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

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

Agenda
ICD-9-CM 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-9-CM and ICD-10-CM/PCS
March 5, 2013

Pat Brooks, CMS – Co-Chairperson

9:00 AM – 12:30 PM	ICD-10-PCS and ICD-9-CM Procedure presentations with public comment
12:30 PM – 1:30 PM	Lunch break
1:30 PM – 5:00 PM	Diagnosis presentations with public comment

Note: Proposals for the diagnosis codes will begin following the conclusion of the procedure presentations 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

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. If participating via the webcast you do NOT need to register for the meeting.

Conference lines will also be available for those participants who are unable to view the webcast or attend in person. Toll free dial in access for external participants is as follows:
Phone: 1-877-267-1577 Meeting ID: 6601
If dialing in you do NOT need to register on-line for the meeting.

Opening remarks	**Marc Hartstein** Director, Hospital and Ambulatory Policy Group, CMS
Introductions and comments on Committee activities	**Pat Brooks**
ICD-10 Topics:	
1. ICD-10 Implementation Announcements Page 9	Pat Brooks Geanelle Herring, CMS
2. ICD-10 MS-DRG v30 mainframe and PC Software Page 9	Pat Brooks
3. ICD-10 Conversions of National Coverage Determinations	Janet Anderson Brock, CMS
4. ICD-10 Impact Analysis Pages 10-15	Ron Mills, 3M
5. ICD-10 HAC and POA Exempt List Page 16	Celeste Beauregard
6. ICD-10 Addendum Updates Page 17	Rhonda Butler, 3M
7. New formatting for ICD-10-PCS addendum Page 18-20	Rhonda Butler, 3M
ICD-9-CM/ICD-10-PCS Topics:	
1. Infusion of 4-Factor Prothrombin Complex Concentrate (4F-PCC) Pages 21-23	Amy Gruber Christian Peters, MD Senior Medical Director CSL Behring, LLC
2. Implantation of Transprostatic Struts ICD-9-CM and ICD-10-PCS code request Pages 24-27	Mady Hue Michael McClure Sr. Dr. Reimbursement Health Economics Neo Tract, Inc.
3. Implantation of Epiretinal Prosthesis Pages 28 -31	Celeste Beauregard James Handa, MD Robert Bond Welch Professor The Johns Hopkins School of Medicine

Registering for the meeting:

Registration for the March 5, 2013 ICD-9-CM Coordination and Maintenance Committee meeting opened on February 1, 2013**. If dialing in or participating by Livestream webcast 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 Mady Hue at 410-786-4510 or marilu.hue@cms.hhs.gov.

Requesting revisions to procedure codes and submitting comments:

Requests for revisions to ICD-9-CM and ICD-10-PCS **procedure codes** and comments on the **procedure** part of the ICD-9-CM Coordination and Maintenance Committee meeting should be sent to:

Pat Brooks: patricia.brooks2@cms.hhs.gov

Requesting revisions to diagnosis codes and submitting comments:

Requests for revisions to ICD-9-CM and ICD-10-CM **diagnosis** codes and comments on the **diagnosis** part of the ICD-9-CM Coordination and Maintenance Committee meeting should be sent to:

Donna Pickett: nchsicd9@cdc.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-9-CM Coordination and Maintenance (C&M) Committee Meeting Conference Calls, Webcasts or on-site Meetings.

Continuing Education Information for American Academy of Professional Coders (AAPC)
If you have attended or are planning to attend a CMS ICD-9-CM Coordination and Maintenance (C&M) Committee Meeting Conference Call, Webcast or on-site Meeting, you should be aware that CMS does not provide certificates of attendance for these. Instead, the AAPC will accept your e-mailed confirmation and call or meeting description as proof of participation. Please retain a copy of your e-mailed confirmation for these as the AAPC will request them for any conference call or meeting 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-9-CM TIMELINE

A timeline of important dates in the ICD-9-CM process is described below:

March 5, 2013	ICD-9-CM Coordination and Maintenance Committee meeting.
April 1, 2013	There were no requests for ICD-9-CM codes to capture new technology for implementation on April 1, 2013. Therefore, there will be no new ICD-9-CM procedure codes implemented on April 1, 2013.
April 6, 2013	**Deadline for receipt of public comments on proposed code revisions discussed at the March 5, 2013 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2013.**
April 2013	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This notice will include the final ICD-9-CM diagnosis and procedure codes for the upcoming fiscal year. It will also include proposed revisions to the DRG system 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 2013	Summary report of the Procedure part of the March 5, 2013 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html Summary report of the Diagnosis part of the March 5, 2013 ICD-9-CM 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 2013	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/ICD9ProviderDiagnosticCodes/addendum.html

