue and Fascia
Includes	Delete	InterStim(R) Therapy neurostimulator
Includes	Add	InterStim(tm) II Therapy neurostimulator
Row		
Term		Stimulator Generator, Single Array Rechargeable for Insertion in Subcutaneous Tissue and Fascia
Includes	Add	InterStim(tm) Micro Therapy neurostimulator

ICD-10-PCS Substance Key Addenda

Section X		New Technology
Axis 6		Device / Substance / Technology
Row	Add	
Term	Add	REGN-COV2 Monoclonal Antibody
Includes	Add	Casirivimab (REGN10933) and Imdevimab (REGN10987)
Includes	Add	Imdevimab (REGN10987) and Casirivimab (REGN10933)

ICD-10-PCS Code Title Addenda

Source	Description	Code specification
2020, public comment & CMS internal review	In table 3E0, revise the code titles for codes that include the qualifier value M Monoclonal Antibody, so that the code titles also include the sixth character substance value 0 Antineoplastic. This change is requested for clarification purposes only, to assist coders with appropriate code assignment.	Revise 62 codes total: 3E00X0M (one code) 3E0[12ARSUVW]30M (8 codes) 3E0[3456][03]0M (8 codes) 3E0[9BCD][37X]0M (12 codes) 3E0[EFGHJKNP][378]0M (24 codes) 3E0[LMY][37]0M (6 codes) 3E0Q[037]0M (3 codes)

ICD-10-PCS Table Addenda

Medical and Surgical Section
Axis 4 Body Part

Ultrasonic Surgical Aspiration of Brain

Source	Description	Code specification
2020, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 00D, Extraction of Central Nervous System and Cranial Nerves, add the body part values 0 Brain and 7 Cerebral Hemisphere to identify procedures such as microsurgical hemispherotomy performed using cavitron ultrasonic surgical aspiration (CUSA).	Add: 00D[07][034]ZZ (6 codes)

EXAMPLE

Section **0** Medical and Surgical
Body System **0** Central Nervous System and Cranial Nerves
Operation **D** Extraction: Pulling or stripping out or off all or a portion of a body part by the use of force

Body Part	*Approach*	*Device*	*Qualifier*
ADD 0 Brain **1** Cerebral Meninges **2** Dura Mater **ADD 7** Cerebral Hemisphere **F** Olfactory Nerve **G** Optic Nerve **H** Oculomotor Nerve **J** Trochlear Nerve **K** Trigeminal Nerve **L** Abducens Nerve **M** Facial Nerve **N** Acoustic Nerve **P** Glossopharyngeal Nerve **Q** Vagus Nerve **R** Accessory Nerve **S** Hypoglossal Nerve **T** Spinal Meninges	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

Medical and Surgical Section
Axis 4 Body Part

Fragmentation of Cerebral Artery

Source	Description	Code specification
2020, public comment &	In the Medical and Surgical section table 03F, Fragmentation of Upper Arteries, add body part value G Intracranial Artery, applied to the approach	Add: 03FG3Z[0Z] (2 codes)

CMS internal review	value Percutaneous, to identify procedures such as clot maceration performed in a cerebral artery using a microcatheter.	

EXAMPLE

Section	**0** Medical and Surgical
Body System	**3** Upper Arteries
Operation	**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 **ADD G** Intracranial Artery **Y** Upper Artery	**3** Percutaneous	**Z** No Device	**0** Ultrasonic **Z** No Qualifier

Administration Section
Axis 5 Approach

Open Approach for Transfusions

Source	Description	Code specification
2020, public comment & CMS internal review	In Administration Section table 302, delete approach value 0 Open, currently applied to body systems 3 Peripheral Vein, 4 Central Vein and 8 Vein. Because a cutdown venous access is classified as a percutaneous approach, the open approach is considered clinically invalid.	Delete: 302[348]0[ABCGHJKLMNPQRSTUVWXY][01234Z] (87 codes)

