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

CENTER FOR MEDICARE

Agenda

ICD-10 Coordination and Maintenance Committee Meeting
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Virtual Meeting
ICD-10-PCS Topics
September 8, 2020

Zoom Webinar and Dial-In Information

- Day 1: September 8, 2020: 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: September 9, 2020: 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.
- 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 are as follows.

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

Option 1: 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: 160 355 5616

*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.

Option 2: 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, as well as, connect to the audio portion of the conference:

Click the following URL:
https://cms.zoomgov.com/s/1603555616?pwd=bmdoSXVKQWMxOTRJS0FtRCtMUDg1Zz09

Detailed instructions for joining the Zoom Webinar or dialing-in are posted in the "Downloads" section located here: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.

If you experience technical difficulties during the meeting, please contact Michele Hudson for assistance at michele.hudson@cms.hhs.gov or 443-821-4266.

Note: Proposals for diagnosis code topics are scheduled for September 9, 2020 and will be led by the Centers for Disease Control (CDC). Some of the proposals for the ICD-10-CM diagnosis topics may begin on September 8, 2020 should CMS complete the ICD-10-PCS procedure topics prior to 5:00 PM ET. Please visit CDCs website for the Diagnosis agenda located at the following address: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm.

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 any 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.

Introductions & Overview	Mady Hue, CMS
ICD-10-PCS Topics:	
1. Antibiotic-eluting Bone Void Filler Pages 14-15	Noel Manlove Douglas R. Dirschl, MD Lowell T. Coggeshall Professor of Orthopedic Surgery Chairman, Department of Orthopaedic Surgery and Rehabilitation Medicine Physician-in-Chief, Musculoskeletal Center UChicago Medicine and Biological Sciences
2. Restriction of Coronary Sinus Pages 16-17	Noel Manlove Shmuel Banai, MD Professor of Cardiology, Tel Aviv University Medical Director, Neovasc Inc Director, Division of Cardiology, Tel Aviv Medical Center
3. Vertebral Body Tethering Pages 18-19	Mady Hue Daniel Hoernschemeyer, MD University of Missouri Health Care
4. Chimeric Antigen Receptor T-cell Immunotherapies Pages 20-22	Andrea Hazeley, CMS
5. Administration of Allogeneic Chimeric Antigen Receptor T-cell Immunotherapy Pages 23-24	Paula Dupee Fred LeMaistre, MD Senior Vice President Sarah Cannon Blood Cancer Network
6. Administration of Lifileucel Pages 25-27	Paula Dupee Maria Fardis, PhD, MBA President & CEO, Iovance Biotherapeutics
7. Administration of Idecabtagene vicleucel (ide-cel) Pages 28-29	Paula Dupee Amit Agarwal, MD Global Disease Lead, Multiple Myeloma, Medical Affairs Bristol Myers Squibb

8. Administration of Narsoplimab Pages 30-31	Michelle Joshua Lawrence Kovalick, PharmD, BCGP, CMPP Senior Director National Medical Science Liaison Lead
9. Embolic Protection Pages 32-33	Michelle Joshua, CMS
10. Single-Use Duodenoscope During Endoscopic Retrograde Cholangiopancreatography Pages 34-35	Paula Dupee Brian Dunkin, MD Chief Medical Officer Boston Scientific Endoscopy
11. Spinal Stabilization Pages 36-38	Mady Hue Carter Lonsberry, CEO icotec medical, Inc. Laurence D. Rhines, MD Professor/Director Spine Tumor Program Dept. of Neurosurgery MD Anderson
12. Section X Updates Pages 39-42	Mady Hue, CMS
13. Addenda and Key Updates Pages 43-51	Andrea Hazeley, CMS
14. Posterior Dynamic Distraction Pages 52-54	Mady Hue Tim Oswald, MD Pediatric Orthopedic Associates Children's Healthcare of Atlanta

Registering for the meeting:
Registration for the September 8-9, 2020 ICD-10 Coordination and Maintenance Committee meeting opened on Monday, August 3, 2020 and closed on Friday, September 4, 2020. ***If participating via the Zoom Webinar or dialing in, you did NOT need to register on-line for the meeting.** For questions about the registration process, please contact Mady Hue at 410-786-4510 or marilu.hue@cms.hhs.gov or Noel Manlove at 410-786-5161 or noel.manlove@cms.hhs.gov.

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

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ICD-10 TIMELINE

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

September 8-9, 2020	The September 2020 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 2020	Recordings and slide presentations of the September 8-9, 2020 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, 2020	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 9, 2020	**Deadline for receipt of public comments on proposed new codes discussed at the September 8-9, 2020 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2021.**
November 2020	Any new ICD-10 codes required to capture new technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2021 will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/
November 9, 2020	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 8-9, 2020 ICD-10**

	Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2021.
December 4, 2020	**Deadline for requestors: Those members of the public requesting that topics be discussed at the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and to NCHS for diagnoses by this date.**
January	Federal Register notice of March 9-10, 2021 ICD-10 Coordination and Maintenance Committee Meeting will be published.
February 2021	Tentative agenda for the Procedure portion of the March 9, 2021 ICD-10 Coordination and Maintenance Committee Meeting posted on CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis portion of the March 10, 2021 ICD-10 Coordination and Maintenance Committee Meeting posted on NCHS homepage as follows: https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm
February 1, 2021	**On-line registration opens for the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee Meeting at:** https://www.cms.gov/apps/events/default.asp. 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 March 1, 2021.
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	Any new ICD-10 codes to capture new diseases or technology will be implemented on April 1, 2021.

April 9, 2021	**Deadline for receipt of public comments on proposed new 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 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	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 1, 2021	Hospital Inpatient Prospective Payment System final rule to be published in the Federal Register as mandated by Public Law 99-509. This rule will also include links to all the final codes to be implemented on October 1, 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.cms.gov/apps/events/default.asp. 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 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 April 1, 2021 and 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
  - October 9, 2020 for codes being considered for April 1, 2021 implementation
  - November 9, 2020 for codes being considered for October 1, 2021 implementation
- Procedure comments to CMS ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to NCHS nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2020 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2020 C&M meeting
- September 2020 – Final rule with links to final codes to be implemented on October 1, 2020
  - Includes any additional codes approved from March 17-18, 2020 C&M meeting
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS

Addendum

- May/June 2020 – Final code updates and addendum posted
  - FY 2021 ICD-10-PCS (Procedures) http://www.cms.gov/Medicare/Coding/ICD10/index.html
  - FY 2021 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
  - October 9, 2020 for codes being considered for April 1, 2021 implementation
  - November 9, 2020 for codes being considered for October 1, 2021 implementation
  - 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 April 1, 2021 or October 1, 2021 implementation

March 9-10, 2021 C&M Code Requests

- December 4, 2020 – Deadline for submitting topics for March 9-10, 2021 C&M meeting
  - Procedure requests to CMS ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis requests to NCHS nchsicd10cm@cdc.gov

Antibiotic-eluting Bone Void Filler

Issue: There are currently no unique ICD-10-PCS codes to describe the insertion of an implantable bone void filler that elutes an antibiotic.

New Technology Application? Yes. The requester intends to submit a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? CERAMENT® G is an FDA-designated breakthrough technology that is classified as a device/drug combination product with a device primary mode of action and is currently under review by the FDA for de novo clearance.

Background: Osteomyelitis and other bone infections are a devastating complication following trauma or orthopedic surgery. Osteomyelitis can be considered a life-threatening and irreversibly debilitating human disease, as it can lead to bone death (osteonecrosis) and ultimately limb amputation, septic arthritis in nearby joints, impaired growth, and skin cancer.

The current treatment for osteomyelitis is a two-stage procedure; in the first stage, surgery is carried out to remove any infected or necrotic bone tissue (debridement), most often antibiotic-loaded bone cement (polymethylmethacrylate (PMMA)) or calcium sulfate mixed with antibiotics off-label is placed in the location of the excised bone, and the wound is closed. PMMA must be removed, as it prevents bone ingrowth that can hinder long-term healing of a fractured bone and can act as a focal point for infection, and calcium sulfates resorb and do not remodel into bone. As a result, 6 to 12 weeks later, a second operation is carried out to manage the bone void, also known as "dead-space." The options for dead-space management are limited to autografts, allografts, or other bone graft substitutes. According to the requester, autografts are well known to cause donor site morbidity such as pain and infection, and are limited in terms of quality and quantity, and mixing products with antibiotics off-label has no proven safety or efficacy.

Technology
CERAMENT® G is an implantable bone void filler (combination device/drug) consisting of hydroxyapatite, calcium sulfate, and gentamicin sulfate. CERAMENT® G is a novel, on-label, combination device/drug implant. It is a uniquely designed, all-in-one, bone void filler + antibiotic, specifically engineered to work as a single product. CERAMENT® G remodels into bone and elutes gentamicin, which prevents colonization of gentamicin-sensitive microorganisms to protect bone healing. It is used for dead-space management (bone voids) as part of the treatment of osteomyelitis associated with bone trauma, joint replacement, hardware revisions, and diabetes-related bone infections.