July 12, 2013	**Those members of the public requesting that topics be discussed at the September 18 – 19, 2013 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses.**
August 1, 2013	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 all the final codes to be implemented on October 1, 2013. 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 2013	Tentative agenda for the Procedure part of the September 18 – 19, 2013 ICD-9-CM 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 18 – 19, 2013 ICD-9-CM 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 18 –19, 2013 ICD-9-CM Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.
August 16, 2013	**On-line registration opens for the September 18-19, 2013 ICD-9-CM Coordination and Maintenance Committee meeting at: https://www.cms.gov/apps/events/default.asp**
September 6, 2013	Because of increased security requirements, those wishing to attend the September 18 - 19, 2013 ICD-9-CM 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 6, 2013; failure to do so may result in lack of access to the meeting.**
September 18 –19, 2013	ICD-9-CM Coordination and Maintenance Committee meeting Those who wish to attend the ICD-9-CM Coordination and Maintenance Committee meeting **must have registered for the**

	meeting online by September 6, 2013. You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.
October 2013	Summary report of the Procedure part of the September 18 – 19, 2013 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on the CMS webpage as follows: http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html Summary report of the Diagnosis part of the September 18– 19, 2013 ICD-9-CM 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, 2013	New and revised ICD-9-CM 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/ICD9ProviderDiagnosticCodes/addendum.html
October 04, 2013	**Deadline for receipt of public comments on proposed code revisions discussed at the September 18-19, 2013 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on April 1, 2014.**
November 2013	Any new ICD-9-CM 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, 2013 will be posted on the following websites: http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/addendum.html http://www.cdc.gov/nchs/icd/icd9cm_addenda_guidelines.htm
November 15, 2013	**Deadline for receipt of public comments on proposed code revisions discussed at the September 18-19, 2013 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2014.**

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

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 which would end one year after the implementation of ICD-10. The implementation of ICD-10 was delayed from October 1, 2013 to October 1, 2014 by final rule CMS-0040-F issued on August 24, 2012. Links to this final rule may be found at http://www.cms.gov/Medicare/Coding/ICD10/Statute_Regulations.html.)
There was considerable support for this partial freeze. The partial freeze will be implemented as follows:

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

• On October 1, 2012 and October 1, 2013 there will be 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, 2014, 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, 2015, regular updates to ICD-10 will begin.

The ICD-9-CM Coordination and Maintenance Committee will continue to meet twice a year during the partial freeze. At these meetings, the public will be asked to comment on whether or not requests for new diagnosis or procedure codes should be created based on the criteria of the need to capture a new technology or disease. Any code requests that do not meet the criteria will be evaluated for implementation within ICD-10 on and after October 1, 2015 once the partial freeze has ended.

ICD-10 Implementation Announcements

- CMS will provide a variety of ICD-10 updates during this meeting
  - Updates on ICD-10 implementation issues
  - Availability of ICD-10 MS-DRG v30 mainframe and PC software
  - Updates on ICD-10 conversions of National Coverage Determinations
  - Updated impact analysis of ICD-10 MS-DRGs

- Detailed timeline within the C&M handouts
  - **April 6, 2013 - Comments due on topics presented today**
    - Procedure comments to Pat Brooks, CMS patricia.brooks2@cms.hhs.gov
    - Diagnosis comments to Donna Pickett, CDC nchsicd9@cdc.gov

Availability of ICD-10 Definitions Manuals and Summary of Changes

- MS-DRG V30.0 ICD-10 Definitions Manual

  – Available in text and HTML versions
- MS-DRG V30.0 ICD-10 "Summary of Changes"
- ICD-10 Definitions of Medicare Code Edits

– Posted on ICD-10 website at http://www.cms.gov/ICD10

ICD-10 MS-DRG V30 Software Update

ICD-10 MS-DRG V30 Software is now available through NTIS. The following software may be ordered:

- MS-DRG v30 ICD-10 Mainframe Software
- MCE v30 ICD-10 Mainframe Software
- MSG/MCE v30 ICD-10 PC software

Available via NTIS at http://www.ntis.gov/products/cms-medicare.aspx

Links are provide on the CMS website at under Related Links at http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html

The pilot MS-DRG ICD-10 software is released for purposes of review and evaluation. The official MS-DRG ICD-10 software to be used to determine FY 2015 inpatient payments will be subject to formal rulemaking. The FY 2015 software (Version 32) will not be available until the IPPS final rule for FY 2015 is issued.

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

Ron Mills, 3M
ICD-9-CM Coordination and Maintenance Committee
March 5, 2013

Objective

To estimate the impact on aggregate IPPS MS-DRG payments to hospitals due to the transition

- Update of September 2010 C&M presentation
    - Discussion of reimbursement map replaced with discussion of reasons for MS-DRG shifts
    - Discussion of hospital-type specific results replaced with discussion of sensitivity to coding and case mix
- New results using MS-DRG v30

Disclaimer

- MS-DRG v32 (FY2015 using ICD-10) will be subject to rule-making.
- These are estimates based on MS-DRG v30, FY2013 weights, and a "replicated" ICD-10 grouper (as much like ICD-9 as possible)
- Estimates use weights only – no provision for outliers, short stays or other adjustments

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)

How estimates made

1. 10 million MedPAR records coded in ICD-9
2. Group using ICD-9 MS-DRG v30
3. Mechanically convert records to ICD-10
4. Group using ICD-10 MS-DRG v30 grouper
5. Compare results using FY2013 weights

Terminology

- "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
- Problem of tiny amounts
  - Weight change of 0.01% easy to misinterpret
  - 1/10000th
  - "One penny per $100 of reimbursement"

