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

CENTER FOR MEDICARE

# Agenda

ICD-10 Coordination and Maintenance Committee Meeting
Department of Health and Human Services
Centers for Medicare & Medicaid Services
CMS Auditorium
7500 Security Boulevard
Baltimore, MD 21244-1850
ICD-10-PCS Topics
March 17, 2020

**WebEx Instructions for Remote Meeting Participation**

Remote participants (attendees wishing to both view slides and ask questions during the Q&A portions of the meeting) must join the meeting by WebEx*.

- Day 1: March 17, 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 1:15 PM.

1. Event address for attendees: https://letsmeet.webex.com/letsmeet/onstage/g.php?MTID=e20f2a065e507d5e156f34aa9076e32e8
2. Event password: This event does not require a password for attendees.

   If you have any questions regarding the presentations, please use the raise hand feature during the Q&A session after each presentation and your line will be unmuted. Once your question has been addressed, please lower the raised hand.

- Day 2: March 18, 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 1:15 PM.

1. Event address for attendees: https://letsmeet.webex.com/letsmeet/onstage/g.php?MTID=e0e9e3e18a86ed9277fac903a52d8880a
   Event password: This event does not require a password for attendees.

   If you have any questions regarding the presentations, please use the raise hand feature during the Q&A session after each presentation and your line will be unmuted. Once your question has been addressed, please lower the raised hand.

*Detailed instructions for joining the WebEx meeting 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 March 18, 2020 and will be led by the Centers for Disease Control (CDC). Please visit CDCs website for the Diagnosis agenda located at the following address: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm.

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 "Chat" feature. All comments and questions submitted using the "Chat " feature, along with and CMS' responses to them, will be posted on the CMS website as soon as possible after the meeting. Remaining questions may be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov.

**ICD-10-PCS Topics:**

| | |
|---|---|
| 1. Intramedullary Joint Fusion System<br>Pages 13-16 | Mady Hue<br>J. Kent Ellington, MD<br>OrthoCarolina |
| 2. Administration of TERLIVAZ® (terlipressin)<br>Pages 17-18 | Mady Hue<br>Khurram Jamil, MD<br>Executive Dir., Clinical Affairs<br>Mallinckrodt Pharmaceuticals |
| 3. Insertion of Subcutaneous Pump System for Ascites Drainage<br>Pages 19-23 | Paula Dupee<br>Ethan M. Weinberg, MD<br>Assistant Professor of Clinical Medicine<br>Division of Gastroenterology and Hepatology<br>Hospital of the University of Pennsylvania |
| 4. Syndromic Infectious Disease Testing for Pneumonia<br>Pages 24-26 | Paula Dupee<br>Brett Barrett<br>Market Access Manager<br>BioFire Diagnostics Market |
| 5. Administration of NUZYRA® (omadacycline)<br>Pages 27-28 | Ashley Standridge<br>Mauricio Rodriguez, PharmD, BCPS, BCCCP,BCIDP<br>Senior Director, Medical Science<br>Paratek Pharmaceuticals |
| 6. Phenotypic Antimicrobial Susceptibility Testing<br>Pages 29-30 | Paula Dupee<br>Natalie Brown, MBA<br>Tactical Marketing Manager<br>Accelerate Diagnostics |
| 7. Administration of XENLETA® (lefamulin)<br>Pages 31-32 | Noel Manlove<br>Matthew Helgeson, PharmD, BCPS<br>Director, Medical Affairs<br>Nabriva Therapeutics |
| 8. Endoscopic Gastrointestinal Hemostat<br>Pages 33-35 | Paula Dupee<br>Seth A. Gross, MD, FACG, FASGE<br>Associate Professor of Medicine |

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| | Chief of Gastroenterology<br>Tisch Hospital, NYU Langone Health |
| 9. Administration of ZERBAXA® (ceftolozane and tazobactam)<br>Pages 36-39 | Michelle Joshua<br>Andrew Parker,<br>Associate Director<br>Merck & Co., Inc.<br>US Policy & Government Relations |
| 10. Administration of KTE-X19<br>Pages 40-41 | Andrea Hazeley<br>Rebecca J. Chan, MD-PhD<br>Associate Director, Oncology & Cell Therapy Medical Affairs<br>Kite Pharma, a Gilead Company |
| 11. Administration of IMFINZI® (durvalumab)<br>Pages 42-43 | Andrea Hazeley<br>Marnie Boron, PharmD<br>AstraZeneca Medical Affairs |
| 12. Bacterial Autofluorescence Detection<br>Pages 44-45 | Andrea Hazeley<br>Thomas Serena, MD<br>CEO and Medical Director, Serena Group Inc.<br>President, Association for the Advancement of Wound Care (AAWC)<br><br>Leah Amir, MS, MHA<br>Executive Director Institute for Quality Resource Management |
| 13. Computer-Aided Triage and Notification Software for Head and Neck CT Angiogram<br>Pages 46-48 | Ashley Standridge<br>Jessica Roth<br>McDernitt+Consulting on behalf of Viz.ai, Inc. |
| 14. Administration of FETROJA® (cefiderocol)<br>Pages 49-50 | Michelle Joshua<br>David Fam, PharmD<br>U.S. Medical Affairs<br>Shionogi, Inc. |
| 15. Implantable Fracture Reduction System<br>Pages 51-52 | Mady Hue<br>Wayne Olan, MD |

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| | Director of Interventional and Endovascular Neurosurgery<br>George Washington University School of Medicine & Health Sciences |
| 16. Covered Stents<br>Pages 53-55 | Mady Hue<br>Dr. Shahab Toursavadkohi<br>Assistant Professor of Surgery<br>Division of Vascular Surgery<br>University of Maryland |
| 17. Administration of lisocabtagene maraleucel<br>Pages 56-57 | Ashley Standridge<br>Mecide Gharibo, MD<br>Juno Therapeutics: Medical Affairs<br>Bristol-Myers Squibb Company |
| 18. Administration of OTL-101<br>Pages 58-60 | Paula Dupee<br>Kent Christopherson, PhD<br>Senior National Director<br>US Medical Affairs<br>Orchard Therapeutics |
| 19. Administration of Soliris® (eculizumab)<br>Pages 61-63 | Noel Manlove<br>Tamar Thompson<br>Vice President, US Government Affairs and Policy<br>Alexion Pharmaceuticals, Inc. |
| 20. Reverse Flow Embolic Neuroprotection During Transcarotid Arterial Revascularization<br>Pages 64-66 | Paula Dupee<br>Charles Matouk, MD<br>Chief, Neurovascular Surgery<br>Director, Neurovascular/ Endovascular Fellowship<br>Associate Professor of Neurosurgery<br>Yale Medicine |
| 21. Administration of TECENTRIQ® (atezolizumab)<br>Pages 67-68 | Noel Manlove<br>Stephen V Liu MD<br>Associate Professor<br>Director of Thoracic Oncology<br>Georgetown University |
| 22. Section X Updates | Mady Hue |

23. Addenda and Key Updates — Andrea Hazeley
Pages 70-80

**Registering for the meeting:**
Registration for the March 17-18, 2020 ICD-10 Coordination and Maintenance Committee meeting opened on Thursday, February 6, 2020 and closed on Friday, March 6, 2020. ***If participating via the Web-Ex or dialing in, you do NOT need to register on-line for the meeting.** For questions about the registration process, please contact Mady Hue at 410-786-4510 or marilu.hue@cms.hhs.gov or Noel Manlove at 410-786-5161 or noel.manlove@cms.hhs.gov.

**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:

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|---|---|
| March 17-18, 2020 | The March 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 Web-Ex or by dialing in. |
| March 2020 | Webcast of the March 17-18, 2020 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html |
| April 1, 2020 | There were no requests for ICD-10 codes to capture new diagnoses or new technology for implementation on April 1, 2020. Therefore, there will be no new ICD-10 procedure codes implemented on April 1, 2020. As announced on January 15, 2020, a new ICD-10-CM diagnosis code, U07.0 - Vaping-related disorder, is being implemented on April 1, 2020. Additional information is posted on the following website:<br><br>https://www.cdc.gov/nchs/icd/icd10cm.htm |
| **April 17, 2020** | **Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 17-18, 2020 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2020**. |
| April 2020 | Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This notice will include references to the finalized FY 2021 ICD-10-CM diagnosis and ICD-10-PCS procedure codes to date. It will also include proposed revisions to the MS-DRG system based on ICD-10-CM/PCS codes on which the public may comment. The proposed rule can be accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS/list.asp |
| June 2020 | Final addendum posted on web pages as follows:<br>Diagnosis addendum -<br>https://www.cdc.gov/nchs/icd/icd10cm.htm |

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| | Procedure addendum - https://www.cms.gov/Medicare/Coding/ICD10/index.html |
| **June 12, 2020** | **Deadline for requestors: Those members of the public requesting that topics be discussed at the September 2020 ICD-10 Coordination and Maintenance Committee meeting, tentatively scheduled for September 8-9, 2020, must have their requests submitted to CMS for procedures and NCHS for diagnoses.** |
| August 1, 2020 | Hospital Inpatient Prospective Payment System final rule to be published in the Federal Register as mandated by Public Law 99-509. This rule will also include links to all the final codes to be implemented on October 1, 2020.<br>This rule can be accessed at:<br>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html |
| August 2020 | Tentative agenda for the Procedure part of the September 2020 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage at –<br>https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html<br><br>Tentative agenda for the Diagnosis part of the September 8-9, 2020 ICD-10 Coordination and Maintenance Committee meeting will be posted on the NCHS webpage at -<br>https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm<br><br>Federal Register notice for the September 2020 ICD-10 Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda. |
| **August 3, 2020** | **On-line registration opens for the September 2020 ICD-10 Coordination and Maintenance Committee meeting at:**<br>https://www.cms.gov/apps/events/default.asp |
| September 4, 2020 | Because of increased security requirements, those wishing to attend the September 2020 ICD-10 Coordination and Maintenance Committee meeting must register for the meeting online at:<br>https://www.cms.gov/apps/events/default.asp<br><br>**Attendees must register online by September 4, 2020; failure to do so may result in lack of access to the meeting.** |
| September 8-9, 2020 | ICD-10 Coordination and Maintenance Committee Meeting. |

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| | Those who wish to attend the ICD-10 Coordination and Maintenance Committee meeting **must have registered for the meeting online by September 4, 2020.** You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building. |
| September 2020 | Webcast of the September 8-9, 2020 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html |
| October 1, 2020 | New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with DRG changes. Final addendum available on web pages as follows:<br><br>**Diagnosis addendum –**<br>https://www.cdc.gov/nchs/icd/icd10cm.htm<br><br>**Procedure addendum –**<br>https://www.cms.gov/Medicare/Coding/ICD10/ |
| October 9, 2020 | **Deadline for receipt of public comments on proposed new codes discussed at the September 8-9, 2020 ICD-10 Coordination and Maintenance Committee meetings for implementation on April 1, 2021.** |
| November 2020 | Any new ICD-10 codes required to capture new technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2021 will be posted on the following websites:<br><br>https://www.cdc.gov/nchs/icd/icd10cm.htm<br><br>https://www.cms.gov/Medicare/Coding/ICD10/ |
| **November 9, 2020** | **Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 8-9, 2020 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2021.** |

## Introductions and Overview

- ICD-10 Coordination & Maintenance (C&M) Committee meeting is a public forum on ICD-10-CM & ICD-10-PCS code updates
- CMS & CDC Co-chair the meetings
  - CMS has lead responsibility on procedure issues
  - CDC has lead responsibility on diagnosis issues
- Coding proposals requested by the public are presented and public given opportunity to comment

## Code Proposals

- ICD-10-PCS code proposals being considered for implementation on October 1, 2020
- No final decisions are made at the meeting
- CMS will describe options and recommendations to facilitate discussion
- Public can comment at meeting and send written comments

## Comments on Code Proposals

- Submit written comments by
  - April 17, 2020 for codes discussed at the March 17-18, 2020 C&M meeting
- 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
- August 1, 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/FY2021-IPPS-Final-Rule-Home-Page.html

## Addendum

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

**Written Comments**

- No matter how you participate – please send written comments by
  - April 17, 2020 for codes to be implemented on October 1, 2020
  - Procedure comments to CMS ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis comments to NCHS nchsicd10cm@cdc.gov

**ICD-10-PCS Codes Implementation**

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

**September 8-9, 2020 C&M Code Requests**

- June 12, 2020– Deadline for submitting topics for September 8-9, 2020 C&M meeting
  - Procedure requests to CMS ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis requests to NCHS nchsicd10cm@cdc.gov

## Intramedullary Sustained Compression Joint Fusion

**Issue:** Currently there are no unique ICD-10-PCS codes to describe fusion of the upper and lower joints using an intramedullary sustained compression internal fixation device.

**New Technology Application?** No.

**FDA Approval**: Yes. Both the original DynaNail® Fusion System (K101934, K113828, and K171376) and DynaNail Mini® Fusion System (K182677) have been granted FDA 510(k) premarket clearance as internal fixation devices.

**Background:** Joint fusion is generally performed to reduce pain, increase stability, and restore function. Current internal fixation devices used in upper and lower joint fusion procedures include screws, plates, and intramedullary nails. These devices are used to hold bone ends together while they fuse, with the surgeon generally manually compressing the bones together before using the fixation devices to "lock" the bones in place. However, according to the requester, these devices nearly universally offer only passive compression, in that they do not incorporate any mechanism to continue to exert compression if any biological or mechanical changes occur at the fusion site. These changes can include bone resorption at the bone ends, implant shifting and loosening, or joint settling, all of which can cause the ends to stop having adequate contact. This often results in fibrous tissue formation rather than bone, preventing fusion from occurring as gaps form between bones. These issues are especially prevalent in challenging patient populations (i.e. diabetics, smokers, etc.) where fusion has been reported to occur at rates as low as 50%. Additionally, these bone gaps cause the internal fixation devices to bear most mechanical loads, such as those transmitted due to weight-bearing activities like walking, rather than the bones to which they are attached. Unlike bones, devices have no capacity to repair themselves, so over time the repeated loads on the devices can cause them to form cracks and break, thus potentially increasing patient pain or harm, and the clinical literature reports that hardware failures represent a large percentage of reported complications. Nonunion and complications following fusion procedures can lead to amputation, which may compromise life-expectancy, quality of life, and create financial burden. The requester reports that intramedullary nails have been used for internal fixation during joint fusion for decades, however, also noted that current nails offer negligible ability to sustain compression post-surgery, or even during surgery following removal of device fixation frames.

**Technology and Procedure:** One method for applying compression that is sustained is using Nitinol, an alloy of Nickel and Titanium. Nitinol can be stretched and recover from large deformations which are about 10X more than traditional metals can withstand. The alloy is biologically safe and corrosion-resistant without cytotoxic, allergic, or genotoxic activity. NiTiNOL devices can exert a sustained force if they are stretched and prevented from returning to their original shape, and this force is largely constant during stretch recovery. Recently, intramedullary nails incorporating an internal Nitinol component (DynaNail® and DynaNail Mini®, MedShape, Inc.) were made available clinically for use in the foot and ankle. These sustained compression intramedullary nails (SCIMN) feature an elongated thin cylindrical Nitinol L compressive element housed within a more traditional titanium cylindrical outer nail body, and proximal and distal screw

slots like other nails. The SCIMN is fixed to bones at the ends using screws which go through the nail holes and slots.

In addition to allowing more traditional manual joint compression, during surgery the SCIMN's compressive element is stretched (DynaNail®, whereas the DynaNail Mini® comes pre-stretched) and secured in its extended length by screws through the proximal and distal nail holes and slots. The element is then released, creating a sustained compressive load across the joints for as long as the element remains elongated. This element-provided compression is retained during potential bone resorption at the joint surfaces or joint settling which may occur post-operatively during the fusion process. If this occurs, the distal screws will shift proximally within slots, along with the connected bone.

The ability of the screws to shift in slots is called dynamization, and dynamization combined with sustained compression promotes load sharing with the bone during weight bearing. Given that the SCIMN's distal screws are in slots from the time of surgery, dynamization is possible from the day of surgery, rather than needing a completely separate surgery later to dynamize screws as occurs with other nails. The presence of the sustained compression provides initial stability which would be absent in a traditional intramedullary nail dynamized during initial surgery. Immediate dynamization plus sustained compression allows for load sharing with the bone during weight bearing, even with resorption, as loads pass from one connected bone to another, while the dynamized compliant hardware only sustains a small portion of the load. Other intramedullary nails can stress shield the bone prior to dynamization, potentially leading to hardware fatigue failure prior to fusion. Additionally, loads to the bones can enhance the fusion process.

The requestor noted that simulation studies have shown that while traditional nails lose nearly all joint compression after only 1 mm of bone resorption, the SCIMN maintains compression beyond 6 mm. Additionally, while other nails take most of the loads from weight-bearing compared to loads felt by bones, the SCIMN carries only a small portion of loads compared to bone loads, which can be beneficial for fusion and preventing hardware failure according to the requester.

Clinically, the requester notes that positive results have been reported for patients treated with the SCIMN, including high-risk cases with multiple co-morbidities. Successful fusions with the SCIMN have been reported in the peer-reviewed published literature, including in challenging cases such as revision fracture in smokers, bulk bone defect cases treated using either large structural bone grafts or 3D-printed spacers, and revision cases of patients with diabetes and Charcot neuroarthropathy.

**Current Coding**: Code fusion of the upper or lower joints with an intramedullary sustained compression internal fixation device to the appropriate body part value in tables 0RG and 0SG, Fusion of Upper Joints and Fusion of Lower Joints, using the device value 4 Internal Fixation Device.

