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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



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
March 18, 2015

Pat Brooks, CMS – Co-Chairperson

Webcast and Dial-In Information

- The meeting will begin promptly at 9am ET and will be webcast.
- Toll-free dial-in access is available for participants who cannot join the webcast: Phone: 1-877-267-1577; Meeting ID: 993 955 453. 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 http://www.cms.gov/live/. 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 March 19, 2015 and will be led by the Centers for Disease Control (CDC). Please visit CDCs website for the Diagnosis agenda located at the following address: http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm

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(blinatumomab) Pages 13-15 Celeste Beauregard Tapan Maniar, MD

Global Development Lead

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Pat Brooks

Robert CG Martin, II, MD, PhD, FACS

Sam and Lolita Weakley Endowed Chair in Surgical

Oncology

Director, Division of Surgical Oncology Director of the Upper GI and HPB Multi-

Disciplinary Clinical Professor of Surgery Academic Advisory Dean University of Louisville

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Baylor University Medical Center

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Virginia Commonwealth University Medical Center

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an official journal of Academy Health

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Registering for the next meeting:

Registration for the September 23-24, 2015 ICD-10 Coordination and Maintenance Committee meeting opens on August 14, 2015. 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: http://www.cms.hhs.gov/apps/events/

For questions about the registration process, please contact Celeste Beauregard at 410-786-8102 or celeste.beauregard@cms.hhs.gov.

Continuing Education Credits:

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

Continuing Education Information for American Academy of Professional Coders (AAPC)

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

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

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

ICD-10 TIMELINE

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

March 18 – 19, 2015 ICD-10 Coordination and Maintenance Committee

meeting.

April 1, 2015 There were no requests for ICD-9-CM codes to capture new diagnoses or

new technology for implementation on April 1, 2015. Therefore, there will be no new ICD-9-CM diagnosis or procedure codes implemented on April

1, 2015.

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 Federal Register 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:

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS

/list.asp

April 2015 Webcast of the March 18-19, 2015 ICD-10 Coordination and Maintenance

Committee meeting will be posted on the CMS webpage as follows:

https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/me

etings.html

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:

http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm

June 2015 Final addendum posted on web pages as follows:

Diagnosis addendum – http://www.cdc.gov/nchs/icd/icd10cm.htm

Procedure addendum –

http://cms.hhs.gov/Medicare/Coding/ICD10/index.html

June 19, 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,

2016.

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:

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS/list.asp

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 –

http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html

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 –

http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm

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: https://www.cms.gov/apps/events/default.asp

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: https://www.cms.gov/apps/events/default.asp

Attendees must register online by September 11, 2015; failure to do so may result in lack of access to the meeting.

September 22 –23, 2015

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 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.

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:

 $\underline{https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html}$

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 1, 2015

ICD-10-CM/PCS codes go into effect along with ICD-10 MS-DRGs

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 –

http://www.cdc.gov/nchs/icd/icd9cm_addenda_guidelines.htm Procedure addendum –

http://www.cms.gov/Medicare/Coding/ICD10/

October 23, 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.

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:

http://www.cms.gov/Medicare/Coding/ICD10/

http://www.cdc.gov/nchs/icd/icd9cm_addenda_guidelines.htm

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.

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
- Public can comment at meeting and send written comments

Comments on Code Proposals

- Submit written comments by
 - April 17, 2015 for codes to be implemented on October 1, 2015
 - June 19, 2015 for codes to be implement on October 1, 2016
- Procedure comments to Pat Brooks, CMS patricia.brooks2@cms.hhs.gov
- Diagnosis comments to Donna Pickett, CDC nchs@cdc.gov

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

Proposed and Final Rules

- April 2015 Notice of Proposed Rulemaking, IPPS
 - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2015 C&M meeting
- August 1, 2015 Final rule with links to final codes to be implemented on October 1, 2015
 - Includes any additional codes approved from March 2015 C&M meeting

Addendum

- June 2015 Final code updates and addendum posted
 - FY 2016 ICD-10-CM (Diagnosis) and ICD-10-PCS (procedure) http://www.cms.gov/Medicare/Coding/ICD10/index.html
 - FY 2016 ICD-10-CM (Diagnosis) http://www.cdc.gov/nchs/icd/icd10cm.htm

GEM and Reimbursement Files

- June 2015 General Equivalence Mappings (GEM) & Reimbursement postings
 - FY 2016 ICD-10-CM and ICD-10-PCS GEMs and Reimbursement mappings posted at http://www.cms.gov/Medicare/Coding/ICD10/index.html
 - Annual GEM updates will be posted early in 2015 year to facilitate implementation planning

September C&M Code Requests

- July 17, 2015 Deadline for submitting topics for September 22–23, 2015 C&M meeting
 - Procedure requests to Pat Brooks, CMS patricia.brooks2@cms.hhs.gov
 - Diagnosis requests to Donna Pickett, CDC nchsicd9@cdc.gov

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

Written Comments

- No matter how you participate please send written comments by
 - April 17, 2015 for codes to be implemented on October 1, 2015
 - June 19, 2015 for codes to be implemented on October 1, 2016
- Procedure comments to Pat Brooks, CMS patricia.brooks2@cms.hhs.gov
- Diagnosis comments to Donna Pickett, CDC <u>nchsicd9@cdc.gov</u>

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.

Partial Code Freeze Implementation

- 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.

C&M Meets During Freeze

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.

ICD-10 Updates

- CMS will provide a variety of ICD-10 updates during this meeting
 - Updates on ICD-10 End-To-End Testing
 - Impacts of implementing ICD-10 MS-DRGs
 - At the conclusion of the procedure topics, CDC will then begin their part of the meeting on diagnosis issues

New Technology Section in ICD-10-PCS

- Public request to create new section in ICD-10-PCS for new technologies
- Issue discussed at September 2014 C&M meeting
- Drugs and supplies were mentioned as concerns
- CMS agreed with this suggestion

New Section X

- General goal of section X is two-fold
 - Create codes uniquely identifying procedures requested via the New Technology Application Process or that capture services not routinely captured in ICD-10-PCS that have been presented for public comment at a C&M meeting
 - Create codes that maintain continuity with the other sections in ICD-10-PCS to the extent possible

Section X Codes

- Section X codes use the same root operation values as their closest counterparts in other sections of ICD-10-PCS
- X section is for types of technologies that are not usually captured by coders or that do not
 usually have the desired specificity within the current ICD-10-PCS structure required for
 new technology approval

New Technology Codes

 Codes for new technologies that are consistent with current ICD-10-PCS codes may still be created within the current ICD-10-PCS structure

Section X Structure

- First character letter X
- Second character body system/region value
- Third character root operation value
- Fourth character body part value
- Fifth character approach value
- Sixth character device/substance/technology value
- Seventh character information indicating the year created

Section X Structure con't.

- Consistent with the general architecture of ICD-10-PCS, each of the seven characters has a consistent definition within the section
- the third, fourth and fifth characters specify the root operation, body part, and approach respectively because that is the type of information defined in those characters for the majority of the ICD-10-PCS sections

Section X Code Transition to ICD-10-PCS

- After section X codes have served their purpose, proposals to delete X codes and create new codes in the body of ICD-10-PCS would be addressed at subsequent C&M meetings
- Details about this structure will be explained during the ICD-10-PCS code requests that follow

Administration of BLINCYTOTM (blinatumomab)

Issue: There is no ICD-10- PCS code for the intravenous administration of BLINCYTO™ (blinatumomab). Blinatumomab is an antineoplastic immunotherapy that is in a new class of molecular constructs called bispecific T-cell engagers (BiTE®). Should a new code be established so hospitals and payers can identify blinatumomab administration for the treatment of Ph- R/R B-precursor ALL on claims?

New Technology Application? Yes. Amgen submitted a New Technology Add-on Payment application for blinatumomab for fiscal year (FY) 2016.

Food and Drug Administration (FDA) Approval: The Biologics License Application (BLA) for blinatumomab was submitted to the FDA on September 19, 2014, and blinatumomab received regulatory approval on December 3, 2014.

Background: Blinatumomab is a bispecific CD19-directed CD3 T-cell engager and is indicated for the treatment of Philadelphia chromosome- CD19-directed CD3 T-cell engager and for the treatment of Philadelphia chromosome- negative (Ph-) relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL).

Acute Lymphoblastic Leukemia

ALL is a rare, aggressive cancer of the blood and bone marrow, the spongy tissue inside bones where blood cells are made. ALL is derived from the precursor of B-cells, which are major components of the immune system. It is a life-threatening disease that requires urgent treatment with approximately 6,050 new cases diagnosed in the U.S. each year. Of these, approximately 2,400 new cases are adults. The majority of these cases are B-lineage, Ph- ALL. Currently, the standard treatment for ALL requires the use of multiple, intensive chemotherapy drugs in combination to try to induce remission. In R/R ALL, the goal of therapy is to induce remission and proceed to allogeneic hematopoietic stem cell transplant (alloHSCT), the only known curative option. Although chemotherapy can sometimes induce remission in R/R ALL, many patients will relapse or stop responding to standard treatment, and the prognosis is poor. Furthermore, chemotherapy toxicities can be cumulative; therefore, patients who have had intensive treatment may not be eligible for further intensive chemotherapy.

Blinatumomab for the Treatment of ALL

Blinatumomab is an antineoplastic immunotherapy that may be effective in cases where the cancer has become resistant to chemotherapy, without many of the cumulative side-effects typically associated with chemotherapy. A major challenge in developing effective antineoplastic immunotherapies has been the difficulty in generating a robust immune response to the cancer in a way that has a positive benefit.

Blinatumomab is a biological that is in a new class of molecular BiTE[®] constructs. BiTE[®] constructs are designed to selectively attach to a molecule on the tumor cell surface and to a molecule on the surface of normal T-cells, one of the major components of the immune system. By attaching to both the tumor and the T-cell and bringing the two into close proximity, the BiTE[®] can direct the T-cell to kill the tumor cell. Blinatumomab is the first and most advanced BiTE[®] which targets a molecule called CD19, which is present on ALL cells. Blinatumomab helps place the T-cells within reach of the

targeted cell (CD19), with the intent of allowing T-cells to inject toxins and trigger the cancer cell to die.

Blinatumomab, given as a monotherapy, has produced complete remission and duration of response in adults with relapsed or refractory disease, including in patients who have not responded to standardly available chemotherapies.

Blinatumomab has a positive benefit risk profile even in elderly or heavily pre-treated patients and therefore represents an option for those who have failed or are ineligible for standard salvage chemotherapy. Blinatumomab is also associated with significantly improved clinical outcomes in R/R ALL as it provides durable relapse-free survival (RFS), a trend towards reduced mortality (prolonged overall survival), and potential ability to bridge to alloHSCT which is currently considered the only curative option, but generally requires patients to be in remission to be successful. Furthermore, blinatumomab confers these benefits as a single agent administered as a 4-week continuous infusion, as opposed to salvage chemotherapy, which is administered in often complex multi-agent regimens.

Inpatient Administration

Blinatumomab administration is initiated in the inpatient setting, and the treatment is delivered by continuous intravenous (IV) infusion at a constant flow rate using an infusion pump. A single cycle of treatment is 28 days of continuous infusion. Each cycle of treatment is separated by a 2-week treatment-free interval. The recommended initial dose of blinatumomab in the first cycle is 9 mcg/day for week 1 (first 7 days) of treatment. The dose is increased to 28 mcg/day starting at week 2 through week 4 of the first cycle. All subsequent cycles are recommended to be dosed at 28 mcg/day throughout the entire 28-day treatment period. The length of stay for inpatient administration varies. The U.S. package insert (USPI) recommends that patients be hospitalized for the first 9 days of the first cycle and the first 2 days of the second cycle; however, clinical trial experience shows that the mean inpatient days for Cycles 1 and 2 are 21.2 and 10.2, respectively. Patients with R/R ALL, regardless of which treatment they are receiving, tend to be sick or clinically precarious. These patients may already be inpatients due to their underlying clinical status prior to treatment with blinatumomab (or agents), and this is why some patients on treatment remain hospitalized for longer periods. Physicians may use their clinical discretion to keep blinatumomab patients as inpatients longer than the initial days recommended in the USPI depending on the patient's clinical condition, comorbidities, or complications.

Current Coding: The administration of blinatumomab can be reported using codes from table 3E0.

Section Body System Operation	0	Administration Physiological Systems and Anatomical Regions Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products				
Body Sy	Body System / Region Approach Substance Qualifier					
3 Peripheral Vein 4 Central Vein		3 Percutaneous	0 Antineoplastic	5 Other Antineoplastic		

Coding Options:

Option 1: Do not create a new ICD-10-PCS code for Blinatumomab. Continue using codes in table 3E0 as shown above in current coding.

Option 2: To capture the intravenous administration of blinatumomab create a new Qualifier value T, Blinatumomab, in the Administration section of ICD-10-PCS.

Section Body System Operation	0	Administration Physiological Systems and Anatomical Regions Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products				
Body S	Body System / Region Approach Substance Qualifier					
3 Peripheral Vein 4 Central Vein				0 Antineoplastic	ADD T Blinatumomab	

Option 3: Create new codes in the New Technology section (section X) of ICD-10-PCS to capture the intravenous administration of blinatumomab by adding value 5, Blinatumomab Antineoplastic, for the sixth character that describes the Device/Substance/Technology.

Body System V	N / D I	New Technology Anatomical Regions ntroduction: Putting in o xcept blood or blood pr	or on a therapeutic, diagnostic, nutritional, physioducts	iological, or prophylactic substance
Body Part Approach Device / Substance / Technology Qualifier				Qualifier
3 Peripheral Vein 4 Central Vein		3 Percutaneous	ADD 5 Blinatumomab Antineoplastic	1 New Technology Group 1

CMS recommendation: Option 3. Create new ICD-10-PCS X codes for Blinatumomab.

Interim Coding Advice: Continue to use codes from table 3E0 as above in current coding.

Irreversible Electroporation (IRE)

Issue: There is not a unique ICD-10-PCS code to describe hepatic and/or pancreatic cancer cell destruction using Irreversible Electroporation (IRE).

New Technology Application? Undetermined, may apply in FY 2017.

Background: Irreversible electroporation (IRE) is a new tissue ablation technique in which micro to millisecond electrical pulses are delivered to undesirable tissue to produce cell necrosis through irreversible cell membrane permeabilization. IRE affects only the cell membrane and no other structure in the tissue.

Locally advanced hepatic and pancreatic cancer patients have limited options for long term durable disease control. Ablation techniques such as cryoablation and thermal ablation are current treatment options. However, these procedures have been associated with destruction of adjacent healthy tissue. In contrast, IRE therapy can be well tolerated with rapid resolution of hepatic and/or pancreatic inflammation and preservation of healthy tissue and vascular structures.

Current Coding: Under ICD-10-PCS, ablation is a term included in the root operation Destruction as, "physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent". The current ICD-10-PCS codes do not identify the specific technique that induces tumor cell membrane porosity thereby causing auto-programmed cancer cell death (i.e. apoptosis).

Body System F H Operation 5 D	Hepatobiliary System and Pancreas				
Body Part	Approach	Device	Qualifier		
0 Liver1 Liver, Right Lobe2 Liver, Left LobeG Pancreas	Open Percutaneous Percutaneous Endoscopic	Z No Device	Z No Qualifier		

Coding Options:

Option 1: Do not create new codes for Irreversible Electroporation. Continue using codes in table 0F5 as indicated above.

Option 2: Create qualifier F, Irreversible Electroporation, in character 7 of table 0F5 to identify IRE versus other destruction techniques.

Section Body System Operation	0 F 5	Medical and Surgical Hepatobiliary System and Pancreas Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent					
Body F	Part	1	Approach	Device	Qualifier		
0 Liver			Open Percutaneous Percutaneous Endoscopic	Z No Device	ADD F Irreversible Electroporation Z No Qualifier		

Option 3: Create new codes in section X, New Technology, to identify the IRE destruction technique.

Section Body System Operation	System F Hepatobiliary System and Pancreas				
Body	Body Part		Approach	Device/Substance/Technology	Qualifier
ADD 0 Liver			0 Open		
ADD 1 Liver, I	ADD 1 Liver, Right Lobe		3 Percutaneous	ADD F Irreversible Electroporation	2 New Technology Group 2
ADD 2 Liver, Left Lobe		Lobe	4 Percutaneous	Technique	Z New Technology Group 2
ADD G Pancreas Endoscopic					

CMS Recommendation: CMS welcomes public comments on these options. CMS recommends that any ICD-10-PCS update receiving public support be considered for October 1, 2016.

Interim Coding Advice: In the interim, continue to assign codes from section 0F5 for Destruction.

Administration of Idarucizumab

Issue: There are no ICD-10-PCS codes to specifically capture administration of Idarucizumab. Idarucizumab is a humanized fragment antigen binding (Fab) molecule being developed to rapidly and specifically neutralize the anticoagulant effect of dabigatran in patients in need of urgent interventions or experiencing life threatening bleeding events.

New Technology Application? Yes. Boehringer Ingelheim submitted a New Technology Add-on Payment application for idarucizumab for fiscal year (FY) 2016.

Food and Drug Administration (FDA) Approval: Boehringer Ingelheim plans to submit a biologic license application (BLA) for idarucizumab to the FDA in the first quarter of 2015. If approved, it is expected to be the only FDA approved therapy to neutralize the anticoagulant effect of dabigatran. In June 2014, FDA granted Breakthrough Therapy Designation for idarucizumab which is intended to expedite the development and review of drugs for serious or life-threatening conditions.

