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

December 4, 2003

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 200 participants who attended the meeting. The procedure part of the meeting was held on December 4, 2003 and was conducted by staff from the Centers for Medicare & Medicaid Services (CMS). The diagnosis part of the meeting was held on December 5, 2003 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: www.cms.hhs.gov/paymentsystems/icd9. A summary report of the diagnosis part of the meeting will be placed on NCHS' web site at www.cdc.gov/nchs/icd9.htm. The public is offered an opportunity to make additional written comments by mail or e-mail until January 12, 2004.

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
Pbrooks1@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.

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. CMS researches the issue and examines possible code revision options. A background paper is prepared which identifies the issue and describes the procedure. The manner in which the procedure is currently coded is described. Possible options are then explored. The paper includes a CMS recommendation on any proposed coding revision. This paper is distributed for discussion at the C&M meeting and included in the summary report. A presentation is made which describes the clinical issues and the procedure. CMS staff then led a discussion of possible code revisions. The participants at the meeting are then 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.

The next C&M meeting will be held on April 1-2, 2004. Requests for code revisions must be received by February 1, 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 each meeting. 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.**

Send your name and the organization you represent to one of the following by March 29, 2004 in order to attend the April 1-2, 2004 meeting:

Pat Brooks pbrooks1@cms.hhs.gov 410-786-5318

Ann Fagan afagan@cms.hhs.gov 410-786-5662
Amy Gruber agruber@cms.hhs.gov 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
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7500 Security Boulevard
Baltimore, MD 21244-1850

Or: Pbrooks1@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 Bill that will impact the updating of ICD-9-CM. Section 503 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."

Coding staff from CMS and NCHS had just learned of this requirement and were beginning to study how this could be implemented. An initial reaction was that a December C&M meeting would not allow enough time for any April updates. Therefore, the C&M meeting originally scheduled for December 2-3, 2004 will be rescheduled for earlier in 2004.

If codes are updated in April, the DRG software and Medicare Code Editor software processing these codes must also be updated effective April 1. These system changes would need to be made by hospitals as well. Recommendations were solicited from the participants on how this process could be implemented with the least negative impact for hospitals and other providers.

A software vendor made the comments that this was the first they had heard of this new requirement. The software vendor has made no plans to update their systems for April 1, 2004 and felt that it would be extremely difficult to do so by then. Several hospital and coding groups also made comments that this would be extremely disruptive and

expensive for hospitals. Midyear software changes are expensive, especially those that are not planned. Several commenters stood up and said they were shocked and speechless at the suddenness of this requirement. The participants were encouraged to recommend a process and timeline in which any April 1st ICD-9-CM code revisions could be made.

ICD-9-CM Procedure Code Topics:

1. **Spinal Disc Replacement Devices**

Pat Brooks led a discussion on the coding issue. There is no code that captures the procedure of inserting an artificial spinal disc. Currently, a code is assigned for removing the disc (80.51, Excision of intervertebral disc), but no code is assigned for the insertion of a partial or total spinal disc. Hansen Yuan, MD, SUNY Health Science Center Syracuse, NY made a presentation on the two types of devices. Several companies are awaiting FDA approval on these devices. Injured discs do not heal, and the load-bearing capability of the disc is ultimately compromised. One participant asked if the devices were being inserted at multiple levels. Dr. Yuan responded that the FDA is currently restricting the device to single level insertion. Dr. Yuan was asked why the devices were not being used in the thoracic spine. Dr. Yuan explained that the rib cage supplies a more stable base for the thoracic spine so that the devices are not indicated for this area.

Pat explained the coding proposal that included new codes for partial and total disc replacements. These would be subdivided by cervical spine versus the lumbar spine. A new code, 84.57, was also recommended for Insertion of other spinal prosthesis, since several new devices are currently under investigation.

There was support for these new codes. One commenter recommended that code 84.57 be deleted as the default code from the proposed index next to spine artificial disc under both the Insertion and Replacement entry. It was felt that making 84.57 a main default was inappropriate, and other commenters supported this recommendation. There was another recommendation that the term “nonfusion arthroplasty” be added to either the inclusion terms or the index. Another participant supported adding this term to the inclusion terms, but was opposed to adding it to the index. This participant felt the term might lead to incorrect code assignments if it had its own index entry.

Two participants voiced concern with using so many codes since ICD-9-CM had limited numbers of empty spaces in the orthopedic section. Others felt the procedure warranted the new codes. Another participant suggested listing the new codes in a different category of the chapter such as 84.6, 84.7, or 84.8 so that they would have more room for expansion.

2. **Automatic Implantable Cardioverter/Defibrillator (AICD) Check**

Amy Gruber described this coding issue and Jim Bowman, MD provided a clinical description of the issue. AICD device checks are currently captured using code 89.59,

Other nonoperative cardiac and vascular measurements. It was felt that a new code describing this less invasive procedure would be helpful. One participant recommended that an excludes note be added for arrhythmia induction. It was also suggested that under code 37.26, Cardiac electrophysiologic stimulation and recording studies, an excludes note be added for "that without induction of arrhythmia" and refer the coder to new code 89.49.

3. **Laparoscopic adjustable gastric procedure**

Ann Fagan described the coding issue. Lee Grossbard, MD, Zephyrhills, Florida described the procedure. Dr. Grossbard also shared the fact that he has had the procedure himself. Dr. Grossbard reported that some hospitals have decided to stop doing gastric bypass surgery because of a high mortality rate of 5 – 10%. One participant asked whether there was a need for plastic surgery after the significant weight loss is achieved through this procedure. Dr. Grossbard stated that women need plastic surgery to a greater extent than do men because of their weight gain and loss patterns. Dr. Grossbard addressed a question about the type of stay for these patients. He stated that most patients are admitted for a 23-hour stay. Some may stay up to two nights. The laparoscopic adjustable banding procedure is currently the only bariatric surgery that is reversible, and is the least invasive form of gastric surgery. Dr. Grossbard reported that the procedure has the lowest postoperative complication rate. 130,000 of these procedures have been performed internationally, mainly in Mexico and Europe. The US is started to perform an increasing number of these procedures.

A mediport is used to adjust the band. One participant asked whether a code was needed for adjustment of the band. Dr. Grossbard stated that this was performed in a physician's office for the most part. In 5-10% of the cases the procedure must be performed with an ultrasound to locate the band. On the rare occasion where an emergency procedure must be performed for an open surgery to remove the band, it was recommended that code 44.99, Other operations on stomach, be used.

There was considerable support for the proposed new codes.

4. **Insertion of Neurostimulator Components**

Amy Gruber described the issue of not being able to distinguish between leads and generators for neurostimulators. It is common to report the leads and devices separately, yet this cannot be adequately identified. In addition, different types of generators cannot be determined with existing codes.

Kenneth Follett, MD, PhD, University of Iowa Hospitals and Clinics, Iowa City described the manner in which the components are inserted as well as the types of devices used. He described how leads are inserted first to see if they work using an external device. If the test is successful, a second stage involves the insertion of the device. He also discussed the various types of patients that receive these devices.

One participant asked if the devices are contraindicated in patients who already have devices such as pacemakers or defibrillators. Dr. Follett stated that there are theoretical concerns with these patients and they are generally contraindicated. However, some patients do received the devices despite these concerns.

One participant suggested that the Not Otherwise Specified (NOS) cases should be defaulted to either single or dual channel devices. Some thought should be given to how these will default. Another suggestion was to include the words "or replacement" in the titles for the new generator codes. A question arose as to how the repositioning of the leads would be captured. A suggestion was made to include this under code 02.93, Implantation of intracranial neurostimulator. The word "revision" could be added as an inclusion term. A typo was noted in the range of codes in the 'code also note' listed under the intracranial, spinal and peripheral neurostimulator leads codes. The range should be 86.94 – 86.96.

There was support for the detail provided by the codes in capturing the pulse generators and leads.