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **R** Upper Joints |
| *Operation* | **G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **L** Elbow Joint, Right<br>**M** Elbow Joint, Left | **0** Open<br>**3** Percutaneous | **4** Internal Fixation Device<br>**5** External Fixation Device | **Z** No Qualifier |

| | | | |
|---|---|---|---|
| **N** Wrist Joint, Right<br>**P** Wrist Joint, Left<br>**Q** Carpal Joint, Right<br>**R** Carpal Joint, Left<br>**S** Carpometacarpal Joint, Right<br>**T** Carpometacarpal Joint, Left<br>**U** Metacarpophalangeal Joint, Right<br>**V** Metacarpophalangeal Joint, Left<br>**W** Finger Phalangeal Joint, Right<br>**X** Finger Phalangeal Joint, Left | **4** Percutaneous Endoscopic | **7** Autologous Tissue Substitute<br>**J** Synthetic Substitute<br>**K** Nonautologous Tissue Substitute | |

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **S** Lower Joints |
| *Operation* | **G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **9** Hip Joint, Right<br>**B** Hip Joint, Left<br>**C** Knee Joint, Right<br>**D** Knee Joint, Left<br>**F** Ankle Joint, Right<br>**G** Ankle Joint, Left<br>**H** Tarsal Joint, Right<br>**J** Tarsal Joint, Left<br>**K** Tarsometatarsal Joint, Right<br>**L** Tarsometatarsal Joint, Left<br>**M** Metatarsal-Phalangeal Joint, Right<br>**N** Metatarsal-Phalangeal Joint, Left<br>**P** Toe Phalangeal Joint, Right<br>**Q** Toe Phalangeal Joint, Left | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **4** Internal Fixation Device<br>**5** External Fixation Device<br>**7** Autologous Tissue Substitute<br>**J** Synthetic Substitute<br>**K** Nonautologous Tissue Substitute | **Z** No Qualifier |

## Coding Options

**Option 1.** Do not create new ICD-10-PCS codes for fusion of the upper or lower joints with an intramedullary sustained compression internal fixation device. Continue using current codes as listed in Current Coding.

**Option 2.** In tables 0RG and 0SG, Fusion of Upper Joints and Fusion of Lower Joints create device value 3 Internal Fixation Device, Intramedullary Sustained Compression applied to the appropriate body part value.

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **R** Upper Joints |
| *Operation* | **G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **L** Elbow Joint, Right<br>**M** Elbow Joint, Left<br>**N** Wrist Joint, Right<br>**P** Wrist Joint, Left<br>**Q** Carpal Joint, Right<br>**R** Carpal Joint, Left<br>**S** Carpometacarpal Joint, Right<br>**T** Carpometacarpal Joint, Left<br>**U** Metacarpophalangeal Joint, Right<br>**V** Metacarpophalangeal Joint, Left<br>**W** Finger Phalangeal Joint, Right<br>**X** Finger Phalangeal Joint, Left | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **ADD 3** Internal Fixation Device, Intramedullary Sustained Compression<br>**4** Internal Fixation Device<br>**5** External Fixation Device<br>**7** Autologous Tissue Substitute<br>**J** Synthetic Substitute<br>**K** Nonautologous Tissue Substitute | **Z** No Qualifier |

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **S** Lower Joints |
| *Operation* | **G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **9** Hip Joint, Right<br>**B** Hip Joint, Left<br>**C** Knee Joint, Right<br>**D** Knee Joint, Left<br>**F** Ankle Joint, Right<br>**G** Ankle Joint, Left<br>**H** Tarsal Joint, Right<br>**J** Tarsal Joint, Left<br>**K** Tarsometatarsal Joint, Right<br>**L** Tarsometatarsal Joint, Left<br>**M** Metatarsal-Phalangeal Joint, Right<br>**N** Metatarsal-Phalangeal Joint, Left<br>**P** Toe Phalangeal Joint, Right<br>**Q** Toe Phalangeal Joint, Left | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **ADD 3** Internal Fixation Device, Intramedullary Sustained Compression<br>**4** Internal Fixation Device<br>**5** External Fixation Device<br>**7** Autologous Tissue Substitute<br>**J** Synthetic Substitute<br>**K** Nonautologous Tissue Substitute | **Z** No Qualifier |

**CMS Recommendation:** Option 2, as described above.

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

## Administration of TERLIVAZ® (terlipressin)

**Issue:** Currently there is no unique ICD-10-PCS code to describe the administration of TERLIVAZ® (terlipressin).

**New Technology Application?** Yes. Mallinckrodt Pharmaceuticals submitted a New Technology Add-on Payment application for TERLIVAZ® (terlipressin) for FY 2021.

**FDA Approval**: No. Terlipressin is an investigational drug for which Mallinckrodt Pharmaceuticals intends to seek FDA approval for the proposed indication of treatment of patients with Hepatorenal Syndrome Type I (HRS-1). FDA approval is anticipated by June 30, 2020.

**Background**: Hepatorenal Syndrome Type 1 (HRS-1) is a serious, life-threatening condition characterized by development of acute or subacute renal failure in patients with advanced chronic liver disease (CLD), often caused by cirrhosis of the liver. HRS-1 is estimated to affect between 30,000 and 40,000 patients in the United States annually and is the leading cause of hospitalizations among all patients with advanced CLD. Studies have shown the median survival time for patients diagnosed with HRS-1 is approximately two weeks. According to the requester, inpatient care management of patients with HRS-1 is time and resource intensive, representing a financial burden to hospitals.

Terlipressin is a potent, selective vasoconstrictor that acts as a prodrug for lysine-vasopressin and has pharmacologic activity on its own. In HRS-1 patients, the V1 receptor-mediated vasoconstrictor activity of terlipressin, particularly in the splanchnic area, results in an increase in effective arterial volume, an increase in mean arterial pressure, and normalization of endogenous vasoconstrictor systems (renin-angiotensin-aldosterone and sympathetic nervous system), resulting in increased renal blood flow.

Terlipressin is not currently approved for use in the United States; however, the requestor reports it has a long history of safe use, having been approved as the first-line treatment for HRS-1 in Europe and Asia under appropriate marketing authorizations in several countries in those regions. Where terlipressin therapy is not available (e.g., in the United States), the standard of care and initial treatment for HRS-1 patients is a combination of midodrine, octreotide, and albumin. The combination therapy of midodrine and octreotide, used off-label currently as the first-line therapy in the United States, is not considered as an option where terlipressin is available. Norepinephrine, also used off-label to treat HRS-1 patients, requires installation of a dedicated central line and the level of medical support available in the intensive care unit setting.

The requestor noted results of the CONFIRM clinical trial demonstrated a higher number of HRS-1 patients achieved the primary endpoint of verified hepatorenal syndrome (HSR) reversal when terlipressin was administered in combination with albumin versus treatment with albumin alone, Verified HRS reversal was defined as renal function improvement, avoidance of dialysis, and short-term survival.

**Current Coding**: There are no unique ICD-10-PCS codes to describe the administration of TERLIVAZ® (terlipressin). Facilities can report the intravenous administration of TERLIVAZ® (terlipressin) 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 TERLIVAZ® (terlipressin). Continue using current codes as listed in Current Coding.

**Option 2.** Create new codes in section X, New Technology, to identify intravenous infusion of TERLIVAZ® (terlipressin).

| | |
|---|---|
| *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<br>**4** Central Vein | **3** Percutaneous | **ADD 5** Terlipressin | **6** New Technology Group 6 |

**CMS Recommendation:** Option 2, as described above.

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

## Insertion of Subcutaneous Pump System for Ascites Drainage

**Issue:** There is currently no unique ICD-10-PCS code to describe the insertion of an implantable pump system for ascites drainage.

**New Technology Application?** A New Technology Add-on Payment (NTAP) application for alfapump® is being considered for FY 2022.

**Food & Drug Administration (FDA) Approval:** FDA approval for alfapump® is anticipated for FY 2022. Investigational Device Exemption (IDE) and verification as a category B device were granted by the FDA in January 2017, and breakthrough designation was granted in January 2019.

**Background:** The buildup of ascitic fluid in the peritoneal cavity is a common complication for patients with cirrhosis, and a major cause of hospital admissions. Approximately 50% of patients with cirrhosis will develop ascites within 10 years of diagnosis. In the United States, cirrhotic liver disease leads to over two million outpatient physician visits and over 750,000 hospitalizations per year. The development of ascites in patients with cirrhosis is associated with a poor prognosis and impaired quality of life. Treatment for ascites includes restriction of dietary sodium and diuretics. Patients affected by ascites suffer from abdominal distention that can cause significant pain, early satiety, nausea and vomiting, shortness of breath, and constipation. Patients can accumulate up to two liters of ascitic fluid in their peritoneal cavity each day, which needs to be removed before the resulting pressure leads to hernias, cardiovascular collapse or suffocation.

Approximately 11% of patients with ascites will develop recurrent or refractory ascites, defined by the American Association for the Study of Liver Diseases (AASLD) as a fluid overload that (1) is unresponsive to sodium-restricted diet (<2g/day) and high dose diuretic treatment (400 mg per day of spironolactone and 160 mg per day of furosemide), or (2) recurred rapidly after therapeutic paracentesis. It is estimated that approximately 190,000 patients in the United States have cirrhosis related non-malignant ascites, of which approximately 21,000 have refractory ascites.

Current treatment for recurrent or refractory ascites includes large volume paracentesis (LVP) with albumin infusion (8g/L of fluid extracted) to decrease the risk of paracentesis-induced circulatory dysfunction (PICD). However, LVP does not prevent the production of ascitic fluid and therefore only provides short term relief for the patient, as re-accumulation starts immediately after LVP. While LVP (paracentesis draining over 5L of ascitic fluid) is considered safe, it can require hospital visits as frequent as once per week and is associated with poor quality of life, malnutrition, and increased complications, which contribute to morbidity and mortality. Median survival in patients with recurrent or refractory ascites is about 6 months.

An alternative to serial paracentesis procedures for select patients is an intrahepatic portosystemic shunt (TIPS). TIPS is not a solution for all patients and requires trained specialists. Contraindications include severe pulmonary hypertension and congestive heart failure; potential complications include acute liver failure, hepatic encephalopathy, hemorrhage, biliary injury, injury to surrounding organs, TIPS thrombosis, TIPS dysfunction, and TIPS migration.

Liver transplantation is considered the ideal treatment for eligible patients with recurrent or

refractory ascites, providing an overall 1-year survival rate of 85%. Many patients with recurrent or refractory ascites do not qualify for liver transplantation.

**Technology:** The alfapump® system is an implanted subcutaneous device with a rechargeable battery that allows fluid to be moved from the peritoneal cavity to the urinary bladder where it is then eliminated via urination. The alfapump® system is wirelessly charged using a hand-held Smart Charger, which can also be used by the physician to wirelessly adjust the settings. Additionally, while charging the alfapump®, the Smart Charger wirelessly collects pump performance data. The system is designed with no external components to allow the patient normal mobility and activity.

One catheter is implanted in the peritoneal cavity to collect fluid and the other catheter is implanted in the urinary bladder to receive fluid. Both catheters incorporate small polyester cuffs to aid in securing them in place. Pressure sensors within the pump monitor fluid movement to prevent pumping from an empty peritoneal cavity or overfilling the bladder. The volume of fluid to be removed and the frequency of pump activity are set by the physician. The physician sets and adjusts the pumping parameters using a dedicated alfapump® system programmer in combination with the Smart Charger. The device functioning parameters can be modified by the physician to meet the patients' requirements.

The alfapump® system may be implanted under local or general anesthesia and typically takes about 45 to 60 minutes. The alfapump® is placed in a subcutaneous pocket made by a single incision of approximately 6cm in length on the abdominal right or left upper quadrant. Two small additional incisions, approximately 1-3cm in length are made for placement of the peritoneal and bladder catheters. Insertion of the catheters is performed percutaneously, most commonly using the Seldinger technique.

Both the peritoneal and bladder catheters are tunneled to the pump pocket and cut to a custom length prior to attachment to the alfapump® system. The physician attaches both catheters to the alfapump® prior to closure of the implantation pocket. The undersurface of the alfapump® has two Dacron pads that promote in-growth of tissue and anchor the alfapump® within the implantation pocket. Prior to closure of the incision, the physician will verify the function of the alfapump® system. The alfapump® system can be removed via a minimally invasive procedure.

**Current coding:** Facilities can report the insertion of an implantable pump system for ascites drainage from the peritoneal cavity to the bladder using the following codes:

> **0JHT0YZ** Insertion of other device into trunk subcutaneous tissue and fascia, open approach for the totally implantable pump
>
> **0W1G3JG** Bypass peritoneal cavity to peritoneal cavity with synthetic substitute, percutaneous approach, for capturing the applicable root operation and body part value for the procedure.

**Coding Options**

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

**Option 2.** Add the qualifier value 6 Bladder to table 0W1, Bypass of Anatomical Regions, for the percutaneous bypass portion of the procedure, in which a fully internal route of passage for the fluid from the peritoneal cavity to the bladder is created.

In addition, create a new device value J Totally Implantable Drainage Pump, in table 0JH Insertion, for the body part value 8 Subcutaneous Tissue and Fascia, to identify the separate, open placement of the implantable subcutaneous pump used for ascites management.

| *Section* | **0** Medical and Surgical | | |
|---|---|---|---|
| *Body System* | **W** Anatomical Regions, General | | |
| *Operation* | **1** Bypass: Altering the route of passage of the contents of a tubular body part | | |
| *Body Part* | *Approach* | *Device* | *Qualifier* |
| **1** Cranial Cavity | **0** Open | **J** Synthetic Substitute | **9** Pleural Cavity, Right<br>**B** Pleural Cavity, Left<br>**G** Peritoneal Cavity<br>**J** Pelvic Cavity |
| **9** Pleural Cavity, Right<br>**B** Pleural Cavity, Left<br>**G** Peritoneal Cavity<br>**J** Pelvic Cavity | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **J** Synthetic Substitute | **4** Cutaneous<br>**ADD 6** Bladder<br>**9** Pleural Cavity, Right<br>**B** Pleural Cavity, Left<br>**G** Peritoneal Cavity<br>**J** Pelvic Cavity<br>**W** Upper Vein<br>**Y** Lower Vein |

| *Section* | **0** Medical and Surgical | | |
|---|---|---|---|
| *Body System* | **J** Subcutaneous Tissue and Fascia | | |
| *Operation* | **H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part | | |
| *Body Part* | *Approach* | *Device* | *Qualifier* |
| **8** Subcutaneous Tissue and Fascia, Abdomen | **0** Open<br>**3** Percutaneous | **0** Monitoring Device, Hemodynamic<br>**2** Monitoring Device<br>**4** Pacemaker, Single Chamber<br>**5** Pacemaker, Single Chamber Rate Responsive<br>**6** Pacemaker, Dual Chamber<br>**7** Cardiac Resynchronization Pacemaker Pulse Generator<br>**8** Defibrillator Generator<br>**9** Cardiac Resynchronization Defibrillator Pulse Generator<br>**A** Contractility Modulation Device<br>**B** Stimulator Generator, Single Array<br>**C** Stimulator Generator, Single Array Rechargeable<br>**D** Stimulator Generator, Multiple Array<br>**E** Stimulator Generator, Multiple Array Rechargeable<br>**H** Contraceptive Device | **Z** No Qualifier |

| | | | |
|---|---|---|---|
| | | **ADD J** Totally Implantable Drainage Pump<br>**M** Stimulator Generator<br>**N** Tissue Expander<br>**P** Cardiac Rhythm Related Device<br>**V** Infusion Device, Pump<br>**W** Vascular Access Device, Totally Implantable<br>**X** Vascular Access Device, Tunneled | |

**Option 3.** Add the qualifier value 6 Bladder to table 0W1, Bypass of Anatomical Regions, for the percutaneous bypass portion of the procedure, in which a fully internal route of passage for the fluid from the peritoneal cavity to the bladder is created.

In addition, create a new code in section X, New Technology, to identify the separate, open placement of the implantable subcutaneous pump used for ascites management.

| *Section* | **0** Medical and Surgical | | |
|---|---|---|---|
| *Body System* | **W** Anatomical Regions, General | | |
| *Operation* | **1** Bypass: Altering the route of passage of the contents of a tubular body part | | |
| *Body Part* | *Approach* | *Device* | *Qualifier* |
| **1** Cranial Cavity | **0** Open | **J** Synthetic Substitute | **9** Pleural Cavity, Right<br>**B** Pleural Cavity, Left<br>**G** Peritoneal Cavity<br>**J** Pelvic Cavity |
| **9** Pleural Cavity, Right<br>**B** Pleural Cavity, Left<br>**G** Peritoneal Cavity<br>**J** Pelvic Cavity | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **J** Synthetic Substitute | **4** Cutaneous<br>**ADD 6** Bladder<br>**9** Pleural Cavity, Right<br>**B** Pleural Cavity, Left<br>**G** Peritoneal Cavity<br>**J** Pelvic Cavity<br>**W** Upper Vein<br>**Y** Lower Vein |

| *Section* | **X** New Technology | | |
|---|---|---|---|
| *Body System* | **H** Skin, Subcutaneous Tissue, Fascia and Breast | | |
| *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* |
| **8** Subcutaneous Tissue and Fascia, Abdomen | **0** Open | **1** Totally Implantable Drainage Pump | **6** New Technology Group 6 |

**Option 4.** Add the qualifier value 6 Bladder to table 0W1, Bypass of Anatomical Regions, for the percutaneous bypass portion of the procedure, in which a fully internal route of passage for the fluid from the peritoneal cavity to the bladder is created.

