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 Volume 3, Procedures
March 11- March 12, 2009

Pat Brooks – Introductions and Committee overview
Co-Chairperson
March 11, 2009

9:00 AM ICD-9-CM Volume 3, Procedure presentations and public comments

Topics:

1.	Intravenous Infusion of Clofarabine Pages 6-7	Amy L. Gruber Yvonne Barnes, RN, MSN, CPNP Genzyme
2.	Virtual Histology Intravascular Ultrasound (VH-IVUS) Pages 8-9	Ann B. Fagan Gail Daubert, RN, JD Reed Smith LLP
3.	Intravascular Optical Coherence Tomography (OCT) Pages 10-13	Mady Hue Gail Daubert, RN, JD Reed Smith LLP
4.	Addenda Pages 14-15	Mady Hue

5. ICD-10 Implementation	Pat Brooks
6. ICD-10 General Equivalence Mappings	Rhonda Butler, 3M
7. MS-DRG Conversion to ICD-10 update	Rhonda Butler, 3M Janice Bonazelli, 3M
9. ICD-10-PCS Updates	Pat Brooks, CMS Rhonda Butler, 3M
10. ICD-10 comments and questions from audience	Pat Brooks, CMS Rhonda Butler, 3M

Registering for the meeting:

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.
ICD-9-CM Volume 3, Procedures Coding Issues:
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Summary of Meeting:

A complete report of the procedure part of the meeting, including handouts, will be available on CMS's homepage within one month of the meeting. The summary can be accessed at:

http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp

A summary of the diagnosis part of the meeting held on March 12 can be found at:
http://www.cdc.gov/nchs/icd9.htm

ICD-9-CM TIMELINE

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

March 11 – March 12 2009	ICD-9-CM Coordination and Maintenance Committee meeting
April 1, 2009	No new codes will be implemented on April 1, 2009.
April 3, 2009	Deadline for receipt of public comments on proposed code revisions discussed at the March 11-12, 2009 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2009.
April 2009	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.hhs.gov/AcuteInpatientPPS/IPPS/list.asp
April 2009	Summary report of the Procedure part of the March 11, 2009 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes Summary report of the Diagnosis part of the March 12, 2009 ICD-9-CM Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm
June 2009	Final addendum posted on web pages as follows: Diagnosis addendum at - http://www.cdc.gov/nchs/icd9.htm Procedure addendum at – http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes
July 17, 2009	Those members of the public requesting that topics be discussed at the September 16 – 17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting must

	have their requests to CMS for procedures and NCHS for diagnoses.
August 1, 2009	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, 2009. This rule can be accessed at: http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp
August 2009	Tentative agenda for the Procedure part of the September 16 – 17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage at - http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes Tentative agenda for the Diagnosis part of the September 16 – 17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on NCHS homepage at - http://www.cdc.gov/nchs/icd9.htm Federal Register notice for the September 16 –17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.
August 14, 2009	**On-line registration opens for the September 16-17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting at: http://www.cms.hhs.gov/events**
September 10, 2009	Because of increased security requirements, those wishing to attend the September 16 - 17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting must register for the meeting online at: http://www.cms.hhs.gov/apps/events **Attendees must register online by September 10, 2009; failure to do so may result in lack of access to the meeting.**
September 16 – 17, 2009	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 10, 2009.** You must

	bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.
October 2009	Summary report of the Procedure part of the September 16 – 17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes Summary report of the Diagnosis part of the September 16–17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm
October 1, 2009	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/icd9.htm Procedure addendum at - http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes
October 9, 2009	**Deadline for receipt of public comments on proposed code revisions discussed at the September 16-17, 2009 ICD-9-CM Coordination and Maintenance Committee meetings for implementation of April 1, 2010.**
November 2009	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, 2010 will be posted on the following websites: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes http://www.cdc.gov/nchs/icd9.htm
December 5, 2009	Deadline for receipt of public comments on proposed code revisions discussed at the September 16-17, 2009 ICD-9-CM Coordination and Maintenance Committee meetings for implementation of October 1, 2010.

