

CMS WILL NO LONGER BE PROVIDING PAPER COPIES OF HANDOUTS FOR THE MEETING. ELECTRONIC COPIES OF ALL MEETING MATERIALS WILL BE POSTED ON THE CMS WEBSITE PRIOR TO THE MEETING AT HTTPS://WWW.CMS.HHS.GOV/ICD9PROVIDERDIAGNOSTICCODES/03_MEETINGS.ASP

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

CENTERS for MEDICARE & MEDICAID SERVICES

Final Agenda ICD-10 Coordination and Maintenance Committee Department of Health and Human Services Centers for Medicare & Medicaid Services CMS Auditorium 7500 Security Boulevard Baltimore, MD 21244-1850 ICD-10-PCS Topics September 23, 2014

Pat Brooks, CMS - Co-Chairperson

Webcast and Dial-In Information

- The meeting will begin promptly at 9am ET and will be <u>webcast</u>.
- Toll-free dial-in access is available for participants who cannot join the webcast: Phone: 1-877-267-1577; Meeting ID: 993 682 630. We encourage you to join early, as the number of phone lines is limited.
- If participating via the webcast or dialing in you do NOT need to register on-line for the meeting.

This meeting is being webcast via CMS at <u>http://www.cms.gov/live/</u>. By your attendance, you are giving consent to the use and distribution of your name, likeness and voice during the meeting. You are also giving consent to the use and distribution of any personally identifiable information that you or others may disclose about you during the meeting. Please do not disclose personal health information.

Note: Proposals for diagnosis code topics are scheduled for September 24, 2014 and will be led by the Centers for Disease Control (CDC). Some of the ICD-10-CM diagnosis topics may begin on September 23, 2014 should CMS complete the ICD-10-PCS procedure topics prior to 5:00 PM. Please visit CDCs website for the Diagnosis agenda located at the following address: http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm

Introductions and comments on Committee activities Pages 8-11

Pat Brooks

ICD-10-PCS Topics:

- 1. Hip and Knee Replacements and Procedures
 - a) Partial Hip Replacement...Pages 12-14
 - b) Hip Resurfacing Procedures...Pages 15-16
 - c) Unicondylar Knee Replacement...Pages 17-18 Department of Orthopaedic Surgery

 - e) Adding New Body Part Values...Pages 21-22
 - f) Revisions Index Entries Updates...Pages 23-24
 - g) Lower Joint Liner...Pages 25-28
- 2. Minimally Invasive Cardiac Valve Surgery Pages 29-35
- 3. Drug-Coated Balloon Angioplasty Pages 36-39

- 4. Face Transplants Pages 40-41
- 5. Hand Transplants Pages 42-43
- 6. Administration of Ceftazidime-Avibactam Pages 44-47

ICD-10 Topics:

Page 54

| 1. | ICD-10 MS-DRGs Update | Pat Brooks, CMS |
|----|---------------------------------------|------------------|
| | Page 48 | |
| 2. | ICD-10-CM Home Health Conversions | Joan Proctor, CM |
| | Pages 49-51 | |
| 3. | Medicare ICD-10 Testing | Stacy Shagena, C |
| | Pages 52-53 | |
| 4. | FY 2017 ICD-10-PCS updates discussion | Pat Brooks, CMS |

Pat Brooks Karl Koenig, MD, MS Total Joint Arthroplasty Division Leader d) Patellofemoral Joint Procedures...Pages 19-20 Dartmouth-Hitchcock Medical Center Lebanon, NH

> Mady Hue Francis Duhay, MD, MBA Chief Medical Director and VP Clinical Affairs. Edwards Lifesciences

Mady Hue Michael R. Jaff, DO Paul and Phyllis Fireman Chair in Vascular Medicine Chair, Institute for Heart, Vascular and Stroke Care Massachusetts General Hospital Professor of Medicine Harvard Medical School

Pat Brooks Steve Phurrough, MD

Pat Brooks Steve Phurrough, MD

Celeste Beauregard Travis Cooper, Pharm. D., BCPS Med. Science Liaison, Inf. Disease

S

MS

Registering for the meeting:

Registration for the September 23-24, 2014 ICD-10 Coordination and Maintenance Committee meeting opened on August 15, 2014. The registration site closed on September 12, 2014. If participating by Livestream webcast or dialing in you do not need to register online.

Information on registering online to attend the meeting can be found at: <u>http://www.cms.hhs.gov/apps/events/</u>. Registration to attend the March 18-19, 2015 meeting will open on February 13, 2015.

For questions about the registration process, please contact Mady Hue at 410-786-4510 or <u>marilu.hue@cms.hhs.gov</u>.

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.

<u>Continuing Education Information for American Health Information Management Association (AHIMA)</u> 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, <u>not CMS</u>.

ICD-10 TIMELINE

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

| September 23 –24, 2014 | ICD-10 Coordination and Maintenance Committee meeting |
|------------------------|---|
| | Those who wish to attend the ICD-10 Coordination and Maintenance Committee meeting must have registered for the meeting online by September 12, 2014. You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building. |
| October 2014 | Summary report of the Procedure part of the September 23, 2014 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: <u>https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html</u> |
| | Summary report of the Diagnosis part of the September 24, 2014 ICD-10 Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: <u>http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm</u> |
| November 21, 2014 | Deadline for receipt of public comments on proposed code revisions discussed at the September 23-24, 2014 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2015. |
| January 16, 2015 | Deadline for requestors: Those members of the public requesting that topics be discussed at the March 18–19, 2015 ICD-10 Coordination and Maintenance Committee meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses by this date. |
| February 2015 | Draft agenda for the Procedure part of the March 18, 2015 ICD-10 Coordination and Maintenance Committee meeting posted on CMS homepage as follows: <u>http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html</u> |
| | Draft agenda for the Diagnosis part of the March 19, 2015 ICD-10 Coordination and Maintenance Committee meeting posted on NCHS homepage as follows: <u>http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm</u> |

| February 2015 | Federal Register notice of March 18–19, 2015 ICD-10 Coordination and Maintenance Committee Meeting will be published. |
|---------------------|--|
| February 13, 2015 | On-line registration opens for the March 18–19, 2015 ICD-10 Coordination and Maintenance Committee meeting at: <u>https://www.cms.gov/apps/events/default.asp</u> |
| March 2015 | Because of increased security requirements, those wishing to attend the March 18–19, 2015 ICD-10 Coordination and Maintenance Committee meeting must register for the meeting online at: <u>https://www.cms.gov/apps/events/default.asp</u> |
| | Attendees must register online by February 13, 2015; failure to do so may result in lack of access to the meeting. |
| March 18 – 19, 2015 | ICD-10 Coordination and Maintenance Committee meeting. |
| April 17, 2015 | Deadline for receipt of public comments on proposed code revisions discussed at the March 18–19, 2015 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2015. |
| April 2015 | Notice of Proposed Rulemaking to be published in the <u>Federal Register</u> as mandated by Public Law 99-509. This notice will include references to the complete and finalized FY 2016 ICD-10-CM diagnosis and ICD-10-PCS procedure codes. 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: <u>http://www.cms.gov/Medicare/Medicare-Fee-for-Service-</u> <u>Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS/I ist.asp</u> |
| April 2015 | Summary report of the Procedure part of the March 18, 2015 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: <u>https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html</u> |
| | Summary report of the Diagnosis part of the March 19, 2015 ICD-10 Coordination and Maintenance Committee meeting report will be posted on the NCHS webpage as follows: <u>http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm</u> |
| June 2015 | Final addendum posted on web pages as follows: Diagnosis addendum - <u>http://www.cdc.gov/nchs/icd/icd10cm.htm</u> |

| June 2015 | Procedure addendum - http://cms.hhs.gov/Medicare/Coding/ICD10/index.html |
|--------------------|--|
| July 17, 2015 | Deadline for requestors: Those members of the public requesting that topics be discussed at the September 22–23, 2015 ICD-10 Coordination and Maintenance Committee meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses. |
| August 1, 2015 | 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, 2015. This rule can be accessed at: <u>http://www.cms.gov/Medicare/Medicare-Fee-for-Service-</u> <u>Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS/I ist.asp</u> |
| August 2015 | Tentative agenda for the Procedure part of the September 22–23, 2015 ICD- 10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage at - <u>http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html</u> |
| | Tentative agenda for the Diagnosis part of the September 22 –23, 2015 ICD-10 Coordination and Maintenance Committee meeting will be posted on the NCHS webpage at - <u>http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm</u> |
| | Federal Register notice for the September 22–23, 2015 ICD-10 Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda. |
| August 14, 2015 | On-line registration opens for the September 22-23, 2015 ICD-10 Coordination and Maintenance Committee meeting at: <u>https://www.cms.gov/apps/events/default.asp</u> |
| September 11, 2015 | Because of increased security requirements, those wishing to attend the September 22-23, 2015 ICD-10 Coordination and Maintenance Committee meeting must register for the meeting online at: <u>https://www.cms.gov/apps/events/default.asp</u> |
| | Attendees must register online by September 11, 2015; failure to do so may result in lack of access to the meeting. |

| November 13, 2015 | Deadline for receipt of public comments on proposed code revisions discussed at the September 22-23, 2015 ICD-10 Coordination and Maintenance Committee meetings for implementation on October 1, 2016. |
|---------------------------|---|
| November 2015 | 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, 2016 will be posted on the following websites: <u>http://www.cms.gov/Medicare/Coding/ICD10/</u> <u>http://www.cdc.gov/nchs/icd/icd9cm_addenda_guidelines.htm</u> |
| October 16, 2015 | Deadline for receipt of public comments on proposed code revisions discussed at the September 22-23, 2015 ICD-10 Coordination and Maintenance Committee meetings for implementation on April 1, 2015. |
| October 1, 2015 | New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with DRG changes. Final addendum posted on web pages as follows: Diagnosis addendum - <u>http://www.cdc.gov/nchs/icd/icd9cm_addenda_guidelines.htm</u> Procedure addendum – <u>http://www.cms.gov/Medicare/Coding/ICD10/</u> |
| October 1, 2015 | ICD-10-CM/PCS codes go into effect along with ICD-10 MS- DRGs |
| | Summary report of the Diagnosis part of the September 22–23, 2015 ICD-10-CM/PCS Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm |
| October 2015 | Summary report of the Procedure part of the September 22–23, 2015 ICD-10 Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: <u>https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html</u> |
| | Those who wish to attend the ICD-10 Coordination and Maintenance Committee meeting must have registered for the meeting online by September 11, 2015. You must bring an official form of picture identification (such as a driver's license) in order to be admitted to the building. |
| September 22 –23, 2015 | ICD-10 Coordination and Maintenance Committee meeting. |

Introductions and Overview

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

Code Proposals

- No final decisions made at the meeting
- CMS will describe options and recommendations to facilitate discussion
- Submit written comments by November 21, 2014 on procedure code topics proposed for implementation on or after October 1, 2015

Partial Code Freeze

- Currently under a partial code freeze
 - ICD-10 will be implemented for services provided on or after October 1, 2015
 - Only ICD-10 codes for new technologies and new diagnoses are being considered for October 1, 2015
 - All other ICD-10 code updates would be made after the code freeze ends on October 1, 2016

Timeline

- Detailed timeline within the C&M handouts
 - November 21, 2014 Comments due on procedure topics presented today
 - Procedure comments to Pat Brooks, CMS patricia.brooks2@cms.hhs.gov
 - November 21, 2014 Comments due on diagnosis topics for October 2015
 - Diagnosis comments to Donna Pickett, CDC <u>nchsicd9@cdc.gov</u>
 - April 2015 Notice of Proposed Rulemaking, IPPS, includes ICD-10-CM/PCS diagnosis and procedure updates

Addendum

- Detailed timeline within the C&M handouts (Continued)
 - June 2014 Final addendum posted
 - FY 2015 ICD-10-CM (Diagnosis) and ICD-10-PCS (Procedure) http://www.cms.gov/Medicare/Coding/ICD10/index.html
 - FY 2015 ICD-10-CM (Diagnosis) <u>http://www.cdc.gov/nchs/icd/icd10cm.htm</u>
- There will be no new ICD-9-CM, ICD-10-CM, or ICD-10-PCS codes implemented on October 1, 2014.