Continue to use existing code 0JHT0YZ Insertion of other device into trunk subcutaneous tissue and fascia, open approach, as above under Current Coding, to identify the separate, open placement of the implantable subcutaneous pump used for ascites management.

| *Section* | **0** Medical and Surgical |
|---|---|
| *Body System* | **W** Anatomical Regions, General |

| *Operation* **1** Bypass: Altering the route of passage of the contents of a tubular body part | | | |
|---|---|---|---|
| *Body Part* | *Approach* | *Device* | *Qualifier* |
| **1** Cranial Cavity | **0** Open | **J** Synthetic Substitute | **9** Pleural Cavity, Right<br>**B** Pleural Cavity, Left<br>**G** Peritoneal Cavity<br>**J** Pelvic Cavity |
| **9** Pleural Cavity, Right<br>**B** Pleural Cavity, Left<br>**G** Peritoneal Cavity<br>**J** Pelvic Cavity | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **J** Synthetic Substitute | **4** Cutaneous<br>**ADD 6** Bladder<br>**9** Pleural Cavity, Right<br>**B** Pleural Cavity, Left<br>**G** Peritoneal Cavity<br>**J** Pelvic Cavity<br>**W** Upper Vein<br>**Y** Lower Vein |

**CMS Recommendation: Option 3.** Add the qualifier value 6 Bladder to table 0W1, Bypass of Anatomical Regions, for the percutaneous bypass portion of the procedure, in which a fully internal route of passage for the fluid from the peritoneal cavity to the bladder is created.

In addition, create a new code in section X, New Technology, to identify the separate, open placement of the implantable subcutaneous pump used for ascites management.

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

## Syndromic Infectious Disease Testing for Pneumonia

**Issue:** There is currently no unique ICD-10-PCS code to describe the utilization of BioFire FilmArray Pneumonia Panel.

**New Technology Application?** A New Technology Add-on Payment (NTAP) application was submitted for the BioFire FilmArray Pneumonia Panel for FY 2021.

**Food & Drug Administration (FDA) Approved?** The BioFire FilmArray Pneumonia Panel was FDA approved by the Food and Drug Administration on November 9th, 2018.

**Background:** The BioFire FilmArray Pneumonia Panel is a new diagnostic technology that simultaneously identifies 33 clinically relevant targets from sputum (including endotracheal aspirate) and bronchoalveolar lavage (including mini-BAL) samples in approximately an hour. This includes eight viral targets, eighteen bacterial targets, and seven antimicrobial resistance gene targets. The BioFire FilmArray Pneumonia Panel reports semi-quantitative results for 15 of the bacterial targets that are commonly found colonizing the respiratory tract at low levels to help differentiate colonization from active infection. Overall sensitivities and specificities for the two approved sample types for the panel are BAL 96.2 % and 98.3 % respectively and sputum 96.3% and 97.2 % respectively.

The BioFire FilmArray Pneumonia panel has been commercialized for the simultaneous detection and identification of multiple respiratory viral and bacterial nucleic acids, as well as select antimicrobial resistance genes, in sputum-like specimens (induced, expectorated, endotracheal) or bronchoalveolar lavage (BAL) like specimens obtained from individuals suspected of lower respiratory tract infection. This assay is a blood culture independent sample to answer and rapid test, providing clinically actionable results in just over an hour compared to standard culture methods that often take days. The detection and identification of specific viral and bacterial nucleic acids, as well as the estimation of relative abundance of nucleic acid from common bacterial analytes, within specimens collected from individuals exhibiting signs and/or symptoms of a respiratory infection, aids in the diagnosis of lower respiratory infection if used in conjunction with other clinical and epidemiological information. A blood culture is required to identify pathogens not detected by the BioFire FilmArray Pneumonia Panel, to further speciate analytes in genus, complex, or group results if desired, to identify bacterial pathogens present below the 10^4 copies/mL bin if desired, and for antimicrobial susceptibility testing.

**Technology**: To administer a BioFire FilmArray Pneumonia Panel, a healthcare professional collects a sputum sample or bronchoalveolar lavage sample from a patient. Once the sample is collected, the operator rehydrates the FilmArray Pouch with provided reagents and loads the sample into the pouch. The pouch is under vacuum and automatically draws the needed volume of hydration solution and sample, no precise measuring is required. The pouch is placed in the FilmArray instrument and the sample is moved to a blister in the pouch and is subject to bead beating to release the nucleic acid from the cells. The nucleic acid is isolated using magnetic beads coated with a material with an affinity to nucleic acid. After isolating the nucleic acid the solution is then amplified in a first stage PCR reaction. This first stage PCR reaction material is diluted and spread over the array where pathogen and antibiotic resistant gene specific PCR primers amplify

target nucleic acid. Fluorescent probes are included in this reaction and changes in fluorescents in each well of the array are detected by the FilmArray instrument to identify positive targets.

The BioFire FilmArray Pneumonia Panel is a rapid and comprehensive FDA approved test for use on patients of all ages, for utilization in outpatient, emergency departments, and hospitalized patients, and for testing sputum and BAL specimens. This test provides semi-quantitative results for bacterial targets that are commonly found colonizing the respiratory tract. This important feature assists clinicians in distinguishing between normal colonization and active infection from these organisms. The BioFire FilmArray instrument that performs the BioFire Pneumonia Panel is a fully automated sample to results system requiring <5 minutes of hands on time.

Preliminary data on the clinical value of the BioFire FilmArray Pneumonia panel indicates the potential to significantly reduce unnecessary antibiotics, time to results, and increase diagnostic yield compared to currently available methods.

**Current Coding:** There is no unique ICD-10-PCS that describes utilization of the BioFire FilmArray Pneumonia Panel.

Facilities can report the collection of bronchoalveolar lavage (BAL) specimens from bronchoscopy for microbial testing using the BioFire FilmArray Pneumonia Panel with the following ICD-10-PCS Codes:

0B9J8ZX Drainage of Left Lower Lung Lobe, Via Natural or Artificial Opening Endoscopic, Diagnostic
0B9F8ZX Drainage of Right Lower Lung Lobe, Via Natural or Artificial Opening, Endoscopic, Diagnostic

**Coding Options**

**Option 1**. Do not create new ICD-10-PCS code to describe the utilization of the BioFire FilmArray Pneumonia Panel. Continue using current codes as listed in Current Coding.

**Option 2.** Create a new code in section X, New Technology, to identify the utilization of the BioFire FilmArray Pneumonia Panel.

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

| *Body Part* | *Approach* | *Device / Substance / Technology* | *Qualifier* |
|---|---|---|---|
| **5** Circulatory | **X** External | **M** Infection, Whole Blood Nucleic Acid-base Microbial Detection | **5** New Technology Group 5 |
| **ADD B** Respiratory | **X** External | **ADD Q** Infection, Lower Respiratory Fluid Nucleic Acid-base Microbial Detection | **ADD 6** New Technology Group 6 |

**CMS Recommendation: Option 2.** Create a new code in section X, New Technology, to identify the utilization of the BioFire FilmArray Pneumonia Panel.

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

## Administration of NUZYRA™ (omadacycline)

**Issue:** Currently there are no unique ICD-10-PCS codes to describe the intravenous (IV) administration of NUZYRA™ to treat patients with community-acquired bacterial pneumonia (CABP) or acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible microorganisms.

**New Technology Application?** Yes. The requester submitted a New Technology Add-on Payment application for FY 2021.

**Food & Drug Administration (FDA) Approval?** Yes. The FDA approved NUZYRA™ (omadacycline) on October 2, 2018.

**Background:** In 2013, the Centers for Disease Control and Prevention (CDC) released a comprehensive analysis outlining the top 18 antibiotic-resistant threats in the U.S., including:

- Methicillin-resistant Staphylococcus aureus (MRSA) (Serious); and
- Drug-resistant Streptococcus pneumoniae (Serious).

NUZYRA™ (omadacycline) is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

- Community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilius parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae*; and
- Acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *Klebsiella pneumoniae*.

*Dosage and Administration*
NUZYRA™ is available in both intravenous and oral formulations. NUZYRA™ for intravenous infusion is available as a lyophilized powder in a single-dose vial for reconstitution and further dilution before intravenous administration. Each vial contains 100 mg of omadacycline (equivalent to 131 mg omadacycline tosylate).

For treatment of adults with CABP or ABSSSI, the recommended dosage regimen of NUZYRA™ for infusion is described below.

| Dosage of NUZYRA for infusion in Adult CABP Patients | | |
|---|---|---|
| Loading Dose | Maintenance Dose | Treatment Duration |

| | | |
|---|---|---|
| 200 mg by intravenous infusion over 60 minutes on day 1<br>Or<br>100 mg by intravenous infusion over 30 minutes, twice on day 1 | 100 mg by intravenous infusion over 30 minutes once daily | 7 to 14 days |

| Dosage of NUZYRA for infusion in Adult ABSSSI Patients | | |
|---|---|---|
| Loading Dose | Maintenance Dose | Treatment Duration |
| 200 mg by intravenous infusion over 60 minutes on day 1<br>Or<br>100 g by intravenous infusion over 30 minutes, twice on day 1 | 100 mg by intravenous infusion over 30 minutes once daily | 7 to 14 days |

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

3E03329 Introduction of other anti-infective into peripheral vein, percutaneous approach
3E04329 Introduction of other anti-infective into central vein, percutaneous approach

**Coding Options**

**Option 1.** Do not create new ICD-10-PCS codes for intravenous administration of NUZYRA™ (omadacycline). Continue using current codes as listed in Current Coding.

**Option 2**. Create new codes in section X, New Technology, to identify intravenous infusion of NUZYRA™ (omadacycline).

| | | | |
|---|---|---|---|
| *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<br>**4** Central Vein | **3** Percutaneous | **ADD B** Omadacycline Anti-infective | **6** New Technology Group 6 |

**CMS Recommendation:** Option 2. Create a new code in section X, New Technology, to capture the administration of NUZYRA™ for infusion.

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

## Phenotypic Antimicrobial Susceptibility Testing

**Issue:** There is currently no unique ICD-10-PCS code to describe the Accelerate PhenoTest™ Blood Culture (BC) kit which is performed on the Accelerate Pheno system.

**New Technology Application?** A New Technology Add-on Payment (NTAP) application was submitted for consideration for the Accelerate PhenoTest™ BC kit for FY 2021.

**Food & Drug Administration (FDA) Approved?** The Accelerate PhenoTest™ BC kit performed using the Accelerate Pheno™ system was originally authorized on February 23, 2017.

**Background:** The Accelerate PhenoTest™ BC kit, performed on the Accelerate Pheno™ system, is a fast, automated, phenotypic, direct-from-positive blood culture identification and antimicrobial susceptibility testing (ID/AST) technology available. The test identifies 16 organisms (6 Gram-positive, 8 Gram-negative bacteria and 2 *Candida* species) and depending on the organism identified, will report minimum inhibitory concentration (MIC) values as well as susceptible, intermediate, or resistant (SIR) categorical designations for 6 Gram-positive drugs, 2 Gram-positive resistance phenotype markers, and 12 Gram-negative drugs. The technology provides results that drive clinical decisions in approximately 7 hours directly from positive blood culture samples.

**Technology:** Microorganism identification is performed using fluorescence *in situ* hybridization (FISH). Colocalization of target (green fluorescence) and universal (red fluorescence) probe signal confirms the presence and identity of the target organism while differentiating from non-specific staining. Identification results are produced in approximately 2 hours. Antimicrobial Susceptibility testing (AST) is performed using morphokinetic cellular analysis (MCA) which measures morphological and kinetic changes over time of organisms exposed to antibiotics.

MCA is a computer vision based analytical method that uses digital microscopy inputs and machine learning technology to observe individual live cells and recognize patterns of change over time. This technology tracks and analyzes multiple morphological and kinetic changes of individual cells and microcolonies under a variety of conditions. These changes include morphokinetic features such as cell morphology, mass as measured by light intensity of growing cells, division rate, anomalous growth patterns, and heterogeneity. During this period, morphokinetic features are measured and used for analysis. The precise quantitative measurement of individual cell growth rate over time is a powerful indicator of antimicrobial efficacy. Onboard software algorithms derive MIC values from the measured features and apply appropriate expert rules for proper interpretation and reporting of SIR categorical interpretations. AST results are reported in approximately 7 hours from the start of the run.

**Current Coding:** There is no unique ICD-10-PCS code to describe the processing and analysis of a positive blood culture using the Accelerate PhenoTest™ BC kit. If desired facilities can report the collection of a patient's specimen from an indwelling vascular catheter using 8C02X6K (Collection of Blood from Indwelling Device in Circulatory System).

**Coding Options**
**Option 1.** Do not create a new ICD-10- PCS code**.** Continue using current codes as listed in Current Coding.
**Option 2.** Create a new code in section X, New Technology, to identify the processing and analysis of a positive blood culture using the Accelerate PhenoTest™ BC kit.

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

| *Body Part* | *Approach* | *Device / Substance / Technology* | *Qualifier* |
|---|---|---|---|
| **5** Circulatory | **X** External | **M** Infection, Whole Blood Nucleic Acid-base Microbial Detection | **5** New Technology Group 5 |
| **5** Circulatory | **X** External | **ADD N** Infection, Positive Blood Culture Fluorescence Hybridization for Organism Identification, Concentration and Susceptibility | **ADD 6** New Technology Group 6 |

**CMS Recommendation: Option 2.** Create a new code in section X, New Technology, to identify the processing and analysis of a positive blood culture using the Accelerate PhenoTest™ BC kit.

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

## Administration of XENLETA™ (lefamulin)

**Issue:** There is currently no unique ICD-10-PCS code to describe the administration of XENLETA™ for the treatment of patients with community acquired bacterial pneumonia (CABP) in adults.

**New Technology Application?** Yes. A New Technology Add-On Payment (NTAP) application for XENLETA™ was submitted for Fiscal Year 2021.

**Food and Drug Administration (FDA) Approval?** Yes. Title VIII of FDASIA (implemented July 9, 2012), Generating Antibiotic Incentives Now (GAIN), provides incentives for the development of antibacterial and antifungal drugs for human use intended to treat serious and life-threatening infections. Under GAIN, a drug may be designated as a qualified infectious disease product (QIDP) if it meets the criteria outlined in the statute. The FDA and granted XENLETA™ both QIDP designation, as well as fast track status under the GAIN Act. FDA approval was received on August 19, 2019.

**Background:** XENLETA™ is a pleuromutilin antibacterial indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP). XENLETA™ was developed to address the unmet medical need for new antibiotic products in the management of CABP.

Description and Method of Action of XENLETA™

XENLETA™ is a pleuromutilin antibacterial indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* and *Chlamydophila pneumoniae.*

XENLETA™ represents the first intravenous (IV) and oral treatment option from a novel class of antibiotics for CABP. Pleuromutilins inhibit bacterial protein synthesis by binding to the A- and P-sites of the peptidyl transferase center (PTC) in the large ribosomal subunit of the bacterial ribosome.[14] This unique binding site in the highly conserved core of the ribosomal PTC is specific to the pleuromutilins, and it confers a lack of cross-resistance with other classes, as well as a low propensity for developing bacterial resistance.

Availability of XENLETA™ in both IV and oral (PO) formulation enables clinicians to use an effective CABP monotherapy in both the inpatient and outpatient settings. The availability of both dosage forms for hospitals facilitates switching from IV to oral formulations among patients who are appropriate candidates.

It is common to begin with a regimen that is administered via the intravenous (IV) route. As the hospitalized patient becomes clinically stable, able to tolerate oral medication, it is safe to transition to an oral (PO) antibiotic. Studies have shown that appropriate conversion from IV to PO antimicrobial therapy permits earlier discharge of patients, thereby decreasing the length of hospitalization and reducing exposure to nosocomial infections without adversely affecting patient

outcomes. Additional benefits of IV to PO conversion include reduced hospital cost, greater patient comfort and easier ambulation.

XENLETA™ is available for oral (600 mg every 12 hours) and IV (150 mg every 12 hours) administration with a 5-to-7-day course of therapy.

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

3E03329 Introduction of other anti-infective into peripheral vein, percutaneous approach
3E04329 Introduction of other anti-infective into central vein, percutaneous approach
3E0DX29 Introduction of other anti-infective into mouth and pharynx, external approach

**Option 1.** Do not create new ICD-10-PCS codes for intravenous administration or oral administration of XENLETA™ (lefamulin). Continue using current codes as listed in Current Coding.

**Option 2.** Create new codes in section X, New Technology, to identify intravenous infusion and oral administration of XENLETA™ (lefamulin).

| | |
|---|---|
| *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<br>**4** Central Vein | **3** Percutaneous | **ADD 6** Lefamulin Anti-infective | **6** New Technology Group 6 |
| **D** Mouth and Pharynx | **X** External | **ADD 6** Lefamulin Anti-infective | **6** New Technology Group 6 |

**CMS Recommendation:** Option 2. Create new codes in section X, New Technology, to identify intravenous infusion and the oral administration of XENLETA™ (lefamulin).

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

## Endoscopic Gastrointestinal Hemostat

**Issue:** There is currently no unique ICD-10-PCS code to describe the application of a mineral-based topical agent used in the Hemospray® Endoscopic Hemostat.

**New Technology Application?** A New Technology Add-on Payment (NTAP) application for Hemospray® Endoscopic Hemostat was submitted for FY 2021.

**Food & Drug Administration (FDA) Approval?** Hemospray® Endoscopic Hemostat was granted *de novo* 510(k) status as a Class II medical device by the FDA on May 7, 2018.

**Background:** Hemospray® Endoscopic Hemostat is indicated for nonvariceal gastrointestinal bleeding, consisting of a mineral-based topical hemostatic agent and a delivery system. The hemostatic agent is an inert, bentonite powder developed for endoscopic hemostasis. The delivery system is an endoscopic accessory used for spraying the powder onto the bleeding surface. The powder is delivered by use of a carbon dioxide powered delivery system through a catheter which is inserted through the working channel of an endoscope, providing access to the site of the bleed. Hemospray® Endoscopic Hemostat acts by creating a mechanical barrier over the site of the bleed. Unlike traditional therapies, it is a nonthermal, nontraumatic, and noncontact modality that does not require the precise targeting of other endoscopic devices.