5. **Axial Flow Left Ventricular Assist Device (LVAD)**

Ann Fagan discussed the need to update the codes for LVADs. Eric Rose, MD, Columbia University Hospital, New York, provided the clinical overview and description of LVAD devices. He described the rapidly changing nature of the field. Dr. Rose suggested that the rapid changes taking place in these devices mandated a simple approach to these codes. He felt it was too early to parse out a number of code distinctions since it was not clear how the field would play out. Others in the audience felt that it would be better to develop more precise codes so that the technology could be tracked. One person stated that with so many new devices, it would be difficult for a coder to determine that type of device without clear documentation. During the lively discussion, it seemed as if the audience was evenly divided on the idea of creating a new code at 37.68, vs. combining all VADs into existing code 37.66.

One participant expressed concerns about the term "temporary heart assist system" that was listed as an 'add term' under code 37.62, Implant of other heart assist system. They felt this would be hard to define and would not add much to the clarity of the code. Another person suggested that code 37.62 be modified to indicate that this code was for the insertion of extracorporeal pumps. Many in the audience supported the proposed code revisions for 37.63, Repair of heart assist system and also supported a new code at 37.68, Implant of implantable axial flow heart assist system, since it allowed for changing technology. Inclusion terms that were recommended for code 37.68 included: Diagonal, axial, and centrifugal. One participant recommended that code 37.68 be titled "Implant of implantable rotary pump heart assist system".

6. **Coronary Intravascular Ultrasound (IVUS)**

Ann Fagan described the proposed new codes and John McB. Hodgson, MD, FSCAI, and President, Society for Cardiac Angiography & Interventions, Cleveland, Ohio, as well as Director, Invasive Cardiology at the Heart & Vascular Center, Cleveland, OH, described the clinical issues and the procedures. Dr. Hodgson explained that IVUS is not a replacement for Intracardiac echocardiography (ICE). ICE obtains pictures inside the cardiac chambers while IVUS provides pictures inside the vessel. IVUS is used with stent placement to determine the severity of lesions.

Several participants recommended that the term "arteries" be changed to "vessels" since IVUS can be used on both arteries and veins. Another participant recommended that the inclusion term IVUS, which is proposed under category heading 00.2, Intravascular arterial, imaging, be repeated as an inclusion term under each of the new codes instead. A recommendation was also made to exclude IVUS from code 37.28, Intracardiac echocardiography (ICE), as well as at 88.72. It was also recommended that a new code 00.25 be created for IVUS of renal vessels.

7. **Prevention of Vein Graft Failure**

Ann Fagan explained the coding proposal and Randall Wolf, MD, University of Cincinnati College of Medicine, Cincinnati, Ohio, discussed the clinical issues and the procedure. This type of biosurgery is said to enhance surgical outcome. There was some discussion about whether the word "pressurized" should be used in the code title for 00.16, Pressurized treatment of venous bypass graft with pharmaceutical substance. It was questioned as to whether this was the best way to describe the technology. However, another commenter stated that if the term were removed, it may appear that we should assign grafts that were treated with heparin to this new code. Others felt it was best to keep the term "pressurized." A recommendation was made to put a 'code also note' under the coronary bypass codes to refer to 00.16. Dr. Wolf will assist CMS in adding 'code also notes' to other appropriate body sites. There was some discussion about whether the term "conduit" should be used instead of "graft" in the code title. It was also recommended that 'E2F Decoy' be added as an inclusion term in the Tabular portion of the book. Others felt this information would be more appropriate as information in AHA Coding Clinic for ICD-9-CM.

8. **Unrelated Allogeneic Bone Marrow Transplantation**

Amy Gruber described this code proposal. John Canning, Children's Hospital of New York-Presbyterian described the clinical issues. One participant stated opposition to creating ICD-9-CM codes for this type of service. It was recommended that the requestor seek to have a revenue code created to describe this service. Another participant agreed that this activity was not the type of service usually captured in ICD-9-CM procedure codes. They were also opposed to the creation of new codes to capture the services involved in seeking transplant donors. The requestor responded with comments that codes were created for drug eluting stents; therefore, codes should also be created for this type of service. Others pointed out problems for the coder in knowing what would be classified as an unrelated donor.

9. **ICD-10-PCS Update**

Pat Brooks announced that the National Committee for Vital and Health Statistics (NCVHS) had sent a letter to the Secretary of Health and Human Services recommending that a Notice of Proposed Rulemaking be written which would propose the implementation of ICD-10-CM and ICD-10-PCS. This was met with applause from the audience. Pat stated that information concerning the NCVHS could be found on their web page at: www.ncvhs.hhs.gov. Pat also mentioned that the RAND Corporation had performed a cost benefit analysis on moving to ICD-10. RAND projected costs of $425 million to 1.15 billion to implement both systems. They projected benefits of $700 million to $7.7 billion. The complete RAND report will be posted on the NCVHS web page soon. Others, such as Blue Cross Blue Shield Association are projecting considerably higher costs. If the US moved to ICD-10-CM and ICD-10-PCS it is not anticipated that it would be implemented prior to October 1, 2007 (FY-2008).

CMS has updated ICD-10-PCS on its web page. The November 2003 version of ICD-10-PCS is now posted at: www.cms.hhs.gov/paymentsystems/icd9/icd10.asp. Thelma Grant provided an overview of ICD-10-PCS. Details on this system are described in a paper, which is posted on the CMS web page. Some of the updates include:

- Updating the body part lists within the medical surgical section
- Root operations, approaches and devices were assigned to more rows to allow more precise coding of new procedures
- Root operation Removal was completely revised for all body systems to allow more precise coding of non-operative removal of devices
- Root operation Revision was completely redone for all body systems in the section
- Code added for drug-eluting intraluminal device
- A new section was added for Substance Abuse Treatment

During 2004 CMS' contractor will begin the conversion process of ICD-10-CM and ICD-10-PCS into the DRG structure. They will also closely examine the mappings between ICD-10-PCS and ICD-9-CM.

The American Hospital Association and the American Health Information Management Association have also agreed to begin work with CMS on developing official coding guidelines for ICD-10-PCS. AHA and AHIMA will report on their progress at the April 1, 2004 C&M meeting. A more detailed report on ICD-10-PCS updates and activities will also be presented at this meeting.

10. **ICD-10-CM Testing**

Sue Prophet Bowman, AHIMA, and Nelly Leon Chisen, AHA, provided an informative report on their joint activities in testing ICD-10-CM. A complete report can be found on their web pages at:
www.ahima.org and www.aha.org

11. **Addenda**

Amy Gruber reviewed the proposed addenda. There was support for all the proposed changes.

The participants were urged to send their written comments to CMS on proposed code revisions by January 12, 2004. Also, those wishing to attend the April 1-2, 2004 C&M meeting must once again send their names to be included on the visitor's list.

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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
December 4-5, 2003

Patricia E. Brooks
Co-Chairperson
December 4, 2003

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

Topics:

1. Spinal Disc Replacement Devices

   Patricia E. Brooks
   Hansen Yuan, MD
   SUNY Health Science Center
   Syracuse, NY

2. Automatic Implantable Cardioverter/Defibrillator (AICD) Check

   Amy L. Gruber
   James Bowman, MD

3. Laparoscopic Adjustable Gastric Banding

   Ann B. Fagan
   Lee Grossbard, MD
   Zephyrhills, FL

4. Insertion of Neurostimulator Components

Amy L. Gruber
Kenneth A. Follett, MD, PhD
University of Iowa Hospitals and Clinics, Iowa City, IA

5. Axial Flow Left Ventricular Assist Device (LVAD)

Ann B. Fagan
Eric A. Rose, MD
Columbia University Hospital
New York, NY

6. Intravascular Ultrasound (IVUS)

Ann B. Fagan
John McB. Hodgson
Society for Cardiac Angiography & Interventions, Cleveland, OH

7. Prevention of Vein Graft Failure

Ann B. Fagan
Randall K. Wolf, MD
University of Cincinnati College of Medicine, Cincinnati, OH

8. Unrelated Allogeneic Bone Marrow Transplantation

Amy L. Gruber
John Canning
Children's Hospital of New York-Presbyterian

9. ICD-10-Procedure Classification System (PCS) - Update

Patricia E. Brooks
Thelma Grant
3M Health Information Systems

10. ICD-10-CM Testing

Nelly Leon Chisen, AHA
Sue Prophet Bowman, AHIMA

11. Addenda

Amy L. Gruber

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ICD-9-CM Volume 3, Procedures Coding Issues:
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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 to be published in the Federal Register 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 will be devoted to discussions of procedure codes. December 5 will be devoted to discussions of diagnosis codes.
December 2003	Summary report of the Procedure part of the December 4-5, 2003 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 Diagnosis part of the December 4-5, 2003 ICD-9-CM Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm
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 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.