Posted ICD-10 Files

- June 2014 GEM postings
 - FY 2015 ICD-10-CM and ICD-10-PCS GEMs posted at
 - http://www.cms.gov/Medicare/Coding/ICD10/index.html
- June 2015 GEMs will be posted in June 2015
 - Annual GEM updates will be posted early in 2015 year to facilitate implementation planning

Important Dates

- Detailed timeline within the C&M handouts (Continued)
 - January 16, 2015 Deadline for submitting topics for March 18 19, 2015
 C&M meeting
 - Around August 1, 2015 IPPS final rule published. Includes all final ICD-10-CM/PCS codes to be implemented October 1, 2015.
 - FY 2016 ICD-10 updates will also be posted in June 2015 at http://cms.hhs.gov/Medicare/Coding/ICD10/index.html

Public Participation

- For this meeting the public may participate in three ways:
 - Attend public C&M meeting
 - Listen to proceedings through free conference lines
 - Participate through a free webcast
- CMS & CDC hope this provides greater opportunity for public participation

Written Comments

• No matter how you participate – please send in your written comments by November 21, 2014 for all issues discussed for October 1, 2015 implementation

MLN Connects™ National Provider Call: Transitioning to ICD-10

Wednesday, November 5; 1:30-3pm ET

To Register: Visit <u>MLN Connects™ Upcoming Calls</u>. Space may be limited, register early.

HHS has issued a <u>rule</u> finalizing October 1, 2015 as the new compliance date for health care providers, health plans, and health care clearinghouses to transition to ICD-10. During this MLN ConnectsTM National Provider Call, CMS subject matter experts will discuss ICD-10 implementation issues, opportunities for testing, and resources. A question and answer session will follow the presentations.

Agenda:

- Final rule and national implementation
- Medicare Fee-For-Service testing
- Medicare Severity Diagnosis Related Grouper (MS-DRG) Conversion Project
- Partial code freeze and annual code updates
- Plans for National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs)
- Home health conversions
- Claims that span the implementation date

Target Audience: Medical coders, physicians, physician office staff, nurses and other non-physician practitioners, provider billing staff, health records staff, vendors, educators, system maintainers, laboratories, and all Medicare providers

Continuing education credit may be awarded for participation in certain MLN Connects Calls. Visit the <u>Continuing Education Credit Information</u> web page to learn more.

Partial Code Freeze for ICD-9-CM and ICD-10

The ICD-9-CM Coordination and Maintenance Committee implemented a partial freeze of the ICD-9-CM and ICD-10 (ICD-10-CM and ICD-10-PCS) codes prior to the implementation of ICD-10. The partial freeze is scheduled to end one year after the implementation of ICD-10. There was considerable support for this partial freeze. On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. No. 113-93) was enacted, which said that the Secretary may not adopt ICD-10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services issued a final rule on August 4, 2014 that changed the compliance date for ICD-10 from October 1, 2014 to October 1, 2015. The final rule also requires HIPAA covered entities to continue to use ICD-9-CM through September 30, 2015. Links to the final rule are provided at http://www.cms.gov/Medicare/Coding/ICD10/Statute_Regulations.html.

The partial freeze will be implemented as follows:

• The last regular, annual updates to both ICD-9-CM and ICD-10 code sets were made on October 1, 2011.

• On October 1, 2012, October 1, 2013, and October 1, 2014 there were only limited code updates to both the ICD-9-CM and ICD-10 code sets to capture new technologies and diseases as required by section 503(a) of Pub. L. 108-173.

• On October 1, 2015, there will be only limited code updates to ICD-10 code sets to capture new technologies and diagnoses as required by section 503(a) of Pub. L. 108-173. There will be no updates to ICD-9-CM, as it will no longer be used for reporting.

• On October 1, 2016 (one year after implementation of ICD-10), regular updates to ICD-10 will begin.

The ICD-9-CM Coordination and Maintenance Committee will continue to meet twice a year during the partial freeze. At these meetings, the public will be asked to comment on whether or not requests for new diagnosis or procedure codes should be created based on the criteria of the need to capture a new technology or disease. Any code requests that do not meet the criteria will be evaluated for implementation within ICD-10 on and after October 1, 2016 once the partial freeze has ended.

Partial Hip Replacement

Issue: The requestor believes coders may have difficulty determining the correct code assignment for partial hip replacements and requests a new device code to clarify the procedure performed.

New Technology Application? No

Background: Partial hip replacement is surgery in which the patient's femur is replaced but **the acetabulum remains intact**. Patients having partial hip replacements are significantly older patients with displaced femoral fractures and are generally older than patients who receive total hip replacement. Depending on the location and type of fracture, patients may receive a total hip, partial hip, or internal fixation device. Many of the components used for total hips are used for partial hips as well, including femoral stems and heads. Partial hip systems include 3-piece bipolar hips, 2-piece modular endoprostheses, or one-piece endoprostheses. Each of these systems have a stem component and a portion of the device or a set of components that are placed into the acetabulum. Collectively, the devices are often referred to as "endofemoral devices" or "partial hip systems."

Partial hip replacements are procedures on the hip joints, not the bone (femur or acetabulum). The differentiation between total and partial hip replacement is critical for arthroplasty device registries and survivor statistics.

Current Coding:

Partial hip replacements are identified by Body Part values R (Hip Joint, Femoral Surface, Right) and S (Hip Joint, Femoral Surface, Left) within table 0SR, Replacement of lower joints. The term femoral surface refers to the femoral part of the hip joint.

| Medical and Surgical 0 Body System | Medical and Lower Joints | Surgical | | |
|---|---------------------------------|---------------|--|--|
| Operation H | function of all | or a portio | or on biological or synthetic material that physically ta in of a body part | kes the place and/or |
| Body Par | t | Approach | Device | Qualifier |
| 9 Hip Joint, Right B Hip Joint, Left | | 0 Open | Synthetic Substitute, Metal Synthetic Substitute, Metal on Polyethylene Synthetic Substitute, Ceramic Synthetic Substitute, Ceramic on Polyethylene J Synthetic Substitute | 9 Cemented A Uncemented Z No Qualifier |
| A Hip Joint, Acetabular E Hip Joint, Acetabular | Surface, Right Surface, Left | 0 Open | 0 Synthetic Substitute, Polyethylene 1 Synthetic Substitute, Metal 3 Synthetic Substitute, Ceramic J Synthetic Substitute | 9 Cemented A Uncemented Z No Qualifier |
| R Hip Joint, Femoral Su S Hip Joint, Femoral Su | ırface, Right ırface, Left | 0 Open | Synthetic Substitute, Metal Synthetic Substitute, Ceramic Synthetic Substitute | 9 Cemented A Uncemented Z No Qualifier |

Coding Options:

Option 1: Do not create new codes for partial hip replacement. Continue using existing codes for hip replacements shown above with body part R (Hip Joint, Femoral Surface, Right) and S (Hip Joint, Femoral Surface, Left) within table 0SR.

Option 2: Add a device character option for partial hip replacement in table 0SR for 9 (Hip Joint, Right) and B (Hip Joint, Left) to indicate a partial hip joint.

| Medical and Surgical Body System | Medical and SLower Joints | Surgical | | | | | | |
|---|--|---|--|--|--|--|--|--|
| Operation | R Replacement function of all | Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of a body part | | | | | | |
| Pody Do | rd for the formation of the | Annroach | | Qualifiar | | | | |
| BOUY Fa | 11 | Арргоаст | Device | Qualifier | | | | |
| 9 Hip Joint, Right B Hip Joint, Left | | 0 Open | Synthetic Substitute, Metal Synthetic Substitute, Metal on Polyethylene Synthetic Substitute, Ceramic Synthetic Substitute, Ceramic on Polyethylene J Synthetic Substitute ADD N Endofemoral Device | 9 Cemented A Uncemented Z No Qualifier | | | | |

If option 2 were selected, the current body parts R (Hip Joint, Femoral Surface, Right) and S (Hip Joint, Femoral Surface, Left) would be deleted since they would no longer describe partial hip replacements.

Option 3: Revise existing body part values to clarify their use in coding partial hip replacement procedures. Change the term "surface" to "component." Make comparable updates for both the Acetabular and Femoral Surface. CMS developed Option 3 and welcomes suggestions as to any other terms such as "portion" instead of "surface."

| Medical and Surgical Body System0Medical and Lower JointsOperationRReplacemen function of al | Surgical :: Putting in l or a portic | or on biological or synthetic material that physically t n of a body part | akes the place and/or |
|--|--|--|--|
| Body Part | Approach | Device | Qualifier |
| Revise from A Hip Joint, Acetabular Surface, Right Revise to A Hip Joint, Acetabular Component, Right Revise from E Hip Joint, Acetabular Surface, Left Revise to E Hip Joint, Acetabular Component, Left | 0 Open | 0 Synthetic Substitute, Polyethylene 1 Synthetic Substitute, Metal 3 Synthetic Substitute, Ceramic J Synthetic Substitute | 9 Cemented A Uncemented Z No Qualifier |
| Revise from R Hip Joint, Femoral Surface, Right Revise to R Hip Joint, Femoral Component, Right Revise from S Hip Joint, Femoral Surface, Left Revise to S Hip Joint, Femoral Component, Left | 0 Open | 1 Synthetic Substitute, Metal 3 Synthetic Substitute, Ceramic J Synthetic Substitute | 9 Cemented A Uncemented Z No Qualifier |

The requestor does not support Option 3, stating that this option might add to any confusion coders might have in using these codes. The requestor states that the word "component" is used to refer to the device itself. If the codes referred to a "component" for the primary replacement procedure, coders may be hesitant to use them since an actual body part is being replaced (rather than a device or "component").

CMS Recommendation: Do not create new codes for partial hip replacement. Continue using existing codes for hip replacements shown above with body part R (Hip Joint, Femoral Surface, Right) and S (Hip Joint, Femoral Surface, Left) within table 0SR. The public should continue to examine whether another term is needed besides "surface" and submit those terms for future consideration.

Interim Coding Advice: In the interim, continue to assign codes using Body Parts R (Hip Joint, Femoral Surface, Right) and S (Hip Joint, Femoral Surface, Left) for partial hip replacements.

Hip Resurfacing Procedures

Issue: Joint resurfacing device is not a current valid device option in the table 0SR, Medical and Surgical, Lower Joints, Replacement, in ICD-10-PCS. Joint resurfacing procedures are captured in table 0SU, Medical and Surgical, Lower Joints, Supplement, for hip joints. The requestor expressed concern that coders may have difficulty coding joint resurfacings and asked that CMS move joint resurfacing procedures from the Supplement to Replacement root operation.

New Technology Application? No

Background: Resurfacing hip procedures are quite similar to those for total hip replacements in that the same bones are affected, the same orthopedic surgeons perform the procedures, and the surgical techniques are substantially the same. The biggest difference is the amount of bone that is resected from the femoral head in the case of a hip resurfacing procedure compared to a total hip. By placing resurfacing devices in a table for a different root operation (0SU), the requestor states the coder will have to consult additional references to find the appropriate code. This is confusing since under the root operation 0SR, there are body parts (Hip Joint, Acetabular Surface and Hip Joint, Femoral Surface) that might lead a coder to use these root operations to describe hip resurfacing, thus reducing the accuracy of statistics that report these procedures.

Current Coding:

Hip resurfacing procedures are identified with the Device value B (Resurfacing Device) within table 0SU, Supplement of Lower Joints.

| Medical and Surgical | 0 | Medical and Surgical | | | | | |
|--|---|----------------------|---------------|--|-----------------------|--|--|
| Body System | S | Lower Joints | | | | | |
| Operation | <i>Operation</i> 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 | | |
| 9 Hip Joint, Right B Hip Joint, Left | | | 0 Open | 7 Autologous Tissue Substitute 9 Liner B Resurfacing Device J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier | | |
| A Hip Joint, Acetabular Surface, Right E Hip Joint, Acetabular Surface, Left R Hip Joint, Femoral Surface, Right S Hip Joint, Femoral Surface, Left | | | 0 Open | 9 Liner B Resurfacing Device | Z No Qualifier | | |

Coding Options:

Option 1. Continue capturing hip resurfacing procedures under the Supplement root operation. While the argument can certainly be made that hip resurfacing procedures are a type of hip replacement procedure, they are currently classified to the root operation Supplement because the principal objective is not to resect a significant amount of bone and replace it with a prosthesis, but to conserve as much of the existing bone as possible, to augment it so as to prolong the functional life of the hip joint. The bone resected is for the most part done to prepare the operative site for the resurfacing device. It was felt that classifying the hip resurfacing procedures to the root operation Supplement would preserve the distinction between full hip replacement and hip resurfacing procedures in the coded data.

