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



## SUMMARY REPORT

## **ICD-9-CM COORDINATION AND MAINTENANCE COMMITTEE**

## April 1-2, 2004

## **PROCEDURE DISCUSSIONS**

#### **Introductions and Overview**

Pat Brooks welcomed the participants to the ICD-9-CM Coordination and Maintenance (C&M) Committee meeting. There were approximately 160 participants who attended the meeting. The procedure portion of the meeting was held on April 1, 2004 and was conducted by staff from the Centers for Medicare & Medicaid Services (CMS). One topic, Vasopressors, was discussed on April 2, 2004 to accommodate a physician presenter. The diagnosis portion of the meeting was held on April 2, 2004 and was conducted by staff from the National Center for Health Statistics, CDC. All participants introduced themselves. There were a wide range of participants representing hospitals, coding groups, manufacturers, physician groups, software vendors, and publishers, among others.

An overview of the C&M Committee was provided. It was explained that the Committee meetings serve as a public forum to discuss proposed revisions to the ICD-9-CM. The public is given a chance to offer comments and ask questions about the proposed revisions. **No final decisions on code revisions take place at the meeting.** A summary report of the procedure part of the meeting will be posted on CMS' website at: <u>www.cms.hhs.gov/paymentsystems/icd9</u>. A summary report of the diagnosis part of the meeting will be placed on NCHS' web site at <u>www.cdc.gov/nchs/icd9.htm</u>. The public is offered an opportunity to make additional written comments by mail or e-mail until April 9, 2004. This abbreviated deadline is necessary in order to include some of the final decisions in the October 1, 2004 update.

Comments on the **procedure** part of the meeting should be sent to: Pat Brooks Centers for Medicare & Medicaid Services (CMS) CMM, HAPG, Division of Acute Care Mail Stop C4-08-06 7500 Security Blvd. Baltimore, MD 21244-1850

## Patricia.brooks1@cms.hhs.gov

Comments on the **diagnosis** part of the meeting should be sent to: Donna Pickett NCHS 3311 Toledo Road Room 2402 Hyattsville, MD 20782 Dfp4@cdc.gov

The participants were informed that this was strictly a coding meeting. No discussion would be held concerning DRG assignments or reimbursement issues. Comments were to be confined to ICD-9-CM coding issues.

## Process for requesting code revisions

The process for requesting a coding change was explained. The request for a procedure code change should be sent to Pat Brooks at least two months prior to the C&M meeting. The request should include detailed background information describing the procedure, patients on whom the procedure is performed, any complications, and other relevant information. If this procedure is a significantly different means of performing a procedure than is already described in ICD-9-CM, this difference should be clearly described. The manner in which the procedure is currently coded should be described along with information from the requestor on why they believe the current code is not appropriate. Possible new or revised code titles should then be recommended.

CMS staff will use this information in preparing a background paper to be presented at the C&M meeting. The CMS background paper includes a CMS recommendation on any proposed coding revisions. The background paper is distributed for discussion at the C&M meeting and included in the summary report.

A presentation is made at the C&M meeting, which describes the clinical issues and the procedure. CMS staff coordinate a discussion of possible code revisions. The participants at the meeting are encouraged to ask questions concerning the clinical and coding issues. Comments concerning proposed code revisions are taken for consideration. Final decisions on code revisions are made through a clearance process within the Department of Health and Human Services. No final decisions are made at the meeting.

The next C&M meeting will be held on October 7-8, 2004. Requests for code revisions must be received by August 9, 2004 in order to be included on the agenda.

## C&M Visitor List Notice

Because of increased security requirements, those who wish to attend a specific ICD-9-CM Coordination and Maintenance Committee meeting in the CMS auditorium must submit their name and organization for addition to the meeting visitor list prior to <u>each</u> meeting. Those wishing to attend the October 7-8, 2004

meeting must submit their name and organization by October 4, 2004 for inclusion on the visitor list. This visitor list will be maintained at the front desk of the Centers for Medicare and Medicaid Services (CMS) and used by the guards to admit visitors to the meeting. Those who attended previous ICD-9-CM Coordination and Maintenance Committee meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you attend. You <u>must bring</u> an official form of picture identification (such as a drivers license) in order to be admitted to the building.

Send your name and the organization you represent to one of the following by October 4, 2004 in order to attend the October 7-8, 2004 meeting:

Pat Brooks	patricia.brooks1@cms.hhs.g	<u>ov</u> 410-786-5318
Ann Fagan	ann.fagan@cms.hhs.gov	410-786-5662
Amy Gruber	amy.gruber@cms.hhs.gov 4	410-786-1542

Due to fire code requirements, should the number of attendants meet the capacity of the room, the meeting will be closed to additional attendees.

ICD-9-CM Volume 3, Procedures Coding Issues:

Mailing Address:

Pat Brooks Centers for Medicare & Medicaid Services CMM, HAPG, Division of Acute Care Mail Stop C4-08-06 7500 Security Boulevard Baltimore, MD 21244-1850

Or: patricia.brooks1@cms.hhs.gov

FAX: (410) 786-0681

## New Issue – Medicare Prescription Drug Bill language concerns coding

The participants were informed of an item in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that will impact the updating of ICD-9-CM. Section 503 (a) of the bill had language concerning the timeliness of data collection. The following clause was included:

"Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date."

The Centers for Medicare & Medicaid Services (CMS) plans to discuss a proposal to accomplish this new congressional requirement in the Notice of Proposed Rulemaking

(NPRM) for the Hospital Inpatient Prospective Payment System. The NPRM will be published this spring. All interested parties should carefully review CMS's proposal and submit comments.

## **Topics:**

1. Left Atrial Appendage Filter System Ann Fagan There was support for the proposed new code.

## 2. Computer Assisted Surgery (CAS) Ann Fagan

One participant stated that Option 2 allows the body system to be identified within the CAS codes. However, this commenter felt the split by body system added very little value. This information is available through the diagnosis and procedure codes, which are also reported. The commenter went on to state, that Option 3 provides the modality, which might be of greater use. If the modality were not needed, then Option 4 would be preferred. The commenter then stated that she had an overall preference for Option 3.

There was a suggestion excludes notes be placed under the fluoroscopy codes if Option 3 were used.

3. Insertion of Palatal Implant Amy Gruber There was support for the recommended new code.

## 4. Internal Limb Lengthening Device Pat Brooks

There was support for the recommended new codes. One participant asked about the removal of this device. Dr. Standard stated that after a year or two, the device is removed. Dr. Standard stated that the current codes for removal of implanted devices from bone (78.60 - 78.69) would be appropriate to identify this procedure. The procedure is similar to the removal of other implanted devices in the bone.

# 5. Carotid Artery Stents

## Ann Fagan

There was support for new codes that would identify the implantation of stents into the carotid artery. One participant suggested that there may be some confusion when stents are implanted in the vertebral artery. It was suggested that the axis for these codes be the location of the stent placement. The recommendation was made that they be located in section 00.6 and called "Other cerebrovascular procedures". This area would include cerebral and pre-cerebral stents. It was also suggested that consideration be given to creating a new code for implantation of stents intracranially, since research is being performed on this surgery.

## 6. Vertebroplasty and Kyphoplasty Amy Gruber

There was support for new codes to capture these procedure. One participant expressed concern that the proposed new inclusion term referring to an "inflatable balloon" might lead coders to think the procedure only applied to one manufacturer's devices. This person suggested using the terminology "bone tamp." Another participant suggested that the inclusion terms be clarified to indicate that no separate code was needed to capture the insertion of a bone void filler (cement). Others suggested that the inclusion terms clarify the fact that kyphoplasty procedures do not reduce the fracture. They simply attempt to restore some of the height lost because of the fracture.

## 7. Addendum

## **Amy Gruber**

There was support for the addendum.

## 8. ICD-10-Procedure Coding System (PCS) – Update Pat Brooks Thelma Grant Rich Averill

Pat Brooks summarized the information provided on the ICD-10-PCS Update handout. Then Thelma Grant provided an overview of how the system is constructed. She used several topics from the morning presentations on new ICD-9-CM codes to illustrate how ICD-10-PCS would currently capture the new technology, and how it could be expanded to more clearly capture the technology.

Rich Averill then led a discussion on issues concerning refinements and updates to ICD-10-PCS. The audience discussed the need for the laboratory section of ICD-10-PCS. The laboratory section was based on an earlier version of the LOINC lab system. However, it has not been updated to capture changes to LOINC. The audience stated that there was no need for the laboratory section. This detail of laboratory studies is not currently captured in ICD-9-CM. Payers have not requested this level of detail for inpatient reporting. There was a consensus that this section of ICD-10-PCS should be deleted.

The audience then discussed the radiation oncology section of ICD-10-PCS. The audience felt there was great value in maintaining this level of detail in the system. The medical records support capturing this information since the records are usually quite clearly documented. Rich explained how characters 5-7 allow for "identification not required" should the hospital or payers not require the current level of detail within this part of the coding system. The audience supported maintaining this two-tier approach to the radiation oncology section.

Coders could code in careful detail, or simply assign the more generic codes for character 5-7 in this section.

The next area of discussion was on the Administration Section. Currently there is not a great deal of detail for the devices implanted or drugs used. However, ICD-9-CM has begun providing greater detail in recent years. Rich asked if the audience felt that attempts should be made to provide more extensive detail across the board in this section, or should CMS simple respond to specific requests to provide greater detail. The audience supported waiting for specific requests for specific details on devices and drugs prior to expanding this section.

