SUMMARY REPORT

ICD-9-CM COORDINATION AND MAINTENANCE COMMITTEE

November 1-2, 2001

November 1, 2001 - Procedures Discussions

Introduction and Overview

Pat Brooks welcomed the participants to the ICD-9-CM Coordination and Maintenance (C&M) Committee meeting. Over 100 participants 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 HCFA. 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. November 1, 2001 was devoted to procedure issues, while November 2 was devoted to diagnosis issues. 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 8, 2002 on the proposed code revisions.

Copies of the timeline were presented to participants. This timeline discusses important events relating to the updating of ICD-9-CM. Topics discussed at this meeting were for code changes effective on October 1, 2002. It was also pointed out that a change has been made to the timeline. As a result of proposals in the Hospital Inpatient Prospective Payment System final rule published in the Federal Register on August 1, 2001, meetings will now take place in April and December of each year. Beginning with the April 18-19, 2002 meeting, procedure topics considered at the April meetings may also be included in code changes for October of the same year. Therefore, procedure topics discussed at the April 18-19, 2002 meeting may also be included in the October 1, 2002 addendum. This will only be possible if the issues are not controversial with differing viewpoints and if

there are not unresolved issues. Issues that cannot be resolved within a few weeks will be held over for study and considered for implementation the following year.

Those requesting that topics be discussed must submit these topics at least two months in advance of the meeting. It was also pointed out that the Notice of Proposed Rulemaking published on April 1, 2002 will include code titles and tentative DRG assignment for codes discussed at the May 2001 and November 2001 meetings. Additional procedure codes discussed at the April 18-19, 2002 C&M meeting may also be included in the final addendum. These codes discussed at the April 2002 meeting and their final DRG assignment will be included in the final rule published on August 1, 2002.

PROCEDURE CODE TOPICS

1. ICD-10-PCS Update

Pat Brooks presented a brief update on ICD-10-PCS. Implementation of ICD-10-PCS was discussed in great detail at the May 17, 2001 C&M meeting. Organizations provided formal statements on their views as to whether or not ICD-10-PCS should be implemented. There was overwhelming support for moving forward with the implementation of ICD-10-PCS. However, there was also a great deal of support for implementing the diagnosis and procedure volumes at the same time. Therefore, CMS was urged to wait until ICD-10 diagnosis was completed by NCHS prior to proceeding with ICD-10-PCS.

CMS is waiting for NCHS to complete ICD-10 diagnosis. Once that is completed, additional public meetings will be held on when and if both systems should be implemented. The National Committee on Vital and Health Statistics is planning to hold public hearings on this topic some time next year.

2. 360 Degree Spinal Fusion

John A. Wilson, MD, FACS, Wake Forest University, Baptist Medical Center, Winston-Salem, NC provided a clinical description of the procedure. Pat Brooks described current coding of the procedure and then described three options. There was considerable support for Option 3, which involved creating a new code for this procedure. However, several participants had concerns about double coding with the new 360-degree fusion code and one of the existing fusion/refusion codes. While this would show the level of the spine fused, it was felt that double coding would be confusing. It was recommended that new codes be created which would singly describe that a 360-degree fusion was performed with one incision and the part of the spine that was fused. Three codes would be required for this suggestion. One would be used for the lumbar part of the spine, one for the thoracic, and possibly one for the cervical spine. Dr. Wilson stated that the cervical spine was rarely fused with this type of a 360-degree fusion, however, it could be done.

Other participants agreed that creating three new codes that could be reported was a much better coding proposal. The participants were urged to send any additional comments or refinements to Pat Brooks.

3. Insertion of Interbody Spinal Fusion Device

John A. Wilson, MD also described the insertion of Interbody spinal fusion devices. Pat Brooks described the coding issues. There is currently no way to capture whether or not interbody spinal fusion devices are used during spinal fusion surgery. A proposal was described for the creation of a new code for this procedure.

The participants agreed with the need for a new code for the insertion of an Interbody spinal fusion device. There was concern expressed by a few participants about the inclusion terms in the draft proposal. One participant objected to the listing of "BAK cages", as this is a brand name. It was suggested that only generic names be listed as inclusion terms. Others in the audience suggested that brand names such as these should be listed in the index to assist the coders. Some participants also objected to using brand names in the index. It was stated that this type of information is more appropriately listed in Coding Clinic articles.

Participants suggested the following as possible inclusion terms: metal, plastic, carbon, ceramic, cages, and spacers. One other participant mentioned that there are no codes for a number of other types of orthopedic procedures such as pins and rods. They asked it these were being created at the same time. Pat Brooks responded that the proposals were limited to those being presented at this meeting. If participants had additional suggestions for new codes, they should be forwarded to CMS two months prior to the April 18-19, 2002 meeting.

4. Bone Morphogenetic Proteins

Thomas Schuler, MD from the Northern Virginia Spine Institute described how bone morphogenetic proteins (BMPs) are being tested for use in promoting bone growth in spinal fusions. Additional studies are being conducted on the use of BMPs for delayed unions and nonunions of fractured long bones. Pat Brooks described two coding options and the recommendation to create a new code once FDA approval is received. Participants supported the concept of waiting for FDA approval and then creating a generic code for insertion of recombinant bone morphogenetic protein. This code would be used for both spinal fusion and long bone insertions.

5. Brain Wafer Chemotherapy

Lawrence S. Chin, MD, FACS, University of Maryland Hospital, Baltimore, MD, provided a clinical overview of the use of brain wafer chemotherapy in treating patients with recurrent glioblastoma multiforme (GBM). Amy Gruber then led a discussion on the coding proposal to create a new code for this procedure. One participant asked if the only place these chemotherapy wafers would be used was in the brain. Dr. Chin stated that they can also be used in the liver and bladder. The concept is being used in other sites. Another participant suggested that additional inclusion terms such as

intracavity/interstitial and brain wafer chemotherapy be included under the proposed new code 00.10, Implantation of chemotherapeutic agent. Participants agreed with the proposal to create this new code.

One participant expressed concerns about the category title being proposed for the new series of codes under 00.xx. A title of Other Procedures is being proposed. The participant suggested a category title of "Other procedures and miscellaneous services".

6. Implantation of Neosphincter

Michael P. Spencer, MD, St. Paul, MN described the process of implanting a neosphincter. Ann Fagan then led a discussion of the code proposals, which involved the creation of two new codes, one for the implantation or revision of an artificial anal sphincter, and one for the removal of an artificial sphincter. One participant asked when a revision might be necessary. Dr. Spencer stated that when an infection occurs there is a need to remove the entire device to stop the infection. It has not been helpful to just remove part of the device. The participants supported the creation of these two new codes.

7. Repair of Aneurysm/Arteriovenous Malformation

Buddy Connors, MD, St. Joseph's Hospital, Tampa, FL described endovascular repair of cerebral vessels. Rupture of cerebral aneurysm leads to immediate death in 20% of cases. Of those who survive, 20% have permanent brain damage. Ann Fagan described the current codes and then led a discussion on the proposal to revise 39.79 and create a new code for endovascular repair of occlusion of head and neck vessels.

There was support for the proposal, which will help identify endovascular repairs of cerebral aneurysms. One participant suggested revising the proposed change for 39.79 to read: Other endovascular repair of other vessels, as it was felt to be unnecessary to include "non-head and neck" in the code title. A recommendation was also made to make the includes notes for 39.79 mirror those of new code 39.72. One participant questioned whether an inclusion term at 39.72, that for repair of aneurysm, arteriovenous malformation (AVM) or fistula, conflicts with the excludes note under 39.72 which reads: repair of arteriovenous fistula (39.53). Where do repairs of fistulas go? Another participant recommended clarifying fistula coding by revising code 39.73 to read: **open** repair of arteriovenous fistula. It was also suggested that the word "endografts" be added to the inclusion terms under 39.72. There was additional discussion about what the term "endograft" means. Dr. Connors stated that this means an artificial thing that is used or a cloth covered stent.

8. Therapeutic Ultrasound

Richard E. Kuntz, MD, Brigham and Women's Hospital, Boston, MA, provided a clinical description of intravascular sonotherapy. Ann Fagan then described coding issues. There is no specific ICD-9-CM code for intravascular sonotherapy procedure. FDA approval of this procedure is not anticipated until Spring 2003. The participants agreed with the

proposal of not creating new codes until there was FDA approval. Once this occurs, there was support for the codes developed by Ann Fagan to capture these procedures. However, as the topic has already been brought before the C&M, it will not be revisited prior to implementation of the codes. One participant asked if new code 00.09, Other therapeutic ultrasound, was for vessels only. If so, it was recommended that the title be changed to Other therapeutic **intravascular** ultrasound. We will leave the proposal as written, as the proposed new code 00.09, Other therapeutic ultrasound, is not intended for vessels only, even though the other proposed codes were geared towards vessels and heart. Code 00.09 would be a more generic classification. Another partcipant suggested that physical therapy be added as an exclusion term under proposed new code 00.09.

9. Infusion of Drotrecogin Alfa (Activated)

Peter E. Morris, MD, FACP, FCCP, Wake Forest University, Winston-Salem, NC described this new drug to treat severe sepsis that is currently under FDA investigation. It is anticipated that it will receive FDA approval within several weeks. Amy Gruber then described how it is currently coded. She led a discussion on the creation of a new code for the drug once there was FDA approval.