According to the requestor, CERAMENT® G is an effective tool for dead-space management to restore healthy bone and reduce the rate of infection recurrence compared to other marketed bone void fillers because of its antibiotic component. Additionally, CERAMENT® G offers the possibility for treatment of osteomyelitis in a single-stage procedure instead of a two-stage procedure, eliminating the need for a second operation, and avoiding donor site morbidity.

Procedure Description
The surgical site must be prepared and dead bone is removed. CERAMENT® G is then prepared by mixing the pre-package components into a paste that is ready for use four minutes after the start of preparing the mixture. CERAMENT® G may then be injected using a tip extender or by attaching a needle to the delivery syringe. It can also be molded into beads and placed into the bone voids.

Current Coding: Facilities can report the insertion of CERAMENT® G bone void filler using the following code.

3E0V3GC Introduction of other therapeutic substance into bones, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the insertion of CERAMENT® G bone void filler. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the insertion of CERAMENT® G bone void filler.

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*
ADD V Bones	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	**ADD** P Antibiotic-eluting Bone Void Filler	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

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

Restriction of Coronary Sinus

Issue: There is currently no unique ICD-10-PCS code to describe the insertion of a reduction device in the coronary sinus for refractory angina.

New Technology Application? Yes. The requester intends to submit a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food and Drug Administration (FDA) Approved? FDA approval for the Reducer ™ System is anticipated for FY 2021. The Reducer Device was granted Breakthrough Medical Device Status by the FDA in October 2018.

Background: Chronic angina pectoris, refractory to medical and interventional therapies, is a common and disabling medical condition, and a major public health problem that affects millions of patients worldwide. The clinical burden of refractory angina (RA) is growing due to an aging population and improved survival from coronary artery disease (CAD). Estimates suggest that in the US up to 1.8 million patients suffer from RA. An increasing number of patients, particularly those with advanced, chronic coronary artery disease, have severe symptoms of angina despite optimal medical therapy. However, RA is common not only in patients who are not good candidates for revascularization, but also in patients following successful revascularization. Persistence or recurrence of angina after PCI or CABG surgery is well recognized and may affect 20–40% of patients during short and medium-term. When further revascularization options are limited, these patients are frequently described as being "no option," and as having RA. The care of these patients is challenging, and the guidance available from national practice guidelines is limited.

The target population are patients with RA that suffer from chest pain that persists in spite of optimal medical therapy, who have evidence of reversible ischemia, and are not amenable to revascularization.

Technology
The Neovasc Reducer System is a device implanted in the coronary sinus vein using minimally invasive techniques. The Reducer creates a permanent and controlled narrowing of the coronary sinus. It is placed via a balloon catheter with a unique hourglass shaped balloon. By modulating blood flow and pressure in the coronary sinus, the Reducer acts to increase the perfusion of oxygenated blood to certain areas of the heart muscle, thereby reducing the pain and disability caused by the condition. The Neovasc Reducer System is comprised of the Reducer Balloon Catheter and the Reducer device. The Reducer Balloon Catheter is an over the wire catheter with a unique hourglass shaped balloon.

Procedure Description
The Neovasc Reducer procedure begins under ultrasound. A right jugular venous access is obtained and an introducer sheath is inserted over a J-wire. A multipurpose (MP) guiding catheter is inserted into the ostium of the coronary sinus (CS) without a guiding wire. After the tip of the catheter is engaged, the catheter is advanced into the CS either with or without guidewire assistance. A long guidewire (0.35"J-wire or a SupraCore wire) is then advanced within the multipurpose catheter deep into the great cardiac vein (as distal as possible into the CS), and the diagnostic catheter is removed.

There are two implantation options:
Implantation option 1: If SupraCore wire is used, the Reducer system inside a 9F guiding catheter (GC), is advanced over the SupraCore guidewire into the CS so that the tip of the GC and the Reducer system's tip is distal to the planned implantation target. The GC is withdrawn to the most proximal marker on the Reducer system, exposing the Reducer, which is held in the landing zone previously identified.

Implantation option 2: If a regular long J-wire is used, the diagnostic 6F MP catheter is inserted into the 9F GC and is advanced over the wire deep into the CS. After the MP's tip is located in the great cardiac vein, the MP and the wire are held in place as an anchor and the GC is advanced. The tip of the GC is placed distal to the target landing zone planned for the Reducer. The MP diagnostic catheter is then removed. The Reducer system is inserted and advanced inside the GC and positioned in the planned implantation target. The GC is now withdrawn to the most proximal marker on the Reducer system, exposing the Reducer, which is held in the landing zone previously identified.

Coronary sinus narrowing has been demonstrated to improve perfusion to ischemic territories of the myocardium which lead to relief of angina symptoms in patients with refractory angina. The Reducer therapy has extensive clinical data, including a randomized, double-blind, sham-controlled study published in the New England Journal Medicine. Available literature demonstrates similar results from hundreds of patients across multiple geographies, including one study with 12-year follow-up demonstrating long-term safety and benefit.

Current Coding: Facilities can report procedures for insertion of a reduction device in the coronary sinus using the following code.

02H43DZ Insertion of intraluminal device into coronary vein, percutaneous approach

Coding Options
Option 1. Do not create new ICD-10-PCS codes for the insertion of a reduction device in the coronary sinus. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the insertion of a reduction device in the coronary sinus.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 7 Coronary Sinus	**3** Percutaneous	**ADD Q** Reduction Device	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

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

Vertebral Body Tethering

Issue: Currently, there is not a unique ICD-10-PCS code to describe vertebral body tethering in the treatment of progressive idiopathic scoliosis.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The Tether™ – Vertebral Body Tethering System received FDA approval under a humanitarian device exemption (HDE) on August 16, 2019.

Background: Scoliosis is a condition that manifests in a significant number of skeletally immature patients annually and is generally defined as an abnormal curvature of the spine greater than 10°. Well known complications of scoliosis include lung and heart damage due to restriction of the rib cage, chronic back pain or problems over time, and psychosocial issues regarding one's physical appearance. Management options for idiopathic scoliosis include observation with or without physical therapy, treatment with an external orthosis (brace), and surgical treatment, most commonly consisting of growing rods for younger children and posterior spinal instrumentation and fusion for adolescents. Standard practice has been to use routine observation for curves up to 20° Cobb. Bracing is typically recommended for curves of 30° to 35°, and surgery has been the prevailing treatment option for curves that are 45° to 50° and beyond. When it is decided that treatment is necessary for an idiopathic scoliosis patient, curve magnitude and skeletal maturity are the top two most important factors in determining treatment pathway. Current thinking is that the higher the magnitude of curve and lower the skeletal maturity, the more aggressive treatment should become.

If conservative treatments (i.e. bracing) have failed, fusion may be the only choice currently available to many patients. Due to the great difficulties of both bracing and spinal fusion, surgeons have searched for alternative surgical approaches that modulate spinal growth and halt curve progression. Among possible non-fusion surgical treatment options, vertebral body tethering (VBT), a way to arrest and obtain some correction of spinal curvature deformities while allowing continued growth to occur, has shown promise as a possible alternative to traditional techniques.

Technology/Procedure Description
The Tether™ – Vertebral Body Tethering System is a non-fusion spinal device indicated for skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30° to 65° whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. The Tether™ - Vertebral Body Tethering System is different from the other surgical treatments for scoliosis, such as spinal fusion, because the spine is still able to bend and flex. Rather than stiff metal rods, The Tether™ - Vertebral Body Tethering System uses a strong, flexible cord to pull on the outside of a scoliosis curve to straighten out the spine. The mechanism of action and technology of the Tether™ – Vertebral Body Tethering System relies upon continued spinal growth (i.e. skeletally immature), limiting the number of patients who could be treated using the system. This population is further refined by those patients who have either failed or who can no longer feasibly be corrected via conservative treatment (i.e. bracing) and have progressed to the point of requiring surgical intervention.

Anchors and vertebral body screws are placed laterally from a thoracoscopic or thoracotomy approach into the vertebral body on the convex side of a spinal deformity. A SULENE® polyethylene terephthalate (PET) tensioning cord is secured to the vertebral body screws with set screws to connect the levels of the construct. The device provides a lateral tension band across the convex side of the spine that, on insertion and tensioning, partially corrects the curvature, and subsequently can arrest or correct the deformity through modulation of remaining spinal growth using a process called "growth modulation". The bones, or "vertebra" in a scoliotic spine are wedge shaped, tall on one side and short on the other. When the vertebra are pulled by the cord, it puts pressure on the tall side of the vertebra on the outside of the curve. This pressure slows the growth on the tall side of the vertebra, so that the short side can grow and catch up. After surgery, the spine may continue to straighten even more over time as the patient grows. The Tether™ – Vertebral Body Tethering system includes instrumentation for insertion, manipulation, and removal of the implants. If over-correction is observed, it is possible to surgically sever the tensioning cord, eliminating the lateral tension band effect.