Option 2. Add a device character option for resurfacing device in hip replacement. Add value B (Resurfacing Device) to the hip joint body part values in table 0SR, Replacement of lower joints

| Medical and Surgical | 0 | Medical and Surgica | al | | | | | |
|---|------------|---|----------------------------------|--|--|--|--|--|
| Body System | S | Lower Joints | Lower Joints | | | | | |
| Operation R Replacement: Putt and/or function of | | | ig in or on bi I or a portion | ological or synthetic material that physicall of a body part | y takes the place | | | |
| Body Part | | | Approach | Device | Qualifier | | | |
| 9 Hip Joint, Right B Hip Joint, Left | t | | 0 Open | Synthetic Substitute, Metal Synthetic Substitute, Metal on Polyethylene Synthetic Substitute, Ceramic Synthetic Substitute, Ceramic on Polyethylene ADD B Resurfacing Device J Synthetic Substitute | 9 Cemented A Uncemented Z No Qualifier | | | |
| A Hip Joint, Acet E Hip Joint, Aceta | abı abı | ılar Surface, Right ılar Surface, Left | 0 Open | 0 Synthetic Substitute, Polyethylene 1 Synthetic Substitute, Metal 3 Synthetic Substitute, Ceramic ADD B Resurfacing Device J Synthetic Substitute | 9 Cemented A Uncemented Z No Qualifier | | | |
| R Hip Joint, Fem S Hip Joint, Fem | ora ora | l Surface, Right I Surface, Left | 0 Open | Synthetic Substitute, Metal Synthetic Substitute, Ceramic ADD B Resurfacing Device J Synthetic Substitute | 9 Cemented A Uncemented Z No Qualifier | | | |

If option 2 were selected, the current device value B (Resurfacing Device) would be deleted from the Supplement Root operation since it would no longer be used to describe hip resurfacing procedures.

CMS Recommendation: Option1. Make no changes for hip resurfacing procedures. Entries can be added to the ICD-10-PCS index as requested to assist coders in coding hip resurfacing procedures using table 0SU.

Interim Coding Advice: Continue to capture hip resurfacing procedures using the Supplement Root operation.

Unicondylar Knee Replacement

Issue: There is not a unique ICD-10-PCS code for unicondylar knee replacements.

New Technology Application? No

Background: Rather than a "total" knee replacement in which both the medial and lateral portions of the femur and tibia are replaced, a unicondylar knee replaces either the medial or the lateral portion of the knee joint. The components used in unicondylar devices mirror those used for total knees; generally a femoral component and a tibial component with an insert that articulates against the femur. There are approximately 60,000 primary unicondylar knee replacements performed annually in hospitals in the US.

Unicondylar knee replacements are procedures on the knee joints, not the bone (tibia, fibula or femur).

The differentiation between total and unicondylar knee replacement is important for arthroplasty device registries and survivor statistics, since unicondylar knee replacements may be converted to a total knee replacement during a later procedure.

Current Coding:

If the knee replacement involves both the femoral and tibial surfaces (medial, lateral or both), use value C or D for the knee joint. If the knee replacement only involves one surface, either the femoral or tibial surface (full or partial), use values T, U, V, or W.

| Medical and Surgical | ⁰ Medical and Surgical | | | |
|--|-----------------------------------|----------------|--------------------------------|--|
| Body System | S Lower Joints | | | |
| Operation | R Replacement: Putting in | n or on biolog | gical or synthetic material th | at physically takes the place and/or |
| | function of all or a porti | on of a body | part | |
| Body Part | | Approach | Device | Qualifier |
| C Knee Joint, Right D Knee Joint, Left F Ankle Joint, Right G Ankle Joint, Left T Knee Joint, Femoral Surface, Right U Knee Joint, Femoral Surface, Left V Knee Joint, Tibial Surface, Right | | 0 Open | J Synthetic Substitute | 9 Cemented A Uncemented Z No Qualifier |

Coding options:

Option 1: Use existing knee replacement codes. Do not create a device value that identifies unicondylar knee replacement.

Option 2: Add two new qualifier value options B and C for Unicondylar, Cemented and Unicondylar, Uncemented knee replacement.

Note: If the proposal to change the body part value terminology from 'surface' to 'component' outlined in option 3 of the partial hip replacement proposal is implemented, the changes will apply to all codes involving those body part values, including those shown in the option below.

| Medical and Surgical0Medical and SurgicalBody SystemSLower JointsOperationRReplacement: Putfunction of all orfunction of all or | Medical and Surgical Lower Joints Replacement: Putting in or on biological or synthetic material that physically takes the place and/or | | | | |
|--|---|------------------------|--|--|--|
| Body Part | Approach | Device | Qualifier | | |
| C Knee Joint, Right D Knee Joint, Left F Ankle Joint, Right G Ankle Joint, Left T Knee Joint, Femoral Surface, Right U Knee Joint, Femoral Surface, Left V Knee Joint, Tibial Surface, Right W Knee Joint, Tibial Surface, Left | 0 Open | J Synthetic Substitute | 9 Cemented A Uncemented ADD B Unicondylar, Cemented ADD C Unicondylar, Uncemented Z No Qualifier | | |

Option 3: Add device value options L and M for Synthetic Substitute, Lateral Condyle and for Synthetic Substitute, Medial Condyle as shown below to identify the location. The concern with this option is that this approach may not allow for future updates to capture device composition as is done for the hip replacements.

| Medical and Surgical Body SystemMedical and SurgSody SystemSLower JointsOperationRReplacement: Pu function of all or a | gical Itting in or a portion o | on biological or synthetic material tha f a body part | t physically takes the place and/or |
|--|--------------------------------------|---|--|
| Body Part | Approach | Device | Qualifier |
| C Knee Joint, Right D Knee Joint, Left F Ankle Joint, Right G Ankle Joint, Left T Knee Joint, Femoral Surface, Right U Knee Joint, Femoral Surface, Left V Knee Joint, Tibial Surface, Right W Knee Joint, Tibial Surface, Left | 0 Open | J Synthetic Substitute ADD L Synthetic Substitute, Lateral Condyle ADD M Synthetic Substitute, Medial Condyle | 9 Cemented A Uncemented Z No Qualifier |

CMS Recommendation: Option 3. Add device value options for Synthetic Substitute, Lateral Condyle and Medial Condyle. This update will be considered for implementation on October 1, 2016 after the end of the partial code freeze.

Interim Coding Advice: In the interim, continue to assign the knee replacement codes.

Patellofemoral Joint Procedures

Issue: There is not a unique ICD-10-PCS code to capture patellofemoral joint procedures performed as a less invasive alternative to knee replacement.

New Technology Application? No

Background: Patellofemoral joint procedures arose as an alternative to total knee replacements and are gaining popularity. Patellofemoral joint procedures involve resurfacing or supplementation of the surface so that it does not grind with movement of the knee joint. A metal component may be placed in the trochlear groove between the medial and lateral condyles of the femur. A patellar button may be placed on the back of the patella where it articulates against the metal surface in the trochlear groove. The indications for this surgery are usually patellofemoral joint pain that is unresponsive to conservative therapy. It sometimes is caused by wearing down, roughening, or softening of the cartilage under the kneecap. It is performed on patients who are younger than typical knee replacement patients, and it is estimated that about 20,000 are performed each year in the United States.

Patellofemoral joint procedures are procedures on the knee joints, not the bone (tibia, fibula or femur). It is important to differentiate between total knee replacements and patellofemoral joint procedures.

Current Coding:

The patellofemoral joint procedures are currently captured by the Device value 9 (Liner) and the qualifier C (Patellar Surface) in table 0SU shown below within the Supplement of Lower Joints section. The liner devices are used to supplement the action of the knee joint to reduce grinding.

| Medical and Surgical | 0 Medical an | nd Surgical | | |
|---|--|--|------------------------|--|
| Body System Operation | S Lower JoinU Supplementation | nts nt: Putting in or on bio the function of a porti | blogical or synthetion | c material that physically reinforces and/or |
| Body Part | A | Approach | Device | Qualifier |
| C Knee Joint, Right D Knee Joint, Left | O | Open | 9 Liner | C Patellar Surface Z No Qualifier |

Coding Options:

Option 1: Do not create new ICD-10-PCS codes to identify patellofemoral joint procedures. Continue to assign knee joint Supplement codes using the Liner Device character.

Option 2: Add a Patellofemoral device character option for the insertion of a patellofemoral joint device within the Replacement of Lower Joints section. With this option the existing codes in the Supplement table would be deleted.

| Medical and Surgical Body System | Medical and Surgical S Lower Joints | | | | |
|--|--|---------------|---|--|--|
| Operation | R Replacement: Putting in or on biological or synthetic material that physically takes the place and function of all or a portion of a body part | | | | |
| Body Part | | Approach | Device | Qualifier | |
| C Knee Joint, Right D Knee Joint, Left F Ankle Joint, Right G Ankle Joint, Left T Knee Joint, Femoral Su U Knee Joint, Femoral Su V Knee Joint, Tibial Surfa W Knee Joint, Tibial Surfa | ırface, Right urface, Left ice, Right ace, Left | 0 Open | J Synthetic Substitute ADD L Patellofemoral Device | 9 Cemented A Uncemented Z No Qualifier | |

While the requestor recommends that the use of these liner devices be added to the joint replacement section, the procedures do not involve the replacement of functional components of the knee joint. Rather, it augments the exposed anterior surface of the joint by interposing an artificial surface to prevent grinding by the overlying sesamoid bone and associated tendons.

CMS Recommendation: Option 1. Do not create new codes for the insertion of a patellofemoral device within the joint replacement section since these are not knee joint replacements. Continue to capture these procedures in the Supplement section using the liner device and patellar surface qualifier.

Interim Coding Advice: Continue to assign codes from the Supplement table 0SR using the liner device and patellar surface qualifier.

Adding New Body Part Values to table 0SP (Removal from Lower Joints)

Issue: Knee and hip joint prosthetic device removal tables do not have the specificity desired by the orthopedic community. The requestor states that adding femoral, tibial, and acetabular body parts and the patellar surface qualifier to table 0SP (Removal from lower joints) would provide additional information on the procedure performed.

New Technology Application? No

Background: The requestor states that the removal of knee and hip joint prostheses as a component of joint replacement revision surgery is currently assigned to table 0QP, Medical and Surgical, Lower Bones, Removal under upper femur, lower femur, and tibia. The requestor was concerned that data users may have difficulty identifying and retrieving the correct codes. The requestor expressed concern that having to search for the specific bones that the devices are explanted from unduly complicates the coding process and will lead to errors in recording and reporting. The requestor suggested that by adding femoral, tibial, acetabular, and patellar surface body parts to 0SP, it will be possible to more specifically identify the devices that were removed as part of a revision procedure, thus enhancing research possibilities and providing more accurate statistics for the joint registries.

| Medical and Surgical | 0 | Medical and Surgical | | | | |
|---|---|----------------------|--|-----------------------|--|--|
| Body System | S | Lower Joints | | | | |
| Operation | Ρ | Removal: Taki | ng out or off a device from a body part | | | |
| Body Part | | Approach | Device | Qualifier | | |
| 9 Hip Joint, Right B Hip Joint, Left | | 0 Open | 0 Drainage Device 3 Infusion Device 4 Internal Fixation Device 5 External Fixation Device 7 Autologous Tissue Substitute 8 Spacer 9 Liner B Resurfacing Device J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier | | |
| C Knee Joint, Right D Knee Joint, Left | | 0 Open | 0 Drainage Device 3 Infusion Device 4 Internal Fixation Device 5 External Fixation Device 7 Autologous Tissue Substitute 8 Spacer 9 Liner J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier | | |

Current Coding:

Coding options:

Option 1. Do not add body part detail for acetabular, femoral, tibial and patellar surfaces to Table 0SP, Medical and Surgical, Lower Joints, Removal. Continue to use the existing ICD-10-PCS codes.