The audience this discussed the benefits and challenges of preparing mapping between ICD-9-CM and ICD-10-PCS. There is a mapping from ICD-10-PCS to ICD-9-CM on the CMS web page. 3M is working on a mapping from ICD-9-CM to ICD-10-PCS. This will be a one code to many codes mapping. There are challenges in doing so, because of the possibility of so many codes. One audience member suggested that the more common example or more illustrative codes should be listed first so that the users could understand the mapping. This may prove to be quite challenging. As 3M works on the mappings, they will report back to the C&M committee.

The audience was informed that future meetings will cover implementation issues. The audience suggested a few topics for discussion including the following:

- Impact on hospitals of a new coding system
- Training needs
- The results of previous testing of ICD-10-PCS
- The number of codes that might be reported with ICD-10-PCS versus ICD-9-CM

# 9. Last Minute Coding Issues as a Result of New Technology Provision in the MMA

## a. Percutaneous External Heart Assist Device Ann Fagan

There was support for the creation of a new code to capture this procedure. One participant expressed concern with the code title, since the device itself is not implanted. A cannula is implanted and the device is used externally. Others pointed out that this type of terminology is used elsewhere in the coding system. The intent of the code appeared clear. Physician terminology refers to the implantation of the device. One participant recommended that explanatory notes be created to clarify the difference between 37.65 Implant of external, pulsatile heart assist system and this new external system. Words such as "open chest approach" were suggest as inclusion terms under 37.65. Additionally, code titles in this area were discussed at the December meeting, and the removal of "pulsatile" was discussed at that time for code 37.66.

## b. Ultrafiltration of Blood for Removal of Excess Fluid Ann Fagan

One participant preferred option 3, since it is a therapeutic procedure. Several physician participants stated that hemodialysis is a much more invasive procedure than Ultrafiltration of blood for removal of excess fluid.

## c. Insertion of Bone Void Filler Pat Brooks

There was support for a new code to capture the insertion of bone void fillers. Several participants voiced concerns about any new codes that would attempt to differentiate between the use of bone void filler that required extensive mixing versus those that required little or not mixing prior to insertion. One participant suggested that data on the amount of mixing may not be an important clinical data element. This person suggested that consideration be given to making two new codes that would capture whether or not the bone void filler was absorbable.

#### 10. Vasopressor Agents Joe Kelly, MD

There was support for the creation of a new code to capture vasopressor agents.

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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 April 1-2, 2004

Patricia E. Brooks Co-Chairperson April 1, 2004

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

## Topics:

1. Left Atrial Appendage Filter System

Ann B. Fagan Robert Van Tassel, MD Minneapolis Heart Institute Minneapolis, MN

2. Computer Assisted Surgery

Ann B. Fagan Richard Bucholz, MD St. Louis University Hospital St. Louis, MO

3.	Insertion of Palatal Implant	Amy L. Gruber
		Thomas Okner, MD Head and Neck Surgery, P.A. St. Paul, MN
4.	Internal Limb Lengthening Device	Patricia E. Brooks Shawn Standard, MD Sinai Hospital
5.	Carotid Artery Stents	
		Ann B. Fagan Mark Wholey, MD Shadyside Hospital Pittsburgh, PA
6.	Vertebroplasty and Kyphoplasty	Amy L. Gruber
7.	Addenda	Amy L. Gruber
8.	ICD-10-Procedure Coding System (PCS) –	Update
		Patricia E. Brooks
		Thelma Grant – 3M Rich Averill - 3M Robert Mullin, MD – 3M
9.	Last Minute Coding Issues as a Result of N in the MMA	ew Technology Provision
	a. Percutaneous External Heart Assist I	
		Ann B. Fagan Howard Cohen, MD UPMC – Pittsburgh, PA

b. Ultrafiltration of Blood for Removal of Excess Fluid Ann B. Fagan

Mitchell Saltzberg, MD Midwest Heart Specialists

c. Injection of Bone Void Filler

Patricia E. Brooks Langdon Hartsock, MD

 Vasopressor Agents – This topic only will be discussed on April 2 (Friday)

Joe Kelly, MD

Pat Brooks	New e-mail: patricia.brooks1@cms.hhs	s.gov
		410-786-5318
Ann Fagan	New e-mail: <u>ann.fagan@cms.hhs.gov</u>	410-786-5662
Amy Gruber	New e-mail: <u>amy.gruber@cms.hhs.gov</u>	410-786-1542

ICD-9-CM Volume 3, Procedures Coding Issues:

Mailing Address:

Centers for Medicare & Medicaid Services CMM, HAPG, Division of Acute Care Mail Stop C4-08-06 7500 Security Boulevard Baltimore, MD 21244-1850 FAX: (410) 786-0681

Summary of Meeting:

A complete report of the meeting, including handouts, will be available on CMS's homepage within one month of the meeting. Written summaries will no longer be routinely mailed. The summary can be accessed at: http://www.cms.hhs.gov/paymentsystems/icd9

NCHS will present diagnosis topics at the conclusion of the procedure topics. For information pertaining to the diagnosis agenda and summary reports, please contact Donna Pickett or Amy Blum at (301) 458-4200 or visit the NCHS Classification of Diseases website at: www.cdc.gov/nchs/icd9.htm.

# **ICD-9-CM TIMELINE**

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

August 1, 2003	Hospital Inpatient Prospective Payment System final rule . published in the <u>Federal Register</u> as mandated by Public Law 99- 509. This included all code titles included in the proposed notice as well as any other procedure code titles that were discussed at the April 3, 2003 meeting and resolved in time for implementation on October 1, 2003. This rule can be accessed at: http://www.cms.hhs.gov/regulations/
Nov. 5-6, 2003	National Committee on Vital and Health Statistics approved letter to the Secretary recommending that the department initiate an NPRM proposing the implementation of ICD-10-CM and ICD-10- PCS. Information on this meeting can be found at: http://www.ncvhs.hhs.gov/
Dec. 4-5, 2003	ICD-9-CM Coordination and Maintenance Committee Meeting. Code revisions discussed are for potential implementation on October 1, 2004. December 4 was devoted to discussions of procedure codes. December 5 was devoted to discussions of diagnosis codes.
December 2003	Summary report of the <u>Procedure part</u> of the December 4-5, 2003 ICD-9-CM Coordination and Maintenance Committee meeting posted on CMS homepage as follows: http://www.cms.hhs.gov/paymentsystems/icd9
	Summary report of the <u>Diagnosis part</u> of the December 4-5, 2003 ICD-9-CM Coordination and Maintenance Committee meeting report posted on NCHS homepage as follows: <u>http://www.cdc.gov/nchs/icd9.htm</u>
January 12, 2004	Deadline for receipt of public comments on proposed code revisions discussed at the April 3, 2003 and December 4-5, 2003 ICD-9-CM Coordination and Maintenance Committee meetings. These proposals are being considered for implementation on October 1, 2004.
February 2, 2004	Those members of the public requesting that topics be discussed at the April 1-2, 2004 ICD-9-CM Coordination and Maintenance Committee meeting should have their requests to CMS for procedures and NCHS for diagnoses.

March 29, 2004	Because of increased security requirements, those who wish to attend a specific ICD-9-CM Coordination and Maintenance Committee meeting must submit their name and organization for addition to the meeting visitor list. Those wishing to attend the April 1-2, 2004 meeting must submit their name and organization by March 29, 2004 for inclusion on the visitor list. This visitor list will be maintained at the front desk of the Centers for Medicare and Medicaid Services (CMS) and used by the guards to admit visitors to the meeting. Those who attended previous ICD-9-CM Coordination and Maintenance Committee meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you attend. You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.	
	Send your name and organization to one of the following by March 29, 2004 in order to attend the April 1-2, 2004 meeting:	
	Pat Brookspatricia.brooks1@cms.hhs.gov410-786-5318Ann Faganann.fagan@cms.hhs.gov410-786-5662Amy Gruberamy.gruber@cms.hhs.gov410-786-1542	
March 2004	Tentative (draft) agenda for the <u>Procedure part</u> of the April 1, 2004 ICD-9-CM Coordination and Maintenance Committee meeting posted on CMS homepage as follows: http://www.cms.hhs.gov/paymentsystems/icd9	
	Tentative agenda for the <u>Diagnosis part</u> of the April 2, 2004 ICD- 9-CM Coordination and Maintenance Committee meeting posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm	
	Federal Register notice of April 1-2, 2004 ICD-9-CM Coordination and Maintenance Committee Meeting published. This included the tentative agenda.	
Spring 2004	Notice of Proposed Rulemaking to be published in the <u>Federal</u> <u>Register</u> as mandated by Public Law 99-509. This will include the final decisions on ICD-9-CM diagnosis and procedure code titles discussed at the meetings held on April 3, 2003 and December 4-5, 2003. It may also include additional procedure codes discussed at the April 1-2, 2004 meeting and that will be included in the October 1, 2004 addendum. It will also include proposed revisions	

	to the DRG system on which the public may comment. The proposed rule can be accessed at: <u>http://www.cms.hhs.gov/regulations/</u>
	<b>Twice Yearly ICD-9-CM Coding Updates</b> The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 contains a provision for the Secretary to add new diagnosis and procedure codes in April 1 of each year (Pub. Law 108-173, Sec. 503). Prior to this legislation, new ICD-9-CM diagnosis and procedure codes were implemented once a year on October 1.
	The Centers for Medicare & Medicaid Services (CMS) plans to discuss a proposal to accomplish this new congressional requirement in the Notice of Proposed Rulemaking (NPRM) for the Hospital Inpatient Prospective Payment System. The NPRM is expected to be published this spring. All interested parties should carefully review CMS's proposal and submit comments.
April 1-2, 2004	ICD-9-CM Coordination and Maintenance Committee Meeting in CMS's auditorium. <u>Diagnosis code revisions</u> discussed are for potential implementation on <u>October 1, 2005</u> . <u>Procedure code revisions</u> may be for <u>October 1, 2004</u> if they can be resolved quickly and finalized by April 15, 2004. Those procedure code proposals that cannot be resolved quickly will be considered for implementation on October 1, 2005.
April 2004	Summary report of the <u>Procedure part</u> of the April 1-2, 2004 ICD- 9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows: http://www.cms.hhs.gov/paymentsystems/icd9
	Summary report of the <u>Diagnosis part</u> of the April 1-2, 2004 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 2004	Final addendum posted web pages as follows: Diagnosis addendum: http://www.cdc.gov/nchs/icd9.htm and procedure addendum at: <u>http://www.cms.hhs.gov/paymentsystems/icd9</u>
August 1, 2004	Hospital Inpatient Prospective Payment System final rule to be published in the <u>Federal Register</u> as mandated by Public Law 99- 509. This will include all code titles, which will be implemented on October 1, 2004. This rule can be accessed at: http://www.cms.hhs.gov/regulations/