Background: Idarucizumab is a humanized Fab molecule directed specifically against dabigatran. PRADAXA[®] (dabigatran etexilate mesylate) is an oral direct thrombin inhibitor currently indicated:

- To reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAF):
- For the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been treated with a parenteral anticoagulant for 5-10 days; and
- To reduce the risk of recurrence of DVT and PE in patients who have been previously treated.

Since FDA approval of dabigatran, nearly 9,000,000 prescriptions have been filled for 935,000 distinct patients in the United States according to marketplace data. There are approximately 256,000 patients currently taking dabigatran. A majority of the patients are 65 years and above, representing 79 percent (approximately 203,000) of the 256,000 unique dabigatran patients. Of the total dabigatran patients, a large majority (93 percent, or approximately 240,000) had a diagnosis of NVAF, with 2 percent (approximately 5,000) having a diagnosis of either DVT or PE. About 5 percent (approximately 11,000) had other diagnoses.

There are no specific antidotes for dabigatran. Patients treated with dabigatran who experience bleeding are managed by supportive care. Protamine sulfate and vitamin K, which are typically used to reverse the effects of heparin and warfarin, respectively, are not effective reversal agents for dabigatran. Other treatment options such as hemodialysis, fresh frozen plasma, blood factor products and prothrombin complex concentrates are available but are not ideal.

Idarucizumab is being developed as a specific antidote to dabigatran. Idarucizumab binds to dabigatran, thereby inactivating it, and allowing thrombin to act in blood clot formation. Idarucizumab represents a new pharmacologic approach to neutralizing the anticoagulant effect of dabigatran. Idarucizumab has a strong binding affinity to dabigatran and a short half-life. There are no expected procoagulant or anticoagulant effects. Idarucizumab has been studied in animal models as well as in healthy human volunteers, and at sufficient doses led to immediate, complete, and sustained reversal of dabigatran anticoagulant activity.

For patients with a need for urgent surgery or with bleeding, the proposed dosage and administration of idarucizumab is a complete dose of 5 gm administered intravenously, as two consecutive infusions over 5 to 10 minutes each or as a bolus.

Current Coding: The administration of idarucizumab can be reported using codes from table 3E0.

Section Body System Operation	3 E 0	Administration Physiological Systems and Anatomical Regions Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products				
Body Syst	Body System / Region Approach Substance Qualifier					
3 Peripheral Vein4 Central Vein		3 Percutaneous	G Other Therapeutic Substance	C Other Substance		

Coding Options:

Coding Option 1: Do not create new ICD-10-PCS codes for the intravenous administration of idarucizumab. Continue using codes in table 3E0 as shown above in current coding.

Coding Option 2: To capture the intravenous administration of idarucizumab create the following new Qualifier value S, Idarucizumab, in the Administration section of ICD-10-PCS.

	dy System E Physiological Systems and Anatomical Regions				
Body Syste	Body System / Region Approach Substance Qualifier				
3 Peripheral Vein 4 Central Vein		3 Percutaneous	G Other Therapeutic Substance	ADD S Idarucizumab	

Coding Option 3: Create new codes in the New Technology section (section X) of ICD-10-PCS to capture the intravenous administration of idarucizumab by adding value 3, Idarucizumab, Dabigatran Antidote.

Section X Body System W Operation 0	New Technology Anatomical Regions Introduction: Putting except blood or blood	n or on a therapeutic, diagnostic, nutritional, physiol products	ogical, or prophylactic substance
Body Part	Approach	Device / Substance / Technology	Qualifier
3 Peripheral Vein 4 Central Vein	3 Percutaneous	ADD 3 Idarucizumab, Dabigatran Antidote	1 New Technology Group 1

CMS recommendation: Option 3. Create new ICD-10-PCS X codes for Idarucizumab.

Interim Coding Advice: Continue to report codes from table 3E0 as above in current coding.

Coronary Orbital Atherectomy

Issue: ICD-10-PCS does not currently have a means of identifying the use of orbital atherectomy in coronary artery interventions to differentiate this procedure from conventional atherectomy (directional, rotational, laser). Should new Qualifiers be added to identify and describe the specific mechanism of action used to perform an atherectomy?

New Technology Application? Yes. Cardiovascular Systems, Inc. (CSI) submitted an application for a New Technology Add-on Payment for FY 2016. The DIAMONDBACK 360[®] Coronary Orbital Atherectomy System (OAS) received FDA approval October 21, 2013.

Background: Coronary artery disease (CAD) is currently the number one cause of death in the USA, killing nearly 380,000 people annually. Angioplasty and stenting are among the leading treatments for more severe or symptomatic coronary artery blockages. With advances in current stent technology, most coronary lesions can be treated effectively with relatively favorable long-term outcomes; however, there remain subsets of the population that are still challenging to treat, including patients with severe coronary calcification. Currently, the prevalence of diabetes, renal failure and advanced age are on the rise in the USA and all are risk factors for coronary calcification.

Calcified lesions have been shown to respond poorly to percutaneous coronary intervention (PCI) and are associated with a high frequency of restenosis, target lesion revascularization (TLR), vessel dissection during PCI, failure to deliver a stent, balloon ruptures and undilatable lesions. Up to 50% of coronary stents deployed in calcified lesions were found to have asymmetric stent expansion, potentially increasing the likelihood of stent thrombosis and/or restenosis.

Patients with severely calcified lesions have been excluded from all FDA PMA trials in the past due to the high complication rates associated with these patients.

Atherectomy is a minimally invasive catheter-based procedure to remove plaque from arteries, and is useful in cases where the plaque is very hard due to calcification, plaque has built up in a coronary artery bypass graft, or to remove other difficult blockages, thus opening up blocked coronary arteries and allowing blood to circulate unobstructed to the heart muscle.

The orbital atherectomy procedure removes calcified stenotic lesion material to increase vessel compliance prior to balloon angioplasty and stent placement, which may lead to reduced acute vascular injury. Treatment of severely calcified plaque with the Orbital Atherectomy System (OAS) not only helps facilitate stent delivery, but improves both acute and 30 day clinical outcomes compared with the outcomes of historic control subjects in this difficult-to-treat severe calcium patient population.

Orbital atherectomy has the following key differences from other atherectomy procedures:

• Differential, circumferential (orbital) sanding mechanism

The orbital path of the OAS crown around the circumference of the lumen allows the OAS crown to differentiate between healthy and diseased tissue. In orbital atherectomy, healthy/compliant tissue should flex away from the OAS crown, whereas fibrotic calcific lesions (diseased tissue) would generate an opposing force. In contrast, the burr of a rotational device, the contact with a laser device or the cutter of a directional device is focused in one place and does not circumferentially differentiate between healthy and diseased tissue.

Further, the circumferential nature of orbital atherectomy facilitates treatment of diffuse arterial disease which can be more challenging and time consuming with focal treatments such as rotational, laser and directional atherectomy.

- The operator can control the speed of the OAS with higher speeds resulting in increasing orbital pressure and larger treatment areas. This ability to increase the orbital area of treatment allows one orbital device to treat multiple vessel sizes (diameters); whereas multiple rotational, directional and laser devices may be required to treat vessels with varying diameters.
- Non-occlusive contact between the OAS device and vessel wall allows for some blood flow which
 flushes debris and facilitates cooling, minimizing the potential for ischemia and thermal trauma.
 Continuous flow of blood and saline during orbital atherectomy minimizes thermal injury and
 potentially decreases no-reflow and periprocedural cardiac enzyme elevation. Rotational,
 directional and laser atherectomy are occlusive devices.
- Orbital atherectomy treats bi-directionally. Orbital atherectomy treats the vessel both while the device is being advanced distally and pulled back proximally thus allowing for more rapid treatment. Rotational, directional and laser atherectomy are unidirectional devices.

Device: The DIAMONDBACK Coronary OAS is a percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for percutaneous transluminal coronary angioplasty (PTCA) or stenting due to *de novo*, severely calcified coronary artery lesions.

The OAS consists of the hand-held CSI DIAMONDBACK 360[®] Coronary Orbital Atherectomy Device (OAD), the CSI Saline Infusion Pump (OAS pump), the CSI VIPERWIRE Advance Coronary Guide Wire (VIPERWIRE guide wire), and the CSI VIPERSLIDE Lubricant. All of the components are required in order to use the OAS. The OAS reduces occlusive material (i.e., coronary plaque) and restores luminal patency to facilitate stent delivery. The DIAMONDBACK Coronary OAS has a unique mechanism of action utilizing a unique combination of differential sanding and centrifugal force to safely and simply reduce coronary arterial calcium, thereby facilitating coronary stent placement.

The OAS utilizes a diamond-coated crown mounted eccentrically and is an "over the wire" device, which requires the use of the VIPERWIRE. The crown orbits at high speeds circumferentially around the interior of the vessel wall and provides therapy by removing arterial plaque. Position of the crown within the vessel is controlled via a control handle. As treatment proceeds, a thin layer of plaque is removed with each pass (in both directions; distal and proximal) of the crown. This allows the crown to "sand" away the calcified lesion while the more elastic tissue flexes away from the crown to increase lumen size and modify plaque compliance, depending on the speed chosen. The crown's orbital diameter expands radially via centrifugal force.

Current Coding: Coronary atherectomy procedures are identified within Table 02C, Extirpation of Heart and Great Vessels, with the Qualifier value Z, No Qualifier.

Section	0	Medical and Surgical			
Body System	2	Heart and Great Vessels			
Operation	С	Extirpation: Taking or cutting out solid matter from a body part			
Body Part		Approach	Device	Qualifier	

Body Part	Approach	Device	Qualifier
O 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 D Papillary Muscle F Aortic Valve G Mitral Valve H Pulmonary Valve J Tricuspid Valve K Ventricle, Right L Ventricle, Left M Ventricular Septum N Pericardium P Pulmonary Artery, Right R Pulmonary Artery, Left S Pulmonary Vein, Right T Pulmonary Vein, Left V Superior Vena Cava W Thoracic Aorta	O Open Percutaneous Percutaneous Endoscopic	Z No Device	Z No Qualifier

Coding Options:

Option 1: Do not add a new Qualifier value to table 02C, Extirpation of Heart and Great Vessels. Continue to use existing codes as shown above.

Option 2: Add a new code for Coronary Orbital Atherectomy to Section X, New Technology, under Body System 2 (Cardiovascular System) since it is a New Technology application.

Section	Х	New Technology		
Body System	2	Cardiovascular S	ystem	
Operation	С	Extirpation: Takin	ig or cutting out solid matter from a body part	
Body Part		Approach	Device / Substance / Technology	Qualifier
ADD 0 Coronary A	rtery	3 Percutaneous	ADD 6 Orbital Atherectomy Technology	2 New Technology Group 1

Option 3: Add new Qualifiers J, Orbital; L, Laser; M, Rotational and N, Directional, to table 02C, Extirpation of Heart and Great Vessels, in the Med/Surg section to differentiate orbital atherectomy from laser, rotational and directional atherectomy procedures.

Section Body System Operation	0 2 C	Medical and Surgical Heart and Great Vessels Extirpation: Taking or cutting out solid matter from a body part					
Body Part			Approach	Device	Qualifier		
 O Coronary Artery, One Site 1 Coronary Artery, Two Sites 2 Coronary Artery, Three Sites 3 Coronary Artery, Four or More Sites 		Open Percutaneous Percutaneous Endoscopic	Z No Device	ADD J Orbital ADD L Laser ADD M Rotational ADD N Directional			

CMS Recommendation: CMS recommends Option 2, add a new code for Coronary Orbital Atherectomy to Section X under Body System 2 (Cardiovascular System) since it is a New Technology application. If the technology is approved for discharges beginning FY 2016 (October 1, 2015), once the established timeframe is met for the Section X code to expire, then Option 3 for a new code(s) in the Med/Surg section could be proposed for implementation. We invite the audience to comment on this recommendation.

Interim Coding Advice: Continue to code with appropriate values from table 02C, Extirpation of Heart and Great Vessels, with the Qualifier value Z, No Qualifier.

Administration of CRESEMBA® (isavuconazonium)

Issue: There is not a unique ICD-10-PCS code to describe the intravenous (IV) and oral administration of CRESEMBA® (isavuconazonium) to treat patients with invasive fungal infections, in particular invasive aspergillosis and mucormycosis.

New Technology Application? Yes. Astellas submitted a New Technology Add-On Payment application for isavuconazonium for fiscal year (FY) 2016.

Food and Drug Administration (FDA) Approval: The New Drug Application (NDA) for isavuconazonium was submitted to the FDA and accepted on September 6, 2014. The target date of regulatory approval is March 8, 2015.

Background: Fungal infections (mycoses) can be classified as superficial, subcutaneous, or systemic. Systemic mycoses are usually acquired exogenously through inhalation, ingestion, or traumatic implantation and develop almost exclusively in debilitated or immunocompromised individuals. The incidence of systemic mycoses has increased dramatically since 1980, largely because of the growing number of immunocompromised patients.

Recent epidemiologic trends indicate a shift toward infections by mucormycetes which were previously uncommon and have little susceptibility to current antifungal agents (Kobayashi et al, 2004; Garber, 2001). Azole-resistant Aspergillus species, particularly A. fumigatus, is becoming a concern in many areas including the United States (Bowyer et al, 2011). Itraconazole-resistant Aspergillus isolates were first reported in the United States in 1997 (isolates from late 1980s), although only a few additional clinical cases have been published since then (Howard et al, 2009). European reports have shown many isolates have cross-resistance to all commercially available azoles and clinical data shows an increase in acquired-resistance subsequent to prolonged azole treatment (Howard et al, 2009; Snelders et al, 2008). Multiple mechanisms of azole-resistance have been revealed, both via alterations of the target enzyme CYP51A and more recently overinduction/overexpression of CYP51B (in the absence of CYP51A mutations) (Buied et al, 2013).

Mucormycosis is most prevalent in immunocompromised patients. With the rising rate of diabetes, transplantation, and natural disasters the number of patients affected is on the rise. Mucormycosis is thought to be under-diagnosed because of its similarity to aspergillosis in clinical presentation, and often becomes apparent as a breakthrough infection or at autopsy (Kontoyiannis & Lewis, 2011; Marty et al, 2004). Mortality in patients with mucormycosis remains high due to a lack of effective treatment options.

Isavuconazonium sulfate is a novel, water-soluble prodrug of the triazole isavuconazole. Following administration, isavuconazonium is rapidly converted by plasma esterases to the active moiety isavuconazole. Unlike other azoles, the IV formulation of isavuconazole does not require the addition of cyclodextrin – a key point of differentiation from other treatments for invasive aspergillosis and mucormycosis.

Isavuconazole blocks the synthesis of ergosterol, a key component of the fungal cell membrane, through the inhibition of cytochrome P450 (CYP) dependent enzyme lanosterol 14α -demethylase responsible for

the conversion of lanosterol to ergosterol in the fungal cell membrane. This results in an accumulation of methylated sterol precursors and a depletion of ergosterol within the cell membrane thus weakening the structure and function of the fungal cell membrane.

The IV formulation is a powder for concentrate for solution for infusion containing 372.6 mg isavuconazonium sulfate corresponding to 200 mg isavuconazole. The oral formulation is a hard capsule containing 186.3 mg isavuconazonium sulfate corresponding to 100 mg isavuconazole.

In the U.S., isavuconazonium was granted FDA fast-track status, designated as a Qualified Infectious Disease Product (QIDP) under the U.S. GAIN Act, and received orphan drug designations for the treatment of invasive aspergillosis and mucormycosis.

Administration of isavuconazonium is not limited to a single setting of care, and will be administered in both inpatient and outpatient settings. For patients who are admitted to the hospital, the first dose of isavuconazonium will be administered either in the emergency department or during the inpatient period. Following the IV loading dose on days 1-2, a patient could be transitioned to oral therapy on day 3 which will continue throughout duration of treatment. Unique ICD-10-PCS codes will be necessary to facilitate the NTAP for hospitals administering both the IV and oral formulations of isavuconazonium to Medicare beneficiaries in the inpatient setting.

Current Coding: There is no ICD-10-PCS code for oral formulations of isavuconazole. The intravenous administration of isavuconazole can be reported using codes from table 3E0.

Section	3	Administration				
Body System	Ε	Physiological Sy	Physiological Systems and Anatomical Regions			
Operation	0	Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products				
Body System / F	Body System / Region		Approach	Substance	Qualifier	
3 Peripheral Vein		3 Percutaneous	2 Anti-infective	9 Other Anti-infective		

Coding Options:

Option 1: Do not create new ICD-10-PCS codes for Isavuconazole for either the oral or intravenous version of the drug.

Option 2: To capture the intravenous administration of isavuconazole create the following new Qualifier value R, Isavuconazole, in the Administration section of ICD-10-PCS.

Section Body System Operation	0	Introduction: Pu	Administration Physiological Systems and Anatomical Regions ntroduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic ubstance except blood or blood products					
Body System / Region			Approach	Substance	Qualifier	l		
3 Peripheral Vein 4 Central Vein			3 Percutaneous	2 Anti-infective	ADD R Isavuconazole			

Option 3: Create new ICD-10-PCS codes in the New Technology section (section X) of ICD-10-PCS to capture the intravenous administration of isavuconazole by adding value 4, Isavuconazole Anti-infective, for the Device/Substance/Technology character.