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March 2004

Tentative agenda for the Procedure part of the April 1, 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 Diagnosis part of the April 2, 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 April 1-2, 2004 ICD-9-CM Coordination and Maintenance Committee Meeting to be published. This will include the tentative agenda.

April 1, 2004

Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This will include the final decisions on ICD-9-CM diagnosis and procedure code titles that were discussed at the meetings held on April 3, 2003 and December 4-5, 2003. It will also include proposed revisions to the DRG system on which the public may comment. It will not include additional procedure codes that will be discussed at the April 1-2, 2004 meeting and that might also be included in the October 1, 2004 addendum. The proposed rule can be accessed at:
http://www.cms.hhs.gov/regulations/

April 1-2, 2004	ICD-9-CM Coordination and Maintenance Committee Meeting in CMS's auditorium. Diagnosis code revisions discussed are for potential implementation on October 1, 2005. Procedure code revisions may be for October 1, 2004 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.
May 2004	Summary report of the Procedure part 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 Diagnosis part 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: http://www.cms.hhs.gov/paymentsystems/icd9
August 1, 2004	Hospital Inpatient Prospective Payment System final rule to be published in the Federal Register 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 1-2, 2004 meeting and resolved in time for implementation on October 1, 2004. This rule can be accessed at: http://www.cms.hhs.gov/regulations/
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

Spinal Disc Replacement Devices

Issue: There are no unique ICD-9-CM codes to capture new procedures involving the replacement of the spinal disc with several types of artificial disc devices. Artificial discs have been approved for commercial use in a number of other countries. They are being inserted as part of clinical trials within the US. It is anticipated that the FDA may approve at least one of the new devices in 2004. These devices involve the replacement of either the entire spinal disc or the replacement of the disc nucleus with new devices. This treatment for back pain does not involve spinal fusion. The entire disc or the nucleus is removed and then replaced with new types of materials designed to restore disc height. This procedure is currently captured using ICD-9-CM code 80.51, Excision of intervertebral disc.

Background:

A number of medical device companies are developing implantable devices to treat patients with degenerative disc disease (DDD), the major cause for low back pain. Currently, spinal fusion or arthrodesis is the treatment option for DDD patients who have failed conservative treatments. These companies are developing minimally invasive alternatives to spinal fusion that would replace the degenerated disc nucleus and restore or maintain the normal function of the disc. Instead of an arthrodesis (or fusion) procedure, the surgeon is performing an arthroplasty procedure on the spine.

Spine Anatomy

The primary function of the spinal disc is to provide motion and support at each spine segment. The disc consists of the nucleus and a fibrous outer material called the annulus. The disc helps to maintain certain movements of the spine such as flexion, extension and torsional movements.

One of the major modes of failure of the disc is prolapse or herniation; this is often associated with early disc degeneration. Degeneration can be caused by a traumatic event or by the normal aging process. Discs are 80% water in youth and gradually desiccate with age. As the nucleus dehydrates and shrinks, the load on the nucleus decreases while the load on the annulus increases.

As the disc dehydrates, the annulus flattens and is susceptible to de-lamination and damage. Radial tears, cracks and fissures occur in the annulus and the nucleus may ultimately transgress through all the layers of the annulus, resulting in a disc herniation. Disc degeneration without herniation is also very common and results in chronic low back pain.

At this stage of degeneration to the spine motion segment, and after failing conservative non-surgical treatment, treatment options other than fusion are available such as a

discectomy and or other decompression procedures. Literature shows a high re-operation rate in patients treated with this option. Although the radicular pain associated with decompressive procedures is initially positive, these patients may have a continuation of the degenerative cascade that can lead to further bony degeneration and further neurologic deficit. This may require more invasive fusion surgery considerations.

Current Treatment

There is controversy among spine surgeons as to the cause, or causes, of back pain, but many believe degeneration of the nucleus and annular destruction is a major source of pain. If patients fail conservative treatment, spinal fusion is currently the primary treatment option. There are a number of fusion products on the market and success has been monitored by "fusion rates". Even if the fusion rate is high, fusing one or more levels in the spine results in increased stress and strain and potential breakdown at adjacent disc levels. Additionally, the success of the surgery is predicated on "fusion" rather than on a positive clinical outcome. It has also been a topic of concern in the spine surgeon community that a phenomenon of "fusion disease" takes place, as these patients develop degeneration at adjacent levels caused by re-distribution of stress to other levels due to the immobilization of the fused level.

Partial Disc Replacement - Nucleus Replacement Device

The nucleus replacement device is designed to replace the degenerated nucleus and restore the normal disc function and anatomy thereby decreasing the stress redistributed to adjacent levels of the spine. This should lead to an interruption of the degenerative cascade and offer a less invasive treatment option to fusion and a treatment that could be used earlier in the degenerative process. Historically patients undergoing fusion surgery have poor return to work results. Allowing the patient an earlier treatment option could have significant return to work and positive daily living ramifications. It should also be noted that this early treatment option does not eliminate the fusion option later in the disease state. This is because the procedure does not involve destruction of healthy anatomy by removal of bony elements, damage to endplate structures or removal of the circumferential annulus. This leaves further treatment options open and facilitates an easy revision procedure if necessary.

To implant the device, the surgeon first performs a complete nuclectomy via a small (5.5mm) annulotomy in the outer portion of the annulus and then the size of the disc space is determined. This annulotomy can be obtained anywhere on the circumferential surface of the annulus using standard and customary approaches to the spine (anterior, lateral or posterior). The size of the disc space is determined using an initial diagnostic and sizing balloon that is inserted into the disc space and then filled with a contrast medium, followed by an intraoperative fluoroscopic evaluation. A compliant size specific balloon is then placed in the disc space and the flow-able polymer is injected filling the balloon in the nucleus space, thus forming a customized patient specific implant. The polymer is allowed to cure and the catheter is removed. The balloon, bonded to the cured polymer, remains in place. The surgeon then closes as usual.

Replacement of Total Disc

The total disc prosthesis is a system consisting of two endplates made of high quality cobalt chromium alloy, an implant material that has been proven to be extremely well tolerated by the body. The endplates are attached to the vertebral body by means of anchoring teeth along the border. A polyethylene sliding core is placed between these endplates, which has been designed to allow near-physiological segment movements with corresponding lateral mobility. Much like an artificial hip or knee system that relies on metal and plastic to replicate normal movement, this disc prosthesis is designed to mimic the function of a healthy disc.

The surgical procedure for the total disc prosthesis places an implant using the anterior approach. Using a retroperitoneal approach the midline was identified and the anterior annulus as excised. A discectomy is performed to the posterior longitudinal ligament. After adequate discectomy the prosthesis was impacted into place.

INCLUSION CRITERIA

* Age between 18 and 60 years

* Diagnosis of Degenerative Disc Disease at the L4/L5 or L5/S1 level

* At least six months of conservative treatment

EXCLUSION CRITERIA

* Previous back surgery (except discectomy, laminotomy, or nucleolysis at the same level) or other spinal surgery at any level

* Multiple levels of degeneration

* Osteoporosis, osteopenia or other metabolic bone disease

* Spondylolisthesis, scoliosis or spinal tumor

* History of chronic steroid use

* Pregnancy

* Autoimmune disorder

* Morbid obesity

Current ICD-9-CM Codes

Currently there are no ICD-9-CM codes that describe the insertion of total or partial spinal disc replacement prostheses. Hospitals are assigning code 80.51, Excision of intervertebral disc, to capture the removal of the disc. However, there is no code to show the insertion of the new prosthetic devices. These devices are being used in the cervical and lumbar spine. New codes are needed to capture the part of the spine where the devices are inserted as well as whether a total or partial disc is inserted. These new codes would provide data, which can be used to examine outcomes of the various types of procedures.