**Technology:** An endoscope is passed into the gastrointestinal tract to identify the source of bleeding. Once the source is located, the Hemospray® delivery system is passed through the accessory channel of the endoscope and positioned just above the bleeding site, without making contact with the gastrointestinal (GI) tract wall. The material is propelled through the application catheter by release of carbon dioxide from the cartridge located in the device handle and sprayed onto the bleeding site. A trigger valve with an activation button allows the physician to control the amount of powder delivered to the affected area. The bentonite powder can absorb 5-10 times its weight in water and swell up to 15 times its dry volume. When delivered as fine particles, bentonite rapidly absorbs water and becomes cohesive to itself and adhesive to tissue, forming a physical barrier to aqueous fluid (e.g., blood). This is the mechanism by which Hemospray® Endoscopic Hemostat achieves its intended purpose, hemostasis. Hemospray® is not absorbed by the body and does not require removal as it passes through the lower GI tract within 72 hours.

Patients with underlying co-morbid conditions such as diabetes, congestive heart failure, liver failure, or malignancy have higher rates of recurrent bleeding and death. Risk of morbidity and mortality, as well as rebleeding have been quantified, and these risks can be predicted using validated scoring methods such as the Rockall Score. Additionally, patients with significant underlying conditions such as malignant lesions from primary disease or metastasis in the GI tract pose additional challenges. While uncommon, cancerous lesions in the GI tract are more frequently identified as a result of oncologic advances and improved methods for locating and

determining the cause of the bleeding. Malignant tumor bleeds also can exhibit unique physiologic features. Bleeding occurs in part because of progressive local vessel damage from direct invasion as well as from friable mucosa of the tumor itself, making the lesions unsuitable for conventional endoscopic treatment methods. Because of these features, the successful hemostasis rate is as low as 40%, with a recurrent bleeding rate over 50% within 1 month after standard treatments, with a mortality rate of 95% in the first 3 months.

Hemospray® does not require the endoscopist to further disrupt the mucosa as is necessary for cautery or clip ligation and can be used in conjunction with these conventional techniques. Because it is a spray, Hemospray® can cover a larger mucosal surface area. Clinical data has demonstrated Hemospray® can achieve immediate hemostasis in all types of NVUGI bleeds and is successful as a "rescue" treatment when conventional hemostasis methods fail. In the first large prospective registry of 202 patients, Haddara et. al. reported immediate hemostasis was achieved in 96.5% of all patients. When used as a first line treatment, immediate hemostasis was achieved in 91/94 (96.8%), and in 104/108 (96.3%) when used as rescue therapy.

**Current Coding**: Endoscopic control of nonvariceal gastrointestinal bleeding using Hemospray® Endoscopic Hemostat is coded to table 0W3 Control of Anatomical Regions, using the body part value Gastrointestinal Tract and the approach value Via Natural or Artificial Opening Endoscopic.

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **W** Anatomical Regions, General |
| *Operation* | **3** Control: Stopping, or attempting to stop, postprocedural or other acute bleeding |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **P** Gastrointestinal Tract<br>**Q** Respiratory Tract<br>**R** Genitourinary Tract | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic<br>**7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **Z** No Device | **Z** No Qualifier |

If desired, facilities can track the application of the hemostatic agent with one of the following ICD-10-PCS codes:

**3E0G8GC** Introduction of Other Therapeutic Substance into Upper GI, Via Natural or Artificial Opening Endoscopic

**3E0H8GC** Introduction of Other Therapeutic Substance into Lower GI, Via Natural or Artificial Opening Endoscopic

**Coding Options**

**Option 1.** Do not create a new code for control of GI bleeding using Hemospray® Endoscopic Hemostat. Continue to use the existing ICD-10-PCS code listed under current coding.

**Option 2.** Create new codes in section X for the application of the mineral-based topical hemostatic agent used in the Hemospray® Endoscopic Hemostat. Continue to report endoscopic control of GI bleeding to table 0W3 Control of Anatomical Regions, using the body part value Gastrointestinal Tract and the approach value Via Natural or Artificial Opening Endoscopic.

| | | | |
|---|---|---|---|
| *Section* **X** New Technology<br>*Body System* **W** Anatomical Regions<br>*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 G** Upper GI<br>**ADD H** Lower GI | **8** Via Natural or Artificial Opening Endoscopic | **ADD 8** Mineral-based Topical Hemostatic Agent | **6** New Technology Group 6 |

**CMS Recommendation: Option 2.** Create new codes in section X for the application of the hemostatic agent used in the Hemospray® Endoscopic Hemostat. Continue to report endoscopic control of GI bleeding to table 0W3 Control of Anatomical Regions, using the body part value Gastrointestinal Tract and the approach value Via Natural or Artificial Opening Endoscopic.

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

## Administration of Zerbaxa® (ceftolozane and tazobactam)

**Issue:** There is currently no unique ICD-10-PCS code to describe the administration of ZERBAXA® (ceftolozane and tazobactam).

**New Technology Application?** Yes, a New Technology Add-on Payment (NTAP) application will be submitted for ZERBAXA® (ceftolozane and tazobactam) for FY 2021.

**Food & Drug Administration (FDA) Approved?** Yes. FDA approval was obtained on December 19, 2014 for the treatment of complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI). On June 13, 2019 ZERBAXA® was approved for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP).

**Background:** ZERBAXA® (ceftolozane and tazobactam) is a combination of ceftolozane, a cephalosporin antibacterial, and tazobactam, a β-lactamase inhibitor (BLI), indicated in patients 18 years or older for the treatment of the following infections caused by designated susceptible microorganisms:

- Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole
- Complicated Urinary Tract Infections (cUTI), Including Pyelonephritis
- Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)

To reduce the development of drug-resistant bacteria and maintain its effectiveness, ZERBAXA® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria. ZERBAXA®, in combination with metronidazole, is indicated to treat patients 18 years and older with cIAI caused by the following susceptible Gram-negative and Gram-positive microorganisms: *Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus,* and *Streptococcus salivarius*.

ZERBAXA® is indicated for the treatment of patients 18 years and older with complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible Gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis,* and *Pseudomonas aeruginosa*.

ZERBAXA® is indicated for the treatment of patients 18 years and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by the following susceptible Gram-negative microorganisms: *Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa*, and *Serratia marcescens.*

*Dosage and Administration*

The recommended dosage of ZERBAXA® for injection is 1.5 gram (g) (ceftolozane 1 g and tazobactam 0.5 g) for cIAI and cUTI and 3 g (ceftolozane 2 g and tazobactam 1 g) for HABP/VABP administered every 8 hours by intravenous infusion over 1 hour in patients 18 years or older and with a creatinine clearance (CrCl) greater than 50 mL/min. The duration of therapy

should be guided by the severity and site of infection and the patient's clinical and bacteriological progress as shown in Table 1.

**Table 1: Dosage of ZERBAXA by Infection in Patients with CrCl Greater than 50 mL/min**

| **Infection** | **Dose** | **Frequency** | **Infusion Time (hours)** | **Duration of Treatment** |
|---|---|---|---|---|
| Complicated Intra-abdominal infections* | 1.5 g | Every 8 hours | 1 | 4-14 days |
| Complicated Urinary tract infections, including Pyelonephritis | 1.5 g | Every 8 hours | 1 | 7 days |
| Hospital-acquired bacterial pneumonia and ventilator-associated /bacterial Pneumonia (HABP/VABP) | 3 g | Every 8 hours | 1 | 8-14 days |

** Used in conjunction with metronidazole 500 mg intravenously every 8 hours*

Dose adjustment is required for patients with CrCl 50 mL/min or less (Table 2). All doses of

ZERBAXA® are administered over 1 hour. For patients with changing renal function, monitor CrCl at least daily and adjust the dosage of ZERBAXA® accordingly.

**Table 2: Dosage of ZERBAXA® in Adult Patients with CrCl 50 mL/min or less**

| **Estimated CrCl (mL/min)*** | **Complicated Intra-abdominal infections and Complicated Urinary Tract Infections, including Pyelonephritis** | **Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)** |
|---|---|---|

| | | |
|---|---|---|
| 30 to 50 | 750 mg (500 mg and 250 mg) intravenously every 8 hours | 1.5 g (1 g and 0.5 g) intravenously every 8 hours |
| 15 to 29 | 375 mg (250 mg and 125 mg) intravenously every 8 hours | 750 mg (500 mg and 250 mg) intravenously every 8 hours |
| End-stage renal disease (ESRD) on hemodialysis (HD) | A single loading dose of 750 mg (500 mg and 250 mg) followed by a 150 mg (100 mg and 50 mg) maintenance dose administered every 8 hours for the remainder of the treatment period (on hemodialysis days, administer the dose at the earliest possible time following completion of dialysis) | A single loading dose of 2.25 g (1.5 g and 0.75 g) followed by a 450 mg (300 mg and 150 mg) maintenance dose administered every 8 hours for the remainder of the treatment period (on hemodialysis days, administer the dose at the earliest possible time following completion of dialysis) |

* *CrCl estimated using Cockcroft-Gault formula*

**Current Coding:** There is no unique ICD-10-PCS code to describe the administration of ZERBAXA (ceftolozane/tazobactam). Facilities can report the intravenous administration of ZERBAXA (ceftolozane/tazobactam) with one of the following ICD-10-PCS codes:

3E03329 Introduction of other anti-infective into peripheral vein, percutaneous approach

3E04329 Introduction of other anti-infective into central vein, percutaneous approach

**Option 1.** Do not create new ICD-10-PCS codes for intravenous administration of ZERBAXA (ceftolozane/tazobactam). Continue using current codes as listed in Current Coding.

**Option 2**. Create new codes in section X, New Technology, to identify intravenous infusion of ZERBAXA (ceftolozane/tazobactam).

| | |
|---|---|
| *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<br>**4** Central Vein | **3** Percutaneous | **ADD 9** Ceftolozane/Tazobactam Anti-infective | **6** New Technology Group 6 |

**CMS Recommendation:** Option 2.

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

## Administration of KTE-X19

**Issue:** There is currently no unique ICD-10-PCS code to describe the administration of KTE-X19.

**New Technology Application?** Yes. Kite Pharma, a Gilead company, submitted a New Technology Add-on Payment application for KTE-X19 for FY 2021.

**Food & Drug Administration (FDA) Approved?** No. Kite Pharma submitted a Biologics License Application (BLA) for KTE-X19 to the FDA on December 11, 2019 with a request for priority review.

**Background:**

*Description of KTE-X19*
KTE-X19, a distinct autologous cellular product, is expected to be the first FDA-approved chimeric antigen receptor (CAR) T-cell therapy for treatment of adult patients with relapsed/refractory (r/r) mantle cell lymphoma (MCL) upon approval by the FDA. KTE-X19 is a distinct cellular product that is customized for B-cell malignancies bearing high levels of circulating tumor cells expressing CD19.

*r/r MCL and Currently Available Treatments*
MCL is a rare, aggressive subtype of non-Hodgkin lymphoma (NHL) with distinctive clinical, biological and molecular characteristics. The median age at diagnosis is 68 years (range: 20 to > 80 years). Patients are often diagnosed with advanced disease (Stage III/IV), which is characterized by an aggressive clinical course and one of the poorest prognoses of all lymphomas; it remains incurable. Most patients eventually relapse after frontline therapy. There is no standard of care for second-line and higher chemotherapies.

- Outcomes are poor with chemotherapy-based regimens with or without rituximab or autologous stem cell transplantation (ASCT): complete response rates ≤ 44% overall and 14% in patients who had received ≥ 2 prior lines of therapy. Prognosis is poor, with a median overall survival (OS) as low as 10.6 months and a median failure-free survival of 4.8 months that declines to 2.5 months in patients who had received ≥ 2 lines of prior treatment.
- Allo-SCT can result in durable remissions for approximately 25% of patients with r/r MCL if their disease demonstrates chemosensitivity prior to transplant; however, allo-SCT is also associated with mortality rates of up to 40% and treatment-related morbidity including graft-versus-host disease. Hence, allogeneic stem cell transplantation is not a suitable option for many patients.
- Within the last 10 years, the immunomodulatory agent lenalidomide, the Bruton's tyrosine kinase (BTK) inhibitor ibrutinib, and the more selective BTK inhibitor acalabrutinib, have been approved in the US for the treatment of patients with r/r MCL. These agents offer some improvement over other chemotherapy based regimens in the relapsed or refractory setting and reflect current treatment practices. Primary and secondary resistance to BTK inhibitors is common, and subsequent therapies are minimally effective with demonstrated poor objective response rates (ORR) and OS rates. Despite the high initial response rates observed with BTK inhibitors, most patients will eventually develop progressive disease.

*Inpatient Administration of KTE-X19*
The clinical study protocol stipulated that KTE-X19 would be administered in the hospital inpatient setting to assure appropriate monitoring and treatment of therapy-related toxicities. Kite anticipates that if KTE-X19 is approved, its FDA-approved prescribing information will be silent on the setting for KTE-X19 administration. KTE-X19 will be supplied as cell suspension for infusion in a single-use, patient-specific infusion bag consisting of 2.0 x $10^6$ anti-CD19 CAR T cells/kg of body weight (± 20%), with a maximum dose of 2 x $10^8$ anti-CD19 CAR T cells (for subjects ≥ 100 kg). KTE-X19 is an autologous single infusion immunotherapy where the entire contents of each single-use, patient-specific bag is infused by gravity or a peristaltic pump over 30 minutes.

**Current Coding:** There is no unique ICD-10-PCS code to describe the administration of KTE-X19. Facilities can report the intravenous administration of KTE-X19 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

**Option 1.** Do not create new ICD-10-PCS codes for intravenous administration of KTE-X19. Continue using codes as listed in Current Coding.

**Option 2.** Create new codes in section X, New Technology, to identify intravenous infusion of KTE-X19.

| | |
|---|---|
| *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<br>**4** Central Vein | **3** Percutaneous | **ADD 4** KTE-X19 Antineoplastic | **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 IMFINZI® (durvalumab)

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

**New Technology Application?** Yes. AstraZeneca submitted a New Technology Add-on Payment application for IMFINZI® (durvalumab) for FY 2021.

**Food & Drug Administration (FDA) Approved?** No. IMFINZI is not currently FDA-approved for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).

On May 1, 2017, the FDA granted approval to IMFINZI® (durvalumab) for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

IMFINZI® (durvalumab) received a FDA-approval for the treatment of patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy on February 16, 2018.

In November 2019, the FDA responded and accepted AstraZeneca's sBLA submission for IMFINZI in the first-line treatment of ES-SCLC with a priority review. A PDUFA date is set for the first quarter of 2020.

**Background:** Small Cell Lung Cancer (SCLC) is considered a rare disease, with approximately 30,000 new cases diagnosed each year, compared to 200,000 cases of Non-Small Cell Lung Cancer (NSCLC). SCLC was identified in the Recalcitrant Cancer Research Act of 2012 which supports research for cancers having a 5-year relative survival rate of less than 20% and estimated to cause approximately 30,000 deaths per year in the US.

SCLC is a rapidly progressive disease with poor prognosis and limited treatment options. The overall 5-year survival rate (early and late stage) is 6%, representing an ongoing significant unmet need. The majority (75%) of patients are diagnosed in the late/metastatic stage described as ES-SCLC and are considered incurable, with a median overall survival of 9-11 months with standard of care (SOC) chemotherapy. The median overall survival for ES-SCLC has remained the same for the past 20 years with essentially no improvements or new therapies in 20 years. The current SOC chemotherapy for first line (1L) treatment of ES-SCLC is systemic therapy with standard doublet chemotherapy with platinum plus etoposide, administered for 4-6 cycles following diagnosis. Although ES-SCLC is highly sensitive to platinum/etoposide in first line treatment with response rates of 50-60%, the majority of patients will relapse within the first year of treatment, with a median progression free survival (PFS) of 4-6 months. Overall, responses to SOC chemotherapy are short-lived and long-term outcomes remain poor.

Durvalumab offers a new mechanism of action for the first line treatment of ES-SCLC beyond the existing SOC chemotherapy. Durvalumab is a selective, high-affinity, human IgG1 monoclonal antibody (mAb) that blocks programmed death-ligand 1 (PD-L1) binding to programmed cell death- 1 and CD80 without antibody-dependent cell-mediated cytotoxicity.

As SCLC is characterized by a high tumor mutational burden, there is good rationale for use of durvalumab based on its novel mechanism of action. Durvalumab, in combination with chemotherapy, demonstrated a statistically and clinically significant improvement in overall survival in a randomized Phase III study (CASPIAN).

*Inpatient Administration of IMFINZI® (durvalumab)*
For the first-line treatment of patients with ES-SCLC, one 1500 mg dose of durvalumab will be administered by intravenous infusion over 60 minutes every three weeks in combination with etoposide and either carboplatin or cisplatin for four cycles, followed by 1500mg every four weeks until disease progression. If a patient weight falls below 30 kg, durvalumab should be administered based on weight at 20 mg/kg.

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

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

**Option 1.** Do not create new ICD-10-PCS codes for intravenous administration of IMFINZI® (durvalumab). Continue using current codes as listed in Current Coding.

**Option 2.** Create new codes in section X, New Technology, to identify intravenous infusion of IMFINZI® (durvalumab).

| | |
|---|---|
| *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<br>**4** Central Vein | **3** Percutaneous | **ADD 3** Durvalumab Antineoplastic | **6** New Technology Group 6 |

**CMS Recommendation:** Option 2. Create new codes in section X, New Technology, to identify intravenous infusion of IMFINZI® (durvalumab).