Body System W Operation 0	New Technology Anatomical Regions Introduction: Putting in o except blood or blood pro	r on a therapeutic, diagnostic, nutritional, physoducts	iological, or prophylactic substance
Body Part	Approach	Device / Substance / Technology	Qualifier
3 Peripheral Vein4 Central Vein	3 Percutaneous	ADD 4 Isavuconazole Anti-infective	1 New Technology Group 1

CMS recommendation: Option 3. Create new ICD-10-PCS X codes for the intravenous versions of Isavuconazole.

Interim Coding Advice: Continue to report codes 3E03329 Introduction of Other Anti-infective into Peripheral Vein, Percutaneous Approach and 3E04329 Introduction of Other Anti-infective into Central Vein, Percutaneous Approach, for the intravenous version of Isavuconazole. Do not report any code for the oral version of Isavuconazole.

Insertion of Tibial Insert

Issue: There is not a unique ICD-10-PCS procedure code for insertion of tibial insert using the VERASENSETM Knee Balancer System (VERASENSETM) during knee replacement surgery.

New Technology Application? Yes. A New Technology Add-On Payment application for the VERASENSETM Knee Balancer System (VERASENSETM) was submitted for (FY) 2016.

Food and Drug Administration (FDA) Approval: Yes. FDA approval was obtained on (provide the date). The FDA defines the product codes associated with the OrthoSensor Verasense Knee Balancer having the intended use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VerasenseTM Knee Balancer System is sterile, for single patient use.

Background: Per the applicant, knee instability is a leading cause of patient dissatisfaction after TKA. In a multi-center study, use of VERASENSETM has been reportedly shown to reduce post-op pain and improve activity and patient satisfaction scores with statistical significance. The applicant noted, in fact, 97% of patients whose knees were balanced using VERASENSETM reported they were satisfied to very satisfied at 1-year post-op. Per the applicant, this compares favorably to peer-reviewed publications that show an average of 81% patient satisfaction after a TKA procedure. According to the applicant, that's a 16% improvement in patient satisfaction for balanced knees; the first significant-notable increase of patient-reported satisfaction in over 30 years. Reducing the number of revision TKA procedures is a major objective of the U.S. healthcare system estimated to save the system over \$94 million annually.

Technology and Procedure: When placed intraoperatively in the open surgical space on the tibia, the VERASENSETM device combines dual sensor elements, coupled with micro-processing technology, to accurately depict intra-articular kinetics and contact point location within the knee. Placement of the VERASENSETM intelligent tibial trial insert by the surgeon does not require any force, surgical placement of tracking pins, or infiltration of the bony or soft tissue of the knee. The VERASENSETM Knee Balancer System is placed on the tibial plateau and transmits inter-compartmental pressure data wirelessly, enabling orthopedic surgeons to make informed decisions on soft tissue balance, tibial-femoral rotation and implant position to improve joint performance, knee kinetics and patient satisfaction immediately affecting their soft tissue dissection. Robust wireless communication protocols are used that overcome line-of-sight or other interference issues, therefore it does not require direct antenna based tracking during the TKA.

Once placed on the tibial surface the VERASENSETM provides objective quantitative data about force and balance metrics that aid the surgeon's understanding and measurement of knee balance. The metrics provide specific spatial, orientational, and rotational information to aid surgical dissection decisions during the placement of the TKA components. During the TKA procedure the surgeon uses the data provided by the VERASENSETM tibial trial insert to make the most reportedly surgically effective soft-tissue releases resulting in improved TKA implant stability.

VERASENSE quantifies dynamic femoral contact points onto the tibial articulating surface enabling the surgeon to quantitatively recognize the femoral component rollback and to set tibial tray rotation to optimize tibial femoral articulation. Kinetic TrackingTM method displays femoral component motion paths in the medial and lateral compartments to enable a full kinetic, force and motion, assessment of

operative knee function during the surgical procedure. Patient outcome reporting is also facilitated by capturing kinetic data from the surgical procedure enabling further evidence based comparative effectiveness data supporting quality metrics in support of patient care, registries and research.

During surgery, the surgeon first evaluates the appropriate size and thickness of the standard tibial trial insert. To verify unobstructed motion, the surgeon takes the leg through a full range of motion (ROM). Once confirmed, the surgeon removes the standard tibial trial insert and replaces it with a replicated (size and thickness) VERASENSETM device placed directly on the tibial tray. It is not secured with bone or tissue piercing tracking pins or nails of any kind. All standard tibial trial thicknesses can be replicated by attaching VERASENSETM shims to the intelligent tibial trial insert device. Once placed within the knee capsule, it provides the surgeon with quantitative data defining "balance" relative to the articulation of the femur to tibia implant components, capturing balance metrics and dynamically track joint kinetics across the bearing surface, through dynamic motion, while the knee capsule is temporarily towel clipped closed.

Current Coding: There is no ICD-10-PCS code for the use of the VERASENSETM device during knee replacement surgery. Hospitals would code the knee replacement surgery and would not add a code for the use of the VERASENSETM device.

Coding Options:

Option 1: Do not create a new ICD-10-PCS code for this device as the use of this device is part of the knee replacement surgery.

Option 2: Create a new ICD-10-PCS code in the Measurement and Monitoring section for the use of the VERASENSETM Knee Balancer System by adding value S, Lower Joint, to the Body System character and value A, Intercompartmental Pressure, for the Function/Device character.

Section	4	Measuren	Measurement and Monitoring			
Body System	Α	Physiolog	Physiological Systems			
Operation	1	Monitoring	Monitoring: Determining the level of a physiological or physical function repetitively over a period of time			
Body System Approach		Approach	Function / Device	Qualifier		
ADD S Lower Joint 0 Open		0 Open	ADD A Intercompartmental Pressure	G Intraoperative		

Option 3: Create new codes in the New Technology section (section X) of ICD-10-PCS to capture the VERASENSETM Knee Balancer System as indicated below by adding value 2, Intraoperative Knee Replacement Sensor, for the Device/Substance/Technology character.

Section	etion X New Technology					
Body System	R	Joints				
Operation	2	Monitoring: Det	ermining the level of a physiological or physical function re	petitively over a period of time		
Body Part Approach		Approach	Device / Substance / Technology	Qualifier		
G Knee Joint Right			ADD 2 Intraoperative Knee Replacement Sensor	1 New Technology Group 1		

CMS recommendation: CMS recommends Option 3 effective October 1, 2015.

Interim Coding Advice: Should no new ICD-10-PCS codes be created, hospitals would code the knee replacement procedure and would not report a code for the VERASENSETM Knee Balancer System.

Removal of Thrombus and Emboli

Issue: There is not a unique code for the AngioVac System, a cannula based system that drains venous blood during extracorporeal bypass and removes thrombi and emboli from the venous system. This system has been used separately from any extracorporeal bypass for the removal of thrombus from the arterial and venous systems.

New Technology Application? Yes, will apply in FY 2017.

FDA Status: The AngioVac System is comprised of the AngioVac Cannula and the AngioVac Circuit. The original clearance for the Cannula and Circuit was received in March 2009 (K091304 & K092486) with a subsequent clearance received for the Cannula March 2014 (K133445). All FDA clearances were obtained by Vortex Medical who was subsequently purchased by AngioDynamics. It is for the Cannula's expanded indication of removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours that an ICD-10-PCS code is requested.

Background: The product is manufactured by AngioDynamics, Inc. and is referred to as AngioVac. AngioVac products include the Venous Drainage Cannula and the Cardiopulmonary Bypass Circuit. The cannula is intended for use as a venous drainage cannula during extracorporeal bypass for up to six hours. The cannula is also indicated for removal of soft, fresh thrombi or emboli utilizing extracorporeal bypass. The cardiopulmonary bypass circuit is intended for use in procedures requiring extracorporeal circulatory support for periods of up to six hours.

<u>Clinical Indications:</u> The AngioVac Extracorporeal bypass circuit is intended for use in procedures requiring extracorporeal circulatory support for periods up to six hours.

The AngioVac system also works to remove soft, fresh thrombus in large venous structures that include the SVC, IVC, the right atrium and the iliofemoral venous systems. Patients are often not surgical thrombectomy/embolectomy candidates as it may provide an unacceptable morbidity and mortality and alternative treatments, such as thrombolysis, are often contraindicated because of recent surgery or bleeding disorders

<u>The Procedure:</u> The removal of thrombi/emboli procedure is typically performed percutaneously with real time fluoroscopy under general anesthesia by a multidisciplinary team of professionals, often including an interventionalist, a surgeon, an anesthesiologist and a perfusionist. However, AngioVac may be also be used with an open surgical procedure, allowing the physician to view the vein before and during the procedure. In either procedure there are two access points required-an incision is made for the AngioVac Cannula and an incision is made for the Reinfusion Cannula.

The AngioVac cannula is commonly inserted (the location of the thrombus determines the point of access) into the right common femoral vein under direct visualization with standard surgical cutdown. With fluoroscopic guidance, the catheter is advanced to the obstructed vessel over a stiff guidewire and the balloon-actuated funnel tip is opened by using a standard balloon inflation device.

A reinfusion cannula is then inserted. Anticoagulation is used to maintain an activated clotting time. The pump circuit is primed with warm saline solution, connected to the AngioVac cannula and reinfusion cannula, cleared of luminal air, and suction then begins. Blood and thrombus flow through the cannula into a filter. The thrombus is trapped in the filter while blood is returned to the body through a second venous cannula. The AngioVac Cannula and Circuit are used with a standard centrifugal pump, bubble trap and reinfusion cannula. A perfusionist supports the pump circuit that aspirates, filters and reinfuses

the blood. Typically the procedure requires approximately one hour from start to finish although this will vary considerably depending on the patient's condition, comorbidities and other extenuating circumstances.

Current Coding: The new approach being described by the requestor involves prophylactic filtering during surgery that uses cardiopulmonary bypass and using the AngioVac Cannula and Circuit during the bypass to remove any thrombus. To capture the extracorporeal bypass and any removal of thrombus one would use codes for the extracorporeal bypass procedure as well as codes for the removal of thrombus as shown below. Reporting both codes does not clearly indicate that the removal of the thrombus occurred through a cannula during an extracorporeal bypass.

Code the extracorporeal bypass procedure 5A1221Z Performance of Cardiac Output, Continuous.

Section 5	Extracorpo	Extracorporeal Assistance and Performance				
Body System A	Body System A Physiological Systems					
Operation 1	Operation 1 Performance: Completely taking over a physiological function by extracorporeal means					
Body System		Duration	Fund	ction	Qualifier	
2 Cardiac		2 Continuous	1 Ou	ıtput	Z No Qualifier	

Procedures to remove thrombus:

Section Body System Operation	0 2 C	Medical and Surgical Heart and Great Vessels Extirpation: Taking or cutting out solid matter from a body part			
Body Part			Approach	Device	Qualifier
4 Coronary Vein S Pulmonary Vein, F T Pulmonary Vein, L V Superior Vena Ca	_eft		Open Percutaneous Percutaneous Endoscopic	Z No Device	Z No Qualifier

Section 0 Body System 5 Operation C	Medical and S Upper Veins Extirnation: Ta	urgical Iking or cutting out solid matter from a b	ody part	
Body Part	Extripation: 10	Approach	Device	Qualifier
 0 Azygos Vein 1 Hemiazygos Vein 3 Innominate Vein, Right 4 Innominate Vein, Left 5 Subclavian Vein, Right 6 Subclavian Vein, Left 7 Axillary Vein, Right 8 Axillary Vein, Left 9 Brachial Vein, Right A Brachial Vein, Left B Basilic Vein, Right C Basilic Vein, Left D Cephalic Vein, Right F Cephalic Vein, Left G Hand Vein, Left G Hand Vein, Left L Intracranial Vein M Internal Jugular Vein, Right N Internal Jugular Vein, Left P External Jugular Vein, Rig Q External Jugular Vein, Rig Q External Vein, Right 	t ght	Open Percutaneous Percutaneous Endoscopic	Z No Device	Z No Qualifier

Body Part	Approach	Device	Qualifier
S Vertebral Vein, Left			
T Face Vein, Right			
V Face Vein, Left			
Y Upper Vein			

Medical and Surgical	0	Medical and Surgical		
Body System	6	Lower Veins		
Operation	С	Extirpation: Taking or cutting out solid matt	er from a body part	
Body Part		Approach	Device	Qualifier
Body Part O Inferior Vena Cava Splenic Vein Gastric Vein Seophageal Vein Hepatic Vein Superior Mesenteric Vein Inferior Mesenteric Vein Colic Vein Portal Vein Renal Vein, Right Renal Vein, Left Common Iliac Vein, Right Common Iliac Vein, Left External Iliac Vein, Left Hypogastric Vein, Right J Hypogastric Vein, Left M Femoral Vein, Right N Femoral Vein, Left P Greater Saphenous Vein, Rig C Greater Saphenous Vein, Left R Lesser Saphenous Vein, Left T Foot Vein, Right V Foot Vein, Left	ft ht	O Open 3 Percutaneous 4 Percutaneous Endoscopic	Z No Device	Qualifier Z No Qualifier

Coding Options:

Option 1: Do not create new codes for removal of thrombus and emboli that use cardiopulmonary bypass. Continue to assign current codes described above.

Option 2: Create new codes to capture the prophylactic filtering during cardiopulmonary bypass in section 5A1 and the removal of thrombus in the Medical Surgical tables 02C, 05C, and 06C as shown below.

Prophylactic filtering during surgery that uses cardiopulmonary bypass:

Section	5	Extracorporeal Assistance and Performance				
Body System A Physiological Systems						
Operation						
Body System		Duration	Function	Qualifier		
2 Cardiac		2 Continuous	1 Output	ADD F Extracorporeal Filtration Z No Qualifier		

Procedures to remove thrombus:

Section Body System Operation	2 F	Medical and Surgical Heart and Great Vessels Extirpation: Taking or cutting out solid matter from a body part				
Body Part		Approach Device Qualifier		Qualifier		
4 Coronary Vein S Pulmonary Vein, Right T Pulmonary Vein, Left V Superior Vena Cava		Open Percutaneous Percutaneous Endoscopic	Z No Device	ADD V Extracorporeal Suction Z No Qualifier		

Section 0	Medica	l and Surgical					
Body System 5	Upper \	er Veins					
Operation C	Extirpat	tion: Taking or cutting out solid mat	ter from a body p	part			
Body Part		Approach	Device	Qualifier			
 0 Azygos Vein 1 Hemiazygos Vein 3 Innominate Vein, Right 4 Innominate Vein, Left 5 Subclavian Vein, Right 6 Subclavian Vein, Left 7 Axillary Vein, Right 8 Axillary Vein, Left 9 Brachial Vein, Right A Brachial Vein, Left B Basilic Vein, Right C Basilic Vein, Right F Cephalic Vein, Right F Cephalic Vein, Left G Hand Vein, Left G Hand Vein, Left L Intracranial Vein M Internal Jugular Vein, Righ N Internal Jugular Vein, Left P External Jugular Vein, Left P External Jugular Vein, Left R Vertebral Vein, Right S Vertebral Vein, Left T Face Vein, Right V Face Vein, Left Y Hace Vein, Left Y Upper Vein 	ht	Open Percutaneous Percutaneous Endoscopic	Z No Device	ADD V Extracorporeal Suction Z No Qualifier			

Section 0 Body System 6 Operation C	Medical and Surgical Lower Veins Extirpation: Taking or cutting out solid matter from a body part				
Body Part	·	Approach	Device	Qualifier	
O Inferior Vena Cava 1 Splenic Vein 2 Gastric Vein 3 Esophageal Vein 4 Hepatic Vein 5 Superior Mesenteric Vein 6 Inferior Mesenteric Vein 7 Colic Vein 8 Portal Vein 9 Renal Vein, Right B Renal Vein, Left C Common Iliac Vein, Right D Common Iliac Vein, Left F External Iliac Vein, Right		Open Percutaneous Percutaneous Endoscopic	Z No Device	ADD V Extracorporeal Suction Z No Qualifier	

Body Part	Approach	Device	Qualifier
G External Iliac Vein, Left			
H Hypogastric Vein, Right			
J Hypogastric Vein, Left			
M Femoral Vein, Right			
N Femoral Vein, Left			
P Greater Saphenous Vein, Right			
Q Greater Saphenous Vein, Left			
R Lesser Saphenous Vein, Right			
S Lesser Saphenous Vein, Left			
T Foot Vein, Right			
V Foot Vein, Left			
Y Lower Vein			

Option 3: Create new codes in section X, New Technology, to identify removal of thrombus using the extracorporeal suction technique.

Body System 2 Ca	w Technology Irdiovascular System tirpation: Taking or cutting out solid matter from a body part				
Body Part	Approach	Device/Substance/Technology	Qualifier		
ADD 0 Inferior Vena Cava ADD 4 Coronary Vein ADD S Pulmonary Vein, Right ADD T Pulmonary Vein, Left ADD V Superior Vena Cava ADD Y Peripheral Vein	Open Percutaneous Intraluminal	ADD V Extracorporeal Suction Technique	2 New Technology Group 2		

Option 4: Create new codes in section X, New Technology, to identify prophylactic filtering using the extracorporeal suction technique, during surgery that uses cardiopulmonary bypass.