Safety Results - Total Adverse Events
In a single-center, non-randomized, clinical study where patients were treated with The Tether™ - Vertebral Body Tethering System, overcorrection was reported as the most common event type for serious adverse events (SAEs).

Current Coding: Code the use of a vertebral body tether with the applicable ICD-10-PCS code(s) from tables 0PS and 0QS, Reposition of Upper and Lower Bones, using the device value 4 Internal Fixation Device.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for vertebral body tethering. Continue coding as listed in current coding.

Option 2. In Tables 0PS and 0QS, Reposition of Upper and Lower Bones, create device value 3 Spinal Stabilization Device, Vertebral Body Tether and create qualifier value 3 Anterior Column and qualifier value 4 Posterior Column applied to the appropriate body part value.

Section	**0** Medical and Surgical
Body System	**P** Upper Bones
Operation	**S** Reposition: Moving to its normal location, or other suitable location, all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
4 Thoracic Vertebra	**0** Open **4** Percutaneous Endoscopic	**ADD 3** Spinal Stabilization Device, Vertebral Body Tether	**ADD 3** Anterior Column **ADD 4** Posterior Column **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**Q** Lower Bones
Operation	**S** Reposition: Moving to its normal location, or other suitable location, all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebra	**0** Open **4** Percutaneous Endoscopic	**ADD 3** Spinal Stabilization Device, Vertebral Body Tether	**ADD 3** Anterior Column **ADD 4** Posterior Column **Z** No Qualifier

CMS Recommendation: Option 2, as described above.

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

Chimeric Antigen Receptor T-cell Immunotherapies

Issue: Effective October 1, 2020, ICD-10-PCS codes for the intravenous administration of CAR T-cell therapies can be identified in two different tables in the classification. Also, the two existing ICD-10-PCS codes for the intravenous administration of CAR T-cell therapies are not product-specific, while the two codes that will be effective October 1, 2020 are product specific.

New Technology Application? No

Food & Drug Administration (FDA) Approved? Two CAR T-cell therapies received FDA approval in 2017: KYMRIAH® (tisagenlecleucel) and Yescarta® (axicabtagene ciloleucel). Tecartus™ (brexucabtagene autoleucel) received FDA approval in 2020.

Background: Chimeric Antigen Receptor (CAR) T-cell immunotherapy is a cell-based gene therapy in which immune cells are removed from a patient, armed with new proteins that allow them to recognize cancer, and given back to the patient in large numbers. These cells persist in the body, becoming "living drugs."

Description of Chimeric Antigen Receptor (CAR) T-cell therapy
The therapy requires drawing blood from patients and separating out the T cells. Next, using a disarmed virus, the T cells are genetically engineered to produce receptors on their surface called chimeric antigen receptors, or CARs. These special receptors allow the T cells to recognize and attach to a specific protein, or antigen, on tumor cells. Once the collected T cells have been engineered to express the antigen-specific CAR, they are "expanded" in the laboratory into the hundreds of millions. The final step is the infusion of the CAR T-cells into the patient (which is preceded by a "lymphodepleting" chemotherapy regimen). Once infused, the engineered cells further multiply in the patient's body and, with guidance from their engineered receptor, recognize and kill cancer cells that harbor the antigen on their surfaces while the individual is observed for potential serious side effects that would require medical intervention.

Research on CAR T-cells is continuing at a swift pace, mostly in patients with blood cancers, but also in patients with solid tumors. As the biopharmaceutical industry has become more involved in the field, the number of clinical trials testing CAR T-cells has expanded dramatically and other refinements or reconfigurations of CAR T-cells are being tested. There are trials for CAR T-cell therapies that use immune cells collected from allogeneic donors as well as trials for other routes of administration including intra-tumor, intra-cranial, and intra-pleura.

Current Coding: Effective October 1, 2017, facilities can report the intravenous administration of CAR T-cell therapies with one of the following ICD-10-PCS codes from table XW0:

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	**C** Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy	**3** New Technology Group 3

Effective October 1, 2020, facilities can report the intravenous administration of Tecartus™ (brexucabtagene autoleucel) or lisocabtagene maraleucel with one of the following ICD-10-PCS codes from table XW2:

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	**4** Brexucabtagene Autoleucel Immunotherapy **7** Lisocabtagene maraleucel Immunotherapy	**6** New Technology Group 6

Coding Options

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

Option 2. Create new codes in section X, New Technology, in table XW2 Transfusion to identify intravenous transfusion of CAR T-cell products KYMRIAH® (tisagenlecleucel) and Yescarta® (axicabtagene ciloleucel). Also add non-product specific codes in table XW2 to identify the transfusion of other engineered autologous CAR T-cell therapies. Delete codes in table XW0 that identify the intravenous infusion of CAR T-cell therapies.

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	**4** Brexucabtagene Autoleucel Immunotherapy **7** Lisocabtagene Maraleucel Immunotherapy	**6** New Technology Group 6
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD F** Engineered Chimeric Antigen Receptor T-cell Immunotherapy, Autologous **ADD H** Axicabtagene ciloleucel Immunotherapy **ADD J** Tisagenlecleucel Immunotherapy	**ADD 7** New Technology Group 7

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	**A** Bezlotoxumab Monoclonal Antibody **B** Cytarabine and Daunorubicin Liposome Antineoplastic **DELETE C** Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy **F** Other New Technology Therapeutic Substance	**3** New Technology Group 3

Option 3. Create new codes in section X, New Technology, in table XW0 Introduction to specifically identify intravenous infusion of CAR-T products KYMRIAH® (tisagenlecleucel), Yescarta® (axicabtagene ciloleucel), Tecartus™ (brexucabtagene autoleucel) and lisocabtagene maraleucel. Revise the device value C to “Engineered Chimeric Antigen Receptor T-cell Immunotherapy, Autologous” to identify the infusion of other engineered autologous CAR-T cell therapies. Delete table XW2 that identifies the intravenous transfusion of Tecartus™ (brexucabtagene autoleucel) or lisocabtagene maraleucel.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**REVISE FROM C** Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy **REVISE TO C** Engineered Chimeric Antigen Receptor T-cell Immunotherapy, Autologous	**3** New Technology Group 3
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD H** Axicabtagene ciloleucel Immunotherapy **ADD J** Tisagenlecleucel Immunotherapy **ADD M** Brexucabtagene Autoleucel Immunotherapy **ADD N** Lisocabtagene maraleucel Immunotherapy	**ADD 7** New Technology Group 7

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**DELETE 2** Transfusion: Putting in blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**DELETE 4** Brexucabtagene Autoleucel Immunotherapy **DELETE 7** Lisocabtagene Maraleucel Immunotherapy	**6** New Technology Group 6

CMS Recommendation: CMS is seeking input from the audience.

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

Administration of Allogeneic Chimeric Antigen Receptor T-cell Therapy

Issue: There is currently no unique ICD-10-PCS code to describe the administration of allogeneic CAR T-cell therapies.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No.

Background: Chimeric Antigen Receptor (CAR) T-cell products are a type of Immune Effector Cell therapy. Immune effector cells are defined as, immune cells from the human body that have differentiated into a form capable of modulation or effecting an immune response. These cells, such as B-cells, dendritic cells, natural killer cells, and T-cells, are made into therapies by collecting them, engineering them into a therapeutic product, and then administering the product to a patient. This is a form of cancer immunotherapy, which uses a patient's own immune system to treat cancer. Research has shown that T-cells play a central role in the immune system and are capable of destroying foreign or abnormal host cells, including tumor cells. Immune effector cell therapies like CAR-T can redirect T-cells to target tumor antigens. CAR T-cell products are created by genetically modifying T-cells to express special receptors called chimeric antigen receptors (CARs) on their surface, which allow the modified cells to hone in on and destroy the tumor cells expressing the target of the transferred receptor. The currently approved CAR T-cell products are autologous, meaning they are created using a patient's own cells, which are engineered and then reinfused into the patient, but the same process can be used to modify "allogeneic" cells obtained from a donor.

Allogeneic products obtained from healthy donors and engineered into CAR T-cell therapies are in clinical trials for a number of cancers. Since these products can be engineered in advance and stored in large numbers, these products are often referred to as "off the shelf" since they would be more rapidly available, relative to the approved autologous therapies that have to be generated individually from a patient's own cells.

The use of healthy donor-derived allogeneic CAR T-cell therapies could allow CAR T-cell therapy to be available to a broader range of patients such as patients who may be unable to wait for the engineering of an autologous therapy.