Intravenous Infusion of Clofarabine

Issue:
There is no ICD-9-CM procedure code that specifically identifies the intravenous infusion of clofarabine.

New Technology Application?
Yes.

Food and Drug Administration (FDA) Approval:
CLOLAR® (clofarabine) is a chemotherapeutic agent with FDA approval granted on December 28, 2004 "for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. This use is based on the induction of complete responses. Randomized trials demonstrating increased survival or other clinical benefit have not been conducted."

A supplement to the pediatric application (sNDA) is pending with the FDA, requesting approval of CLOLAR® for the treatment of previously untreated older adults with acute myeloid leukemia (AML) with at least one unfavorable baseline prognostic factor. Unfavorable prognostic factors include:

- Age greater than or equal to 70 years
- Antecedent hematologic disorder (AHD)
- Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 2:
    - Ambulatory and capable of all self care but unable to carry out any work activities. Up and about more than 50% of waking hours
- Intermediate/unfavorable risk karyotype

According to the requestor, it is anticipated that CLOLAR® will receive FDA approval for this new indication in 2009.

Background: CLOLAR® represents an alternative chemotherapy option for elderly patients with AML. These patients have a universally poor prognosis and often cannot tolerate standard induction chemotherapy with its attendant toxicity, especially if they have one or more poor prognostic indicators such as poor performance status, advanced age or unfavorable cytogenetics. CLOLAR® has been shown to offer improved complete and partial remission rates in elderly patients with AML with less toxicity.

CLOLAR® is supplied in single use vials, containing 20 mg of product in 20 mL of solution. For patients with AML, CLOLAR® likely will be administered by intravenous (IV) infusion for 5 consecutive days (1 cycle) at the following dosage levels:

- Previously Untreated (First Line) – 30mg/m2
- Consolidation – 20mg/m2

Current Coding: Code 99.25, Injection or infusion of cancer chemotherapeutic substance.

Coding Options:
Option 1. Do not create a new code. Continue to assign code 99.25, Injection or infusion of cancer chemotherapeutic substance.

Option 2. Create a new subcategory and unique code that identifies the IV infusion of clofarabine.

New subcategory	17.7 Other pharmaceuticals
New code	17.70 Intravenous infusion of clofarabine Excludes: injection or infusion of cancer chemotherapeutic substance (99.25)

CMS's Recommendation:

Option 2. Create a new subcategory and unique code that identifies the IV infusion of clofarabine.

New subcategory	17.7 Other pharmaceuticals
New code	17.70 Intravenous infusion of clofarabine Excludes: injection or infusion of cancer chemotherapeutic substance (99.25)

Interim Coding:
Continue to assign code 99.25, Injection or infusion of cancer chemotherapeutic substance, for the IV infusion of clofarabine.

Virtual Histology Intravascular Ultrasound – VH-IVUS

Issue:
There are a variety of older catheter-based invasive methods of intravascular imaging; however there is no specific ICD-9-CM procedure code which accurately describes the visualization and evaluation of coronary vasculature in real-time colorized tissue maps that illustrate plaque composition.

New Technology Application?
No.

Food & Drug Administration (FDA) Approval:
The FDA has cleared this technology for use, and it is currently being used in hospital catheterization labs.

Background:
VH-IVUS is the first and one of the newest technologies enabling real time (in the cardiac catheterization lab) compositional assessment of atherosclerotic plaques in coronary arteries. Previously, assessment has been limited to 2-D views (coronary angiography) of symptom-causing narrowing of the coronary arteries by way of contrast-agent enhanced X-ray imaging. VH-IVUS uses advanced spectral analysis techniques to allow exact interpretations of ultrasound images and to provide detailed information on the composition of each patient's atherosclerotic plaques.

Acute coronary syndromes (ACS) and sudden cardiac death are a main cause of death in the US. Histopathology studies have revealed that the majority of thrombi result from plaque rupture. Additionally, the importance of non-stenotic coronary lesions has been highlighted as more is learned about the role of inflammation in the progression of atherosclerosis and the rupture of coronary plaque. *In vivo* lesion analysis of plaque classification using newer technology is important for better understanding of this condition and improving the treatment and management of these patients.