Section Body System Operation	X 2 1	Cardiovaso	New Technology Cardiovascular System Performance: Completely taking over a physiological function by extracorporeal means			
Body Part		Approach	Device/Substance/Technology	Qualifier		
2 Cardiac		0 Open	ADD F Extracorporeal Filtration Technique	2 New Technology Group 2		

CMS Recommendation: CMS welcomes public comment on these options.

Interim Coding Advice: In the interim, continue to capture extracorporeal bypass procedures using code 5A1221Z Performance of Cardiac Output Continuous and assign codes from tables 02C, 05C, and 06C for the removal of the thrombus.

Organ Perfusion for Transplant

Issue: There is no ICD-10-PCS code to capture organ perfusion and the ex-vivo functional assessment of initially unacceptable donor organs, such as marginal lungs, for transplantation when these organs are implanted into a patient.

New Technology Application? Yes, there will be an application in FY 2017.

FDA Approval: FDA approved XVIVO Perfusion System with STEEN Solution in August, 2014 under an HDE. The manufacturer, XVIVO Perfusion, Inc. is pursuing a more broad FDA approval, beyond the HDE approval, and then anticipates applying the same technological principles to other soft tissue donor organs such as kidneys, livers, and hearts.

Background: The ex-vivo functional assessment of initially unacceptable donor organs, such as marginal lungs, for transplantation is not part of the organ procurement process. The assessment is performed by transplanting facilities directly before an organ transplant procedure. There is considerable time, effort and equipment devoted to this process. The donor organ perfusion and assessment is not currently captured or reported with ICD-9-CM procedure codes. The request was to provide a means for transplant facilities to identify the organ perfusion and assessment procedures so that important data on patient outcomes and hospital utilization can be captured. With the advent of ICD-10-PCS, the requestor states that this is a rare and important opportunity to recognize through procedure coding the process of perfusion and examining marginal organs for transplantation.

About the XVIVO Perfusion System for Donor Lung Preservation:

Currently the XVIVO Perfusion System is used to flush and provide temporary continuous normothermic machine perfusion to donor lungs that do not initially meet the standard criteria for lung transplantation (referred to as "marginal" lungs) but may be transplantable if there is more time to observe and evaluate the organ's function to determine whether the lung is viable for transplant.

Product Description:

The XVIVO Perfusion consists of the XPSTM System Hardware, fluid path and non-fluid path disposables, XPSTM System Software and STEEN SolutionTM. The STEEN SolutionTM is a clear, sterile, non-pyrogenic, non-toxic, physiological, extracellular electrolyte solution containing human serum albumin and dextran 40. The XPSTM System is an integrated cardiac bypass system comprised of various components (centrifugal pump, hico-variotherm heater/cooler, C2 ICU pressure/volume controller ventilator, perfusate gas monitors and display monitors). The XPSTM System is responsible for housing the donor lung(s) providing the normothermic environment and perfusing the organ with the STEEN SolutionTM.

General Description of Procedure:

Prior to the backbench work on the donor lungs (preparation of donor lung allograft for transplantation), the marginal donor lung(s) are placed onto the XVIVO Perfusion SystemTM (XPSTM) to perfuse the STEEN SolutionTM through the lungs. This warms and preserves the marginal donor lung(s) and removes waste products. Thereafter the ex-vivo function of the lung(s) are physiologically assessed hourly for pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis. A bronchoscopy and / or X-ray may also be performed. The procedure requires approximately 6-8 hours,

although the time can vary depending on the condition and status of the donor lungs. Following this extensive examination and perfusion of the cadaver lung(s) the transplant occurs including recipient pneumonectomy and care of transplantee following normal surgical procedure.

Current Coding: The perfusion and assessment of donor organs is currently not captured in ICD-9-CM or ICD-10-PCS. Hospitals would code and report the procedure performed, such as the organ transplant.

Coding Options:

Option 1: Do not create new ICD-10-PCS codes for organ perfusion and assessment for transplant. Continue to code the organ transplant.

Note: For Options 2-4 the new codes would only be assigned for the recipient if the perfusion led to the organ being implanted into the patient. If the perfusion was not successful, and the organ was discarded, then no code would be reported for the unsuccessful donor organ perfusion.

Option 2: Create new X codes to capture successful organ perfusion prior to transplant as indicated below.

Section Body System Operation	X X ADD B	New Technology Extracorporeal Perfusion: Extracorporeal treatment by diffusion of therapeutic fluid			
Body Part		Approach	Device/Substance/Technology	Qualifier	
ADD 5 Heart ADD B Lung(s) ADD F Liver ADD T Kidney(s)	X Extern	nal	ADD B Donor Organ	ADD 2 New Technology Group 2	

CMS welcomes comments on the root operation Perfusion and its definition.

Option 3: Create new codes in Section 6, Extracorporeal Therapies, to capture organ successful perfusion for transplant as indicated below.

Extracorporeal Therapies Body System Operation	6 A ADD B	Extracorporeal Therapies Physiological Systems Perfusion: Extracorporeal treatment by diffusion of therapeutic fluid			
Body	System		Duration	Qualifier	Qualifier
ADD 5 Circulatory System ADD B Respiratory System ADD F Hepatobiliary System and Pancreas ADD T Urinary System			0 Single	ADD B Donor Organ	Z No Qualifier

CMS welcomes comments on the root operation Perfusion and its definition.

Option 4: Create new codes in Section 8, Other Procedures, to capture successful organ perfusion for transplant as indicated below.

Other Procedures	8	Other Procedures
Body System	В	Transplant Organs
Operation	0	Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease

Body Region	Approach	Method	Qualifier
2 Circulatory System ADD B Respiratory System ADD F Hepatobiliary System and Pancreas ADD T Urinary System	X External	ADD 2 Perfusion and Assessment	ADD B Donor Organ

CMS Recommendation: CMS welcomes public comments on these options. CMS recommends that any ICD-10-PCS update receiving public support be considered for October 1, 2016.

Interim Coding Advice: Continue to code the organ transplant.

Fenestrated and Branched Endograft Repair of Abdominal Aortic Aneurysms

Issue: Currently, under ICD-9-CM there are unique codes to distinguish between a standard endovascular repair of abdominal aortic aneurysm (AAA) and endovascular repair of AAA using fenestrated and/or branched devices. Within ICD-10-PCS, a procedure code currently exists that generically describes the endovascular repair of AAA, however, there is not a unique code that specifically describes an endovascular repair with a branched or fenestrated graft. Should a new ICD-10-PCS code be created?

New Technology Application? No. The Cook Medical Zenith[®] Fenestrated AAA Endovascular Graft (ZFEN) was approved for a New Technology Add-On Payment (NTAP) August 31, 2012, effective for cases performed on or after October 1, 2012. The Cook Medical Zenith[®] Fenestrated AAA Endovascular Graft's NTAP is scheduled to expire September 30, 2015.

Background: Effective October 1, 2011, ICD-9-CM procedure code 39.78, Endovascular implantation of branching or fenestrated graft(s) in aorta, was created to differentiate endovascular repair with a branching or fenestrated graft from standard endovascular AAA repair, identified by procedure code 39.71, Endovascular implantation of other graft in abdominal aorta.

The ICD-10-PCS code 04V03DZ (Restriction of Abdominal Aorta with Intraluminal Device, Percutaneous Approach) does not allow differentiation between standard endovascular repair and endovascular repair of AAA with a branched or fenestrated graft in the same way that ICD-9-CM does.

The endovascular repair of an infrarenal aneurysm utilizing a fenestrated device is distinct in that it typically requires:

- 1. More, and more complex, endovascular components,
- 2. Additional planning and measuring to customize,
- 3. Stenting of visceral vessels (typically renal arteries),
- 4. More operating room time,
- 5. More fluoroscopy time,
- 6. And increased amounts of contrast,

A fenestrated and/or branched stent-graft is significantly more complicated than a standard stent-graft, and leads to a procedure that is significantly more complicated than a standard endovascular AAA repair. From a clinical perspective, it will be important to have a mechanism to differentiate the fenestrated/branched endovascular aneurysm repairs from standard endovascular aneurysm repair procedures.

Stenting of visceral vessels

In a standard endovascular aneurysm repair procedure, it is rarely necessary to stent a branch vessel. When it is required, it is typically a renal artery requiring stenting due to the endovascular device being placed too high and impinging on the renal artery ostium.

In a fenestrated endovascular aneurysm repair procedure, most often both renal arteries require stenting and sometimes mesenteric vessels, as well. In these procedures, the fenestrated portion of the endovascular graft is first partially deployed in the aorta, making sure to carefully align the fenestrations of the stent-graft body with the origins of the arterial ostia. Guidewires are then passed through the

fenestrations in the stent-graft body into the relevant arteries. This allows for catheterization of the arteries and subsequent stenting to assure the stent-graft fenestrations remain aligned with the visceral arteries over time.

Current Coding:

04V03DZ	Restriction of Abdominal Aorta with Intraluminal Device, Percutaneous Approach
04V04DZ	Restriction of Abdominal Aorta with Intraluminal Device, Percutaneous Endoscopic
Approach	
04793DZ	Dilation of Right Renal Artery with Intraluminal Device, Percutaneous Approach
04794DZ	Dilation of Right Renal Artery with Intraluminal Device, Percutaneous Endoscopic
Approach	
047A3DZ	Dilation of Left Renal Artery with Intraluminal Device, Percutaneous Approach
047A4DZ	Dilation of Left Renal Artery with Intraluminal Device, Percutaneous Endoscopic Approach
04753DZ	Dilation of Superior Mesenteric Artery with Intraluminal Device, Percutaneous Approach
04754DZ	Dilation of Superior Mesenteric Artery with Intraluminal Device, Percutaneous Endoscopic
Approach	

Section Body System Operation	0 4 V	Medical and Surgical Lower Arteries Restriction: Partially closing an orifice or the lumen of a tubular body part					
Body Part		Approach	Approach Device Qualifier				
0 Abdominal Aorta		0 Open3 Percutaneous4 Percutaneous Endoscopic	C Extraluminal Device Z No Device	Z No Qualifier			
0 Abdominal Aorta		0 Open3 Percutaneous4 Percutaneous Endoscopic	D Intraluminal Device	J Temporary Z No Qualifier			

Coding Options:

Option 1: Do not create a new Device value for branched or fenestrated grafts for table 04V, Restriction of Lower Arteries. Continue to use current device value D, Intraluminal Device.

Option 2: Add the Device value F, Intraluminal Device, Branched or Fenestrated to table 04V, Restriction of Lower Arteries, to differentiate between a standard endovascular aneurysm repair procedure and endovascular repair with a branched or fenestrated graft.

Section Body System Operation	0 4 V	Medical and Surgical Lower Arteries Restriction: Partially closing an orifi	ce or the lumen of a tubular body part	
Body Part		Approach	Device	Qualifier
0 Abdominal Aorta		0 Open3 Percutaneous4 Percutaneous Endoscopic	C Extraluminal Device Z No Device	Z No Qualifier
0 Abdominal Aorta		0 Open3 Percutaneous4 Percutaneous Endoscopic	D Intraluminal Device	J Temporary Z No Qualifier
0 Abdominal Aorta		Open Percutaneous Percutaneous Endoscopic	ADD F Intraluminal Device, Branched or Fenestrated	Z No Qualifier

CMS Recommendation: CMS recommends Option 2 effective October 1, 2016. In the interim, continue to code endovascular repair of AAA using fenestrated or branched device procedures with the appropriate ICD-10-PCS codes from tables 04V, Restriction of Lower Arteries and 047, Dilation of Lower Arteries.

Interim Coding: Continue to code with the appropriate existing codes as listed under Current Coding.

Modified Blalock-Taussig Shunt

Issue: Advice was published in AHA's Third Quarter 2014 *Coding Clinic for ICD-10-CM and ICD-10-PCS* to use ICD-10-PCS code 021W0JQ, Bypass thoracic aorta to right pulmonary artery with synthetic substitute, open approach, to describe the Modified Blalock-Taussig Shunt procedure that was performed in a specific case. More appropriate body part and qualifier values for this type of procedure currently exist within ICD-10-PCS, however, they are not currently available options in table 021 (Bypass of Heart and Great Vessels). Should additional body part and qualifier values be added to this table to better reflect this type of procedure?

New Technology Application? No.

Background: The Modified Blalock-Taussig Shunt involves creation of a "bypass" from the innominate artery to the pulmonary artery with a synthetic type of tissue substitute. In this procedure, the surgeon reroutes the blood flow by placing a graft (usually Gore-Tex) from the innominate or subclavian artery to the pulmonary trunk or the right or left pulmonary artery; there are two anastomoses to place the graft – one proximally at either the innominate or subclavian artery and the distal one at the pulmonary trunk or the right or left pulmonary artery. The purpose of the procedure is to create a systemic-to-pulmonary shunt as a palliative surgery for patients with cyanotic heart defects such as TOF (Tetralogy of Fallot), tricuspid or pulmonary atresia, etc.

Current Coding: Code bypass from thoracic aorta to a pulmonary artery body part value as appropriate, based on Coding Clinic advice.

Section	0	Medical and Surg	Medical and Surgical			
Body System	2	Heart and Great \	/essels			
Operation	1	Bypass: Altering t	Bypass: Altering the route of passage of the contents of a tubular body part			
Body Part		Approach	Device	Qualifier		
W Thoracic Aorta		0 Open	J Synthetic Substitute	P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left		

Option 1: Continue to code as above under current coding.

Option 2: Add the qualifier values M, Pulmonary Artery, Right; N, Pulmonary Artery, Left and P, Pulmonary Trunk, to table 031, Bypass of Upper Arteries, for the body parts displayed below.

Section 0 Body System 3 Operation 1	Medical and Surgical Upper Arteries Bypass: Altering the ro	ute of passage of the contents of a tubul	ar body part
Body Part	Approach	Device	Qualifier
2 Innominate Artery	0 Open	9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute Z No Device	 Upper Arm Artery, Right Upper Arm Artery, Left Upper Arm Artery, Bilateral Lower Arm Artery, Right Lower Arm Artery, Left Lower Arm Artery, Bilateral Upper Leg Artery, Right

Body Part	Approach	Device	Qualifier
			7 Upper Leg Artery, Left 8 Upper Leg Artery, Bilateral 9 Lower Leg Artery, Right B Lower Leg Artery, Left C Lower Leg Artery, Bilateral D Upper Arm Vein F Lower Arm Vein J Extracranial Artery, Right K Extracranial Artery, Left ADD M Pulmonary Artery, Right ADD N Pulmonary Artery, Left ADD P Pulmonary Trunk
3 Subclavian Artery, Right 4 Subclavian Artery, Left	0 Open	9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute Z No Device	0 Upper Arm Artery, Right 1 Upper Arm Artery, Left 2 Upper Arm Artery, Bilateral 3 Lower Arm Artery, Right 4 Lower Arm Artery, Bilateral 6 Upper Leg Artery, Right 7 Upper Leg Artery, Left 8 Upper Leg Artery, Bilateral 9 Lower Leg Artery, Right B Lower Leg Artery, Right B Lower Leg Artery, Bilateral D Upper Arm Vein F Lower Arm Vein F Lower Arm Vein J Extracranial Artery, Right K Extracranial Artery, Left M Pulmonary Artery, Right N Pulmonary Artery, Left ADD P Pulmonary Trunk
H Common Carotid Artery, Right	0 Open	 9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute Z No Device 	G Intracranial Artery J Extracranial Artery, Right ADD M Pulmonary Artery, Right ADD N Pulmonary Artery, Left ADD P Pulmonary Trunk
J Common Carotid Artery, Left	0 Open	 9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute Z No Device 	G Intracranial Artery K Extracranial Artery, Left ADD M Pulmonary Artery, Right ADD N Pulmonary Artery, Left ADD P Pulmonary Trunk

Option 3: Add body part values P, Pulmonary Trunk; Q, Pulmonary Artery, Right and R, Pulmonary Artery, Left and the relevant qualifier values Innominate Artery, Subclavian and Carotid to table 021.

Section	0	Medical	Medical and Surgical			
Body System	2	Heart an	nd Great Vessels			
Operation	1	Bypass:	Altering the route of	passage of the contents of a tubular body pa	rt	
Body F	Part		Approach	Device	Qualifier	
				9 Autologous Venous Tissue		
ADD P Pulmonar	y Trun	ık	0 Open	A Autologous Arterial Tissue	ADD A Innominate Artery	
ADD Q Pulmonar	y Arte	ry, Right	4 Percutaneous	J Synthetic Substitute	B Subclavian	
ADD R Pulmonar	y Arte	ry, Left	Endoscopic	K Nonautologous Tissue Substitute	D Carotid	
		_	•	Z No Device		

CMS Recommendation: CMS recommends option 3, as shown above for October 1, 2016 implementation. There is already precedent for reversing the classification of upstream/downstream body parts in this same body system and root operation.

Interim Coding Advice: Continue to code bypass from thoracic aorta to a pulmonary artery body part value as appropriate, based on Coding Clinic advice.

Arterial Switch Operation with Repositioning of the Coronary Artery Buttons

Issue: The appropriate body part values are currently not available options within ICD-10-PCS table 02S, Reposition of Heart and Great Vessels, to accurately report repositioning of the coronary arteries from the aorta to the pulmonary trunk, which is an integral component in the arterial switch operation.

New Technology Application? No.