Option 2. Add body part character options for acetabular, femoral, tibial, and patellar surfaces in Table OSP, Medical and Surgical, Lower Joints, Removal. Note: If the proposal to change the body part value terminology from 'surface' to 'component' outlined in option 2 of the partial hip replacement proposal is implemented, the changes will apply to new codes involving those body part values, including those shown in the option below.

| Medical and Surgical | 0 | Medical and S | Medical and Surgical | | | |
|--|--|---|---|------------------------|--|--|
| Douy System | 5 | Lower Joints | | alu cana ant | | |
| Operation | ۲ | Removal. Taki | ng out of on a device from a bo | by part | | |
| Body Part | | | Approach | Device | Qualifier | |
| ADD A Hip Joint, Acetal ADD E Hip Joint, Acetal ADD R Hip Joint, Femor ADD S Hip Joint, Femor ADD T Knee Joint, Fem ADD U Knee Joint, Fem ADD V Knee Joint, Tibia ADD W Knee Joint, Tibia | oular oular ral Su ral Su oral oral al Su al Su | Surface, Right Surface, Left urface, Right urface, Left Surface, Right Surface, Left rface, Right urface, Left | 0 Open 3 Percutaneous 4 Percutaneous Endoscopic | J Synthetic Substitute | Z No Qualifier | |
| C Knee Joint, Right D Knee Joint, Left | | | 0 Open 3 Percutaneous 4 Percutaneous Endoscopic | J Synthetic Substitute | ADD C Patellar Surface Z No Qualifier | |

This additional detail could be added to the Revision section (0SW) as shown below.

| Medical and Surgical Body System Operation | 0 S W | Medical and Surgical Lower Joints Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device | | | | |
|---|--|---|---|------------------------|--|--|
| Body Part | | | Approach | Device | Qualifier | |
| ADD A Hip Joint, Aceta ADD E Hip Joint, Acetal ADD R Hip Joint, Femo ADD S Hip Joint, Femo ADD T Knee Joint, Fem ADD U Knee Joint, Fem ADD V Knee Joint, Tibia ADD W Knee Joint, Tibia | bula ral S ral S iora nora al S al S | ar Surface, Right ar Surface, Left Surface, Right Surface, Left I Surface, Right I Surface, Left urface, Right Surface, Left | 0 Open 3 Percutaneous 4 Percutaneous Endoscopic | J Synthetic Substitute | Z No Qualifier | |
| C Knee Joint, Right D Knee Joint, Left | | | 0 Open 3 Percutaneous 4 Percutaneous Endoscopic | J Synthetic Substitute | ADD C Patellar Surface Z No Qualifier | |

CMS Recommendation: Option 2. Add the additional detail described above. This update would be considered for implementation on October 1, 2016. CMS also welcomes comments on the term "surface" used in the Body Parts above and any suggestions for new terms.

Interim Coding Advice: Continue using existing codes in table 0SP (Removal from Lower Joints).

Hip and Knee Arthroplasty Revisions Index Entries Updates

Issue: The term 'Revision' has its own definition in ICD-10-PCS that may cause confusion with coders leading to inaccurate coding and reporting of hip and knee arthroplasty revisions.

New Technology Application? No

Background Revisions of primary hip and knee replacements and causes of failure are carefully captured, tracked and researched by joint replacement registries and reported with survivor statistics. Orthopedic surgeons use the term "revision" when dictating operative reports to describe the operation performed to remove and replace devices that have failed, become displaced or to address infection.

The ICD-10-PCS definition of the root operation "Revision" states "Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device." While this definition may meet the needs of reporting procedures to address devices of other sites, orthopedic surgeons almost never leave a malfunctioning or displaced device in the hip or knee joint.

Further complicating the procedural terminology are "single-stage" and "two-stage" revisions. Single stage revisions are generally performed if there is no underlying infection in the bone, such as breakage, aseptic loosening, or periprosthetic fracture. In this case, the surgeon will remove the malfunctioning component and replace it with a new one. In a two-stage revision, generally performed for deep infections, the first surgical procedure involves the removal of the components, and the insertion of an antibiotic-eluting spacer. The spacer is left in place for several weeks, and then the patient is brought back for a second operation, in which the spacer is removed and new implant components are implanted. **In both cases (single stage and two-stage), the procedures are referred to as "revisions" by the orthopedic community.**

The concern is that coders will report these procedures as **Revisions** (as is the nomenclature of the orthopedic surgeon community) and not report them as **Removal** and **Replacement** with two codes. We are suggesting that the ICD-10-PCS Index provide guidance for coders to accurately report these clinically very significant procedures.

Current Coding: ICD-10-PCS Index

Revision of device in Joint Hip Left 0SWB Right 0SW9 Knee Left 0SWD Right 0SWC

Coding options:

Option 1: Do not modify the index for hip and knee arthroplasty revision.

Option 2: Change the index entries under **Revision** as follows to assist coders in correctly reporting joint revisions.

ICD-10-PCS Index

| No change | Revision of device in |
|-----------|--|
| Add | Removal of existing device without replacement |
| Add | See Removal |
| Add | Replacement of existing device |
| Add | See Removal |
| Add | See also root operation to place new device, e.g., Insertion, Replacement, |
| | Supplement |

CMS Recommendation: Option 2. Make index entry updates as described above to clarify the correct coding of joint revisions.

Interim Coding Advice: Continue coding revisions of joint procedures utilizing codes for Removal and Replacement.

Lower Joint Liner

Issue: The device term 'liner' used in tables 0SP, 0SU and 0SW in Medical and Surgical, Lower Joints in ICD-10-PCS does not explicitly include tibial inserts. The requestor has asked that this term be changed from 'liner' to 'bearing surface.'

New Technology Application? No

Background: To decrease friction and reduce wear on a mechanical joint, inserts, liners or cups can be inserted into the joint to separate the two opposing surfaces, just as a nylon washer can be used to separate two metal automotive parts that would otherwise rub and wear out. In the hip, these inserts are cup shaped and consequently often referred to as cups or liners. In the knee, these inserts are relatively flat and are simply referred to as inserts. Because there is considerable variation in nomenclature from one institution to another, ICD-10-PCS attempts to identify and use words to consistently link analogous concepts to the same term. In this case, liner is used to signify a device that is inserted into a joint as a new structure for the purpose of protecting (lining) one or more surfaces from frictional forces. Although at present hip joint inserts tend to cover the entire surface (liner) and knee joint inserts tend to cover a much more limited area (insert) there is no impediment to larger knee inserts and smaller hip inserts. Options available to capture this information include continuing to identify all of these interposed surface barriers as liners, changing the device to a more generic "insert," creating a distinction between insert and liner, electing a new common name such as "bearing surface," or allowing different names for similar devices in different joints.

Current Coding:

| Medical and Surgica | / 0 | Medical and Surgical | | |
|---|-----|---------------------------------|--|-----------------------|
| Body System | S | Lower Joints | | |
| Operation | Ρ | Removal: Taking out or off a de | evice from a body part | |
| Body Part | | Approach | Device | Qualifier |
| 9 Hip Joint, Right B Hip Joint, Left | | 0 Open | 0 Drainage Device 3 Infusion Device 4 Internal Fixation Device 5 External Fixation Device 7 Autologous Tissue Substitute 8 Spacer 9 Liner B Resurfacing Device J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier |
| C Knee Joint, Right D Knee Joint, Left | | 0 Open | 0 Drainage Device 3 Infusion Device 4 Internal Fixation Device 5 External Fixation Device 7 Autologous Tissue Substitute 8 Spacer 9 Liner J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier |

Medical and Surgical Body System

- 0 Medical and Surgical
- S Lower Joints

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 |
|--|---------------|--|--|
| 9 Hip Joint, Right B Hip Joint, Left | 0 Open | 7 Autologous Tissue Substitute 9 Liner B Resurfacing Device J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier |
| A Hip Joint, Acetabular Surface, Right E Hip Joint, Acetabular Surface, Left R Hip Joint, Femoral Surface, Right S Hip Joint, Femoral Surface, Left | 0 Open | 9 Liner B Resurfacing Device | Z No Qualifier |
| C Knee Joint, Right D Knee Joint, Left | 0 Open | 9 Liner | C Patellar Surface Z No Qualifier |
| T Knee Joint, Femoral Surface, Right U Knee Joint, Femoral Surface, Left V Knee Joint, Tibial Surface, Right W Knee Joint, Tibial Surface, Left | 0 Open | 9 Liner | Z No Qualifier |

| Medical and Surgical | 0 Medical and Surgical | | | | | |
|---|---------------------------|--|--|-----------------------|--|--|
| Body System | S Lower Joint | Lower Joints | | | | |
| Operation | W Revision: C displaced d | Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device | | | | |
| Body Part | | Approach | Device | Qualifier | | |
| 9 Hip Joint, Right B Hip Joint, Left | | 0 Open | 0 Drainage Device 3 Infusion Device 4 Internal Fixation Device 5 External Fixation Device 7 Autologous Tissue Substitute 8 Spacer 9 Liner B Resurfacing Device J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier | | |
| C Knee Joint, Right D Knee Joint, Left | | 0 Open | 0 Drainage Device 3 Infusion Device 4 Internal Fixation Device 5 External Fixation Device 7 Autologous Tissue Substitute 8 Spacer 9 Liner J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier | | |

Coding options:

Option 1. Maintain the current coding using device value 9 Liner to capture the acetabular liner (for the hip joint) and tibial insert (for the knee joint).

| Medical and Surgical | 0 Medical and Surgical | | | | |
|---|------------------------------|---|-----------------------|--|--|
| Body System | S Lower Joints | | | | |
| Operation | P Removal: Taking out or off | a device from a body part | | | |
| Body Part | Approach | Device | Qualifier | | |
| 9 Hip Joint, Right B Hip Joint, Left | 0 Open | 0 Drainage Device 3 Infusion Device 4 Internal Fixation Device 5 External Fixation Device 7 Autologous Tissue Substitute 8 Spacer Change From 9 Liner Change To 9 Bearing Surface B Resurfacing Device J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier | | |
| C Knee Joint, Right D Knee Joint, Left | 0 Open | 0 Drainage Device 3 Infusion Device 4 Internal Fixation Device 5 External Fixation Device 7 Autologous Tissue Substitute 8 Spacer Change From 9 Liner Change To 9 Bearing Surface J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier | | |

Option 2. Rename "Liner" to "Bearing Surface" as suggested by the requestor so that both acetabular liner and tibial insert are included with this term.

| Medical and Surgical Body System | 0 Medical and SurgicalS Lower Joints | | |
|-------------------------------------|---|---|-------------------------|
| Operation | U Supplement: Putting in or o augments the function of a | n biological or synthetic material that physi portion of a body part | cally reinforces and/or |
| Body Part | Approach | Device | Qualifier |
| | | 7 Autologous Tissue Substitute | |

| Body Part | Approach | Device | Qualifier |
|--|---------------|---|--|
| 9 Hip Joint, Right B Hip Joint, Left | 0 Open | 7 Autologous Tissue Substitute Change From 9 Liner Change To 9 Bearing Surface B Resurfacing Device J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier |
| A Hip Joint, Acetabular Surface, Right E Hip Joint, Acetabular Surface, Left R Hip Joint, Femoral Surface, Right S Hip Joint, Femoral Surface, Left | 0 Open | Change From 9 Liner Change To 9 Bearing Surface B Resurfacing Device | Z No Qualifier |
| C Knee Joint, Right D Knee Joint, Left | 0 Open | Change From 9 Liner Change To 9 Bearing Surface | C Patellar Surface Z No Qualifier |
| T Knee Joint, Femoral Surface, Right U Knee Joint, Femoral Surface, Left V Knee Joint, Tibial Surface, Right W Knee Joint, Tibial Surface, Left | 0 Open | Change From 9 Liner Change To 9 Bearing Surface | Z No Qualifier |

| Medical and Surgical | 0 Medical and | Surgical | | | | |
|---|---|---------------|---|-----------------------|--|--|
| Body System | S Lower Joints | Lower Joints | | | | |
| Operation | W Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device | | | | | |
| Body Part | | Approach | Device | Qualifier | | |
| 9 Hip Joint, Right B Hip Joint, Left | | 0 Open | 0 Drainage Device 3 Infusion Device 4 Internal Fixation Device 5 External Fixation Device 7 Autologous Tissue Substitute 8 Spacer Change From 9 Liner Change To 9 Bearing Surface B Resurfacing Device J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier | | |
| C Knee Joint, Right D Knee Joint, Left | | 0 Open | 0 Drainage Device 3 Infusion Device 4 Internal Fixation Device 5 External Fixation Device 7 Autologous Tissue Substitute 8 Spacer Change From 9 Liner Change To 9 Bearing Surface J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier | | |

CMS Recommendation: Option 1. Continue using "liner" to indicate the insertion of a friction reducing barrier of any dimensions into either the hip or the knee. Add the requisite terminology to the ICD-10-PCS Device Key to assist coders.

