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 6, 2002

December 6, 2002 - Procedures Discussions

Introduction and Overview

Pat Brooks welcomed the participants to the ICD-9-CM Coordination and Maintenance (C&M) Committee meeting. The first day of the meeting, December 5, 2002 had been cancelled because of inclement weather. Both the diagnosis and procedure part of the meeting were held on December 6, 2002. There were about 70 participants who attended the meeting. All participants introduced themselves. 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**.

As this is strictly a coding meeting, no discussion is held concerning DRG assignment or reimbursement issues. After the meeting, a summary of the procedure part of the meeting is posted on the home pages of CMS. The diagnosis part of the meeting is conducted by the National Center for Health Statistics (NCHS). NCHS posts a summary of the diagnosis part of the meeting on their home page.

We encourage the public to submit written comments by mail or e-mail concerning issues raised at the meeting. The deadline for these comments is January 10, 2003 for proposed procedure code revisions. Proposed procedure code revisions are under consideration to be included in the October 1, 2003 addendum.

Copies of the timeline were presented to participants. This timeline discusses important events relating to the updating of ICD-9-CM. The next C&M meeting will be held on April 3-4, 2003. Suggestions for the agenda must be received by February 3, 2003.

1. Total Replacement Heart

Ed Berger, Abiomed ,Inc., Danvers, MA provided a clinical description of the procedure. Amy Gruber then led a discussion on the coding proposal to create three new codes to capture

procedures associated with the total replacement heart under proposed new category 37.5, Heart replacement procedures. One participant expressed concern with the use of "total" when in fact it is not a total replacement of the heart. It was pointed out that "total" in this context means total functionality of the heart. Another participant questioned when this device will receive FDA approval. It is anticipated FDA approval in 2004.

There were two comments regarding proposed new code 37.54, Replacement or repair of implantable component or components of total replacement heart system, excluding thoracic unit. One commenter suggested that the title be: Replacement or repair of non-thoracic component of total replacement heart system as proposed new code 37.53, Replacement or repair of thoracic unit of total replacement heart system, captures the thoracic unit. Another commenter believes that we should not limit replacement or repair codes to total replacement heart system due to advancing technology.

2. Multi-level Spinal Fusion

Pat Brooks led this discussion on multi-level spinal fusion. She mentioned that a number of options had been discussed at the April 18, 2002 C&M meeting. There was no consensus on how to capture this information. Many wrote in to suggest caution and to recommend additional means of capturing this information. Pat acknowledged the efforts of Sue Prophet Bowman, AHIMA and Linda Holtzman in developing the current proposal.

The proposal keeps the existing fusion codes as they are. It adds a series of codes that show a range of vertebrae that are fused. The audience supported this new proposal and called it "simple but elegant."

3. High-Dose Interleukin-2 (IL-2) Therapy

Ann Fagan led the discussion on this topic which was previously discussed at the November 2001 C&M meeting. Some participants expressed concern about creating codes which differentiates whether or not it is a high dose infusion. One person stated that coders could have difficulty correctly identifying these cases.

4. Injection or Infusion of Therapeutic Radioimmunoconjugates

Ann Fagan led the discussion on this topic. Some participants suggested that a code might not be necessary if this were an outpatient treatment.

5. Laparoscopic/Thoracoscopic Approaches

Ann Fagan led the discussion on this topic. This was part of a continuing effort to identify and differentiate procedures that may be performed using a scope. Ann plans to bring additional recommendations of this type to future C&M meetings. There was support for the creation of the proposed codes.

6. Addenda

Amy Gruber led a discussion on the proposed addenda. There was general support for all the recommendations. One participant inquired about the proposed index entry :

Evaluation (of)
Add subterm device
Add subterm implantable automatic cardioverter/defibrillator (bedside
Add subterm device check) – omit code

if non-invasive programmed electrical stimulation (NIPS) currently included under code 37.26, Cardiac electrophysiologic stimulation and recording studies, is subject to this instruction as well. CMS will investigate this inquiry.

7. ICD-10-PCS Update

Pat Brooks discussed ICD-10-PCS and why no progress has been made to implement the coding system. She discussed the annual updates and revisions to the system that will be posted by the end of the year. She also went through an extensive summary of activities involving the creation, testing, and updating of ICD-10-PCS and the National Committee for Vital and Health Statistics (NCVHS) (See attachment – NCVHS and ICD-10-PCS Timeline). The NCVHS has not been able to make any recommendations on replacing ICD-9-CM. To illustrate some of the competing views on replacing the procedure part of ICD-9-CM ICD-10-PCS, Pat discussed the letters (attached) from AHA, FAH, and AdvaMED as well as the letter from the AMA's physician specialty groups.

Members of the audience expressed frustration that a recommendation to move to ICD-10-PCS had not been forth coming from the NCVHS. The staff from CMS and NCHS are beginning to draft language for a Notice of Proposed Rulemaking which would propose ICD-10-CM and ICD-10-PCS. This is being done in hope that the NCVHS will be able to make a recommendation by mid 2003. The draft language would then be useful.

This concluded the procedure part of the meeting. For a summary report on the diagnosis part of the meeting, go to:

www.cdc.gov/nchs/icd9.htm

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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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 5-6, 2002

Patricia E. Brooks
Co-Chairperson
December 5, 2002

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

Topics:

1. Total Replacement Heart

   Amy L. Gruber
   Robert Dowling, M.D.
   Rudd Heart and Lung Center
   Louisville, Kentucky

2. Multi-level Spinal Fusion

   Patricia E. Brooks

3. High-Dose Interleukin-2 (IL-2) Therapy

   Ann B. Fagan
   Bryan Walser, MD
   Chiron Corporation

4. Injection or Infusion of Therapeutic Radioimmunoconjugates

   Ann B. Fagan
   Catherine M. Russell, BS, CNMT
   Corixa Corporation

5. Laparoscopic/Thoracoscopic Approaches
Ann B. Fagan

6. Addenda
Amy L. Gruber

7. ICD-10 Procedure Classification System (PCS) - Update
Patricia E. Brooks

ICD-9-CM Volume 3, Procedures Coding Issues:
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Amy Gruber (410) 786-1542 email: agruber@cms.hhs.gov

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, 2002	Hospital Inpatient Prospective Payment System final rule 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 18, 2002 meeting and resolved in time for implementation on October 1, 2002. This rule can be accessed at: http://www.cms.hhs.gov/regulations/
October 1, 2002	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
Nov. 19-20, 2002	National Committee on Vital and Health Statistics, Subcommittee on Standards and Security - Hearing on HIPAA Code Set Issues. A discussion was held on whether or not ICD-10-PCS should be named a national standard. Information on this meeting can be found at: http://www.ncvhs.hhs.gov/
Dec. 6, 2002	ICD-9-CM Coordination and Maintenance Committee Meeting. Code revisions discussed are for potential implementation on October 1, 2003. December 5 was to have been devoted to discussions of procedure codes; however, a snowstorm led to the cancellation of the first day's meeting. December 6 was devoted to discussions of both diagnosis and procedure codes.
December 2002	Summary report of the Procedure part of the December 6, 2002 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 6, 2002 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 10, 2003	Deadline for receipt of public comments on proposed code revisions discussed at the April 18 - 19, 2002 and December 5-6, 2002 ICD-9-CM Coordination and Maintenance Committee meetings. These proposals are being considered for implementation on October 1, 2003.

February 3, 2003	Those members of the public requesting that topics be discussed at the April 3-4, 2003 ICD-9-CM Coordination and Maintenance Committee meeting should have their requests to CMS for procedures and NCHS for diagnoses.
April 2003	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 which were discussed at the meetings held on April 18-19, 2002 and December 5-6, 2002. 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 3-4, 2003 meeting and that might also be included in the October 1, 2003 addendum. The proposed rule can be accessed at: http://www.cms.hhs.gov/regulations/
April 3-4, 2003	ICD-9-CM Coordination and Maintenance Committee Meeting in CMS's auditorium. Diagnosis code revisions discussed are for potential implementation on October 1, 2004. Procedure code revisions may be for October 1, 2003 if they can be resolved quickly and finalized by April 30, 2003. Those procedure code proposals that cannot be resolved quickly will be considered for implementation on October 1, 2004.
June 2003	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, 2003	Hospital Inpatient Prospective Payment System final rule to be published in the Federal Register as mandated by Public Law 99-509. This will include all code titles included in the proposed notice as well as any other procedure code titles that were discussed at the April 3-4, 2003 meeting and resolved in time for implementation on October 1, 2003. This rule can be accessed at: http://www.cms.hhs.gov/regulations/
October 4, 2003	Those members of the public requesting that topics be discussed at the December 5-6, 2002 ICD-9-CM Coordination and Maintenance Committee meeting should have their requests to CMS for procedures and NCHS for diagnoses.
November 2003	Tentative agenda for the Procedure part of the December 4, 2003 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 December 5, 2003 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 December 4-5, 2003 ICD-9-CM Coordination and Maintenance Committee Meeting to be published. This will include the tentative agenda.

Dec. 4-5, 2003 — ICD-9-CM Coordination and Maintenance Committee Meeting. Code revisions discussed are for potential implementation on October 1, 2004. December 5 will be devoted to discussions of procedure codes. December 6 will be devoted to discussions of diagnosis codes.

Total Replacement Heart System

Issue:
Should new ICD-9-CM procedure codes be created to capture procedures associated with the total replacement heart?

Background:
Replacement heart patients hail from any end stage heart failure diagnoses. The patient's heart failure can originate from coronary heart disease, valvular disease, congenital disease, or from congestive heart failure conditions. The heart disease can be chronic or acute.