Several participants stated their opposition to creating new drug or device specific codes. It was stated that this is contrary to the design and use of ICD-9-CM as a classification system that captures groups of similar services or procedures. The participants were particularly opposed to the creation of a drug specific code since hospitals rarely use the drug codes in this part of the book anyway. Using up remaining codes s in the ICD-9-CM to create drug specific codes would lead to the remaining codes being used up quickly. It was recommended that if new codes are created for drugs thatthey be more generic to include classes of drugs as is currently captured with ICD-9-CM. One participant stated that all recombinant drugs should not be captured in one code because of outcomes. A precedent has been set with a code for tissue plasminogen activator (TPA)

10. Application of Adhesion Barrier

F.J. Montz, MD, Johns Hopkins Hospital, Baltimore, MD, described this procedure. Ann Fagan then led a discussion on the code proposals. One participant questioned why there was a need to code the application of adhesion barriers when we do not currently assign codes for such things as sutures. Dr. Montz responded that this was a somewhat difficult substance to apply correctly, but it benefits patients by reducing adhesions. Others asked if it would be well enough documented in the medical record so that coders could identify its use. Dr. Montz responded that if it were being used, it most probably would be described. Others asked if it were so beneficial, why wasn't it being more widely used. Dr. Montz responded that there is a learning curve to correctly apply it. If it isn't used correctly, there could be more damage. While some participants supported this new code, others questioned the need. Commenters pointed out that application of a substance could be considered inherent to the procedure, and also noted out that grafts and patches are not specifically coded.

11. Extracorporeal Immunoadsorption (ECI)

Victor A. Silva, MD, Fresenius HemoCare, Inc, Redmond, WA. described extracorporeal immunoadsorption (ECI). Amy Gruber then led a discussion on the coding proposal. One participant asked if the procedure could be performed on both an inpatient and an outpatient basis. Dr. Silva stated that the procedure was done in relationship with transplant surgery. It could be done on either an inpatient or outpatient basis. It could be done after the transplant if the patient is rejecting the transplant.

The participants supported the creation of a new code for ECI. One participant also recommended adding an excludes note under code 99.71, Therapeutic plasmapheresis, to exclude ECI.

12. intraoperative Magnetic Resonance Imaging (iMRI)

Ann Fagan described the request for code revisions to capture iMRI. Ann described three options but did not recommend any of the three, seeking instead the participant's input on this issue. Several participants preferred option 2, which involved creating new code 88.99, Intraoperative magnetic resonance imaging. It was felt that this single code would capture the use of iMRI. One participant opposed option 3 with its variety of iMRI codes by site. It was felt that this level of detail was unnecessary. One would know the location of iMRI use by looking at the procedure code, which also would be reported. Another participant recommended that the new excludes note being proposed under category 88.9, Other diagnostic imaging, be moved to the code level under 88.91. Otherwise the category would exclude a code within the category.

13. Administration of Inhaled Nitric Oxide (INO)

Robin Steinhorn, MD, Children's Memorial Hospital, Chicago, IL described the use of inhaled nitric oxide (INO) for newborns. She contrasted INO with the more intensive and intrusive use of extracorporeal membrane oxygenation (ECMO). Amy Gruber then led a discussion on the proposal to create a new code to capture the administration of INO. There was t support for this new code.

14. Cardiac Resynchronization Therapy

Stephen Mester, MD, Bay Area Cardiology, Tampa, FL, described the new type of pacing device known as cardiac resynchronization therapy (CRT). He further described CRT devices that also perform defibrillation. He described how these devices are different from current pacemakers and defibrillators and how an extra lead is utilized. Pat Brooks led a discussion on the proposal to create a new series of codes to capture these devices. There was a great deal of support for the concept of creating these new series of codes. However, since this was a rather lengthy series of codes, lengthy includes and excludes notes, several participants stated that they would be sending in written comments later on the details of the proposals. The participants plan to review

the codes along with documentation in their medical records. However, it was felt that unique codes for these devices was needed.

15. Drug-eluting Stent

Jeffrey Popma, MD, Brigham and Women's Hospital, Boston, MA, described the use of these new devices. The FDA has not yet approved drug-eluting stents. Dr. Popma stated that studies seem to indicate that this new type of stent eliminates restenosis. However, only 238 cases have been analyzed to date. Ann Fagan led a discussion of the coding proposal. Since the device has not yet received FDA approval, no CMS recommendation was made. Participant's comments were solicited. One participant questioned the need for a new, precise code for drug-eluting stent. This participant pointed out that if, in fact, the stent proves to be a significant improvement over current stents, then the drug-eluting stent will probably replace those currently on the market, and will become the new standard of care. Dr. Popma stated that it would be useful to capture information on the use to the new stent to tell whether this were true.

One participant stated that existing code 36.06 should probably be renamed "Insertion of **non-eluting** coronary artery stent(s)" if code 36.07 were created. Another participant suggested that new sub-section 00.5 be renamed Other **cardiovascular** procedures.

Because FDA approval on this product is not expected until the third or fourth quarter of 2002, meeting attendees were not overwhelmingly in favor of immediately assigning new codes. As the topic has already been brought before the C&M, it will not be necessary to revisit this topic if the decision is made to implement new codes.

16. Injection or Infusion of Human B-Type Natriuretic Peptide (hBNP)

Robert C. Bjourge, MD, University of Alabama at Birmingham described the use of hBNP. Amy Gruber then led a discussion on the code proposals. One participant voiced opposition with the creation of a new code that would describe a single drug. Other participants agreed and stated similar concerns as were mentioned on topic 9, Infusion of Drotrecogin Alfa (Activated). It was felt that codes for specific drugs is an inappropriate use of ICD-9-CM. In addition, hospitals do not routinely code and report the existing drug codes in ICD-9-CM.

17. Administration of Oxazolidinone

Barry Hafkin, MD, Pharmacia Corporation, Peapack, NJ, described this new drug which represents a new class of antibiotics. It received FDA approval on April 18, 2000. Ann Fagan then led a discussion on the code proposals. Once again participants stated their opposition to the creation of codes for specific drugs. It was stated that ICD-9-CM is not a drug naming coding system. One participant stated that if there were a need for codes for new types of drugs, that the category of drugs should be captured. Codes should not be developed for specific drugs. A recommendation was made to create a new code for antibiotics for drug resistant infections. Another participant pointed out that there is

already a code for the administration of antibiotics. This participant stated that hospitals do not currently report 99.21, Injection of antibiotic, with any great frequency. One person asked if Oxazolidinone must always be injected. Dr. Hafkin stated that the drug is also available in pill form.

18. Addenda

Amy Gruber led a discussion on the proposed addenda. There was general support for all the recommendations. One participant suggested that code 51.01 be renamed as: Percutaneous **cholecystotomy for drainage.** In addition it was recommended that the inclusion term, that by: needle, catheter, also be added.

This concluded the procedure part of the meeting. The meeting was adjourned until November 2 when diagnosis topics would be addressed by NCHS.

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
November 1-2, 2001

Patricia E. Brooks
Co-Chairperson

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

Topics:

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

2. 360 Degree Spinal Fusion
   Patricia E. Brooks
   John A. Wilson, MD, FACS
   Wake Forest University,
   Baptist Medical Center

3. Insertion of Interbody Spinal Fusion Device
   Patricia E. Brooks
   John A. Wilson, MD, FACS
   Wake Forest University,
   Baptist Medical Center

4. Bone Morphogenetic Proteins
   Patricia E. Brooks
   Thomas Schuler, MD
   Northern Virginia Spine
   Institute

5. Brain Wafer Chemotherapy

Amy L. Gruber
Lawrence S. Chin, MD, FACS
University of Maryland

6. Implantation of Neosphincter

Ann B. Fagan
Michael P. Spencer, MD
St. Paul, MN

7. Repair of Aneurysm/Arteriovenous Malformation

Ann B. Fagan
Buddy Connors, MD
St. Joseph's Hospital, Tampa, FL

8. Therapeutic Ultrasound

Ann B. Fagan
Richard E. Kuntz, MD
Brigham and Women's Hospital
Boston, MA

9. Infusion of Drotrecogin Alfa (Activated)

Amy L. Gruber
Peter E. Morris, MD, FACP, FCCP
Wake Forest University

10. Application of Adhesion Barrier

Ann B. Fagan
F.J. Montz, MD
Johns Hopkins Hospital

11. Extracorporeal Immunoadsorption (ECI)

Amy L. Gruber
Victor A. Silva, M.D.
Fresenius HemoCare, Inc.

12. Intraoperative Magnetic Resonance Imaging (iMRI)

Ann B. Fagan

13. Administration of Inhaled Nitric Oxide (INO)

Amy L. Gruber
Robin Steinhorn, MD
Children's Memorial Hospital
Chicago, IL

14. Cardiac Resynchronization Therapy

Patricia E. Brooks
Stephen Mester, MD
Bay Area Cardiology, Tampa, FL

15. Drug-eluting Stent

Ann B. Fagan
Jeffrey Popma, MD
Brigham and Women's Hospital
Boston, MA

16. Injection or Infusion of Human B-Type Natriuretic Peptide (hBNP)

Amy L. Gruber
Robert C. Bourge, MD
University of Alabama at Birmingham

17. Administration of Oxazolidinone

Ann B. Fagan
Barry Hafkin, MD
Pharmacia Corporation

18. Addenda

Amy L. Gruber

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

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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.hcfa.gov/medicare/icd9cm.htm

NCHS will present diagnosis topics at the conclusion of the procedure topics. For information pertaining to the diagnosis topics, 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:

May 17-18, 2001	ICD-9-CM Coordination and Maintenance Committee Meeting in CMS's auditorium. Code revisions discussed were for potential implementation on October 1, 2002.
August 1, 2001	Hospital Inpatient Prospective Payment System final rule published in the Federal Register as mandated by Public Law 99-509.
September 1, 2001	Those members of the public requesting that topics be discussed at the November 1-2, 2001 ICD-9-CM Coordination and Maintenance Committee meeting should have their requests to CMS for procedures and NCHS for diagnoses.
October 1, 2001	New and revised ICD-9-CM go into effect along with all other DRG changes.
October 5, 2001	Federal register notice of meeting published.
October 2001	Tentative agenda for the Procedure part of the November 1, 2001 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS=s homepage as follows: http://www.hcfa.gov/medicare/icd9cm.htm Tentative agenda for the Diagnosis part of the November 2, 2001 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on NCHS= homepage as follows: http://www.cdc.gov/nchs/icd9.htm
Nov.1-2, 2001	ICD-9-CM Coordination and Maintenance Committee Meeting. Code revisions discussed are for potential implementation on October 1, 2002. November 1 will be devoted to discussions of procedure codes. November 2 will be devoted to discussions of diagnosis codes.
December 2001	Summary report of the Procedure part of the November 1, 2001 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS=s homepage as follows: http://www.hcfa.gov/medicare/icd9cm.htm

Summary report of the Diagnosis part of the November 2, 2001 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 8, 2002 — Deadline for receipt of public comments on proposed code revisions discussed at the May 17-18, 2001 and November 1-2, 2001 ICD-9-CM Coordination and Maintenance Committee meetings. These proposals are being considered for implementation on October 1, 2002.