Background: The arterial switch operation is used to treat patients with transposition of the great arteries (TGA). During the procedure, the aortic root and pulmonary trunk are switched and connected to the correct ventricles. In addition, the coronary arteries (called buttons) are removed from the original aortic root and reconnected to the switched pulmonary trunk – the new neo-aorta.

Current Coding: Currently, there is not a way to report repositioning of the coronary arteries.

Section Body System Operation	0 2 S	Medical and Surgical Heart and Great Vessels Reposition: Moving to its norma	l location, or other s	suitable location, all or a p	ortion of a body part
		Body Part	Approach	Device	Qualifier
P Pulmonary Q Pulmonary R Pulmonary S Pulmonary T Pulmonary V Superior Ve W Thoracic Ad	Arter Arter Vein, Vein, na C	y, Right y, Left Right Left	0 Open	Z No Device	Z No Qualifier

Coding Options:

Coding Option 1: Do not create new codes. Continue not to report this component.

Coding Option 2: Add the body part value 0, Coronary Artery, One Site and body part value 1, Coronary Artery, Two Sites, to table 02S, Reposition of Heart and Great Vessels.

Section Body System	0	Medical and Surgical Heart and Great Vessels					
Operation	S	Reposition: Moving to its normal location	n, or other suitabl	e location, all or a porti	on of a body part		
		Body Part	Approach	Device	Qualifier		
ADD 0 Corona	ry A	rtery, One Site					
ADD 1 Corona	ry A	rtery, Two Sites					
P Pulmonary Trunk							
Q Pulmonary A	۱rter	y, Right					
R Pulmonary A	Arter	y, Left	0 Open	Z No Device	Z No Qualifier		
S Pulmonary V	ein,	Right					
T Pulmonary V	'ein,	Left					
V Superior Ver	V Superior Vena Cava						
W Thoracic Ac	rta						

CMS Recommendation: CMS recommends Option 2 for implementation on October 1, 2016.

Interim Coding Advice: Continue not to report this component of the arterial switch operation.

Rastelli Procedure

Issue: Existing values within ICD-10-PCS are not currently available options in table 02L, Occlusion of Heart and Great Vessels, to accurately report oversewing of the pulmonary valve or ligation and division of a Modified Blalock-Taussig Shunt, both of which are components involved with the Rastelli procedure. Should the existing ICD-10-PCS values be added and/or new values be created to better describe how the components of the procedure are accomplished?

New Technology Application? No.

Background: The Rastelli procedure is an extensive correction operation. It is performed for repair of transposition of the great vessels with pulmonary stenosis or atresia and ventricular septal defects. In the Rastelli operation, a right ventricular outflow tract (RVOT) or conduit is created to the pulmonary artery using graft material and the ventricular septal defect (VSD) is repaired with graft material. During the operation, the pulmonary valve is oversewn and sutured along with the stump of the pulmonary artery. The Modified Blalock-Taussig Shunt, which has been acting as a pulmonary artery shunt due to the anomalous heart defects, will no longer be needed after the more definitive RVOT construction procedure is ligated and divided.

Current Coding: In the context of the Rastelli procedure, do not code the oversewing of the pulmonary valve and the ligation and division of a modified Blalock-Taussig shunt separately.

Coding Options:

Coding Option 1: Do not add existing values or create new values for table 02L, Occlusion of Heart and Great Vessels, to report oversewing of the pulmonary valve or ligation and division of a Modified Blalock-Taussig Shunt. Continue as above under current coding and do not code the oversewing of the pulmonary valve and the ligation and division of a modified Blalock-Taussig shunt separately.

Coding Option 2: Add the body part value H, Pulmonary Valve to table 02L, Occlusion of Heart and Great Vessels, for coding the oversewing of the pulmonary valve during the Rastelli procedure. Do not code the ligation and division of a Modified Blalock-Taussig Shunt separately.

Section Body System Operation	0 2 L	Heart and	Medical and Surgical Heart and Great Vessels Occlusion: Completely closing an orifice or the lumen of a tubular body part			
Body Pa	art		Approach	Device	Qualifier	
ADD H Pulmonary Valve S Pulmonary Vein, Right T Pulmonary Vein, Left V Superior Vena Cava			Open Percutaneous Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	Z No Qualifier	

Coding Option 3: Add the body part value H, Pulmonary Valve, to table 02L, Occlusion of Heart and Great Vessels, to describe oversewing of the pulmonary valve. Also add the body part value Q, Pulmonary Artery, Right, and the qualifier value U, Pulmonary Artery Shunt, to table 02L to describe ligation and division of a Modified Blalock-Taussig Shunt.

Section Body System Operation	2 Heart an	Medical and Surgical Heart and Great Vessels Occlusion: Completely closing an orifice or the lumen of a tubular body part			
Body Pa	art	Approach	Device	Qualifier	
ADD H Pulmonary Valve S Pulmonary Vein, Right T Pulmonary Vein, Left V Superior Vena Cava		Open Percutaneous Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	Z No Qualifier	

Section Body System Operation	y System 2 Heart and Great Vessels			
Body Part		Approach	Device	Qualifier
ADD Q Pulmonary Artery, Right		0 Open3 Percutaneous4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	ADD U Pulmonary Artery Shunt
R Pulmonary Artery, Left		0 Open3 Percutaneous4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	T Ductus Arteriosus ADD U Pulmonary Artery Shunt

CMS Recommendation: For implementation on October 1, 2016, CMS recommends option 2. Add the body part value H, Pulmonary Valve, to table 02L, Occlusion of Heart and Great Vessels, for coding the oversewing of the pulmonary valve and do not code the ligation and division of a Modified Blalock-Taussig Shunt separately.

Interim Coding Advice: In the context of the Rastelli procedure, do not code the oversewing of the pulmonary valve and the ligation and division of a modified Blalock-Taussig shunt separately.

Repair of Complete Common Atrioventricular Canal Defect

Issue: Under the current version of ICD-10-PCS there is an inability to fully identify the structures involved to code repair of a complete common atrioventricular canal defect. Should new body part and qualifier values be created to improve the quality and reporting of the coded data for this procedure?

New Technology Application? No.

Background: The atrioventricular canal defect is a cluster of associated congenital heart conditions: atrial septal defect, ventricular septal defect and abnormally formed valves that separate the atria (upper heart chambers) from the ventricles (lower heart chambers), often resulting in one large "common" valve rather than the usual two separate valves – mitral and tricuspid.

Current Coding: Code using the body part values G, Mitral Valve and H, Pulmonary Valve and the root operation Repair or Supplement as appropriate for the creation of a right and left atrioventricular valve from a common atrioventricular canal defect.

Body System 2 Heart and	nd Surgical Great Vessels estoring, to the extent possible, a body part to its norm	nal anatomic structure	and function
Body Part	Approach	Device	Qualifier
 O Coronary Artery, One Site 1 Coronary Artery, Two Sites 2 Coronary Artery, Three Sites 3 Coronary Artery, Four or Model 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, Left M Ventricular Septum N Pericardium P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Vein, Right T Pulmonary Vein, Left V Superior Vena Cava W Thoracic Aorta 		Z No Device	Z No Qualifier

function of a	reat Vessels	thetic material that physically reinforces and	d/or augments the
Body Part	Approach	Device	Qualifier
5 Atrial Septum 6 Atrium, Right 7 Atrium, Left 9 Chordae Tendineae A Heart D Papillary Muscle F Aortic Valve G Mitral Valve H Pulmonary Valve J Tricuspid Valve K Ventricle, Right L Ventricle, Left M Ventricular Septum N Pericardium P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left S Pulmonary Vein, Right T Pulmonary Vein, Left V Superior Vena Cava W Thoracic Aorta	O Open Percutaneous Percutaneous Endoscopic	7 Autologous Tissue Substitute 8 Zooplastic Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	Z No Qualifier

Coding Options:

Coding Option 1: Do not create new codes. Continue to code as above under current coding.

Coding Option 2: Add the qualifier values E, Atrioventricular Valve, Left and G, Atrioventricular Valve, Right, to table 02Q, Repair of Heart and Great Vessels, and table 02U, Supplement of Heart and Great Vessels, for procedures performed to create the atrioventricular valves and any subsequent procedures on the atrioventricular valves.

By convention, ICD-10-PCS classifies detail further specifying a body part value in the seventh character qualifier, and refers to the qualifier value rather than the body part value in the code title, for example: 02QG0ZE, Repair of Left Atrioventricular Valve, Open Approach.

Section	0	Medical and Surgical		
Body System	2	Heart and Great Vessels		
Operation	Q	Repair: Restoring, to the extent possib	ole, a body part to its	s normal anatomic structure and function
Body Pa	art	Approach	Device	Qualifier
G Mitral Valve	G Mitral Valve O Open S Percutaneous Percutaneous Endoscopic Z No Device Z No Qualifier ADD E Atrioventricular Valve, Left Z No Qualifier			
H Pulmonary V	alve	0 Open3 Percutaneous4 Percutaneous Endoscopic	Z No Device	ADD G Atrioventricular Valve, Right Z No Qualifier

Body System 2 H Operation U S	Medical and Surgical Heart and Great Vessels Supplement: Putting in or on bion Inction of a portion of a body p		sically reinforces and/or augments the
Body Part	Approach	Device	Qualifier
G Mitral Valve	Open Percutaneous Percutaneous Endoscopic	7 Autologous Tissue Substitute 8 Zooplastic Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	ADD E Atrioventricular Valve, Left Z No Qualifier
H Pulmonary Valve	Open Percutaneous Percutaneous Endoscopic	7 Autologous Tissue Substitute 8 Zooplastic Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	ADD G Atrioventricular Valve, Right Z No Qualifier

Coding Option 3: In addition to the changes in option 2, add the root operation Creation to the Heart and Great Vessels body system, for the creation of a right and left atrioventricular valve from a common atrioventricular valve. Add the qualifier value 2, Common Atrioventricular Valve, applied to the body part values G, Mitral Valve and H Pulmonary Valve, to table 024, Creation of Heart and Great Vessels.

Section 0 Medical and Surgical Body System 2 Heart and Great Vessels Operation ADD 4 Creation: Putting in biological or synthetic material to form a new body part that takes the place and/o function of an absent body part			
Body Part Approach Device		Device	Qualifier
ADD G Mitral Valve ADD H Pulmonary Valve	0 Open	7 Autologous Tissue Substitute 8 Zooplastic Tissue J Synthetic Substitute K Nonautologous Tissue Substitute Z No Device	ADD 2 Common Atrioventricular Valve

Note: This option necessitates revising the definition of the root operation Creation. Currently the definition is limited to creation of genital body parts in gender reassignment procedures.

Revise from

Creation: Making a new genital structure that does not take over the function of a body part.

Explanation: Used only for gender reassignment surgery

Includes/Examples: Creation of vagina in a male, creation of penis in a female

Revise to

Creation: Putting in or on biological or synthetic material to form a new body part that to the extent possible replicates the anatomic structure or function of an absent body part.

Explanation: Used for gender reassignment surgery and corrective procedures in individuals with congenital anomalies

Includes/Examples: Creation of vagina in a male, creation of right and left atrioventricular valve from common atrioventricular valve

CMS Recommendation: CMS is interested in hearing comments from the audience regarding the options presented above being proposed for October 1, 2016 implementation.

Interim Coding Advice: As above under current coding.

Truncus Arteriosus Repair

Issue: Currently there is not an ICD-10-PCS value to identify the creation of a truncal valve that acts as the aortic valve after truncus arteriosus repair. As the truncal valve may require further repair and/or replacement during the patient's lifetime, a new qualifier value would assist in identifying procedures performed on it. There is also not an option for the device value Zooplastic Tissue within table 021, Bypass of Heart and Great Vessel, which can be utilized in a graft during a component procedure of the truncus arteriosus repair.

New Technology Application? No.

Background: Patients with a congenital defect known as a "truncus arteriosus" have a single, large great vessel that failed to divide into the aorta and the pulmonary artery during development. These patients also usually have a large ventricular septal defect in conjunction with the abnormality to their great vessels. Treatment to correct the truncus arteriosus involves the creation of a right ventricular outflow conduit from the right ventricle to the pulmonary arteries and separation/repair to the truncus so that it becomes a functioning aorta.

Current Coding: Code using the body part value Aortic Valve and the root operation Repair or Supplement as appropriate, for the creation of a truncal valve that acts as the aortic valve after truncus arteriosus repair. Code the appropriate device value from table 021, Bypass of Heart and Great Vessel, to identify the type of graft material that may be utilized during a component procedure of the truncus arteriosus repair.

Body Part	Approach	Device	Qualifier
T Pulmonary Vein, Left			
V Superior Vena Cava W Thoracic Aorta			
W Thoracic Aorta			

Section 0 Medical and Surgical Body System 2 Heart and Great Vessels Operation 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 Qualifier Device 5 Atrial Septum 6 Atrium, Right 7 Atrium, Left 9 Chordae Tendineae A Heart **D** Papillary Muscle **F** Aortic Valve **G** Mitral Valve **H** Pulmonary Valve 7 Autologous Tissue Substitute **J** Tricuspid Valve 0 Open 8 Zooplastic Tissue K Ventricle, Right **3** Percutaneous **Z** No Qualifier J Synthetic Substitute L Ventricle, Left 4 Percutaneous Endoscopic K Nonautologous Tissue Substitute M Ventricular Septum **N** Pericardium P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left S Pulmonary Vein, Right T Pulmonary Vein, Left V Superior Vena Cava

W Thoracic Aorta

Body System 2 Heart an	and Surgical d Great Vessels Altering the route of passage	of the contents of a tubular body pa	art
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 	0 Open	9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	3 Coronary Artery 8 Internal Mammary, Right 9 Internal Mammary, Left C Thoracic Artery F Abdominal Artery W Aorta
 0 Coronary Artery, One Site 1 Coronary Artery, Two Sites 2 Coronary Artery, Three Sites 3 Coronary Artery, Four or More Sites 	0 Open	Z No Device	3 Coronary Artery 8 Internal Mammary, Right 9 Internal Mammary, Left C Thoracic Artery F Abdominal Artery
 O Coronary Artery, One Site 1 Coronary Artery, Two Sites 2 Coronary Artery, Three Sites 3 Coronary Artery, Four or More Sites 	3 Percutaneous	Intraluminal Device, Drug- eluting D Intraluminal Device	4 Coronary Vein
 O Coronary Artery, One Site 1 Coronary Artery, Two Sites 2 Coronary Artery, Three Sites 3 Coronary Artery, Four or More Sites 	4 Percutaneous Endoscopic	Intraluminal Device, Drug- eluting D Intraluminal Device	4 Coronary Vein

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 Percutaneous Endoscopic	9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	3 Coronary Artery 8 Internal Mammary, Right 9 Internal Mammary, Left C Thoracic Artery F Abdominal Artery W Aorta
0 Coronary Artery, One Site 1 Coronary Artery, Two Sites 2 Coronary Artery, Three Sites 3 Coronary Artery, Four or More Sites	4 Percutaneous Endoscopic	Z No Device	3 Coronary Artery 8 Internal Mammary, Right 9 Internal Mammary, Left C Thoracic Artery F Abdominal Artery
6 Atrium, Right	Open Percutaneous Endoscopic	9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left
6 Atrium, Right	Open Percutaneous Endoscopic	Z No Device	7 Atrium, Left P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left
7 Atrium, Left V Superior Vena Cava	Open Percutaneous Endoscopic	 9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute Z No Device 	P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left
K Ventricle, Right L Ventricle, Left	Open Percutaneous Endoscopic	9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left
K Ventricle, Right L Ventricle, Left	Open Percutaneous Endoscopic	Z No Device	5 Coronary Circulation 8 Internal Mammary, Right 9 Internal Mammary, Left C Thoracic Artery F Abdominal Artery P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left W Aorta
W Thoracic Aorta	Open Percutaneous Endoscopic	9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute Z No Device	B Subclavian D Carotid P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left

Coding Options:

Coding Option 1: Do not create a new qualifier value for tables 02Q, Repair of Heart and Great Vessels, and 02U, Supplement Heart and Great Vessels, to report procedures performed on the truncal valve. Do not create a new device value in table 021, Bypass of Heart and Great Vessel, to identify the type of graft material that may be utilized during a component procedure of the truncus arteriosus repair. Continue to code as above under current coding.

Coding Option 2: Add a new qualifier value J, Truncal Valve, applied to the body part value Aortic Valve, to table 02Q, Repair of Heart and Great Vessels, and table 02U, Supplement of Heart and Great Vessels, for procedures performed on the truncal valve. Also add device value, 8, Zooplastic Tissue, to table 021, Bypass of Heart and Great Vessel, to identify this type of graft material when utilized during a component procedure of the truncus arteriosus repair.

By convention, ICD-10-PCS classifies detail further specifying a body part value in the seventh character qualifier, and refers to the qualifier value rather than the body part value in the code title, for example: 02QF0ZJ Repair of Truncal Valve, Open Approach.