A patient that is a candidate for a replacement heart system is either in Class IV Heart Failure (New York Heart Association Functional Classification) or has an acutely failing heart not treatable by other medical means. Class IV patients are unable to carry on any physical activity without symptoms. Symptoms are present even at rest, and if any physical activity is undertaken, symptoms increase. Terminal acute heart failure patients do not recover due to irreversible heart muscle damage.

Symptoms of heart failure would be shortness of breath, easy fatigability, edema, orthopnea, paroxysmal nocturnal dyspnea, jugular venous distention, or rales.

In January 2001, the Food and Drug Administration (FDA) approved ABIOMED, Inc. to conduct a clinical trial of the AbioCor Replacement Heart. Fifteen patients are to be implanted with the AbioCor, with submission of patient information and FDA interim review after each five patients. There are six FDA approved clinical trial teams:

- ♥ Jewish Hospital, Louisville, Kentucky
- ♥ Texas Heart/ St. Luke's Episcopal Hospital, Houston, Texas
- ♥ Hahnemann University Hospital, Philadelphia, Pennsylvania
- ♥ University of California, Los Angeles (UCLA), Los Angeles, California
- ♥ University Medical Center, Tucson, Arizona
- ♥ Massachusetts General/Brigham & Women's Hospital, Boston, Massachusetts

The initial goals of the AbioCor clinical trial are:

- To determine whether a first generation AbioCor can extend a patient's life, with an acceptable quality of life, for those patients with less than 30 days to live, and no other therapeutic alternative.
- To learn what we need to know in order to deliver the next generation AbioCor, for the treatment of less sick patients, for gradually longer, higher quality, lives.

Three quality of life assessment tools are being used during the clinical trial. The AbioCor trial is using the Minnesota Living with Heart Failure Questionnaire, Short Form 36 Health Survey, and the Missoula – VITAS Hospice Questionnaire. Patients are evaluated 2 months after surgery and every 30 days there after. Several clinical trial benchmarks are mortality at 60 days, quality of life measurements and repeat quality of life assessments at 30-day intervals until the patient passes away.

At this time, seven patients have been implanted with the AbioCor replacement heart. Two patients did not survive the first 24 hours. Four patients lived a duration of 1.8 months, 4.8 months, 5.0 months and 9.4 months. The last patient is alive and living at home with the AbioCor replacement heart at 12.8 months as of October 4, 2002.

Eight more patients will be enrolled in the initial AbioCor clinical trial under the current Investigational Device Exemption (IDE). Clinical trial centers are continuously screening for patients. The number of AbioCor implants will increase significantly in the next year and the manufacturer had deemed it would be appropriate to have codes to recognize and identify these procedures prior to commercialization.

Clinical criteria and AbioFit™

To determine the clinical and anatomic candidacy of potential AbioCor™ replacement heart patients a number of tools are used, one of which is a proprietary computer program developed by ABIOMED.

At this time, in order to be considered a candidate for the AbioCor replacement heart the patient must not be a candidate for a heart transplant. Clinically, a patient must have bi-ventricular heart failure and unstable hemodynamics under inotropic support to be considered for the AbioCor replacement heart.

Currently, the AbioCor thoracic unit will fit in 50% of the U.S. male population and 18% of the U.S. female population. To determine if the AbioCor thoracic unit would fit in a patient that is considering the AbioCor replacement heart, ABIOMED developed the AbioFit™ computer assisted drawing/modeling software tool. From cat-scans and/or MRI's taken of the patient, the AbioFit computer model color codes the patient's existing thoracic organs, spine and rib cage. Computer sizing and removal of the patient's native heart can be carried out and implantation and orientation of the AbioCor is done. From these measurements and virtual tool, it can be anatomically determined whether the AbioCor thoracic unit will fit in the patient being screened. In fact, the AbioFit program and technology allow for a virtual surgery to be done. This mock computer surgery has been utilized by some AbioCor surgeons in preparation for individual AbioCor implants.

Listed below are the three procedures related to total replacement heart:

Implantation of Replacement Heart System

Induction of anesthesia and median sternotomy is performed. Pockets for the implanted transcutaneous energy transfer (TET) coil, the implanted battery, and the implanted controller are created before administering heparin. Simultaneous with the creation of these pockets, preparations are made for cardiopulmonary bypass (CPB).

Depending on the patient's anatomy, the battery and controller are implanted anterior to the posterior rectus sheath of the rectus abdominis muscle, and just below the ribs. The TET pocket in most patients is implanted below the fat layer anterior to the pectoral muscle fascia. Alternative sites may be used governed by patient anatomy. Plastic replica molds of the implantable components are used while assuring proper pocket size and location, before the

actual implantable TET, implantable controller and implantable battery are set in. The implantable TET is set in place with the corresponding connecting cable tunneled for connection to the controller.

Following proper heparinization, the patient is placed on cardiopulmonary bypass. The native heart is exposed with care to avoid injury to the phrenic nerves. Ventriculectomy is performed by resecting the ventricles on the ventricular side of the valvular annuli. The aorta and pulmonary artery is transected just distal to their respective valves. A Millar™ catheter is placed through the wall of the left atrium using suturing techniques that permit catheter removal post-recovery.

In preparation for implantation of the replacement heart, trimming is performed so that adequate left atrial (LA) and right atrial (RA) tissue remains for attaching the dacron inflow cuffs. The two inflow cuffs are trimmed such that they are well-aligned with the atrial remnants and the thoracic unit inflow tracts. Before proceeding, an inspection for patent foramen ovale (PFO) is performed. Any size PFO is oversewn, because of the alternating right-left systole of the replacement heart device. An inspection is made of the coronary sinus to determine whether it should be tied off. Anastomoses of the left and right atrial cuffs are then accomplished with continuous polypropylene suture, butressed with a double layer of PTFE surgical felt. The atria are examined for the presence of excessive atrial appendage tissue, which might potentially invaginate into the inflow tracts of the replacement heart or cause stasis and increase the risk of thromboemboli. Excessive left or right atrial appendage tissue is ligated so as to mitigate such risks.

In order to assess the lengths for the outflow grafts, a plastic mold of the thoracic unit is placed in the chest. After determining the appropriate length for the pulmonary arterial (PA) graft, the PA graft is cut and the thoracic model is removed. The graft is anastomosed to the pulmonary artery using continuous polypropylene suture, butressed with a single layer of PTFE surgical felt. A similar procedure is followed for the aorta graft and ascending aorta anastomoses. The integrity of all anastomoses are ascertained with leak-checking accessories that are provided with the replacement heart.

The replacement heart thoracic unit is next attached in sequence to the left atrium, pulmonary artery, aorta, and right atrium connectors. Tools are provided to facilitate this process. Removal of residual air in the thoracic unit (de-airing) is performed through a sequence of steps. The perfusionist is instructed to ‘fill the heart.’ The tourniquet on the inferior vena cava (IVC) cannula is released, allowing for augmented blood flow to the device when the venous line is partially occluded. The tourniquet around the superior vena cava (SVC) is released and the SVC cannula is clamped to aid filling of the device. The AbioCor console operator begins to ‘toggle’ the thoracic unit pumps of the replacement heart system, left to right and right to left in sequence as commanded by the surgeon. After 3-4 minutes, the SVC cannula is removed, the site is over-sewn, and toggling continues. When adequate volume return to the right atrium is established, the console operator commences operation of the thoracic unit in a beat rate selective mode. Suture lines are assessed, and additional volume may be needed from the heart lung machine. Incrementally the stroke volume is increased, carefully assessing volume status, until ‘full stroke’ is achieved. Left atrial pressure is monitored and if necessary adjustments are made to

the beat rate or balance settings of the replacement heart. Assess blood pumps and sidearms for the presence of air, noting particularly the left side.

The length of time at a beat rate setting is dependent on the presence of air and the volume available in the venous return as observed by the surgeons and as assessed by transesophageal echo. Once the right side is satisfactorily de-aired, the side arm of the pulmonary arterial outflow graft is clamped. The left side of the device continues to be vented via the side arm of the aortic outflow graft. The sidearm of the aortic outflow graft is partially occluded and continues to be vented. Beat rate setting and volume to the right atrium are controlled by the surgeon's commands to insure full de-airing of the left pump. The perfusionist is asked to 'go down on the flow,' and the cross clamp is removed. The left sidearm is then clamped off. The console operator sets the beat rate of the device as directed by the surgeon. Cardiopulmonary bypass is rapidly weaned to approximately 2L/min and then to 'off.'

Pressor medications are titrated, and adjustments of the replacement heart occluder setting and beat rate are made to achieve appropriate hemodynamics. Volume replacement is given as indicated based on filling pressures.

Cardiopulmonary bypass is discontinued. Both the side arms of the outflow grafts are permanently closed using vascular clamps and then tied off close to their origin. Readiness for volume replacement is essential. Constant observation of filling pressures (left atrial pressure (LAP), measured with Millar™) after the discontinuation of bypass is critical to avoid entrainment of air into the device due to inadequate volume status. A central venous line is put in place to continue central venous pressure (CVP) monitoring. Following termination of bypass, the cannulae are removed and protamine sulfate is administered to reverse the heparinization.

Additionally, the surgeon may optionally elect to restrain the thoracic unit in the mediastinum by utilizing #5 stainless steel ligature. The appropriateness of this must be determined in each individual case. TET operation is confirmed. The controller and internal battery are positioned properly in their respective abdominal pockets.