VH-IVUS uses advanced analytical techniques to overcome the main limitations of gray-scale IVUS by providing a more detailed analysis of plaque morphology. This includes a reconstructed color-coded tissue map of plaque composition superimposed on cross-sectional images of the coronary artery. Also real-time VH-IVUS provides images in tomographic and longitudinal views as well as a quantitative measure of the cross-section of the vessel and a quantitative measure of lesion length and tissue characterization. Additionally, VH-IVUS has the potential of providing patient-specific plaque analysis and monitoring the treatment response to drug therapy for ACS.

Current Coding:
The most appropriate existing code for this procedure is:

00.24 Intravascular imaging of coronary vessels
Intravascular ultrasound [IVUS], coronary vessels
Excludes:
diagnostic ultrasound (non-invasive) of heart (88.72)
intracardiac echocardiography [ICE] (ultrasound of heart chamber(s)) (37.28)

Coding Options:
Option 1:
Do not create a new code for this procedure. Continue to use code 00.24, Intravascular imaging of coronary vessels. Add an inclusion term, as follows:

00.24 Intravascular imaging of coronary vessels
Add inclusion term Virtual histology intravascular ultrasound [VH-IVUS]

Option 2:
Create a new code describing this procedure, as follows:

New code 00.26 Virtual histology intravascular ultrasound [VH-IVUS]
Excludes:
coronary angiography for visualizing atherosclerotic disease (88.57)
IVUS of coronary vessels (00.24)

CMS Recommendation:
CMS believes that this technology is adequately captured under the existing IVUS code, therefore is recommending that no new code be created. Additionally, we are concerned that the VH-IVUS will not be clearly distinguished from the existing IVUS procedure in the medical record, making it difficult for the coders to capture.

Interim Coding:
Use code 00.24, Intravascular imaging of coronary vessels to describe Virtual Histology Intravascular Ultrasound (VH-IVUS).

Intravascular Optical Coherence Tomography

Issue: While coronary angiography is an established imaging technique for visualizing atherosclerotic disease, it is limited by its two-dimensional imaging aspect and the fact that it cannot identify certain details of a particular lesion, including the presence and composition of coronary atherosclerotic plaques. Should a new code(s) be created to describe the use of intravascular optical coherence tomography (OCT)?

New technology application? No.

FDA Approval: Intravascular OCT imaging technology is expecting FDA approval in mid-2009.

Background: Intravascular ultrasound or IVUS is currently the most commonly employed adjunctive method to better define coronary vascular lesions. However, IVUS also has some limitations, specifically due to its low resolution. Consequently, researchers have pushed forward with the development of new technologies for improved coronary plaque characterization.

Intravascular optical coherence tomography (OCT) is used for the visualization and evaluation of coronary and peripheral vasculature to provide images of the vessel lumen and wall structures, and to determine proper lumen sizing, facilitate full stent apposition, and optimal stent expansion. In addition, intravascular OCT can provide super high resolution to identify:

- Intraluminal thrombus
- Thin cap fibroatheromas
- Additional detail and specificity to assess vulnerable plaques

Technology: Optical coherence tomography uses near-infrared electromagnetic radiation light for the cross-sectional visualization of the vessel wall at the microscopic level. It enables excellent resolution of coronary architecture and precise characterization of plaque architecture. Quantification of macrophages within the plaque is also possible. These capabilities allow precise identification of the most clinically significant type of vulnerable plaque, the thin-cap fibroatheroma.

The pulse of low-coherence light from the laser source is split 50/50 to send half the beam to the tissue sample and the other half to the reference moving mirror. Light reflected from the tissue is combined with light returning from the mirror, which moves a microscopic distance. Constructive interference results when the path length of light to the mirror and back equals that of the light reflected from the tissue. The mirror position, therefore, gives a measure of the depth within the tissue sample where reflection took place.