Option 1:

TABULAR

84.5 Implantation of other musculoskeletal devices and substances
Add: Spine arthroplasty with prosthesis insertion

New: 84.53 Insertion of partial spinal disc prosthesis, cervical
Nuclear replacement device, cervical
Partial artificial disc prosthesis (flexible), cervical
Replacement of nuclear disc (nucleus pulposus), cervical
Includes: discectomy

New: 84.54 Insertion of spinal disc prosthesis, total or unspecified, cervical
Replacement of cervical spinal disc, NOS
Replacement of total spinal disc, cervical
Total artificial disc prosthesis (flexible), cervical
Includes: discectomy

New: 84.55 Insertion of partial spinal disc prosthesis, lumbar
Nuclear replacement device, lumbar
Partial artificial disc prosthesis (flexible), lumbar
Replacement of nuclear disc (nucleus pulposus), lumbar
Includes: discectomy

New: 84.56 Insertion of spinal disc prosthesis, total or unspecified, lumbar
Replacement of lumbar spinal disc, NOS
Replacement of total spinal disc, lumbar
Total artificial disc prosthesis (flexible), lumbar
Includes: discectomy

New: 84.57 Insertion of other spinal prosthesis

New: 84.59 Revision of artificial spinal disc prosthesis
Partial artificial spinal disc prosthesis
Total artificial spinal disc prosthesis

80.51 Excision of intervertebral disc
Excludes:
Add: That for: Insertion of spinal disc prosthesis (84.53 – 84.57)

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Option 2:
Do not create new codes for this procedure.

Recommendation:

CMS recommends option 1. In the meantime coders are to capture these procedures by assigning code 80.51.

Automatic Implantable Cardioverter/Defibrillator (AICD) Check

Issue:
Should a new procedure code be created to capture the interrogation only check of the AICD itself? Currently, there is a code for artificial pacemaker rate check.

Background:
The bedside check of the AICD device is not the same as a cardiac electrophysiologic stimulation and recording study, which is performed on a patient's heart. The AICD test is performed on the device itself. (See AHA's Coding Clinic, Third Quarter 2003, page 23). Evaluation of an AICD itself to ensure that the device is operating appropriately such as checking pacing thresholds of the device is a non-invasive procedure that can be safely performed at the bedside. This procedure is analogous to the pacemaker check.

Options:

1. Continue to code this procedure to code 89.59, Other nonoperative cardiac and vascular measurements.

2. Create a new code to uniquely identify the check of the AICD.

   Revise category title 89.4 Cardiac stress tests, pacemaker and defibrillator checks

   New code 89.49 Automatic implantable cardioverter/defibrillator (AICD) check

   Bedside AICD check
   Checking pacing thresholds of device

CMS Recommendation:

Option 2. Create a new code to uniquely identify the check of the AICD.

Revise category title 89.4 Cardiac stress tests, pacemaker and defibrillator checks

New code 89.49 Automatic implantable cardioverter/defibrillator (AICD) check

Bedside AICD check
Checking pacing thresholds of device

In the interim, continue to code this procedure to code 89.59, Other nonoperative cardiac and vascular measurements.

Laparoscopic Adjustable Gastric Procedure

Issue:
CMS has received a request from the Israel Ministry of Health's National Committee on Clinical Coding to create specific codes for procedures used by their physicians – one code for laparoscopic adjustable gastric banding, and a code for the non-surgical revision of this banding. Specific coding would replace the more general code currently in use: 44.69, Other repair of stomach, Other.

Background:
Obesity: This type of surgery is intended for adults who are morbidly obese - those who are at least 100 pounds overweight or who are at least twice their ideal body weight. The term "morbidly" connotes the fact that individuals who carry this much excess weight face an increased risk of developing a number of serious health conditions, including diabetes, high blood pressure, cardiovascular disease, obstructive sleep apnea, cancer, and osteoarthritis. People who may not meet the weight criteria for morbid obesity but suffer from these co-morbid conditions might also qualify as surgical candidates.

The National Institute of Health Consensus Conference recognized morbid obesity as a medical disease in 1991, and supported surgery as treatment for individuals with a body mass index (BMI) pf 40 kg/m or greater. (Surgery was also recommended for individuals of BMI equal to or greater than 35 kg/m if some of the obesity related co-morbidities mentioned above were present.) The BMI uses weight and height information to calculate body mass. Federal health agencies classify the results as follows:

BMI > 25: Overweight
BMI > 30: Obese
BMI > 35: Severely Obese
BMI > 40: Morbidly Obese

Obesity is a chronic disease with staggering statistics, affecting approximately 60 million American adults, or nearly one-third of the population. In addition, another 127 million Americans (64.5% of the population) are overweight and at risk for becoming obese.

The estimated medical costs of treating obesity total approximately $238 billion per year, with roughly $100 billion of that devoted to treating related health problems. According to the NIH, National Institute of Diabetes and Digestive and Kidney Diseases, Americans spend $33 billion annually on weight-loss products and services.

Healthcare costs associated with obesity are higher than with smoking. Obesity is associated with a 36% increase in inpatient and outpatient costs and a 77% increase in medications, compared with a 21% increase in inpatient and outpatient costs and a 28% increase in medications for current smokers.

Since 1991, the prevalence of obesity has increased by 61%. From 1998 and 1999 alone, there was a 6% increase. Given that the rates are climbing so precipitously, experts predict that obesity will only continue to escalate as a national health crisis. Alarmingly,

obese individuals have a 50-100 percent increased risk of death from all causes, compared with normal-weight individuals. Obesity and its complications are the second leading cause of preventable death, surpassed only by smoking. Approximately 300,000 deaths are attributable to obesity each year.

Rationale for Surgical Treatment: Recent research reveals that conventional methods of weight loss generally fail to produce permanent weight loss. Several studies have shown that patients on diets, exercise programs, or medication are able to lose approximately 10% of their body weight but tend to regain two-thirds of it within one year, and almost all of it within five years. Another study found that less than 5% of patients in weight loss programs were able to maintain their reduced weight after five years.

In contrast, weight loss surgery can produce profound, sustained weight loss. A recent U.S. clinical paper demonstrated an average excess weight loss of 54% after three years of follow-up. In trials conducted in Europe, where physicians have nearly a decade of experience with the device, the results were even more favorable. Patients in two large-scale studies with approximately 800 patients combined reported an excess body weight loss of more than 60% at the three-year mark.

Device: The FDA approved the device we will be discussing today, the LAP-BAND™, in June 2001. It induces weight loss by reducing the capacity of the stomach and thus restricting the amount of food that can be consumed at one time. During the procedure, surgeons use a laparoscopic technique to implant an inflatable silicone band into the patient's abdomen. Like a wristwatch, the band is fastened around the upper stomach to create a new, tiny stomach pouch. As a result, patients experience an earlier sensation of fullness and are satisfied with smaller amounts of food. (This device is not the same as the vertical banded gastroplasty (VBG), as the stomach is not stapled.)

As there is no cutting, stapling or stomach rerouting involved in this procedure, it is considered the least traumatic of all weight loss surgeries. The surgeon makes several tiny incisions and uses long, slender instruments to implant the silicone band around the upper stomach just below the gastroesophageal junction. The band is connected by way of hollow silicone tubing to an access port that is secured to the abdominal wall fascia. The access port allows the clinician to inject saline into the band. This fluid expands the inner balloon of the band, causing external compression of the stomach, resulting in increased appetite suppression, early satiety, and weight loss. By avoiding the large incision of open surgery, patients generally experience less pain, infection, and scarring. In addition, the average hospital stay is typically less than 24 hours, including overnight hospitalization. Patients can typically resume normal activities within one week, which is earlier than with other surgical alternatives.

The need for an adjustment to the band is determined individually, based on the patient's weight loss and feelings of satiety and hunger. Band patients are seen frequently in outpatient follow-up so that serial adjustments can be performed to gradually and incrementally tighten the band until it is functioning optimally. If a patient is losing weight, is restricted in their food intake, and is not hungry, the band is not adjusted. If

they are not losing weight, are not restricted, and are hungry, saline is added to the band during an adjustment, to narrow the stoma. The average number of adjustments performed during the first year is 5, and during subsequent years is 3. Adjustment may necessitate fluoroscopic guidance in order to locate the port or to visualize the band stoma. Adjustments to remove fluid volume may be necessary if the stoma is too narrow and the patient is having symptoms of obstruction, i.e., vomiting, heartburn, or dysphagia.