August 9, 2004	Those members of the public requesting that topics be discussed at the October 7-8, 2004 ICD-9-CM Coordination and Maintenance Committee meeting should have their requests to CMS for procedures and NCHS for diagnoses.
September 2004	Tentative agenda for the <u>Procedure part</u> of the October 7-8, 2004 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows: http://www.cms.hhs.gov/paymentsystems/icd9
	Tentative agenda for the <u>Diagnosis part</u> of the October 7-8, 2004 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm
	Federal Register notice of October 7-8, 2004 ICD-9-CM Coordination and Maintenance Committee Meeting to be published. This will include the tentative (draft) agenda.
October 1, 2004	New and revised ICD-9-CM codes go into effect along with DRG changes. Final addendum posted web pages as follows: Diagnosis addendum http://www.cdc.gov/nchs/icd9.htm and procedure addendum at: http://www.cms.hhs.gov/paymentsystems/icd9
October 4, 2004	Because of increased security requirements, those who wish to attend a specific ICD-9-CM Coordination and Maintenance Committee meeting must submit their name and organization for addition to the meeting visitor list. Those wishing to attend the October 7-8, 2004 meeting must submit their name and organization by October 4, 2004 for inclusion on the visitor list. This visitor list will be maintained at the front desk of the Centers for Medicare and Medicaid Services (CMS) and used by the guards to admit visitors to the meeting. Those who attended previous ICD-9-CM Coordination and Maintenance Committee meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you attend. You must also present an official form of picture identification, such as a driver's license, in order to be admitted to the building.
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Ann Faganann.fagan@cms.hhs.gov410-786-5662Amy Gruberamy.gruber@cms.hhs.gov410-786-1542October 2004Summary report of the Procedure part of the October 7, 2004ICD-9-CM Coordination and Maintenance Committee meeting<br/>posted on CMS homepage as follows:<br/>http://www.cms.hhs.gov/paymentsystems/icd9Summary report of the Diagnosis part of the October 8, 2004 ICD-<br/>9-CM Coordination and Maintenance Committee meeting report<br/>will be posted on NCHS homepage as follows:

http://www.cdc.gov/nchs/icd9.htm

# Left Atrial Appendage Filter System

#### Issue:

Currently there are no ICD-9 codes that describe implanting a device in the left atrial appendage. This procedure is similar to the septal defect procedure as far as the access to the heart; however the devices are implanted in the left atrial appendage, not the septum.

#### Background

Atrial fibrillation (AF) is the primary cardiac abnormality associated with ischemic stroke. It is the most important risk factor for stroke in patients older than 80, especially women. Among patients with AF, there is a 5 percent annual risk of stroke, which is about five times greater than for people of the same age who are in sinus rhythm. The risk of stroke increases with age, previous TIA or stroke, hypertension, diabetes, impaired left ventricular function and a large left atrium.

Most ischemic strokes associated with AF are probably due to embolism or thrombi forming in the left atrial appendage (LAA). Evidence from transesophageal echocardiography (TEE) shows left atrial thrombi to be more frequent in AF patients with ischemic stroke as compared to AF patients without stroke.

AF is the most common sustained cardiac arrhythmia and affects about affects 5 percent of people older than 65 and 10 percent of people older than 75 years. AF is commonly associated with rheumatic heart disease, especially mitral stenosis. Non-valvular AF is caused by factors other than valvular heart disease such as cardiomyopathy, diabetes, and/or coronary artery disease.

There is a wealth of published literature from controlled trials on stroke prevention in AF. The Stroke Prevention in Atrial Fibrillation (SPAF) studies examined treatment strategies for patients with non-valvular AF and provided evidence that forms the backbone of today's standard stroke prevention modalities. SPAF I showed an event reduction of 67 percent at 1 year with a minor hemorrhagic risk, confirming that an antithrombotic therapy with aspirin or warfarin was efficient in ischemic stroke prevention. SPAF III confirmed that the combination of low-dose warfarin and aspirin is not effective, and if the risk of thromboembolism justified antithrombotic therapy, warfarin adjusted for a target INR of 2.0 to 3.0 was most effective.

Chronic anticoagulation presents problems of safety and tolerability in many patients, especially those older than 75, the age group encompassing perhaps half of AFassociated stroke patients. The efficacy of aspirin for stroke prevention in AF patients is less clear and remains controversial. Aspirin is somewhat effective in AF-related stroke prevention, but it is clearly less effective than that of anticoagulation.

Although chronic warfarin therapy has been proven to reduce the risk of clinical thromboembolism among those with non-valvular AF and clinical risk factors, there are several difficulties in administering it. Frequent blood tests to monitor INR are required, at some cost and patient inconvenience. And because warfarin INR is affected by a large number of drug and dietary interactions, it can be unpredictable in some patients and difficult to manage. If INR values fall below 1.8, there is an increased risk of thromboembolism; and if they rise above 3.0, there is an increased risk of hemorrhagic

complications. Even an INR within the range of 2.0 to 3.0 is associated with an increased risk for major and minor hemorrhagic complications. Thus the potential for hemorrhagic events combined with the narrow therapeutic range renders warfarin a problematic drug for patients and health care providers alike.

With the known disutility of warfarin, and the questionable effectiveness of aspirin, a device-based solution may provide added protection against thromboembolism in certain patients with AF.

There are currently three companies that have devices that are being placed into the LAA in patients with non-valvular atrial fibrillation. In these device-based solutions, placing a filter just distal to the ostium of the LAA isolates the LAA. These devices have been designed to prevent harmful sized emboli that may form in the LAA from exiting, thereby preventing the occurrence of ischemic stroke and systemic thromboembolism. The placement procedure is generally done under local anesthesia in a catheterization laboratory setting using a standard transseptal technique.

While the design of these devices may vary they are all implanted via a catheter-based delivery system under local sedation in a catheterization laboratory setting. The device comprised primarily of a nitinol (metal) frame is permanently implanted distal to or at the ostium of the left atrial appendage using a standard percutaneous transseptal catheterization technique.

The primary benefit of using this technology is its expected ability to prevent thromboembolic events originating in the LAA. As such, this technology may protect the patient from ischemic stroke and systemic thromboembolism. In addition, the elimination of warfarin therapy in those patients that require the therapy may reduce bleeding complications associated with long-term anticoagulation. Economic and patient benefits related to the elimination of life-long compliance to warfarin therapy and the frequent blood tests and lifestyle changes associated with blood thinning medications are numerous. Lastly, a device-based solution to addressing the mechanism of stroke in atrial fibrillation patients may prove to be simple, quite tolerable, and very cost-effective.

Clinical experience: There are three companies developing similar implantable devices. In the US there have been 75 implants performed to date. Pilot studies in the U.S. began in 2002 with pivotal studies anticipated to start later in 2004.

## Coding Options:

<u>Option 1</u>: Do not assign a unique code for this device and procedure. Administration of this system can be described by using code 37.99, Other operations on heart and pericardium, Other. The American Hospital Association, at a *Coding Clinic* Editorial Advisory Board meeting in March 2003, suggested use of code 37.99.

<u>Option 2</u>: Create a unique code identifying the use of this catheter-based filter technology.

	37.9 Othe	er operations on heart and pericardium
new code	37.90	Insertion of left atrial appendage device Left atrial filter Left atrial occluder Transseptal catheter technique
add note	37.99	Other Excludes: insertion of left atrial appendage device (37.90)
		insertion of left athal appendage device (37.30)

Some thought had been given to locating this code in the 35.5, Repair of atrial and ventricular septa with prosthesis, section of the book. However, this procedure is performed in a catheterization laboratory setting using a transseptal technique delivered intravascularly via jugular vein approach or femoral vein approach. This procedure may not be a repair as such, because it is a procedure performed for prevention, and is not repairing a defect.

#### Recommendation:

Create a new code as described in Option 2, above.

#### Interim Coding:

Continue to use ICD-9-CM procedure code 37.99, Other operations on heart and pericardium, Other, to describe the insertion of this device.

# **Computer-Assisted Surgery (CAS)**

#### Issue:

ICD-9-CM does not currently contain codes for the use of computer-assisted surgery (CAS). Because it cannot be identified, procedures in which CAS is used cannot be tracked. Moreover, CAS procedures cannot be differentiated from conventional procedures, leading to difficulty in assessing the relative outcomes.