While complications such as graft-versus-host disease (where the donor-derived cells attack the recipient) and rejection of the allogeneic cells by the donor are more likely to occur with allogeneic CAR T-cells, gene editing and other strategies are being developed to reduce or eliminate these potential limitations. Once infused into the patients, the cells will target and kill the diseased cells, similar to autologous CAR T-cell therapies.

There are currently no FDA approved allogeneic CAR T-cell therapy products on the market, but there are a number of clinical trials underway for B-cell malignancies, other cancers including solid tumors, and autoimmune diseases.

Inpatient administration of allogeneic chimeric antigen receptor t-cell immunotherapy immune effector cell therapy
The allogeneic CAR T-cell therapy products will be administered utilizing the same or similar administration procedure as for autologous CAR T-cell products where a peripheral or central line

is established, and a physician will administer the cells via infusion. There are several allogeneic CAR T-cell therapies currently in clinical trial.

Current Coding: Facilities can report the intravenous administration of allogeneic CAR T-cell immunotherapy with one of the following ICD-10-PCS codes:

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

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for intravenous administration of allogeneic CAR T-cell immunotherapy. 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 allogeneic CAR T-cell immunotherapy.

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 G** Engineered Chimeric Antigen Receptor T-cell Immunotherapy, Allogeneic	**ADD 7** New Technology Group 7

Option 3. Create new codes in section X New Technology, table XW0 Introduction, to identify intravenous administration of allogeneic CAR T-cell cell immunotherapy.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD G** Engineered Chimeric Antigen Receptor T-cell Immunotherapy, Allogeneic	**ADD 7** New Technology Group 7

CMS Recommendation: CMS is seeking input from the audience.

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

Administration of Lifileucel

Issue: There is currently no unique ICD-10-PCS code to describe the administration of lifileucel, an autologous Tumor Infiltrating Lymphocyte (TIL) cell-based therapy.

New Technology Application? Yes. The requester intends to submit a New Technology Add-on Payment (NTAP) application for FY 2022 consideration. The requester is seeking implementation of the ICD-10-PCS code on April 1, 2021.

Food & Drug Administration (FDA) Approval? No, lifileucel has not yet received FDA approval.

Background: Tumor Infiltrating Lymphocyte (TIL) cell-based therapy is an autologous cell therapy for solid tumors. Lifileucel is a one-time autologous T-cell based immunotherapy being studied for effectiveness in solid tumors where patients have exhausted most, if not all, other treatment options.

Lifileucel is anticipated to be indicated for:

- patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy, including a PD-1 blocking antibody and, if BRAF V600 mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor.
- Lifileucel is also being studied in patients with recurrent, metastatic or persistent cervical cancer with disease progression on chemotherapy, which is expected to be the second regulatory filing.

Although a new and a completely different mechanism of action from Chimeric Antigen Receptor (CAR) T-cell therapy, both TIL and FDA approved CAR T-cell therapies are autologous and start with the collection of a patient's cells. Then the respective manufacturing processes occur during which patients receive a course of nonmyeloablative chemotherapy conditioning regimen. Next, patients are infused with the specific cell therapy.

TIL therapy with lifileucel involves the adoptive cell transfer (ACT) of autologous T-cells directly isolated from the resected tumor tissue and expanded ex vivo without any prior selection or genetic modification. Tumor antigen-specific T-cells are located within tumor lesions, where a dysfunctional state and low numbers prevent them from effectively eradicating the tumor. By isolating autologous TIL from the tumor microenvironment and expanding them, the lifileucel manufacturing process produces large numbers of reinvigorated T-cells. Following the intravenous infusion of lifileucel, the TIL migrates back into the tumor, including metastases, where they trigger specific tumor cell killing upon recognition of tumor antigens.

Malignant Melanoma
Melanoma represents 5.5% of all new cancer cases with over 96,000 new cases and 7,000 deaths in the US. The rates for new melanoma cases are rising. Major advances in the treatment of advanced melanoma have been made with the integration of immune checkpoint inhibitors (ICIs) and targeted therapies into clinical practice. However, the treatment options for patients with advanced melanoma who have progressed on or after these therapies are limited, with chemotherapy expected to offer objective response rates (ORR) between 4% and 10%. Clinical

trial studies are ongoing evaluating the safety and efficacy of lifileucel in patients that have been diagnosed with unresectable or metastatic Stage IIIc or IV melanoma.

Cervical Cancer
Cervical cancer is a leading cause of cancer-related death in women with over 12,000 new cases and 4,000 deaths in the US alone. Most patients are young, and survival rates are poor. ORR for second-line therapies in the metastatic setting are between 4 and 14% for the recently approved anti-PD-1 antibody immunotherapy. Clinical trial studies are ongoing enrolling patients with recurrent, metastatic or persistent cervical carcinoma who have exhausted the therapeutic options with surgery and/or radiation, as well as palliative chemotherapy administered in the metastatic setting.

Inpatient Administration of Lifileucel
TIL manufacturing starts with the surgical resection of a tumor lesion. Upon placement of tumor fragments in media, the TIL egress from the tumor and expand exponentially to yield 10^9–10^{11} cells ultimately after a 22-day growth period. During the growth period, interleukin 2 (IL-2) is provided in the media to assist in T-cell expansion. The patient's cells are then washed, formulated as a cell suspension, and cryopreserved at the end of the 22-day manufacturing process resulting in a cryopreserved live cell suspension formulated for intravenous infusion. The biological product must pass a sterility test before release for shipping as a frozen suspension in a patient-specific infusion bag (or bags). The ex-vivo expanded autologous TIL are formulated in cryopreservation medium and Plasma-Lyte with 0.5% human serum albumin and 300 IU/mL (12 ng/mL) of IL-2. The biological product is thawed prior to administration. Prior to the infusion of lifileucel, the patient receives a course of nonmyeloablative lymphodepletion (NMA-LD) using cyclophosphamide 60 mg/kg intravenously daily for 2 days followed by fludarabine 25 mg/m2 intravenously daily for 5 days to eliminate potentially suppressive immune cells and maximize engraftment and potency of the lifileucel therapy. Lifileucel is then administered via intravenous infusion into either a peripheral or central vein of a single dose of between 1 x 10^9 to 150 x 10^9 viable autologous TIL cells, provided in up to 4 patient- specific infusion bags. The patient should receive the full dose of product provided. Lifileucel should be infused within approximately 24 hours, or as soon as practical thereafter, following the last dose of fludarabine in the NMA-LD regimen. Three to 24 hours after lifileucel is infused, a short course of high dose IL-2 (eg, aldesleukin) (interleukin 2; IL-2) is administered at 600,000 IU/kg every 8 to 12 hours for up to 6 doses to support cell expansion in vivo.
Lifileucel is expected to be primarily administered in the hospital inpatient setting to assure appropriate patient monitoring and to ensure the supervision of a qualified physician experienced with the use and administration of IL-2.

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

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

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

Coding Options

Option 1. Do not create new ICD-10-PCS codes for intravenous administration of lifileucel. 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 lifileucel.

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 L** Lifileucel Immunotherapy	**ADD 7** New Technology Group 7

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

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 L** Lifileucel Immunotherapy	**ADD 7** New Technology Group 7

CMS Recommendation: CMS is seeking input from the audience.

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

Administration of Idecabtagene vicleucel (ide-cel)

Issue: There is currently no unique ICD-10-PCS code to describe the administration of idecabtagene vicleucel (ide-cel), a B-cell maturation antigen (BCMA) directed chimeric antigen receptor (CAR) T-cell therapy.

New Technology Application? Yes. The requester intends to submit a New Technology Add-on Payment (NTAP) application for FY 2022 consideration. The requester is seeking implementation of the ICD-10-PCS code on April 1, 2021.

Food & Drug Administration (FDA) Approval? No. Ide-cel was granted breakthrough therapy designation by the FDA in November 2017 for the treatment of patients with multiple myeloma. Ide-cel has not yet received FDA approval.

Background: Multiple myeloma (MM) is a rare and incurable cancer of plasma cells, characterized by clinical features of renal failure, bone lesions, hypercalcemia, and bone marrow suppression, resulting from excessive production of monoclonal proteins as well as direct tumor cell effects. MM accounts for approximately 10 to 15 percent of all hematologic malignancies and primarily affects older individuals — it is extremely rare in patients less than 30 years old.

Notwithstanding steady improvement in clinical outcomes, MM remains incurable, and patients eventually relapse and require several lines of therapy. With each line of therapy, patients become increasingly resistant to treatment, which may be partly attributed to genetic heterogeneity of myeloma cells, clonal evolution and progressive immune dysfunction. Furthermore, increasing toxicities associated with later lines of therapy lead to a greater likelihood of treatment discontinuation. Following relapse after exposure to the three main classes of therapy (immunomodulatory agents, proteasome inhibitors and anti-CD38 antibodies), there is no recommended standard of care and no widely used regimen or selection of regimens and overall survival (OS) remains poor.