Mediastinal and pleural chest tubes are placed, if indicated, into the right and the left hemithorax and pleural spaces. The sternal and abdominal incisions are closed in consecutive layers. The thoracic unit positioning is assessed using transesophageal echocardiograph (TEE). The chest is closed using sternal wire, and continuous multifilament absorbable sutures for muscle layers, subcutis and skin. Staples may be used to close the skin.

During incision closure, the patient is given decreasing levels of Isoflurane until the patient is completely off anesthetic gas. The patient is brought to the recovery room for post-operative recovery and when stable transferred to the cardiovascular intensive care unit (CVICU). A series of step-down transfers occur during the patient's in-patient hospitalization; each moves closer to discharge-to-home.

Replacement or Repair of Thoracic Unit

Surgical preparation, patient sternotomy, and commencement of cardiopulmonary bypass are all identical to those procedures as carried out in the implantation of the entire replacement heart system. Replacement of the thoracic unit involves, at a minimum, disconnecting and reconnecting the thoracic unit. This process is done with special 'quick-connect' tools developed in conjunction with the cuffs and grafts of the replacement heart. De-airing the device is done as described above in the initial implantation surgery. At the time of replacing or repairing the thoracic unit, it may be necessary to deal with trimming tissue overgrowth. Time and care is taken assessing all suture lines. In some cases, cuffs and grafts may be replaced requiring anastomoses to be performed. Weaning on to the replacement heart and off of cardiopulmonary bypass are done exactly as the procedures described previously, as is chest and suture closure.

Replacement or Repair of Implantable Components (Excluding Thoracic Unit)

These procedures do not require a sternotomy or cardiopulmonary bypass. Replacement or repair of one or more of the implantable components requires blunt dissection of the pocket containing the component and accessing the tunneled cable(s). The implantable component being replaced is by-passed in the system and the function is temporarily taken over by an external controller. The cable or cables of the component being removed is disconnected and the external controller is connected. The component that is being replaced is removed from the patient's body. The replacement component is implanted and the corresponding cable(s) are tunneled and connected to the replacement heart cable system, replacing the external controller the patient used during this procedure. Proper function of the replacement heart system is confirmed and the patient's incision is closed. Replacement or repair of an implantable component(s) is done under general anesthesia.

Options:

1. Continue to code implantation of total replacement heart system to code 37.62, Implant of other heart assist system. In addition, continue to code replacement or repair of total replacement heart system to code 37.63, Replacement and repair of heart assist system.

2. Create three new codes under new category 37.5, Heart replacement procedures:

   New category 37.5 Heart replacement procedures

   New code 37.51 Heart transplantation

   New code 37.52 Implantation of total replacement heart system
   Artificial heart
   Implantation of fully implantable total replacement heart system, including ventriculectomy

Excludes: implantation of heart assist system (37.62, 37.65, 37.66)

New code 37.53 Replacement or repair of thoracic unit of total replacement heart system

Excludes: Replacement and repair of heart assist system (37.63)

New code 37.54 Replacement or repair of implantable component or components of total replacement heart system, excluding thoracic unit

Implantable battery
Implantable controller
Transcutaneous energy transfer (TET) device

Excludes: Replacement and repair of heart assist system (37.63)
Replacement or repair of thoracic unit of total replacement heart system (37.53)

3. Create three new procedure codes under category 00.5, Other cardiovascular procedures. New codes 00.56,00.57 and 00.58 would be utilized to capture these procedures.

CMS Recommendation:

Option 2. Create three new codes under new category 37.5, Heart replacement procedures.

New category 37.5 Heart replacement procedures

New code 37.51 Heart transplantation

New code 37.52 Implantation of total replacement heart system
Artificial heart
Implantation of fully implantable total replacement heart system, including ventriculectomy

Excludes: implantation of heart assist system (37.62, 37.65, 37.66)

New code 37.53 Replacement or repair of thoracic unit of total replacement heart system

Excludes: Replacement and repair of heart assist system (37.63)

New code 37.54 Replacement or repair of implantable component or components of total replacement heart system, excluding thoracic unit

Implantable battery

Implantable controller
Transcutaneous energy transfer (TET) device

Excludes: Replacement and repair of heart assist system (37.63)
Replacement or repair of thoracic unit of total replacement heart system (37.53)

In the interim, continue to code implantation of total replacement heart system to code 37.62, Implant of other heart assist system. Continue to code replacement or repair of total replacement heart system to code 37.63, Replacement and repair of heart assist system.

Multi-Level Spinal Fusion

Issue: Current ICD-9-CM codes for spinal fusion and refusion do not capture the number of discs fused. There is no way to identify patients who have fusion of two discs versus those who have more than two discs fused.

Background: This topic was previously discussed at the April 18-19, 2002 meeting of the ICD-9-CM Coordination and Maintenance Committee. Despite lengthy discussions and numerous written comments, we were unable to arrive at a manner in which codes could be created that would capture this information without causing widespread confusion among coders. The topic is being discussed once again in an attempt to resolve this coding problem. A complete description of proposals considered and comments made at the last Committee meeting where this was discussed can be found at:

http://www.cms.hhs.gov/paymentsystems/icd9

A Note on Counting Vertebrae

To make the new coding structure work, we need a simple method by which coders can differentiate between fusions of 2-3 levels versus fusions involving significantly more levels. Although there are technical definitions of "segment" and "level", usage and documentation of these terms can vary widely among clinicians.

The simplest approach is to define the codes in terms of the number of vertebrae, because this information is consistently documented and is not subject to interpretation. For example, a surgeon may document fusion of L4-S1. This involves 2 levels (L4-L5 and L5-S1) and 3 vertebrae (L4 and L5 and S1). By definition, a fusion of 1 level involves 2 vertebrae, a fusion of 2 levels involves 3 vertebrae, and a fusion of 3 or more levels involves 4 or more vertebrae.

> **Note: Number of vertebrae**
> The vertebral spine consists of 25 vertebrae in the following order and number:
> Cervical: C1 (atlas), C2 (axis), C3, C4, C5, C6, C7
> Thoracic or Dorsal: T1, T2, T3, T4, T5, T6, T7, T8, T9, T10, T11, T12
> Lumbar and Sacral: L1, L2, L3, L4, L5, S1

Index

Indexing issues are complicated by the large number of existing subterms already in use under "Fusion". To completely annotate each one would require so many additional subterms that it might actually be more confusing. Several revisions will simplify this and clearly show the new structure for multi-level fusion.

1. **Under the main term Fusion, delete the following entries for the subterms relating to spinal fusion: "atlas-axis,""cervical," "craniocervical," "dorsal, dorsolumbar,"**

and "lumbar, lumbosacral", and "occiput." Reference the subterm "spinal" instead.

The Index entries will then appear as:

Fusion
cervical (spine) (C2 level or below) – *see Fusion, spinal, cervical*
dorsal, dorsolumbar (spine) – *see Fusion, spinal, dorsal*
lumbar, lumbosacral (spine) – *see Fusion, spinal, lumbar*

It should also be noted that the Index entry for **Refusion** currently does not have separate subterms for cervical, dorsal and lumbar. All of them are indexed under the subterm "spinal" so no changes are needed. Deleting the subterms under **Fusion** actually increases consistency.

2. Add a boxed note to the Index under Fusion and Refusion to direct coders to add 81.62, 81.63, or 81.64 to show the total number of vertebrae fused.

TABULAR

14. OPERATIONS ON THE MUSCULOSKELETAL SYSTEM (76-84)

81 Repair and Plastic Operations on Joint Structures

81.0 Spinal Fusion
Includes: Arthrodesis of spine with:
Bone graft
Internal fixation

ADD: Code also the total number of vertebrae fused (81.62-81.64)
Code also any 360 degree spinal fusion by a single incision (81.61)
Code also any insertion of interbody spinal fusion device (84.51)
Code also any insertion of recombinant bone morphogenetic Protein (84.52)
Excludes: *corrections of pseudarthrosis of spine (81.30-81.39)*
refusion of spine (81.30-81.39)

81.3 Refusion of spine
Includes: arthrodesis of spine with:
bone graft
Internal fixation
correction of pseudoarthrosis of spine

ADD: Code also the total number of vertebra fused (81.62-81.64)
Code also any 360 degree spinal fusion by a single incision (81.61)
Code also any insertion of interbody spinal fusion device (84.51)
Code also any insertion of recombinant bone morphogenetic protein (84.52)

81.6 Other Procedures on Spine
Note: Number of vertebrae
The vertebral spine consists of 25 vertebrae in the following order and number:
Cervical: C1 (atlas), C2 (axis), C3, C4, C5, C6, C7
Thoracic or Dorsal: T1, T2, T3, T4, T5, T6, T7, T8, T9, T10, T11, T12
Lumbar and Sacral: L1, L2, L3, L4, L5, S1

Coders should report only one code from the series 81.62, 81.63,81.64 to show the total number of vertebrae fused on the patient. Code also the level and approach of the fusion or refusion (81.00-81.08, 81.30-81.39)

81.61 360 Degree spinal fusion, single incision

Add: Code also the total number of vertebrae fused (81.62-81.64)

New: 81.62 Fusion or refusion of 2-3 vertebrae

New: 81.63 Fusion or refusion of 4- 8 vertebrae

New: 81.64 Fusion or refusion of 9 or more vertebrae

INDEX

Note : Also use 81.62, 81.63, or 81.64 once as an additional code to show the total number of vertebrae fused