#### **Background:**

Computer-assisted surgery is an adjunctive surgical process in which the coordinated use of imaging, markers, reference frames, intra-operative sensing and computer workstations allows increased visualization and precise navigation through minimally invasive approaches. Use of CAS results in substantially different surgical methodology, which in effect, constitutes a unique procedure, compared to the same operation performed conventionally.

In conventional procedures, surgeons review the patient's internal anatomy and pathology by studying preoperative images and then relying on their own anatomical knowledge during the course of the procedure. For open procedures, they must usually create major incisions to expose the surgical site for proper orientation and visualization. Placing implants is done by highly skilled "feel", a complex task in joint replacement for example where precision angles are essential.

In contrast, CAS planning often involves creation of 3D graphic models of the patient's anatomy, which are then linked seamlessly to the surgery through the use of an intraoperative computer workstation. In surgery, CAS allows identification of the precise contours of the patient's anatomical structures, the location of surgical instruments and the positioning of any implants. Moreover, it does this in real-time throughout the course of the procedure.

Computer-assisted surgery encompasses three key activities: planning, registration and navigation.

*Surgical planning* is based on imaging. Typically, CAS uses preoperative and/ or intraoperative images taken by MR, CT and/ or fluoroscopy. Different combinations of images can be used, each providing unique benefits to the surgeon. CAS can also merge anatomical images with physiological data, such as electrophysiological recordings. This is particularly helpful, for example, in defining an epileptic focus in the brain.

*Registration* takes place at the start of the procedure. Registration is the process of establishing a spatial relationship between all locations on the images and the corresponding locations on the actual patient anatomy in the surgical field. A key element of registration is the use of landmarks. Landmarks are locations on the surface of the patient anatomy, which may be reliably identified in both the images and the surgical field. In addition to being readily identifiable, these locations must be rigid with respect to the surrounding anatomy so that their positions never change. Landmarks may be discrete anatomical structures like the tragus on the ear or artificial markers such as implanted pins, called fiducials, which are screwed into the bone.

Registration establishes "image to actual anatomy" relationships, but that is not enough. The spatial relationships must then be maintained throughout the course of the surgery. This is done either by immobilization or by a process called dynamic referencing.

Immobilization simply means keeping the anatomy fixated in one place. This is common for example in some cranial procedures where the patient's head is rigidly clamped in a stereotactic frame. No relative movement between the frame and the skull is allowed since this would invalidate the relationship established.

In contrast, dynamic referencing allows movement while still preserving the relationship. It involves rigidly fixing a reference frame to the surgical anatomy. The purpose of this type of frame is not to immobilize. Rather, it allows infrared, electromagnetic and/ or radio - frequency sensors to detect and measure movement of the patient, for which the computer then compensates. Dynamic referencing is used in hip replacement surgery, for example, where movement is needed to determine and test the correct angle for placement of the implant.

It should be emphasized that while stereotaxis is sometimes a component of CAS, it refers strictly to immobilizing a body part and calculating a single target location, for a biopsy for example. It also involves only one point in time. Stereotaxis does not support merging of multiple data sets, or real-time tracking and navigation of multiple instruments relative to patient anatomy or dynamic referencing to allow for patient movement.

*Navigation* is intra-operative. In essence, this is the tracking of instruments and tools within the surgical field in real-time and displaying this movement overlaid on the images and 3D models of patient anatomy. This feature means that the surgeon does not have to make a large incision to directly see the anatomy and to follow the progress of the procedure. This then allows minimally invasive procedures to be safely conducted.

Computer-assisted surgery is already being used in intracranial and ENT procedures. It is coming into use in spinal procedures and orthopedics as well and is expected to expand to other applications. The use of CAS genuinely transforms these procedures. It greatly improves the precision and accuracy of the procedures while simultaneously allowing less invasive approaches. In many cases, incisions that are conventionally quite long can be reduced to 5mm or less. This can reduce surgical risk and patient morbidity. CAS assistance in placing implants improves the precision by which angles can be calculated and results in less wear-and-tear and reduction in revision surgeries.

CAS is not necessary in many standard, uncomplicated procedures. For example, its use is generally not warranted in primary endoscopic sinus surgery. However, CAS is a key surgical adjunct in those complicated procedures where normal anatomical reference points have been altered or destroyed, by extensive disease or multiple prior surgeries, or when the target is small and near a vital structure.

Computer-assisted surgery (CAS) is sometimes referred to as image-guided surgery (IGS) and image-guided navigation (IGN). Coders may see these terms in a medical record. However, computer-assisted orthopedic surgery sometimes uses kinematics (angles and measurements) to determine location of anatomy without the use of images. Because these types of procedures are known as "imageless" or "CT-free", the phrase "computer-assisted surgery" is used as an umbrella term.

Coders will also be able to easily identify the use of navigation in CAS in the patient's medical record. Operative reports for CAS procedures including navigation routinely document the use of reference frames, registration, landmarks and guided instruments or navigation. Documentation may also note measurements of accuracy and error, usually given in mm.

Coding Options:

<u>Option 1</u>: Do not assign a unique code for this procedure. This is an adjunctive technique, not a stand-alone procedure. Any computer assistance during surgery could be considered inherent to the procedure performed.

Option 2:

Create a new category 00.3 for Computer-Assisted Surgery and differentiate the codes by application.

New subcategory 00.3	Computer-Assisted Surgery Code also diagnostic or therapeutic procedure CT-free navigation Image guided navigation (IGN) Image guided surgery (IGS) Imageless navigation Excludes: stereotactic frame application only (93.59)
New code	00.31 Computer-assisted surgery, nervous system
New code	00.32 Computer-assisted surgery, nose, mouth and pharynx
New code	00.33 Computer-assisted surgery, musculoskeletal system
New code	00.34 Computer-assisted surgery, cardiovascular system
New code	00.39 Other computer-assisted surgery
Option 3: Create a new cate the codes by imaging.	egory 00.3 for Computer-Assisted Surgery and differentiate
New subcategory 00.3	Computer-Assisted Surgery Code also diagnostic or therapeutic procedure CT-free navigation Image guided navigation (IGN) Image guided surgery (IGS) Imageless navigation Excludes: stereotactic frame application only (93.59)
New code	00.31 Computer-assisted surgery with CT/ CTA
New code	00.32 Computer-assisted surgery with MR/ MRA
New code	00.33 Computer-assisted surgery with fluoroscopy

New Code	00.34	Imageless computer-assisted surgery
New code	00.35	Computer-assisted surgery with multiple datasets
New code	00.39	Other computer-assisted surgery Computer assisted surgery NOS

<u>Option 4</u>: This technology is adjunctive, but allows potentially better outcomes with minimally invasive techniques. However, coding to the extent shown above gives more precision than is needed to capture the concept. Create one code, as follows:

99.9 Other miscellaneous procedures

New codes 99.90	<ul> <li>Computer-Assisted Surgery</li> <li>Code also diagnostic or therapeutic procedure</li> <li>CT-free navigation</li> <li>Image guided navigation (IGN)</li> <li>Image guided surgery (IGS)</li> <li>Imageless navigation</li> <li>Excludes: stereotactic frame application only (93.59)</li> </ul>
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#### Recommendation:

CMS requests the assistance of the audience in determination of the coding option to choose.

#### Interim Coding:

There are no codes that describe this technique, therefore do not code.

## **Insertion of Palatal Implant**

**Issue:** Should a new ICD-9-CM procedure code be created for an insertion of palatal implant used in the treatment of snoring and obstructive sleep apnea?

## **Background:**

A minimally invasive treatment that does not involve heating or removing tissue that is used in the treatment of snoring is the Pillar<sup>TM</sup> system. The Pillar<sup>TM</sup> system consists of a non-absorbable polyester implant and its delivery tool. This device is FDA approved for the treatment of snoring and is under an Investigational Device Exemption (IDE) multicenter clinical trial for the treatment of obstructive sleep apnea.

The system involves the placement of three inserts into the soft palate, which is located in the back of the roof of the mouth. One insert is placed in the midline of the soft palate, and two are placed laterally. The inserts serve to promote fibrosis within the soft palate, which reduces the soft tissue flutter that is largely responsible for the snoring sound. In a patient with obstructive sleep apnea, the stiffening effect of the inserts reduces the tendency of the soft palate to create obstruction. The inserts are carefully designed to provide these effects without adversely affecting normal palate function.

The Pillar<sup>™</sup> system is primarily used in a physician office procedure room setting using local anesthesia. A representative of the manufacturer of this device stated that although this procedure can be done as a stand-alone procedure, many surgeons feel it usually will be utilized in conjunction with other nasopharyngeal procedures such as tonsillectomies, uvulopalatopharyngoplasties (UPPP), laser-assisted uvulopalatoplasties (LAUP) and various tongue based procedures.

## **Options:**

- 1. Continue to code this procedure to code 27.69, Other plastic repair of palate.
- 2. Create a new code to capture the insertion of palatal implant.

New code 27.64 Insertion of palatal implant

## **CMS Recommendation:**

Option 2. Create a new code to capture the implant of the palate.

New code 27.64 Insertion of palatal implant

In the interim, continue to code this procedure to code 27.69, Other plastic repair of palate.

## INTERNAL LIMB LENGTHENING DEVICE

**Issue:** ICD-9-CM does not differentiate between the types of internal limb lengthening devices. Category 78.3X, Limb lengthening procedures, captures procedures performed for limb lengthening. There is a "code also" note for coding the application of an external fixation device (78.10 - 78.19). However, there are no unique codes to capture new types of internal limb lengthening devices.

**Background:** It is estimated that approximately 3,000 limb-lengthening procedures are performed yearly in the United States alone. These lengthenings are primarily performed in adult patients who need osteogenic distraction due to congenital deformities or who have bone loss due to infection, trauma, etc.