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

## Bacterial Autofluorescence Detection

**Issue:** Currently, there is no unique ICD-10-PCS code to identify the use of portable real-time imaging of an acute or chronic wound and surrounding tissue for the presence, location, and load of bacteria using autofluorescence detection.

**New Technology Application?** No

**Food & Drug Administration (FDA) Approved?** Yes. MolecuLight *i:X*®, an autofluorescence detection device for general surgery and dermatological use, received 510(k) clearance from the FDA on December 04, 2019. De novo clearance was previously granted on August 14, 2018.

**Background:** Assessing and managing bacteria in chronic wounds is problematic, often leaving the physician uncertain of the presence of bacteria, pathogenicity or infection. Chronic wounds often harbor moderate-to-heavy levels of bacteria, causing delays in healing. In a compromised patient population due to comorbidities, the presence of harmful bacteria may be asymptomatic and difficult to diagnose. The rise of an aging population with increase in diabetes and obesity create a matrix of a critical need to bring wounds to closure in less time. Most of these patients have multiple diagnoses and once the wound is closed or under predictable management, their other chronic conditions can be appropriately managed. A recent study reported almost 5% of Medicare beneficiaries (8.2 million) had a wound infection. The highest number was surgical infections, followed by diabetic infections. The presence of bacteria challenges the accuracy of clinical diagnosis and, when present, contributes to poor patient outcomes. Indeed, a level of bacteria of $10^4$ CFU reduces wound healing. Chronic wounds or traumatic wounds having a presence of moderate-to-heavy bacterial loads take longer to heal, often leading to amputation and seriously worsening systemic condition compromising the patients' quality of life (QoL).

The MolecuLight *i:X*® is a handheld imaging tool that allows clinicians diagnosing and treating skin wounds at the point of care, to (a) view and digitally record images of a wound, and (b) view and digitally record images of fluorescence emitted from a wound when exposed to an excitation light enabling real-time standard light and fluorescence imaging of bacteria and tissue components in wounds and surrounding healthy skin of patients. The information aids critical wound treatment planning bringing acute and chronic wounds to closure.

The device is comprised of a high-resolution color LCD display and a touch-sensitive screen with integrated optical and microelectronic components. MolecuLight *i:X*® uses its patented technology to enable real-time image capture (in JPEG format) and videos (MOV format) in Standard Imaging Mode aid immediate documentation in the patient's medical record being present to reference previous measurements, bacterial load, and location. It visualizes the presence of potentially harmful levels of bacteria commonly found within or around wounds through endogenous autofluorescence using no contrast agents. This includes gram positive and gram-negative species, aerobes and anaerobes (e.g., Staphylococcus, E. coli, Klebsiella, Proteus, Enterobacter, Acinetobacter, Aeromonas, Bacteroides, and others). Using a safe violet light (405nm) and specialized optical filters to remove extraneous information and capture the resulting, relevant fluorescence from tissues and bacteria, the MolecuLight *i:X*® offers an immediate image of the presence of bacteria at loads >104 CFU/g. Images appear on screen in real-time, localizing bacterial fluorescence. Most species appear red or cyan (Pseudomonas aeruginosa). Bacterial

fluorescence (red or cyan) is spectrally and visually different than background tissue fluorescence which appears in various shades of green. The appearance of red or cyan fluorescence is associated with a positive finding for moderate-to- heavy bacterial growth represented as fluorescence + (FL+).

C**urrent Coding:** Do not separately report the use of a portable real-time bacterial autofloresescence detection device to assess the presence, location, and load of bacteria in a wound and/or surrounding tissue. Report as appropriate any procedure performed to treat the wound (e.g. debridement) using the applicable ICD-10-PCS code.

**Coding Options**

**Option 1.** Do not create new ICD-10-PCS codes for the bacterial autofluorescence detection device. Continue coding as listed in current coding.

**Option 2.** Create a new code in section X, New Technology, to identify use of the bacterial autofluorescence detection device.

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

| *Body Part* | *Approach* | *Device / Substance / Technology* | *Qualifier* |
|---|---|---|---|
| **ADD K** Skin and Subcutaneous Tissue | **X** External | **ADD P** Infection, Autofluorescence Bacterial Detection | **ADD 6** New Technology Group 6 |

**Option 3.** Create new table BW5, Other Imaging of Anatomical Regions, to identify use of the bacterial autofluorescence detection device. Create new body part value 2 Trunk, and add existing body part values 9 Head and Neck, C Lower Extremity, and J Upper Extremity. Add new 6th character qualifier Bacterial Autofluorescence, applied to the 5th character contrast value Z None.

| | |
|---|---|
| *Section* | **B** Imaging |
| *Body System* | **W** Anatomical Regions |
| *Type* | **ADD 5** Other Imaging: Other specified modality for visualizing a body part |

| *Body Part* | *Contrast* | *Qualifier* | *Qualifier* |
|---|---|---|---|
| **ADD 2** Trunk<br>**9** Head and Neck<br>**C** Lower Extremity<br>**J** Upper Extremity | **Z** None | **ADD 1** Bacterial Autofluorescence | **Z** None |

**CMS Recommendation:** CMS is seeking input from the audience.

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

## Computer-Aided Triage and Notification Software for Head and Neck CT Angiogram

**Issue:** Currently there are no unique ICD-10-PCS codes to describe the analysis of head and neck computed tomography angiogram (CTA) using computer-aided triage and notification software.

**New Technology Application?** Yes. The requestor submitted a New Technology Add-on Application (NTAP) for FY 2021.

**Food & Drug Administration (FDA) Approval?** Yes. On February 13, 2018, the FDA approved ContaCT under the de novo 510(k) pathway.

**Background:** Every year, more than 795,000 people in the United States have a stroke. About 87% of these strokes are ischemic strokes[1] and of those, approximately 24% to 46% are caused by large vessel occlusions (LVOs).[2] In patients with ischemic stroke, a major predictor of outcomes is time to treatment and delays are associated with an increase in post-stroke disability.[3, 4]

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

1) Patient presents with stroke/suspected stroke to hospital emergency department (ED).
2) Patient receives head and neck CT/CTA imaging after brief initial evaluation by hospital ED physician.
3) Technologist processes and reconstructs the CT/CTA imaging and manually routes to hospital picture archiving and communication system (PACS).
4) Radiologist reads CT/CTA imaging.
5) If needed, a neuroradiology consult is sought.
6) A radiological diagnosis of LVO (ischemic stroke) is made.
7) The radiologist informs hospital ED physician of positive LVO either verbally or in the radiologist report.
8) ED physician performs comprehensive exam and refers the patient to a stroke neurologist.
9) The stroke neurologist reviews the CT/CTA imaging and clinical history and determines whether to prescribe or recommend prescription of thrombolysis with tPA.
10) The stroke neurologist refers the patient to a neurointerventional surgeon. Together they decide whether the patient is a candidate for mechanical thrombectomy.
11) If appropriate, the patient proceeds to treatment with mechanical thrombectomy.

**Technology:**

ContaCT is radiological computer-assisted triage and notification software system intended for use by hospital networks and trained clinicians that analyzes CT angiogram (CTA) images of the brain acquired in the acute setting. The ContaCT analysis runs in parallel to the hospital's usual standard of care CTA image analysis workflow.

According to the requester, facilities utilizing the ContaCT system can substantially shorten the period of time between when the patient receives stroke CT/CTA imaging (step 2) and when the patient is referred to a stroke neurologist and neurointerventional surgeon (steps 9 and 10). In

addition, the requester reported ContaCT streamlines this workflow by using artificial intelligence to analyze CTA images of the brain automatically and notifying the stroke neurologist and neurointerventional surgeon that a suspected LVO has been identified, enabling them to review images and make treatment decisions faster. Shortening the time to identification of LVO is critical because the efficacy of treatment in patients with acute ischemic stroke decreases as the time from symptom onset to treatment increases.

**Current Coding:** The interpretation of imaging procedures and notification of findings is not reported separately for inpatient hospital coding. Facilities can report the CT or CT angiogram using the appropriate code in section B, Imaging.

**Option 1.** Do not create new ICD-10-PCS codes for head and neck CTA with computer-aided triage and notification. Continue using current codes as listed in current coding.

**Option 2.** Add existing qualifier value D Intracranial in table 4A0, Measurement of Physiological Systems, applied to the physiological system Arterial, the approach value External, and the function value Flow, to identify the use of software that analyzes CT angiogram of the head and neck for large vessel occlusion (LVO). Continue to report the CT angiogram using the appropriate code in section B, Imaging, as listed in current coding.

| | | | |
|---|---|---|---|
| *Section* **4** Measurement and Monitoring<br>*Body System* **A** Physiological Systems<br>*Operation* **0** Measurement: Determining the level of a physiological or physical function at a point in time | | | |
| *Body System* | *Approach* | *Function / Device* | *Qualifier* |
| **3** Arterial | **X** External | **5** Flow | **ADD D** Intracranial |

**Option 3.** Create a new code in Section X, New Technology, to identify the use of software that analyzes CT angiogram of the head and neck for large vessel occlusion (LVO). Continue to report the CT angiogram using the appropriate code in section B, Imaging, as listed in current coding.

| | | | |
|---|---|---|---|
| *Section* **X** New Technology<br>*Body System* **X** Physiological Systems<br>*Operation* **E** Measurement: Determining the level of a physiological or physical function at a point in time | | | |
| *Body Part* | *Approach* | *Device / Substance / Technology* | *Qualifier* |
| **D** Intracranial Artery | **X** External | **P** Arterial Flow Analysis | **6** New Technology Group 6 |

**CMS Recommendation:** We are inviting public comment.

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

**References:**


1. Benjamin EJ, Muntner P, Alonso A, etal. Heart disease and stroke statistics—2019 update: a report from the American Heart Association. Circulation. 2019;139:e56–e528.
2. Rennert RC, Wali AR, Steinberg JA, et al. Epidemiology, Natural History, and Clinical Presentation of Large Vessel Ischemic Stroke. Neurosurgery. 2019;85(suppl_1):S4–S8. doi:10.1093/neuros/nyz042

3. Mueller-Kronast NH, Zaidat OO, Froehler MT, et al. Systematic evaluation of patients treated with neurothrombectomy devices for acute ischemic stroke: primary results of the STRATIS registry. Stroke. 2017;48(10):2760-2768.
4. Fransen PS, Berkhemer OA, Lingsma HF, et al. Time to reperfusion and treatment effect for acute ischemic stroke: a randomized clinical trial. JAMA Neurol. 2016;73:190-196.

## Administration of Fetroja® (cefiderocol)

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

**New Technology Application?** Yes, a New Technology Add-on Payment (NTAP) application was submitted for FETROJA® (cefiderocol) for FY 2021.

**Food & Drug Administration (FDA) Approved?** Yes. FDA approval was obtained on November 14, 2019. FETROJA® received the FDA's Qualified Infectious Disease Product (QIDP) designation. The QIDP designation is given to antibacterial and antifungal drug products intended to treat serious or life-threatening infections under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act.

**Background:** FETROJA® (cefiderocol) is a cephalosporin antibacterial drug for treatment of patients 18 years of age or older with complicated urinary tract infections (cUTI), including pyelonephritis caused by susceptible Gram-negative microorganisms, who have limited or no alternative treatment options.

Complicated urinary tract infections (cUTIs) are the second leading cause of hospitalization in the elderly and have substantial morbidity and worse outcomes if the causative pathogens are carbapenem-resistant (CR). cUTIs are most frequently caused by *Escherichia coli* (65%) and *Klebsiella pneumoniae* (8%). Bloodstream infection (BSI) is often associated with cUTI, known as urosepsis, with an associated mortality rate of 9–31%. The most frequent causes of urosepsis with CR organisms are *Pseudomonas aeruginosa* (44%), *K. pneumoniae* (22%), *E. cloacae* (8%), *P. mirabilis* (8%) and *Stenotrophomonas maltophilia* (5%). Patients who develop cUTI due to a CR pathogen are at greater risk for prolonged hospital stays and progression to a BSI or urosepsis. Carbapeneum resistance is a growing problem in the US and around the world, with increasing infections due to strains that are resistant to most or all currently available antibiotics.

FETROJA® has potent bactericidal activity against all the above listed pathogens, which includes the three bacterial pathogens categorized as "Priority 1, Critical" in the World Health Organization (WHO) "Global Priority List of Antibiotic-Resistant Bacteria to Guide Research, Discovery, and Development of New Antibiotics", namely:

• *Acinetobacter baumannii*, carbapenem-resistant

• *Pseudomonas aeruginosa*, carbapenem-resistant

• *Enterobacteriaceae*, carbapenem-resistant, 3rd generation cephalosporin-resistant

*Dosage and Administration*

The recommended dosage of FETROJA® is 2 grams administered every 8 hours by intravenous (IV) infusion over 3 hours in adults with a creatinine clearance (CLcr) of 60 to 119 mL/min.

Dosage adjustment is recommended for patients with CLcr less than 60 mL/min or for patients with CLcr 120 mL/min or greater.

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

3E03329 Introduction of other anti-infective into peripheral vein, percutaneous approach3E04329 Introduction of other anti-infective into central vein, percutaneous approach

**Option 1.** Do not create new ICD-10-PCS codes for intravenous administration of FETROJA® (cefiderocol). Continue using current codes as listed in Current Coding.

**Option 2.** Create new codes in section X, New Technology, to identify intravenous infusion of FETROJA® (cefiderocol).

| | | | |
|---|---|---|---|
| *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<br>**4** Central Vein | **3** Percutaneous | **ADD A** Cefiderocol Anti-infective | **6** New Technology Group 6 |

**CMS Recommendation:** Option 2.

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

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## Implantable Fracture Reduction System

**Issue:** Currently there are no unique ICD-10-PCS codes to describe the implantation of a fracture reduction system to restore vertebral body height in osteoporotic vertebral compression fractures.

**New Technology Application?** Yes. A New Technology Add-on Application (NTAP) has been submitted for FY 2021.

**Food and Drug Administration (FDA) Approval?** Yes. The implantable fracture reduction system (SpineJack® Expansion Kit) received 510(k) clearance on August 30, 2018 (K181262) and is indicated for use in the reduction of painful osteoporotic vertebral compression fractures. It is intended to be used in combination with Stryker VertaPlex and VertaPlex HV bone cements.

**Background:** Osteoporotic vertebral compression fractures (VCFs) generally occur in patients with osteoporosis. Vertebral compression fractures occur when a vertebral body collapses usually in the thoracic or lumbar spine. Osteoporotic VCF treatment outcomes are heavily tied to the amount of vertebral body height restored and current surgical fracture treatments like vertebroplasty and kyphoplasty do not restore the vertebral body to full height. The SpineJack® implantable fracture reduction system is a mechanical expandable implant intended to reduce the fracture and restore the anatomy. The restoration of the vertebral body height and stabilization of the fracture provides pain relief and improves mobility for the patient. The SpineJack® system also protects against adjacent level fractures, which may occur due to changes in the load distributed to adjacent vertebral bodies after an osteoporotic compression fracture.

**Technology and Procedure:** The minimally invasive surgical technique is performed via a percutaneous transpedicular approach using fluoroscopic guidance. The typical patient is implanted with two SpineJack® devices for each vertebral body treated. The SpineJack® intervertebral body implants are inserted bilaterally into the vertebral body then mechanically expanded in a craniocaudal direction, restoring the vertebral height and creating a cavity supported by the expanded implants. The area surrounding the implants is then filled with PMMA bone cement injected at low pressure. As it hardens, the bone cement encapsulates the SpineJack® implants, which helps stabilize the restored vertebral body.

**Current Coding**: Facilities can report the implantation of a fracture reduction system to restore vertebral body height in osteoporotic vertebral compression fractures using the following codes:

0PU43JZ Supplement thoracic vertebra with synthetic substitute, percutaneous approach
0QU03JZ Supplement lumbar vertebra with synthetic substitute, percutaneous approach

This is consistent with published AHA Coding Clinic advice from Second Quarter 2019.

**Coding Options**

**Option 1.** Do not create new ICD-10-PCS codes for the implantation of a fracture reduction system. Continue using current codes as listed in Current Coding.

**Option 2.** Create new codes in section X, New Technology, to identify the implantation of a fracture reduction system.

| | |
|---|---|
| *Section* | **X** New Technology |
| *Body System* | **N** Bones |
| *Operation* | **ADD U** Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part |

| *Body Part* | *Approach* | *Device / Substance / Technology* | *Qualifier* |
|---|---|---|---|
| **0** Lumbar Vertebra<br>**4** Thoracic Vertebra | **3** Percutaneous | **ADD 5** Synthetic Substitute, Mechanically Expandable (Paired) | **6** New Technology Group 6 |

**CMS Recommendation:** Option 2, as described above.

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

## Covered Stents

**Issue:** Currently there is not a unique ICD-10-PCS device value to identify a covered stent (stent graft) for dilation procedures performed to treat peripheral arterial disease in the upper or lower extremity arteries.

**New Technology Application?** No.

**Background:** The use of covered stents (also known as stent grafts) in the management of peripheral arterial disease have been widely used in the U.S. since 2002. Covered stents can be used individually or in combination with other medical devices. With current ICD-10-PCS codes, researchers cannot differentiate between covered stents and non-covered stents (drug-eluting or non-drug eluting).

**Current Coding**: Treatment for an upper or lower extremity artery using a covered stent (stent graft) is coded to table 037 Dilation of Upper Arteries or table 047 Dilation of Lower Arteries using the appropriate body part value, approach value and device value that most accurately describes the intraluminal device (stent).

**Coding Options**

**Option 1.** Do not create new ICD-10-PCS codes to identify a covered stent (stent graft) for dilation procedures performed in the upper or lower extremity arteries. Continue using current codes as listed in Current Coding.