Procedure: OCT is a catheter based system that can be used to assess vascular morphology, vessel lumen and plaque components in vascular lesions. The acquisition of images using OCT requires simple flush clearance of the vessel of interest at the moment the images are acquired. This is routinely done through the use of contrast injections, saline injections or some combination of saline and contrast (i.e.; 50% contrast and 50% saline). The injection process is managed in the same way as any other angiographic injection. The user can use a hand held injection system or a power injector, hooked up to a guide catheter, or other localized vascular sheath. When the user has the imaging catheter placed in the intravascular region of interest, such as a coronary artery, the injection of the flush solution is initiated and the acquisition of the images begins. The inner member of the catheter is pulled back or pushed forward across the region of interest while the recording process takes place. The inner member of the catheter is a rotating optical fiber with an imaging lens attached to it (similar to the principle of a rotational IVUS catheter, only using near infrared light as opposed to ultrasound). Once the images are acquired, the physician has the ability to review, analyze, make measurements and clinical decisions based on the images.

Patient Population: OCT technology is intended for use in the diagnosis and treatment of patients with cardiovascular disease. More specifically, OCT allows for the visualization and evaluation of coronary and peripheral vascular morphology by providing a cross-sectional image of the coronary and peripheral vessels. The OCT imaging catheter is designed for use as an adjunct to conventional angiographic procedures by providing an image of the vessel lumen and wall structures.

Benefits: Results from clinical studies indicate that optical coherence tomography is a better imaging technique for improved characterization of the coronary atherosclerotic plaque. The key advantage of OCT over ultrasound is in its ability to visualize tissue down to the 10 to 15 micron range, as compared to ultrasound which has a resolution in the 100 to 150 micron range. This order of magnitude change in the resolution capability allows physicians to better assess the vessel and determine a course of action (treatment plan) in ways that have never been possible before.

A major benefit of this high resolution in the clinical setting would include the ability to see and measure the thickness of a fibrous cap over a vessel lesion. Clinical experts have long known that a Thin-Cap Fibroatheroma (TCFA) where the fibrous cap is less than 65 microns is a hallmark and potential site for Acute Myocardial Infarction (AMI). Physicians have long sought to better understand and develop strategies to manage and or prevent AMI's resulting from these TCFAs, but ultrasound has not been able to determine the cap thickness accurately enough to allow such diagnosis. The OCT resolution would allow the physician the opportunity to assess a lesions cap thickness well below the 65 micron range.

Another advantage of OCT high resolution is the ability to assess the thickness of tissue coverage over a previously implanted stent. Late stent thrombosis and re-stenosis is often related to tissue growth over the stent. Drug-eluting stents (DES) have sought to inhibit this process but the data is still being analyzed. For this reason, physicians are

currently using OCT to assess the concentration, thickness and uniformity of endothelial growth over stented vessels.

Importantly, the use of OCT may enable physicians to assess the stent and determine whether it is appropriately covered and then make some changes in the procedural and or pharmacological treatments of the patient if needed.

- The ability to determine that a previously deployed stent is appropriately covered could allow the physician to decrease or eliminate certain high-risk medications from the patient's treatment. (Studies to validate this are on-going).
- Physicians may also assess a vessel for the presence of intraluminal thrombus and could consider removing the stent to decrease potential for further ischemia and distal embolization. This could prevent the thrombus from moving downstream and occluding distal branches of the vasculature causing further damage due to a lack of adequate blood supply.

OCT will also allow the user to:

- Visualize dissections in both stented and non stented vessels that would have been unobservable by ultrasound, yet often seen on angiograms as curious flow disturbances.
- Visualize the stent, its apposition, intraluminal vessel sizing, dissections, thrombus, endothelialization, thin caps and other previously un-identifiable vessel changes. Visualization of abnormalities will allow the user faster, easier assessments with never before seen pin-point accuracy leading to shortened procedural times, increased confidence in the strategical decisions for care and thus cost savings related to short and long term patient events and the efficacy of care.