Osteogenic distraction is the mechanical induction of new bone between surgically cut bone segments that are gradually pulled apart. In osteogenic distraction, a corticotomy is required in which the cortex of the bone is cut without severing the outer periosteum surrounding the cortex. This serves to both preserve the blood supply and to purposely initiate the inflammatory response of the limb to be lengthened. The inflammatory response triggers the movement of osteoblasts from the inner layer of the periosteal sheath to the corticotomy site or the "artificial fracture site". Given the appropriate conditions, the periosteal callus fills the gap with newly woven bone. This provides the foundation for the passage of osteons that connect one segment to the other. The regenerate distraction is initially bridged by fibroblast cells. These cells produce longitudinally directed collagen fibrils when distraction is applied.

Osteoids form micro columns of bone that span the vascularized fibrous distraction gap between the corticotomy surfaces. And eventually, bone grows across the fibrous distraction gap. In all methods of gradual osteogenic distraction, the bone is simply tricked into repeatedly healing itself as the distraction gap widens. And regardless of the distraction device used, if favorable conditions exist, the bone will heal itself by regeneration.

Gradual osteogenic distraction is typically achieved in these patients by using traditional external fixation devices alone or in conjunction with an intramedullary nail (a relatively new technique). But despite the significant number of lengthening procedures performed yearly, there are still many patients who actually need lengthening and do not seek treatment. These are typically adult patients with discrepancies of 3 cm or less that will not accept treatment with these external fixation devices, and thus, go untreated.

There are a number of these external devices commercially available to the U.S. orthopedic surgeon that may be used for limb lengthening. And though these external devices may ultimately achieve lengthening in many cases, there are disadvantages to these systems, and significant opportunity for improvement.

#### EXTERNAL LENGTHENING DEVICES

#### Overview of External Limb Lengtheners

The external lengthening devices are the commercially available external unilateral or circular limb lengthening frames that are attached to the bone by fixation pins. These external fixators vary in design, but all essentially consist of supporting frames, fixation pins, connecting joints and a drive mechanism. The supporting frame provides axial, torsional and bending support. The fixation pins are drilled into the bone through both cortices and project out through the skin and anchor the frame to the bone segments. These pins transmit the axial load that is normally applied to the bone during ambulation to the external frame instead. The joints connect the fixation pins to the frame and the drive mechanism provides the osteogenic distraction.

In the vast majority of these devices, the patient turns a screw mechanism that mechanically lengthens the device. When the desired limb length is reached the external frame and fixation pins remain in place while the newly formed bone (i.e., the regenerate) consolidates and heals to the point where weight bearing is possible. Then the fixation pins and external frame is removed.

#### Disadvantages of External Lengtheners

Infection, pain, malalignment and psychological stresses are common problems associated with limb lengthening by the external frames. Infection is common with these external devices, as the area at which the fixation pins exit the skin is a common point of entry for infectious organisms. These pin tract infections are the source of the majority of medical complications associated with the limb lengthening process. Pin site inflammation often leads to soft tissue infection and eventually to osteomyelitis.

Pain is another common problem associated with the external frames due to the impingement of the soft tissues surrounding the bone by the fixation pins. Contraction of any muscle transfixed by fixation pins is particularly painful. During the distraction phase, patients often report a constant dull ache. (This is most common among the longer lengthenings procedures.) The probable cause of this pain is the stretching of the muscles and nerves.

Malalignment is yet another complication associated with the external lengthening devices. These devices are eccentrically loaded and the smaller uniplanar frames and screws can bend under higher loads causing angulation of the bone as it lengthens. The external frames are not always capable of resisting the asymmetrical loads of the soft tissues on the newly forming regenerate bone. And in adults where such loads can be substantial if the frame is unable to overcome these loads, complications including rotational and angular deformity of the regenerate bone can result. The occurrence of an angulation deformity may require reapplication of the external frame, premature stopping the lengthening process, or reoperation following lengthening to correct the deformity.

In addition, adults with a limb length discrepancy due to trauma or infection often have a rate of lengthening that is usually slower than the average 1mm/day. As a result, the

external frame must remain in place for longer periods of time. This further increases the risk of infection and problems associated with pain.

The increased risk of infection, pain and malalignment, coupled with the disruption to the patient's normal activities due to the existence of the bulky external frame clearly demonstrates a need for an improved method of managing limb length discrepancies.

#### LENGTHENING OVER AN INTRAMEDULLARY NAIL

In the last several years a technique of combining an external frame in conjunction with an intramedullary nail is gaining rapid acceptance for use in limb lengthening procedures. The technique is commonly referred to as "lengthening over a nail".

Intramedullary nails are intended for fracture reduction and are designed for insertion into the intramedullary canal of long bones to act as an internal splint and alignment device. Cross-bolts enable locking of the intramedullary nail to the bone in order to hold the bone at the correct length and to prevent rotation. The advantage of combining the intramedullary nail with an external fixator is that the nail provides internal support and alignment while the external device provides the distraction. The presence of an intramedullary nail can decrease the amount of time that the patient has to have the external device attached after distraction. And by allowing the intramedullary nail to provide stability during the regeneration and consolidation phase of the lengthening process, pain may be reduced and patient acceptance of the procedure increases.

This technique of external lengthening over an intramedullary nail has addressed at least one of the concerns associated with external lengthening devices alone, and that is malalignment. When the intramedullary nail is in place, it provides an improved construct for better internal support and alignment of the bone segments. Consequently, the external construct more effectively resists angular deviation of the regenerate due to asymmetrical loading during lengthening. And, as stated previously, the intramedullary nail may replace the external frame during the consolidation phase.

However, the complications of infection, pain during distraction and increased disruption of the patient's lifestyle continue to be problematic because the external frame is still present. And in fact, the risks associated with pin tract infections take on greater importance when lengthening over a nail is performed because the intramedullary nail has the potential to act as a ladder for the spread of organisms introduced through the external pin sites throughout the intramedullary canal. Thus, there is the potential to turn a relatively minor infection isolated to a single pin site, into a serious threat to the success of the entire lengthening procedure.

Despite the potential problems associated with lengthening over a nail, this technique is considered the standard of care for lengthening of adult patients.

## CLOSED LENGTHENING DEVICE

A new internal limb-lengthening device was developed to avoid some of the problems inherent with the use of commercially available external devices alone and the lengthening over a nail technique.

The device is "closed" lengthening system. There are no fixation pins exiting the skin, thus eliminating this portal for entry of infectious organisms. The device is implanted in the intramedullary canal and thus provides mechanical stability and support to the bone segments during the distraction, regeneration and consolidation phases, thus reducing the opportunity for malalignment. And while some level of pain is normal in all lengthening procedures, lengthening with the internal limb lengthening device occurs gradually and with no soft tissue impingement, reducing two factors commonly associated with pain during distraction. Distraction is achieved through small rotational oscillations that occur as the patient ambulates. And finally, the lengthening procedure is discreet. There is no cumbersome external frame that may hinder the patient's activities of daily living, or draw further attention to the discrepant limb. The patient may have partial weight bearing during the lengthening process.

The internal lengthening device is comprised of <sup>a)</sup> proximal and distal telescoping sections, <sup>b)</sup> a distraction mechanism; and <sup>c)</sup> a length indication feedback mechanism. The proximal and distal components of the internal device are the only components that have exposed surfaces.

## Telescoping Sections - Proximal and Distal

The internal lengthening device distracts as the distal section of the implant gradually telescopes out of the proximal section. The proximal and distal components rotate relative to one another. The telescoping action of the proximal and distal components is controlled by a distraction mechanism that is made up of two one-way clutches and a threaded rod.

The telescoping action (i.e., distraction) is initiated with small rotational oscillations of the affected limb that occur as the patient ambulates. The rate of distraction depends on the frequency and intensity with which the patient oscillates the limb.

## **Options:**

- 1. Do not create new codes for limb lengthening devices. Continue coding the procedure performed.
- 2. Create new codes as follows in the proposed Tabular and Indexing.

## TABULAR

78.3 [0,2-5 Add:	Limb lengthening procedures [7-9] Bone graft with or without internal fixation devices or osteotomy Distraction technique with or without corticotomy/osteotomy Code also any application of an external fixation device (78.10-78.19) <b>Code also implantation of internal limb lengthening device (84.53 – 84.54)</b>		
78.4 [0-9]	Other repair	or plastic operations on bone	
[0, 2]		ion on bone NEC dunion or nonunion fracture NEC application of external fixation device (78.10-78.19) <b>implantation of internal limb lengthening device (84.53 – 84.54)</b> limb lengthening procedures (78.30-78.39) limb shortening procedures (78.20-78.29) osteotomy (77.3) reconstruction of thumb (82.61-82.69) repair of pectus deformity (34.74) repair with bone graft (78.00-78.09)	
New o	ode: 84.53	B Implantation of internal limb lengthening device with kinetic distraction Code also: Limb lengthening procedure (78.30 – 78.39)	
New o	code: 84.54	Implantation of other internal limb-lengthening device Implantation of internal limb lengthening device, Not Otherwise Specified Code also: Limb lengthening procedure (78.30 – 78.39)	

## INDEX

Implant, implantation – limb lengthening device, internal (NOS) 84.54 with kinetic distraction 84.53

Insertion –

limb lengthening device, internal (NOS) 84.54 with kinetic distraction 84.53

**Recommendation:** CMS proposes option 2, create new codes as described above.

# **Carotid Stent(s)**

#### Issue:

There is no specific ICD-9-CM code describing stents inserted into the carotid artery. When we originally created a stent code in 1995, we only described coronary stent(s) (36.06). The code for peripheral (non-coronary) stent(s) (39.90) was created in 1996. At that time, there was no need to describe other specific vessels, as the insertion technique was not being performed, and the stents were not commercially available.