Ide-cel is a genetically modified autologous T-cell immunotherapy product consisting of T-cells transduced with an anti-BCMA02 CAR lentiviral vector (LVV) and which therefore express the anti-BCMA02 CAR on the T-cell surface. After transduction, the cells are expanded and harvested. Ide-cel is composed of a highly pure T-cell population, which includes helper (CD4+) and cytotoxic (CD8+) T-cell subsets that can be further defined by central and effector memory composition. Antigen-specificity is conferred by the BCMA targeting CAR, as demonstrated by antigen-specific T-cell activation, cytokine secretion, T-cell proliferation, and cytolytic activity.

Inpatient Administration of Idecabtagene vicleucel (ide-cel)
Ide-cel is given as a single intravenous infusion administered through the central or peripheral vein primarily in the hospital inpatient setting as a standalone procedure. Once infused into the patient, CAR T-cells expressing the anti-BCMA02 CAR construct are able to recognize MM cells and mount an immune response against them leading to cell death. Thus, ide-cel acts to boost the natural immune response to tumor cells, allowing for prolonged anti-myeloma activity following a single treatment. The target dose is 450 x 10^6 CAR+ T-cells, and ide-cel can be given within a dose range of 150 to 540 x 10^6 CAR+ T-cells. Because of the risk of cytokine release syndrome (CRS) and neurological toxicities, ide-cel is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) at a REMS-certified healthcare facility.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of idecabtagene vicleucel (ide-cel). Facilities can report the intravenous administration of idecabtagene vicleucel (ide-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 idecabtagene vicleucel (ide-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 idecabtagene vicleucel (ide-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 K** Idecabtagene Vicleucel Immunotherapy	**ADD 7** New Technology Group 7

Option 3. Create new codes in section X New Technology, table XW0 Introduction, to identify intravenous administration of idecabtagene vicleucel (ide-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 K** Idecabtagene Vicleucel Immunotherapy	**ADD 7** New Technology Group 7

CMS Recommendation: CMS is seeking input from the audience.

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

Administration of Narsoplimab

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

New Technology Application? Yes. The requester intends to submit a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? No. At the time of this request, Omeros is in the process of completing a rolling submission to FDA of its Biologics License Application (BLA) for Narsoplimab in the treatment of Hematopoietic Stem Cell Transplantation - associated Thrombotic Microangiopathy (HSCT-TMA). Additionally, Narsoplimab has been granted breakthrough therapy designation from FDA and is expected to lead to priority review of the BLA.

Background: HSCT-TMA is a serious multisystem and life-threatening complication of hematopoietic stem cell transplantation (HSCT) presenting with signs of microangiopathic hemolytic anemia, consumptive thrombocytopenia in the absence of coagulopathy, and microvascular thrombosis with end-organ damage that is associated with highly unfavorable post-HSCT survival.

The HSCT procedure, and associated adoptive cell therapy, involve multiple factors that can damage endothelial cells. These factors include chemoradiotherapy, cytokine release, immunosuppressive therapies, bacterial endotoxins, engraftment syndrome and allogenic reactions with donor-derived immune cells. HSCT-TMA is initiated when various factors associated with HSCT lead to endothelial damage. Injured endothelial cells present Damage-Associated Molecular Patterns (DAMPs) that activate the lectin pathway of complement on the endothelial cell surface. Mannan Binding Lectin Serine Peptidase 2 (MASP-2) is the effector enzyme of the lectin pathway of complement that initiates a proteolytic cascade leading to a membrane attack complex that disrupts cell membrane integrity. These complement-mediated activities may further amplify endothelial injury and dysfunction leading to worsening clinical conditions. Injured endothelium releases procoagulant microparticles, causing platelet aggregation and microthrombi formation (i.e., TMA). The increasing endothelial damage leads to further microthrombi formation, mechanical damage to red blood cells and lumen-obstruction, leading to HSCT-TMA-related organ damage and organ failure.

Currently HSCT-TMA has no approved treatment. When a patient is diagnosed with HSCT-TMA, clinicians may reduce or discontinue anti-GVHD (graft-vs-host disease) therapies, initiate therapeutic plasma exchange, and/or administer anti-CD20 antibody therapies, terminal complement inhibitors and/or oligonucleotide therapies.

Mechanism of Action
Narsoplimab is a fully human monoclonal antibody with a unique mechanism of action targeting MASP- 2, the effector enzyme of the lectin pathway of the complement system. Importantly, inhibition of MASP-2 does not interfere with the antibody-dependent classical complement activation pathway, which is a critical component of the acquired immune response to infection. By inhibiting MASP-2 and the lectin pathway, narsoplimab prevents complement-mediated inflammation and endothelial damage while leaving intact the respective functions of the other pathways of innate immunity.

Inpatient Administration of Narsoplimab
The proposed dosing for Narsoplimab in HSCT-TMA is 4mg/kg administered by a health care professional via intravenous infusion over 30 minutes.

Current Coding: Facilities can report the intravenous administration of narsoplimab with one of the following ICD-10-PCS codes:

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

Coding Options

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

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

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	**5** Narsoplimab Monoclonal Antibody	**7** New Technology Group 7

CMS Recommendation: Option 2.

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

Embolic Protection

Issue: Should new ICD-10-PCS codes be created in section 5, Extracorporeal or Systemic Assistance and Performance, to describe temporary intraoperative embolic protection?

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Not applicable.

Background: Several embolic protection devices are available to capture and remove debris that may dislodge during an interventional procedure with the intent to reduce the incidence of adverse events. Effective October 1, 2017, ICD-10-PCS procedure code X2A5312 Cerebral embolic filtration, dual filter in innominate artery and left common carotid artery, percutaneous approach, new technology group 2, was created to describe cerebral embolic protection using the SENTINEL™ Cerebral Protection System. Effective October 1, 2019, ICD-10-PCS procedure code X2A6325 Cerebral embolic filtration, single deflection filter in aortic arch, percutaneous approach, new technology group 5, was created to describe cerebral embolic protection using the TriGUARD 3™ Cerebral Embolic Protection Device.

Current Coding: As noted above, ICD-10-PCS procedure codes X2A5312 and X2A6325 currently exist to describe cerebral embolic protection. There are no ICD-10-PCS codes in section 5, Extracorporeal or Systemic Assistance and Performance, to describe temporary intraoperative embolic protection during peripheral vascular system procedures or for procedures that utilize cerebral embolic protection systems other than those identified in the two section X codes above. In these other cases, only the circulatory procedure performed is reported.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for temporary intraoperative embolic protection. Continue coding as listed in current coding.

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

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

CMS Recommendation: CMS is seeking input from the audience.

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

Single-Use Duodenoscope During Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures

Issue: There is currently no unique ICD-10-PCS code to describe single-use duodenoscope during endoscopic retrograde cholangiopancreatography (ERCP) procedures.

New Technology Application? Yes. The requester intends to submit a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food and Drug Administration (FDA) Approval? Yes. The FDA granted Breakthrough Device Designation for the EXALT Model D Single-Use Duodenoscope on November 19, 2019 and granted 510(k) clearance on December 13, 2019.

Background: Approximately 700,000 ERCP procedures are performed annually in the U.S. to diagnose and treat many disease states in the pancreaticobiliary system in patients of all ages. Most commonly, ERCP is used to remove gallstones from the bile duct, dilate strictures in the bile or pancreatic ducts, or to relieve an obstruction in these ducts related to cancer.

ERCP procedures are performed using a duodenoscope and are used to diagnose and/or treat many disease states including but not limited to the following:

- Biliary tract cancer
- Pancreatic cancer
- Intraductal papillary mucinous neoplasms of the pancreas
- Choledocholithiasis
- Primary sclerosing cholangitis
- Pancreatitis
- Pancreatic strictures/masses
- Pancreatic stones/debris
- Pancreatic leaks or fistulas
- Biliary strictures/masses

Prior to the FDA's 510(k) clearance of the EXALT Model D Single-Use Duodenoscope, ERCP procedures were only performed with reusable duodenoscopes. Given their reusability, these instruments must be reprocessed with a high-level disinfection in order to prevent the spread of nosocomial infections. These devices have complex designs with hard to clean components and failure to correctly reprocess a duodenoscope could result in patient-to-patient disease transmission.

Technology: EXALT Model D is a single-use duodenoscope. It is differentiated from current reusable duodenoscopes as it is single-use, eliminating the need for reprocessing and therefore eliminating the risk of patient-to-patient transmitted disease due to ineffective reprocessing. It

serves as a platform to deliver diagnostic and therapeutic devices into the pancreaticobiliary system via its working channel. As the duodenoscope is intended for use for a single patient, it is disposed of after the ERCP procedure is completed.