EXAMPLE

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

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

			4 Allogeneic, Unspecified
3 Peripheral Vein **4** Central Vein	**DELETE 0** Open **3** Percutaneous	**H** Whole Blood **J** Serum Albumin **K** Frozen Plasma **L** Fresh Plasma **M** Plasma Cryoprecipitate **N** Red Blood Cells **P** Frozen Red Cells **Q** White Cells **R** Platelets **S** Globulin **T** Fibrinogen **V** Antihemophilic Factors **W** Factor IX	**0** Autologous **1** Nonautologous
3 Peripheral Vein **4** Central Vein	**DELETE 0** Open **3** Percutaneous	**U** Stem Cells, T-cell Depleted Hematopoietic	**2** Allogeneic, Related **3** Allogeneic, Unrelated **4** Allogeneic, Unspecified
7 Products of Conception, Circulatory	**3** Percutaneous **7** Via Natural or Artificial Opening	**H** Whole Blood **J** Serum Albumin **K** Frozen Plasma **L** Fresh Plasma **M** Plasma Cryoprecipitate **N** Red Blood Cells **P** Frozen Red Cells **Q** White Cells **R** Platelets **S** Globulin **T** Fibrinogen **V** Antihemophilic Factors **W** Factor IX	**1** Nonautologous
8 Vein	**DELETE 0** Open **3** Percutaneous	**B** 4-Factor Prothrombin Complex Concentrate	**1** Nonautologous

Administration Section
Axis 5 Approach

Laparoscopic Irrigation of Peritoneal Cavity

Source	Description	Code specification
2020, public comment & CMS internal review	In Administration Section table 3E1, add approach value 4 Percutaneous Endoscopic, applied to body part value M Peritoneal Cavity, to identify procedures such as laparoscopic irrigation of the peritoneal cavity, for therapeutic purposes or diagnostic purposes.	Add: 3E1M48[XZ] (2 codes)

EXAMPLE

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

Body System / Region	*Approach*	*Substance*	*Qualifier*
M Peritoneal Cavity	**ADD 4** Percutaneous Endoscopic	**8** Irrigating Substance	**X** Diagnostic **Z** No Qualifier

New Technology Section
Axis 6 Device / Substance / Technology

Source	Description	Code specification
2020, FDA & CMS internal review	In New Technology Section table XW1, Transfusion, create new substance values 8 Hyperimmune Globulin, and 9 High-Dose Intravenous Immune Globulin to identify the intravenous administration of Hyperimmune globulin or High-Dose Intravenous Immune Globulin to enable efficient tracking of these substances when used for treatment of COVID-19.	Add: XW1[34]3[89]7 (4 codes)

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**1** Transfusion: Putting in blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 8** Hyperimmune Globulin **ADD 9** High-Dose Intravenous Immune Globulin	**ADD 7** New Technology Group 7

ICD-10-PCS Index Addenda

Lttr A
Main Add Anti-SARS-CoV-2 hyperimmune globulin use Hyperimmune Globulin

Lttr G
Main Add GAMUNEX-C, for COVID-19 treatment use High-Dose Intravenous Immune Globulin

Lttr H
Main Add hdIVIG (high-dose intravenous immunoglobulin), for COVID-19 treatment use High-Dose Intravenous Immune Globulin

Main Add HIG (hyperimmune globulin), for COVID-19 treatment use Hyperimmune Globulin

Main Add High-Dose Intravenous Immune Globulin XW1

Main Add High-dose intravenous immunoglobulin (hdIVIG), for COVID-19 treatment use High-Dose Intravenous Immune Globulin

Main Add hIVIG (hyperimmune intravenous immunoglobulin), for COVID-19 treatment use Hyperimmune Globulin

Main Add Hyperimmune Globulin XW1

Main Add Hyperimmune intravenous immunoglobulin (hIVIG), for COVID-19 treatment use Hyperimmune Globulin

Lttr I
Main Add IGIV-C, for COVID-19 treatment use Hyperimmune Globulin

Lttr N
Main New Technology
Add High-Dose Intravenous Immune Globulin XW1
Add Hyperimmune Globulin XW1

Lttr O
Main Add Octagam 10%, for COVID-19 treatment use High-Dose Intravenous Immune Globulin

ICD-10-PCS Substance Key Addenda

Section X		New Technology
Axis 6		Device / Substance / Technology
Row	Add	
Term	Add	High-Dose Intravenous Immune Globulin
Includes	Add	GAMUNEX-C, for COVID-19 treatment
Includes	Add	hdIVIG (high-dose intravenous immunoglobulin), for COVID-19 treatment
Includes	Add	High-dose intravenous immunoglobulin (hdIVIG), for COVID-19 treatment
Includes	Add	Octagam 10%, for COVID-19 treatment
Row	Add	
Term	Add	Hyperimmune Globulin
Includes	Add	Anti-SARS-CoV-2 hyperimmune globulin
Includes	Add	HIG (hyperimmune globulin), for COVID-19 treatment
Includes	Add	hIVIG (hyperimmune intravenous immunoglobulin), for COVID-19 treatment
Includes	Add	Hyperimmune intravenous immunoglobulin (hIVIG), for COVID-19 treatment
Includes	Add	IGIV-C, for COVID-19 treatment

Patient Specific Intervertebral Body Fusion

Issue: There are currently no unique ICD-10-PCS codes to describe spinal fusion performed with a patient specific intervertebral body fusion device for the correction of adult spinal deformity.