**Option 2.** Create new device values L, M, N, and P in table 037, Dilation of Upper Arteries and table 047, Dilation of Lower Arteries, to identify a covered stent used in the treatment of arterial disease.

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

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **0** Internal Mammary Artery, Right<br>**1** Internal Mammary Artery, Left<br>**2** Innominate Artery<br>**3** Subclavian Artery, Right<br>**4** Subclavian Artery, Left<br>**5** Axillary Artery, Right<br>**6** Axillary Artery, Left<br>**7** Brachial Artery, Right<br>**8** Brachial Artery, Left | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **4** Intraluminal Device, Drug-eluting<br>**5** Intraluminal Device, Drug-eluting, Two<br>**6** Intraluminal Device, Drug-eluting, Three<br>**7** Intraluminal Device, Drug-eluting, Four or More<br>**E** Intraluminal Device, Two<br>**F** Intraluminal Device, Three<br>**G** Intraluminal Device, Four or More<br>**ADD L** Intraluminal Device, Covered Stent<br>**ADD M** Intraluminal Device, Covered Stent, Two<br>**ADD N** Intraluminal Device, Covered Stent, Three<br>**ADD P** Intraluminal Device, Covered Stent, Four or More | **Z** No Qualifier |

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **4** Lower Arteries |
| *Operation* | **7** Dilation: Expanding an orifice or the lumen of a tubular body part |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **C** Common Iliac Artery, Right<br>**D** Common Iliac Artery, Left<br>**E** Internal Iliac Artery, Right<br>**F** Internal Iliac Artery, Left<br>**H** External Iliac Artery, Right<br>**J** External Iliac Artery, Left<br>**K** Femoral Artery, Right<br>**L** Femoral Artery, Left<br>**M** Popliteal Artery, Right<br>**N** Popliteal Artery, Left<br>**P** Anterior Tibial Artery, Right<br>**Q** Anterior Tibial Artery, Left<br>**R** Posterior Tibial Artery, Right<br>**S** Posterior Tibial Artery, Left<br>**T** Peroneal Artery, Right<br>**U** Peroneal Artery, Left<br>**V** Foot Artery, Right<br>**W** Foot Artery, Left<br>**Y** Lower Artery | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **5** Intraluminal Device, Drug-eluting, Two<br>**6** Intraluminal Device, Drug-eluting, Three<br>**7** Intraluminal Device, Drug-eluting, Four or More<br>**E** Intraluminal Device, Two<br>**F** Intraluminal Device, Three<br>**G** Intraluminal Device, Four or More<br>**ADD L** Intraluminal Device, Covered Stent<br>**ADD M** Intraluminal Device, Covered Stent, Two<br>**ADD N** Intraluminal Device, Covered Stent, Three<br>**ADD P** Intraluminal Device, Covered Stent, Four or More | **Z** No Qualifier |

**Option 3.** Create new codes in section X, New Technology, to uniquely identify the use of a covered stent (stent graft) for the treatment of arterial disease in the upper or lower arteries.

| | |
|---|---|
| *Section* | **X** New Technology |
| *Body System* | **2** Cardiovascular System |
| *Operation* | **7** Dilation: Expanding an orifice or the lumen of a tubular body part |

| *Body Part* | *Approach* | *Device / Substance / Technology* | *Qualifier* |
|---|---|---|---|
| **ADD 0** Internal Mammary Artery, Right<br>**ADD 1** Internal Mammary Artery, Left<br>**ADD 2** Innominate Artery<br>**ADD 3** Subclavian Artery, Right<br>**ADD 4** Subclavian Artery, Left<br>**ADD 5** Axillary Artery, Right<br>**ADD 6** Axillary Artery, Left<br>**ADD 7** Brachial Artery, Right<br>**ADD 8** Brachial Artery, Left | **3** Percutaneous | **ADD L** Intraluminal Device, Covered Stent<br>**ADD M** Intraluminal Device, Covered Stent, Two<br>**ADD N** Intraluminal Device, Covered Stent, Three<br>**ADD P** Intraluminal Device, Covered Stent, Four or More | **6** New Technology Group 6 |

| | |
|---|---|
| *Section* | **X** New Technology |
| *Body System* | **2** Cardiovascular System |
| *Operation* | **7** Dilation: Expanding an orifice or the lumen of a tubular body part |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **ADD C** Common Iliac Artery, Right<br>**ADD D** Common Iliac Artery, Left<br>**ADD E** Internal Iliac Artery, Right<br>**ADD F** Internal Iliac Artery, Left<br>**ADD H** External Iliac Artery, Right<br>**ADD J** External Iliac Artery, Left<br>**ADD K** Femoral Artery, Right<br>**ADD L** Femoral Artery, Left<br>**ADD M** Popliteal Artery, Right<br>**ADD N** Popliteal Artery, Left<br>**ADD P** Anterior Tibial Artery, Right<br>**ADD Q** Anterior Tibial Artery, Left<br>**ADD R** Posterior Tibial Artery, Right<br>**ADD S** Posterior Tibial Artery, Left<br>**ADD T** Peroneal Artery, Right<br>**ADD U** Peroneal Artery, Left<br>**ADD V** Foot Artery, Right<br>**ADD W** Foot Artery, Left<br>**ADD Y** Lower Artery | **3** Percutaneous | **ADD L** Intraluminal Device, Covered Stent<br>**ADD M** Intraluminal Device, Covered Stent, Two<br>**ADD N** Intraluminal Device, Covered Stent, Three<br>**ADD P** Intraluminal Device, Covered Stent, Four or More | **6** New Technology Group 6 |

**CMS Recommendation:** CMS is interested in receiving public input. There are concerns with this proposal with respect to the following:

1. Disrupting trend data since there has not been a distinction in the past
2. Inconsistency within/across the classification since not all body systems within the Medical/Surgical section that utilize a covered stent (stent graft) would be included
3. There are other means of collecting this information within facilities, therefore new codes are not necessary

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

## Administration of Lisocabtagene Maraleucel

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

**New Technology Application?** Yes. The requester submitted a New Technology Add-on Payment application for FY 2021.

**Food & Drug Administration (FDA) Approval?** No

**Background:** Diffuse large B-cell lymphoma (DLBCL) is the most common type of Non-Hodgkin Lymphoma (NHL), accounting for approximately 30% percent of newly diagnosed cases of B-cell NHL in the United States.[1] Safety profiles of existing therapies exclude relapsed or refractory (R/R) large B-cell lymphoma patients from being able to undergo treatment with these therapies.[2] For patients who received two or more lines of therapy and have R/R disease, or who are not candidates for existing potentially curative therapies due to advanced age or poor performance status, large B-cell lymphoma remains an incurable disease.

Lisocabtagene maraleucel is anticipated to be indicated for the treatment of adult patients with R/R large B-cell lymphoma after at least two prior therapies. Lisocabtagene maraleucel is an investigational, CD19-directed, autologous chimeric antigen receptor (CAR) T-cell immunotherapy comprising individually formulated CD8 and CD4 CAR T-cells. Lisocabtagene maraleucel component CD4 and CD8 T-cells are purified and cultured separately to maintain compositional control of each cell type. During culture each cell type is separately modified to have the CAR on the cell surface, expanded and quantified, and frozen in two separate cell suspensions (the CD4 and CD8 cell components). Lisocabtagene maraleucel is administered via infusion at the same target dose of CD4 and CD8 CAR T-cells.

Lisocabtagene maraleucel is expected to be administered in both the hospital inpatient and outpatient settings to assure appropriate monitoring of patient adverse events. Lisocabtagene maraleucel is comprised of two individually formulated autologous CD8+CAR+ and CD4+CAR+ cryopreserved T-cell suspensions that are thawed and infused separately in a defined composition. The target dose of Lisocabtagene maraleucel for each patient is 100 x 106 CAR+ viable T-cells (consisting of CD8+ and CD4+ components). The precise number of cells from each component, the dose, is calculated as a volume of final drug product and is administered, in its entirety, by infusion to the patient.

Once the vials of CAR-positive viable T-cells (CD8 component and CD4 component) are removed from frozen storage, the thaw must be carried to completion and the cells administered within two hours. Based on the final count from manufacturing, more than one vial of each of the CD8 and CD4 components may be required to complete a dose.

A separate syringe is prepared for each CD8 and CD4 component vial received. The CD8 component is administered first at an infusion rate of approximately 0.5 mL/minute. If more than one syringe is required for full cell dose of the CD8 component, the volume in each syringe should be administered consecutively without any time between (unless there is a clinical reason to hold

the does, e.g. infusion reaction). The CD4 component is administered second using the same steps described for the CD8 component.

**Current Coding:** There is no unique ICD-10-PCS code to describe administration of lisocabtagene maraleucel. Facilities can report intravenous administration of lisocabtagene maraleucel 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

**Option 1.** Do not create new ICD-10-PCS codes for intravenous administration of lisocabtagene maraleucel. Continue using current codes as listed in Current Coding.
**Option 2.** Create new codes in section X, New Technology, to identify intravenous infusion of 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<br>**4** Central Vein | **3** Percutaneous | **ADD 7** Lisocabtagene maraleucel Antineoplastic | **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.

**References:**


1. Ferlay J, Colombet M, Soerjomataram, et al., Estimating the global cancer incidence and mortality in 2018: GLOBOCAN sources and methods, Int J Cancer. 144: 1941-1953; NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V. 5.2019. © National Comprehensive Cancer Network, Inc. 2019.
2. Smith SD, Reddy P, Sokolova A, et al., Eligibility for CAR T-cell therapy: An analysis of selection criteria and survival outcomes in chemorefractory DLBCL, Am. J. Hematol. 2019; E119: 1-4.

## Administration of OTL-101

**Issue:** There is currently no unique ICD-10-PCS code to describe the Administration of OTL-101.

**New Technology Application?** No.

**Food & Drug Administration (FDA) Approval?** A rolling submission of OTL-101 to the FDA is currently expected to begin in 2020. Orphan Drug Designation was granted on October 21, 2014 and Breakthrough Therapy designation on August 17, 2015.

**Background:** Adenosine deaminase severe combined immunodeficiency (ADA-SCID) is a rare autosomal recessive, monogenic, inherited immune disorder. ADA is a ubiquitously expressed purine salvage enzyme, which metabolizes adenosine and deoxyadenosine. In the absence of ADA, these substrates accumulate in tissues, causing cytotoxicity. As ADA is strongly expressed in the thymus, its absence particularly affects developing thymocytes. The main features of ADA-SCID are profound lymphopenia; impaired differentiation and function of T cells, B cells, and natural killer (NK) cells; recurrent infections; and failure to thrive (Whitmore 2016). However, as ADA is lacking in all tissues, patients are also affected by non-immunological abnormalities, such as hepatic dysfunction, pulmonary insufficiency, renal disease, skeletal alterations, neurological deficits affecting motor function and hearing, and cognitive/behavioral deficits (Whitmore 2016; Booth 2012; Rogers 2001). Many patients with ADA-SCID are diagnosed in the first year of life and rarely survive beyond 1 to 2 years of age unless immune function is restored.

In the United States (US), SCID is usually diagnosed via newborn screening, allowing identification of patients with ADA-SCID early in life (IDF 2019; Kohn 2019a).

- Although ADA-SCID is fatal in the first to second year of life if left untreated, several therapeutic options have been explored over time, in the form of pegylated adenosine deaminase enzyme replacement therapy (PEG-ADA ERT) and allogeneic hematopoietic stem cell transplant (HSCT). PEG-ADA ERT, marketed under the tradename Adagen®, has been available in the US since 1990 and has now been discontinued. More recently, in October 2018, a recombinant form of PEG-ADA ERT has also become available, through the same marketing authorization holder, under the tradename Revcovi®. Patients require either weekly or biweekly intramuscular injections of PEG-ADA ERT to control disease symptoms. Short-term ERT with PEG-ADA provides rapid metabolic detoxification of vital organs and systems, and is useful for stabilizing a recently diagnosed patient while long-term options are explored (Gaspar 2009).

- While long-term use of PEG-ADA ERT can provide clinical stabilization, PEG-ADA ERT alone has not been successful in providing full immune reconstitution and is often associated with autoimmune complications (Gaspar 2009; Sauer 2012). A retrospective study of the long-term effects of PEG-ADA ERT for 5 to 12 years found that, despite initial improvements, lymphocyte counts were below the lower limit of normal for all patients and progressively worsened over time (Chan 2005). A gradual reduction in thymic function and a decline in mitogenic proliferative responses were also observed over time, demonstrating

reduced T-cell function (Chan 2005). Additionally, about 50 to 60% of children treated with PEG-ADA develop anti-ADA antibodies; 10% of these patients produce antibodies which are able to neutralize ADA activity, necessitating an increase in dose, administration of corticosteroids, or cessation of therapy (Gaspar 2009). Sustained autoimmune manifestations have also been reported in 5% of patients receiving PEG-ADA ERT, including 3 cases of fatal autoimmune hemolytic anemia (Sauer 2012; Gaspar 2009). Uncertainty exists about maintenance of long-term immunological and clinical benefits, beyond 8 to 10 years. An additional concern with PEG-ADA ERT beyond 5 years is the emergence of serious complications, including lymphoid and possibly hepatic malignancies, and progression of chronic pulmonary insufficiency (Gaspar 2009).

Hematopoietic stem cell transplant (HSCT) is a potentially curative treatment for ADA-SCID, the effectiveness of which is heavily dependent upon the degree of human leukocyte antigen (HLA) matching between the donor and the patient. A recent study found that the overall survival (OS) rates in a cohort of 106 children with ADA-SCID, followed for a median of 6.5 years, were 86% and 83% after HSCT from a matched sibling or a matched family donor, respectively (Hassan 2012). Less than 20% of patients affected by ADA-SCID are estimated to have access to either of these donor types (i.e., a matched related donor [MRD]) (Sauer 2012; Ferrua 2010). The outcomes were less favorable if an MRD was not available, with OS rates of 67% for patients receiving HSCTs from matched unrelated donors and 43% and 29% for patients receiving HSCTs from haploidentical and mismatched unrelated donors, respectively. The main risks associated with patients receiving an allogeneic HSCT arise from the use of chemotherapeutic conditioning and alloreactivity, particularly in patients receiving grafts from a mismatched donor. For example, patients can develop graft-versus-host disease (GvHD), a condition in which donor cells recognize patient tissues as foreign and mount an immune response. GvHD is a well-known cause of early death following allogeneic HSCT, accounting for 15% of deaths in the first 100 days after transplant (Hassan 2012). The risk of GvHD is usually managed with pre-transplant chemotherapy and potent immunosuppressive medication pre- and post-transplant, which also increases the risk of infection (Pai 2014; Neven 2009). Depending on the degree of matching between donor and recipient, patients undergoing HSCT receive either no conditioning, most often when an MRD HSCT is performed, or a higher dose of chemotherapeutic conditioning than used prior to OTL-101 infusion.

If approved by the FDA, OTL-101 would be the first *ex vivo* autologous $CD34^+$ hematopoietic stem cell progenitor cells (HSPC) based gene therapy (HSPC-GT) available for use in the US intended for the treatment of patients diagnosed with ADA-SCID.

**Technology:** OTL-101 is an investigational autologous $CD34^+$ enriched cell fraction that contains $CD34^+$ HSPCs genetically modified *ex vivo* using a lentiviral vector encoding the ADA complementary deoxyribonucleic acid (cDNA) sequence. These cells are reinfused into patients following a non-myeloablative conditioning regimen, which reduces defective cells and favors the engraftment of genetically modified cells expressing ADA.

Autologous $CD34^+$ HSPCs are harvested from the patient's bone marrow and then genetically modified *ex vivo* with self-inactivating lentiviral vector, which encodes the human ADA cDNA sequence under the regulation of elongation factor 1 alpha short form (EFS), a shortened, intron-less version of the elongation factor 1 alpha gene promoter. The transduced $CD34^+$ HSPCs are then cryopreserved ensuring that the drug product can be released following quality-control testing, prior to the conditioning regimen being administered to the patient. OTL-101 will then be transported to the treatment site in a dry nitrogen shipping container.

The administration details of OTL-101, including information regarding conditioning, will be described in the final prescribing information. OTL-101 should be administered within 2 hours of thawing, and infused intravenously over 5 to 15 minutes without use of a leukocyte depleting filter.

Description and Method of Action of OTL-101

- Unlike allogeneic HSCT, the cells utilized in the OTL-101 procedure originate from the patient; thus, removing the risk of GvHD and eliminating the need for a donor search (Orchard Therapeutics DOF 2018).
- OTL-101, unlike ERT, is a durable treatment that can provide comprehensive immune reconstitution and is a one-time administration of the genetically corrected HSPCs (Orchard Therapeutics DOF 2018).
- OTL-101 utilizes cryopreservation, which allows for a flexible schedule of the infusion of OTL-101, an important feature in patients at risk for recurrent infections and complications from their disease and also permits distribution of the drug product to multiple potential treatment centers (Flinn 2018).

**Current Coding:** There is currently no ICD-10-PCS code to adequately describe the Administration of OTL-101. Facilities can report the intravenous infusion of hematopoietic stem/progenitor cells with the following ICD-10-PCS codes:

30233Y0 Transfusion of autologous hematopoietic stem cells into peripheral vein, percutaneous approach

30243Y0 Transfusion of autologous hematopoietic stem cells into central vein, percutaneous approach

**Code Options**

**Option 1**. Do not create new ICD-10-PCS codes for the intravenous infusion of hematopoietic stem/progenitor cells. Continue using current codes as listed in current coding.