February 18, 2002 — Those members of the public requesting that topics be discussed at the April 18-19, 2002 ICD-9-CM Coordination and Maintenance Committee meeting should have their requests to CMS for procedures and NCHS for diagnoses.

March 2002 — Tentative agenda for the Procedure part of the April 18-19, 2002 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS=s homepage as follows:
http://www.hcfa.gov/medicare/icd9cm.htm

Tentative agenda for the Diagnosis part of the April 18-19, 2002 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 18-19, 2002 ICD-9-CM Coordination and Maintenance Committee Meeting to be published. This will include the tentative agenda.

April 1, 2002 — 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 May 17-18, 2001 and November 1-2, 2001. 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 18-19, 2002 meeting that might also be included in the October 1, 2002 addendum. The proposed rule can be accessed at:
www.hcfa.gov/medicare/ippsmain.htm

April 18-19, 2002 — ICD-9-CM Coordination and Maintenance Committee Meeting in CMS's auditorium. Diagnosis code revisions

	discussed are for potential implementation on October 1, 2003. Procedure code revisions discussed will be for October 1, 2002. Those procedure code proposals that cannot be resolved quickly will be considered for implementation on October 1, 2003.
April 30, 2002	Written comments due on procedure code proposals discussed at the April 18, 2002 meeting.
April 2002	Summary report of the Procedure part of the April 18, 2002 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS=s homepage as follows: http://www.hcfa.gov/medicare/icd9cm.htm Summary report of the Diagnosis part of the April 19, 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
August 1, 2002	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 discussed at the April 18, 2002 meeting and resolved in time for implementation on October 1, 2002.
October 1, 2002	New and revised ICD-9-CM go into effect along with all other DRG changes.
October 5, 2002	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 2002	Tentative agenda for the Procedure part of the December 5, 2002 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS=s homepage as follows: http://www.hcfa.gov/medicare/icd9cm.htm Tentative agenda for the Diagnosis part of the November 6, 2002 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 5-6, 2002 ICD-9-CM Coordination and Maintenance Committee Meeting to be published. This will include the tentative agenda.
Dec. 5-6, 2002	ICD-9-CM Coordination and Maintenance Committee Meeting. Code revisions discussed are for potential implementation on October 1, 2003. December 5 will be devoted to discussions of procedure codes. December 6 will be devoted to discussions of diagnosis codes.
December 2002	Summary report of the Procedure part of the December 5, 2002 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS=s homepage as follows: http://www.hcfa.gov/medicare/icd9cm.htm 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

360 DEGREE SPINAL FUSION

Issue: Medical technology has changed since physicians began performing 360-degree spinal fusions. A 360-degree spinal fusion is a fusion of both the anterior and posterior portion of the spine performed during the same operative session. Historically this was performed with two incisions. One incision was made with the patient facing the surgeon and the other incision was made through the patient's back. These are called anterior and posterior approaches. Current instrumentation allows surgeons to perform fusions of the anterior and posterior portion of the spine (or 360-degree fusion) by using a single approach. This procedure gives the patient the benefits of an anterior and posterior fusion without having two incisions. Reporting only the code for the single approach used does not adequately describe this procedure.

Background:

In the classic anterior approach, the procedure is performed from the front, with the patient facing the surgeon, through an incision in the neck or abdomen. The fusion is carried out from the front of the vertebrae through the anterior annulus. In the classic posterior approach, the procedure is performed through an incision in the patient's back directly over the vertebrae. The fusion is carried out from the back of the vertebrae through the lamina, removing the spinous processes. In another approach, lateral transverse, the incision is made on the patient's side but this is also considered a posterior approach because the patient is lying face down and the vertebrae are approached through the lamina.

A surgeon can perform both an anterior fusion and a posterior fusion during the same operative session, in which both the front and back of the vertebrae are fused. This has traditionally involved both an anterior approach and a posterior approach, accomplished by repositioning the patient and making two incisions. However, improved technology and surgical techniques allow both an anterior and a posterior spinal fusion to be accomplished through a single incision, predominantly via the lateral transverse approach. Therefore**,** in a 360^{o} spinal fusion, both anterior and posterior vertebrae are fused, sometimes through both anterior and posterior approaches and sometimes through a single lateral transverse approach.

Operations in which both an anterior and posterior fusion are performed are clinically more complex and require significantly higher resources including operative time, implantable devices, and recovery time than when a fusion is performed to only one part of the spine (anterior or posterior).

Currently, hospitals assign codes for the fusions and refusions based on the approach to the patient and the level of the fusion. Therefore, for a patient who undergoes a fusion where the surgeon makes an incision in the back, the hospital assigns a posterior fusion code. If the surgeon approaches the procedure from the back, but uses instrumentation to

perform both a posterior and anterior spinal fusion, the hospital assigns only the code for the posterior fusion. The fact that there has been a 360-degree fusion is therefore lost.

There are several options for solving this problem. Hospitals could be instructed to code both the anterior and posterior approaches when a 360-degree fusion is performed. A problem with this solution is that patients who have incisions from both the back and front would be grouped with patients receiving only a single approach to a 360-degree fusion.

The problem could also be solved by creating a new code for 360-degree fusion. This code would be used in addition to the fusion/refusion code to show that while only a single approach may have been used, both the anterior and posterior of the spine have been fused.

Options:

1. Make no changes. Instruct coders to continue assigning only the code for the approach to the patient that is used for 360-degree fusions. Therefore only the posterior code would be assigned when this was the approach to the patient.
2. Instruct coders to assign codes for the part of the spine that is fused, no matter how many incisions were made. Therefore both posterior and anterior approach codes would be assigned for 360-degree fusions even if there were a single approach to the patient.
3. Create a new code for 360-degree fusion to be reported along with the current fusion (81.0X) and refusion (81.3X) codes to show that a 360-degree fusion was performed.

Recommendation: CMS recommends the use of Option 3, create a new code for 360-degree fusion. This option will clearly identify those patients who have a 360 degree fusion performed through a single approach. The code would be reported along with the current fusion (81.0x) and refusion (81.3X) codes, which would show the approach to the patient and the level of the spine. This new code would be as follows:

New Category:

81.6 Other procedures on spine

New Code: 81.61 360-degree spinal fusion, single incision approach
Includes: that by a single approach but fusing or refusing both anterior and posterior spine

81.0 Spinal fusion
Add: Code also any 360-degree spinal fusion (81.61) by a single approach

81.3 Refusion of spine
Add: Code also any 360-degree spinal refusion (81.61) by a single approach

In the meantime hospitals should continue assigning a single approach code for those who receive a 360-degree spinal fusion through a single anterior or posterior approach.

INSERTION OF INTERBODY SPINAL FUSION DEVICE

Issue: ICD-9-CM does not currently capture spinal fusion devices such as the interbody spinal fusion device, which are used during spinal fusion procedures. These devices are also referred to as interbody fusion cages, Bak cages, and titanium cages. The current spinal fusion codes do not describe when such devices are used.

Background: Spinal fusions are performed when excessive vertebral motion causes chronic back pain. The fusion of the vertebrae stops the motion, which should then reduce the pain. Non-instrumented spinal fusions have been performed using bone graft only. Donor bone or a harvested bone graft from the patient's hip is used. This bone graft is inserted between the vertebrae or around the posterior of the spine. The graft is used in an attempt to immobilize this portion of the patient's spine. Shortcomings of the current fusion techniques include lower fusion success rates, bone graft migration and collapse, bone graft site pain, long recovery, and less post-operative stability.

Current fusion techniques involving instrumented techniques include the use of pedicle screws. Using this technique, the surgeon inserts bone graft and then inserts rods and screws for stability. Shortcomings of this technique include long surgery, high blood loss, long rehabilitation, as well as a high re-operation rate.

Interbody fusion devices (or cages) were designed to stabilize and fuse the degenerative disc spaces(s). The systems were designed to provide an immediately stable segment to allow fusion and relief of symptoms. The procedure utilizes small, threaded metal cylinders to restore the degenerated disc space to or near its original height, relieving pressure on the nerves. The devices are not used on patients with severe infections. During surgery the physician removes portions of the disc and vertebral bones allowing the implants to be inserted into the disc space. Bone graft are not always used but when used are packed inside the implant. The devices may be implanted from a posterior or anterior approach. Multiple fusion devices/cages may be implanted. Hospitals may implant up to four of these devices.