MS-DRG v30 Results

- 99% no change in MS-DRG
- DRG shifts on 1% of the records
  - 45% of the shifts to higher weight DRGs
  - 55% of the shifts to lower weight DRGs
- Net impact across all DRGs:
  - Reduction by 4/10000th or
  - Minus 4 pennies per $100

Anatomy of net impact

- 10 million MedPAR sample:
  - Total for negative shifts: -14 cents per $100
  - Total for positive shifts: +10 cents per $100
  - Net: -4 cents per $100
- Net change for an institution?
  - Depends on case mix and coding habits

These results are very sensitive to the quality of the ICD-10 coding

Translation intentions

- "What would the coder do?"
- Using the information in the ICD-9 codes, correctly code the record in ICD-10
- Ignore the MS-DRG logic

A coder with access to the original medical record can often do a better job

Impact of translation techniques

Translation technique	DRG shifts
Translation as performed.	1.0%
Do not look for groups of ICD-9 codes that translate into single ICD-10 codes	3.1%
Do not add procedures where appropriate to reflect procedural information in ICD-9 diagnoses which ICD-10 does not have.	3.5%
When the GEMs translate one ICD-9 code into two or more ICD-10 codes (a "cluster") to get the same meaning, put *only one of* the ICD-10 codes in the cluster on the record. Quick and easy – one ICD-10 code for each ICD-9 code.	4.5%

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.

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 which use the less frequent ICD-9 code now become shifts
- Example: **F32.9**, Major depression, unspecified
  311 Depressive disorder, NEC
  296.20 Major depression, unspecified (a CC)

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

Top 10 MS-DRG shifts (1-5)

DRG	Description	+/-	Reason
812	MS-DRG 812, Red blood cell disorders w/o MCC	Pos	Change in coding guidelines for anemia
981	MS-DRG 981, Extensive O.R. procedure unrelated to principal diagnosis w/MCC	Neg	Mostly MCC loss. Sometimes more detailed ICD-10 can better relate procedure to diagnoses
391	Esophagitis, gastroent & misc disgest disorders w MCC	Neg	**K22.8** Other diseases of esophagus, treated like **530.89** (not an MCC) instead of **530.82** (MCC).
885	Psychoses	Neg	**F32.9**, Major depression, unspecified, treated like **311** Depression NEC instead of **296.20** (a CC).
066	Intracranial hemorrhage or cerebral infarction w/o CC/MCC	Pos	**I63.59**, Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery, treated like **433.81** (not excluded as CC) instead of **433.31** (excluded as CC)

Top 10 MS-DRG shifts (5-10)

DRG	Description	+/-	Reason
191	Chronic obstructive pulmonary disease with CC	Neg	ICD-10 does not differentiate sub-types of COPD the way ICD-9 does. **J44.1**, COPD with exacerbation, treated like more common non-CCs. Better documentation and coding of the cause of the COPD exacerbation (e.g. pneumonia) can bring back the CC or MCC.
011	Tracheostomy for face, mouth and neck diagnoses with MCC	Pos	Tracheostomy was included in ICD-9 procedure **304**, Radical laryngectomy, but is coded separately in ICD-10.
974	HIV with major related condition and MCC	Neg	In ICD-10 **A41** sepsis codes treated like **995.91**, excluded as MCC for 974.
292	Heart failure and shock with CC	Neg	Hypertension in ICD-10 no longer has malignant/benign distinction. Coding of the specific manifestation that led in ICD-9 to the "malignant" determination will often justify a CC.
37	Extracranial procedures with MCC	Pos	See above for MS-DRG 066

Lessons learned

- 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.
- Documentation improvement targeted only on new ICD-10 detail may be useful in the long run, but may not help much with first year MS-DRG reimbursement.
- What will help is general documentation improvement in areas that are not fully coded now, especially where there are differences in the classifications.

Some good news

- Anecdotal evidence from some institutions which have dual coded ICD-9 and ICD-10, or have re-coded in 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
  - When the day comes, net reimbursement impact may be less than that estimated here.

FY 2014 Hospital Acquired Condition (HAC) ICD-9-CM Codes
Conversion to ICD-10-CM/PCS and POA Exempt List

Information on the v30 HAC conversion to ICD-10-CM/PCS is part of the ICD-10 MS-DRG Conversion Project which can be found at http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html in Appendix I 'Hospital Acquired Conditions (HACs) List'.

We encourage the public to review these translations and to submit comments on these translations. A CMS ICD-10-CM/PCS HAC Translation Feedback Mailbox has been set up for this purpose. This feedback link is titled 'CMS HAC Feedback' and is located under the HAC website on the ICD-10-CM/PCS HACs List sub-website:

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html.

Again we welcome all input on these HAC translations into ICD-10-CM/PCS.

In the meantime, we continue to encourage readers to review the educational materials and draft code sets currently available for ICD-10-CM/PCS at the CMS Web site at: http://www.cms.gov/ICD10/. In addition, the ICD-10-CM coding guidelines can be viewed on the CDC Web site at http://www.cdc.gov/nchs/icd/icd10cm.htm.