Because no permanent changes are made to the body's physiology, the procedure can be surgically reversed. If necessary, all of the system components can be removed from the body with no damage to the digestive organs. The stomach will generally return to its original form and capacity once the band is removed.

Coding Options:
Option 1: Do not create a new code for this device. Cases can be identified with a principal diagnosis of morbid obesity and the existing procedure code 44.69, Other repair of stomach, Other. Saline adjustment of the size of the stomach is an outpatient procedure, so will not need an inpatient code.

Option 2: Create specific codes identifying this type of gastric restrictive procedure, as the field of bariatric surgery has rapidly expanded. It is possible that patients will require inpatient admissions for revision or removal of this device due to other comorbid conditions and secondary diagnoses. We should anticipate that possibility and create codes now to describe these procedures.

44.9 Other operations on stomach

new code 44.95 Laparoscopic gastric restrictive procedure
Adjustable gastric band and port insertion

new code 44.96 Laparoscopic revision of adjustable gastric restrictive procedure
Revision or replacement of:
Adjustable gastric band
Subcutaneous port device

new code 44.97 Laparoscopic removal of adjustable gastric restrictive device(s)
Removal of either or both:
Adjustable gastric band
Subcutaneous port device

Recommendation:
CMS recommends the adoption of three new codes as outlined in Option 2, above. New codes will identify the laparoscopic approach as well as differentiating the adjustable gastric band from the vertical banded gastroplasty (VBG) that divides the stomach with staples to create a smaller gastric pouch.

Interim Coding:
Continue to code this procedure to 44.69, Other repair of stomach, Other. Advice given in the May-June 1985 Coding Clinic, page 17, advises the use of this code, noting that it is to be used to describe: "Gastric partitioning without anastomosis, using staples (gastric stapling) to restrict oral intake of food in massive or morbid obesity".

Insertion of Neurostimulator Components

Issue: Current ICD-9-CM codes do not distinguish between leads and generators for neurostimulators, although there are distinctions for other electronic devices such as pacemakers. This creates difficulties when components are inserted or replaced individually. Although instructions are in place, these are awkward and do not reflect the true nature of the procedures. In addition, existing codes also do not differentiate between single and dual array neurostimulator generators, although they do make this distinction between single and dual chamber pacemakers.

Background:
There are three main types of neurostimulators, based on the area of the nervous system being targeted. They are: intracranial, spinal, and peripheral.

Like other electronic pacing and stimulation devices, neurostimulators consist of two key components: 1) a pulse generator which is inserted in a subcutaneous pocket, usually on the abdomen or chest, and 2) one or more leads which are connected to the generator, tunneled subcutaneously and then inserted at the target organ. The pulse generator has a battery that eventually wears out and must be replaced. Barring complications, leads are permanent.

Clinically, pulse generator insertion is essentially the same for all three types of neurostimulators. The lead placement is the differentiating element. Intracranial leads are physically inserted into the brain and spinal leads are inserted over the spinal cord. Insertion at the sacral nerve is an example of lead placement for a peripheral neurostimulator.

The two components can be inserted together during the same operative episode or they can be inserted individually during separate encounters. In replacements, such as for complications or for routine generator end-of-life (battery depletion), it is common to replace just one component rather than replacing both.

Current neurostimulator generators are “single array”, also known as “single channel.” Patients who need stimulation on both sides of the brain must have two complete single array systems implanted. In other words, these patients require one generator and lead on the left side plus a second generator and lead on the right side. This involves multiple incisions on the chest to create two generator pockets as well as tunneling on both sides of the neck for the extensions to the leads.

In contrast, “dual array” or “dual channel” neurostimulators involve a single generator and a single tunnel with connection to two leads. This reduces the surgical trauma to the patient and also reduces the risks for infection and mechanical complications. FDA approval for dual array neurostimulators for use for intracranial procedures is expected in 1st quarter 2004. There are dual array neurostimulator generators in use for spinal and peripheral procedures.

Current Coding

Current ICD-9-CM codes consider neurostimulator devices as a single unit and provide just one code for insertion and one code for removal.

Neurostimulator Type	*Insertion*	*Removal*
intracranial	02.93	01.22
spinal	03.93	03.94
peripheral	04.92	04.93

Coding Clinic has advised that the regular insertion code should be used for a total system implant of both leads and generator in a single-stage procedure. Recognizing that components are sometimes inserted separately in a two-stage procedure, Coding Clinic also advised using the regular insertion code for insertion of the leads in the first stage and then using code 86.09, Other incision of skin and subcutaneous tissue, for subsequent insertion of the pulse generator, along with 86.99, Other operations on skin and subcutaneous tissue, for tunneling the wire connector, in the second stage (Coding Clinic. 4th Quarter 1997, p.57-58).

This provides instruction in assigning the same insertion code twice in a two-stage procedure. However, it is awkward in that code 86.09 is a very broad code. It does not provide adequate identification or tracking of pulse generator insertion, either as part of a staged procedure or in a replacement-only procedure.

Similarly, when the regular insertion codes 02.93, 03.93 and 04.92 are used, it is not clear whether an entire system is being placed or only the leads. It also cannot be determined under the current codes if the neurostimulator involves a single array generator or a dual array generator.

The Coding Clinic article did not address removal of generators when done as a stand-alone procedure, for example when the patient has an infection. It is not clear if removal of the generator is properly coded 01.22, 03.94 and 04.93 or if a skin procedure code such as 86.05, Incision with removal of foreign body from skin and subcutaneous tissue, should be used.

Options:
Option 1. Continue to code these procedures as indicated above.

Option 2.
A much simpler alternative is to create three new codes for insertion of neurostimulator pulse generators and to redefine the existing neurostimulator codes for insertion and removal of leads only. This recognizes that creation of a subcutaneous pocket and insertion of the pulse generator is primarily an Integumentary procedure while surgically, the Nervous System component of the procedure revolves around the leads. Two codes for generator insertion will allow single and dual array neurostimulator generators to be identified separately.

1. Create three new codes in category 86 for insertion of any neurostimulator pulse generator along with a "code also" note for the leads.

86.9 Other operations on skin and subcutaneous tissue

New code 86.94 Insertion of single array neurostimulator pulse generator
Pulse generator (single array, single channel)
for intracranial, spinal, and peripheral neurostimulator

Code also any associated lead implantation (02.93,03.93,04.92)

New code 86.95 Insertion of dual array neurostimulator pulse generator
Pulse generator (dual array, dual channel) for
intracranial, spinal, and peripheral neurostimulator

Code also any associated lead implantation (02.93,03.93,04.92)

New code 86.96 Insertion of other neurostimulator pulse generator

Excludes: insertion of single array neurostimulator pulse generator (86.94)
insertion of dual array neurostimulator pulse generator (86.95)

Code also any associated lead implantation (02.93,03.93,04.92)

2. Revise the title of code 86.05 and add an inclusion note for removal of a neurostimulator pulse generator. This recognizes that the code is already used for removal of devices, which would now include neurostimulator pulse generators.

Revise code title 86.05 Incision with removal of foreign body <u>or device</u> from skin and subcutaneous tissue

Add inclusion term <u>Removal of neurostimulator pulse generator (single array, dual array)</u>

3. Revise the definitions of all neurostimulator insertion codes and removal codes to reflect leads only, and add "code also" notes to show that insertion or removal of the pulse generator, if any, is coded separately.

<u>Insertion</u>

Revise code title 02.93 Implantation <u>or replacement</u> of intracranial neurostimulator l<u>ead(s)</u>

Add code also note Code also any insertion of neurostimulator pulse generator (86.94-86.96)

Revise code title 03.93 ~~Insertion~~ Implantation or replacement of spinal neurostimulator lead(s)

Add code also note Code also any insertion of neurostimulator pulse generator (86.94- 86.96)

Revise code title 04.92 Implantation or replacement of peripheral neurostimulator lead(s)

Add code also note Code also any insertion of neurostimulator pulse generator (86.94-86.96)

Removal

Revise code title 01.22 Removal of intracranial neurostimulator lead(s)

Add code also note Code also any removal of neurostimulator pulse generator (86.05)

Revise code title 03.94 Removal of spinal neurostimulator lead(s)

Add code also note Code also any removal of neurostimulator pulse generator (86.05)

Revise code title 04.93 Removal of peripheral neurostimulator lead(s)

Add code also note Code also any removal of neurostimulator pulse generator (86.05)

CMS Recommendation:

Option 2. Create three new codes for insertion of neurostimulator pulse generators and to redefine the existing neurostimulator codes for insertion and removal of leads only as stated above.