Clinical trials have shown that fusion and clinical outcomes are comparable or superior to those of traditional types of fusion. The elimination of the need for an autograft bone harvest is described as a benefit to patients.

The devices were originally used for patients with no previous fusions. However, they are now being used on refusions. The current ICD-9-CM codes capture the level and approach for both fusions and refusions. A new code to show that an interbody fusion device/cage was inserted would allow the capture of this new technique.

Options:

1. Create a new category and code for the insertion of an interbody fusion device as follows:

84.5 Implantation of other musculoskeletal devices and substances
84.51 Insertion of interbody spinal fusion device
Insertion of: interbody fusion cage
Bak cages
Titanium cages

In addition, add a "code also" note under the spinal fusion (81.0x) and refusion (81.3x) categories as follows:

Code also any insertion of interbody spinal fusion device (84.51)

2. Do not create a new code for the insertion of an interbody spinal fusion device. Continue assigning only the codes for the spinal fusion or refusion.

Recommendation: CMS recommends Option 1, create a new code for the insertion of an interbody fusion device as follows:
84.51 Insertion of interbody spinal fusion device

In the meantime continue assigning codes for the types of fusions and other procedures performed. There is currently no additional code that can currently be assigned to capture the insertion of the interbody spinal fusion device.

BONE MORPHOGENETIC PROTEINS

Issue: Bone morphogenetic proteins (BMP) have been isolated and shown to have the capacity to induce new bone formation. Using recombinant techniques, some BPMs (referred to as rhBMPs) can be produced in large quantities. This has led the way for their potential use in a variety of clinical applications such as in delayed unions and nonunions of fractured bones and spinal fusions. There have been fifteen BMPs developed so far. There is currently no means to capture whether or not the BMP is inserted into a patient. Currently, one would simply code the orthopedic procedure such as the spinal fusion. There is no separate code for the insertion of BMP as part of the procedure.

Background: The FDA has not yet approved any of the BMP products. BMP is under investigation for several applications. One use being studied is for use in with spinal fusions. The FDA is investigating the use of one such product, rhBMP-2, for use instead of a bone graft with spinal fusions. FDA approval of rhBMP-2 is not expected for at least nine months. Other BMPs are being studied for use in promoting healing for long-bone fractures. Long bone fractures have a high rate of healing complications such as delayed union or non-union. The long bones being studied for use include the humerus, radius/ulna, femur, and tibia/fibula.

The BMP product must be surgically implanted. For treatment of long-bone fractures the product is used for cases requiring open surgical management of the fracture. Only long bone fractures that present to the surgeon as open fractures or are severe enough to require open surgical management are considered potential candidates for the product. These open surgical fracture repair procedures are coded as open reduction internal fixations. The fact that BMP was also applied to promote bone growth is not captured.

As stated previously, rhBMP-2 is being tested for use in the treatment of spinal fusions. The product is being applied through use of an absorbable collagen sponge or in an interbody fusion device, which is then implanted at the fusion site. The patient undergoes a spinal fusion, and the product is placed at the fusion site to promote bone growth. This is done in place of the more traditional use of autogenous iliac crest bone graft. The hospital would assign the appropriate codes for the spinal fusion; however, there is not an ICD-9-CM code to capture the application of the BMP.

Current coding practice is not to code the application of a bone graft separately with a spinal fusion. The inclusion notes under category 81.0 state that bone graft are included. However, BMPs are not a bone graft. They are a bone graft replacement for which there is currently no unique code.

Options:

1. Do not create a new code. Consider a code once the product has received FDA approval.

2. Create a new code for the application of BMP for use at any site. Since the hospital would also be coding the open reduction or spinal fusion, one would know the site at which the BMP was inserted.

   Create the following new category and code for the application of BMP

   84.5 Implantation of other musculoskeletal devices and substances
   84.52 Insertion of recombinant bone morphogenetic protein
   Bone grafting material
   rhBMP
   That via collagen sponge, coral, ceramic and other carriers
   Code also primary procedure performed:
   spinal fusion (81.00 - 81.09)
   spinal refusion (81.30 - 81.39)
   fracture repair

Code also notes would be added under the spinal fusion and reduction codes as follows: Code also any insertion of recombinant bone morphogenetic protein (BMP) 84.52.

Recommendation:

Select option 1. Do not consider the creation of a new code until BMP has received FDA approval. In the meantime, continue assigning existing codes for the type of orthopedic procedure performed such as open reduction of fracture or spinal fusion. No additional code would be assigned for the insertion of BMP. Once FDA approval is received, consider option 2 for the creation of a new code.

Brain Wafer Chemotherapy

Issue:
Should a new procedure code be created for the implantation of chemotherapeutic agent?

Background:
GLIADEL® Wafer received FDA approval in 1996 and is used as an adjunct to surgery to prolong survival in patients with recurrent glioblastoma multiforme (GBM) for whom surgical resection is indicated. Implanted directly into the cavity that is created when a brain tumor is surgically removed, GLIADEL® Wafer (prolifeprosan 20 with carmustine implant) directly delivers anti-tumor medication to the site of the removed tumor. It is the only implantable drug that delivers chemotherapy directly to the tumor site, thereby avoiding the side effects of systemic agents.

GBM is the most common and rapidly fatal form of brain cancer. The prognosis for those with malignant gliomas is poor, and there are few alternatives for these patients. This year approximately 36,000 primary brain tumors are expected to be diagnosed. About 10,000 of these (30 percent of brain tumors) are high-grade astrocytomas. Approximately 80 percent of these patients undergo a first surgery; 40 percent of these patients will have a second surgery. Over 6,000 patients have been treated with GLIADEL® Wafer since 1996. The median survival results of the recurrent malignant glioma trial indicate patients treated with GLIADEL® was 31 weeks, while the placebo group was 23 weeks.

As part of the base service, the tumor is resected using standard techniques. When the tumor is resected, a sample of the tumor is evaluated by a neuropathologist who determines that the tumor is in fact a glioblastoma multiforme and not radiation necrosis. The neurosurgeon determines that it is appropriate to implant the wafers in the resected tumor cavity, which is prepared by inspection for bleeding and any communication with a ventricle.

The number of wafers implanted is dependent on the size and location of the tumor cavity. It is recommended that eight wafers be placed in the resection cavity if the size and shape of it allows. The wafers are placed against the wall of the tumor cavity by forceps, close together with only slight overlapping. Great care is taken to ensure that the wafers cover the greatest area of the walls of the tumor cavity while avoiding the ventricles and large vascular structures. Once full coverage of the surgical cavity is achieved, the neurosurgeon applies a topical absorbable hemostatic agent to the area to secure the wafers in place.

Options:

1. Continue to code this procedure that is adjunct to surgery to code 99.25, Injection or infusion of cancer chemotherapeutic substance.

2. Assign a new code to capture the implantation of chemotherapeutic agent.

New code 00.10 Implantation of chemotherapeutic agent

CMS Recommendation:

Option 2. Assign a new code to capture the implantation of chemotherapeutic agent.
New code 00.10 Implantation of chemotherapeutic agent

In the interim, continue to code this procedure that is adjunct to surgery to code 99.25, Injection or infusion of cancer chemotherapeutic substance.

Implantation of Anal Neosphincter

Issue:
There are no ICD-9-CM codes that capture the implantation of an anal neosphincter, used in the treatment of fecal incontinence.

Background:
Fecal incontinence is a distressing handicap that can lead to social isolation, loss of independence, and a reduced quality of life. A cross-sectional, community-based study of 778 men and 762 women from Olmstead County, Minnesota found the age-adjusted prevalence of fecal incontinence in men to be 11.1% and that of women to be 15.2%.

Intractable or severe fecal incontinence (SFI) is the involuntary loss of solid or liquid stool more than once a week. SFI is experienced by less than 3% of those suffering from fecal incontinence.

There is a device on the market that was granted a Humanitarian Device Exemption by the Food and Drug Administration in September 1999. Patients who are candidates for this artificial anal sphincter have intractable fecal incontinence due to anorectal trauma (obstetrical, surgical, or accidental), congenital malformations (spina bifida or imperforate anus) or neurological disorders (neuropathy or myasthenia gravis) and have failed conventional management of their fecal incontinence. In the Artificial Bowel Sphincter Clinical Trial Group, the etiology distribution was as follows: Obstetric – 30%, Neurogenic – 20%, Congenital – 20%, Anorectal trauma – 18%, and Other – 12%.

The neosphincter currently on the market is composed of a cuff that is placed around the anal canal, a pressure-regulating balloon, and a control pump that is placed in the scrotum or labia. Tubing connects the cuff to the control pump. Separate tubing connects the control pump to the reservoir balloon. The usual hospital stay is 5 days. The patient returns for activation of the device six weeks after surgery, if adequate healing has occurred.

Of 112 patients (75% Female / 25% Male) who underwent implantation of this device in the Artificial Bowel Sphincter Clinical Trial Group, there were a total of 342 adverse events in 92 patients. Of these events, 179 required no intervention or only non-invasive intervention. The infection rate was 24%, surgical revisions were required in 41%, and 30% of patients underwent explantation of the device. In patients with a functioning neosphincter, improvement in the quality of life and anal continence was documented.

Coding Options:

Option 1:

Do not create a new code. Continue to code this procedure to 49.79, Other repair of anal sphincter

Option 2:

Create two new codes to capture the implantation of an artificial anal sphincter, as follows:

49.7 Repair of anus
- 49.75 Implantation or revision of artificial anal sphincter
- 49.76 Removal of artificial anal sphincter

Recommendation:

Option 2:

Create two new codes to capture the implantation of an artificial anal sphincter, as follows:

49.7 Repair of anus

- 49.75 Implantation or revision of artificial anal sphincter
  Excludes: other repair of anal sphincter (49.79)

- 49.76 Removal of artificial anal sphincter

Interim Coding

In the interim, continue to use code 49.79, Other repair of anal sphincter to describe this procedure.