Finally, the FY 2013 ICD-10 POA Exempt List is posted on our website at http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Coding.html

ICD-10-PCS New and Deleted Codes for October 1, 2013

New Codes for 2014

0 Medical and Surgical
4 Upper Arteries
V Restriction: Partially closing an orifice or the lumen of a tubular body part

Body Part	Approach	Device	Qualifier
0 Abdominal Aorta	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	D Intraluminal Device	J Temporary

04V00DJ Restriction of Abdominal Aorta with Temporary Intraluminal Device, Open Approach
04V03DJ Restriction of Abdominal Aorta with Temporary Intraluminal Device, Percutaneous Approach
04V04DJ Restriction of Abdominal Aorta with Temporary Intraluminal Device, Percutaneous Endoscopic Approach

Deleted Codes for 2014

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

Body Part	Approach	Device	Qualifier
W Thoracic Aorta	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	D Intraluminal Device	J Temporary

02VW0DJ Restriction of Thoracic Aorta with Intraluminal Device, Temporary, Open Approach
02VW3DJ Restriction of Thoracic Aorta with Intraluminal Device, Temporary, Percutaneous Approach
02VW4DJ Restriction of Thoracic Aorta with Intraluminal Device, Temporary, Percutaneous Endoscopic Approach

Revised ICD-10-PCS Section Title for 2014

Received in public comment, a proposal to change the title of Section D, Radiation Oncology to Radiation Therapy, in order to allow codes in this section to be used for radiation therapy procedures regardless of the diagnosed condition for which they were performed. Such information will be contained in the diagnosis code.

ICD-10-PCS Annual Update Addenda for Index and Definitions Files

In response to public comment, CMS is undertaking the development of a more detailed set of addenda for the Index and Definitions files for future updates, to be posted in both PDF and text file formats.

The files will be produced using an automated process and must meet federal accessibility requirements for using assistive technologies to read documents. The PDF file is intended for individual users who want to review the changes made. The text file format is a machine readable file that uses a separate term to identify each element defined in the source content. It is intended for organizations that use automated processes to analyze and update the ICD-10-PCS content.

Examples of the proposed Index and Definitions files addenda formats are provided below. CMS welcomes input from users and technical developers concerning the ICD-10-PCS addenda file formats.

Index Addenda, PDF example (addenda entries beginning with D)

Blank line
No change

D

Add
Distal humerus
Add
use Humeral Shaft, Right
Add
use Humeral Shaft, Left
Add
Distal humerus, involving joint
Add
use Joint, Elbow, Right
Add
use Joint, Elbow, Left

Add
Driver stent (RX) (OTW) *use* Intraluminal Device
Blank line

Index Addenda, Text example (addenda entries beginning with D)

Lttr D

Main Add Distal humerus

Add use Humeral Shaft, Right

Add use Humeral Shaft, Left

Main Add Distal humerus, involving joint

Add use Joint, Elbow, Right

Add use Joint, Elbow, Left

Main Add Driver stent (RX) (OTW) use Intraluminal Device

Definitions Addenda, PDF example (Device definitions addenda in E-I)

No change	Extraluminal Device	
Revise from		LAP-BAND® Adjustable Gastric Banding System
Revise to		LAP-BAND® adjustable gastric banding system
Delete	Hearing Device, Bone Conduction in Head and Facial Bones	Bone anchored hearing device
Add	Hearing Device in Head and Facial Bones	Bone anchored hearing device
No change	Infusion Device	
Add		InDura, intrathecal catheter (1P) (spinal)
Add		Tunneled spinal (intrathecal) catheter

Definitions Addenda, Text example (Device definitions addenda in E-I)

Row

Term Extraluminal Device

Includes Revise from LAP-BAND® Adjustable Gastric Banding System

Includes Revise to LAP-BAND® adjustable gastric banding system

Row Delete

Term Delete Hearing Device, Bone Conduction in Head and Facial Bones

Includes	Delete	Bone anchored hearing device

Row	Add	
Term	Add	Hearing Device in Head and Facial Bones
Includes	Add	Bone anchored hearing device

Row		
Term		Infusion Device
Includes	Add	InDura, intrathecal catheter (1P) (spinal)
Includes	Add	Tunneled spinal (intrathecal) catheter

Infusion of 4-Factor Prothrombin Complex Concentrate (4F-PCC)

Issue: Should new ICD-9-CM and ICD-10 PCS codes be created to identify a potential new blood clotting factor drug, 4F-PCC, that contains blood clotting Factors II,VII, IX and X, and Proteins C and S?

New Technology Application?
CSL Behring has submitted a new technology application for Kcentra™ 4-Factor Prothrombin Complex Concentrate (4F-PCC) for FY 2014.

FDA Approval:
A Biologics License application (BLA) for Kcentra™ is currently under review and anticipated FDA approval is expected in April 2013. Upon FDA approval, it is anticipated that Kcentra™ 4-Factor Prothrombin Complex Concentrate (4F-PCC) will be indicated for the urgent reversal of vitamin k antagonist (e.g. warfarin) therapy in patients with acute major bleeding.