**Option 2.** Create new codes in section 3, Administration, to identify intravenous infusion of hematopoietic stem/progenitor cells.

| | | | |
|---|---|---|---|
| *Section* | **3** Administration | | |
| *Body System* | **0** Circulatory | | |
| *Operation* | **2** Transfusion: Putting in blood or blood products | | |
| *Body System / Region* | *Approach* | *Substance* | *Qualifier* |
| **3** Peripheral Vein<br>**4** Central Vein | **0** Open<br>**3** Percutaneous | **A** Stem Cells, Embryonic | **Z** No Qualifier |
| **3** Peripheral Vein<br>**4** Central Vein | **0** Open<br>**3** Percutaneous | **ADD C** Hematopoietic Stem/Progenitor Cells, Genetically Modified | **ADD 0** Autologous |

**CMS Recommendation: Option 2.** Create new codes in section 3, Administration, to identify intravenous infusion of hematopoietic stem/progenitor cells.

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

## Administration of Soliris® (eculizumab)

**Issue:** There is currently no unique ICD-10-PCS code to describe the administration of Soliris® (eculizumab)

**New Technology Application?** Yes, a New Technology Add-on Payment (NTAP) application was submitted for Soliris® (eculizumab) for the treatment of Neuromyelitis Optica Spectrum Disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) positive for FY 2021.

**Food & Drug Administration (FDA) Approved?** Yes. FDA approval was obtained on June 27, 2019 for the treatment of Neuromyelitis Optica Spectrum Disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) positive.

**Background:** Neuromyelitis Optica Spectrum Disorder (NMOSD) is a rare autoimmune disorder of the Central Nervous System (CNS). This disease affects approximately 1.96 per 100,000 individuals and is characterized by neuroinflammatory relapses that result in progressive and irreversible damage to the optic nerve and spine. Relapses in NMOSD are unpredictable and can cause blindness, paralysis and increased overall mortality. Approximately 90% of patients with NMOSD suffer relapses, approximately 50% of patients with NMOSD have experienced a relapse within one year and approximately 76% of patients do not recover completely from their first relapse. Therefore, a primary goal in the treatment of NMOSD is prompt initiation of relapse prevention upon a diagnosis of NMOSD.

Patients with anti-AQP4 antibody-positive NMOSD develop AQP4-IgG autoantibodies to the water channel protein, AQP4, which is expressed on astrocytes in the CNS. Binding of anti-AQP4 autoantibodies to AQP4 activates the complement cascade which is one of the underlying causes of damage in NMOSD. AQP4 is a specific biomarker for NMOSD, with detection of anti- AQP4 antibodies in serum allowing for a precise diagnosis of NMOSD.

**Description and Method of Action of Soliris®**

Soliris® (eculizumab), a first-in-class complement inhibitor, is the first and only FDA approved therapy for adults with anti-AQP4 antibody-positive NMOSD. Soliris® (eculizumab) is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris® (eculizumab) REMS, prescribers must enroll in the program.

Soliris® (eculizumab) is administered via an IV infusion by a healthcare professional according to the following schedule:

- 900 mg weekly for the first 4 weeks, followed by
- 1200 mg weekly for the fifth dose 1 week later, then
- 1200 mg every 2 weeks thereafter

Soliris® (eculizumab) should be administered at the recommended dosage regimen time points, or within two days of these time points.

Supplemental dosing is required in the setting of concomitant plasmapheresis or plasma exchange, or fresh frozen plasma infusion.

| Type of Plasma Intervention | Most Recent Soliris® | Supplemental Soliris® Dose with Each Plasma | Timing of Supplemental Soliris® Dose |
|---|---|---|---|
| Plasmapheresis or plasma exchange | 300 mg | 300 mg per each plasmapheresis or plasma exchange | Within 60 minutes after each plasmapheresis or plasma exchange |
| | >=600 mg | 600 mg per each plasmapheresis or plasma exchange | |
| Fresh frozen plasma infusion | >=300 mg | 300 mg per infusion of fresh frozen plasma | 60 minutes prior to each infusion or fresh frozen plasma |

**Preparation of Soliris®:**

Dilute Soliris® (eculizumab) to a final admixture concentration of 5 mg/mL by adding the appropriate amount (equal volume of diluent to drug volume) of 0.9% Sodium Chloride Injection, USP; 0.45% Sodium Chloride Injection, USP; 5% Dextrose in Water Injection, USP; or Ringer's Injection, USP to the infusion bag.

The final admixed Soliris® (eculizumab) 5 mg/mL infusion volume is 60 mL for 300 mg doses, 120 mL for 600 mg doses, 180 mL for 900 mg doses or 240 mL for 1200 mg doses.

| Soliris | Diluent | Final |
|---|---|---|
| 300 mg | 30 mL | 60 mL |
| 600 mg | 60 mL | 120 mL |
| 900 mg | 90 mL | 180 mL |
| 1200 mg | 120 mL | 240 mL |

Discard any unused portion left in a vial, as the product contains no preservatives. Prior to administration, the admixture should be allowed to adjust to room temperature [18°-25° C, 64°-77° F]. The admixture must not be heated in a microwave or with any heat source other than ambient air temperature. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Administer the Soliris® (eculizumab) admixture by intravenous infusion over 35 minutes in adults via gravity feed, a syringe-type pump, or an infusion pump. Admixed solutions of Soliris® are stable for 24hr at 2°-8° C (36°- 46° F) and at room temperature.

If an adverse reaction occurs during the administration of Soliris® (eculizumab), the infusion may be slowed or stopped at the discretion of the physician. If the infusion is slowed, the total infusion time should not exceed two hours in adults. Monitor the patient for at least one hour following completion of the infusion for signs or symptoms of an infusion reaction.

Soliris® (eculizumab) has a boxed warning for risk of serious meningococcal infections. Life-

threatening and fatal meningococcal infections have occurred in patients treated with Soliris® (eculizumab) and may become rapidly life-threatening or fatal if not recognized and treated early. Vaccination reduces, but does not eliminate, the risk of meningococcal infections. Patients should be immunized with meningococcal vaccines, in compliance with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies, at least 2 weeks prior to administering the first dose of Soliris® (eculizumab), unless the risks of delaying Soliris® (eculizumab) therapy outweigh the risks of developing a meningococcal infection. Patients should be monitored for early signs of meningococcal infections, and evaluated immediately if infection is suspected.

**Current Coding:** There is no unique ICD-10-PCS code to describe the administration of Soliris® (eculizumab). The following ICD-10-PCS procedure codes may be used to report the administration of Soliris® (eculizumab) in the inpatient settings:

3E0330M Introduction of monoclonal antibody into peripheral vein, percutaneous approach
3E0430M Introduction of monoclonal antibody into the central vein, percutaneous approach
3E033GC Introduction of other therapeutic substance into the peripheral vein, percutaneous approach
3E043GC Introduction of other therapeutic substance into central vein, percutaneous approach

**Coding Options:**

**Option 1.** Do not create new ICD-10-PCS codes for intravenous administration of Soliris® (eculizumab). Continue using current codes as listed in Current Coding.

**Option 2.** Create new codes in section X, New Technology, to identify intravenous infusion of Soliris® (eculizumab).

| | |
|---|---|
| *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<br>**4** Central Vein | **3** Percutaneous | **ADD C** Eculizumab | **6** New Technology Group 6 |

**Recommendation: Option 2.** Create new codes in section X, New Technology, to identify intravenous infusion of Soliris® (eculizumab).

## Reverse Flow Embolic Neuroprotection During Transcarotid Arterial Revascularization

**Issue:** There is currently no unique ICD-10-PCS code to describe Reverse Flow Embolic Neuroprotection During Transcarotid Arterial Revascularization (TCAR), an intraoperative filtration procedure that utilizes an extracorporeal flow reversal circuit.

**New Technology Application?** No.

**Food & Drug Administration (FDA) Approval?** The system used to perform the intraoperative neuroprotection procedure was FDA approved in 2015 for use with placement of a carotid artery stent via transcarotid access, which is its sole application at this time.

**Background:** The Reverse Flow Embolic Neuroprotection procedure is performed during TCAR to reduce the risk of stroke with placement of a carotid artery stent. Conventionally, access for carotid artery stenting is obtained via the femoral artery with the instrumentation being advanced under fluoroscopy to the site of plaque obstructing the carotid artery. TCAR is a variation on placement of a carotid artery stent. In TCAR, access is obtained directly at the carotid artery below the plaque, precluding the need to navigate instrumentation throughout the peripheral and central vasculature and reducing fluoroscopy exposure time.

Periprocedural neurological injury, particularly stroke, is a known complication of carotid artery stenting. Dilation of the atherosclerotic lesion and placement of the stent can cause debris to break loose, creating emboli which travel to the brain. Similarly, stroke is also a known complication of other procedures, particularly transcatheter aortic valve replacement (TAVR), and adjunctive filtration procedures are sometimes performed with TAVR to capture the emboli before they can reach the brain. The neuroprotection procedure described here uses a different technique.

**Technology:** During the Reverse Flow Embolic Neuroprotection procedure performed with TCAR, an extracorporeal circuit is created intraoperatively to temporarily redirect and reverse blood flow away from the carotid artery during placement of the stent. Flow reversal keeps debris moving away from the brain, protecting it from emboli.

The TCAR procedure begins with a cut-down in the neck to access the common carotid artery. After placement of a vessel loop and puncture of the common carotid artery, a sheath is placed within the artery and connected to an extracorporeal circuit that redirects the blood away from the carotid artery and into the femoral vein. There is no pump involved. The circuit works via a pressure gradient, in which blood naturally moves from the high-pressure carotid artery to the low-pressure femoral vein.

After the blood flow reversal is established, the same transcarotid access site and sheath are used to deliver the predilation balloon to the site of the plaque followed by delivery of the stent itself. These interventions take place above the site of the puncture so there is no blood flow within the carotid artery at that time. After the physician confirms satisfactory placement of the stent, the sheath is removed disconnecting the flow reversal neuroprotection circuit. The return of normal blood flow through the carotid artery is observed and the vessel is closed to complete the procedure.

Clinical studies have demonstrated that temporary reversal of blood flow away from the carotid artery on one side does not itself cause neurological injury. This is because the brain continues to be perfused by blood flow from the contralateral side as well as blow flood through collateral vessels within the brain.

Unlike other cerebral embolic filtration procedures currently used with carotid artery stenting and TVAR, the filter is not placed within the vasculature. The filter is within the apparatus of the extracorporeal circuit and continually filters out debris during the length of the procedure, returning the refined blood into the femoral vein where it reenters the general circulation.

**Current Coding:** There is no unique ICD-10-PCS code for Embolic Neuroprotection during TCAR procedures using an extracorporeal flow reversal circuit. Code for the TCAR procedure only, with the appropriate values from table 037, Dilation of Upper Arteries.

**Coding Options**

**Option 1**. Do not create new ICD-10-PCS codes to identify Embolic Neuroprotection during TCAR procedures using an extracorporeal flow reversal circuit. Continue using current codes as listed in Current Coding.

**Option 2.** Create new qualifier value A Extracoporeal Flow Reversal Circuit in table 5A0, Extracorporeal or Systemic Assistance, applied to the physiological system 5 Circulatory, the duration value A Intraoperative, and the function value 0 Filtration, to identify the use of an extracorporeal flow reversal circuit for embolic neuroprotection during TCAR. A separate code is assigned for the TCAR procedure, as listed in current coding.

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

| *Body System* | *Duration* | *Function* | *Qualifier* |
|---|---|---|---|
| **5** Circulatory | **1** Intermittent<br>**2** Continuous | **2** Oxygenation | **1** Hyperbaric<br>**C** Supersaturated |
| **5** Circulatory | **ADD A** Intraoperative | **ADD 0** Filtration | **ADD A** Extracorporeal Flow Reversal Circuit |

**Option 3.** Create new codes in Section X, New Technology, to identify the use of an extracorporeal flow reversal circuit for embolic neuroprotection during TCAR. A separate code is assigned for the TCAR procedure, as listed in current coding.

| | |
|---|---|
| *Section* | **X** New Technology |
| *Body System* | **2** Cardiovascular System |
| *Operation* | **A** Assistance: Taking over a portion of a physiological function by extracorporeal means |

| *Body Part* | *Approach* | *Device / Substance / Technology* | *Qualifier* |
|---|---|---|---|
| **5** Innominate Artery and Left Common Carotid Artery | **3** Percutaneous | **1** Cerebral Embolic Filtration, Dual Filter | **2** New Technology Group 2 |
| **6** Aortic Arch | **3** Percutaneous | **2** Cerebral Embolic Filtration, Single Deflection Filter | **5** New Technology Group 5 |

| | | | |
|---|---|---|---|
| **ADD H** Common Carotid Artery, Right<br>**ADD J** Common Carotid Artery, Left | **3** Percutaneous | **ADD 3** Cerebral Embolic Filtration, Extracorporeal Flow Reversal Circuit | **6** New Technology Group 6 |

**CMS Recommendation: Option 3.** Create new codes in Section X, New Technology, to identify the use of an extracorporeal flow reversal circuit for embolic neuroprotection during TCAR. A separate code is assigned for the TCAR procedure, as listed in current coding.

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

## Administration of TECENTRIQ® (atezolizumab)

**Issue:** There is currently no unique ICD-10-PCS code to describe the administration of TECENTRIQ® (atezolizumab) for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

**New Technology Application?** Yes. A New Technology Add-On Payment (NTAP) the administration of TECENTRIQ® (atezolizumab) was submitted for Fiscal Year 2021.

**Food & Drug Administration (FDA) Approved?** Yes. TECENTRIQ® (atezolizumab) received FDA approval for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) on March 18, 2019.
Note: While not subject to this application, TECENTRIQ® (atezolizumab) has also received the following FDA approvals.

- May 18, 2016 for the treatment of patients with locally advanced or metastatic urothelial carcinoma;
- October 18, 2016 for the treatment of metastatic NSCLC patients who have disease progression during or following platinum-containing chemotherapy;
- December 6, 2018 to be used in combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations for the first-line treatment of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations;
- March 8, 2019 for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer; and
- December 3, 2019 to be used in combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations

**Background:** TECENTRIQ® (atezolizumab) is an intravenous cancer drug indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). Small cell lung cancer (SCLC) is a high-grade neuroendocrine tumor that comprises small cells with minimal cytoplasm and poorly defined cell borders, and in which a nucleolus is either absent or unremarkable. The most aggressive of all lung cancers, SCLC accounts for about 10%-15% of lung cancer cases. Key characteristics of SCLC include rapid doubling time and early development of widespread metastases. About 72% of SCLC cases are diagnosed at the extensive stage, which is associated with a 5-year survival rate of only 2.9%.

TECENTRIQ® (atezolizumab) is a programmed death-ligand 1 (PD-L1) blocking antibody with several different oncology indications, including one in combination with carboplatin and etoposide, for the first-line treatment of adult patients with ES-SCLC. PD-L1, a protein expressed on the surface of cancer cells, allows them to deactivate the T cells of the patient's immune system that would otherwise kill them. TECENTRIQ® (atezolizumab) blocks the protective PD-L1 protein, rendering the cancer cells susceptible to attack.

TECENTRIQ® (atezolizumab) plus standard of care is a category 1 preferred initial treatment for patients with ES-SCLC presently listed in the NCCN guidelines.

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

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

**Option 1.** Do not create new ICD-10-PCS codes for intravenous administration of TECENTRIQ® (atezolizumab). Continue using current codes as listed in Current Coding.

**Option 2**. Create new codes in section X, New Technology, to identify intravenous infusion of TECENTRIQ® (atezolizumab).

| | | | |
|---|---|---|---|
| *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<br>4 Central Vein | 3 Percutaneous | **ADD D** Atezolizumab Antineoplastic | 6 New Technology Group 6 |

**Recommendation:** Option 2. Create new codes in section X, New Technology, to identify intravenous infusion of TECENTRIQ® (atezolizumab).