Section Body System Operation	0 2 Q	Medical and Surgical Heart and Great Vessels Repair: Restoring, to the extent possible, a body part to its normal anatomic structure and function			
Body Pa	Body Part Approach Device Qualifier				
F Aortic Valve 0 Open 3 Percutaneous 4 Percutaneous Endoscopic		Z No Device	ADD J Truncal Valve Z No Qualifier		

Section 0 Body System 2 Operation U	Medical and Surgical Heart and Great Vessels 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	
F Aortic Valve	Open Percutaneous Percutaneous Endoscopic	7 Autologous Tissue Substitute 8 Zooplastic Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	ADD J Truncal Valve Z No Qualifier	

Body System 2 Heart and	nd Surgical I Great Vessels Altering the route of passa	ge of the contents of a tubular body p	part
Body Part	Approach	Device	Qualifier
O Coronary Artery, One Site Coronary Artery, Two Sites Coronary Artery, Three Sites Coronary Artery, Four or More Sites	0 Open	ADD 8 Zooplastic Tissue 9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	3 Coronary Artery 8 Internal Mammary, Right 9 Internal Mammary, Left C Thoracic Artery F Abdominal Artery W Aorta
O Coronary Artery, One Site Coronary Artery, Two Sites Coronary Artery, Three Sites Coronary Artery, Four or More Sites	4 Percutaneous Endoscopic	ADD 8 Zooplastic Tissue 9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	3 Coronary Artery 8 Internal Mammary, Right 9 Internal Mammary, Left C Thoracic Artery F Abdominal Artery W Aorta
6 Atrium, Right	Open Percutaneous Endoscopic	ADD 8 Zooplastic Tissue 9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left
7 Atrium, Left V Superior Vena Cava	Open Percutaneous Endoscopic	ADD 8 Zooplastic Tissue 9 Autologous Venous Tissue A Autologous Arterial Tissue	P Pulmonary Trunk Q Pulmonary Artery, Right

Body Part	Approach	Device	Qualifier
		J Synthetic Substitute K Nonautologous Tissue Substitute Z No Device	R Pulmonary Artery, Left
K Ventricle, Right L Ventricle, Left	Open Percutaneous Endoscopic	ADD 8 Zooplastic Tissue 9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left
W Thoracic Aorta	Open Percutaneous Endoscopic	ADD 8 Zooplastic Tissue 9 Autologous Venous Tissue A Autologous Arterial Tissue J Synthetic Substitute K Nonautologous Tissue Substitute Z No Device	B Subclavian D Carotid P Pulmonary Trunk Q Pulmonary Artery, Right R Pulmonary Artery, Left

Coding Option 3: In addition to the changes in option 2, add the root operation Creation to the Heart and Great Vessels body system, for the creation of a truncal valve from the truncus arteriosus repair. Add the qualifier value J, Truncal Valve, applied to the body part value F, Aortic Valve, to table 024, Creation of Heart and Great Vessels.

Section Body System Operation	0 2 ADD		5	w body part that takes the place
Body Par	rt	Approach	Device	Qualifier
F Aortic Valve		0 Open	7 Autologous Tissue Substitute 8 Zooplastic Tissue J Synthetic Substitute K Nonautologous Tissue Substitute	ADD J Truncal Valve

This option necessitates revising the definition of the root operation Creation. Currently the definition is limited to creation of genital body parts in gender reassignment procedures.

Revise from

Creation: Making a new genital structure that does not take over the function of a body part.

Explanation: Used only for gender reassignment procedures

Includes/Examples: Creation of vagina in a male, creation of penis in a female

Revise to

Creation: Putting in or on biological or synthetic material to form a new body part that to the extent possible replicates the anatomic structure or function of an absent body part.

Explanation: Used for gender reassignment procedures and corrective procedures in individuals with congenital anomalies

Includes/Examples: Creation of vagina in a male, creation of a truncal valve

CMS Recommendation: CMS is interested in hearing comments from the audience regarding the options presented above being proposed for October 1, 2016 implementation.

Interim Coding Advice: As above under current coding.

Enlargement of Existing Atrial Septal Defect and Creation of New Atrial Septal Defect

Issue: The body part value atrial septum, which is already incorporated within ICD-10-PCS, is currently not an available option in table 027, Dilation of Heart and Great Vessels, or table 028, Division of Heart and Great Vessels. Should this value be added to these tables to accurately report the enlargement of an existing atrial septal defect and the creation of a new atrial septal defect?

New Technology Application? No.

Background: Stabilization and palliation of some congenital heart defects, such as transposition of the great arteries, require creation of a new atrial septal defect or enlargement of an existing atrial septal defect. An atrial septal defect is an abnormal orifice between the left and right atria. The first surgical technique was described by Blalock and Hanlon in 1950, but has now been essentially replaced by Rashkind and Miller's percutaneous procedure using a balloon catheter. These procedures increase mixing of oxygenated and deoxygenated blood, and thereby improve delivery of oxygenated blood to the systemic circulation.

Current Coding: The enlargement of an existing atrial septal defect is currently coded to table 02Q, Repair of Heart and Great Vessels, with the body part value A, Heart. The creation of a new atrial septal defect is currently coded to table 02B, Excision of Heart and Great Vessels, with the body part value 5, Atrial Septum.

Section 0 Medical and Surgical			
Body System 2 Heart and Great Vessels			
Operation Q Repair: Restoring, to the exter	nt possible, a body part to its normal ar	natomic structure	and function
Body Part	Approach	Device	Qualifier
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	0 Open		
F Aortic Valve	3 Percutaneous	Z No Device	Z No Qualifier
G Mitral Valve	4 Percutaneous Endoscopic		
H Pulmonary Valve			
J Tricuspid Valve			
K Ventricle, Right			
L Ventricle, Left			
M Ventricular Septum			
N Pericardium			
P Pulmonary Trunk			
Q Pulmonary Artery, Right			
R Pulmonary Artery, Left			
S Pulmonary Vein, Right			
T Pulmonary Vein, Left			
V Superior Vena Cava			
W Thoracic Aorta			

Section 0 Body System 2 Operation B	Heart and	nd Surgical Great Vessels Cutting out or off, without replacen	nent, a portion of a bo	dy part
Body Part		Approach	Device	Qualifier
4 Coronary Vein 5 Atrial Septum 6 Atrium, Right 8 Conduction Mechanisr 9 Chordae Tendineae D Papillary Muscle F Aortic Valve G Mitral Valve H Pulmonary Valve J Tricuspid Valve K Ventricle, Right L Ventricle, Left M Ventricular Septum N Pericardium P Pulmonary Trunk Q Pulmonary Artery, Rig R Pulmonary Vein, Right T Pulmonary Vein, Right T Pulmonary Vein, Left V Superior Vena Cava W Thoracic Aorta	ht t	O Open Percutaneous Percutaneous Endoscopic	Z No Device	X Diagnostic Z No Qualifier
7 Atrium, Left		0 Open3 Percutaneous4 Percutaneous Endoscopic	Z No Device	K Left Atrial AppendageX DiagnosticZ No Qualifier

Coding Options:

Coding Option 1: Do not add the body part value atrial septum to tables 027, Dilation of Heart and Great Vessels and 028, Division of Heart and Great Vessels. Continue to code as above under current coding.

Coding Option 2: Add the body part value 5, Atrial Septum, to tables 027, Dilation of Heart and Great Vessels and table 028, Division of Heart and Great Vessels to accurately report the enlargement of an existing atrial septal defect and the creation of a new atrial septal defect.

Section Body System	0 2		Medical and Surgical Heart and Great Vessels			
Operation	7	Dilatio	Dilation: Expanding an orifice or the lumen of a tubular body part			
Body Pa	Body Part Approach Device Qualifier			Qualifier		
			0 Open3 Percutaneous4 Percutaneous Endoscopic	Z No Device	Z No Qualifier	

Body System 2	Rody System 2 Heart and Great Vessels				
E	Body Part Approach Device Qualifier				
ADD 5 Atrial Septum 8 Conduction Mechanism 9 Chordae Tendineae D Papillary Muscle Approach Approach Approach Approach Approach Approach Approach Approach Approach Z No Device Z No Qualifier				Z No Qualifier	

CMS Recommendation: CMS recommends option 2 as noted above, for implementation on October 1, 2016.

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

Body Part and Device Key Items

Definitions Body Part Key

Term Head and Neck Bursa and Ligament

Includes Add Interspinous ligament

Term Internal Iliac Artery, Left
Term Internal Iliac Artery, Right

Includes Revise from Uterine artery
Includes Revise to Uterine Artery

Term Larynx

Includes Delete Cricoid cartilage

Term Shoulder Bursa and Ligament, Left
Term Shoulder Bursa and Ligament, Right
Includes Delete Glenoid ligament (labrum)

Term Shoulder Joint, Left
Term Shoulder Joint, Right

Includes Add Glenoid ligament (labrum)

Term Sphenoid Bone, Left
Term Sphenoid Bone, Right
Includes Revise from Sella tur

Includes Revise from Sella turcica Includes Revise to Sella Turcica

Term Add Trachea

Includes Add Cricoid cartilage

Definitions Device Key

Term Delete Epiretinal Visual Prosthesis in Eye

Includes Delete Epiretinal visual prosthesis

Term Liner in Lower Joints
Includes Add Acetabular cup
Includes Add Tibial insert

Addenda

Index Addenda

Add Acetabular cup use Liner in Lower Joints

Add Circumcision 0VTTXZZ

Revise from Cricoid cartilage use Larynx
Revise to Cricoid cartilage use Trachea
No change Epiretinal Visual Prosthesis
Delete use Epiretinal Visual Prosthesis in Eye

Delete Insertion of device in

No change Left 08H105Z No change Right 08H005Z

No change Glenoid ligament (labrum)

Delete use Shoulder Bursa and Ligament, Right Delete use Shoulder Bursa and Ligament, Left

Add use Shoulder Joint, Right

Add use Shoulder Joint, Left

No change Interspinous ligament

Add use Head and Neck Bursa and Ligament

Delete Meniscectomy

Delete see Excision, Lower Joints 0SB

Delete see Resection, Lower Joints 0ST

Add Meniscectomy, knee see Excision, Lower Joints 0SB

Revise from PEG (percutaneous endoscopic gastrostomy) 0DH64UZ
Revise to PEG (percutaneous endoscopic gastrostomy) 0DH63UZ
Revise from PEJ (percutaneous endoscopic jejunostomy) 0DHA4UZ
Revise to PEJ (percutaneous endoscopic jejunostomy) 0DHA3UZ

Add Repair, obstetric laceration, periurethral 0UQMXZZ

Add Replacement, hip

Add Partial or total see Replacement, Lower Joints 0SR

Add Resurfacing only see Supplement, Lower Joints 0SU

Add Revision

Add Correcting a portion of existing device see Revision of device in

Add Removal of device without replacement see Removal of device from

Add Replacement of existing device

Add see Removal of device from

Add see Root operation to place new device, e.g., Insertion, Replacement, Supplement

Add Tibial insert use Liner in Lower Joints

Add VH-IVUS (virtual histology intravascular ultrasound) see Ultrasonography, Heart B24

ICD-10 GEMs FY2016 Version Update

Update Summary

The updated FY2016 General Equivalence Mappings (GEMs) are posted for public comment. All changes to date resulting from public comment and internal review have been incorporated into the FY2016 GEMs. The types of changes made include

- Cluster translations expanded for completeness
- Single entries expanded to better meet inclusion criteria
- Entries revised to better meet inclusion criteria

All changes meeting inclusion criteria were included in the updated files. Documentation for general and technical users of the GEMs is posted with the GEMs files.

In particular, the GEMs Documentation for Technical Users

- Specifies GEMs entry inclusion criteria and provides examples
- Discusses GEMs flags in detail and provides examples
- Answers other frequently asked technical questions
- Discusses translation rules for obstetrics and angioplasty

Examples of updated GEMs entries are provided in the following pages. Diagnosis GEMs entries are first, followed by procedure GEMs entries.

DIAGNOSIS GEMs

Public comment:

ICD-10-CM to ICD-9-CM GEM entry for "Persistent atrial fibrillation"

2015 entry	Updated 2016 entry	Comment
I48.1 Persistent atrial fibrillation	I48.1 Persistent atrial fibrillation	Typographical error. The ICD-10-
То	То	CM code specifies atrial
427.32 Atrial flutter	427.31 Atrial fibrillation	fibrillation.

Internal review:

ICD-10-CM to ICD-9-CM GEM entry for "thoracic disc disorder with radiculopathy"

2015 entry	Updated 2016 entry	Comment
Example	Example	The updated entry is a closer
M51.1[4-5] Intervertebral disc disorders with radiculopathy, thoracic region (2 codes) To 724.4 Thoracic or lumbosacral neuritis or radiculitis, unspecified	M51.1[4-5] Intervertebral disc disorders with radiculopathy, thoracic region (2 codes) To 722.92 Other and unspecified disc disorder, thoracic region	match. The ICD-9-CM tabular instruction for 724.4 excludes radiculitis due to intervertebral disc disorder.

Internal review:

ICD-10-CM to ICD-9-CM GEM entry for "lumbar disc disorder with radiculopathy"

2015 entry	Updated 2016 entry	Comment
Example M51.1[6-7] Intervertebral disc disorders with radiculopathy, lumbar region (2 codes) To 724.4 Thoracic or lumbosacral neuritis or radiculitis, unspecified	Example M51.1[6-7] Intervertebral disc disorders with radiculopathy, lumbar region (2 codes) To 722.93 Other and unspecified disc disorder, lumbar region	The updated entry is a closer match. The ICD-9-CM tabular instruction for 724.4 excludes radiculitis due to intervertebral disc disorder.

Internal review:

ICD-10-CM to ICD-9-CM GEM entry for "Hydronephrosis with ureteral stricture"

2015 entry	Updated 2016 entry	Comment
N13.1 Hydronephrosis with ureteral stricture, not elsewhere classified To 591 Hydronephrosis	N13.1 Hydronephrosis with ureteral stricture, not elsewhere classified To Choice List 1 591 Hydronephrosis AND Choice List 2 593.3 Stricture or kinking of ureter	The updated entry is a more complete translation of the condition specified in the ICD-10-CM code. N13.1 is a combination code, and requires an ICD-9-CM translation cluster specifying both the hydropnephrosis and the ureteral stricture.

ICD-10-CM to ICD-9-CM GEM entry for "Hydronephrosis with renal/ureteral calculous"

2015 entry	Updated 2016 entry	Comment
N13.2 Hydronephrosis with renal and ureteral calculous obstruction To 591 Hydronephrosis	N13.2 Hydronephrosis with renal and ureteral calculous obstruction To Choice List 1 591 Hydronephrosis AND Choice List 2 592.0 Calculus of kidney OR 592.1 Calculus of ureter OR 592.9 Urinary calculus, unspecified	The updated entry is a more complete translation of the condition specified in the ICD-10-CM code. N13.2 is a combination code, and requires an ICD-9-CM translation cluster specifying both the hydropnephrosis and the urinary calculous.

Public comment:

ICD-9-CM to ICD-10-CM GEM entries for "Open skull fracture with concussion"

2015 entry	Updated 2016 entry	Comment
Example 80[013].99 Open fracture of vault of skull with intracranial injury of other and unspecified nature, with concussion, unspecified (3 codes)	Example 80[013].99 Open fracture of vault of skull with intracranial injury of other and unspecified nature, with concussion, unspecified (3 codes)	Typographical error. 800.99, 801.99 and 803.99 are translated to S06.9X9A in choice list 2 of the cluster. This has been changed to S06.9X0A.
Choice List 1 To S02.0XXA Fracture of vault of skull, initial encounter for closed fracture AND Choice List 2 S06.890A Other specified intracranial injury without loss of consciousness, initial encounter OR S06.9X9A Unspecified intracranial injury with loss of consciousness of unspecified duration, initial encounter	Choice List 1 To S02.0XXA Fracture of vault of skull, initial encounter for closed fracture AND Choice List 2 S06.890A Other specified intracranial injury without loss of consciousness, initial encounter OR S06.9X0A Unspecified intracranial injury without loss of consciousness, initial encounter	

PROCEDURE GEMs

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "Revision of hip replacement (1 of 2)"

2015 entry	Updated 2016 entry	Comment
Example	Example	The updated entry is a more
00.70 Revision of hip	00.70 Revision of hip	complete translation of the procedure
replacement, both acetabular	replacement, both acetabular	specified in the ICD-9-CM code. The
and femoral components	and femoral components	complete meaning of the ICD-9 hip
То	То	revision procedure codes as
Choice List 1	Choice List 1	specified in PCS clusters includes
0SP[9B]0JZ Removal of	0SP[9B]0JZ Removal of	insertion of the ceramic on
Synthetic Substitute from Right	Synthetic Substitute from Right	polyethylene synthetic hip joint.
Hip Joint, Open Approach (2	Hip Joint, Open Approach (2	
codes)	codes)	
AND	AND	
Choice List 2	Choice List 2	
0SR[9B]0[123J][9AZ]	0SR[9B]0[1234J][9AZ]	
Replacement of Right Hip Joint	Replacement of Right Hip Joint	
with Metal Synthetic	with Ceramic on Polyethylene	
Substitute, Cemented, Open	Synthetic Substitute,	
Approach (24 codes)	Cemented, Open Approach	
	(30 codes)	

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "Revision of hip replacement (2 of 2)"

2015 entry	Updated 2016 entry	Comment
Example 00.7[0-3] Revision of hip replacement, both acetabular and femoral components (4 codes) To	Updated 2016 entry Example 00.7[0-3] Revision of hip replacement, both acetabular and femoral components (4 codes) To	Comment The updated entry is a more complete translation of the procedure specified in the ICD-9-CM code. The complete meaning of the ICD-9 hip revision procedure codes as specified in PCS clusters includes
Choice List 1 0SP[9B]0JZ Removal of Synthetic Substitute from Right Hip Joint, Open Approach (2 codes) AND Choice List 2 0SR[9ABERS]0[01234J][9AZ] Replacement of Right Hip Joint with Ceramic on Polyethylene Synthetic Substitute, Cemented, Open Approach (72 codes)	Choice List 1 0SP[9B]0[89BJ]Z Removal of Spacer from Right Hip Joint, Open Approach (8 codes) AND Choice List 2 0SR[9ABERS]0[01234J][9AZ] Replacement of Right Hip Joint with Ceramic on Polyethylene Synthetic Substitute, Cemented, Open Approach (72 codes)	removal of spacer, liner and resurfacing devices prior to insertion of the new prosthetic hip joint.