Background:
Warfarin is highly effective at preventing blood clots for indications such as atrial fibrillation, deep vein thrombosis, and mechanical heart valves and is widely used. However, warfarin significantly raises the risk of bleeding in treated patients due to the development of coagulation factor deficiency. Plasma and vitamin K are the current standard treatments for patients on warfarin experiencing an acute major bleed, but the limitations include 1) inability to rapidly reverse warfarin in bleeding patients further complicating and possibly delaying necessary interventions in these critical patients, 2) scant evidence of efficacy, 3) risk of pathogen transmission, and 4) transfusion associated adverse reactions, including but not limited to Transfusion Associated Circulatory Overload (TACO) and Transfusion Related Acute Lung Injury (TRALI).

Upon FDA approval, Kcentra™ will be the first and only 4-factor prothrombin complex concentrate that is FDA-approved for rapid warfarin reversal in patients experiencing an acute major bleed. Kcentra™ has been specifically-engineered to provide all four essential vitamin K-dependent, non-activated coagulation factors (Factor II, Factor VII, Factor IX, and Factor X) in addition to antithrombotic proteins C and S. Kcentra™ is heat treated, virus filtered and lypophilized plasma protein concentrate made from pooled human plasma administered by intravenous infusion. The potency and dosing of Kcentra™ is based on Factor IX units. According to the manufacturer, the product is 25 times more concentrated than the equivalent plasma dose, meaning that Kcentra™ therapy requires 87% less volume than plasma. It is anticipated that Kcentra™ will be utilized primarily for inpatient hospital use. In addition, some patients will receive the product in hospital emergency departments and outpatient hospitals. 4-Factor Prothrombin Complex Concentrate has been available in Europe and Asia for more than 15 years.

According to the manufacturer, Kcentra™ represents a substantial clinical improvement in the treatment of patients with acute severe bleeding who require immediate reversal of their warfarin therapy by 1) providing a rapid, beneficial resolution of the patient's blood clotting factor

deficiency, 2) decreasing the risk of exposure to blood borne pathogens, and 3) reducing the rate of transfusion-associated complications.

ICD-9-CM Procedure Coding Options:
Option 1. Continue to assign code 99.06, Transfusion of coagulation factors, for the Infusion of 4-Factor Prothrombin Complex Concentrate (4F-PCC).

Option 2. Create a new code under subcategory 00.9, Other procedures and interventions, to uniquely capture the Infusion of 4-Factor Prothrombin Complex Concentrate (4F-PCC).

New code 00.96 Infusion of 4-Factor Prothrombin Complex Concentrate
Infusion of 4F-PCC
Excludes: transfusion of coagulation factors (99.06)
transfusion of Factor IX complex (99.06)

CMS Recommendation: Option 2. As described above.

Interim Coding: In the interim, continue to assign code 99.06, Transfusion of coagulation factors for the infusion of 4-Factor Prothrombin Complex Concentrate (4F-PCC).

ICD-10-PCS Coding Options:
Option 1. Continue to assign one of the following ICD-10-PCS codes under section 3 - Administration, body system 0 – Circulatory, operation 2 – Transfusion, for the Infusion of 4-Factor Prothrombin Complex Concentrate (4F-PCC).

30230W1 Transfusion of Nonautologous Factor IX into Peripheral Vein, Open Approach

30233W1 Transfusion of Nonautologous Factor IX into Peripheral Vein, Percutaneous Approach

30240W1 Transfusion of Nonautologous Factor IX into Central Vein, Open Approach

30243W1 Transfusion of Nonautologous Factor IX into Central Vein, Percutaneous Approach

30250W1 Transfusion of Nonautologous Factor IX into Peripheral Artery, Open Approach

30253W1 Transfusion of Nonautologous Factor IX into Peripheral Artery, Percutaneous Approach

30260W1 Transfusion of Nonautologous Factor IX into Central Artery, Open Approach

30263W1 Transfusion of Nonautologous Factor IX into Central Artery, Percutaneous Approach

Option 2. Create a new substance, B, 4-Factor Prothrombin Complex Concentrate, under section 3 - Administration, body system 0 – Circulatory, operation 2 – Transfusion, for the Infusion of 4-Factor Prothrombin Complex Concentrate (4F-PCC).

3 Administration
0 Circulatory
2 Transfusion: Putting in blood or blood products

Body System/Region	Approach	Substance	Qualifier
3 Peripheral Vein 4 Central Vein	0 Open 3 Percutaneous	B 4-Factor Prothrombin Complex Concentrate	1 Nonautologous
5 Peripheral artery 6 Central artery	0 Open 3 Percutaneous	B 4-Factor Prothrombin Complex Concentrate	1 Nonautologous

CMS Recommendation: Option 2. As described above.

Interim Coding: In the interim, continue to assign one of the following ICD-10-PCS codes under section 3 - Administration, body system 0 – Circulatory, operation 2 – Transfusion, for the infusion of 4-Factor Prothrombin Complex Concentrate (4F-PCC).