Interim Coding Advice: Maintain the current coding using device value 9 Liner to capture the acetabular liner (for the hip joint) and tibial insert (for the knee joint).

Minimally Invasive Cardiac Valve Surgery

Issue: ICD-10-PCS does not adequately capture a minimally invasive approach to aortic valve or mitral valve surgeries. Minimally invasive cardiac surgery (MICS) procedures utilize separate techniques within the open approach that result in unique patient effects, hospital resource use and physician skills and expertise.

New Technology Application? No

Background: Aortic valve replacement (AVR) is a procedure in which a patient's failing aortic valve is replaced with an artificial heart valve. The aortic valve, which lies between the left ventricle and the aorta, can be affected by a range of diseases such as aortic insufficiency / regurgitation whereby the valve can either become leaky or by aortic stenosis where the valve is partially blocked or narrowed. Current AVR approaches include surgery via a conventional median sternotomy, minimally invasive cardiac surgery (MICS) and catheter-based (percutaneous) AVR.

Open Approach

Traditional AVR is most frequently performed via a median sternotomy, in which the entire sternum is divided with a 6 to 10 inch incision. In traditional AVR, the patient is attached to a cardiopulmonary bypass machine, also known as the heart-lung machine. This machine circulates oxygenated blood through the patient's body during the procedure. Once the patient is on cardiopulmonary bypass, a cross-clamp is placed to obstruct the ascending aorta and isolate the heart. A cardioplegia solution is then introduced to temporarily arrest the heart and prevent cell death during the procedure. An incision is made in the aorta, exposing the aortic valve. The surgeon excises the patient's diseased valve and replaces it with a mechanical or bioprosthetic valve. Once the valve is in place and the aorta has been closed, the cross clamp is removed. The patient is then weaned from the heart-lung machine and the heart returns to normal function. Transesophageal echocardiogram (TEE, an ultrasound of the heart done through the esophagus) can be used to verify that the new valve is functioning properly.

Transcatheter Approach

The latest technological advancement in heart valve replacement, known as Transcatheter Aortic Valve Replacement (TAVR), resembles a balloon angioplasty in which a catheter is threaded through an artery and a balloon device on the end inflates to help open up a narrowing in an artery in the heart. In the case of TAVR, the replacement valve collapses to a very small diameter and is crimped onto the balloon device. The surgeon positions the replacement valve inside the patient's natural aortic valve and inflates the balloon. This causes the replacement valve to expand, pushing the faulty valve aside. The replacement valve begins to function as soon as the balloon catheter deflates to permit the flow of blood. A key aspect to TAVR is that it does not require the chest wall to be opened. The U.S. Food and Drug Administration (FDA) recently approved TAVR for appropriate patients with aortic valve stenosis who are not candidates for open surgery to replace their natural aortic valve.

Minimally Invasive Technique

Minimally invasive aortic valve replacement (minimally invasive AVR) provides an alternative approach for surgical candidates who want to reap the benefits of a minimally invasive approach, but do not meet the requirements for TAVR. Cardiac surgeons are now routinely performing AVR procedures via a variety of minimally invasive approaches. The most common approach, an upper hemisternotomy or "mini-sternotomy," involves a J-shaped, partial division of the sternum that is extended to the 3rd or 4th right intercostal space. An alternative minimally invasive approach, commonly referred to as right anterior thoracotomy (RAT), involves a four to six cm incision in the right 3rd intercostal space, although the

location may vary from patient to patient. The operative field with these approaches is smaller and typically requires the placement of cannulae outside of the operative field, as well as the use of long shafted surgical instruments. Like with traditional AVR, the patient is attached to a heart-lung machine, a cross-clamp is applied to the smaller access point, and a cardioplegia solution is introduced prior to an incision into the aorta to expose the aortic valve. After the valve has been replaced the aorta has been closed, and cross-clamp removed, the patient is weaned from the heart-lung machine and a TEE is performed.

Mitral Valve

Minimally invasive techniques are also being performed for the purposes of mitral valve replacement and repair (MVR). The mitral valve lies between the left atrium and left ventricle of the heart. Occasionally, the mitral valve is abnormal from birth (congenital). More often, the mitral valve becomes abnormal with age (degenerative) or as a result of rheumatic fever. In rare instances the mitral valve may be destroyed by infection or a bacterial endocarditis. Mitral regurgitation may also occur as a result of ischemic heart disease (coronary artery disease) or non-ischemic heart disease (dilated cardiomyopathy). Mitral valve surgery is performed by cardiac surgeons to treat mitral valve stenosis (narrowing) or regurgitation (leakage). However, unlike aortic valve procedures, where the majority of diseased valves are replaced, mitral valves can be repaired or replaced.

MVR may include the implantation of a cloth-covered ring around the annulus of the valve to correct the shape and ensure that the leaflets coapt correctly (annuloplasty), removal of redundant/loose segments of the leaflets (quadrangular resection), or re-suspension of the leaflets by means of chordal replacement.

Similar to the aortic valve, the mitral valve can be replaced with a mechanical or bioprosthetic valve using either a traditional open or minimally invasive technique. For either technique, cardiopulmonary bypass is instituted, as described previously for AVR. The ascending aorta can be obstructed with use of a cross-clamp, or occluded with an endovascular balloon catheter. Cardioplegia is used to arrest and protect the heart during the procedure, and the valve is accessed via an incision in the left atrium. After the valve is repaired or replaced, the left atrium is closed, the cross-clamp is removed, and the patient is weaned from cardiopulmonary bypass.

As in AVR, the traditional open technique for a MVR procedure is a median sternotomy. However, just as with the aortic valve, there have been advances in minimally invasive procedures. For mitral valve surgery, minimally invasive methods allow for surgery with only a partial sternotomy or thoracotomy. Similar to aortic valve procedures, a mini-sternotomy can also be utilized. This technique, typically referred to as a lower hemisternotomy, involves a division of the sternum from the xiphoid to the second intercostal space. Minimally invasive mitral surgery via a right thoracotomy is performed through a small incision in the 4th or 5th intercostal space (ICS). The sternum is not divided during a right thoracotomy.

Benefits of MICS^{1, 2}

Minimally invasive approaches for MVR have been associated with the same benefits described for minimally invasive AVR. These benefits include a shorter length of stay (LOS), reduced complications, fewer readmissions, quicker recovery, etc. According to the requester, minimally invasive techniques for heart valve surgery are well represented in the literature with established safety and efficacy. The requestor also reports that numerous studies demonstrate that minimally invasive techniques offer patients a number of advantages over conventional valve surgery, including:

- *Less pain*: Since the incision is much smaller and the breastbone remains intact or less affected than with traditional open-heart surgery, most patients report that they have less pain.
- *Lower risk of complications*: The minimally invasive heart valve surgery approach greatly reduces the possibility of complications related to a full incision through the breastbone.
- *Faster recovery and return to normal activity*: Most patients recover more quickly after a minimally invasive valve procedure. Patients typically spend less time in intensive care unit (ICU) after surgery, and are able to return home sooner. Many patients return to work and normal activities within 4-8 weeks. In comparison, it takes an average of ten weeks recovery with an openheart surgery procedure.
- *A smaller, less visible scar*: Most patients (99%) are very pleased with the cosmetic results of the procedure. Unlike a larger scar in the middle of the chest that patients would receive with traditional open-heart surgery, the smaller scar is hardly visible.

| Section: | 0 | Medical and Surgical | | | | |
|---|------|--|--|----------------|--|--|
| Body System: | 2 | Heart and Great Vessels | Heart and Great Vessels | | | |
| Operation: | R | Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part | | | | |
| Body Part | | Approach | Device | Qualifier | | |
| F Aortic Valve G Mitral Valve H Pulmonary V | alve | 0 Open 4 Percutaneous Endoscopio e | 7 Autologous Tissue Substitute 8 Zooplastic Tissue J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier | | |

Current Coding:

¹ Brown ML, McKellar SH, Sundt TM, et al. Ministernotomy versus conventional sternotomy for aortic valve replacement: A systematic review and meta-analysis. *The Journal of Thoracic and Cardiovascular Surgery*. 2009;137:670-679.

² Malaisrie SC, Barnhart GR, Farivar RS, et al. Current era minimally invasive aortic valve replacement: Techniques and practice. *The Journal of Thoracic and Cardiovascular Surgery*. 2014;147:6-14.

| Section: 0 Medical and | Surgical | | | | |
|--|--|-------------|----------------|--|--|
| Body System: 2 Heart and Gr | eat Vessels | | | | |
| Operation: Q Repair: Resto | Operation: Q Repair: Restoring, to the extent possible, a body part to its normal anatomic structure and function | | | | |
| Body Part | Approach | Device | Qualifier | | |
| 0 Coronary Artery, One Site 1 Coronary Artery, Two Sites 2 Coronary Artery, Three Sites 3 Coronary Artery, Four or More Sites 4 Coronary Vein 5 Atrial Septum 6 Atrium, Right 7 Atrium, Left 8 Conduction Mechanism 9 Chordae Tendineae A Heart B Heart, Right C Heart, Left D Papillary Muscle F Aortic Valve G Mitral Valve H Pulmonary Valve J Tricuspid Valve K Ventricle, Right L Ventricle, Right L Ventricle, Right N Pericardium P Pulmonary Artery, Right R Pulmonary Vein, Right T Pulmonary Vein, Right T Pulmonary Vein, Left V Superior Vena Cava W Thoracic Aorta | 0 Open 3 Percutaneous 4 Percutaneous Endoscopic | Z No device | Z No Qualifier | | |

| Section: | 0 | Medical and Surgical | | | | | |
|----------------|---|---|---|-----------------------|--|--|--|
| Body System: | 2 | Heart and Great Vessels | | | | | |
| Operation: | Ρ | Removal: Taking out of off a device from a l | emoval: Taking out of off a device from a body part | | | | |
| Body Part | | Approach | Device | Qualifier | | | |
| A Heart | | 0 Open 3 Percutaneous 4 Percutaneous Endoscopic | 2 Monitoring Device 3 Infusion Device 7 Autologous Tissue Substitute 8 Zooplastic Tissue C Extraluminal Device D Intraluminal Device J Synthetic Substitute K Nonautologous Tissue Substitute M Cardiac Lead Q Implantable Heart Assist System R External Heart Assist System | Z No Qualifier | | | |

Coding Options:

Option 1. Do not create new qualifier values in root operations Replacement, Repair and Removal to capture the right thoracotomy, and mini-sternotomy techniques for open aortic or mitral valve replacement. Continue to code with the No Qualifier value Z.

Option 2. Create new qualifier values L and M to capture the right thoracotomy, and mini-sternotomy techniques for open aortic or mitral valve replacement, repair, and removal.

| Section: | 0 | Medical and | Surgical | | | |
|---|------|-----------------|---|--|--|--|
| Body System: | 2 | Heart and Gr | Heart and Great Vessels | | | |
| Operation: | R | Replacement | Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all | | | |
| | | or a portion of | or a body part | | | |
| Body Part | | | Approach | | Device | Qualifier |
| F Aortic Valve G Mitral Valve H Pulmonary V | alve | 9 | 0 Open | | 7 Autologous Tissue Substitute 8 Zooplastic Tissue J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier ADD L Right Thoracotomy ADD M Mini-Sternotomy |

| Section: | 0 | Medical and Surgical | | | | | |
|---|------|--|-------------------------|--|--------------------|--|--|
| Body System: | 2 | Heart and Gr | Heart and Great Vessels | | | | |
| Operation: | Q | Repair: Restoring, to the extent possible, a body part to its normal anatomic structure and function | | | | | |
| Body Part | | | Approach | | Device | | Qualifier |
| F Aortic Valve G Mitral Valve H Pulmonary V | alve | 2 | 0 Open | | Z No device | | Z No Qualifier ADD L Right Thoracotomy ADD M Mini-Sternotomy |

| Section: | 0 | Medical and Surgica | Medical and Surgical | | | | |
|----------------|---|---------------------|-------------------------|---|--|--|--|
| Body System: | 2 | Heart and Great Ves | Heart and Great Vessels | | | | |
| Operation: | Ρ | Removal: Taking out | t of off a device from | a body part | | | |
| Body Part | | | Approach | Device | Qualifier | | |
| A Heart | | | 0 Open | 2 Monitoring Device 3 Infusion Device 7 Autologous Tissue Substitute 8 Zooplastic Tissue C Extraluminal Device D Intraluminal Device J Synthetic Substitute K Nonautologous Tissue Substitute M Cardiac Lead Q Implantable Heart Assist System R External Heart Assist System | Z No Qualifier ADD L Right Thoracotomy ADD M Mini-Sternotomy | | |

For Discussion Purposes

Option 3. Create new codes using a new fifth character approach value that would specify a minimally invasive open approach in a more general way and could be applied to other body systems and root operations as needed in the future. This would create a general repository in the coded data for the intent of this type of procedure, and could facilitate tracking the efficacy of a new open surgical technique against the current standard open technique at any given point in time.