In the interim, continue to code these procedures according to coding guidance.

Heart Assist Systems – the Next Generation
Axial Flow Left Ventricular Assist Device (LVAD)

Issue:
This topic is being discussed today because of the advances being made in heart assist devices. We will discuss the most appropriate way to capture, via ICD-9-CM code(s), insertion of such devices. We need to keep in mind that we must be able to distinguish these devices from each other in the source document. Additionally, we need to evaluate the need for a single code vs. multiple, more specific codes, and consider the needs of researchers and the data community.

Background:
When the Ninth Revision of ICD-9-CM was adopted for use in 1979, it contained the following codes at 37.6, Implantation of heart assist system:

37.61, Implant of pulsation balloon
37.62, Implant of other heart assist system
37.63, Replacement and repair of heart assist system
37.64, Removal of heart assist system.

Since the creation of these codes in 1979, giant strides have been made in the development of cardiac devices. A ventricular assist device (VAD), also known as a left ventricular assist device (LVAD), is used to assist a damaged or weakened heart in pumping blood. The timeframe surrounding LVAD insertion can be as short as *post-cardiotomy* for the period following open heart surgery, to the most current application, *destination therapy*, where the LVAD is permanently inserted and takes over the function of the damaged heart, thereby sustaining life. In light of the technological developments concerning LVADs, this committee reviewed the existing codes in 1994, found them not quite specific enough, and suggested the addition of two more codes to describe the most current technology at that time. The following codes were created for use beginning October 1, 1995:

37.65, Implant of external, pulsatile heart assist system
37.66, Implant of implantable, pulsatile heart assist system.

Along with these two new codes came "Notes" describing these devices for coders to assist coding accuracy.

Today we're discussing the next generation of heart assist devices, the DeBakey VAD™ axial flow heart assist system. This device weighs less than 4 ounces and measures 30 mm by 76 mm, and is approximately 1/10th the size of the LVADs currently in commercial use. Its size makes it ideal for use in a broad population, especially people whose bodies cannot accommodate the larger VADs. The smaller size of the axial flow pump requires less surgical dissection and a smaller pump pocket, but is also implanted by open procedure through a median sternotomy and requires cardiopulmonary bypass, similar to the surgical procedure for traditional pulsatile devices.

This device is a miniaturized axial flow device that pumps blood from the left ventricle through a titanium inflow cannula inserted into the heart's apex. After passing through the pump, blood flows back to the body through a Dacron outflow graft sewn to the ascending aorta. The simple pump has only one moving part called the inducer-impeller. Magnets sealed in the blades of the inducer-impeller work with the motor to cause the inducer-impeller to spin between 7,500 and 12,500 rpm. The device is capable of providing blood flow in excess of 10 liters/minute. The pump is driven by a direct current (DC) motor, and is connected to the controller via a percutaneous cable that is passed through the skin just above the right iliac crest. The controller is designed to operate the pump and is primarily powered by two 12-volt DC batteries. The controller, batteries, and VADPAK carrying case weigh less than five pounds, providing untethered mobility for the patient

There are some fine points, semantically, concerning these devices that we need to be aware of. The "pulsatile" device described by code 37.66, above, pumps blood with an oscillating pusher plate (i.e., positive displacement). The axial flow technology, using a rotary pump, moves the blood through the body with a spinning impeller, and has a centrifugal component. However, strong arguments could be made that both of these systems, and the future generations which are now in development, could be described as "pulsatile" because they accommodate the transfer of native pulsation by augmenting the patient's own pulse – resulting in a pulsatile flow.

Coding Options:
Option 1:
Do not create new codes to describe these VADs or LVADs, as adequate coding already exists, and existing space in the current ICD-9-CM procedure book is limited. Instead, put all implantable long term VADs connected directly to the heart into the same code and change the code title to a more generic description that will accommodate future generation of VADs. Add inclusion notes under code 37.66 reflecting the types of VADs that the coders could expect to be assigned to this code.

37.6, Implantation of heart assist system

37.62, Implant of other heart assist system

revise term	Insertion of non-implantable, ~~centrifugal pump~~ heart assist system
delete term	~~Insertion of heart assist system, not specified as pulsatile~~
add term	Temporary heart assist system

revise code	37.63, ~~Replacement and r~~Repair of heart assist system
add term	Replacement of parts of an existing ventricular assist device (VAD)

Replacement of an entire existing system should be removed from 37.63, as replacement of an existing system is actually an implant of a new system. Explantation is not coded separately when a system is replaced, but is considered an integral part of the replacement procedure. Explantation is, however, coded separately for explantation alone, or with heart transplantation. Additions would be made to the Index showing that Replacement, heart assist system, should be assigned to the specific type of system implanted, such as 37.53, Replacement or repair of thoracic unit of total replacement heart system, and 37.54, Replacement or repair of other implantable component of total replacement heart system. Excludes notes at these 37.53, 37.54, and 37.63 would have to be revised as well.

revise code	37.66, Implant of implantable~~, pulsatile~~ heart assist system
add term	Axial flow heart assist system
add term	Left ventricular assist device (LVAD)
add term	Pulsatile heart assist system
add term	Right ventricular assist device (RVAD)
add term	Ventricular assist device (VAD)

Option 2:
Create a new code describing the axial flow heart assist system. There is room available in this category despite the paucity of available codes in ICD-9-CM overall. A unique code would simplify tracking of this type of device for outcomes follow-up, without reference to the source document.

37.6, Implantation of heart assist system

37.62, Implant of other heart assist system

revise term	Insertion of non-implantable, ~~centrifugal pump~~ heart assist system
delete term	~~Insertion of heart assist system, not specified as pulsatile~~
add term	Temporary heart assist system

revise code	37.63, ~~Replacement and r~~Repair of heart assist system
add term	Replacement of parts of an existing ventricular assist device (VAD)

new code	37.68, Implant of implantable axial flow heart assist system

Recommendation:
CMS is leaning toward Option 1, as it is our understanding from the industry that the source document will adequately describe which device was implanted. There will also be a national registry of these devices for the use of those who

gather data. CMS invites the public to advise the C&M committee on the most appropriate way of classifying these LVAD systems.
To be considered:

- It is not the role of the procedure code to determine the end use of a product. Whether this particular device is implanted as a bridge-to-transplant or as destination therapy is not appropriately described by the procedure code.
- Will the source document (medical record) be documented in such a way that a coder will be able to determine (possibly without the operative report) what type of device was implanted – pulsatile, axial flow, or a later generation of VAD?
- What is the most appropriate way of describing this category of devices so that coding accuracy can be assured? What, if any, additional inclusion terms are needed?
- The implementation of ICD-10-PCS in the not-so-distant future is a distinct possibility. Should we begin now to be as specific in ICD-9-CM as we will be able to be in ICD-10-PCS by assigning unique codes for each device?
- As the DeBakey generation of VAD is a miniature size and low weight, and is potentially a candidate for minimally invasive implantation versus an open procedure, should a code be created reflecting the minimally invasive approach? (We understand from one source that no minimally invasive approach will be available in the near future, but this option has been mentioned on one hospital's web page.)

Interim Coding:
Use the following code to describe all LVADs: 37.66, Implant of implantable, pulsatile heart assist system, to describe LVADs that are being used for both bridge-to-transplant and destination therapy, as well as to describe axial flow devices. The American Hospital Association's publication *Coding Clinic for ICD-9-CM* will publish instructions on this advice in their Fourth Quarter 2003 issue.

Coronary Intravascular Ultrasound (IVUS)

Issue:
Intravascular ultrasound (IVUS) is currently assigned to code 88.72, diagnostic ultrasound of heart. However, IVUS differs from other procedures captured by this code, such as echocardiography. As it is a distinct procedure, should a unique code be assigned?