30230W1 Transfusion of Nonautologous Factor IX into Peripheral Vein, Open Approach
30233W1 Transfusion of Nonautologous Factor IX into Peripheral Vein, Percutaneous Approach
30240W1 Transfusion of Nonautologous Factor IX into Central Vein, Open Approach
30243W1 Transfusion of Nonautologous Factor IX into Central Vein, Percutaneous Approach
30250W1 Transfusion of Nonautologous Factor IX into Peripheral Artery, Open Approach
30253W1 Transfusion of Nonautologous Factor IX into Peripheral Artery, Percutaneous Approach
30260W1 Transfusion of Nonautologous Factor IX into Central Artery, Open Approach
30263W1 Transfusion of Nonautologous Factor IX into Central Artery, Percutaneous Approach

Implantation of Transprostatic Struts

Issue: Currently there is not a unique ICD-9-CM or ICD-10-PCS procedure code to describe the implantation of transprostatic struts. This therapy was developed to treat symptoms due to urinary outflow obstruction, secondary to benign prostatic hyperplasia (BPH).

New Technology Application? No, not at this time. The requester is considering submitting an application for FY 2015.

FDA Approval: NeoTract, Inc. indicates that indication specific FDA de nova 510(k) clearance for the Urolift® Permanent Adjustable Transprostatic Strut Implants and Delivery Device is pending.

Background: Benign prostatic hyperplasia (BPH) is a naturally occurring and common overgrowth of tissue in the prostate that can cause obstruction of the urethra as it courses through the prostate. This obstruction can result in lower urinary tract symptoms (LUTS) such as frequent urination, difficulty urinating, and nocturia (frequent need to urinate during the night). LUTS can significantly impair work productivity, quality of life, and if left unaddressed, can lead to chronic retention and kidney failure.

Transurethral resection of the prostate (TURP) has long been considered the gold standard for BPH. However, TURP has a 20% perioperative morbidity rate and potential long-term complications that require additional treatments and procedures, including

- 2% - 8% bleeding requiring transfusion;
- 3% permanent incontinence, often requiring artificial sphincter implant;
- 7% strictures, typically requiring urethral dilatation procedures;
- 10% erectile dysfunction, typically requiring medication or penile implant.[1]

In addition to the standard TURP, tissue can be removed via various laser technologies. While these procedures have been shown to reduce bleeding, other complication rates remain similar to TURP.

Technology and Procedure: The adjustable transprostatic UroLift® struts are designed as permanent implants intended to reduce symptoms due to urinary outflow obstruction, secondary to BPH. An endoscopically guided delivery device is placed in the prostatic urethra and the surgeon compresses the encroaching prostate lobe, thereby opening the prostatic urethra. The transprostatic strut is then permanently implanted to hold the urethra in its new, less obstructed shape. The implanted strut resists tension loading, thereby holding the urethra open. According to the manufacturer, an important feature of the transprostatic strut is that it is adjustable in situ. Because prostate wall thickness varies from patient to patient and even at different locations in a single prostate, each implanted strut is sized to a unique shape to address the particular location of implantation. Over time the prostate tissue remodels to a durable less obstructed

[1] See Roehrborn, et. al. AUA Guideline on the Management of BPH: Diagnosis and Treatment Recommendations. American Urological Association Education and Research, Inc. 2003.

configuration. Opening the urethra and reducing prostatic obstruction has been shown to mitigate LUTS due to BPH.

The following steps are involved in the implant procedure:

- Anesthesia – transprostatic strut implantation may be performed under general, spinal or local anesthesia with oral or intravenous sedation.
- Cystoscopy is conducted to assess urethral condition, rule out obstructive median lobe, assess the condition of the bladder, and plan the placement for the various implantable struts as needed (typically 4 transprostatic struts are implanted).
- The cystoscopy sheath is then advanced into the bladder and the telescope bridge is replaced with the UroLift® strut delivery device.
- Under endoscopic guidance the physician determines precise location to compress the obstructing prostatic lobe and implant each UroLift® transprostatic strut. The exact number of implants is determined by the physician and can vary depending on size and shape of the prostatic obstruction.
- Conducting a final cystoscopy, the physician assesses the result with the goal of creating a continuously open channel through the anterior aspect of the prostatic urethra.

Patient Population: The adjustable transprostatic UroLift® struts are designed as permanent implants intended to reduce symptoms due to urinary outflow obstruction, secondary to BPH for men over the age of 50. The device is specifically indicated for prostates less than or equal to 80 cc and with no obstructive median lobe.

BPH is a significant health care burden, and is the fourth most common diagnosis for men over age 50. BPH is a progressive disease and drugs are palliative in nature but do not effectively treat the underlying condition. The gold standard surgery for patients diagnosed with BPH, TURP, is typically performed as an inpatient procedure with a multi-night hospital stay and the related complications can be considerable. BPH impacts 70 percent of men in their 60's and 90 percent of men in their 80's. In the US, 15 million men suffer from symptoms severe enough to discuss treatment.[2] The majority of men are adequately treated with BPH medication and approximately 150,000 are surgically treated each year. The requester anticipates that a subset of this population will require transprostatic strut implantation once introduced to the US market due to its reduced morbidity, rapid onset of symptom relief.

Outcomes: Clinical studies conducted outside the US[3,4] have demonstrated that the implantation of transprostatic struts is a straightforward procedure that produces immediate, visible results and significantly lower morbidity.