Endovascular Repair of Cerebral Vessels

Revision of category 39.7, Endovascular repair of vessel

Issue:

Effective for discharges on or after October 1, 2000, we had created new ICD-9-CM codes 39.71, Endovascular implantation of graft in abdominal aorta, and 39.79, Other endovascular graft repair of aneurysm. We had moved the concept of endovascular repair out of code 39.52, Other repair of aneurysm, as the endovascular approach is so unique.

However, in creating these two new codes, we didn't go quite far enough in recognizing the endovascular approach for other vessels and sites. Therefore, we're bringing this topic back in order to discuss cerebral vessels.

Background*

Stroke and cerebrovascular diseases are the third leading cause of death and a leading cause of major disability in the United States. More than 600,000 new strokes occur each year, resulting in >200,000 deaths and >250,000 permanent disabilities per year. There are currently more than 4.4 million stroke victims living with disability. Hemorrhagic stroke is due to bleeding into the brain, causing either death or major disability. Cerebral aneurysm rupture accounts for the majority of these hemorrhagic strokes each year.

Cerebral Aneurysms

An aneurysm is an area of weakness in a blood vessel, which usually enlarges over time. It is often described as a "ballooning" out of the blood vessel. If a cerebral aneurysm gets very large, it may begin to produce pressure on the normal brain tissue or adjacent nerves. This pressure can cause difficulty with vision, numbness or weakness of an arm or leg, difficulty with memory or speech, or seizures. Typically, there is no warning before an aneurysm ruptures, at which point it causes bleeding into or around the brain and/or death. If the brain tissue is damaged, this is termed a "hemorrhagic stroke".

Surgical Treatment Options:

Neurosurgery: Depending upon risk factors, open surgery may be recommended. Patients are placed under general anesthesia, the brain tissue is spread apart, and the aneurysm is surgically exposed in order to allow the neurosurgeon to place a surgical clip (similar to a bobby pin) around the base of the aneurysm. The clip acts to externally "seal off" the aneurysm so that blood can no longer enter from the blood vessel and leak through the aneurysm into the brain. For an uncomplicated surgical clipping procedure of an unruptured aneurysm, the hospital stay is usually 4-6 days with 3-6 weeks for post-operative recovery. If the aneurysm has already ruptured, the hospital stay is usually 2-4 weeks, mostly in an ICU.

Endovascular Neurosurgery: Depending upon the aneurysm size, location, and shape, it may be possible to treat the aneurysm from inside the blood vessel.

Typically, after patients are placed under general anesthesia in an endovascular

neurosurgical operating suite, and utilizing x-ray guidance, a neuro-microcatheter is guided into the aneurysm. Soft platinum micro-coils are carefully placed individually and sequentially into the aneurysm and detached. The coils remain within the aneurysm acting as a mechanical barrier to blood flow, and sealing it off, similar to filling a pothole in the street. For an uncomplicated procedure, the hospital stay may be as short as 2-4 days with minimal post-operative out-of-hospital recovery. However, as stated above, for a complicated surgery or endovascular treatment, or if an aneurysm has already bled into the brain, hospitalization is typically 2-4 weeks (depending upon the medical condition of the patient and any complications that occur as a result of the hemorrhage).

Cerebral Arteriovenous Malformation (AVM)

A cerebral AVM is a tangle of blood vessels located within the brain or on the surface of the brain that bypasses normal brain tissue and that directly shunts blood from the arteries to the veins.

There is a 1-3% chance per year of a cerebral AVM bleeding, resulting in stroke or death. Over a 15-year period, there is a 25% total chance of an AVM bleeding into the brain and causing brain damage or death. There is a 10%-15% chance of death related to each bleed, and a 20%-30% chance of permanent brain damage (e.g., hemorrhagic stroke). Each time blood leaks into the brain; there is direct damage to the normal brain tissue. This results in permanent or temporary loss of normal function, such as arm or leg weakness/paralysis, or difficulty with speech, vision, and memory. The amount of brain damage depends upon how much blood has leaked from the AVM.

Surgical Treatment Options for AVM
Neurosurgery: If an AVM has bled and/or is in an area that can be easily operated upon, then surgical removal may be recommended. The patient is anesthetized, a portion of the cranium removed, then the AVM is surgically excised. When the AVM is completely removed, the patient will be cured and there should no longer be any chance of further bleeding to occur.

Endovascular Neurosurgery: It may be possible to treat part or all of the AVM by going inside the blood vessels that supply the AVM and blocking off the abnormal blood vessels. A variety of materials can be used as occluding agents, including liquid tissue adhesives (glues), micro-coils, particles, and other materials that act to stop blood flowing to the AVM.

The best treatment will depend upon what type of symptoms the patient is having, what type of AVM is present, and the AVM size and location. Typically, a combination of blocking blood vessels to make surgery safer and then following this with surgery is performed.

Coding Advice

In order to capture the concept of the endovascular repair, and in anticipation of coding changes being presented at the C&M meeting today, the American Hospital Association published a recommendation in *Coding Clinic for ICD-9-CM, 3*rd Quarter 2001, page 18, concerning liquid embolization of AVM. The advice given was to assign code 39.79, Other endovascular graft repair of aneurysm, to describe endovascular repair of AVM.

Option
Revise the current codes and create new structure in this subcategory as follows.

39.7 Endovascular repair of vessel
Endoluminal repair

39.71 Endovascular implantation of graft in abdominal aorta

New code 39.72 Endovascular repair or occlusion of head and neck vessels
that for repair of aneurysm, arteriovenous malformation (AVM) or fistula
Coil embolization or occlusion
Liquid tissue adhesive (glue) embolization or occlusion
Other implant or substance for repair, embolization or occlusion

Excludes: clipping of aneurysm (39.51)
repair of arteriovenous fistula (39.53)
endovascular repair or occlusion of non-head and neck vessel or aneurysm (39.79)

Revised code 39.79 Other endovascular ~~graft~~ repair or occlusion of non-head and neck vessels or aneurysm
Coil embolization or occlusion
Endograft
Liquid tissue adhesive (glue) embolization or occlusion
Other implant or substance for repair, embolization or occlusion

Add *Excludes: insertion of non-coronary artery stent or stents (for other than aneurysm repair) (39.90)*
other surgical occlusion of vessels (38.8x)
percutaneous transcatheter infusion (99.29)
repair of arteriovenous fistula (39.53)
transcatheter embolization for gastric or duodenal bleeding (44.44)

Delete ~~Implantation of graft in:~~
~~lower extremity artery(s):~~
~~celiac~~
~~femoral~~
~~hepatic~~
~~iliac~~
~~mesenteric~~
~~popliteal~~
~~renal~~
~~splenic~~

~~tibial~~
~~thoracic aorta~~
~~upper extremity artery(s):~~
~~axillary~~
~~brachial~~
~~brachiocephalic~~
~~carotid~~
~~radial~~
~~ulnar~~
~~Stent graft(s)~~

Recommendation
CMS recommends that the format described above be adopted.

Interim Coding
Continue to capture the endovascular approach to intracranial vessel repair by using 39.79, Other endovascular graft repair of aneurysm. Source: *Coding Clinic for ICD-9-CM,* 3rd Quarter 2001, page 18.

* The background sections were extracted from forthcoming Patient Education Brochures (American Heart Association) authored by Randall Higashida, MD.

Intravascular Sonotherapy** Procedure

- Anti-restenotic Vascular Therapy
Utilizing Therapeutic Ultrasound -

Issue:
There is no specific ICD-9 code describing the Intravascular Sonotherapy™ procedure. Are unique codes needed?

Background:
Intravascular Sonotherapy™ was developed to provide clinicians that treat patients for atherosclerotic vascular disease with a therapy that does not utilize ionizing radiation or drugs. Intravascular Sonotherapy™ is an interventional treatment modality that uses a selective spectrum of therapeutic ultrasound energy. It is a lower frequency and higher intensity levels than used in diagnostic ultrasound applications. Intravascular Sonotherapy™ is below the high intensity levels of therapeutic ultrasound used to break tissue such as such as lithotripsy or lysis of clots.

The Intravascular Sonotherapy™ system has two components: 1) a catheter introduced percutaneously (through the skin) and 2) a dedicated ultrasound instrument to generate and control the ultrasound therapy. The instrument is the size of a standard infusion pump.

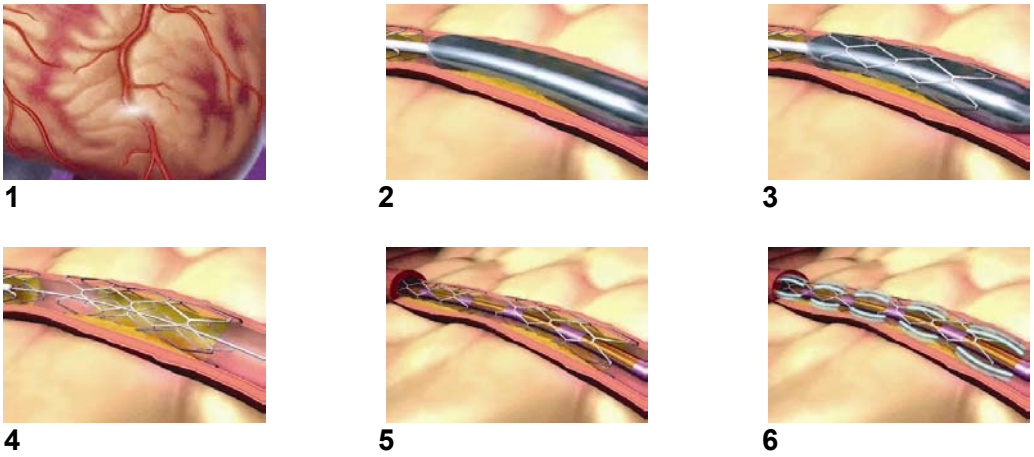
Patients with coronary and peripheral vascular atherosclerotic and recurrent stenotic diseases are candidates for Intravascular Sonotherapy™. FDA-approved percutaneous revascularization procedures for atherosclerotic vascular disease include, but are not limited to, balloon angioplasty (coronary and peripheral vascular), stenting (coronary only) and atherectomy (coronary only).