Coding options:

Option 1: Do not create a new code. Continue to use existing intravascular diagnostic procedure codes to identify the use of intravascular optical coherence tomography (OCT) as listed below. Possibly add inclusion terms for OCT if warranted, where applicable.

00.2 Intravascular imaging of blood vessels
- 00.21 Intravascular imaging of extracranial cerebral vessels
- 00.22 Intravascular imaging of intrathoracic vessels
- 00.23 Intravascular imaging of peripheral vessels
- 00.24 Intravascular imaging of coronary vessels

38.2 Diagnostic procedures on blood vessels
- 38.23 Intravascular spectroscopy

Option 2: Create two new codes to identify the use of intravascular optical coherence tomography (OCT) of coronary and non-coronary vessels. Exclusion terms would be added to the existing IVUS codes listed above in option 1.

New code 38.24 Intravascular imaging of coronary vessel(s) by optical coherence tomography [OCT]

New code 38.25 Intravascular imaging of non-coronary vessel(s) by optical coherence tomography [OCT]
Excludes: intravascular imaging of coronary vessel(s) by OCT (38.24)

Option 3: Create a new subcategory and six new codes to identify the use of intravascular optical coherence tomography (OCT) of vessels. Exclusion terms would be added to the existing IVUS codes in option 1.

New subcategory 17.8 Intravascular imaging of vessel(s) by optical coherence tomography [OCT]

New code 17.81 Intravascular imaging of extracranial cerebral vessel(s) by optical coherence tomography [OCT]

New code 17.82 Intravascular imaging of coronary vessel(s) by optical coherence tomography [OCT]

New code 17.83 Intravascular imaging of intrathoracic vessel(s) by optical coherence tomography [OCT]

New code 17.84 Intravascular imaging of peripheral vessel(s) by optical coherence tomography [OCT]

New code 17.88 Intravascular imaging of other specified vessel(s) by optical coherence tomography [OCT]

New code 17.89 Intravascular imaging of unspecified vessel(s) by optical coherence tomography [OCT]
Excludes: intravascular imaging of cerebral vessel(s) by OCT (17.81)
intravascular imaging of coronary vessel(s) by OCT (17.82)
intravascular imaging of intrathoracic vessel(s) by OCT (17.83)
intravascular imaging of peripheral vessel(s) by OCT (17.84)
intravascular imaging of other specified vessel(s) by OCT (17.88)

CMS Recommendation: CMS is interested in hearing comments from the audience and has concern for how this differs from code 38.23, Intravascular spectroscopy, however would lean towards recommending option 2 over option 3, as stated above.

Addenda

Tabular

Revise code title	00.57 Implantation or replacement of subcutaneous device for intracardiac or great vessel hemodynamic monitoring
Revise subcategory title	27.5 Plastic repair of lip and mouth
Add code also note	34.1 Incision of mediastinum Code also any biopsy, if performed
Revise code also note	34.22 Mediastinoscopy Code also any ~~lymph node~~ biopsy, if performed ~~(40.11)~~
Revise code title	39.90 Insertion of non-drug-eluting peripheral (non-coronary) vessel stent(s)

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Add subterm	Adjustment orthopedic device (noninvasive)
Add subterm	external fixator – *omit code*
Add term	Chamberlain procedure - *see* Mediastinotomy
Add subterm	Conversion atrial rhythm (to sinus rhythm) 99.61
Add term	Impella® percutaneous external heart assist device 37.68
Add subterm	Implant, implantation heart assist system Impella® percutaneous external circulatory assist device - *see* Insertion, circulatory support device
Add subterm	Insertion circulatory support device external heart assist device Impella® 37.68

	heart
Add subterm	Impella® 37.68
	Measurement
Revise subterm	intrauterine pressure ~~89.62~~ 75.35
Revise term	Mediastinoscopy ~~(transpleural)~~ 34.22
Revise subterm	Mediastinotomy (Chamberlain procedure) 34.1
	Reconstruction
	breast, total, NOS 85.70
Add subterm	other 85.79
Add term	Retightening (noninvasive)
Add subterm	external fixator device – *omit code*