Background:
IVUS is a diagnostic adjunct to therapeutic coronary artery procedures. To perform intravascular ultrasound, a catheter with a special transducer at the tip is introduced into the coronary arteries. Unlike conventional angiography, the IVUS catheter-transducer set enables imaging of the inside of the coronary artery *from* the inside of the coronary artery. This produces images of great clarity and detail, identifying the length of the lesion, its type (e.g. calcified, arteriosclerosis, thrombosis), the precise degree of occlusion, and other key features. Based on this information, the physician engages in real-time decision-making about the options for treating the lesion, such as PTCA or stenting, and then goes on to perform the therapeutically appropriate procedure. After the intervention, IVUS is again performed to assess the outcome of the procedure, such as determining if the stent covers the full length of the lesion, checking for intra-operative dissection and other complications, and identifying the likelihood of re-stenosis based on cross-sectional area.

Conventional ultrasound of the heart, echocardiography, also coded to 88.72, focuses on the structure of the heart's chambers rather than on the tissue structure and lesion characteristics of the coronary arteries. Conventional ultrasound is an external non-invasive procedure in which ultrasound waves move through the chest wall and back out. In contrast, IVUS is an invasive procedure that takes place internally from within the coronary artery.

IVUS shares some features with 37.28, Intracardiac echocardiography (ICE). Both are invasive procedures and use transducer-tipped catheters to create ultrasound images from within heart structures. Both can provide real-time visualization of the surgical instruments while procedures are being performed. The key distinction is that ICE catheters are placed in the chambers of the heart while IVUS catheters are positioned within the coronary arteries. The indications are different as well. ICE is generally used for arrhythmia ablation and with other minimally invasive heart valve and septum procedures. IVUS is used with PTCA, stenting, atherectomy and other interventions for atherosclerosis and other obstructions.

Because of its unique role as a therapeutic adjunct, IVUS has had a dramatic effect on treatment patterns for coronary artery disease and continues to revolutionize the treatment of these lesions. However, because it is currently coded to the same code as conventional ultrasound of the heart, it is not possible

to track the use of IVUS in coronary artery procedures to evaluate its function and effectiveness in therapeutic decision-making. It is also not possible to track its role in the development of treatment guidelines for prophylactic intervention on high-risk patients built on an understanding of cardiovascular tissue characterization.

Discussion: Does this adjunct to a therapeutic intervention warrant a unique code for data collection purposes? Will this technique ultimately be used in vessels other than cardiac? Should provision be made for that contingency now, or should we wait several years for the adoption of ICD-10-PCS?

Coding Options:

Option 1:

Do not create a new code for this therapeutic intervention. Continue to code this adjunct procedure to 88.72, Diagnostic ultrasound of heart, recognizing that non-invasive echocardiography is also included in this code.

Option 2:

Revise the definition of code 37.28 to include both ICE and IVUS. This revision will allow IVUS to be captured without creating a new code, based on its similarities to ICE.

37 Other Operations on Heart and Pericardium
37.2 Diagnostic Procedures on Heart and Pericardium

revise title	37.28	Transcatheter ultrasound of heart and heart vessels
add term		Intravascular ultrasound of coronary arteries (IVUS)
revise term		Intracardiac echocardiography (ICE)
	88.72	Diagnostic ultrasound of heart
		Echocardiography
delete term		~~Intravascular ultrasound of heart~~

Option 3:

Create a new code in subcategory 88.7, Diagnostic Ultrasound. This option allows unique data collection without referencing the source document.

88 Other Diagnostic Radiology and Related Techniques
88.7 Diagnostic Ultrasound

new code	88.70	Intravascular ultrasound of (coronary) arteries
		IVUS
		Code also any synchronous therapeutic procedures

88.72 Diagnostic ultrasound of heart
Echocardiography
delete term ~~Intravascular ultrasound of heart~~

Option 4:
Create a new code in subcategory 36.9, Other Operations on Vessels of Heart This option will allow IVUS to be captured with a code that is accurately classified with other procedures on vessels of the heart. As with the creation of 37.28 for ICE, it also recognizes the invasive nature of IVUS as distinct from conventional ultrasound of the heart.

36 Operations on Vessels of Heart
36.9 Other Operations Vessels of Heart

new code 36.92 Intravascular ultrasound of coronary arteries
IVUS

Code also any:
Coronary angiography (88.50 –88.58)
Percutaneous transluminal coronary artery angioplasty or atherectomy (36.01, 36.02, 36.05)
Intracoronary artery thrombolytic infusion (36.04)
Intravascular brachytherapy (92.27)

Option 5:
Create a new subcategory 00.2, Intravascular arterial imaging, and create new codes describing this diagnostic technique. This technique can be used to visualize a number of different arteries throughout the body, not just the coronary arteries. The technology (intravascular catheter) and clinical applications (imaging of the arterial system) are more closely related to “arteriography” than “diagnostic ultrasound” code categories. Unfortunately, there is a lack of space in the 88.xx section of the procedure book, so grouping these similar diagnostic techniques logically is not possible.

New subcategory
00.2 Intravascular arterial imaging
Endovascular ultrasonography
Intravascular ultrasound
IVUS

new code 00.21 Intravascular arterial imaging of extracranial cerebral arteries
Common carotid arteries and branches
Excludes: Diagnostic ultrasound of head and neck (88.71)

new code 00.22 Intravascular arterial imaging of aorta and aortic arch
Excludes: Diagnostic ultrasound of other sites of thorax (88.73)

new code 00.23 Intravascular arterial imaging of peripheral arteries
Imaging of:
Arteries of arm(s)
Arteries of leg(s)
Excludes: Diagnostic ultrasound of peripheral vascular system (88.77)

new code 00.24 Intravascular arterial imaging of coronary arteries
Excludes: Diagnostic ultrasound of heart (88.72)

new code 00.28 Intravascular arterial imaging, other specified site

new code 00.29 Intravascular arterial imaging, unspecified site

88.72 Diagnostic ultrasound of heart
Echocardiography
Delete term ~~Intravascular ultrasound of heart~~

Recommendation:
CMS has reviewed the cardiovascular chapter, and looked at the suggestion for creation of a new code at subcategory 36.9, Other operations on vessels of heart. However, we believe that IVUS, or endovascular ultrasonography, is an adjunct diagnostic procedure, not an operation in and of itself. Therefore, we recommend Option 5, as laid out above.

Interim Coding:
Continue to code coronary intravascular ultrasound (IVUS) to existing code 88.72, Diagnostic ultrasound of heart.

Pressurized Treatment of Venous Bypass Graft with Pharmaceutical Substance for the Prevention of Vein Graft Failure

Issue:
There is no specific code that captures the chemical treatment of a vein graft prior to coronary and peripheral artery bypass surgery. Should a code be created to identify this extra step in the operative procedure?

Background:
E2F Decoy (CGT003) is a drug-device treatment that has been developed to prevent neointimal hyperplasia and subsequent graft failure in autogenous vein grafts in coronary (CABG) and peripheral artery bypass patients. Inhibition of neointimal hyperplasia should prevent the accelerated atherosclerosis that typically occurs in vein grafts after they become transplanted into the arterial circulation. Currently, 50% of all vein grafts fail within 10-15 years after coronary bypass and within 5 years after peripheral bypass surgery, but treatment with E2F Decoy should prolong the functional life of the graft.

E2F Decoy consists of a short stretch of double-stranded DNA that is recognized by the E2F transcription factor, which is responsible for expression of multiple genes that facilitate cell division. Inhibition of this transcription factor by E2F Decoy effectively shuts down cell division in vascular smooth muscle cells, preventing the formation of neointima that is responsible for accelerated atherosclerosis and loss of graft patency over time.