Current Coding: Do not separately report use of a single-use duodenoscope in endoscopic pancreaticobiliary procedures. Report the applicable ICD-10-PCS pancreaticobiliary system code(s) using the approach value 8 Via Natural or Artificial Opening Endoscopic. Facilities may choose to report the radiologic portion of the ERCP procedure with a code from Imaging section table BF1, Fluoroscopy of Hepatobiliary System and Pancreas.

Coding Options:

Option 1. Do not create new codes to identify use of a single-use duodenoscope in endoscopic pancreaticobiliary system procedures.

Option 2. Create new codes in section X, New Technology, to identify use of a single-use duodenoscope in endoscopic pancreaticobiliary system procedures. Separately assign the applicable ICD-10-PCS pancreaticobiliary system code(s) using the approach value 8 Via Natural or Artificial Opening Endoscopic, as listed in current coding. Facilities may choose to report the radiologic portion of the ERCP procedure with a code from Imaging section table BF1, Fluoroscopy of Hepatobiliary System and Pancreas.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD B Hepatobiliary Duct **ADD D** Pancreatic Duct	**8** Via Natural or Artificial Opening Endoscopic	**ADD A** Single-use Duodenoscope	**ADD 7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

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

Spinal Stabilization

Issue: There is not a unique ICD-10-PCS code to describe the insertion of a radiolucent Carbon/PEEK spinal stabilization device for the treatment of early or advanced stage spinal tumors.

New Technology Application? Yes. The requester intends to submit a New Technology Add-on Payment (NTAP) application for FY 2022 consideration.

Food & Drug Administration (FDA) Approval? Yes. On May 22, 2020, FDA 510(k) clearance was issued for an expanded indication for the VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0.

Background: Surgical treatment of spinal tumors regularly includes spinal instrumentation to restore spinal stability due to segmental defects or the loss of posterior elements resulting from the presence of early or late stage spinal tumors or prior tumor resection. Posterior procedures to restore the integrity of the spine utilize pedicle screw systems which historically have been manufactured from titanium or titanium alloy. These metal implants generate image artifacts across all common imaging modalities such as x-ray, computer tomography (CT), and magnetic resonance imaging (MRI) that can hamper radiation treatment planning, execution, and follow-up imaging in different ways:

- **Radiation therapy planning:** Planning of the therapy and radiation doses to be applied to the spatially defined areas of and around the tumor is difficult due to the blurring and distortion of CT- and MRI images around the metal implants. These artifacts may impede the ability to define the appropriate areas to be radiated and the ones to be saved (e.g. spinal cord and other organs at risk).
- **Radiation treatment:** Metal implants cause absorption as well as scatter of radiation applied to nearby biologic structures. This may result in underdosing the tumor mass and decreased local control, potentially leading to tumor recurrences; or, can result in the scatter of radiation increasing the damage to the organs at risk which may result in morbidity.
- **Patient follow up:** Follow-up imaging is critical in primary spinal tumors and for spinal metastases due to improved tumor therapies which have been proven to increase survival times. Radiation free imaging (MRI) is the imaging modality of choice. In MRI, metal implants cause blurring and distortion, reducing the possibility of detecting tumor recurrences dramatically. Small recurrences may be blurred, whereas they show up later when they have increased in size. The late detection of recurrences often leads to additional surgeries to remove the tumors.

The quality of life for patients with spinal column neoplasms has improved significantly over recent years due to the development of next generation spinal instrumentation supporting advanced surgical techniques and improvements in radiation protocols. The requester states that radiolucent carbon fiber-reinforced polyetheretherketone (Carbon/PEEK) screws have been shown to decrease artifacts in post-surgical imaging allowing improved assessment of anatomical structures such as tumor mass, dural sac with epidural tissues, and bony structures around the construct. The requester also notes that decreased artifacts help to improve isodose calculation in post-surgical radiation therapy, allowing focused therapy planning and surveillance.

Technology/Device Description: VADER®one and Lightmore® are radiolucent Carbon/PEEK pedicle screw systems intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy, prior to oncological treatment, is of insufficient duration to permit achievement of fusion. The VADER®one and Lightmore® pedicle systems are manufactured from Carbon/PEEK using a proprietary manufacturing process and comprised of polyaxial pedicle screws and curved, straight and J-rods. They are not similar to standard titanium or titanium alloy pedicle screw systems used for the treatment of degenerative diseases and spinal deformities. These Carbon/PEEK pedicle screw systems differ in that they are made of high-strength BlackArmor® Carbon/PEEK material through a combination of continuous high-strength carbon fiber reinforced PEEK and a proprietary Composite Flow Molding (CFM) manufacturing process. This process results in an interwoven 3D fiber architecture that provides implant strength and endurance, but most importantly creates a radiolucent device.

The carbon fiber-reinforced polyetheretherketone (Carbon/PEEK) that is used to produce the rod and screw shaft is a thermoplastic composite biomaterial exhibiting properties suitable for load-bearing orthopedic implants. According to the requester, the Carbon/PEEK material does not cause artifacts or shadows on adjacent tissues with imaging modalities such as x-ray, CT, and MRI. The screw tip has a small tantalum or titanium marker for visualization during implantation. To enhance bone integration, pedicle screws are spray coated with titanium at the area of the pedicle. The requester reports that while this coating facilitates osteointegration, it does not deter from the radiolucency.

Procedure Description: The VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 are inserted at one or more levels of the thoracic or lumbar spine, via a percutaneous or open approach for spine stabilization with or without the intention to fuse the posterior column in patients with early or advanced stage spinal tumors to restore the integrity of the spinal column. Both are indicated for single or multiple level fixations in the non-cervical spine. If the surgeon's intention is to fuse the segment, the concomitant use of grafting material is at the discretion of the implanting surgeon and is influenced by patient-specific factors. According to the requester, it is critical to note that the intention of the surgeon may be to promote bony fusion, however, understanding that as a consequence of the exposure to high dose radiation or chemotherapy, it might take longer in these patients to achieve bony fusion compared to other patient groups.

Current Coding: Code the procedure to place a radiolucent Carbon/PEEK spinal stabilization device from tables 0RH and 0SH, Insertion of Upper and Lower Joints. Separately assign the applicable ICD-10-PCS code from table 0RG or 0SG if spinal fusion also performed.

Section	**0** Medical and Surgical
Body System	**R** Upper Joints
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*
6 Thoracic Vertebral Joint **A** Thoracolumbar Vertebral Joint	**0** Open **3** Percutaneous	**C** Spinal Stabilization Device, Pedicle Based	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**S** Lower Joints
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 Lumbar Vertebral Joint **3** Lumbosacral Joint	**0** Open **3** Percutaneous	**C** Spinal Stabilization Device, Pedicle Based	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the use of a radiolucent Carbon/PEEK spinal stabilization device. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the use of a radiolucent carbon/PEEK spinal stabilization device. Separately assign the applicable ICD-10-PCS code(s) from table 0RG or 0SG if spinal fusion also performed.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 6 Thoracic Vertebral Joint **ADD 7** Thoracic Vertebral Joints, 2 to 7 **ADD 8** Thoracic Vertebral Joints, 8 or more **ADD A** Thoracolumbar Vertebral Joint **ADD B** Lumbar Vertebral Joint **ADD C** Lumbar Vertebral Joints, 2 or more **ADD D** Lumbosacral Joint	**0** Open **3** Percutaneous	**ADD R** Spinal Stabilization Device, Pedicle Based, Radiolucent Carbon/PEEK	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

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

Section X Update
September 2020 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 in 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.

For the September 2020 ICD-10 C&M meeting we will review the updated analysis results in more detail and encourage participants to consider the options listed above while reviewing the data for discussion. We are proposing changes at this time.