ICD-9-CM to ICD-10-PCS GEM entry for "Revision of knee replacement" (1 of 2)

2015 entry	Updated 2016 entry	Comment
Example	Example	The updated entry is a more
00.8[1-2] Revision of knee	00.8[1-2] Revision of knee	complete translation of the procedure
replacement, tibial component	replacement, tibial component	specified in the ICD-9-CM code. The
(2 codes)	(2 codes)	complete meaning of the ICD-9 tibial
То	То	and femoral component revision
Choice List 1	Choice List 1	procedure codes as translated to
0SP[CD]0JZ Removal of	0SP[CD]0JZ Removal of	PCS clusters includes insertion of
Synthetic Substitute from Right	Synthetic Substitute from Right	the qualifiers specifying cemented
Knee Joint, Open Approach (2	Knee Joint, Open Approach (2	and uncemented.
codes)	codes)	
AND	AND	
Choice List 2	Choice List 2	
0SR[TUVW]0JZ Replacement	0SR[TUVW]0J[9AZ]	
of Right Knee Joint, Tibial	Replacement of Right Knee	
Surface with Synthetic	Joint, Tibial Surface with	
Substitute, Open Approach (4	Synthetic Substitute,	
codes)	Cemented, Open Approach (12	
	codes)	

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "Revision of knee replacement" (2 of 2)

2015 entry	Updated 2016 entry	Comment
Example 00.8[0-2] Revision of knee replacement, total (all components) (3 codes) To Choice List 1	Updated 2016 entry Example 00.8[0-2] Revision of knee replacement, total (all components) (3 codes) To Choice List 1	Comment The updated entry is a more complete translation of the procedure specified in the ICD-9-CM code. The complete meaning of the ICD-9 knee revision procedure code as translated to PCS clusters includes
OSP[CD][04]JZ Removal of Synthetic Substitute from Right Knee Joint, Open Approach (4 codes) AND Choice List 2 OSR[CDTUVW]0J[9AZ] Replacement of Right Hip Joint with Metal Synthetic Substitute, Cemented, Open Approach (18 codes)	OSP[CD][04][89J]Z Removal of Liner from Right Knee Joint, Open Approach (10 codes) AND Choice List 2 OSR[CDTUVW]0J[9AZ] Replacement of Right Hip Joint with Metal Synthetic Substitute, Cemented, Open Approach (18 codes)	removal of spacer and liner prior to insertion of the new prosthetic knee joint.

Internal review:

ICD-9-CM to ICD-10-PCS entry for "Insufflation of fallopian tube"

2015 entry	Updated 2016 entry	Comment
66.8 Insufflation of fallopian tube	66.8 Insufflation of fallopian tube	The updated entry is a more
То	То	accurate translation of the
3E1P[378]8Z Irrigation of Female	3E0P[378][GS][CF] Introduction	procedure specified in the ICD-9-
Reproductive using Irrigating	of Other Gas into Female	CM code. The root operation
Substance, Percutaneous	Reproductive, Via Natural or	Introduction is a closer
Approach (3 codes)	Artificial Opening (6 codes)	translation match than the root
		operation Irrigation.

Internal review:

ICD-10-PCS to ICD-9-CM GEM entry for "Treatment of LAA with occlusive device" (1 of 2)

2015 entry	Updated 2016 entry	Comment
2015 entry 02L7[034][CD]K Occlusion of Left Atrial Appendage with Extraluminal Device, Open Approach (6 codes) To 37.36 Excision, destruction, or exclusion of left atrial appendage (LAA)	Updated 2016 entry 02L7[034][CD]K Occlusion of Left Atrial Appendage with Extraluminal Device, Open Approach (6 codes) To 37.90 Insertion of left atrial appendage device	The updated entry is a more accurate translation of the procedure specified in the ICD-10-PCS codes. 37.90 is a more accurate translation of the procedure to occlude the left atrial appendage when a device is used. This change has also been made to
		the ICD-9-CM to ICD-10-PCS GEM.

Internal review:

ICD-9-CM to ICD-10-PCS GEM entry for "Treatment of LAA with occlusive device" (2 of 2)

2015 entry	Updated 2016 entry	Comment
37.90 Insertion of left atrial appendage device To 02L7[034][CD]K Occlusion of Left Atrial Appendage with Extraluminal Device, Open Approach (6 codes) OR	37.90 Insertion of left atrial appendage device (LAA) To 02L7[034][CD]K Occlusion of Left Atrial Appendage with Extraluminal Device, Open Approach (6 codes)	The updated entry is a more accurate translation of the procedure specified in the ICD-9-CM code. The complete meaning of 37.90 is fully translated with root operationOcclusion and does not need to be translated to the root
02U7[34]JZ Supplement Left Atrium with Synthetic Substitute, Percutaneous Endoscopic		operation Supplement of left atrium.
Approach (2 codes)		

Internal review:

ICD-9-CM to ICD-10-PCS GEM entry for "Excision/destruction/exclusion of LAA"

2015 entry	Updated 2016 entry	Comment
37.36 Excision, destruction, or	37.36 Excision, destruction, or	The updated entry is a more
exclusion of left atrial appendage	exclusion of left atrial appendage	accurate translation of the
(LAA)	(LAA)	procedure specified in the ICD-9-
То	То	CM code.
02[5BL]7[034]ZK Destruction of	02[5BL]7[034]ZK Destruction of	The complete meaning of 37.36
Left Atrial Appendage, Open	Left Atrial Appendage, Open	is fully translated with root
Approach (9 codes)	Approach (9 codes)	operations Excision, Destruction
OR		and Occlusion and does not
02Q7[034]ZZ Repair Left Atrium,		need to be translated to the
Open Approach (3 codes)		"NEC option" Repair of left
, , ,		atrium.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "Abdominal proctopexy"

2015 entry	Updated 2016 entry	Comment
48.75 Abdominal proctopexy	48.75 Abdominal proctopexy	The updated entry is a more
То	То	accurate translation of the
0DSP[04]ZZ Reposition Rectum,	0DSP[04]ZZ Reposition Rectum,	procedure specified in the ICD-9-
Open Approach (2 codes)	Open Approach (2 codes)	CM code.
	OR	Per index, code 48.75 includes
	0DUP[04]JZ Supplement	transabdominal Ripstein repair,
	Rectum with Synthetic	which is coded to the root
	Substitute, Open Approach (2	operation Supplement using the
	codes)	device value Synthetic
		Substitute.

Internal review:

ICD-10-PCS to ICD-9-CM GEM entry for "Irrigation of eye"

2015 entry	Updated 2016 entry	Comment
3E1C38[XZ] Irrigation of Eye using Irrigating Substance, Percutaneous Approach (2 codes) To 96.52 Irrigation of ear	3E1C38[XZ] Irrigation of Eye using Irrigating Substance, Percutaneous Approach (2 codes) To 10.91 Subconjunctival injection	Typographical error. The ICD-10-PCS code specifies the eye.

ICD-10-PCS to ICD-9-CM GEM entry for "Insertion of monitoring device in SVC"

2015 entry	Updated 2016 entry	Comment
02HV[034]2Z Insertion of	02HV[034]2Z Insertion of	The updated entry is a closer
Monitoring Device into	Monitoring Device into Superior	translation match. The complete
Superior Vena Cava,	Vena Cava, Percutaneous	meaning of code 89.64 specifies
Percutaneous Approach (3	Approach (3 codes)	Swan-Ganz catheterization, which
codes)	То	under normal circumstances is
То	89.64 Pulmonary artery wedge	placed in the superior vena cava.
38.7 Interruption of the vena	monitoring	This translation alternative has also
cava		been added to the ICD-9-CM to ICD-
		10-PCS GEM.

Public comment:

ICD-10-PCS to ICD-9-CM GEM entry for "Introduction of other therapeutic substance"

2015 entry	Updated 2016 entry	Comment
3E013GC Introduction of Other	3E013GC Introduction of Other	The updated entry is a more
Therapeutic Substance into	Therapeutic Substance into	complete accurate translation of the
Subcutaneous Tissue,	Subcutaneous Tissue,	ICD-10-PCS code. The translation
Percutaneous Approach	Percutaneous Approach	alternatives for 3E013GC include
To/From	То	four specific ICD-9-CM codes that do
99.12 Immunization for allergy	99.29 Injection or infusion of	not meet inclusion criteria for the
OR	other therapeutic or	ICD-10-PCS to ICD-9-CM GEM.
99.13 Immunization for	prophylactic substance	3E013GC should translate to 99.29
autoimmune disease		instead, because its level of
OR		specificity is the closer translation
99.27 Iontophoresis		match of the source code.
OR		The specific alternatives will remain
99.75 Administration of		in the ICD-9-CM to ICD-10-PCS
neuroprotective agent		GEM.

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "Injection of Rh immune globulin"

2015 entry	Updated 2016 entry	Comment	
99.11 Injection of Rh immune	99.11 Injection of Rh immune	The updated entry is a more	
globulin	globulin	accurate translation of the ICD-9-CM	
То	То	code.	
302[3-6]3S1 Transfusion of	3E0234Z Introduction of Serum,	The ICD-10-PCS code 3E0234Z is a	
Nonautologous Globulin into	Toxoid and Vaccine into	closer translation match than the	
Peripheral Vein, Percutaneous	Muscle, Percutaneous	alternatives in the root operation	
Approach (4 codes)	Approach	Transfusion tables.	
		This translation alternative has also	
		been added to the ICD-10-PCS to	
		ICD-9-CM GEM.	

ICD-9-CM to ICD-10-PCS GEM entry for "Endoscopic destruction of esophagus tissue"

2015 entry	Updated 2016 entry	Comment	
42.33 Endoscopic excision or	42.33 Endoscopic excision or	The updated entry is a more	
destruction of lesion or tissue	destruction of lesion or tissue of	complete translation of the ICD-9-CM	
of esophagus	esophagus	code.	
То	То	The ICD-10-PCS code from table	
0D[B5]5[48]ZZ Destruction of	0D[B5]5[48]ZZ Destruction of	3E0 also specifies the procedure	
Esophagus, Via Natural or	Esophagus, Via Natural or	included in the source code 42.33.	
Artificial Opening Endoscopic	Artificial Opening Endoscopic (4	This translation alternative has also	
(4 codes)	codes)	been added to the ICD-10-PCS to	
	OR	ICD-9-CM GEM.	
	3E0G8TZ Introduction of		
	Destructive Agent into Upper		
	GI, Via Natural or Artificial		
	Opening Endoscopic		

Public comment:

ICD-9-CM to ICD-10-PCS GEM entry for "Medical induction of labor"

2015 entry	Updated 2016 entry	Comment
73.4 Medical induction of labor To 3E0DXGC Introduction of Other Therapeutic Substance into Mouth and Pharynx, External Approach OR	73.4 Medical induction of labor To 3E0DXGC Introduction of Other Therapeutic Substance into Mouth and Pharynx, External Approach OR	Comment The updated entry is a more complete translation of the ICD-9-CM code. 73.4 currently translates to 3E0PXGC for induction of labor via oral route. 3E0P7GC has been added to include the transvaginal
3E0[3-6][03]VJ Introduction of Other Hormone into Peripheral Vein, Percutaneous Approach (8 codes)	3E0P7GC Introduction of Other Therapeutic Substance into Female Reproductive, Via Natural or Artificial Opening (2 codes) OR 3E0[3-6][03]VJ Introduction of Other Hormone into Peripheral Vein, Percutaneous Approach (8 codes)	route. This translation alternative has also been added to the ICD-10-PCS to ICD-9-CM GEM.

ICD-9-CM to ICD-10-PCS GEM entry for "Cardiac contractility modulation system"

2015 entry	Updated 2016 entry	Comment	
Example	Example	Typographical error. The body part	
17.51 Implantation of	17.51 Implantation of	value for the insertion of cardiac lead	
rechargeable cardiac	rechargeable cardiac	ICD-10-PCS codes should specify	
contractility modulation [CCM],	contractility modulation [CCM],	the right side of the heart.	
total system	total system		
То	То		
0JH[68][03]AZ Insertion of	0JH[68][03]AZ Insertion of		
Contractility Modulation Device	Contractility Modulation Device		
into Chest Subcutaneous	into Chest Subcutaneous		
Tissue and Fascia, Open	Tissue and Fascia, Open		
Approach (4 codes)	Approach (4 codes)		
AND	AND		
02HL[034]MZ Insertion of	02HK[034]MZ Insertion of		
Cardiac Lead into Left	Cardiac Lead into Right		
Ventricle, Percutaneous	Ventricle, Percutaneous		
Approach (3 codes)	Approach (3 codes)		

Public comment:

ICD-10-PCS to ICD-9-CM GEM entry for "Open insertion of feeding gastrostomy tube"

2015 entry	Updated 2016 entry	Comment	
0DH60UZ Insertion of Feeding	0DH60UZ Insertion of Feeding	The updated entry is a more	
Device into Stomach, Open	Device into Stomach, Open	accurate translation of the ICD-10-	
Approach	Approach	PCS code.	
To	To	This translation alternative has also	
43.0 Gastrotomy	43.19 Other gastrostomy	been added to the ICD-9-CM to ICD-	
,		10-PCS GEM.	

Estimating the Impact of the Transition to ICD-10 on Medicare Inpatient Hospital Payments

Ron Mills, 3M ICD-10 Coordination and Maintenance Committee March 18, 2015

Objective

To estimate the impact on aggregate IPPS MS-DRG payments to hospitals due to the transition to ICD-10 on October 1, 2015

Disclaimer

- MS-DRG v33 for FY2016 using ICD-10 is going through the rule-making process.
- These are estimates based on
 - MS-DRG v32
 - FY 2015 weights

Terminology

- "Grouper"
 - The software that assigns a MS-DRG based on coded diagnoses, procedures, sex and discharge status.
- "DRG shift"
 - When the MS-DRG from a record coded in ICD-9 is different from the MS-DRG from the same record coded in ICD-10
- "MCC" or "CC"
 - Secondary diagnosis designated (major)complication/co-morbidity

Results

(Using about 10 million FY2013 MedPAR records)

- 0.41% had DRG shift to higher paying DRG \$13 more per \$10,000 (+0.13%)
- 0.66% had DRG shift to lower paying DRG \$17 more per \$10,000 (-0.17%)
- Net: 1.07% with a DRG shift \$4 less per \$10,000 (-0.04%)
- Statistically zero

More good news...

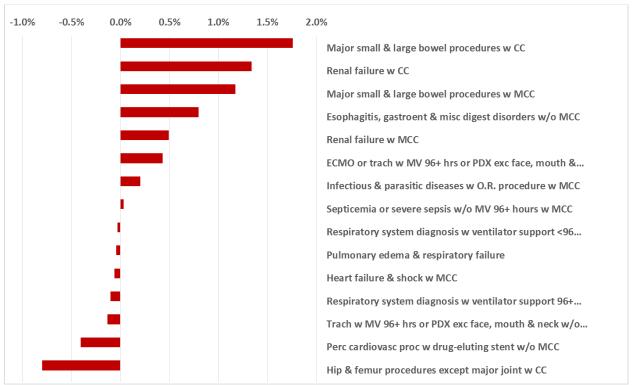
- Anecdotal evidence from some institutions which have dual coded ICD-9 and ICD-10, or have recoded ICD-10 records with apparent MS-DRG shifts:
 - Coder coded records are less likely to change their MS-DRG from ICD-9 to ICD-10
 - Actual net reimbursement impact may be even less than that estimated here.

Impact by hospital type

		Avg	DRG	Net reimb
Hospital type	Hospitals	reimb	shifts	change
All	3,205	10,678	1.07%	-0.04%
Indirect Medi	cal Educati	on		
Top 10%	103	20,993	1.25%	-0.01%
All others	3,102	9,993	1.06%	-0.05%
Disproportion	ate Share	Hospitals		
To 20%	641	13,186	1.22%	-0.05%
Middle 60%	1,923	10,146	1.05%	-0.04%
Bottom 20%	641	9,716	0.98%	-0.02%
Location		·		
Large Urban	1,340	11,908	1.13%	-0.04%
Other Urban	1,084	10,112	1.02%	-0.04%
Rural	781	7,081	1.00%	-0.06%
Size				
Top 10%	320	12,757	1.08%	-0.02%
All others	2,885	9,676	1.07%	-0.05%

All statistically zero





Your results will depend on case mix

Why can't the ICD-10 grouper be made to behave exactly like the ICD-9 grouper?

Unavoidable differences

- Myth:
 - ICD-10 just adds detail to ICD-9
- Reality:
 - Distinctions no longer in common use have been removed from ICD-10.
 - Some areas (e.g. OB) use a different approach to classification.
 - ICD-10-PCS procedure codes have no diagnostic content.
 - Some coding guidelines have changed.