New Technology Application? Yes. The requestor has submitted a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? The aprevo™ Intervertebral Body Fusion Device was granted FDA Breakthrough Device Designation on July 1, 2020 and 510(k) market clearance on December 8, 2020.

Background: Spinal deformities are conditions affecting the curve or rotation of the spinal vertebrae and may occur as a result of birth defects, degeneration, or trauma. Examples of spinal deformities include scoliosis (spine curves to the right or left), kyphosis (upper spine curves forward), and lordosis (lower back curves inward (swayback)). Surgical realignment of the spine involves the use of permanent intervertebral body fusion (IBF) devices to stabilize the spine and facilitate fusion.

According to the requestor, unlike traditional IBF devices, the aprevo™ devices are personalized to incorporate patient-specific features to allow the surgeon to tailor the deformity correction to the individual needs of the patient. The personalized features include height, width, depth, front-to-back angulation, side-to-side angulation, and an anatomical interface to provide a more precise fit against the anatomy of the patient's vertebral endplates. The requestor stated that achieving the specific alignment goals for each patient has been shown to improve outcomes, reduce complications, and contribute to greater patient satisfaction.

Technology and Procedure
There are four basic steps involved in the creation of a personalized intervertebral body fusion device.

1. Using the patient's own computed tomography (CT) scan, create a 3D model of the deformity
2. Plan surgical correction by using the 3D models
3. After approval of proposed correction plan by surgeon, implants are designed to specifically match the requirements of the plan
4. Manufacture personalized implants from 3D printed titanium

The implantation method is similar to pre-fabricated IBF devices, however, the trial-and-error fit process to select the closest possible size and fit for the patient's anatomical needs is eliminated. The surgical technique may be anterior, lateral, or transforaminal/posterior. A discectomy is performed and endplate cartilage is removed. The endplate preparation must facilitate vascular supply to the bone graft while also maintaining the integrity of the endplate. Distractors may be used to distract the vertebral segments to restore disc height, open the neural foramen, and allow delivery of the implant. Three aprevo™ implants are provided for each level: a nominal size, which matches the surgical plan requirements; a size that is 1mm smaller in superior/inferior height; and a size that is 2mm larger in superior/inferior height. The smallest device is attached to the inserter, packed with bone graft and seated into position. If additional height is desired, the nominal or large

size is used. Once an implant has been placed, anterior/posterior (A/P) and lateral fluoroscopy is used to confirm that the final position is appropriate. The requestor noted supplemental fixation, such as posterior pedicle screws with rods should be used. Hyperlordotic anterior IBF devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

Current Coding: There are no unique ICD-10-PCS codes to describe the use of a patient specific intervertebral body fusion device. Facilities can report the use of interbody fusion devices for spinal fusion using the appropriate body part value in tables 0RG, Fusion of Upper Joints, and 0SG, Fusion of Lower Joints, as listed below.

Section **0** Medical and Surgical *Body System* **R** Upper Joints *Operation* **G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile			
Body Part	*Approach*	*Device*	*Qualifier*
A Thoracolumbar Vertebral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**A** Interbody Fusion Device	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

Section **0** Medical and Surgical *Body System* **S** Lower Joints *Operation* **G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile			
Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebral Joint **1** Lumbar Vertebral Joints, 2 or more **3** Lumbosacral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**A** Interbody Fusion Device	**0** Anterior Approach, Anterior Column **J** Posterior Approach, Anterior Column

Coding Options

Option 1. Do not create new ICD-10-PCS codes to describe the use of a patient specific intervertebral body fusion device. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to describe the use of a patient specific intervertebral body fusion device.

Section **X** New Technology *Body System* **R** Joints *Operation* **G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
A Thoracolumbar Vertebral Joint **B** Lumbar Vertebral Joint **C** Lumbar Vertebral Joints, 2 or more **D** Lumbosacral Joint	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**ADD R** Interbody Fusion Device, Customizable	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.