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

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

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	Add	alfapump(R) system use Other Device
Main	Add	Associating liver partition and portal vein ligation (ALPPS)
	Add	See Division, Liver 0F8
	Add	See Resection, Liver 0FT
Lttr		D
Main	Add	Dorsal root ganglion
	Add	use Spinal Cord
	Add	use Cervical Spinal Cord
	Add	use Thoracic Spinal Cord
	Add	use Lumbar Spinal Cord
Lttr		F
Main	Add	Fibular sesamoid
	Add	use Metatarsal, Right
	Add	use Metatarsal, Left
Lttr		G
Main	Add	Gammaglobulin
	Add	use Globulin
Lttr		H
Main	Add	Hyperimmune globulin
	Add	use Globulin
Lttr		I
Main	Add	Immunoglobulin
	Add	use Globulin
Lttr		P
Main	Add	Parapharyngeal space use Neck
Main	Add	Polyclonal hyperimmune globulin
	Add	use Globulin
Lttr		R
Main	Add	Retropharyngeal space use Neck
Lttr		S
Main	Add	Staged hepatectomy
	Add	See Division, Liver 0F8
	Add	See Resection, Liver 0FT
Lttr		T
Main	Add	Tecartus(tm) use Brexucabtagene Autoleucel Immunotherapy
Main	Add	Tibial sesamoid
	Add	use Metatarsal, Right
	Add	use Metatarsal, Left

Lttr		Y
Main	Add	Yescarta(tm) use Axicabtagene Ciloleucel Immunotherapy

ICD-10-PCS Body Part Key Addenda

Section 0		Medical and Surgical
Axis 4		Body Part
Row	Add	
Term	Add	Cervical Spinal Cord
Includes	Add	Dorsal root ganglion
Row		
Term		Lumbar Spinal Cord
Includes	Add	Dorsal root ganglion
Row	Add	
Term	Add	Metatarsal, Left
Term	Add	Metatarsal, Right
Includes	Add	Fibular sesamoid
Includes	Add	Tibial sesamoid
Row	Add	
Term	Add	Neck
Includes	Add	Parapharyngeal space
Includes	Add	Retropharyngeal space
Row	Add	
Term	Add	Spinal Cord
Includes	Add	Dorsal root ganglion
Row	Add	
Term	Add	Thoracic Spinal Cord
Includes	Add	Dorsal root ganglion

ICD-10-PCS Device Key Addenda

Axis 6		Device
Row	Add	
Term	Add	Other Device
Includes	Add	alfapump(R) system

ICD-10-PCS Substance Key Addenda

Section 3		Administration
Axis 6		Substance
Row		
Term		Globulin
Includes	Add	Gammaglobulin
Includes	Add	Hyperimmune globulin
Includes	Add	Immunoglobulin

Includes	Add	Polyclonal hyperimmune globulin

Section X	New Technology	
Axis 6		Device / Substance / Technology
Row		
Term		Axicabtagene Ciloleucel Immunotherapy
Includes	Add	Yescarta(tm)
Row		
Term		Brexucabtagene Autoleucel Immunotherapy
Includes	Add	Tecartus(tm)

ICD-10-PCS Table Addenda

Medical and Surgical Section
Axis 4 Body Part

Restriction of Left Ventricle

Source	Description	Code specification
2020, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 02V, Restriction of Heart and Great Vessels, add body part value L Ventricle, Left, applied to the device values C Extraluminal Device, D Intraluminal Device and Z No Device and all available approaches, to identify procedures such as the placement of the Ancora Accucinch® device which treats heart failure and functional mitral regurgitation by targeting left ventricular (LV) dysfunction and dilation.	Add: 02VL[034][CDZ]Z (9 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
ADD L Ventricle, Left **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**Z** No Qualifier

Extraction of Bone Marrow, Other Sites

Source	Description	Code specification
2020, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 07D, Extraction of Lymphatic and Hemic Systems, add body part value T Bone Marrow, to identify when bone marrow is extracted from other sites, such as the femur.	Add: 07DT[03]Z[XZ] (4 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**7** Lymphatic and Hemic Systems
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*
Q Bone Marrow, Sternum **R** Bone Marrow, Iliac **S** Bone Marrow, Vertebral **ADD T** Bone Marrow	**0** Open **3** Percutaneous	**Z** No Device	**X** Diagnostic **Z** No Qualifier

Division of Liver for Staged Hepatectomy

Source	Description	Code specification
2020, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0F8, Division of Hepatobiliary System and Pancreas, add body part values 0 Liver, 1 Liver, Right Lobe, and 2 Liver, Left Lobe, to identify the partitioning of the liver, or ALPPS procedure, performed as the first step of a staged hepatectomy.	Add: 0F8[012][034]ZZ (9 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**F** Hepatobiliary System and Pancreas
Operation	**8** Division: Cutting into a body part, without draining fluids and/or gases from the body part, in order to separate or transect a body part

Body Part	*Approach*	*Device*	*Qualifier*
ADD 0 Liver **ADD 1** Liver, Right Lobe **ADD 2** Liver, Left Lobe **G** Pancreas	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**Z** No Qualifier

Medical and Surgical Section
Axis 5 Approach

Percutaneous Bypass of Brachial Artery for AV Fistula Creation

Source	Description	Code specification
2020, public comment & CMS internal review	In the Medical and Surgical section table 031, Bypass of Upper Arteries, add approach value 3 Percutaneous, applied to the body part values 7 Brachial Artery, Right and 8 Brachial Artery, Left and applied to the qualifier value F Lower Arm Vein, to identify procedures such as the creation of an arteriovenous (AV) fistula by connecting the brachial artery to a lower arm vein using the Ellipsys® Vascular Access System.	Add: 031[78]3ZF (2 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**3** Upper Arteries
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
7 Brachial Artery, Right	**0** Open	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**0** Upper Arm Artery, Right **3** Lower Arm Artery, Right **D** Upper Arm Vein **F** Lower Arm Vein **V** Superior Vena Cava **W** Lower Extremity Vein
7 Brachial Artery, Right	**ADD 3** Percutaneous	**ADD Z** No Device	**ADD F** Lower Arm Vein
8 Brachial Artery, Left	**0** Open	**9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**1** Upper Arm Artery, Left **4** Lower Arm Artery, Left **D** Upper Arm Vein **F** Lower Arm Vein **V** Superior Vena Cava **W** Lower Extremity Vein
8 Brachial Artery, Left	**ADD 3** Percutaneous	**ADD Z** No Device	**ADD F** Lower Arm Vein

Proposed Index Addenda

Lttr E
Main Ellipsys(R) vascular access system
Add Brachial Artery, Left 03183ZF
Add Brachial Artery, Right 03173ZF

Endoscopic Banding of Hemorrhoidal Plexus

Source	Description	Code specification
2019, public comment & CMS internal review	In the Medical and Surgical section table, 06L Occlusion of Lower Veins, add approach values 7 Via Natural or Artificial Opening and 8 Via Natural or Artificial Opening Endoscopic applied to the body part value Y Lower Vein, to identify procedures such as endoscopic banding of the hemorrhoidal plexus.	Add: 06LY[78][CDZ][CZ] (12 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
Y Lower Vein	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **ADD 7** Via Natural or Artificial Opening **ADD 8** Via Natural or Artificial Opening Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**C** Hemorrhoidal Plexus **Z** No Qualifier

Endoscopic Division of Pharynx Muscle

Source	Description	Code specification
2019, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0K8, Division of Muscles, add approach values 7 Via Natural or Artificial Opening and 8 Via Natural or Artificial Opening Endoscopic, applied to the body part value 4 Tongue, Palate, Pharynx Muscle, to identify procedures such as the stapling of Zenker's diverticulum performed via a transorifice or transorifice endoscopic approach.	Add: 0K84[78]ZZ (2 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**K** Muscles
Operation	**8** Division: Cutting into a body part, without draining fluids and/or gases from the body part, in order to separate or transect a body part

Body Part	*Approach*	*Device*	*Qualifier*
4 Tongue, Palate, Pharynx Muscle	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **ADD 7** Via Natural or Artificial Opening **ADD 8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**Z** No Qualifier

Medical and Surgical Section
Axis 6 Device

Insertion of Infusion Device in Skull

Source	Description	Code specification
2019, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0NH, Insertion of Head and Facial Bones, add device value 3 Infusion Device, applied to the body part value 0 Skull, to identify procedures such as the implantation of an Ommaya reservoir for the intracranial administration of chemotherapy.	Add: 0NH0[034]3Z (3 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Skull	**0** Open	**ADD 3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **M** Bone Growth Stimulator **N** Neurostimulator Generator	**Z** No Qualifier
0 Skull	**3** Percutaneous **4** Percutaneous Endoscopic	**ADD 3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **M** Bone Growth Stimulator	**Z** No Qualifier

Medical and Surgical Section
Axis 7 Qualifier

Sesamoidectomy of Great Toe

Source	Description	Code specification
2020, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0QB, Excision of Lower Bones, add qualifier value 2 Sesamoid Bone(s) 1st Toe, applied to the body part values N Metatarsal, Right and P Metatarsal, Left, to identify procedures such as the excision of the fibular or tibial sesamoid bone.	Add: 0QB[NP][034]Z2 (6 codes)

EXAMPLE

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

Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebra **1** Sacrum **2** Pelvic Bone, Right **3** Pelvic Bone, Left **4** Acetabulum, Right **5** Acetabulum, Left **6** Upper Femur, Right **7** Upper Femur, Left **8** Femoral Shaft, Right **9** Femoral Shaft, Left **B** Lower Femur, Right **C** Lower Femur, Left **D** Patella, Right **F** Patella, Left **G** Tibia, Right **H** Tibia, Left **J** Fibula, Right **K** Fibula, Left **L** Tarsal, Right **M** Tarsal, Left **Q** Toe Phalanx, Right **R** Toe Phalanx, Left **S** Coccyx	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**X** Diagnostic **Z** No Qualifier
N Metatarsal, Right **P** Metatarsal, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**ADD 2** Sesamoid Bone(s) 1st Toe **X** Diagnostic **Z** No Qualifier