#### Background:

An estimated 730,000 people in the United States have a new or recurrent stroke each year. Twenty – thirty percent of strokes are believed to be due to carotid artery atherosclerosis with 25% of stroke victims dying and 60% becoming permanently disabled. More than 70% of stroke victims are over 65 years of age and an estimated 4.5 million stroke victims are alive today. Stroke is the third leading cause of death and according to the American Heart Association Fact Book, in 1999 the societal cost for the care of stroke victims was \$45 billion dollars. An estimated 180-200,000 carotid endarterectomy procedures are performed annually in the USA. Numerous FDA approved, category B, clinical trials have been or are currently being conducted to evaluate carotid stenting as an alternative to carotid endarterectomy for the treatment of carotid artery atherosclerosis. On April 21, 2004, the FDA will be convening an Advisory Panel Meeting to review the first PMA application for carotid stenting. Assuming a favorable Panel recommendation, it is believed that a carotid stenting system (stent and embolic protection device) will be FDA approved in the U.S. in the third quarter of 2004.

## Carotid Endarterectomy (CEA):

When a patient's carotid artery is blocked, blood flow to the brain is reduced. If it closes up completely, the patient is likely to have a stroke, which can result in death, paralysis, brain damage or coma. In addition, arteries narrowed with atherosclerosis are an important source of emboli to the brain that can cause transient neurological deficits or permanent strokes. A surgical procedure to remove the blockage, called carotid endarterectomy, involves making an incision—approximately six inches long—along the neck to access the carotid artery. The surgeon then clears out the internal portion of the vessel that is blocked. Patients undergoing this surgery are usually under general anesthesia, and they typically have to stay in the hospital for two to four days. Surgery is always associated with a scar in the neck and in some patients may be accompanied by transient or permanent cranial nerve damage.

## Stenting:

Carotid artery stenting is a promising alternative to CEA for the treatment of extra-cranial cerebrovascular disease. During the stenting procedure, a physician makes a small puncture in the leg and snakes a catheter through it to the carotid artery. Once the catheter is in place, the doctor can use a guide wire to deliver the stent to the blockage in the carotid artery. Typically a device, called an emboli capture device, is deployed distal to the lesion prior to the stent deployment and emboli are collected in the emboli capture device as the blood passes through it. After the stent is deployed, the emboli

capture device is removed. Compared with endarterectomy, carotid stenting could offer the following advantages:

- Morbidity and mortality could be reduced in patients who have severe coexisting disease (e.g. coronary artery disease, pulmonary disease, prior radiation or surgery to the head and neck).
- The procedure does not need to be restricted to the cervical segment of the carotid artery; lesions above the jaw and below the clavicle can be readily treated.
- Simultaneous procedures can be done on carotid, vertebral, and coronary arteries.
- General anesthesia is not required.
- The small but important risk of cranial nerve palsies is eliminated.

## Coding Options;

<u>Option 1</u>: Do not create a new code for this stent. Cases can be identified with a principal diagnosis of 433.10 or 433.11, Occlusion and stenosis of carotid artery, with or without mention of cerebral infarction (5<sup>th</sup> digit), and existing procedure codes, 39.50, Angioplasty or atherectomy of non-coronary vessel plus code 39.90, Insertion of non-drug-eluting, non-coronary artery stent(s).

Option 2: Create a code identifying stent insertion specifically in the carotid artery.

39.7 Endovascular repair of vessel

New code	39.73	Endovascular insertion of non-drug-eluting carotid artery stent(s) Includes: any embolic protection device, distal protection device, balloon device, filter device, or stent delivery system Bare stent(s) Bonded stent(s) Drug-coated stent(s), e.g. heparin coated Endograft(s) Endovascular graft(s) Self-expanding stent(s) Stent graft(s) Code also any non-coronary angioplasty or atherectomy (39.50)
Add	39.79	Other endovascular repair (of aneurysm) of other vessels Excludes: <u>endovascular stent, carotid artery (39.73)</u>
Add	39.90	Insertion of non-drug-eluting, non-coronary artery stent(s) Excludes: <u>endovascular stent, carotid artery (39.73)</u>

## **Recommendation:**

CMS recommends the adoption of the code as outlined in Option 2, above, to identify this specific insertion method and site.

## Interim Coding:

Continue to code this procedure to 39.90, Insertion of non-drug-eluting, non-coronary artery stent(s) plus 39.50, Angioplasty or atherectomy of non-coronary vessel. Clinical

trials are currently underway for this product, therefore coders should also record V70.7, Examination of participant in clinical trial, to further identify these cases.

## Vertebroplasty and Kyphoplasty

**Issue:** Should two unique ICD-9-CM procedure codes be created for vertebroplasty and kyphoplasty?

## **Background:**

Vertebroplasty and kyphoplasty are both minimally invasive surgical procedures for treating vertebral compression fractures due to osteoporosis or osteolysis, where a cement- like material is injected into the collapsed bone. This stabilizes the fracture and provides immediate pain relief in many cases. Kyphoplasty differs from vertebroplasty in that the procedure involves additional steps in an attempt to restore the collapsed vertebral body back towards its native height.

Vertebroplasty is an image-guided, minimally invasive, surgical therapy used to strengthen a broken vertebra (spinal bone) that has been weakened by osteoporosis or, less commonly, cancer. Often performed on an outpatient basis, vertebroplasty is accomplished by injecting an orthopedic cement mixture through a needle into the collapsed vertebra. A hollow needle (trocar) is passed into the vertebral bone, and a cement mixture including polymethylmethacrylate (PMMA), barium powder and a solvent is injected. The cement mixture resembles toothpaste or epoxy. The physician will monitor the entire procedure on a fluoroscopy imaging screen and make sure that the cement mixture does not back up into the spinal canal.

A possible risk of this procedure is that a small amount of orthopedic cement can leak out of the vertebral body. This does not usually cause a serious problem, unless the cement comes into contact with and compresses or irritates the surrounding nerves or spinal cord. All the other typical risks of any therapeutic intervention (i.e. infection, deep vein thrombosis, and anesthetic reactions) apply to kyphoplasty as well. Other possible complications include bleeding, increased back pain, and neurological symptoms such as numbness or tingling. Paralysis is extremely rare. Sometimes, the procedure causes another fracture in the spine or ribs.

Kyphoplasty is also an image-guided, minimally invasive procedure typically performed in an inpatient setting but can also be performed as an outpatient procedure. It is indicated in patients with vertebral compression fractures where restoration of the vertebral body height is important, most typically in the majority of acute fractures and some chronic fractures. The restoration of vertebral body height normalizes the anatomy and allows for the reversal of many of the physiologic and functional consequences of vertebral compression fractures. Kyphoplasty involves placing a narrow tube that creates a path through the back into the fractured area through the pedicle of the involved vertebrae under general anesthesia. A balloon or other device such as bone tamp is inserted through the cannula and inflated, leaving a cavity into which a cement-like material (polymethylmethacrylate) is introduced. The goal is that by inflating the balloon, the height of the vertebrae will be at least partially re-established. The difference in kyphoplasty and an actual fracture reduction is that if a reduction is not accomplished, the surgeon will not try again. Possible risks and complications associated with kyphoplasty include reaction to anesthesia, infection, and deep vein thrombosis. Other possible complications include bleeding, increased back pain and neurological symptoms such as numbness or tingling. Although with the kyphoplasty technique, the risk of cement leaks is relatively low, there is still a very remote chance that some cement may come into contact with or irritate the surrounding nerves or spinal cord. Paralysis is extremely rare.

## **Options:**

- 1. Continue to code both these procedures to code 78.49, Other repair or plastic operations on bone, other.
- 2. Create two new codes for vertebroplasty and kyphoplasty.

81.6 Other Procedures on Spine
New code 81.65 Vertebroplasty

Injection of cement like material into the collapsed
vertebral body
Excludes: kyphoplasty (81.66)

New code 81.66 Kyphoplasty

Insertion of an inflatable balloon or other device to
create a cavity and restore vertebral body back to refractured height prior to injection of cement like

Excludes: vertebroplasty (injection of cement like material into the collapsed vertebral body) (81.65)

material into the collapsed vertebral body

In the interim, continue to code both these procedures to code 78.49, Other repair or plastic operations on bone, other.

# Proposed Addenda for April 1, 2004 Meeting

Tabular List		
Add code also note		Complete nephrectomy also any synchronous excision of: <u>adrenal gland (07.21-07.3)</u>
Add inclusion term	65.99	Other Ovarian drilling
Add inclusion term	75.34	Other fetal monitoring <u>Antepartum fetal nonstress test</u>
Index		

Revise subterm	Drilling <del>, bone see also Incision, bone 77.10</del>
Add subterm	bone - see also Incision, bone 77.10
Add subterm	<u>ovary</u> <u>65.99</u>
	Monitoring
	fetus (fetal heart)
	antepartum
Change code	nonstress (fetal activity acceleration determinations) 75.354

## **ICD-10-PCS Update**

#### Current status

The National Committee on Vital and Health Statistics (NCVHS) sent a recommendation to the Secretary, Department of Health and Human Services (DHHS) regarding ICD-10-CM and ICD-10-PCS. The NCVHS recommended that the department initiate a Notice of Proposed Rulemaking proposing ICD-10-CM and ICD-10-PCS as national HIPAA standards. DHHS is studying these recommendations. No decisions have been made.