Surgeons are constantly striving to improve techniques in ways that benefit the patient, as stated above: less pain, shorter hospital stays, fewer complications, and smaller scars. To achieve these results, the 'next generation' open technique typically uses specialized equipment and requires additional training. If both the standard open technique and the next generation open technique are coded using an undifferentiated open approach value, this data is not readily available for research and outcomes tracking.

PCS' regular, multi-axial structure makes data analysis much more effective when the system is modified in accordance with its structure to the extent possible (i.e., body part information is captured in the body part value, approach information is captured in the approach value, device information is captured in the device value). PCS has the capacity to create specific new fifth character approach values as needed. A new approach value for a minimally invasive open approach would allow the continued use of the qualifier to capture information other than approach. For example, minimally invasive coronary artery bypass procedures could be coded using a specific new approach value. However, the left thoracotomy qualifier proposed for minimally invasive valve surgery could not be applied for use in the PCS Bypass table 021, because the qualifier is already used in the PCS root operation Bypass to specify the source of the bypass material, (e.g., internal mammary artery).

Below is an example of a possible new PCS approach value for minimally invasive open procedures, that could be used as an alternative to option 2 above, of the current valve replacement proposal.

| Section: | 0 | Medical and Surgical | | | | |
|---|------------|---|---|--------------------------------------|--|--|
| Body System: | 2 | Heart and Great Vessels | Heart and Great Vessels | | | |
| Operation: | R | Replacement: Putting in or on biological of | or synthetic material that physically ta | kes the place and/or function of all | | |
| | | or a portion of a body part | | | | |
| Body Part | | Approach | Device | Qualifier | | |
| F Aortic Valve G Mitral Valve H Pulmonary V | e /alvo | 0 Open ADD 1 Open with Reduced Exposure 4 Percutaneous Endoscopic | 7 Autologous Tissue Substitute 8 Zooplastic Tissue J Synthetic Substitute K Nonautologous Tissue Substitute | Z No Qualifier | | |

Proposed New Approach: 1 Open with Reduced Exposure

Proposed Definition: Cutting through the skin or mucous membrane and any other body layers necessary to directly visualize the site of the procedure with reduced exposure

CMS Recommendation: Option 2. Create new qualifier values L and M to capture the right thoracotomy and mini-sternotomy techniques for open aortic or mitral valve replacement, repair, and removal.

Interim Coding: Continue coding these procedures with the appropriate Root Operation, Approach and the No Qualifier value Z.

Drug-Coated Balloon Angioplasty in Peripheral Vessels

Issue: ICD-10-PCS currently does not have a means of identifying the use of drug-coated balloons in peripheral angioplasty to differentiate this procedure from conventional angioplasty.

New Technology Application: Yes. C.R. Bard and Medtronic plan to submit applications for a New Technology Add-on Payment for FY 2016. FDA approval is expected in 4th Quarter 2014 for the Lutonix[®] DCB drug-coated balloon angioplasty catheter (C.R. Bard). An application for the In.PACT Admiral[®] drug-coated angioplasty balloon (Medtronic) was submitted to the FDA in May 2014 with approval expected in early to mid-2015.

Background: Drug-coated balloons are a new treatment for obstructive atherosclerotic lesions in the lower extremities. Angioplasty has been the first-line treatment for these lesions but is associated with a high rate of restenosis, up to 67% at one year³. Placement of bare metal stents and drug-eluting stents has reduced the rate of restenosis but it still occurs in 18% to 40% of patients at one year^{4,5,6}. Restenosis happens because injury to the arterial wall is inherent to endovascular procedures such as angioplasty and stenting. In many patients, this triggers a natural physiologic response leading to cell proliferation and hyperplasia within the artery. Stenting also has additional drawbacks. It results in leaving a device within the artery, which limits future treatment options for open surgical revascularization if needed. Stents may also occlude side branches, resulting in altered blood flow. Further, some peripheral vessels are simply not appropriate for stenting due to anatomic and functional considerations. Drug-coated balloons were developed to obtain the benefits of angioplasty with drug elution, while avoiding the potential complications and the consequences of a permanent implant. In drug-coated balloons, a standard angioplasty balloon catheter receives an anti-proliferative coating which consists of a drug and a carrier. Both of the drug-coated balloons noted above use Paclitaxel, the same drug found on many drug-eluting stents. The carriers, which may vary, are natural substances designed to allow for rapid transfer of the drug into the artery wall. Drug-coated balloons do not require more inflations or longer inflations than a conventional angioplasty. As the balloon expands, the coating is fully exposed to the vessel wall and the carrier facilitates deposit of the drug into the arterial tissues.

The Paclitaxel remains in the artery wall and is detectable at therapeutic levels for 60 to 90 days. In some studies, some level of the drug was detectable for 180 days. This enables drug action to inhibit restenosis during the critical phase. This reduces the risk of restenosis because the dilation injury generally heals

³ Rocha-Singh KJ, Jaff MR, Crabtree TR, Bloch DA, Ansel G. Performance goals and endpoint assessments for clinical trials of femoropopliteal bare nitinol stents in patients with symptomatic peripheral arterial disease. Catheter Cardiovasc Interv 2007; 69: 910-9.

⁴ Laird JR, Yeo KK. The treatment of femoropopliteal in-stent restenosis: back to the future. J Am Coll Cardiol 2012; 59: 24-5

⁵ Schillinger M., Sabeti S., Loewe C.; Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. *N Engl J Med.* 354 2006:1879-1888.

⁶ Laird J.R., Katzen B.T., Scheinert D.; Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial. *Circ Cardiovasc Interv.* 3 2010:267-276.

during the time the drug is present. In US clinical studies of two drug-coated balloons, the one year rates of primary patency (freedom from restenosis) were between 73.5% and 89.8%^{7,8}.

Between them, the two drug-coated balloons Lutonix[®] DCB and IN.PACT Admiral[®] expect to have initial indications specifically for the superficial femoral artery and popliteal artery. Other vessels, such as "below the knee" vessels like the peroneal artery and tibial artery, will likely be added over time.

| Section: 0 Medical an | d Surgical | | |
|--|--|---|----------------|
| Body System: 4 Lower Arte | eries | | |
| Operation: 7 Dilation: Ex | xpanding an orifice or the | lumen of a tubular body part | |
| Body Part | Approach | Device | Qualifier |
| 0 Abdominal Aorta 1 Celiac Artery 2 Gastric Artery 3 Hepatic Artery 4 Splenic Artery 5 Superior Mesenteric Artery 6 Colic Artery, Right 7 Colic Artery, Left 8 Colic Artery, Middle 9 Renal Artery, Right A Renal Artery, Right A Renal Artery, Left B Inferior Mesenteric Artery C Common Iliac Artery, Right D Common Iliac Artery, Right F Internal Iliac Artery, Right J External Iliac Artery, Left H External Iliac Artery, Right J External Iliac Artery, Left K Femoral Artery, Right J External Artery, Right J External Artery, Left M Popliteal Artery, Left M Popliteal Artery, Left P Anterior Tibial Artery, Right Q Anterior Tibial Artery, Left R Posterior Tibial Artery, Left T Peroneal Artery, Right U Peroneal Artery, Right U Peroneal Artery, Right W Foot Artery, Right W Foot Artery, Left Y Foot Artery, Left Y Foot Artery, Left Y Eover Artery | 0 Open 3 Percutaneous 4 Percutaneous Endoscopic | 4 Intraluminal Device, Drug-eluting D Intraluminal Device Z No Device | Z No Qualifier |

⁷ Lutonix Drug Coated Balloon PTA Catheter; PMA P130024 Panel Package Executive Summary

⁸ Tepe G. IN.PACT SFA: randomized trial of IN.PACT Admiral DCB vs. PTA for the treatment of atherosclerotic lesions in the SFA and/or PPA. Presented at: Charing Cross International Symposium. April 5, 2014. London, United Kingdom.

Coding options:

Option 1: Do not create new codes for Drug-Coated Balloon Angioplasty in Peripheral Vessels. Continue to code these angioplasty procedures to the appropriate body part in table 047 with the no qualifier value.

Option 2: Add a Qualifier value for Drug-Coated Balloon Angioplasty in Peripheral Vessels to table 047 Dilation of Lower Arteries, making the qualifier available for all vessels. For coding purposes, drug-coated balloons are not considered devices because they are not left in the body after the procedure. Use of drug-coated balloons in angioplasty can be identified by the Qualifier character.

| Section: | 0 Medical and S | Surgical | | |
|---|---|---|---|---|
| Body System | n: 4 Lower Arteries | 6 | | |
| Operation: | 7 Dilation: Expan | nding an orifice or the | lumen of a tubular body part | |
| Body Part | | Approach | Device | Qualifier |
| 0 Abdomina 1 Celiac Arta 2 Gastric Arta 2 Gastric Arta 3 Hepatic Arta 4 Splenic Arta 4 Splenic Arta 5 Superior M 6 Colic Arta 7 Colic Arta 8 Colic Arta 9 Renal Arta 8 Renal Arta 9 Renal Arta 8 Inferior Mathematication 9 Common I 9 Internal Ilia F External Ilia F External Ilia F Emoral A M Popliteal A N Posterior T S Posterior T T Peroneal A V Foot Artan W Foot Artan Y Foot Artan Y Lower Arta | al Aorta tery tery rtery rtery Wesenteric Artery wry, Right tery, Right tery, Niddle tery, Right tery, Left tesenteric Artery Iliac Artery, Right liac Artery, Left tiac Artery, Left tiac Artery, Left Artery, Right Artery, Right Artery, Right Artery, Left Tibial Artery, Right Tibial Artery, Left Tibial Artery, Left Tibial Artery, Left Tibial Artery, Left Artery, Right Artery, Right Artery, Right Artery, Right Artery, Right Artery, Left Tibial Artery, Left Tibial Artery, Left Artery, Right Artery, Left Artery, Left | 0 Open 3 Percutaneous 4 Percutaneous Endoscopic | 4 Intraluminal Device, Drug-eluting D Intraluminal Device Z No Device | ADD 1 Drug-Coated Balloon Z No Qualifier |

Option 3: Add a Qualifier value for Drug-Coated Balloon Angioplasty in Peripheral Vessels to table 047 Dilation of Lower Arteries, specifically for the Body Part values for femoral and popliteal arteries as currently indicated.

| Section: 0 Medical and Surgical | | | |
|--|---|---|---|
| Body System: 4 Lower Arteries | | | |
| Operation: 7 Dilation: Expanding an orifice or the lumen of a tubular body part | | | |
| Body Part | Approach | Device | Qualifier |
| 0 Abdominal Aorta 1 Celiac Artery 2 Gastric Artery 3 Hepatic Artery 3 Splenic Artery 4 Splenic Artery 5 Superior Mesenteric Artery 6 Colic Artery, Right 7 Colic Artery, Left 8 Colic Artery, Kight 7 Colic Artery, Kight 9 Renal Artery, Left 8 Inferior Mesenteric Artery C Common Iliac Artery, Right D Common Iliac Artery, Left E Internal Iliac Artery, Left H External Iliac Artery, Left H External Iliac Artery, Left P Anterior Tibial Artery, Left R Posterior Tibial Artery, Right S Posterior Tibial Artery, Right V Peroneal Artery, Right V Foot Artery, Right W Foot Artery, Left Y Lower Artery | 0 Open 3 Percutaneous 4 Percutaneous Endoscopic | 4 Intraluminal Device, Drug-eluting D Intraluminal Device Z No Device | Z No Qualifier |
| K Femoral Artery, Right L Femoral Artery, Left M Popliteal Artery, Right N Popliteal Artery, Left | 0 Open3 Percutaneous4 PercutaneousEndoscopic | 4 Intraluminal Device, Drug-eluting D Intraluminal Device Z No Device | ADD 1 Drug-Coated Balloon Z No Qualifier |

CMS Recommendation: CMS recommends option 2, add a Qualifier value for Drug-Coated Balloon to table 047 Dilation of Lower Arteries, making the qualifier available for all vessels.