Refusion

cervical (spine) (C2 level and below) – *see Refusion, spinal, cervical*
dorsal, dorsolumbar (spine) – *see Refusion, spinal, dorsal, dorsolumbar*
lumbar, lumbosacral (spine) – *see Refusion, spinal, lumbar, lumbosacral*
spinal, NOS 81.30
atlas-axis (anterior) (transoral) (posterior) 81.31
cervical (C2 vertebra and below) NEC
anterior (interbody), anterolateral technique 81.32
C1-C2 vertebra (anterior) (posterior) 81.31
posterior (interbody), posterolateral technique 81.33
craniocervical (anterior) (transoral) (posterior) 81.31
dorsal, dorsolumbar NEC 81.35
anterior (interbody), anterolateral technique 81.34
posterior (interbody), posterolateral technique 81.35
lumbar, lumbosacral NEC 81.38
anterior (interbody), anterolateral technique 81.36
lateral transverse process technique 81.37
posterior (interbody), posterolateral technique 81.38
number of vertebrae – *see* codes 81.62 – 81.64
occiput-C2 (anterior) (transoral) (posterior) 81.31

Note :	**Also use 81.62, 81.63, or 81.64 once as an additional code to show the total number of vertebrae fused**

HIGH-DOSE INTERLEUKIN-2 (IL-2) THERAPY

Issue Revisited:
We discussed this topic at the November 2001 C&M meeting. Currently there is no specific procedure code to uniquely capture use of high-dose interleukin-2 (IL-2) therapy, a specialized treatment regimen for the treatment of certain types of cancer. ICD-9-CM Volume 3 identifies high-dose IL-2 therapy using code 99.28, Injection or infusion of biological response modifier (BRM) as anti-neoplastic agent. In addition to high-dose IL-2 therapy, this code also includes therapy using low-dose IL-2, anti-neoplastic immunotherapy, and tumor vaccine. Usage and provision of these products can be very dissimilar, and the use of a single code to describe them does not allow for the differentiation the varied courses of treatment required. A unique ICD-9-CM code is needed to distinguish high-dose IL-2 from the other BRMs, and facilitate accurate data capture for this important therapy.

Background:
High-dose IL-2 therapy is a hospital inpatient-based regimen requiring experienced oncology professionals for treatment of patients with **advanced renal cell cancer** and **advanced melanoma**. Currently, this treatment modality is the only approved therapy in both Stage IV metastatic renal cell carcinoma and Stage IV metastatic melanoma. Unlike other cancer therapies, including other immunotherapies, long-term follow-up data on high-dose IL-2 has shown complete and durable responses in a subset of patients. In other words, high-dose IL-2 therapy can evoke an immune response that completely eradicates the tumor and the patient's response is long lasting, for some over 10 years.

High-dose IL-2 therapy is performed only in very specialized treatment settings, such as an intensive care unit (ICU) or a bone marrow transplant unit. This therapy requires oncology health care professionals experienced in the administration and management of patients undergoing this intensive treatment. Unlike most cancer therapies, high-dose IL-2 therapy is associated with predictable toxicities that require extensive monitoring. Often patients require one-on-one nursing or physician care for extended portions of their stay. Clearly, high-dose IL-2 therapy differs from conventional chemotherapy in the resources required to administer it, as chemotherapy may be given to patients either on an outpatient basis or through a series of short (i.e. 1 to 3 day) inpatient stays.

Typically, the institutions that provide high-dose IL-2 therapy have standing orders specifically for administration of high-dose IL-2 therapy, and are similar to those below:

> **I. Pre-administration guidelines.** Upon admission, patients undergo a series of lab tests to ensure they are healthy enough to undergo high-dose IL-2 therapy, including: vital signs; cardiopulmonary functioning (pulse oximetry reading, cardiac monitoring, oxygen); intake and output monitoring, and blood tests. Prior to administration of each dose of IL-2 therapy, nurses will repeat a series of lab tests to ensure patients can tolerate the next dose.
>
> **II. Dosing.** For the first cycle, the IL-2 is administered in a 600,000 IU/kg dose every 8 hours by a 15-minute IV bolus infusion over 5 days. Patients are then discharged to rest at home for 9 days and then admitted again for the second cycle of therapy, in which the same regimen and dosing is repeated. The two cycles complete the first course of high-dose IL-2 therapy.

III. Specific high-dose IL-2 Administration. 60 minutes prior to drug administration, clinicians will administer analgesic/antipyretics, non-steroidal anti-inflammatory drugs (NSAIDs), and H2 blockers for gastrointestinal prophylaxis. A triple-lumen central venous catheter is inserted into the patient, through which IV fluids (i.e., 5% dextrose/.9% sodium chloride with 20 mEq KCl/liter) are administered at 100 cc/hr. If signs of capillary leak syndrome occur, clinicians may administer dopamine (1-5 ug/kg/min) prior to the onset of hypotension. Antibiotics are often administered after central line placement for prophylaxis of staphylococcus infection.

Currently, there is only one IL-2 approved for marketing in the US. However, other IL-2 agents are currently in development. Unlike traditional cytotoxic chemotherapies that attack cancer cells themselves, interleukin-2 enhances the body's defenses by mimicking the way natural IL-2 activates the immune system and stimulates the growth and activity of cancer-killing cells. The IL-2 product on the market has study data, recently updated in 2000, showing extended durability data in patients. These updated data show a median 80+ months survival for metastatic renal cell carcinoma complete responses (range of 7 to 131+ months, or over 11 years) and 59+ months for complete responses in metastatic melanoma (range of 3 to 122+ months, or over 10 years).

Analysis of Current ICD-9-CM Assignment:

The existing 99.28 code to which IL-2 therapy is assigned broadly describes a number of immunotherapies that work through different mechanisms of action, use widely disparate associated services and resources, and are administered with heterogeneous treatment regimens and doses. Furthermore, of all the therapies included in 99.28, high-dose IL-2 is the only therapy that must be administered on an inpatient basis, and the only therapy performed by medical staff trained in specialized treatment settings such as intensive care units.

Use of the existing 99.28 ICD-9-CM biologic response modifier code for high-dose IL-2 therapy has made it difficult for hospitals, researchers, and policy analysts to specifically track high-dose IL-2 admissions, their related services, and costs. The 99.28 code simply does not fully describe the specialized procedure of high-dose IL-2 therapy.

Coding Options

1. Continue to use code 99.28**,** Injection or infusion of biological response modifier [BRM] as an antineoplastic agent.

2. Create a new code in subcategory 00.1, Pharmaceuticals

New code 00.15 High-dose infusion interleukin-2 (Il-2)
Infusion (IV bolus, CIV) Interleukin
Infusion Proleukin® (aldesleukin for injection)

Add an Excludes note for high-dose IL-2 therapy at code 99.28.

Recommendation:

Addition of a new code that specifically describes administration of high-dose IL-2 will allow effective tracking of this procedure for the healthcare community without significant disruption to the ICD-9-CM system. While the move to an ICD-10-CM Procedure Coding System (PCS) will likely solve the difficulty of tracking specialized procedures like high-dose IL-2 therapy, implementation may take several years. The healthcare community would benefit from a unique

ICD-9 code in the interim to track high-dose IL-2 services. Therefore, we recommend that Option 2, the creation of a new code in category 00.1, be adopted as follows:

00 Procedures and interventions, not elsewhere classified

00.1 Pharmaceuticals

00.15 High-dose infusion interleukin-2 (Il-2)
Infusion (IV bolus, CIV) Interleukin
Infusion Proleukin® (aldesleukin for injection)

In the interim, coders are to continue to use code 99.28**,** Injection or infusion of biological response modifier [BRM] as an antineoplastic agent, to describe administration of high dose Interleukin-2 (IL-2).

Injection or Infusion of Therapeutic Radioimmunoconjugates (Radioimmunotherapy)

Issue:
Should a new procedure code be created for the injection or infusion of therapeutic radioimmunotherapy, also known as radioimmunoconjugates?

Background:
Non-Hodgkin's lymphoma (NHL) is the fifth most common type of cancer in the United States, and its prevalence is increasing at a rate approaching 4% per year. There are approximately 300,000 people living with NHL in the US today. The disease, which has several manifestations, is the sixth leading cause of death from cancer, and it has the second fastest growing mortality rate of all cancers.

Conventional treatment for NHL depends on the stage of the disease, the type of cells involved (whether they are indolent or aggressive), and the age and general health of the patient. NHL can be treated with chemotherapy, radiation therapy, or a combination of these treatments. In some cases, bone marrow transplantation, biological therapies, or surgery may be treatment options.

A recent addition to the treatment options for NHL is the use of monoclonal antibodies. Monoclonal antibodies are used to destroy some types of cancer cells while causing little harm to normal cells. They are designed to recognize certain proteins that are fond on the surface of some cancer cells. The monoclonal antibody recognizes the protein and attaches to it. This triggers the body's immune system to attack the cancer cells and can cause the cells to destroy themselves. A variety of antigens on lymphoma cells have been targeted for therapy with monoclonal antibodies. The CD20 antigen is an antigen associated with B-cell tumors. Several characteristics make this antigen a good target for therapy with monoclonal antibodies. The first monoclonal antibody approved in the U.S. to treat NHL was Rituxan® (rituximab).

Over the past decade, further research has been conducted on the use of monoclonal antibodies to carry radioactive isotopes to tumor sites for the purpose of selective radiation of the tumor with relative sparing of normal tissues. These trials have involved patients with lymphoma, and cancers of the breast, ovary, prostate, colon and lung.

The conjugation of monoclonal antibodies to radioactive isotopes (radioisotopes) creates products known as radioimmunoconjugates. The treatment of cancer patients with these products is commonly referred to as radioimmunotherapy. NHL is ideal for this therapy because it is sensitive to both the monoclonal antibodies and the radioisotopes.