## ICD-10-PCS

The annual update of the ICD-10-PCS draft system was posted on our web page at: <u>www.cms.hhs.gov/paymentsystems/icd9</u> The new version is interactive. You can click on an index entry and it will take you to the correct page of the tabular. You do not have to download the system first.

## Guidelines

CMS' contractor, 3M, has begun the process of combing through the ICD-10-PCS system as well as the training manual posted on our web page. 3M is identifying guiding principals in the use of ICD-10-PCS. This includes basic principals about how the codes are constructed, how terms are defined, and how to use the system.

CMS recently held a meeting with AHA, AHIMA, and CDC to discuss the process for development of coding guidelines for ICD-10-PCS. A discussion was held about which guiding principals should be rewritten into a format more consistent with that of a coding guideline. Attempts were made to identify areas where coding guidelines were needed. There was a discussion on the organization of this draft material. At the conclusion of this meeting, 3M agreed to further identify areas needing coding guidelines and to begin to put structure to these recommendations.

Once a rough draft is prepared, this draft will be shared with the public through the ICD-9-CM Coordination and Maintenance Committee. CMS will solicit reactions, comments, and suggestions on this draft. These coding guidelines will be posted on the CMS web page and will be used by organizations developing training materials.

## PERCUTANEOUS EXTERNAL HEART ASSIST DEVICE

#### MMA - Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Section 412.87 (b)(2) of the CFR states that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new service or technology. Once a new technology status is approved, it is sometimes necessary to issue a unique ICD-9-CM code in order to track this technology.

Because of this requirement in the MMA, CMS reopened the new technology add-on payment application process. As a result, we received requests for new ICD-9-CM codes after the original C&M Committee Meeting deadline of February 2, 2004. We are making an exception to the deadline, and have added this topic after the publication of our original agenda.

#### Issue:

There is no unique ICD-9-CM code describing the use of percutaneous external heart assist systems, otherwise known as percutaneous ventricular assist device (pVAD) or percutaneous external heart assist device. This technology is used in a patient population not appropriate for implantable VADs, and represents a procedure often performed by interventional cardiologists. These percutaneous devices are not to be confused with VADs that are implanted in the chest cavity, as the external devices are inserted into the left atrium via transseptal catheter.

#### **Background:**

When the ICD-9-CM Coordination and Maintenance Committee originally created new procedure codes for heart assist systems, otherwise know as ventricular assist devices (VADs), all heart-assist systems required cardiothoracic surgery. Today, other types of heart assist systems are available, such as the TandemHeart® pVAD<sup>TM</sup> (percutaneous ventricular assist device). This percutaneous external heart assist system is based on centrifugal flow technology that moves the blood with a spinning impeller through a blood pump located outside the body via use of a percutaneous transseptal catheter inserted directly into the left atrium.

This technology provides support for patients whose clinical condition warrants mechanical circulatory support, but who are ineligible for surgery due to their deteriorating clinical condition and would otherwise expire without cardiac support. This device does not require surgical implantation, yet provides cardiac support comparable to surgically implanted VADs. An interventional cardiologist usually performs the process of implanting a percutaneous ventricular assist device. The critical issue is the transseptal technique required to insert the catheter and pass across the septal wall directly into the left ventricle.

This device represents the next generation of technology in the field of extracorporeal heart assist technology: miniaturized centrifugal flow devices, inserted to directly bypass the left ventricle. Similar to other heart assist systems currently available, the TandemHeart® consists of an external blood pump, control unit, and the connections between the heart and the blood vessels. Blood flow of 4 liters per minute can be achieved without the need for an open surgical procedure.

The advantage to this less invasive approach is that patients currently denied surgery due to criticality of illness might be provided ventricular assistance. Both the insertion and removal of the system do not require invasive surgical procedures. This less traumatic approach eliminates the physiologic insult typical of cardiac surgery with full cardiopulmonary bypass. Patients can be provided full cardiac unloading, allowing their left ventricle to rest with improvement of microvascular circulation in the ventricle.

<u>Surgical Procedure</u>: This percutaneous external heart assist device is typically inserted in the cardiac catheterization laboratory. Access to the femoral vein and artery is accomplished with standard percutaneous procedures. An alternative cut-down procedure to access the vessels may be required in some patients. Once vessel access is gained, a needle and guiding catheter are threaded through the venous access into the right atrium and a transseptal puncture from the right atrium into the left atrium is performed. A guiding wire is placed across the septum into the left atrium. The transseptal inflow cannula of the device is then advanced over the wire and placement of the cannula is confirmed through angiography or echocardiography. Upon confirmation of proper cannula placement, the guiding wire is removed and the cannula is secured in position.

A second cannula is placed in the femoral artery to allow for return blood flow. Both cannulae are then connected to the pVAD<sup>TM</sup> pump and complete deaeration of the system is performed. The pump is then started and adjusted to the desired level of ventricular unloading. Patients are maintained on the device either until recovery, or until other therapy to treat the underlying condition is completed.

The TandemHeart® is designed for inpatient use only. Patient care following insertion of the TandemHeart® requires intensive post-operative management; typically patients are followed in the Intensive Care Unit. Once stabilized, patients are weaned from support. If patients are unable to be weaned from support, consideration is given to device replacement with an implantable long-term VAD. Length of stay will vary depending on the patient's clinical status and speed of recovery. Removal of the cannulae and closure of the vascular site, either surgical or with direct compression, completes the procedure.

#### **Coding Options:**

<u>Option 1</u>: Do not assign a unique code for this device. The percutaneous external heart assist system should remain in code 37.62, Implant of other heart assist system.

<u>Option 2</u>: Create unique codes for this procedure to allow tracking for utilization and efficacy, as follows:

37.6 Revise	Implantation of heart assist system 37.62 Implant of other heart assist system Excludes: implantation of total replacement heart system (37.52) insertion of percutaneous external heart assist device (37.68)
Revise	37.64 Removal of heart assist system Excludes: <u>explantation [removal] of percutaneous external heart assist</u> <u>device (97.44)</u>
Revise	<ul> <li>37.65 Implant of external, pulsatile heart assist system Excludes: insertion of percutaneous external heart assist device (37.68)</li> <li>37.66 Implant of implantable, pulsatile heart assist system</li> </ul>
Revise	Excludes: insertion of percutaneous external heart assist device (37.68)

new code	37.68	Insertion of percutaneous external heart assist device Extrinsic heart assist device pVAD Percutaneous ventricular assist device TandemHeart®
Add Add Add Add Add	97.44	Nonoperative removal of heart assist system Explantation [removal] of percutaneous external heart assist device Extrinsic heart assist device Percutaneous ventricular assist device pVAD TandemHeart®

## **Recommendation**:

CMS recommends that Option 2, as described above, be adopted.

## Interim Coding:

There is no code adequately describing this device and its percutaneous insertion. Therefore, code 37.62, Implant of other heart assist system, should be used until a more descriptive code can be created and put into the ICD-9-CM system.

# Ultrafiltration of Blood for Removal of Excess Fluid

#### MMA - Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Section 412.87 (b)(2) of the CFR states that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new service or technology. Once a new technology status is approved, it is sometimes necessary to issue a unique ICD-9-CM code in order to track this technology.

Because of this requirement in the MMA, CMS reopened the new technology add-on payment application process. As a result, we received requests for new ICD-9-CM codes after the original C&M Committee Meeting deadline of February 2, 2004. We are making an exception to the deadline, and have added this topic after the publication of our original agenda.

#### Issue:

There is no clear way to identify and track this type of procedure for patients suffering from fluid overload in conditions such as congestive heart failure.

#### Background:

At this meeting we will be discussing the general concept of ultrafiltration of blood for removal of excess fluid. Specifically, we will be discussing a device called the Aquadex<sup>™</sup> System 100 Fluid Removal System. We will, however, make any coding changes generic, rather than specific to this particular device or manufacturer. However, we will continue to refer to this particular system by name in this background paper. Treatment with the System 100 is prescribed by a physician and can be performed by any nurse trained in its use. Treatment can be performed in any inpatient or outpatient setting where telemetry monitoring is available, utilizing floor nurses and minimal monitoring. The size and weight of this device is comparable to a standard IV pump. Operation requires the same nursing skill level and amount of monitoring as a blood transfusion or standard IV pump.

This system is indicated for ultrafiltration treatment of patients with fluid overload, such as those with congestive heart failure (CHF), renal failure, post-surgical fluid overload, metabolic disease, and hyponatremia. Patients with CHF represent the largest group of fluid overloaded patients. CHF is the progressive inability of the heart to pump enough blood to support the vital organs; deterioration of the heart muscle leads to decreased pumping capacity, elevated stress on the heart, and increased fluid retention. An estimated 5 million people suffer from the condition in the United States. CHF is the fastest growing cardiovascular disease, with 550,000 diagnoses annually in the United States. The American Heart Association calls CHF "the disease of the millennium".

The System 100 is a mechanical pump/ultrafiltration system that can remove up to four liters (one gallon) of excess fluid from the body over eight hours. Conventional diuretic treatment typically takes several days. Physicians can specify and adjust the amount and rate of fluid to be removed, with no clinically significant impact on blood chemistry, blood pressure or heart rate. Catheters inserted into a peripheral or central vein connect the patient to the ultrafiltration device.