The vein graft is treated with E2F Decoy by the surgeon during the coronary and peripheral artery bypass graft surgery. It involves the preparation of the vein post-harvesting, device set-up, entering the vein into the vein trough and hyperbaric chamber, pressurizing the system to treat the vein, and additional preparation of the vein for bypass surgery. The surgeon first needs to select the proper vein that will fit the CPDS. Delivery of E2F Decoy to the vein graft is performed after it is excised or harvested from the patient but before it is implanted onto the arteries using the Corgentech Pressure-mediated Delivery System (CPDS). The CPDS is comprised of the pressure system, a hyperbaric chamber, a vein trough, and other components that have been specially designed to fit the E2F Decoy treatment and require assembly at the time of treatment. The entire system is specially designed to apply non-distending pressure to the vein graft in order for the drug to penetrate the cell nucleus and at the same time ensure its integrity.

The harvested vein is fixed to the cannula and placed in the appropriate length of vein trough. Depending on the vein anatomy, either the suture or non-suture technique is used to keep the vein in its elongated position within the trough. The trough with the vein is inserted into the hyperbaric chamber, which in turn is connected to the CPDS. The pressure system is set up and primed with E2F Decoy drug solution. Drug flows through the cannula and the lumen of the vein,

to the top of the vein and then around the sides of the vein filling the hyperbaric chamber completely. It is important to minimize air bubbles in the CPDS system, since they can limit delivery of the drug if they prevent contact of the drug solution to the vein. The air pocket in the distal end must be removed before the system is sealed. The pressure system is then turned on and changed to read in pounds per square inch (psi). After removal of the vein from the hyperbaric chamber it is treated with the drug at a pressure of 6 psi for 10 minutes. The treated vein is flushed with heparinized solution to remove any excess drug from the lumen and outside of the vein. The vein is now ready for use in the bypass procedure.

E2F Decoy is not administered to the patient systemically either through infusion or injection methods, but comprises additional steps or processes in the coronary and peripheral artery bypass graft surgery. This requires specialized handling of the tissue, proprietary equipment, specialized training for proficiency, and time. Further, unlike the drugs in the existing ICD-9-CM code 99.20 (Injection or infusion of platelet inhibitor), it is administered ex-vivo to the vein graft during a surgical procedure.

Coding Options:

Option 1:

Do not create a new code. Manipulation of a harvested vessel prior to the coronary artery bypass graft surgery can be considered inherent in the procedure.

Option 2:

Use of this treatment causes additional steps in the coronary artery bypass graft procedure. It requires specialized handling of the tissue, proprietary equipment, and specialized training for proficiency. As there is additional time and expense involved with adding this step to the bypass procedure, a new code should be created as follows:

	00.1	Pharmaceuticals
new code		00.16 Pressurized Treatment of Venous Bypass Graft with Pharmaceutical Substance

Recommendation:

CMS invites the public to advise the C&M committee on the most appropriate way of identifying this step in the operative procedure. If it should be given a unique code, is the suggestion in Option 2 acceptable?

Interim Coding:

There is no code describing this drug and graft treatment. Do not code.

Unrelated Allogeneic Bone Marrow Transplantation

Issue: Should procedure codes be created to distinguish between related and unrelated donors for allogeneic bone marrow transplantation (BMT)?

Background:
There are currently four ICD-9-CM codes for allogeneic bone marrow transplants (BMT) that do not differentiate between related and unrelated donors. Unrelated allogeneic BMT is a relatively new procedure that has extensive procurement costs and higher length of stay (LOS) than related donor procedures. An unrelated stem cell transplant of either bone marrow, peripheral blood, or cord blood, is associated with significantly higher costs secondary to the following:

1. Acquisition of donor cells, approximate costs of 20-30,000[i]
2. Intended length of stay 12-25 days[ii]
3. Increased use of costly immunosuppressive drugs
4. Higher incidence of serious Graft vs. Host Disease (GVHD)[iii]
5. Higher incidence of serious infections
6. More and prolonged expensive supportive care drugs (i.e. Antibodies)
7. Increased ICU admissions and stays.

Although outcomes may vary somewhat, the actual procedure (allogeneic BMT or stem cell transplant) is basically the same, regardless of donor source.

Options:

1. We do not feel this warrants a new series of procedure codes. The actual procedure is the same, regardless of donor source. We do not distinguish between related and unrelated donor in other transplants.

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[i] Mishra, V. Vaaler, S. and Brinch L. A Prospective Cost Evaluation Related to Allogeneic Haemopoietic Stem Cell Transplantation Including Pretransplant Procedures, Transplantation and 1 Year Follow-Up Procedures. Bone Marrow Transplantation, 2001; 28, 1111-1116

[ii] Agthovan et al. Cost analysis of HLA-identical Sibling and Voluntary Unrelated Allogeneic Bone Marrow and Peripheral Blood Stem Cell Transplantation in Adults with Acute Myelocytic Leukaemia or Acute Lymphoblastic Leukaemia. Bone Marrow Transplantation, 2002; 30 243-251

[iii] Alyea et al. Comparable Outcome with T-Cell-Depleted Unrelated-Donor versus Related-Donor Allogeneic Bone Marrow Transplantation. Biology of Blood and Marrow Transplantation, 2002; 8, 601-607

2. Create new codes to capture related and unrelated BMT. If we create codes for stem cell and bone marrow transplantations, we should be consistent across all transplanted organs such as: kidney, pancreas, liver, intestine, heart, and lung.

Revise code title 41.02 Related donor allogeneic bone marrow transplant with purging

Add exclusion term Excludes: unrelated donor allogeneic bone marrow transplant with purging (41.61)

Revise code title 41.03 Related donor allogeneic bone marrow transplant without purging

Add exclusion term Excludes: that with purging (41.02,41.61) unrelated donor allogeneic bone marrow transplant without purging (41.62)

Revise code title 41.05 Related donor allogeneic hematopoietic stem cell transplant without purging

Add exclusion term Excludes: unrelated donor allogeneic hematopoietic stem cell transplant without purging (41.63)

Revise code title 41.06 Related donor cord blood stem cell transplant

Add exclusion term Excludes: unrelated donor cord blood stem cell transplant (41.64)

Revise code title 41.08 Related donor allogeneic hematopoietic stem cell transplant with purging

Add exclusion term Excludes: unrelated donor allogeneic hematopoietic stem cell transplant with purging (41.65)

New category 41.6 Unrelated donor bone marrow and stem cell transplantation

New code 41.61 Unrelated donor allogeneic bone marrow transplant with purging

Allograft of bone marrow with in vitro removal (purging) of T-cells

Excludes: related donor allogeneic bone marrow transplant with purging (41.02)

New code 41.62 Unrelated donor allogeneic bone marrow transplant without purging
Allograft of bone marrow NOS
Excludes: that with purging (41.02,41.61)
related donor allogeneic bone marrow transplant without purging (41.03)

New code 41.63 Unrelated donor allogeneic hematopoietic stem cell transplant without purging
Excludes: that with purging (41.08, 41.65)
related donor allogeneic hematopoietic stem cell transplant without purging (41.05)

New code 41.64 Unrelated donor cord blood stem cell transplant
Excludes: related donor cord blood stem cell transplant (41.06)

New code 41.65 Unrelated donor allogeneic hematopoietic stem cell transplant with purging
Excludes: related donor allogeneic hematopoietic stem cell transplant with purging (41.08)

CMS' Recommendation:

Option 1**.** We do not feel this warrants a new series of procedure codes. The actual procedure is the same, regardless of donor source.

In the interim, continue to assign appropriate codes for bone marrow and stem cell transplantation.

Proposed Addenda
FY 2005

Index

Add term Discectomy – *see also* Diskectomy

Therapy
respiratory NEC 93.99
Add subterm non-invasive positive pressure (NIPPV) 93.90

Ventilation
Add subterm non-invasive positive pressure (NIPPV) 93.90

Tabular List

Revise code title 36.11 (Aorto)coronary bypass of one coronary artery

Revise code title 36.12 (Aorto)coronary bypass of two coronary arteries

Revise code title 36.13 (Aorto)coronary bypass of three coronary arteries

Revise code title 36.14 (Aorto)coronary bypass of four or more coronary arteries

93.90 Continuous positive airway pressure [CPAP]
Add inclusion term Bi-level airway pressure
Add inclusion term Non-invasive positive pressure (NIPPV) 93.90

96.7 Other continuous mechanical ventilation
Excludes:
Add exclusion term non-invasive positive pressure (NIPPV) 93.90