Various radioisotopes have been developed for radioimmunoconjugate use. The two major radioisotopes currently in use are Yttrium-90 (Y-90) and Iodine-131 (I-131). Y-90 emits beta radiation and I-131 emits both gamma and beta radiation. Monoclonal antibodies labeled with Y-90 can be administered in an outpatient setting. Monoclonal

antibodies labeled with I-131 can be administered in an outpatient setting but restrictions to protect the patient's family and the environment must be imposed because of the gamma radiation associated with its use. In three states (Nevada, New Hampshire, and New Mexico) regulatory requirements mandate inpatient admission for radioimmunotherapy using I-131.

On February 19, 2002, Zevalin™ (Yttrium-90 ibritumomab tiuxetan) became the first radioimmunotherapy to be approved by the Food and Drug Administration (FDA). Zevalin™ is indicated for the treatment of relapsed or refractory low grade, follicular, or transformed B-cell NHL including patients with follicular NHL refractory to rituximab.

Linking monoclonal antibodies to radioisotopes creates radioimmunotherapies such as Zevalin™. Zevalin™ is a murine monoclonal antibody that targets the CD20 antigen. A chelating agent links this antibody to the radioisotope Yttrium-90. When infused into a patient, these radiation-carrying antibodies circulate in the body until they locate and bind to the surface of specific cells, and then deliver their cytotoxic radiation directly to malignant cells. Zevalin™ binds to and destroys malignant and normal B-cells. Normal B-cells are generally replenished with six to nine months following therapy.

Bexxar™ is an investigational radioimmunotherapy currently undergoing review by the FDA. It has not yet been given FDA approval. The monoclonal antibody in Bexxar™ is tositumomab and the radioisotope is I-131. The patient population that has been studied includes patients with transformed low-grade NHL and patients who have relapsed after, or are refractory to, chemotherapy. The monoclonal antibody in Bexxar™ targets a protein found on the surface of the B-cells and the radioactive iodine delivers radiation directly to these cells.

The injection or infusion of therapeutic radioimmunoconjugates is the final step in a treatment regimen that typically includes a series of diagnostic studies prior to the administration of the therapeutic dose. These studies are performed as safety measures or to calculate an individualized dose of the therapeutic radioimmunoconjugate. For example, before radioimmunotherapy with Zevalin™, imaging is performed using In-111 ibritumomab tiuxetan immediately following an infusion of rituximab. The biodistribution of In-111 ibritumomab tiuxetan is assessed by a visual evaluation of whole-body, planar view, and anterior and posterior gamma images at 2 to 24 hours and 48 to 72 hours after injection. If visual inspection of the gamma images reveals an altered biodistribution, the patient does not proceed to the therapeutic dose of Yttrium-90 ibritumomab tiuxetan.

Radioimmunotherapy represents a major advance in the treatment of patients with relapsed or refractory low-grade or follicular NHL or transformed B-cell NHL. For example, a Phase III randomized, controlled trial with Zevalin™ showed an overall response rate of 80%, compared to 56% in patients who received the monoclonal antibody (rituximab) alone. This trial also showed that 30% of Zevalin™ patients achieved a complete remission, compared to 16% of patients treated with rituximab alone.

Coding Discussion:

Per Dr. Richard Wahl, Professor of Radiology and radiological Science, Johns Hopkins Hospital, Bexxar™ and Zevalin™ differ from other radiopharmaceutical therapy infusions in the following ways:

- Most radiopharmaceutical therapy infusions are performed as rather rapid infusions. The infusion of radiolabeled antibodies is typically a slower process, as risks of infusion-related toxicity are real and potentially dangerous. Additionally, since for both Bexxar™ and Zevalin™, an unlabeled antibody pre-dose has been given before the RIT dose, the patient may be suffering from some degree of immunological side effect prior to the antibody infusion. Thus, the patient acuity and the duration of infusion are grater for the radioimmunotherapy than most other radiopharmaceutical therapy infusions.
- The degree of instruction to the patients regarding radiation safety is more extensive for these therapies than for other radiopharmaceutical therapy infusions. Radiation safety requirements can be more extensive, and the treatment room prep/shielding/monitoring and calculations are increased from other therapies.
- Imaging quality control is more extensive for Radioantibody therapy than or other radionuclide therapy.
- As both tracer and therapy doses are given for radioantibodies, this sequence is probably more complex than other radiopharmaceutical therapies in which an empirical dose is given.

It is anticipated that most of this type of therapy will be given in an outpatient setting. HCPCS G-codes for use in the outpatient setting have already been created:

GO273 – Radiopharmaceutical biodistribution, single or multiple scans on one or more days, pre-treatment planning for radiopharmaceutical therapy of non-Hodgkin's lymphoma, includes administration of radiopharmaceutical (e.g., radiolabeled antibodies)

GO274 – Radiopharmaceutical therapy, non-Hodgkin's lymphoma, includes administration of radiopharmaceutical (e.g., radiolabeled antibodies)

Options:

1. Do not create a new code. Use code 92.28, Injection or instillation of radioisotopes, to describe this therapy. The Zevalin™ therapy will be performed in the outpatient setting. It is anticipated that Bexxar™, too, will be given in the outpatient setting with the possible exception of the three states mentioned above.

2. Create a unique code, as follows:

92.2 Therapeutic radiology and nuclear medicine

New code 92.20 Injection or infusion of radioimmunoconjugate
Yttrium-90 (Y-90) ibritumomab tiuxetan
Iodine-131 (I-131) tositumomab

Recommendation:
Do not create a new code at this time, due to limited space in the procedure section of the ICD-9-CM as well as the anticipation that this therapy will be given in the outpatient setting. It should be noted that Zevalin™ has not requested an ICD-9-CM code for inpatient use.

Interim Coding:
Coders should use 92.28, Injection or instillation of radioisotopes, to capture the administration of this type of therapy.

PROCEDURES PERFORMED THROUGH A SCOPE

Topic Background:

The ICD-9-CM procedure coding system is not up-to-date with regard to describing procedures performed through a scope, such as a thoracoscope or laparoscope. We propose to discuss the addition of one new code at this meeting and address additional topics future meetings. If you have any suggestions, please forward them.

Laparoscopic Supracervical Hysterectomy

Background:

Hysterectomy is the second most common major surgery performed on women today, just behind C-sections. Annually, more than 500,000 women have hysterectomies in the United States. The laparoscopic supracervical □ysterectomy (LSH) procedure spares the cervix and maintains the integrity of the pelvic floor, which helps maintain internal pelvic support and causes no trauma to the vagina. Preservation of the cervix may result in fewer long-term problems with pelvic relaxation and urinary symptoms. Some disadvantages of traditional total abdominal hysterectomy include increased operative and postoperative complications, vaginal shortening, vault prolapse, abnormal cuff granulations and oviductal prolapse, all of which are eliminated with an LSH procedure.

The major benefit of LSH is a shorter recovery time compared with traditional abdominal hysterectomy. Most patients attain full recovery in one-to-two weeks compared to the six-to-eight week recovery with abdominal hysterectomy. Other benefits of this procedure include shorter operating times, less bleeding, minimal dead tissue to heal, no sutures, and less pain related to surgery. Many patients are able to return home on the day of the surgery. In addition, as this is a much less invasive procedure than abdominal hysterectomy, the cervix remains intact and bladder and urinary tract complications are virtually eliminated.

This procedure has been performed since 1990. This type of surgery is technically more difficult and requires more skill than a traditional abdominal hysterectomy, so patients are advised to choose an experienced surgeon. Though LSH will benefit many women, it is not for everyone. For example, women with a history of an abnormal Pap smear are not candidates for the procedure.

ANALYSIS OF CURRENT ICD-9-CM ASSIGNMENT(S):

Currently, the following codes describe hysterectomy:

68.3, Subtotal abdominal hysterectomy
Supracervical hysterectomy
68.4, Total abdominal hysterectomy
68.51, Laparoscopically assisted vaginal hysterectomy (LAVH)
68.59, Other vaginal hysterectomy
68.6, Radical abdominal hysterectomy
68.7, Radical vaginal hysterectomy
68.9, Other and unspecified hysterectomy
Excludes:
abdominal hysterectomy, any approach (68.3, 68.4, 68.6)
vaginal hysterectomy, any approach (68.51, 68.59, 68.7)

Code 68.3, while supracervical, describes open approach, not a laparoscopic approach. In code 68.4, the uterus and cervix are removed through an open abdominal incision. Use of code 68.51 uses a laparoscope to perform the severing of the supporting structures, then the uterus and cervix are removed through the vagina. Use of codes 68.59 and 68.7 describes removal of the uterus and cervix through the vagina after it is opened. In all of the above approaches, the pelvic floor is surgically disrupted.

Coding Options

1. Use code 68.3, Subtotal abdominal hysterectomy, capturing the supracervical approach, as specified by the excludes note at 68.9.

2. Create a new code in subcategory 68.3, as follows:

68.3 Subtotal abdominal hysterectomy

New code 68.31 Subtotal abdominal hysterectomy
Supracervical hysterectomy

New code 68.32 Laparoscopic supracervical hysterectomy (LSH)
Classic infrafascial SEMM hysterectomy (CISH)
Laparoscopically assisted supracervical hysterectomy (LASH)

68.9 Other and unspecified hysterectomy
Excludes:
Change note abdominal hysterectomy, any approach (~~68.3~~, 68.31, 68.32, 68.6)

67.59 Other repair of internal cervical os
Excludes:
Transabdominal cerclage of cervix (67.51)
Add note Laparoscopically assisted supracervical hysterectomy (LASH) (68.32)

Recommendation:
We suggest the adoption of Option 2, as written above.