## Section X Updates

## ICD-10-PCS Index Addenda

Lttr S
Main Add Sentinel (tm) Cerebral Protection System (CPS) X2A5312

## ICD-10-PCS Body Part Key Addenda

Axis 4 Body Part
Row
Term Abdominal Sympathetic Nerve
Includes Add Renal nerve

## ICD-10-PCS Definitions Addenda

Section 0 Medical and Surgical
Axis 3 Operation
Row
Term Supplement
Includes Delete Herniorrhaphy using mesh, free nerve graft, mitral valve ring annuloplasty, put a new acetabular liner in a previous hip replacement
Includes Add Herniorrhaphy using mesh, mitral valve ring annuloplasty, put a new acetabular liner in a previous hip replacement

## ICD-10-PCS Table Addenda

**Medical and Surgical Section**
**Axis 3 Root Operation**

**Male Reproductive Organ Transplant**

| Source | Description | Code specification |
|---|---|---|
| 2019, Coding Clinic Editorial Advisory Board and CMS internal review | In the Male Reproductive body system of the Medical and Surgical section, create new ICD-10-PCS table 0VY Transplantation of Male Reproductive System applied to the body part values 5 Scrotum and S Penis, and the approach value Open, to identify transplant procedures of these organs. | Add: 0VY[5S]0Z[012] (6 codes) |

**EXAMPLE**

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **V** Male Reproductive System |
| *Operation* | **ADD Y** Transplantation: Putting in or on all or a portion of a living body part taken from another individual or animal to physically take the place and/or function of all or a portion of a similar body part |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **5** Scrotum<br>**S** Penis | **0** Open | **Z** No Device | **0** Allogeneic<br>**1** Syngeneic<br>**2** Zooplastic |

**Peripheral Intravascular Lithotripsy (IVL)**

| Source | Description | Code specification |
|---|---|---|
| 2019, public comment | In the Lower Arteries body system of the Medical and Surgical section, create new ICD-10-PCS table 04F Fragmentation of Lower Arteries applied to the lower extremity body part values, the percutaneous approach, and qualifier value Z No Qualifier, to identify peripheral intravascular lithotripsy (IVL) utilized to treat calcified lesions in the lower extremities. | Add:<br>04F[CDEFHJKLMNPQRSTUY]3ZZ<br>(17 codes) |

**EXAMPLE**

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

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **C** Common Iliac Artery, Right<br>**D** Common Iliac Artery, Left<br>**E** Internal Iliac Artery, Right<br>**F** Internal Iliac Artery, Left<br>**H** External Iliac Artery, Right<br>**J** External Iliac Artery, Left<br>**K** Femoral Artery, Right<br>**L** Femoral Artery, Left<br>**M** Popliteal Artery, Right<br>**N** Popliteal Artery, Left<br>**P** Anterior Tibial Artery, Right<br>**Q** Anterior Tibial Artery, Left<br>**R** Posterior Tibial Artery, Right<br>**S** Posterior Tibial Artery, Left<br>**T** Peroneal Artery, Right<br>**U** Peroneal Artery, Left<br>**Y** Lower Artery | **3** Percutaneous | **Z** No Device | **Z** No Qualifier |

**Peripheral Intravascular Lithotripsy (IVL) - ICD-10-PCS Index Addenda**

Lttr I
Main Add Intravascular Lithotripsy (IVL) see Fragmentation

Lttr L
Main Add Lithoplasty see Fragmentation

| | | |
|---|---|---|
| Lttr | P | |
| Main | Add | Peripheral Intravascular Lithotripsy (Peripheral IVL) see Fragmentation |
| Lttr | S | |
| Main | Add | Shockwave Intravascular Lithotripsy (Shockwave IVL) see Fragmentation |

**Medical and Surgical Section**
**Axis 6 Device**

**Removal of External Fixation Device**

| Source | Description | Code specification |
|---|---|---|
| 2019, public comment & CMS internal review | In the Medical and Surgical section table 0QP, Removal, Lower Bones, add device value 5 External Fixation Device, applied to the body part values 0 Lumbar Vertebra, 1 Sacrum, 4 Acetabulum Right, 5 Acetabulum Left and S Coccyx to identify when an external fixation device is removed from these body parts. | Add: 0QP[0145S][034]5Z (15 codes)<br><br>0QP[0145S]X5Z (5 codes) |

**EXAMPLE**

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **Q** Lower Bones |
| *Operation* | **P** Removal: Taking out or off a device from a body part |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **0** Lumbar Vertebra<br>**1** Sacrum<br>**4** Acetabulum, Right<br>**5** Acetabulum, Left<br>**S** Coccyx | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **4** Internal Fixation Device<br>**ADD 5** External Fixation Device<br>**7** Autologous Tissue Substitute<br>**J** Synthetic Substitute<br>**K** Nonautologous Tissue Substitute | **Z** No Qualifier |

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **Q** Lower Bones |
| *Operation* | **P** Removal: Taking out or off a device from a body part |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **0** Lumbar Vertebra<br>**1** Sacrum<br>**4** Acetabulum, Right<br>**5** Acetabulum, Left<br>**S** Coccyx | **X** External | **4** Internal Fixation Device<br>**ADD 5** External Fixation Device | **Z** No Qualifier |

**Insertion of Radioactive Element**

| Source | Description | Code specification |
|---|---|---|
| 2019, public comment & CMS internal review | In the Medical and Surgical section, add the device value 1 Radioactive Element to the following root operation Insertion tables, to support complete coding for brachytherapy procedures where a radioactive element is left in the body at the end of the procedure:<br>– 00H Insertion of Central Nervous System and Cranial Nerves<br>– 01H Insertion of Peripheral Nervous System<br>– 07H Insertion of Lymphatic and Hemic Systems<br>– 09H Insertion of Ear, Nose, Sinus<br>– 0CH Insertion of Mouth and Throat<br>– 0DH Insertion of Gastrointestinal System<br>– 0FH Insertion of Hepatobiliary System and Pancreas<br>– 0GH Insertion of Endocrine System<br>– 0TH Insertion of Urinary System<br>– 0UH Insertion of Female Reproductive System<br>– 0VH Insertion of Male Reproductive System | Add:<br>00H[06EUV][034]1Z (15 codes)<br>01HY[034]1Z (3 codes)<br>07H[KLMNPT][034]1Z (18 codes)<br>09H[DE][034]1Z (6 codes)<br>09H[HJKY][03478]1Z (20 codes)<br>09HN[78]1Z (2 codes)<br>0CH[AS][0378]1Z (8 codes)<br>0CHY[03]1Z (2 codes)<br>0CHY[78]1Z (2 codes)<br>0DH6[034]1Z (3 codes)<br>0DH6[78]1Z (2 codes)<br>0DH[89AB][03478]1Z (20 codes)<br>0DHE[03478]1Z (5 codes)<br>0FH[04G][034]1Z (9 codes)<br>0GHS[034]1Z (3 codes)<br>0TH[59BD][03478]1Z (20 codes)<br>0UH3[034]1Z (3 codes)<br>0UH3[78]1Z (2 codes)<br>0UH9[078]1Z (3 codes)<br>0VHD[03478]1Z (5 codes) |

**EXAMPLES**

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **0** Central Nervous System and Cranial Nerves |
| *Operation* | **H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **0** Brain | **0** Open | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**3** Infusion Device<br>**4** Radioactive Element, Cesium-131 Collagen Implant<br>**M** Neurostimulator Lead<br>**Y** Other Device | **Z** No Qualifier |
| **0** Brain | **3** Percutaneous<br>**4** Percutaneous Endoscopic | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**3** Infusion Device<br>**M** Neurostimulator Lead<br>**Y** Other Device | **Z** No Qualifier |
| **6** Cerebral Ventricle<br>**E** Cranial Nerve<br>**U** Spinal Canal<br>**V** Spinal Cord | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**3** Infusion Device | **Z** No Qualifier |

| | | | |
|---|---|---|---|
| | | **M** Neurostimulator Lead<br>**Y** Other Device | |

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **1** Peripheral Nervous System |
| *Operation* | **H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part |

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **Y** Peripheral Nerve | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**M** Neurostimulator Lead<br>**Y** Other Device | **Z** No Qualifier |

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **7** Lymphatic and Hemic Systems |
| *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* |
|---|---|---|---|
| **K** Thoracic Duct<br>**L** Cisterna Chyli<br>**M** Thymus<br>**N** Lymphatic<br>**P** Spleen<br>**ADD T** Bone Marrow | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **ADD 1** Radioactive Element<br>**3** Infusion Device<br>**Y** Other Device | **Z** No Qualifier |

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **9** Ear, Nose, Sinus |
| *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* |
|---|---|---|---|
| **D** Inner Ear, Right<br>**E** Inner Ear, Left | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **ADD 1** Radioactive Element<br>**4** Hearing Device, Bone Conduction<br>**5** Hearing Device, Single Channel Cochlear Prosthesis<br>**6** Hearing Device, Multiple Channel Cochlear Prosthesis<br>**S** Hearing Device | **Z** No Qualifier |
| **H** Ear, Right<br>**J** Ear, Left<br>**K** Nasal Mucosa and Soft Tissue<br>**Y** Sinus | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic<br>**7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**Y** Other Device | **Z** No Qualifier |
| **N** Nasopharynx | **7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**B** Intraluminal Device, Airway | **Z** No Qualifier |

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

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **A** Salivary Gland<br>**S** Larynx | **0** Open<br>**3** Percutaneous<br>**7** Via Natural or Artificial Opening | **ADD 1** Radioactive Element<br>**Y** Other Device | **Z** No Qualifier |

| | | | |
|---|---|---|---|
| | **8** Via Natural or Artificial Opening Endoscopic | | |
| **Y** Mouth and Throat | **0** Open<br>**3** Percutaneous | **ADD 1** Radioactive Element<br>**Y** Other Device | **Z** No Qualifier |
| **Y** Mouth and Throat | **7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**B** Intraluminal Device, Airway<br>**Y** Other Device | **Z** No Qualifier |

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

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **6** Stomach | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**3** Infusion Device<br>**D** Intraluminal Device<br>**M** Stimulator Lead<br>**U** Feeding Device<br>**Y** Other Device | **Z** No Qualifier |
| **6** Stomach | **7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**3** Infusion Device<br>**D** Intraluminal Device<br>**U** Feeding Device<br>**Y** Other Device | **Z** No Qualifier |
| **8** Small Intestine<br>**9** Duodenum<br>**A** Jejunum<br>**B** Ileum | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic<br>**7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**3** Infusion Device<br>**D** Intraluminal Device<br>**U** Feeding Device | **Z** No Qualifier |
| **E** Large Intestine | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic<br>**7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**D** Intraluminal Device | **Z** No Qualifier |

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **F** Hepatobiliary System and Pancreas |
| *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** Liver<br>**4** Gallbladder<br>**G** Pancreas | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**3** Infusion Device<br>**Y** Other Device | **Z** No Qualifier |

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

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **S** Endocrine Gland | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **ADD 1** Radioactive Element | **Z** No Qualifier |

| | | | |
|---|---|---|---|
| | | **2** Monitoring Device<br>**3** Infusion Device<br>**Y** Other Device | |

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

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **5** Kidney | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic<br>**7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**3** Infusion Device<br>**Y** Other Device | **Z** No Qualifier |
| **9** Ureter | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic<br>**7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**3** Infusion Device<br>**M** Stimulator Lead<br>**Y** Other Device | **Z** No Qualifier |
| **B** Bladder | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic<br>**7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**3** Infusion Device<br>**L** Artificial Sphincter<br>**M** Stimulator Lead<br>**Y** Other Device | **Z** No Qualifier |
| **D** Urethra | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic<br>**7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**2** Monitoring Device<br>**3** Infusion Device<br>**L** Artificial Sphincter<br>**Y** Other Device | **Z** No Qualifier |

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

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **3** Ovary | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic | **ADD 1** Radioactive Element<br>**3** Infusion Device<br>**Y** Other Device | **Z** No Qualifier |
| **3** Ovary | **7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**Y** Other Device | **Z** No Qualifier |
| **9** Uterus | **0** Open<br>**7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **ADD 1** Radioactive Element<br>**H** Contraceptive Device | **Z** No Qualifier |

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

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **0** Prostate<br>**ADD D** Testis | **0** Open<br>**3** Percutaneous<br>**4** Percutaneous Endoscopic<br>**7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **1** Radioactive Element | **Z** No Qualifier |

**Medical and Surgical Section**
**Axis 7 Qualifier**

**Left to Right Atrial Shunt**

| Source | Description | Code specification |
|---|---|---|
| 2019, public comment & CMS internal review | In the Medical and Surgical section table 021, Bypass of Heart and Great Vessels, create new qualifier value 6 Atrium, Right applied to the body part value 7 Atrium, Left and applied to the approach value Percutaneous, to identify procedures such as unidirectional left to right atrial shunt performed for treatment of congestive heart failure. | Add: 02173J6 (1 code) |

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

| *Body Part* | *Approach* | *Device* | *Qualifier* |
|---|---|---|---|
| **7** Atrium, Left<br>**V** Superior Vena Cava | **0** Open<br>**4** Percutaneous Endoscopic | **8** Zooplastic Tissue<br>**9** Autologous Venous Tissue<br>**A** Autologous Arterial Tissue<br>**J** Synthetic Substitute<br>**K** Nonautologous Tissue Substitute<br>**Z** No Device | **P** Pulmonary Trunk<br>**Q** Pulmonary Artery, Right<br>**R** Pulmonary Artery, Left<br>**S** Pulmonary Vein, Right<br>**T** Pulmonary Vein, Left<br>**U** Pulmonary Vein, Confluence |
| **7** Atrium, Left | **ADD 3** Percutaneous | **J** Synthetic Substitute | **ADD 6** Atrium, Right |

**Pancreaticogastrostomy**

| Source | Description | Code specification |
|---|---|---|
| 2019, CMS internal review | In the Medical and Surgical section table 0F1, Bypass of Hepatobiliary System and Pancreas, add qualifier value 4 Stomach, applied to the body part value D Pancreatic Duct, to identify procedures such as pancreaticogastrostomy performed for decompression of the pancreatic ductal system. | Add: 0F1D[04][DZ]4 (4 codes) |

**EXAMPLE**

| | |
|---|---|
| *Section* | **0** Medical and Surgical |
| *Body System* | **F** Hepatobiliary System and Pancreas |

| *Operation* | **1** Bypass: Altering the route of passage of the contents of a tubular body part | | |
|---|---|---|---|
| *Body Part* | *Approach* | *Device* | *Qualifier* |
| **D** Pancreatic Duct | **0** Open<br>**4** Percutaneous Endoscopic | **D** Intraluminal Device<br>**Z** No Device | **3** Duodenum<br>**ADD 4** Stomach<br>**B** Small Intestine<br>**C** Large Intestine |

**Transapical Mitral Valve Repair with Device**

| Source | Description | Code specification |
|---|---|---|
| 2019, public comment & CMS internal review | In the Medical and Surgical section table 02U, Supplement of Heart and Great Vessel, add qualifier value H Transapical applied to the body part value G Mitral Valve, the percutaneous approach, and device value J Synthetic Substitute, to identify mitral valve repair using a transapical approach. | Add: 02UG3JH (1 code) |

**EXAMPLE**

| *Section* | **0** Medical and Surgical | | |
|---|---|---|---|
| *Body System* | **2** Heart and Great Vessels | | |
| *Operation* | **U** Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part | | |
| *Body Part* | *Approach* | *Device* | *Qualifier* |
| **G** Mitral Valve | **3** Percutaneous | **J** Synthetic Substitute | **E** Atrioventricular Valve, Left<br>**ADD H** Transapical<br>**Z** No Qualifier |

**Section 1 Obstetrics**
**Axis 5 Approach**

**Extraction of Productions of Conception, Ectopic**

| Source | Description | Code specification |
|---|---|---|
| 2019, public comment & CMS internal review | In the Obstetrics section in table 10D, Extraction of Productions of Conception, add approach values 0 Open and 4 Percutaneous Endoscopic, applied to the body part value 2 Products of Conception, Ectopic, to identify the removal of ectopic pregnancy using an open or laparoscopic approach. | Add: 10D2[04]ZZ (2 codes) |

**EXAMPLE**

| *Section* | **1** Obstetrics | | |
|---|---|---|---|
| *Body System* | **0** Pregnancy | | |
| *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* |
| **2** Products of Conception, Ectopic | **ADD 0** Open<br>**ADD 4** Percutaneous Endoscopic<br>**7** Via Natural or Artificial Opening<br>**8** Via Natural or Artificial Opening Endoscopic | **Z** No Device | **Z** No Qualifier |

**Section 4 Measurement and Monitoring Section**
**Axis 5 Approach**

**Percutaneous Endoscopic Measurement of Portal Venous Pressure**

| Source | Description | Code specification |
|---|---|---|
| 2019, public comment & CMS internal review | In the Measurement and Monitoring section, add approach value 4 Percutaneous Endoscopic, applied to body system 4 Venous, function value B Pressure, and qualifier value 2 Portal. This will allow the capture of measurements of venous portal pressure using a percutaneous endoscopic approach. | Add: 4A044B2 (1 code) |

**EXAMPLE**

| | |
|---|---|
| *Section* | **4** Measurement and Monitoring |
| *Body System* | **A** Physiological Systems |
| *Operation* | **0** Measurement: Determining the level of a physiological or physical function at a point in time |

| *Body System* | *Approach* | *Function / Device* | *Qualifier* |
|---|---|---|---|
| **4** Venous | **0** Open<br>**3** Percutaneous<br>**ADD 4** Percutaneous Endoscopic | **B** Pressure | **2** Portal |

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

**High Flow/Velocity Nasal Cannula**

| Source | Description | Code specification |
|---|---|---|
| 2019, public comment & CMS internal review | In the Extracorporeal or Systemic Assistance and Performance table 5A0, add new qualifier value A High Flow/Velocity, applied to the body system value 9 Respiratory, and function value 5 Ventilation to identify ventilatory assistance provided by high flow or high velocity nasal cannula devices. | Add: 5A09[345]5A (3 codes) |

**EXAMPLE**

| | |
|---|---|
| *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* |
|---|---|---|---|
| **9** Respiratory | **3** Less than 24 Consecutive Hours<br>**4** 24-96 Consecutive Hours<br>**5** Greater than 96 Consecutive Hours | **5** Ventilation | **7** Continuous Positive Airway Pressure<br>**8** Intermittent Positive Airway Pressure<br>**9** Continuous Negative Airway Pressure<br>**ADD A** High Nasal Flow/Velocity<br>**B** Intermittent Negative Airway Pressure<br>**Z** No Qualifier |

**Section D Radiation Therapy**
**Axis 5 Modality Qualifier**

**Intraoperative Radiation Therapy (IORT)**

| Source | Description | Code specification |
|---|---|---|
| 2019, public comment & CMS internal review | In the Radiation Therapy table D0Y, Other Radiation of Central and Peripheral Nervous System, add the modality qualifier C Intraoperative Radiation Therapy (IORT) to enable the capture of intraoperatively administered radiation for targeted therapy of intracranial tumors or tumor beds. | Add: D0Y[0167]CZZ (4 codes) |

**EXAMPLE**

| | |
|---|---|
| *Section* | **D** Radiation Therapy |
| *Body System* | **0** Central and Peripheral Nervous System |
| *Operation* | **Y** Other Radiation |

| *Treatment Site* | *Modality Qualifier* | *Isotope* | *Qualifier* |
|---|---|---|---|
| **0** Brain<br>**1** Brain Stem<br>**6** Spinal Cord<br>**7** Peripheral Nerve | **7** Contact Radiation<br>**8** Hyperthermia<br>**ADD C** Intraoperative Radiation Therapy (IORT)<br>**F** Plaque Radiation<br>**K** Laser Interstitial Thermal Therapy | **Z** None | **Z** None |