For certain high-risk patients (with or without complex lesions) who receive balloon angioplasty to treat coronary or lower peripheral vascular atherosclerotic disease, the restenosis rates can be as high as 50%. The restenosis rates are considerably lower, 15-25%, for patients who receive a stent to treat an atherosclerotic lesion.

However, for those patients whose stent has restenosed, referred to as “in-stent” restenosis, the resulting in-stent lesion is clinically more challenging to treat than the restenosis. While stenting decreases negative remodeling and vascular recoil, stenting can encourage excessive intimal hyperplasia (i.e. in-stent restenosis).

To lower the restenosis rates following balloon angioplasty or stenting, especially for high-risk patients, or to treat in-stent restenosis, requires the use of adjunctive agents such as Sonotherapy, radiation, drugs or possibly genes. Currently, radiation has been FDA-approved to treat coronary in-stent restenosis; the other adjunctive agents are under clinical trial investigation.

Intravascular Sonotherapy Applied After the Placement of a New Coronary Stent



1. Coronary Left Anterior Descending Artery plaque buildup (i.e. atherosclerotic lesion).
2. A balloon catheter is used to perform angioplasty.
3. A stent is deployed into place.
4. The balloon catheter is removed, leaving the guide wire and stent in place.
5. The Sonotherapy catheter is advanced using the same guide wire and is positioned within the stented lesion segment. Once the catheter is in place the Sonotherapy treatment can begin by pressing the start/stop button on the catheter or the start button on the instrument.
6. Therapeutic ultrasound energy is emitted from the Sonotherapy catheter. Then the catheter is moved towards the operator approximately 6mm-one transducer length- and the second ultrasound emission is repeated.

   A lesion up to 50mm in length can be treated in 10 minutes by deploying two five-minute exposures. Treatment will stop automatically after the preset time of five (5) minutes or may be manually stopped. The combined system set up and treatment time is 15 minutes.
7. Following Sonotherapy treatment, the guidewire, Sonotherapy catheter and guiding catheter are removed and discarded in the appropriate medical waste receptacle.

A similar procedure is employed to treat restenosis at a lesion with a stent already in place (in-stent restenosis situation).

Characteristics of Sonotherapy

Restenosis is a process by which vascular smooth muscle cells excessively proliferate back into the lumen of the artery (neointimal hyperplasia) following balloon angioplasty or stent placement, causing restenosis (re-narrowing) of the blood vessel. By treating the revacularized lesion with Sonotherapy, the over-proliferative response of the vascular smooth muscle cells is regulated and may reduce the incidence of restenosis.

In addition to its anti-proliferative effect, Sonotherapy has demonstrated that it does not interfere with the vessel's normal healing processes, which need to occur following the stenting. This is important for patient safety.

- Sonotherapy may provide prophylaxis and treatment solutions in a wide variety of cases, for both stented and non-stented applications. These include peripheral vascular cases; multiple-stented lesions; multiple vessel diseased patients; bifurcated and Ostial lesions and other challenging lesion types; and high-risk patients such as diabetics.

    - In the recently completed FDA-approved Phase I registry SILENT, there were no patient reports of stent edge effects, diffuse in-stent restenosis or late-stent thrombosis. The latter is important because it demonstrates that vessel re-healing, following stenting, has occurred in patients.

- An inherently safe technology, ultrasound does not require the types of precautions and concerns that are involved in the use of ionizing radiation; the risk of exposing healthy tissue to a high cumulative radiation dose; the need for a radiation oncologist and safety personnel to be present during the procedure, and the handling, storage and shelf-life issues associated with handling radioactive materials.

- Sonotherapy does not involve concerns regarding uniform drug delivery, therapeutic windows and cellular drug interactions. In addition, because Sonotherapy is independent of any stent design, it can be used with any commercially available stent. This allows physicians to use the stent of their choice, based on the patient's medical needs.

- For certain patients, a combination of treatments may be the best solution. For in-stent restenosis patients Sonotherapy is well suited to be the first line of treatment before the use of more complex or invasive therapies, such as radiation or bypass surgery. Sonotherapy's wide therapeutic window, high safety margin and ease of use make it ideal to be used for complex denovo stented patients. If drug-coated stenting proves successful, Sonotherapy could be used to enhance the delivery of a drug into the stented vessel wall. The research to establish Sonotherapy's interaction with drug-coated stents is underway.

- In addition to the anti-restenotic applications of Sonotherapy for coronary and peripheral vascular diseases, Sonotherapy is undergoing development for other uses, such as;
    - Treatment for vulnerable plaque
    - Enhancing the delivery of non-viral vector gene delivery for myocardial and peripheral vascular angiogenesis (creation of new blood vessels)
    - Enhancing the delivery of DNA vaccines

***Caution: Investigational Device. Limited by United States law to investigational use.*

Coding Options:

Option 1 Do not create a new code or series of codes. This type of therapy is not yet FDA approved, and is considered an investigational device. It is therefore limited by United States law to investigational use in a clinical trial setting(s).

Option 2 Create a new subsection to describing therapeutic ultrasound, which sets this technique apart from diagnostic ultrasound.

new code 00 Other Procedures

new code 00.0 Therapeutic Ultrasound

new code 00.01 Therapeutic ultrasound of vessels of head and neck
Intravascular non-ablative ultrasound
Excludes:
angioplasty or atherectomy of non-coronary vessel (39.50)
diagnostic ultrasound of head and neck (88.71)
endarterectomy (38.11, 38.12)
incision of vessel (38.01, 38.02)
other incision, excision, and destruction of inner ear (20.79)
ultrasound study of eye (95.13)

new code 00.02 Therapeutic ultrasound of heart
Intravascular non-ablative ultrasound
Excludes:
catheter ablation of lesion or tissues of heart (37.34)
diagnostic ultrasound of heart (88.72)
multiple vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy performed during the same operation with or without mention of thrombolytic agent (36.05)
other removal of coronary artery obstruction (36.09)
single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy without mention of thrombolytic agent (36.01)
single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy with thrombolytic agent (36.02)

new code 00.03 Therapeutic ultrasound of peripheral vascular vessels
Intravascular non-ablative ultrasound
Excludes:
angioplasty or atherectomy of non-coronary vessel (39.50)
diagnostic ultrasound of peripheral vascular system (88.77)
incision of vessel (38.03 - 38.09)

new code 00.09 Other therapeutic ultrasound
Excludes:

Transurethral (ultrasound) guided laser induced prostatectomy (TULIP) (60.21)

Recommendation
Adopt the new codes as listed above in Option 2 after FDA approval has been granted.

Interim Coding
There is no way to specifically identify this technology. Therefore, use 99.99, Other miscellaneous procedure, Other.

Infusion of Drotrecogin Alfa (Activated)

Issue:

Drotrecogin alfa (activated)[1] is a new biological agent to treat severe sepsis. There is no current ICD-9-CM procedure code that accurately reflects the infusion of this biological.

Background:

The professional medical community recognizes severe sepsis as a major cause of morbidity and mortality worldwide. More than 751,000 cases of severe sepsis occur in the US annually with a 26.7% mortality rate and an estimated national annual cost of $16.7 billion.[2] The rate of death from severe sepsis has ranged from 30% to 50% despite advances in critical care medicine.[3] Severe sepsis is especially prevalent in the elderly, even in clinical trials. In fact, over 45% of the United States patients enrolled in the Protein C Worldwide Evaluation in Severe Sepsis (PROWESS) were over 65 years of age.[4]

The sepsis continuum begins with known or suspected infection and progresses to include a systemic inflammatory response (SIRS) and include coagulation and impaired fibrinolysis leading to organ failure. This presence of organ failure defines severe sepsis.

- SIRS is a clinical response arising from a nonspecific insult including as least two of the following: temperature >38C or <36C, HR> 90 beats/min., respiration's >20 per min., WBC count > 12,000 mm or < 4,000 or >10% neutrophils.[5]
- Sepsis is the systemic response to infection. This systemic response is manifested by two or more of the SIRS conditions as a result of infection.[6]
- Severe sepsis is sepsis with at least one organ failure, which could be cardiovascular, renal, respiratory, hepatic, hematological, central nervous system, or unexplained metabolic acidosis.[7]

The current standard of care for severe sepsis includes antibiotics, intravenous fluids, nutrition, mechanical ventilation for respiratory failure, and surgery to eradicate the source of infection. There has been an increase in the use of more potent and broader spectrum antibiotics, immunosuppressive agents and new technologies in the treatment of inflammation, infection, and neoplastic disease. These factors will have a direct impact on severe sepsis and its incidence.[8]

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[1] Xigris™ (Lilly).
[2] Angus et al., Crit Care Med. 2001, vol.29, no.7, pages 1303-1310.
[3] Rangel-Frausto et. al., JAMA 1995, vol 273, pages 117-123.
[4] Bernard et. al., NEJM 2001, vol. 344, no. 10, pages 699-709.
[5] Bone et al., Chest 1992, 101: pages 1644-1655.
[6] Bone et al., Chest 1992, vol. 20, no. 6, pages 864-874.
[7] Wheeler and Bernard, NEJM 1999; vol. 340:207.
[8] Bone et al., Chest 1992, 101:pages 1644-1655.