In the interim, coders are to continue to use code 68.3, Subtotal abdominal hysterectomy to describe laparoscopic supracervical hysterestomy (LSH).

Proposed Addenda For FY 2004 (October 1, 2003)

Index

Revise term Diversion,~~urinary~~
Add subterm biliopancreatic (BPD) 43.7 [45.51] [45.91]
Add subterm with duodenal switch 43.89 [45.51] [45.91]
Add subterm urinary
Revise subterm cutaneous 56.61
Revise subterm ileal conduit 56.51
Revise subterm internal NEC 56.71
Revise subterm ureter to
Revise subterm intestine 56.71
Revise subterm skin 56.61
Revise subterm uretero-ileostomy 56.51

Add term Drotrecogin alfa (activated), infusion 00.11

Evaluation (of)
Add subterm device
Add subterm implantable automatic cardioverter/defibrillator (bedside
Add subterm device check) – omit code

Operation
Roux-en-y
Add subterm gastroenterostomy 44.39
Add subterm gastrojenunostomy 44.39

Repair
aneurysm (false) (true) 39.52
by or with
Revise subterm endovascular graft 39.79

Revision
Revise subterm cardiac pacemaker (CRT-P)
Revise subterm cardioverter/defibrillator (automatic)(CRT-D)

Test, testing (for)
Add subterm device
Add subterm implantable automatice cardioverter/defibrillator (bedside
device check) – omit code

Add term Vertebroplasty (percutaneous) 78.49

Tabular List

02.41 Irrigation and exploration of ventricular shunt

Add inclusion term Re-programming of ventriculoperitoneal shunt

37.26 Cardiac electrophysiologic stimulation and recording studies

Excludes:

Add exclusion term testing of implantable automatic cardioverter/defibrillator (AICD or CRT-D) device – omit code

37.94 Implantation or replacement of automatic cardioverter/defibrillator, total system [AICD]

Add inclusion term Implantation of defibrillator with leads (epicardial patches), formation of pocket (abdominal fascia) (subcutaneous), any transvenous leads, intraoperative procedures for evaluation of lead signals, and obtaining defibrillator threshold measurements (Electrophysiologic studies [EPS])

78.4 Other repair or plastic operations on bone

Add inclusion term Vertebroplasty

ICD-10-PCS
SUMMARY OF CHANGES
2001/2002

SECTIONS

- **Added new section**
  Substance Abuse Treatment
  - Input from representatives from Substance Abuse Programs

- **Renamed Section**
  Rehabilitation and Diagnostic Audiology renamed:
  Physical Rehabilitation and Diagnostic Audiology

- **Updated all sections with new procedure codes effective 10-1-01 and 10-1-02**
  - (These new codes include the new codes for drug eluting stents, 00.55 and 36.07, as well as the new CRT-P and CRT-D devices 00.50 – 00.54)

- **Added or deleted codes from appropriate characters based on review and feedback**.

(ICD-10-PCS presentations are given on an ongoing basis. Feedback from audiences as well as review of the system on the CMS website has prompted calls to 3M for clarification/additional entries in PCS.)

BODY SYSTEMS

Endocrine
- Added Body Part - Parathyroid Gland

Peripheral Nervous System
- Added Body Part -Sacral Plexus Nerve

Skin and Breast
- Added Body Part - Breast, Bilateral

Lower Bones
- Added Body Part - Coccyx

Hepatobiliary System and Pancreas
- Added Drainage Device to Root Op 'Insertion'

Gastrointestinal System
- Added Transorifice Intraluminal Endoscopic approach to Root Op "Bypass"

Female Reproductive System

- Added Open approach to Root Op “Restriction”

Heart and Great Vessels

- Added Intraluminal Device to Root Op “Bypass” - Coronary Arteries
- Added Qualifier Coronary Artery to Bypass, Coronary Artery
- Added Qualifier Coronary Vein to Bypass, Coronary Artery

Head and Facial Bones

- Removed Body Part - Cranial Bone, Other (redundant)

Measurement & Monitoring

- Added Body System, Products of Conception, when coding external Fetal Monitoring

TRAINING MANUAL

- Added new section – Substance Abuse
- Renamed Rehabilitation and Diagnostic Audiology to Physical Rehabilitation and Diagnostic Audiology
- Updated Answer key based on Q & A in Substance Abuse Treatment Section

INDEX

- Index updated to reflect new Tabular entries

VIA HAND DELIVERY AND U.S. MAIL

November 19, 2002

John R. Lumpkin, M.D., M.P.H.
Illinois Department of Public Health
535 W. Jefferson Street
Springfield, IL 62761

Dear Dr. Lumpkin:

On behalf of the members of the American Hospital Association, the Federation of American Hospitals and the Advanced Medical Technology Association, we would like to make clear our common position on certain coding standards.

We feel that important decisions need to be made about the future of clinical standards for diagnosis and procedural coding because the ability of hospitals to provide complete, accurate and precise reporting of clinical codes is critically important. These clinical coding systems are essential for hospitals' use in patient care, benchmarking, quality assessment, research, public health reporting, strategic planning and reimbursement.

The current issue, however, is how to proceed with the future of coding and which coding system or systems can best lead us into that future. We would like to share with you our common views on this important issue.

- The 23-year-old ICD-9-CM coding classification system has severely limited reporting capabilities for today's needs and no growth capacity for future needs, making it an increasingly unacceptable coding classification system for the future for both inpatient and outpatient diagnosis, as well as hospital inpatient services' procedure coding.

- We support replacing that system with ICD-10-CM for diagnosis codes and ICD-10-PCS for procedure code reporting for all hospital inpatient services. The results of ICD-10-PCS testing show that it is a vast improvement over ICD-9-CM, and more than satisfies the reporting requirements for hospital inpatient services.

- It is important that both ICD-10-CM and ICD-10-PCS be implemented at the same time. This will help to ensure the most efficient and cost effective implementation of the new systems with time for education, training and operational preparedness.

- We oppose the use of Common Procedure Terminology (CPT) for hospital inpatient services. CPT was designed for services more commonly provided in physicians' offices, not services provided in a hospital.

We feel that adoption of ICD-10-CM and ICD-10-PCS will better position health care providers to improve the quality of health care data, and believe that complete, accurate and consistent information is an essential health care resource, which ultimately improves the quality of patient care.

We urge you, as a member of the National Committee on Vital and Health Statistics, to recommend to the Secretary of the Department of Health and Human Services (DHHS) that a proposed rule implementing ICD-10-CM and ICD-10-PCS be issued as soon as possible. Many changes will be required. Hospitals need to plan now for ICD-10 changes so they can be most cost-effectively incorporated into broader information system, required to be made new, for hospitals to comply with provisions of the Health Insurance Portability and Accountability Act of 1996.

We look forward to working with you and DHHS to resolve any remaining issues and to successfully assist in the implementation of ICD-10-CM and ICD-10-PCS. We are available to provide additional information and support at your request.

Advanced Medical Technology Association
American Hospital Association
Federation of American Hospitals

CC: Tommy G. Thompson, Secretary, U.S. Department of Health and Human Services
Thomas A. Scully, Administrator, Centers for Medicare and Medicaid Services

September 23, 2002

The Honorable Tommy G. Thompson
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Thompson;

The medical organizations listed below are writing to register our concerns regarding the possible implementation of ICD-10-PCS to replace ICD-9-CM, Vol. 3 and to state our strong preference for the investigation of *Current Procedural Terminology* (CPT®) as a viable candidate to meet the inpatient coding needs of hospitals and other facilities. Our preferences are a result of many years experience with the CPT code set and with the CPT editorial process. They are also based on the serious technical limitations, educational needs, system changes and overall costs that will be required to implement a new coding system as fundamentally different as ICD-10-PCS.

We believe that the implementation of ICD-10-PCS will only add to the regulatory burden faced by hospitals, physicians and other health care providers. We find it ironic that the imposition of a more complex coding system is being contemplated as your own Advisory Committee on Regulatory Reform is urgently seeking solutions to remove or eliminate the regulatory burden already existing in federal programs. While we understand that ICD-10-PCS is only being considered to replace ICD-9-CM, Vol. 3 for inpatient coding and not for professional services, a change of such magnitude must be considered in the context of the health care system as a whole and not compartmentalized.

It is unnecessary and potentially detrimental to replace ICD-9-CM, Vol. 3, which has served its purpose well and contains only approximately 4,000 codes, with ICD-10-PCS which contains nearly 200,000 codes and is unproven in any setting. The possible proliferation of all these codes will inevitably lead to a significant increase in data and reporting errors for inpatient procedure coding. A higher coding error rate could have system wide effects and the very real possibility of facility payment errors will affect physicians and other health care professionals who practice in hospitals.

Our organizations believe that this complex new coding system and excessive formalism contained therein will cause problems for users and will certainly require significant education of physicians, coders, and others billing or paying for these services. It is also important to consider the context of system changes. Currently many physicians, other providers, and payors are undergoing changes to comply with requirements for electronic transaction and privacy standards in the Health Insurance Portability and Accountability Act (HIPAA). System changes

necessitated by ICD-10-PCS are in addition to expensive changes already taking place, making the overall bill even larger and the project more complex.

The lack of involvement of organized medicine and the leadership of allied health professionals in the development and maintenance of ICD-10-PCS is a substantial limitation. The undersigned medical organizations believe it is important for clinical leadership to be actively involved in the updating and maintenance of any procedure code set. The input of physicians who perform the services and procedures under consideration is an essential component of an accurate code descriptor. Similarly the input of physicians and other health care professionals in the decision making process is critical for coherence with generally accepted medical practice and clinical terminology. Our experience with the CPT Editorial process suggests that the input of other stakeholders, including the American Hospital Association, the American Health Information Association and the private payer community, is important and that broad clinical and administrative input on editorial decisions is essential for the development of a quality end product. The proliferation of new codes contained in ICD-10-PCS will involve a greater degree of complexity and the need for substantially more clinical decision making. The CPT Editorial process works well for all of its users.