- Clinically Effective – Study results demonstrate that mechanically opening the prostatic urethra by retracting encroaching prostate lobes relieves obstruction and successfully

[2] US Census Bureau International Database.
[3] McNicholas, TA, Woo HH, et al Minimally Invasive Prostatic Urethral Lift: Surgical Technique and Multinational Experience", Eur Urol, Jan 2013, pp 1-8
[4] Chin PT, Bolton DM, et al: Prostatic Urethral Lift: Two Year Results After Treatment for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. Urology, 2012. Pgs 5-11

treats lower urinary tract symptoms stemming from BPH. Symptom mitigation far exceeds that of medical therapy and durability has been shown to three years.
- Safe – Results indicate that implantation is safe and effective at treating lower urinary tract symptoms due to BPH with few complications as compared to other treatments. There has been no incidence of transfusion, permanent incontinence, or sexual dysfunction, all common with the gold standard BPH surgery.

ICD-9-CM Procedure Coding options:
Coding option 1. Do not create a new code. Due to the restrictions of the Partial Code Freeze, CMS is unable to propose a new ICD-9-CM procedure code at this time to uniquely describe the implantation of transprostatic struts as the requester did not submit an application for New Technology. Should the requester decide to submit an application for FY 2015 we can reconsider a new code request.

Interim Coding: CMS recommends procedure code 58.6, Dilation of urethra, to identify the implantation of transprostatic struts used to open the prostatic urethra.

ICD-10-PCS Coding Options:
Option 1. Code the implantation of transprostatic struts to open the prostatic urethra to the root operation Supplement.

0 Medical and Surgical
T Urinary System
U Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part

Body Part	Approach	Device	Qualifier
D Urethra	0 Open 4 Percutaneous Endoscopic 7 Via Natural or Artificial Opening 8 Via Natural or Artificial Opening Endoscopic X External	7 Autologous Tissue Substitute J Synthetic Substitute K Nonautologous Tissue Substitute	Z No Qualifier

0TUD8JZ Supplement Urethra with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic
0TUDXJZ Supplement Urethra with Synthetic Substitute, External Approach

Rationale: Currently, in ICD-10-PCS, the female equivalent "lift" procedures for incontinence are coded in this manner. In this procedure for males, the device is being used to keep the urethra open and functioning correctly, instead of having the prostate push on it.

The body part key currently instructs to use the body part "Urethra" for prostatic urethra.

Prostatic urethra	**Use**: Urethra

Option 2. Code the procedure with root operation Dilation.

0 Medical and Surgical
T Urinary System
7 Dilation: Expanding an orifice or the lumen of a tubular body

Body Part	Approach	Device	Qualifier
3 Kidney Pelvis, Right 4 Kidney Pelvis, Left 6 Ureter, Right 7 Ureter, Left 8 Ureters, Bilateral B Bladder C Bladder Neck D Urethra	0 Open 3 Percutaneous 4 Percutaneous Endoscopic 7 Via Natural or Artificial Opening 8 Via Natural or Artificial Opening Endoscopic	D Intraluminal Device Z No Device	Z No Qualifier

Option 3. Code the procedure with root operation Insertion, body part Prostate and consider new device value?

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

Body Part	Approach	Device	Qualifier
0 Prostate	0 Open 3 Percutaneous 4 Percutaneous Endoscopic 7 Via Natural or Artificial Opening 8 Via Natural or Artificial Opening Endoscopic	1 Radioactive Element M ?	Z No Qualifier

Option 4. Add the body part value Prostate to root operation Supplement in the ICD-10-PCS tables, with applicable approach values (3 codes)

0 Medical and Surgical
V Male Reproductive System
U Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part

Body Part	Approach	Device	Qualifier
0 Prostate	0 Open 7 Via Natural or Artificial Opening 8 Via Natural or Artificial Opening Endoscopic	J Synthetic Substitute	Z No Qualifier

Implantation of Epiretinal Prosthesis

Issue: Currently, there are not ICD-9-CM procedure codes which clearly capture the procedures involving the implant of an epiretinal visual prosthesis to restore vision.

New Technology Application? Yes.
This procedure is currently being considered for a New Technology Add-on Payment for FY 2014.

Food and Drug Administration (FDA) approval?
The Argus ® II Retinal Prosthesis System received an HDE approval by the FDA in February 2013.

Background: The Argus ® II System is an active implantable medical device that partially restores vision for patients that are profoundly blind due to retinitis pigmentosa. The system employs electrical signals to bypass dead photo-receptor cells and stimulate the overlying neurons according to a real-time video signal that is wirelessly transmitted from an externally worn video camera.

The Argus ® II System consists of an epiretinal implant that is fully implanted in and around the eye, a video camera mounted on a pair of glasses, and a control unit that is worn or carried by the patient. The system provides electrical stimulation of the retina to induce visual perception in blind patients (analogous to a cochlear implant for the restoration of hearing). It is indicated for use in patients with severe to profound retinitis pigmentosa with bare or no light perception in both eyes.