Over the past two decades, over thirty agents in numerous clinical trials have failed to reduce mortality in severe sepsis. Agents targeting host cell activation, mediators of the inflammatory response, and prostaglandin inhibition failed to produce an effect on mortality. Historically, most attention has been focused on the inflammatory response as the dominant mechanism in the cascade of severe sepsis events leading to organ failure. More recently, investigations into the time, course and extent of coagulation and fibrinolysis abnormalities in severe sepsis, their relationship to endothelial dysfunction, and the factors that may initiate these changes have highlighted the crucial role of an imbalance in homeostatic mechanisms. This imbalance manifests as microvascular coagulation abnormalities and endothelial dysfunction and may ultimately be a primary factor driving hypoperfusion, organ failure, and death.

One of the crucial new concepts that has radically changed the view of severe sepsis is improved understanding of the impact of inflammation, coagulation and fibrinolysis acting simultaneously in the disease process. Severe sepsis is a heterogeneous syndrome. Blocking a single inflammatory mediator was too simplistic an approach.

Drotrecogin alfa (activated) is a biotechnology product that is a recombinant version of naturally occurring Activated Protein C (APC). APC is needed to ensure the control of inflammation and clotting in the blood vessels. In patients with severe sepsis, Protein C cannot be converted in sufficient quantities to the activated form. It appears that drotrecogin alfa (activated) has the ability to bring blood clotting and inflammation back into balance and restore blood flow to the organs.

As reported in the March 8, 2001, New England Journal of Medicine, treatment with drotrecogin alfa (activated) significantly reduced mortality in patients with severe sepsis. This study was conducted at 164 centers in 11 countries. A total of 1690 randomized patients were treated (840 in the placebo group and 850 in the drotrecogin alfa activated group). The drotrecogin alfa activated group received an intravenous infusion of 24ug per kilogram of body weight per hour for a total duration of 96 hours. The mortality rate in the treatment group was 24.7% compared to 30.8% mortality in the placebo group (P = 0.006) at day 28. [9] This therapeutic advance is associated with a 19.4% reduction in the relative risk of death (95% confidence interval, 6.6 to 30.5). The data suggest that one in five people who would have died from severe sepsis survived due to drotrecogin alfa (activated). This reduction in mortality was so significant that an independent external Data and Safety Monitoring Board to PROWESS phase III trial recommended conclusion of the trial early due to pre-determined criteria related to reduce mortality. Bleeding was the only notable side effect.

Options:

1. Continue to code this infusion to code 99.l9, Injection of anticoagulant.

2. Create a new procedure code that captures the infusion of drotrecogin alfa (activated) pending FDA approval.

New code	00.11	Infusion of drotrecogin alfa (activated)
	99.19	Injection of anticoagulant
Add exclusion note		Excludes: Infusion of drotrecogin alfa (activated) (00.11)

CMS Recommendation:

Option 2. Create a new procedure code that captures the infusion of drotrecogin alfa (activated) pending FDA approval.

New code	00.11	Infusion of drotrecogin alfa (activated)
	99.19	Injection of anticoagulant
Add exclusion note		Excludes: Infusion of drotrecogin alfa (activated) (00.11)

In the interim, continue to code the infusion of drotrecogin alfa (activated) to code 99.19, Injection of anticoagulant.

Application of Adhesion Barrier

Issue

We previously discussed application of adhesion barrier at the November 1999 Coordination and Maintenance Committee meeting. At the meeting, we recommended addition of a new ICD-9-CM code at 99.76, Administration or application of adhesion barrier. However, commenters did not support this concept, stating that application of an adhesion barrier was integral to the procedure, and did not warrant a unique code. A new code was therefore not assigned at that time.

Another manufacturer is bringing this topic before the Committee today. Genzyme Corporation manufactures biomaterials for the prevention of post-operative adhesions following abdominopelvic and sinus procedures. In addition to Genzyme, three other medical device companies manufacture adhesion barriers. The application of these products requires a procedural technique in addition to the primary surgical procedure performed by the surgeon; an example follows.

Seprafilm™ Adhesion Barrier

Seprafilm™ Adhesion Barrier is a temporary bioresorbable membrane indicated for use in patients undergoing abdominal or pelvic laparotomy. It is an adjunct proven to reduce the incidence, extent and severity of postoperative adhesions between the abdominal wall and the underlying viscera such as omentum, small bowel, bladder, and stomach, and between the uterus and surrounding structures such as tubes and ovaries, large bowel, and bladder. When placed between adhesiogenic tissue surfaces prior to closure, Seprafilm™ acts as a physical adhesion barrier during the critical 7-day period of adhesion formation. Seven days following the placement of Seprafilm™ in abdominopelvic surgery, the body's natural mechanism for adhesion prevention (the reformation of the peritoneum, particularly the completion of a confluent layer of mesothelial cells) is complete and Seprafilm™ has been resorbed into the abdominopelvic cavity. Components of Seprafilm™ are excreted from the body in less than 28 days.

The procedure for placing Seprafilm™ prior to closure requires a significant change in operative technique and use of operating room (OR) resources regardless of the nature of the primary procedure. Seprafilm™ application requires the attention of the surgeon as well as preparation and handling of the product by OR nurses and physician assistants (PAs). The product is customized to fit the desired application site, and the packaging altered to ensure proper placement. Once the product is prepared, it is necessary to retract the abdominal wall and organs from the desired site of application. The surgeon places Seprafilm at the site of trauma and must obtain clean, dry instruments to aid in the adherence to tissue surfaces. In addition, the average procedure requires the preparation and placement of multiple adhesion barriers. In a recent abdominopelvic study, the average amount of Seprafilm™ applied for adhesion prevention was 4.5 sheets. Seprafilm™ application is an additional procedure, and diverges from the classical method of patient closure, thereby altering the tasks each individual contributes to the open procedure.

In a prospective, randomized, double blind, multicenter clinical trial, Seprafilm™ prevented the formation of adhesions in 51% of patients, compared with 6% in the

control group. In patients who developed adhesions, Seprafilm™ reduced the incidence of dense adhesions by 42% and the length of the abdominal incision involved in adhesions by 40%.

The clinical relevance of these efficacy indicators has led to the adoption of Seprafilm™ for adhesion prevention around the world. More than 500,000 sheets of Seprafilm™ have been placed in human patients worldwide since the product's introduction in 1996. Seprafilm™ has the potential for use in over 1.5 Million abdominopelvic procedures annually in the U.S., and is used in many specialties including colorectal surgery, gynecologic oncology, gynecology, and bariatric surgery.

The impact of Seprafilm™ on long-term outcomes such as chronic pain, infertility and small bowel obstruction has not been determined in clinical studies. However, the impact of adhesions on these significant complications is well documented. A study of a 5% random sample of the U.S. Medicare population indicated that for patients undergoing open abdominal surgery 17% are readmitted within 2 years for intestinal obstruction, 20% of who will require surgical treatment. Adhesive disease accounts for 49-74% of small bowel obstructions (a life threatening disease), 15-20% of infertility cases, and 20-50% of chronic pain cases. In addition, adhesions increase the risk of complications during subsequent surgery. A recent study showed a 19% rate of adhesion-related inadvertent enterotomy, in which case patients had significantly greater postoperative complications such as intestinal leaks, wound infections, hemorrhages and length of stay. The morbidity and/or mortality associated with these adhesion-related complications is well documented and poses a significant burden on the patient, the patient's family, the practitioner, and the healthcare system.

In addition to the impact on clinical outcomes, the economic cost of adhesion-related hospitalizations was estimated at $1.33 billion in 1994, a $100 million increase from 1988. This is attributed to more than 303,000 hospitalizations due to adhesions and nearly 850,000 days of inpatient care, but does not take into account indirect and quality of life costs such as loss of workdays or productivity, infertility, psychological impact, pain and suffering or the impact on family members and community support services.

Coding Options

Option 1: Do not assign a new code for this adjunct product. Application of this product is integral to the procedure being performed.

Option 2: Create a new code to capture this technology. As it has the potential of reducing rehospitalization and subsequent complications, its use should be tracked via a specific code.

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

New code 99.77 Application or administration of an adhesion barrier substance

Recommendation

Adopt option 2, creation of a new code, to specifically identify use of this product.

Interim Coding

As there is currently no way to capture use of adhesion barrier substances, do not code

Intraoperative Magnetic Resonance Imaging (iMRI)

Issue
There are no current ICD-9-CM codes specific to the iMRI procedure. In order to identify the procedure, a variety of codes are used, none of which, separately or in combination, accurately describes the procedure. For example, code 88.91, Magnetic resonance imaging of brain and brain stem, may be used in combination with 01.24, Other craniotomy, when describing iMRI of the brain.

However, code 88.91 does not specify the type or scope of stereotactic computer involvement; that is, there are systems that involve equipment that is located outside the operating room performing the procedure pre-operatively or that necessitate moving the patient out of the operating room during the surgical procedure. Nor does 88.91 distinguish pre-operative imaging from intra-operative imaging. iMRI does not utilize attachment of a stereotactic frame and is denominated thereby as a frameless stereotactic technique. Although iMRI is a stereotactic navigational technique, code 92.30, Stereotactic radiosurgery NOS, does not apply, as the iMRI is not a surgical procedure, but is an adjunct to the surgical procedure.