Shoulder Hemiarthroplasty

Source	Description	Code specification
public comment & CMS internal review	In the Medical and Surgical section tables 0RP, Removal of Upper Joints and 0RW Revision of Upper Joints, add qualifier values 6 Humeral Surface and 7 Glenoid Surface, applied to the body part values J Shoulder Joint, Right and K Shoulder Joint, Left, to identify the revision or removal of the components of partial shoulder arthroplasties.	Add: 0RP[JK][034]J[67] (12 codes) Add: 0RW[JK][034X]J[67] (16 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**R** Upper Joints
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device*	*Qualifier*
J Shoulder Joint, Right **K** Shoulder Joint, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**J** Synthetic Substitute	**ADD 6** Humeral Surface **ADD 7** Glenoid Surface

Section	**0** Medical and Surgical
Body System	**R** Upper Joints
Operation	**W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	*Approach*	*Device*	*Qualifier*
J Shoulder Joint, Right **K** Shoulder Joint, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**J** Synthetic Substitute	**ADD 6** Humeral Surface **ADD 7** Glenoid Surface

Section 5 - Extracorporeal or Systemic Assistance and Performance Section
Axis 7 Qualifier

Automated Chest Compression

Source	Description	Code specification
2020, CMS internal review	In the Extracorporeal or Systemic Assistance and Performance table 5A1, add new qualifier value J Automated, applied to the body system value 2 Cardiac, duration value 2 Continuous, and function value 1 Output to identify the usage of devices such as the Lucas device & Defibtech for mechanical chest compressions.	Add: 5A1221J (1 code)

EXAMPLE

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*
2 Cardiac	**2** Continuous	**1** Output	**Z** No Qualifier **ADD J** Automated
2 Cardiac	**2** Continuous	**3** Pacing	**Z** No Qualifier

Section B - Imaging
Axis 4 Body Part
Fluoroscopic Guidance of Hepatobiliary Sites

Source	**Description**	**Code specification**
2020, public comment & CMS internal review	In the Imaging section table BF1, Fluoroscopy of Hepatobiliary System and Pancreas, add qualifier A Guidance, applied to the new body part value 5 Liver to identify when fluoroscopic guidance is used with procedures such as the drainage of liver abscesses.	Add: BF15[01Y]ZZ (3 codes) BF15ZZA (1 code)

EXAMPLE

Section	**B** Imaging
Body System	**F** Hepatobiliary System and Pancreas
Operation	**1** Fluoroscopy: Single plane or bi-plane real time display of an image developed from the capture of an external ionizing radiation on a fluorescent screen.

Body Part	*Contrast*	*Qualifier*	*Qualifier*
0 Bile Ducts **1** Biliary and Pancreatic Ducts **2** Gallbladder **3** Gallbladder and Bile Ducts **4** Gallbladder, Bile Ducts and Pancreatic Ducts **ADD 5 Liver** **8** Pancreatic Ducts	**0** High Osmolar **1** Low Osmolar **Y** Other Contrast	**Z None**	**Z** No Qualifier
ADD 5 Liver	**ADD Z** None	**Z None**	**ADD A Guidance**

Posterior Dynamic Distraction

Issue: Currently, there is not a unique ICD-10-PCS code to identify the utilization of a posterior dynamic distraction device for treating spinal deformities such as adolescent idiopathic scoliosis.

New Technology Application? Yes. The requester intends to submit a New Technology Add-on Payment (NTAP) application for FY 2022 consideration. The requester is seeking implementation of the ICD-10-PCS code on April 1, 2021.

Food & Drug Administration (FDA) Approval? Yes. ApiFix Ltd.'s Minimally Invasive Deformity Correction (MID-C) System received FDA approval under a humanitarian device exemption (HDE) on August 23, 2019.

Background: Adolescent idiopathic scoliosis (AIS) is a disorder of unknown etiology in which the spine gradually develops a curvature that is first typically detected in patients between 10 and 17 years of age. The deformity is 3-dimensional, with a coronal curve measured from radiographs using the Cobb method. The Cobb angle measurement is well standardized and represents the severity of a scoliotic curve. Although a slight curve is well tolerated and does not require treatment, a larger curve can interfere with chest wall mechanics resulting in pulmonary dysfunction, present risk of progression if left untreated leading to sequalae of back pain and disability in the adult, and may have associated body image psychosocial impact on the individual.

The risk of curve progression in AIS is correlated with the magnitude of the Cobb angle. Although bracing has the potential for adequate stabilization to prevent the need for surgery in some cases, it is generally limited to less severe cases. Adolescents in whom the Cobb angle has progressed beyond 45° are typically treated surgically with spine arthrodesis (fusion) to both surgically correct the deformity and to prevent further curve progression. The ultimate goal of spinal fusion in the adolescent is usually not to address pain or symptoms, which are generally absent or minor, but to prevent potential problems related to further curve progression in later life. Operative intervention with spine fusion, which fuses nine spinal vertebrae on average, typically significantly corrects the scoliotic curve. However, the procedure also results in a long scar, requires significant interruption in school and other daily activities, and leaves young patients with impaired spinal flexibility and a large amount of permanent metallic implants.

Technology
The ApiFix Minimally Invasive Deformity Correction (MID-C) System is a posterior dynamic deformity correction system that, according to the requester, enables surgeons to provide permanent curve correction while retaining spine flexibility with a less invasive approach. The ApiFix MID-C System device is a ratchet-based expandable rod, designed to be anchored to pedicle screws located on the concave side of a scoliotic deformity. The system acts as an "internal brace" with motion-preserving polyaxial joints and its patented unidirectional, self-adjusting rod mechanism allows additional post-operative correction over time and is ultimately removable. It is made of medical-grade titanium alloy (Ti-6Al4V ELI) components. All moving parts are coated with an amorphous diamond-like coating (ADLC), resulting in a ceramic-on-ceramic motion couple, which has been shown in in-vitro testing to result in very low levels of wear debris generation. Deformity correction is achieved intraoperatively by distraction leading to rod elongation. Further curve correction can be achieved after the surgical procedure by performing scoliosis specific exercises or with normal daily activities. These exercises activate the ratchet with further rod expansion and curve reduction. The self-adjusting rod mechanism also accommodates future growth without the

need for additional surgical intervention.

Indications for Use
The MID-C System is indicated for use in patients with adolescent idiopathic scoliosis (AIS) for treatment of single curves classified as Lenke 1 (thoracic major curve) or Lenke 5 (thoracolumbar/lumbar major curve), having a Cobb angle of 35 to 60 degrees which reduces to less than or equal to 30 degrees on lateral side-bending radiographs, and thoracic kyphosis less than 55 degrees as measured from T5 to T12. Use of the MID-C System in patients with curves of lower magnitudes (i.e., less than 40 degrees) is based on the risk for curve progression.

Procedure Description
The device is implanted at the concave side, around the apex of a flexible single major curve in adolescent idiopathic scoliosis (AIS) patients and acts as an internal brace to correct and stabilize scoliotic deformity. The implant connects to the pedicle screws via integrated polyaxial joints and allows near normal spinal range of motion. In addition, the polyaxial joints prevent any moment from being transferred to the screw-rod or the screw-bone interface. A ratchet and pawl mechanism permits one-way expansion, so that the length of the device remains constant under compressive loads. The system comes in several sizes of 85-125mm in length, which expand in increments of 1.3mm for a total extension of 30-50 mm, depending on the initial size chosen.

The primary purpose of the MID-C System is to avoid spinal fusion by stabilizing the spine, resulting in maintenance or improvement of the pre-operative curve, in order to achieve a lower risk of curve progression. According to the requester, because the MID-C System is permanently attached to the spine, it provides better correction and greater stability than an external brace, whose effectiveness depends on indirect pressure (ribs vs. the spine itself) and the number of hours per day it is being worn, and subject to often poor patient compliance, as well as other patient specific factors. The MID-C System has been used outside the U.S. to treat more than 400 young patients diagnosed with progressive scoliosis with follow-up now exceeding eight years.

Current Coding: Code the use of a posterior dynamic distraction device with the applicable ICD-10-PCS code(s) from tables 0PS and 0QS, Reposition of Upper and Lower Bones, using the device value 4 Internal Fixation Device.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify the utilization of a posterior dynamic distraction device. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the utilization of a posterior dynamic distraction device. Separately assign the applicable ICD-10-PCS code(s) from table 0RG or 0SG for any spinal fusion performed at the non-instrumented segment of the vertebrae.

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

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Lumbar Vertebra **4** Thoracic Vertebra	**0** Open **3** Percutaneous	**C** Posterior (Dynamic) Distraction Device	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

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