Replicating the MS-DRG grouper for ICD-10

- Distinctions made by ICD-10 not available in ICD-9?
 - No problem.
 - 130,000 out of 140,000 codes (93%)
- Distinctions made by ICD-9 (and used by grouper) no longer available in ICD-10?
 - Presents challenges that must be handled individually.

How shifts were minimized

- When an ICD-10 code contains conditions previously classified in different ICD-9 codes:
 - Treat the ICD-10 code like the more frequently occurring ICD-9 code
 - Cases coded with the less frequent ICD-9 code, when re-coded in ICD-10 may go into a different MS-DRG

Example – reconciling differences

- Two codes different in ICD-9
 - 311, Depressive disorder, NEC

Not a CC. About 50 per 1,000 records

- 296.20, Major depression, unspecified

A CC. About 5 per 1,000 records

• Both translate to F32.9 in ICD-10

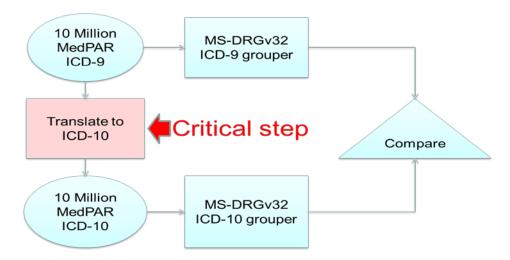
Must make F32.9 like 311 (a non-CC)

Records with 296.20 in ICD-9 but F32.9 in ICD-10 will shift to a lower paying MS-DRG

Impact estimates are sensitive to the quality of the ICD-10 coding

How our estimates were made

- 1. Start with 10 million FY2013 MedPAR records coded in ICD-9
- 2. Group them using ICD-9 MS-DRG v32
- 3. Mechanically convert the records to ICD-10
- 4. Group those using ICD-10 MS-DRG v32 grouper
- 5. Compare results using FY2015 weights



Mechanical translation

- Using only the information in the ICD-9 codes, correctly code the record in ICD-10
- Ask "What would the coder do?"
- Using the GEMs requires careful logic
- The next three slides provides some specific examples

Translating procedures

- Groups of ICD-9 procedure codes may translate into single ICD-10-PCS codes.
 - Example: PTCAs
 - Up to 5 codes in ICD-9, one code in ICD-10
- ICD-10 does not include procedure information in diagnoses
 - Example: Obstetrics codes
 - Imply delivery in ICD-9 but need explicit procedure in ICD-10

Using clusters

- One ICD-9 code sometimes translates into more than one ICD-10 code in order to convey the same meaning. Example:
- ICD-9:
 - 241.11, Secondary diabetes with ketoacidosis, uncontrolled
- ICD-10
 - E08.10 Diabetes ... with ketoacidosis
 - E08.65 Diabetes ... with hyperglycemia

Using the GEMs

- A careful interpretation of the flow of meaning between codes in the GEMs is required to use them effectively.
- Explanation of GEMs formation is provided on the CMS site where GEMs are found
- Much written about this elsewhere

When these techniques aren't used...

Translation technique	DRG shifts

Common MS-DRG shifts

- 40% of shifts to lower weight MS-DRGs come from losing a CC or MCC
- 75% of shifts to higher weight MS-DRGs come from gaining a CC or MCC

Dual coding study

A coder with access to the original medical record will create more accurate codes than mechanical translation

- Coders code in ICD-9
- Group the ICD-9 coded records
- Coders code the same records in ICD-10
- Group the ICD-10 coded records
- Compare

Cautionary example

- 100 cases (a pilot study)
- 20 of them appeared to have a DRG shift but further analysis showed:
 - In 9 of these the ICD-10 coder found clinical facts the ICD-9 coder missed
 - In 9 others the ICD-9 coder found clinical facts the ICD-10 coder missed
 - Only 2 cases out of the 100 actually had DRG shifts due to differences between ICD-9 and ICD-10

Coding issues can impact DRG reimbursement more than the differences between ICD-9 and ICD-10

First year documentation improvement

- Documentation improvement targeted only on new ICD-10 detail may be useful in the long run, but may not impact the first year MS-DRG reimbursement.
- Areas where ICD-10 no longer works like ICD-9:
 - Code procedures. Do not rely on diagnoses.
 - "Malignant" hypertension
 - "Unspecified" diagnoses accepted as CC/MCC

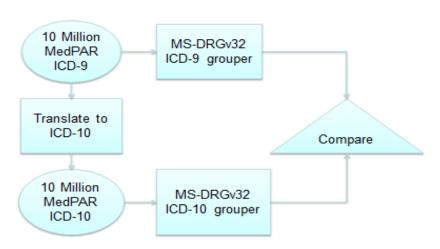
Summary

- For a typical case mix, expect
 - About 1% of the cases shift MS-DRG
 - Net impact statistically zero
- Coding issues can have a greater impact than the differences between ICD-9 and ICD-10
- If you do an analysis like this with your own data, pay close attention to the mechanism you use to translate from ICD-9 to ICD-10.

Article Describing Impact

- Estimating the Impact of the Transition to ICD-10 on Medicare Inpatient Hospital Payments
- http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html (First zipped documents under Downloads)

Questions



The Impact of the Transition to ICD-10 on Medicare Inpatient Hospital Payments

Ronald E. Mills, Ph.D., Rhonda R. Butler, CCS, Richard F. Averill, M.S., Elizabeth C. McCullough, M.S., Richard L. Fuller, M.S., Mona Z. Bao, M.A.

On October 1, 2015, ICD-9-CM is scheduled to be replaced by the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for reporting diagnosis data across all sites of service and the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) for reporting inpatient procedures. ICD-10-CM/PCS substantially increases the level of clinical detail that can be captured and reported. In the FY 2014 update of ICD-9-CM there were 14,567 diagnosis codes and 3,882 procedure codes. In the FY 2014 update of ICD-10-CM there were 69,823 diagnosis codes and in ICD-10-PCS there were 71,924 procedure codes. For brevity ICD-10-CM/PCS will be referred to as ICD-10 and ICD-9-CM will be referred to as ICD-9.

The Medicare inpatient prospective payment system (IPPS) uses the Medicare Severity - Diagnosis Related Groups (MS-DRGs) as the basis of payment. An ICD-10 version of the MS-DRGs is available for download from the CMS website ¹. The ICD-10 MS-DRGs are a replication of the ICD-9 MS-DRGs. A replication means that the same hospital inpatient medical record coded independently in ICD-10 and ICD-9 would have the same MS-DRG assigned by the ICD-10 MS-DRGs using the ICD-10 codes and the ICD-9 MS-DRGs using the ICD-9 codes.

Because the ICD-10 MS-DRGs replicate the ICD-9 MS-DRGs, they do not take advantage

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of the increased specificity of ICD-10. If the ICD-10 MS-DRGs had been optimized to take full advantage of ICD-10, they would have been inconsistent with the existing MS-DRG payment weights. Since there is no substantial database of records coded in ICD-10 available, there is no way of recalibrating the MS-DRG payment weights to correspond to ICD-10 optimized MS-DRGs. Hence the MS-DRGs cannot take full advantage of ICD-10 until there is enough ICD-10 data available to allow the recalculation of the MS-DRG payment weights.

If the only difference between ICD-9 and ICD-10 were the increased specificity in ICD-10, then the ICD-10 MS-DRGs could be an exact replication of the ICD-9 MS-DRGs since it would be possible to treat each ICD-10 code the same way its less specific ICD-9 code was treated. However, ICD-10 differs from ICD-9 in more complex ways. For example, distinctions no longer in common use, such as malignant versus benign hypertension have been removed from ICD-10. In some areas the axis of classification differs. For example, in ICD-10 many obstetric conditions are classified by the trimester of the pregnancy instead of the ICD-9 distinction as to whether a delivery took place. In addition, some of the coding guidelines differ in ICD-10. For example, anemia as manifestation of a chronic disease is no longer coded as principal diagnosis in ICD-10 but is instead reported as a secondary diagnosis. Due to these differences an exact replication of the MS-DRGs in ICD-10 is not possible. The purpose of this article is to describe the extent to which the differences between the ICD-9 and ICD-10 MS-DRGs may impact hospital payment.

Creating ICD-10 Data

Since there is no large-scale database available that contains diagnosis and procedure data coded in ICD-10, it was necessary to create a simulated ICD-10 database by translating the ICD-9 codes on each record to ICD-10. The objective of the translation of a record from ICD-9 to ICD-10 was to create a *correctly coded* ICD-10 version of the same record.

A set of context specific translation rules (described in detail in a previous article) was developed to automate the determination of the best possible ICD-10 translation. ² The ICD-9 codes on a record were *not* translated one by one, but instead the ICD-9 codes on the record were evaluated as a group in creating an ICD-10 coded version of the record. By evaluating the ICD-9 codes as a group, selection of the ICD-10 codes that best represented how the record would be coded in ICD-10 was more accurate.

Database

The database used to create the simulated ICD-10 data was the FY 2013 Medicare Provider Analysis and Review (MedPAR) data. The FY 2013 MedPAR database contained all Medicare inpatient admissions from acute care hospitals with a discharge date from 10/1/2012 through 9/30/2013. Non-IPPS hospitals were removed from the database, including skilled nursing facilities, long-term care hospitals, rehabilitation hospitals, psychiatric hospitals, critical access hospitals, children's hospitals, and oncology hospitals. Further, hospitals that had insufficient or inaccurate cost report information or with missing IME or DSH adjustment factors were also excluded from the database. Cases from IPPS hospitals in stand-alone units were also excluded. Cases were matched to the FY2014 CMS standardization file to assign wage indices, IME, DSH, COLA and cost to charge ratios. MS-DRG weights were obtained from FY 2015 Table 5. The analysis data set contained 10,009,934 admissions from 3,205 hospitals.

A base payment amount for each admission was computed using the full update standard operating amount for FY15, multiplying by the MS-DRG weight, adjusting the labor share of the claim by the wage index and COLA and then inflating the entire claim by the DSH and IME coefficients. A separate calculation for high cost outlier was estimated based on the operation portion of the cost. No further adjustments were made for capital related costs nor quality adjustments that may result in less than a full update.

Payment Impact

The ICD-9 MS-DRG Version 32 was used to assign the MS-DRGs to the ICD-9 MedPAR data and the ICD-10 MS-DRG Version 32 was used to assign the MS-DRGs to the converted ICD-10 MedPAR data. Based on the MS-DRG assigned, the payment amount for each admission in the database was computed. If the ICD-9 MS-DRG assignment differed from the ICD-10 MS-DRG assignment, two separate payment amounts were computed.

The ICD-9 MS-DRG and ICD-10 MS-DRG assignments differed for 1.07% percent of the admissions. The ICD-10 MS-DRG assignment was to a higher paying MS-DRG in 0.41 percent of the admissions, resulting in a payment increase of 0.13 of a percent. The ICD-10 MS-DRG assignment was to a lower paying MS-DRG in 0.66 percent of the admissions, resulting in a payment decrease of 0.17 of a percent. The net payment change due to differences in MS-DRG assignment was -0.04 of a percent (i.e., 4 one-hundredths of one percent of the ICD-9 based MS-DRG payments). Thus, estimated payment increases and decreases due to changes in MS-DRG assignment essentially netted out.

The results of the payment impact analysis by hospital type are contained in Table 1. The estimated change in MS-DRG assignment is relatively consistent across hospital types, with the 20 percent of hospitals with the smallest dis-

proportionate share having the smallest change in MS-DRG assignment (0.98 of a percent), and the 10 percent of hospitals with the biggest indirect medical education adjustment having the largest change in MS-DRG assignment (1.25 percent). The change in payment was more consistent across hospital types, with the 10 percent of hospitals with the biggest indirect medical education adjustment having a -0.01 of a percent decrease in payment and the rural hospitals having a -0.06 of a percent payment decrease.

Discussion

The increased specificity of ICD-10 will require hospitals to improve documentation and coding precision. Although this represents a change in hospital coding practices, the change in coding practices will have minimal impact on MS-DRG assignment because the ICD-10 MS-

DRGs are a replication of the ICD-9 MS-DRGs and do not take advantage of the increased specificity of ICD-10. Essentially, the replicated ICD-10 MS-DRG function at the same level of specificity as the ICD-9 MS-DRGs.

When the MS-DRGs are optimized to take advantage of the detail in ICD-10, there may be a substantial impact on payments. However, the ICD-10 optimization of MS-DRGs cannot occur until there is sufficient ICD-10 data available to allow MS-DRG payment weights corresponding to the ICD-10 optimized MS-DRGs to be computed. Realistically, the earliest an ICD-10 optimized version of MS-DRGs can be implemented is FY2018. This means that there will be two years of ICD-10 coded data available before an ICD-10 optimized version of the MS-DRGs is implemented.

The availability of two years of ICD-10 data

Table 1: Payment Impact of ICD-10 vs ICD-9 MS-DRG assignment based on MedPAR FY 2015

Hospital	Count	Count	Tot Pay	% Diff	% Diff
Type	Hospitals	Discharges	(\$000,000)	Count	Payment
All	3,205	10,009,934	106,889,989	1.07%	-0.04%
IME ¹					
Top 10%	103	623,877	13,097,323	1.25%	-0.01%
All others	3,102	9,386,057	93,792,666	1.06%	-0.05%
DSH ²					
Top 20%	641	1,980,029	26,107,820	1.22%	-0.05%
Middle 60%	1,923	6,420,531	65,145,068	1.05%	-0.04%
Bottom 20%	641	1,609,374	15,637,101	0.98%	-0.02%
Location					
Large Urban	1,340	4,974,766	59,240,865	1.13%	-0.04%
ther Urban	1,084	3,957,329	40,016,872	1.02%	-0.04%
Rural	781	1,077,839	7,632,253	1.00%	-0.06%
Size					
Top 10%	320	3,257,861	41,560,229	1.08%	-0.02%
All other	2,885	6,752,073	65,329,760	1.07%	-0.05%

¹ IME = Indirect Medical Education

² DSH = Disproportionate Share Hospital

will allow any systematic changes in coding practices under ICD-10 to be reviewed and evaluated. Potential opportunities for up-coding under ICD-10 can be mitigated by using the two years of ICD-10 data to find the changes in coding practices under ICD-10 that impact MS-DRG definitions and payment weights. Although an ICD-10 optimized version of the MS-DRGs must wait two years for recalibrated MS-DRG payment weights, the two-year delay allows for the evaluation of changes in coding practices, to minimize opportunities for up- coding in the ICD-10 optimized MS-DRGs.

Conclusions

The transition from the ICD-9 version of the MS-DRGs to the ICD-10 version of the MS-DRGs will have a minimal impact on aggregate payments to hospitals (-0.04 of a percent) and on the distribution of payments across hospital types (-0.01 to -0.06 of a percent). Although the transition from the ICD-9 version of the MS-DRGs to the ICD-10 version resulted in 1.07 percent of the patients being assigned to different MS-DRGs, overall payment increases and decreases due to a change in MS-DRG assignment essentially net out.

References

 $^{^{1}\} http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html$

² Mills, R, Butler, R, McCullough, E, Bao, M, Averill, R, "Impact of the Transition to ICD-10 on Medicare Inpatient Hospital Payments", *Medicare & Medicaid Research Review 2011*, Vol 2, No. 2, 2011, pp E1-E13 2011.

Medicare ICD-10 Testing

Medicare's Testing Plan for ICD-10 Success

Stacey Shagena, CMS Center for Medicare

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

Testing is Key to Success

- CMS completed two successful Acknowledgement Testing Weeks with submitters in March 2014 and November 2014.
- CMS recently completed the first of three end-to-end testing weeks in January 2015.

Acknowledgement Testing

- Allows testers to submit claims with ICD-10 codes to the Medicare Fee-For-service (FFS) claims systems and receive electronic acknowledgements confirming that their claims were accepted.
- This testing can be performed at any time, or during targeted testing weeks.
- All electronic submitters are eligible to participate, and no registration is required.

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.
- Testing did not identify any issues with the Medicare FFS claims systems.

November '14 Acknowledgement Testing Success

- During the November testing week, testers submitted almost 13,700 claims.
- More than 500 providers, suppliers, billing companies, and clearinghouses participated in the testing week.
- Testing did not identify any issues with the Medicare FFS claims systems.

March '15 Acknowledgement Testing Success

• Our third acknowledgement testing week was held March 2 through 6, 2015.

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 real-time help desk support and allows CMS to analyze testing data. Registration is not required. Mark your calendar:
 - June 1 through 5, 2015

End to End Testing

- End-to-end testing allows providers to submit ICD-10 test claims that will be fully processed and produce a remittance advice.
- This is the first time this type of testing has been available to providers.
- 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 con't.

- Registration is required for end-to-end testing, as a limited number of volunteers may be chosen.
- 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 was conducted January 26-February 3, 2015.
- Approximately 660 providers and billing companies submitted nearly 15,000 test claims.
- Only 3% of test claims were rejected for invalid submission of ICD-10 diagnosis or procedure code.
- One ICD-10 system problem was found related to Home Health claims, which will be corrected before the next week of testing.

Future End to End Testing

- Round 2 of end-to-end testing will be April 27-May 1, 2015
 - Testers for April have already been selected, and are preparing to test.
- Round 3 of end-to-end testing will be July 20-24, 2015.
 - Registration on the MAC and CEDI websites will be open through April 17, 2015.