In many hospitalized patients with fluid overload, central venous access has already been established. Recent marketing clearance for central venous access permits the use of this same access point to remove fluid reliably and predictably with the System

100. Central access can be appropriate for patients with fluid overload who require intensive care.

Fluid overloaded patients often have compromised peripheral blood vessels due to their advanced age, poor cardiac output and fluid-overload condition. The current System 100 peripheral access option requires two venous access sites. The newly approved dual lumen extended length catheter [dELC] requires only one access site and expands the number of patients who can be treated with the System 100. This peripheral venous access catheter is inserted into one of the superficial veins near the elbow (i.e. antecubital) area of the arm. The dELC, together with the central venous access, allows a physician to choose the most clinically appropriate venous access approach for fluid removal.

In a System 100 study involving congestive heart failure patients with fluid overload, overall health benefits were substantial enough to improve patients' overall heart ranking on the New York Heart Association classification scale, a widely used measurement. Further, treatment with this device reduced the average hospital stay by two days, when compared to patients receiving conventional diuretic treatment. On average, six (6) liters of fluid (primarily water) were removed from patients, reducing overall weight that caused a strain on the heart, and often increasing mobility. Many patients who had been sleeping in chairs to ease breathing could return to sleeping in a horizontal position. Some patients, whose feet were so swollen that they couldn't wear shoes, left the hospital with their shoes laced up.

#### Coding Options:

<u>Option 1:</u> Do not create a code for this device. It represents an auxiliary procedure, integral to the treatment of patients with fluid retention, and does not require either a unique code or additional coding in the record.

<u>Option 2</u>: Do not create a code for this device. Instead, classify this procedure to existing code 39.95, Hemodialysis. Hemofiltration, which is already a part of 39.95, includes the process of ultrafiltration, which removes fluid only, and not other blood constituents. Add specific includes notes in the Tabular as well as specific Index entries to guide the coder to the correct code.

	39.95	Hemodialysis
add term		Aquapheresis
		Artificial kidney
		Hemodiafiltration
		Hemofiltration
		Renal dialysis
Add term		Ultrafiltration

<u>Option 3:</u> Revise code 99.71, Therapeutic plasmapheresis, to reflect the extraction of plasma water from the blood. The primary clinical application of "apheresis" has typically referred to the removal of various cellular components from whole blood, however the strict definition specifies the removal of any blood component, including plasma water.

99.7 Therapeutic apheresis or other injection, administration, or infusion other therapeutic or prophylactic substance

	99.71	Therapeutic plasmapheresis
Add term		aquapheresis
Add term		plasma water removal
Add term		ultrafiltration

<u>Option 4</u>: Create a new code in subcategory 99.7, Therapeutic apheresis or other injection, administration, or infusion of other therapeutic or prophylactic substance. Pheresis is defined as blood withdrawal with the desired portion removed and retained, with the remainder transferred back into the patient. This definition of pheresis describes this device with blood removal, extraction of plasma water, and return of blood back to the patient through a venous access device.

99.7 Therapeutic apheresis or other injection, administration, or infusion of other therapeutic or prophylactic substance

New code	99.78	Aquapheresis
		Extracorporeal aquapheresis
		Removal of plasma water
		Ultrafiltration

#### Recommendation:

The end results of this procedure are closely related to both hemodialysis (39.95) and aquapheresis (99.71). CMS would be interested in hearing the comments of the attendees regarding whether a new code should be created, or whether an existing code should be modified.

## Interim Coding:

We believe that an argument could be made for either the use of existing codes 39.95, Hemodialysis, or 99.71, Therapeutic plasmapheresis. Therefore, we are not prepared to make a statement concerning coding of this technique. Please provide CMS with your opinion concerning the best interim coding advice.

## **Injection of Bone Void Filler**

MMA - Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Section 412.87 (b)(2) of the CFR states that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new service or technology. Once a new technology status is approved, it is sometimes necessary to issue a unique ICD-9-CM code in order to track this technology.

Because of this requirement in the MMA, CMS reopened the new technology add-on payment application process. As a result, we received requests for new ICD-9-CM codes after the original C&M Committee Meeting deadline of February 2, 2004. We are making an exception to the deadline, and have added this topic after the publication of our original agenda.

**Issue:** We received a request for the creation of an ICD-9-CM procedure code to capture the insertion of bone void fillers. The bone void fillers are also referred to as cements. The bone void fillers or cements are being used to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery. Currently, hospitals assign a code for the surgery performed, such as a fracture reduction. There is no separate code to indicate that bone void filler was inserted.

**Background:** Physicians have augmented fracture repair with autologous bone grafts for many years. Treating fracture patients with delays in healing has been problematic. Delayed healing or nonunion can lead to extended recovery periods and significant pain. Bone grafting utilizing autologous bone grafts has been described as the gold standard when filling bony voids. The bone graft is usually harvested from the iliac crest of the patient's pelvis. However, there are a number of disadvantages in using autologous bone graft including limited availability of grafting material for filling large defects, donor site morbidity, lack of immediate mechanical stability afforded by the graft, and longer operative times for patients.

There has been significant work on the development of synthetic products to use in filling bony voids. These synthetic products lack the properties needed for promoting bone growth. However, they eliminate many of the complications from bone graft procurement and difficulties of acquiring enough graft to fill large voids. Many of the synthetic products in use today include calcium-based materials, which offer greater absorption qualities that allow bone growth to slowly replace the absorbed synthetic materials. These synthetic alternatives range from calcium sulfate and calcium phosphate materials to more complex products that include bone morphogenetic proteins. Calcium sulfate has been used as a synthetic bone graft material for over 100 years.

There are several types of cement that can be used as alternatives to autologous bone grafts. Polymethylmethacrylate cement (PMMA) cement is used to mold into a defect. PMMA is composed of acrylic cement that never goes away. Therefore, no new bone can form in its place.

Injectable osteoconductive calcium phosphate cements have been introduced as an adjunct to internal fixation for treating selected fractures. These cements develop high compressive strength, share the compressive load of the fracture with the local bone, and

are then remodeled slowly into new bone. The main purpose of the cement is to fill voids in metaphyseal bone (bone adjacent to a joint), thereby reducing the need for bone graft. Cements also may improve the holding strength around metal devices in osteoporotic bone. The surgeon prepares the bony void and then mixes the cement injection. The surgeon then has three minutes to inject the bone void cement into the void. The cement must be allowed to set for 10 minutes prior to closing the surgical wound.

The Food and Drug Administration published a Final Rule on Resorbable Calcium Salt Bone Void Filler Devices on June 2, 2003. This Final Rule classifies the devices into class II (special controls) and states that these bone filler devices are intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure.

There are several commercial bone substitutes available and their number is growing. However, there is no ICD-9-CM code that would allow these patients to be identified. In order to track the outcome of patients who use these bone void fillers, it is important that a code be created to capture the use of bone void fillers. There are two major classes of products: those bone void fillers that are directly inserted, and those cements that require preparation including mixing the cements and then inserted the cement through specialized devices. While the second type may require additional steps in preparing the cement prior to inserting it, coders may not easily be able to differentiate between the two types. The types of products on the market will likely expand and perhaps change. Therefore, a generic code should be established to capture the use of bone void fillers and cements.

## **Options:**

1. Create a new code for the insertion of bone void filler as follows:

New code:	84.55	Insertion of bone void filler
		Bone void cement
		Calcium based bone void filler
		Synthetic bone void filler

2. Create two new codes to attempt to differentiate between those products that require mixing and preparations versus those that may require a lesser degree of pre-mixing.

New code: 84.55 Insertion of bone void filler

New code: 84.56 Injection of bone void filler cement

These new codes may be extremely difficult for coders to identify. The codes attempt to differentiate based on the amount of pre-mixing. However, this may not be clearly documented in the medical record. Also, physicians may use the term "cement" when referring to both types of products.

3. Do not create a new code for bone void filler. Continue to capture the procedure performed.

**Recommendation:** CMS recommends option 1, create a new code for insertion of bone void filler. In the meantime continue to assign codes for the surgery performed.

## VASOPRESSORS

## **ISSUE**

At present, a specific ICD-9 Code that describes the use of vasopressor agents does not exist, and therefore patients who receive vasopressors cannot be differentiated from those who do not. This therapy currently is captured in Code 99.29 (Injection or infusion of other therapeutic or prophylactic substance), which does not adequately describe the use of a vasopressor drug or its clinical implications.

## BACKGROUND

Vasopressors are used in the treatment of shock, which is a state of inadequate tissue perfusion due to abnormally low systemic blood pressure. There are many causes of shock, such as hemorrhage, generalized infection, heart failure, poisonings, fluid loss from burns and severe hypoxemia, but if left untreated the ultimate consequence of shock is inadequate cellular perfusion, end organ failure, and death. Vasopressors act primarily by causing the arteries of the body to constrict, thereby raising blood pressure, and they are administered via temporary, continuous intravenous infusion.

Medical therapy of shock involves various efforts to restore and maintain normal blood pressure, primarily through the restoration of normal intravascular blood volume and the treatment of any underlying causative illnesses or injuries. If these initial measures are not immediately successful, however, vasopressor agents are often used in order to maintain blood pressure. and prevent death.

The use of vasopressors implies a higher level of patient acuity. Because these agents are used to maintain blood pressure and prolong life when other measures have failed, it is easily inferred that patients who require vasopressors are more ill, and more likely to die, than those who do not. For this reason, it is reasonable that a separate ICD-9 code be assigned to vasopressor agents in order to specify and quantify this subset of patients.

## CODING OPTIONS

1. Do not create an ICD-9 Code to capture Infusion of Vasopressor Agents.

2. Create a unique code to describe vasopressor use: 00.17 Infusion of vasopressor agent.

## **RECOMMENDATION**:

We recommend Option 2.

## **INTERIM CODING:**

Continue to use code 99.29 to capture infusion of vasopressor agents.