Interim Coding Advice: In the interim, continue to code these angioplasty procedures to the appropriate body part in table 047 with the no qualifier value.

Face Transplant

Issue: There is not a unique ICD-10-PCS code to capture a face transplant.

New Technology? No

Background: A face transplant involves replacing a disfigured/nonfunctioning face with a cadaveric face. It can be a partial or a full transplant and involve tissue from skin to bone. The world's first partial face transplant on a living human was carried out in France in 2005 and several have been recently performed in the US.

The procedure consists of a series of operations requiring rotating teams of specialists. With issues of tissue type, age, sex, and skin color taken into consideration, the patient's face is removed and replaced (sometimes including the underlying fat, nerves, blood vessels, bones, and/or musculature). The surgery typically lasts 10 - 24 hours. After the procedure a lifelong regimen of immunosuppressive drugs is necessary to prevent rejection.

This is still considered an experimental procedure and four people have died of complications related to the procedure.

Current coding:

Code the root operation Replacement and the device value Nonautologous Tissue Substitute for the body parts and tissue layers replaced. The codes assigned vary depending on the procedure performed. For example, a partial face transplant consisting of the nose, right cheek and upper lip is coded as follows:

09RK0KZ Replacement of Nose with Nonautologous Tissue Substitute, Open Approach

0HR1XK3 Replacement of Face Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach

0JR10KZ Replacement of Face Subcutaneous Tissue and Fascia with Nonautologous Tissue Substitute, Open Approach

0CR00KZ Replacement of Upper Lip with Nonautologous Tissue Substitute, Open Approach

Coding options:

Option 1: Continue to code the root operation Replacement and the device value Nonautologous Tissue Substitute for the body parts and tissue layers replaced.

Option 2: Create the following new ICD-10-PCS codes to capture face transplant by creating a new table in the General Anatomical Regions body system and separate qualifiers in table 0WY as shown below. This option is limited to body part value 2 Face and an open approach.

| Medical and Surgical Body System Operation | 0 W Y | Medical and Surgical Anatomical Regions, General ADD 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 | | |
| 2 Face 0 Open K Nonautologous Tissue Substitute | | K Nonautologous Tissue Substitute | 5 ADD Complete6 ADD PartialZ No Qualifier | |

CMS Recommendation: Option 2: Create new ICD-10-PCS codes to capture face transplant by creating a new table in the General Anatomical Regions body system and separate qualifiers in table 0WY as shown above.

Interim Coding Advice: Code the root operation Replacement and the device value Nonautologous Tissue Substitute for the body parts and tissue layers replaced.

Hand Transplant

Issue: There is not a unique ICD-10-PCS code to capture a hand transplant.

New Technology? No

Background: Hand transplants have occurred as early as 1964; however, patients commonly suffered rejections. Since the advent of better immunosuppressives and newer surgical techniques, the number of procedures has increased but still remains relatively low. It is a technically difficult procedure involving bone, tendons, arteries, nerves and veins. As in most transplants, immunosuppressives are required lifelong with their attendant side effects.

There is some suggestion that newer, more functional prosthetics have lessened the interest and investment in this research. There is at least one patient reported in the literature that had a hand transplant removed to allow for prosthetic fitting.

This remains an experimental procedure.

Current ICD-10-PCS Codes:

0XQJ0ZZ Repair Right Hand, Open Approach

0XQK0ZZ Repair Left Hand, Open Approach

Coding options:

Option 1: Continue to assign the following ICD-10-PCS codes:

0XQJ0ZZ Repair Right Hand, Open Approach

0XQK0ZZ Repair Left Hand, Open Approach

Option 2: Create the following new ICD-10-PCS codes to capture hand transplant by creating a new table in the Upper Extremity Anatomical Regions body system and separate qualifiers in table 0XY as shown below. This option is limited to J Right Hand and K Left Hand body part values and an open approach.

| Medical and Surgical Body System Operation | 0 X Y | Medical and Surgical Anatomical Regions, Upper Extremities ADD 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 | |
| I Right Hand K Left Hand I Left Hand | | K Nonautologous Tissue Substitute | 5 ADD Complete6 ADD PartialZ No Qualifier | |

CMS Recommendation: Option 2, create new ICD-10-PCS codes to capture hand transplant as described above.

Interim Coding Advice: In the interim continue to assign the following codes:

0XQJ0ZZ Repair Right Hand, Open Approach 0XQK0ZZ Repair Left Hand, Open Approach

Administration of Ceftazidime-Avibactam

Issue: There is not a unique ICD-10-PCS code to describe the intravenous (IV) administration of ceftazidime-avibactam to treat patients with complicated urinary tract infections (cUTI), complicated intra-abdominal infections (cIAI), or aerobic Gram-negative infections with limited treatment options.

New Technology Application? Yes. Forest Laboratories, LLC is planning to submit a New Technology Add-On Payment application for ceftazidime-avibactam for fiscal year (FY) 2016.

FDA Approval: The New Drug Application (NDA) for ceftazidime-avibactam was submitted to the FDA on June 25, 2014. Based on the Prescription Drug User Fee Act V performance goals, the target date of FDA approval is February 25, 2015.

Background: Public health officials have recognized the rise of drug-resistant infections as one of the biggest modern threats to public health. The Centers for Disease Control and Prevention (CDC) has categorized the threat level of each bacteria as Urgent, Serious, or Concerning. Highly resistant Gram-negative bacteria are of great concern: Carbapenem-resistant Enterobacteriaceae (CRE) is listed in the Urgent category, while both Enterobacteriaceae that are resistant to β -lactam antibiotics (ESBLs) and multidrug-resistant *Pseudomonas aeruginosa* are included in the Serious category.¹

The loss of effective antibiotic treatments due to the increasing number of resistant pathogens has the potential to cripple the ability to fight routine infectious diseases, and could also undermine treatment of infectious complications in high-risk patients with other diseases. In the U.S. approximately 2 million people each year acquire serious infections caused by bacteria that are resistant to one or more of the antibiotics designed to treat the infection. ¹ For serious and life-threatening infections in particular, the increasing resistance is associated with an increase in morbidity and mortality. At least 23,000 people in the U.S. die each year as a direct result of antibiotic-resistant infections.¹

Ceftazidime-avibactam combines a third generation cephalosporin (ceftazidime) – with a novel non- β -lactam, β -lactamase inhibitor (avibactam) that improves the overall activity of ceftazidime.² Avibactam inactivates bacterial enzymes called β -lactamases that break down β -lactam antibiotics (such as cephalosporins) before the drugs can kill the bacteria. Avibactam is designed to be co-administered with select antibiotics to enhance the antibiotics spectrum of activity and counteract bacterial resistance, and has been specifically studied with ceftazidime.^{2,3}

¹ "Antibiotic Resistance Threats in the United States, 2013." *Centers for Disease Control and Prevention*. U.S. Department of Health and Human Services, 10 Mar. 2014. Web. 29 Apr. 2014. <u>http://www.cdc.gov/drugresistance/threat-report-2013/</u>.

² Lucasti, C. "Comparative study of the efficacy and safety of ceftazidime/avibactam plus metronidazole versus meropenem in the treatment of complicated intra-abdominal infections in hospitalized adults: results of a randomized, double-blind, Phase II trial." *Journal of Antimicrobial Chemotherapy*. 2013; 68: 1183–1192.

³ Wang, X et al. "In vitro activity of ceftazidime-avibactam and aztreonam-avibactam against 372 Gram-negative bacilli collected in 2011 and 2012 from 11 teaching hospitals in China." American Society for Microbiology. 2013: 1-16. Print.

Currently approved inhibitors such as clavulanic acid, tazobactam and sulbactam lack the spectrum of inhibition against many of the contemporary and emerging β -lactamases such as the KPC, AmpC and CTX-M enzymes.

Ceftazidime-avibactam, in contrast, is a unique IV combination that provides potent bactericidal activity against a broad range of multi-drug resistant Gram-negative pathogens. Ceftazidime-avibactam is the only agent that inhibits both Class A (ESBL and KPC), Class C (AmpC) and some Class D enzymes produced by *Enterobacteriaceae* and *Pseudomonas aeruginosa*.³ Ceftazidime-avibactam is active against Gram-negative MDR pathogens that cause serious life-threatening infections, including resistant *E. coli, Klebsiella pneumoniae*, and *P. aeruginosa*. In addition, it is particularly active against multiple classes of β -lactamases, including the emergent carbapenemases, which confer resistance to the carbapenem class of antibiotics currently used to treat many resistant pathogens. There are very limited safe and effective treatments available for these challenging infections.

Two Phase 2 studies have been completed: one assessing the safety, tolerability, and efficacy of ceftazidime-avibactam plus metronidazole versus meropenem in the treatment of hospitalized adults with cIAI, and a second study assessing the safety, tolerability, and efficacy of ceftazidime-avibactam versus imipenem cilastatin followed by appropriate oral therapy in treatment of hospitalized adults with cUTI. In the cIAI study, the primary efficacy analysis evaluated clinical response at the test-of-cure (TOC) visit in the microbiologically modified intent-to-treat (mMITT) Population. Favorable clinical response was high for both ceftazidimeavibactam plus metronidazole (82.4%) and meropenem (88.8%) treatment groups. In the cUTI study, the primary efficacy analysis evaluated microbiological outcome at TOC in the mMITT Population, which demonstrated a similar favorable microbiological outcome between the ceftazidime-avibactam (67.4%) and imipenem cilistatin (63.3%) treatment groups. Importantly, favorable outcomes were comparable between treatment groups, both within and between the subgroups of subjects with ceftazidime-susceptible or ceftazidime non-susceptible pathogens. Secondary analyses in a subset of 85 subjects enrolled in these studies demonstrated ceftazidimeavibactam efficacy in treating cIAI and cUTI caused by ceftazidime non-susceptible Gramnegative bacilli. Among 53 subjects with cIAI caused by ceftazidime-nonsusceptible pathogens, favorable clinical response rates at TOC in the mMITT Population were 90.0% for the ceftazidime-avibactam group compared with 82.6% for the meropenem group. For 32 subjects with cUTI caused by ceftazidime-nonsusceptible pathogens, favorable microbiological response rates were 64.3% and 55.6% for the ceftazidime-avibactam and imipenem cilistatin groups, respectively. In both studies, ceftazidime-avibactam also demonstrated a safety and tolerability profile that was both similar to comparator and consistent with the established safety profile of ceftazidime.

In the proposed label, ceftazidime-avibactam is dosed 2.5g, every 8 hours over a 2 hour infusion. The average dose duration recommendation is 5-14 days. Ceftazidime-avibactam is administered via infusion through a peripheral or central line. Based on the proposed label, ceftazidime-avibactam is anticipated to be approved for use in adult patients with the following indications:

Complicated Intra-abdominal Infection (cIAI)

Complicated intra-abdominal infections (in combination with metronidazole) caused by *Escherichia coli* (including cases with concurrent bacteremia), *Klebsiella pneumoniae*, *Proteus mirabilis*, *Providencia stuartii*, *Enterobacter cloacae*, *Klebsiella oxytoca*, *Pseudomonas aeruginosa*, and *Pseudomonas stutzeri*; and polymicrobial infections caused by aerobic and anaerobic organisms including *Bacteroides* spp., (many strains of *Bacteroides fragilis* are resistant to ceftazidime-avibactam).

Complicated Urinary Tract Infection (cUTI), including Acute Pyelonephritis (AP)

Complicated urinary tract infections, including acute pyelonephritis, caused by *Escherichia coli* (including cases with concurrent bacteremia), *Klebsiella pneumoniae*, *Citrobacter koseri*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Citrobacter freundii*, *Proteus* spp., including *Proteus mirabilis* and indole-positive *Proteus*, and *Pseudomonas aeruginosa*.

Limited Use Indication

Aerobic Gram-negative Infections with Limited Treatment Options

Ceftazidime-avibactam may be used for Hospital-acquired Bacterial Pneumonia (HABP)/Ventilator-associated Bacterial Pneumonia (VABP) and Bacteremia where limited or no alternative therapies are available and the infection is proven or suspected to be caused by the following susceptible organisms, including ceftazidime-resistant, β -lactamase-producing, Gramnegative bacteria: *Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca, Pseudomonas aeruginosa, Pseudomonas stutzeri, Providencia stuartii, Citrobacter freundii, Citrobacter koseri, Serratia spp., Enterobacter aerogenes, Enterobacter cloacae, and Proteus spp., including <i>Proteus mirabilis* and indole-positive *Proteus*.