The Argus ® II System provides visual information that can range, depending on the patient, from light detection to form detection. Patients are able to use this visual information to perform functional tasks (e.g., locating windows and doors, following lines in a cross walk, sort laundry, read letters), allowing them to feel more connected with others (e.g., seeing when a person approaches them or when someone walks away). For people with bare or no light perception, even limited restoration of vision can make a significant difference in their lives.

In the Argus ® II System, the video camera on the patient-worn glasses captures a video image. The camera signal is sent to the Video Processing Unit (VPU) which processes the camera image and transforms it into electrical signals. The electrical signals are then sent to a transmitter coil mounted on the glasses. The transmitter coil sends both data and power via radio- frequency (RF) telemetry to the implanted epiretinal visual prosthesis. The implant receives the radio-frequency commands and delivers stimulation to the retina via an array of electrodes that is secured to the retina with a retinal tack.

In patients with retinitis pigmentosa, the photoreceptor cells in the retina, which normally transduce incoming light into an electro-chemical signal, have lost most of their function. The stimulation pulses delivered to the retina via the electrode array of the Argus ® II Retinal Prosthesis are intended to mimic the function of these degenerated photoreceptor cells. These pulses induce cellular responses in the remaining, viable retinal nerve cells that travel through the optic nerve to the visual cortex, where they are perceived as phosphenes (spots of light). Patients learn to interpret the visual patterns produced by these phosphenes to use them for functional actions.

The epiretinal visual prosthesis implant is responsible for receiving information from the external components of the system and electrically stimulating the retina to induce visual perception.

The retinal implant consists of: (a) a receiving coil for receiving information and power from the external components of the Argus ® II System; (b) electronics to drive stimulation of the electrodes; and (c) an electrode array. The receiving coil and electronics are secured to the outside of the eye using a standard scleral band and sutures, while the electrode array is secured to the surface of the retina inside the eye by a retinal tack. A cable, which passes through the eye wall, connects the electronics to the electrode array. A pericardial graft is placed over the extra-ocular portion on the outside of the eye.

The implant receives power and data commands wirelessly from an external unit. The external components include the Argus ® II Glasses and the Argus II Video Processing Unit (VPU). A small, light-weight video camera and transmitting coil are mounted on the glasses. The telemetry coils and radio-frequency system are mounted on the temple arm of the glasses for transmitting data from the VPU to the implant.

The glasses are connected to the VPU by a cable. The VPU is worn by the patient, typically, on a belt or a strap. The VPU is used to process the images from the video camera and convert the images into electrical stimulation commands which are transmitted wirelessly to the implant. The surgical implant procedure is performed under general anesthesia. The implant procedure takes approximately four hours and consists primarily of lens removal (if present), scleral buckling, three port pars plana vitrectomy, epiretinal membrane peeling, and pericardial grafting.

As the results of the studies indicate, the Argus II System provides subjects with clinical benefit as measured by objectively-scored functional vision tests. Subjects performed better with the Argus ® II System ON vs. OFF on orientation and mobility tests (finding a door and following a line on the ground or street) and on functional vision tasks (sorting white, black and grey socks; following an outdoor sidewalk; and determining the direction of a person walking by).

ICD-9-CM Procedure Coding Options:

Option 1: Do not create any new procedure codes for the implant of epiretinal visual prosthesis.

There is currently no ICD-9-CM code for the implant of epiretinal visual prosthesis. Codes 14.73(Mechanical vitrectomy by anterior approach) and 14.74 (Other mechanical vitrectomy) are reported for the vitrectomy. The vitrectomy codes can continue to be used as a proxy for the implant of the epiretinal visual prosthesis. Any other associated procedures could also be reported.

Option 2: Create new ICD-9-CM procedure codes for Implantation of epiretinal visual prosthesis.

Create new subcategory 14.8 Implantation of epiretinal visual prosthesis

New code 14.81 Implantation of epiretinal visual prosthesis
Includes lens removal if present, scleral buckling, vitrectomy, epiretinal membrane peeling and pericardial grafting

New code 14.82 Removal of epiretinal visual prosthesis
Includes 360-degree limbal peritomy and vitrectomy if performed, and device extraction

New code 14.83 Revision of epiretinal visual prosthesis
Includes tack replacement, device relocation, and/or replacement of pericardial grafting, if needed

CMS Recommendation: Option 2. Create new codes to capture the implantation of an epiretinal visual prosthesis.

Interim Coding: In the interim, continue reporting codes 14.73 (Mechanical vitrectomy by anterior approach) and 14.74 (Other mechanical vitrectomy) for the vitrectomy as well as any other associated procedures.

Proposed ICD-10-PCS Code:
New ICD-10-PCS device value Epiretinal Visual Prosthesis in table 08H Insertion of Eye for the retina body part values.

Section **0** **Medical and Surgical**
Body System **8** **Eye**
Operation **H** **Insertion:** Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	Approach	Device	Qualifier
0 Eye, Right 1 Eye, Left	3 Percutaneous x External	1 Radioactive Element 3 Infusion Device	Z No Qualifier
E Retina, Right F Retina, Left	0 Open 3 Percutaneous	5 Epiretinal Visual Prosthesis	Z No Qualifier