CPT has been successfully used for physician services under the Medicare program since 1983 and associated with the Resource Based Relative Value Scale since 1992. Use of CPT to replace ICD-9-CM, Vol. 3 for facility payments would be a relatively minor change since it is already widely used in hospitals for outpatient and physician services.

The combination of educational needs and expenses, system changes and expenses, and the possibility of reporting errors, all result in plausible and serious system-wide disruptions and financial disorder. We believe that considerable further study is necessary regarding the cost-benefit of implementing ICD-10-PCS. In addition, any study on the costs and benefits of implementing a new inpatient code set should examine CPT as a viable alternative. We therefore urge the Department to consider adoption of CPT as a viable, workable alternative to ICD-10-PCS.

Sincerely,

American Academy of Dermatology Association
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Family Physicians
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngology-Head and Neck Surgery
American Academy of Pediatrics
American Association of Clinical Endocrinologists
American Association of Clinical Urologists
American Association of Neurological Surgeons

American Association of Orthopaedic Surgeons
American Association for Thoracic Surgery
American Association for Vascular Surgery
American Association of Electrodiagnostic Medicine
American College of Chest Physicians
American College of Emergency Physicians
American College of Nuclear Physicians
American College of Obstetricians and Gynecologists
American College of Occupational and Environmental Medicine
American College of Osteopathic Family Physicians
American College of Physicians – American Society of Internal Medicine
American College of Radiology
American College of Surgeons
American Medical Association
American Medical Group Association
American Osteopathic Association
American Society for Clinical Pathology
American Society for Therapeutic Radiology and Oncology
American Society of Addiction Medicine
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Colon and Rectal Surgeons
American Society of General Surgeons
American Society of Hematology
American Society of Plastic Surgeons
American Thoracic Society
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
National Association for Medical Direction of Respiratory Care
North American Spine Society
Society for Vascular Surgery
Society of Interventional Radiology
Society of Nuclear Medicine
Society of Thoracic Surgeons
Thomas Jefferson University, Nuclear Medicine Division

NCVHS AND ICD-10-PCS TIMELINE

1979
ICD-9-CM was implemented in the United States.

1984
The inpatient Prospective Payment System was implemented and hospitals became increasingly concerned about coding.

1985
The ICD-9-CM Coordination and Maintenance Committee was developed to update and revise ICD-9-CM.

1986
May 1986 a meeting was convened by HCFA to open discussion among people interested in procedure coding. As a result of that meeting, AHA and AMA agreed to co-chair a task force that would outline and set priorities for the objectives of a common procedure coding system. This task force was charged to undertake a through evaluation of the purpose and scope of Volume 3 of ICD-9-CM and CPT to evaluate the feasibility of developing a new procedure coding system to achieve the objectives of a common system.

1990
Earlier review efforts uncovered structural problems in both Volume 3 of ICD-9-CM and CPT. Concern for data quality issues and the cost of submitting data in more than one classification is significant. The feasibility of creating a single procedure coding system that will satisfy all users is as yet unknown. The AMA sponsored a study to investigate the costs and benefit of a single system for physician payment. The study conducted by Coopers and Lybrand, compared two alternatives: 1) a major restructuring of CPT to serve uses beyond physician offices; and 2) a replacement of both Volume 3 of ICD-9-CM and CPT. The results of the study showed that the costs of a replacement system were significant and that the identification of benefits was difficult, thus the consultants concluded that a replacement system, for measuring physician services, was not justified.

The November 1990 Report of the National Committee on Vital and Health Statistics Concerning Issues Relating to the Coding and Classification Systems concludes the following:

- The Subcommittee review found structural problems with both CPT-4 and Volume 3 of ICD-9-CM.

- An ongoing study and evaluation of the feasibility of a uniform procedures code is necessary. Such an evaluation should address HCFA's responsibility as a catalyst in determining the efficacy of a single procedure code.

HCFA awards contract for a pilot project that would review the cardiovascular procedures in all of the procedure coding systems (CPT, HCPCS, local HCPCS and Volume 3 of ICD-9-CM, standardize the nomenclature with definitions recommend a standard format amenable to updating and expansion, and develop a cardiovascular chapter for ICD-9-CM, Volume 3.

1991
HCFA funds a continuation of the pilot project for the development of a revision of the respiratory system chapter consistent with the approach, design and format of the cardiovascular chapter.

1993
During 1993, the NCVHS Subcommittee held three meetings and three working sessions dedicating a substantial portion of the meetings to developing and reviewing its report to recommend that steps be taken to create a single procedure classification system for multiple purposes in the United States.

The 1993 NCVHS issues report on desirability of a single procedure coding system containing the following conclusions:

- The single procedure classification system should possess utility as a statistical classification and an administrative tool. Characteristics of such a system are defined.
- There is general resistance to altering existing systems except where changes are considered necessary to reflect current medical trends
- Current systems are badly in need of overhaul and consolidation
- Pressures for change derive not only from end users who must contend with deficiencies of current systems, but also from political forces that must address major health care reform. The Committee notes that data sets currently do not permit the ability to track patients through the system as they enter and leave various care settings over the course of an illness or over a long period of time.
- The Committee realizes that recognition of the necessity for the development and implementation of a single procedure classification system is only the first step in a difficult and time-consuming process. Public and private sector resources will be required to achieve a successful and timely solution to the issues addressed in the report.

Commonly cited flaws of ICD-9-CM and CPT-4 procedure classification systems were also included in the report:

Both Classifications

- Lack of space for expansion
- Overlapping and duplicative codes
- Inconsistent and noncurrent use of terminology
- Lack of codes for preventive services

ICD-9-CM (Volume 3)

- Insufficient specificity and detail
- Insufficient structure to capture new technology

CPT-4

- Nonhierarchical structure
- Physician service orientation (not multidisciplinary)
- Poorly defined, nondiscrete coding categories, witrh variable detail

1994

1994 HCFA announced plans to initiate a solicitation for a contract to develop a new procedure coding system for use with hospital inpatients to replace Volume 3 of ICD-9-CM. The new system is referred to as ICD-10 PCS

DHHS OIG issues a report on Coding of Physician Services that describes vulnerabilities in the maintenance, use, and management of the CPT-4, as they relate to Medicare reimbursement. The report identified several flaws in CPT-4 codes, guidelines, and index that can lead to improper coding. The report also notes that the guidelines on hospital outpatient services appear to be a particular problem. In November 1988, HCFA informed the CPT Editorial Panel of its concerns in applying CPT-4 to outpatient services. In a December 1992 position statement, AHIMA stated, "attempts to effectively use this (CPT-4) coding system for the hospital setting have resulted in the inconsistent application of the CPT conventions and the general guidelines. The report also contains several recommendations for HCFA and the AMA that would correct the deficiencies noted.

1995

As noted in the Proceedings of the 45th Anniversary Symposium of the NCVHS, NCVHS in 1983 and again in 1986 has called for "strong efforts" to develop a single procedure coding system for the United States to replace the use of Volume 3 of ICD-9-CM in hospitals and the

American Medical Association's CPT-4 in ambulatory settings [NCVHS Annual Report 1983-85; Annual Report, 1993).

March 1995 HCFA awarded a contract to 3M HIS to develop the procedure classification to replace Volume 3 of ICD-9-CM (hospital inpatient procedures), which is called ICD-10-PCS. The contract is based on the prototype 7-digit alphanumeric procedure classification system developed by 3M HIS in previous contracts. Primary objective is developing a new procedure coding system to replace the current Volume 3 of ICD-9-CM; the project's additional objectives are to improve the accuracy and efficiency of coding, to reduce training efforts, to improve communications with physicians, and to be compatible with the current billing infrastructure.

May 1995, the NCVHS Subcommittee convened hearings whose primary purpose was to discuss data needs of managed care organizations, using the proposed criteria for a unified procedure classification. Four different models of managed care participated in the discussion (network, group and staff, IPA, and mixed models). There appeared to be consensus for a unified system, given the varied needs of managed care organizations.

The consistent message in written and oral testimony before the Subcommittee was that existing coding systems were not meeting their needs.

ICD-10-PCS was developed using an open process. A Technical Advisory Panel provided review and comments throughout development. The TAP included American Health Information Management Association (Sue Prophet), American Hospital Association (Nelly Leon-Chisen), American Medical Association (Barry Eisenberg), CPRI/ANSI-HISSP (Dr. Simon Cohn), and other federal agencies, American Association of Medical Transcription (Claudia Tessier), NIH/NLM (Betsy Humphreys), AHCPR (Michael Fitzmaurice), state health system repress (Kevin Ray), hospital information (Laura Green), NCHS (Donna Pickett), ProPAC (Julian Pettingil), Dr. Clement McDonald, American College of Surgeons (Dr. George Spaulding), United HealthCare (James Cross and Philip Bryson), and the National Association of Children's Hospitals and Related Institutions (John Muldoon). ICD-10-PCS was sent to approximately 30 specialty groups for their review and comments. Additionally, HCFA also provided an onsite presentation at the AMA to more than 20 specialty groups.

1996

3M HIS develops a training program for ICD-10-PCS, and informal testing and training were conducted. AHIMA national conventions trained 65 coders in two half-day sessions. Another 70 volunteered to test the system, but were not able to attend the training. The coders received 400 records that were coded with ICD-10-PCS during next 3 months (received by January 1997).