Current coding:

Use the current ICD-10-PCS Codes of 3E03329 Introduction of Other Anti-infective into Peripheral Vein, Percutaneous Approach and 3E04329 Introduction of Other Anti-infective into Central Vein, Percutaneous Approach as shown below:

| Section: 3 | Administra | Administration | | | |
|-------------------|-------------|--|------------------|--|--|
| Body System: E | Physiolog | Physiological Systems and Anatomical Regions | | | |
| Operation: 0 | Introductio | Introduction | | | |
| Body System/Re | gion | Approach | Substance | Qualifier | |
| 3 Peripheral Vein | | 3 Percutaneous | 2 Anti-infective | 8 Oxazolidinones 9 Other Anti-infective | |
| 4 Central Vein | | 3 Percutaneous | 2 Anti-infective | 8 Oxazolidinones 9 Other Anti-infective | |

Coding options:

Option 1. Do not create new ICD-10-PCS codes. Continue to code with current coding shown above.

Option 2: Create a new qualifier S in table 3E0 as shown below. The following new ICD-10-PCS codes 3E0332S and 3E0432S could capture the administration of ceftazidime – avibactam.

| Section: | 3 Adn | Administration | | | |
|--|----------------|--|------------------|---|--|
| Body System: | E Phy | Physiological Systems and Anatomical Regions | | | |
| Operation: | 0 Introduction | | | | |
| Body System/Region | | Approach | Substance | Qualifier | |
| 3 Peripheral Vei 4 Central Vein | in | 3 Percutaneous | 2 Anti-infective | 8 Oxazolidinones 9 Other Anti-infective ADD S Ceftazidime-avibactam | |

CMS Coding Recommendation: CMS is asking for audience input as this is a New Technology Add-On Payment application.

Interim Coding Advice: Option 1as noted above:

3E03329 Introduction of Other Anti-infective into Peripheral Vein, Percutaneous Approach

3E04329 Introduction of Other Anti-infective into Central Vein, Percutaneous Approach

ICD-10 MS-DRGs Update

Availability of ICD-10 MS-DRG/MCE V32.0 Definitions Manuals and Summary of Changes

The following will be available on the CMS.GOV website in November 2014:

- ICD-10 MS-DRG V32.0 Definitions Manual
 - Available in text and HTML versions
- ICD-10 MS-DRG V32.0 "Summary of Changes"
- ICD-10 Definitions of Medicare Code Edits

Will be posted on ICD-10 website at <u>http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html</u>

Availability of Mainframe and PC Software via NTIS in November 2014

- ICD-10 MS-DRG v32 Mainframe Software
- ICD-10 MCE v32 Mainframe Software
- ICD-10 MSG/MCE v32 PC software

Links for ordering will be posted at <u>http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html</u>

The pilot ICD-10 MS-DRG v 31 software was released for purposes of review and evaluation. We welcome additional review and comments on pilot ICD-10 MS-DRG v32.

ICD-10 MS-DRGs v33

The official ICD-10 MS-DRG v33 will be subject to formal rulemaking in the spring of 2015. <u>http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/index.html</u>

Converting the Home Health Prospective Payment System Grouper to ICD-10-CM

Home Health PPS Grouper

- The Home Health Prospective Payments System (HHPPS) bases payment on data submitted as part of the OASIS data set
 - The OASIS is a core standard assessment data set that agencies integrate into their own patient-specific, comprehensive assessment.
 - OASIS collects information that is used to produce risk-adjusted quality measures and to classify patients into clinical and functional status levels that are used in determining Medicare HH episode payments.

Home Health Resource Group

- A Home Health Resource Group (HHRG) is one of 153 payment categories under the Medicare HH PPS.
- Patients in each HHRG are projected to require similar levels of home health resources for their care during the episode and are therefore assigned the same payment weight.

HHRG is determined by:

- Clinical characteristics (e.g. surgical wounds) including diagnoses in one of the 22 Diagnostic Groups
- Functional characteristics (e.g. ability to walk)
- Therapy needs (e.g. PT, OT, SLP)
 - Payment for nonroutine supplies (NRS) is determined using a separate 6group system, also based on OASIS data.

ICD-10 Translation List Development

- Initial Diagnosis and Supply code list translation based on ICD-9-CM to ICD-10-CM GEMs Tool
- Clinical review led to manual adjustments of translation list to accommodate HH setting
- ICD-10 codes were excluded
 - when ICD-10 code was not appropriate for HH
 - when clinician can identify a more specific diagnosis

Excluded Codes - Inappropriate for HH

- Initial encounter codes were removed as such codes are only appropriate when receiving active treatment for an injury
 - Initial encounter codes ending in "A" were replaced with suffix of D, E, F, G, H, J, K, M, N, P, Q and R, to reflect when the patient is being treated for a subsequent encounter (care during the healing or recovery phase)
- Example: S72.024A "Nondisplaced fracture of epiphysis (separation)(upper) right femur, initial encounter for closed fracture" deleted and replaced with S72.024 with suffix of D, E, F, G, H, J, K, M, N, P, Q and R

Excluded Codes – Non-specific

- Non-Specific Codes removed whenever a clinician should be able to identify a more specific diagnosis based on clinical assessment.
- Example: Cutaneous abscess of hand
 - Clinician should be able to identify which hand had the abscess, and therefore, would report using the code that specifies the right or left hand
 - Retained: L02.511 Cutaneous abscess of right hand and L02.512 Cutaneous abscess of left hand
 - Excluded: L02.519 Cutaneous abscess of unspecified hand

Diagnosis Group Assignment

- Replication of the diagnosis group assignment was maintained when possible
- Assignment issues arose because ICD-9-CM to ICD-10-CM translation is not a 1 to 1 mapping process
- Assignment made based on clinical appropriateness and relative resource use

Rulemaking

- July 2013 Home Health Payment System Rate Update for CY 2014 Proposed Rule was posted for public comment on July 3, 2013 at <u>http://www.gpo.gov/fdsys/pkg/FR-2013-07-03/pdf/2013-15766.pdf</u>
- December 2013 Final Rule posted December 2, 2013 at <u>http://www.gpo.gov/fdsys/pkg/FR-2013-12-02/pdf/2013-28457.pdf</u>

Highlights of 2013 Rulemaking

- Published the ICD-10-CM Draft Translation List located at <u>http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html</u>
- Outlined the steps undertaken to develop the list and transition to ICD-10-CM coding
- Proposed a timeframe for posting of a ICD-10-CM HH PPS Grouper
- Notified the industry that we propose to implement additional claims processing edits on home health claims effective October 2014

PAMA Impact

- On 4/1/14, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. No. 113-93) was enacted
 - Section 212 said that the Secretary may not adopt ICD-10 prior to October 1, 2015
 - Delayed implementation of ICD-10-CM Grouper (originally scheduled for 10/1/14)
 - Delayed implementation of revised OASIS data set (OASIS-C1) that had updated clinical items, reduced burden and was modified to collect ICD-10-CM codes (originally scheduled for 10/1/14)

On 8/4/14 HHS published a Final Rule changing the compliance date for ICD-10 from 10/1/14 to 10/1/15 and requiring covered entities to continue using ICD-9-CM through September 30, 2015 [https://federalregister.gov/a/2014-18347]

2014 Rulemaking

- On 7/7/14, the CY 2015 HH PPS Notice of Proposed Rulemaking was published in the Federal Register [https://federalregister.gov/a/2014-15736]
 - Informed agencies of the ICD-10 delay
 - Announced CMS's plans to disseminate information on the planned transition from ICD-9-CM to ICD-10-CM
 - Public comment period closes 9/2/14

2014 Rulemaking continued

- HH PPS Final Rule (November 2014) will
 - announce 10/1/15 as the date for ICD-9-CM to ICD-10-CM HH PPS Grouper transition
 - restate plans for dissemination of further information through the HHA Center Web site and the Home Health, Hospice and DME Open Door Forum
 - provide additional information on planned beta-testing

HH PPS Grouper Status

- For assessment completion dates 10/1/14 12/31/14
 - HH PPS Grouper V3514 was posted 8/6/14 <u>http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/CaseMixGrouperSoftware.html</u>
 - Uses ICD-9-CM codes and other OASIS-C data and contains no clinical or logic changes from current grouper
- For assessment completion dates 1/1/15 9/30/15
 - An updated HH PPS Grouper will be published in fall 2014
 - Will use ICD-9-CM codes and other data collected in the OASIS-C1/ICD-9 version
- For assessment completion dates beginning 10/1/15
 - An updated HH PPS Grouper will be published in the spring/summer of 2015
 - Will use ICD-10-CM codes and other data collected in the OASIS-C1/ICD-10 version

Medicare ICD-10 Testing

Our Approach

CMS is taking a comprehensive four-pronged approach to preparedness and testing to ensure that CMS, as well as the Medicare Fee-For-Service (FFS) provider community, is ready:

- CMS internal testing of its claims processing systems
- Beta testing tools available from CMS
- Acknowledgement testing
- End-to-end testing

What We Have Already Accomplished

- CMS internal system testing of its claims processing systems was completed in October 2013.
- Since that time, only minor system changes were needed to revise the implementation date to 10/1/2015.
- MACs have verified their systems have been updated, and will also be tested and ready for the implementation.
- CMS completed the first Acknowledgement Testing Week with submitters.

March '14 Acknowledgement Testing Success

- Testers submitted more than 127,000 claims with ICD-10 codes and received electronic acknowledgements confirming that their claims were accepted.
- Approximately 2,600 participating providers, suppliers, billing companies and clearinghouses participated in the testing week, representing about five percent of all submitters.
- Testers included large and small physician practices, small and large hospitals, labs, ambulatory surgical centers, dialysis facilities, home health providers, and ambulance providers.
- Nationally, CMS accepted 89% of the test claims, with some regions reporting acceptance rates as high as 99 percent. The normal FFS Medicare claims acceptance rates average 95-98 percent.
- Testing did not identify any issues with the Medicare FFS claims systems.

Future Acknowledgement Testing

- Providers, suppliers, billing companies, and clearinghouses are welcome to submit acknowledgement test claims anytime up to the October 1, 2015 implementation date.
- In addition, special acknowledgement testing weeks give submitters access to realtime help desk support and allows CMS to analyze testing data. Registration is not required. Mark your calendar:
 - November 17 through 21, 2014
 - March 2 through 6, 2015
 - June 1 through 5, 2015

End to End Testing

- CMS plans to offer providers the opportunity to participate in end-to-end testing with Medicare Administrative Contractors (MACs), the Railroad Retirement Board (RRB) and the Common Electronic Data Interchange (CEDI) contractor in January, April, and July of 2015.
- As planned, approximately 850 providers will have the opportunity to participate during each testing period, for a total of 2,550 testers. The goals of this testing are to demonstrate that:
 - Providers and submitters are able to successfully submit claims containing ICD-10 codes to the Medicare FFS claims systems
 - CMS software changes made to support ICD-10 result in appropriately adjudicated claims
 - Accurate Remittance Advices are produced

End to End Testing continued

- 50 volunteers will be chosen by each MAC to participate in each testing round.
- Volunteers chosen will be allowed to submit 50 test claims during the testing week.
- Volunteers will be chosen to provide a representative sample of submitters.
- Once selected, volunteers will be able to submit 50 additional claims in subsequent testing rounds without re-registering.

January 2015 End to End Testing

- The first End to End Testing Week will be **January 26-30, 2015**.
- Registration is available now on each MAC's website.
- Volunteers must register by October 3, 2015.
- Volunteers will be notified by **October 24, 2015** whether or not they have been selected. Those not selected are encouraged to re-apply for the subsequent rounds of testing in April and July.

FY 2017 ICD-10-PCS Updates

- ICD-10-PCS updates have been considered for a number of topics for after the partial code freeze ends
- Regular updates will be made on October 1, 2016 (FY 2017).
- Many have received positive support
- CMS will share a combined draft of ICD-10-PCS updates at the March 2016 ICD-10 Coordination and Maintenance Committee Meeting
- This will include proposed code updates for after the partial code freeze ends which the public supported
- The updates would be made on October 1, 2016