1997
HCFA's contractors, the Clinical Data Abstraction Centers (CDACs) conduct formal testing of ICD-10-PCS. HCFA trained CDACs 5/14-15/97 with follow-up training after the CDACs informally coded 30 records (6/3/97). Final training session 6/18/97 where CDACs tested system on 5,000 medical records (2500 per CDAC) identifying cases with a wide distribution of ICD-9-CM procedure codes

1998
Additional formal testing of ICD-10-PCS using ambulatory records conducted 10/98 - 2/99. 582 ambulatory records obtained by CDACs. 369 records of the 582 had procedures that were tested using ICD-10-CM and reported as part of the 3/99 on findings. CMS not able to obtain OB records. CMS also tested ICD-10-PCS on list of problem cases from Editorial Advisory Board for Coding Clinic for ICD-9-CM submitted by AHA. Based on issues and problems identified, ICD-10-PCS and the training manual was revised.

Final version of ICD-10-PCS, training material and crosswalk to ICD-9-CM procedure codes posted on CMS website released spring 1998.

2000
In the Benefits Improvement and Protections Act of 2000 (BIPA), Congress addressed requirements for incorporation of new medical services and technologies into the Medicare inpatient prospective payment system. Some of the requirements involve the lack of detail and shortage of available codes in the current coding system. In the September 7, 2001 Federal Register, CMS noted the limitation of ICD-9-CM regarding the ability to expeditiously incorporate new medical services and technologies into the classification. A number of approaches and techniques used for procedures (such as lasers, minimally invasive techniques and the use of scopes) cannot be readily captured by the current structure of Volume 3.

August 17, 2000
Standards for Electronic Transactions Final Rule published. This rule named ICD-9-CM as a national standard. However, the notice mentioned the many problems with ICD-9-CM and stated that it may be replaced by systems such as ICD-10-CM and ICD-10-PCS.

May 17-18, 2001
A public meeting on whether ICD-10-PCS should be named as a replacement for Volume 3 of ICD-9-CM held at the ICD-9-CM Coordination and Maintenance Committee. Written comments from presenters, with one exception, supported implementation of ICD-10-PCS.

Eleven organizations requested the opportunity to present comments on whether ICD-10-PCS should replace ICD-9-CM, Volume 3. Of the eleven, only one organization, the American Medical Association did not support going forward with the process that would lead toward the replacement of Volume 3 with ICD-10-PCS. Those offering their support included the American Hospital Association, the Federation of American Hospitals, the American Health Information Management Association, and ADVAMED. A summary report of this meeting can be found at: www.cms.hhs.gov/paymentsystems/icd9.

February 2002

NCVHS held hearings on whether the national coding standards accepted under HIPAA should be updated. ICD-10-CM and ICD-10-PCS were not on the agenda of this meeting.

April 2002

NCVHS subcommittee holds hearings on ICD-10-PCS. There was a great deal of support from hospitals and coders to move forward with ICD-10-PCS. The AMA was opposed and recommended CPT for inpatient use.

May 2002

NCVHS Subcommittee on Standards and Security holds hearings on ICD-10-CM. There was considerable support to move forward with ICD-10-CM. The subcommittee votes to draft a letter from the NCHVS to the Secretary recommending that he begin the regulatory process for implementing ICD-10-CM and ICD-10-PCS. The full committee would vote on the letter at their June 2002 meeting.

June 2002

The full committee of the NCVHS met to discuss a draft letter from the committee to the Secretary recommending that the regulatory process begin for implementing ICD-10-CM and ICD-10-PCS. Several members of the Subcommittee on Standards and Security, which drafted the letter raised concerns. The letter was not voted upon. It was referred back to the subcommittee.

August 2002

The Subcommittee on Standards and Security met to hear additional testimony on ICD-10-CM and ICD-10-PCS from Blue Cross Blue Shield Association who opposed changing the current coding standards. AMA continued to express opposition to ICD-10-PCS and recommended CPT instead. The draft letter to the Secretary recommending initiation of the regulatory process to implement ICD-10-CM and ICD-10-PCS was discussed. A decision was made to once again refer the letter to the full committee for a vote at their September 2002 meeting.

8/9/02
A GAO report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Represetnatives, *HIPAA Standards: Dual Code Sets Are Acceptable for Reporting Medical Procedures*". The GAO states in the concluding observations, "Considering the adequacy of ICD-9-CM, Volume 3, and CPT in meeting all of the criteria recommended for HIPAA standard code sets, the practical challenges of implementing a single procedure code set, and lack of empirical evidence to either support or disprove the merits of doing so, we believe that dual code sets for reporting medical procedures are acceptable under HIPAA. In addition, we concur with those representatives of the health care industry who contend that more study is needed to examine the possible benefits of adopting a single code set for medical procedures before its implementation could be considered."

8/27/02
AHA sends letter to Secretary Thompson. Letter summarizes the AHA position that ICD-9-CM has outlived its usefulness and supports replacing with ICD-10-CM for diagnoses and ICD-10-PCS for inpatient procedures; ICD-10-PCS testing show it is a vast improvement over ICD-9-CM; and that both ICD-10-CM and ICD-10-PCS should be implemented at the same time. The AHA does not support adoption of a single procedure classification system for all services. Rather, as suggested by the GAO, the AHA supports a dual approach to procedure coding with ICD-10-PCS for hospital inpatient services and CPT for hospital outpatient and physicians services. The AHA opposes the use of CPT for hospital inpatient services.

September 2002

The full committee of the NCVHS met to discuss a draft letter from the committee to the Secretary recommending that the regulatory process begin for implementing ICD-10-CM and ICD-10-PCS. Once again, several members of the Subcommittee on Standards and Security, which drafted the letter raised concerns. The letter was not voted upon. It was decided that with the concerns expressed by some subcommittee members, that the full committee did not have enough information. The issue was referred back to the subcommittee who were requested to prepare briefing materials on the issues.

9/23/02
AMA sends letter to Secretary Thompson. Letter summarizes the AMA position that it is "unnecessary and potentially detrimental to replace ICD-9-CM, Volume 3 which has served its purpose well and contains only 4,000 codes, with ICD-10-PCS which contains nearly 2000,000 codes and is unproven in any setting." They also cite lack of involvement of organized medicine and the leadership of allied health professionals in the development and maintenance of ICD-10-PCS. Lastly, they urge the Department to consider adoption of CPT as a viable workable alternative to ICD-10-PCS.

9/24/02

A letter signed by BCBSA, American Association of Health Plans, JCAHO, Health Insurance Association of America, and the American Public Human Services Association/National Association of State Medicaid Directors sent to Dr. John R. Lumpkin regarding transition to ICD-10-CM and ICD-10-PCS. The letter urges that a detailed analysis on the impact the replacement of ICD-9-CM on the entire health care industry be conducted prior to the NCVHS making a recommendation to the Secretary for Health and Human Services.

October 2002

The Subcommittee on Standards and Security met to discuss ICD-10-CM and ICD-10-PCS. Instructions were given to committee staff to evaluate the possibility of developing a contract for a cost benefit analysis for new coding systems. They were also instructed on the preparation of briefing materials for the full committee. CMS staff offered to have Rich Averill, 3M HIS make a presentation on ICD-10-PCS to the full committee. Subcommittee members declined the offer to have a presentation by Rich Averill. Staff worked with Simon Cohen, MD, chairman of the subcommittee on a briefing package.

November 19-20, 2002

NCVHS met to discuss the replacement of ICD-9-CM with ICD-10-CM and ICD-10-PCS. Once again the committee was unable to agree on a recommendation to the Secretary. The CMS representative informed the NCVHS that an extensive lead time was required to make system and program changes to support the adoption of a new coding system for inpatient use. ICD-0-CM was rapidly approaching a point where it could not be adequately updated. She urged them to quickly make a recommendation or to acknowledge that CMS must begin work leading to a Notice of Proposed Rulemaking. The NCVHS deferred to the Subcommittee on Standards and Security for discussions on initiating a contract to analyze the impact of staying with ICD-9-CM or moving to a new coding system. May 2003 was established as a tentative date to have the results of this study. The NCVHS representative urged the NCVHS to set June 2003 as a firm deadline on making a recommendation to the Secretary. No vote was taken on this suggestion.

A letter of support for ICD-10-CM and ICD-10-PCS from the American Hospital Association, the Federation of American Hospitals, and Advanced Medical Technology Association was presented to the full committee, but not discussed. The letter urged the NCVHS to recommend to the Secretary of DHHS that a proposed rule implementing ICD-10-CM and ICD-10-PCS be issued as soon as possible.

Appendix I

NCVHS Recommendations for a Single Procedure Classification System, November 1993

An Outline of the Characteristics of a Procedure Classification System

Hierarchical structure
- Ability to aggregate data from individual codes into larger categories
- Each code has a unique definition forever - not reused

Expandability
- Flexibility to new procedures and technologies (□empty□ code numbers)

Mechanism for periodic updating
- Code expansion must not disrupt systematic code structure

Comprehensiveness
- Provides NOS and NEC categories so that all possible procedures can be classified somewhere

Non-overlapping
- Each procedure (or component of a procedure) is assigned to only one code

Ease of Use
- Standardization of definitions and terminology
- Adequate indexing and annotation for all users

Setting and Provider Neutrality
- Same code regardless of who or where procedure is performed

Multi-axial
- Body system(s) affected
- Technology used

Limited to classification of procedures
- Should not include diagnostic information
- Other data elements (such as age) should be elsewhere in the record