Background
Magnetic resonance imaging (MRI) is a diagnostic imaging technique that uses magnet and electromagnetic waves to produce an image of internal organs, such as the brain. Intraoperative MRI (iMRI) allows the surgeon to scan real-time pictures during surgery, providing guidance and stereotactic navigation, using registration and optical tracking, increasing accuracy and improving the effectiveness of surgical procedures in the operating room. Frameless navigation systems represent a significant improvement in the treatment of intracranial conditions.

The compact iMRI unit does not require a specially constructed surgery suite. New iMRI systems are compact systems that can be installed in the conventional operating room and operated by the neurosurgeon. The magnetic field is confined to the volume between the magnet poles and its immediate neighborhood. This iMRI system allows neurosurgeons to perform and view scans of target sites in the brain before, during and after a surgical procedure. Prior to beginning the surgery, the Neurosurgeon images the patient's brain and plans the optimal surgical entry with the newly acquired images. Sequential images are obtained throughout the surgery as the tumor is excised, to confirm removal and to identify any remaining tumor. The iMRI provides the Neurosurgeons with real time images to confirm complete tumor removal, prior to the patient leaving the operating room and navigational information to avoid sensitive areas and structures within the surgical site. This ready access to intraoperative images that can be updated during neurosurgical operations greatly enhances the ease and precision of locating vital structures and confirming tumor resection.

Systems using images acquired preoperatively cannot provide the surgeon with information about dynamic changes that occur intra-operatively nor can they compare resection images as the surgery occurs. Stereotactic coordinates derived from pre-operative images may become inaccurate due to intra-cranial topography changes and brain shifts during surgery. Neurosurgeons or radiologists may perform the iMRI procedure. The procedure is used primarily for removal of brain tumors at this time.

Coding Options
Option 1: Continue to use codes from the 88.91 - 88.97 series, Magnetic resonance imaging, by site, to describe this procedure.

Option 2: Add a new code to describe this procedure, as follows. Use this code in combination with surgery codes, as appropriate, to fully describe the procedures performed.

88.9 Other diagnostic imaging
Add *Excludes: Intraoperative magnetic resonance imaging (88.99)*
Real-time magnetic resonance imaging (88.99)

88.91 Magnetic resonance imaging of brain and brain stem

New code 88.99 Intraoperative magnetic resonance imaging
iMRI
Real-time magnetic resonance imaging

Option 3: Add a new category and subcategory to the ICD-9-CM coding scheme to describe this procedure. Use these codes in combination with surgery codes, as appropriate, to fully describe the procedures performed.

New category 00.6 Other Radiology
iMRI
Intraoperative real-time magnetic resonance imaging
Excludes: Other diagnostic imaging, by site, not real-time or intraoperative (88.90 - 88.97)

New code 00.60 Intraoperative magnetic resonance imaging of brain and brain stem
New code 00.61 Intraoperative magnetic resonance imaging of chest and myocardium
New code 00.62 Intraoperative magnetic resonance imaging of spinal canal
New code 00.63 Intraoperative magnetic resonance imaging of musculoskeletal system
New code 00.64 Intraoperative magnetic resonance imaging of pelvis, prostate, and bladder
New code 00.65 Intraoperative magnetic resonance imaging of other and unspecified sites

Recommendation
Audience participation and discussion. Is there a need for this level of specificity? Which option is most helpful to the industry?

Interim Coding
In the meantime, continue to code intraoperative MRIs using existing codes from the 88.91 - 88.97 series.

Administration of Inhaled Nitric Oxide (INO)

Issue:
Should a new code be created to capture the administration of inhaled nitric oxide? Currently, there is an ICD-9-CM procedure code 39.65 that captures extracorporeal membrane oxygenation [ECMO] but there is no existing code that uniquely identifies the administration of INO.

Background:
Nitric oxide is a drug administered by inhalation, usually over a course of four days. It is a potent pulmonary vasodilator used to treat pulmonary hypertension in patients with respiratory failure and hypoxia from a number of different causes. In clinical trials conducted over the last 6 years, treatment with inhaled nitric oxide resulted in improved oxygenation and reduced need for extracorporeal membrane oxygenation (ECMO) for term and near-term neonates with pulmonary hypertension and hypoxic respiratory failure. Largely as a result of these studies, the FDA approved the use of inhaled nitric oxide for use in treating these neonates in December 1999 for the following label uses:

> INOmax™, in conjunction with ventilator support and other appropriate agents, is indicated for the treatment of term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, where it improves oxygenation and reduces the need for extracorporeal membrane oxygenation (ECMO).

Traditional treatment for neonates with these conditions has included intensive mechanical ventilation and oxygen therapy in conjunction with pulmonary vasodilators available at the time. More recently, ECMO, an intensive and invasive means to oxygenate patient blood outside of the body, has become standard therapy for patients unresponsive to aggressive mechanical ventilation. However, with the availability and apparent efficacy of inhaled nitric oxide (INO), the need for the more invasive ECMO procedure may be avoided for a subset of the more severely affected neonates.

The number of patients who could benefit from INO may be considerably greater than the number of patients currently receiving ECMO. Neonates treated with ECMO receive care at large, specialized neonatal intensive care units because such facilities and resources are available only at a limited number of institutions. However, because INO can be administered at most institutions which have the capability to provide mechanical ventilation, its use could increase significantly in the future. Furthermore, one clinical trial found that infants with less severe respiratory failure appeared more likely to have complete responses to the initial administration of INO and to survive without ECMO, suggesting that the earlier use of INO may be beneficial. With the widespread availability of INO, its introduction at an earlier point in the course of an illness might lead both to a larger number of avoided ECMO procedures and also to an even larger number of INO-treated neonates.

Options:

1. Continue to code this procedure to code 93.98, Other control of atmospheric pressure and composition.

2. Create a new code to capture inhaled nitric oxide (INO).

   New code 00.12 Administration of inhaled nitric oxide
   Nitric oxide therapy

CMS Recommendation:

Option 2. Create a new code to capture inhaled nitric oxide (INO).

New code 00.12 Administration of inhaled nitric oxide
Nitric oxide therapy

In the interim, continue to code this procedure to code 93.98, Other control of atmospheric pressure and composition.

CARDIAC RESYNCHRONIZATION THERAPY

Issue: Cardiac resynchronization therapy for heart failure, provides strategic electrical stimulation to the right atrium, right ventricle, and left ventricle in order to re-coordinate ventricular contractions and improve cardiac output. While similar to conventional pacemakers and internal cardioverter-defibrillators (ICDs), cardiac resynchronization therapy (CRT) is different because it requires the implantation of a special electrode within the coronary vein, so that it can be attached to the exterior wall of the left ventricle. There is no way to identify CRT with existing ICD-9-CM codes.

Background: Cardiac resynchronization (bi-ventricular pacing), is a new therapy designed to treat cardiac ventricular dysynchrony, common in 20% of patients with heart failure. It provides strategic electrical stimulation to the right atrium, right ventricle, and left ventricle (often called bi-ventricular pacing), in order to re-coordinate ventricular contractions and improve cardiac output.

There are two types of cardiac resynchronization devices. One is a cardiac resynchronization pacemaker, which is used to provide cardiac resynchronization therapy to patients with ventricular dysfunction, who do not also meet the indication for an automatic cardioverter-defibrillator (AICD) type device. This device contains programming and treatment algorithms, sensing and controlling features, advanced battery technology, and diagnostic functions. These types of devices are currently coded with the pacemaker codes.

A second device, the cardiac resynchronization defibrillator, is similar to the pacemaker, but additionally includes an implantable automatic cardioverter-defibrillator (AICD). The later is used to deliver high-energy shocks to prevent and treat life threatening ventricular tachyarrhythmias. These types of devices are currently coded with the defibrillator codes.

The type of device selected by the physician depends on patient indications and the risk for sudden cardiac death due to tachyarrhythmias. The cardiac resynchronization pacemaker currently has market clearance from the FDA. Cardiac resynchronization defibrillator devices have been reviewed by the FDA physician panel and are nearing final approval. It is anticipated these will be approved in early 2002.

The procedure for cardiac resynchronization therapy pacemakers and defibrillators requires the implantation of a pacemaker or AICD device and electrodes inserted through the subclavian vein and placed directly within the right atrium and right ventricle. Additionally, a third electrode is inserted through the subclavian vein and is placed within the coronary vein, to facilitate its attachment to the external wall of the left ventricle. This procedure often requires a left heart venogram to delineate the coronary vascular system prior to placing the left ventricular electrode.

After the device senses an atrial contraction, the two ventricles are stimulated to contract simultaneously. This synchronization of the ventricular contraction sequence optimizes filling of the left ventricle with oxygenated blood and reduces the backward flow of blood into the left atrium. The result is an improved cardiac output.

To understand how the system works, it is important to know how the heart normally functions and what happens to this function in patients with heart failure. The heart has four chambers. The right atrium receives deoxygenated blood from the body and then pumps the blood to the right ventricle. The right ventricle pumps the deoxygenated blood to the lungs. Oxygenated blood is received from the lungs by the left atrium and is pumped into the left ventricle.

In a normal heart, the right and left ventricles contract almost simultaneously. However, in some patients with dilated or enlarged hearts secondary to heart failure, the right ventricle contracts before the left one. This lack of proper synchronization impairs the filling of the left ventricle. When the left ventricle contracts to pump oxygenated blood to the body, some blood may be pumped back into the left atrium instead of to the body, a condition called mitral regurgitation. The CRT senses the atrial contraction and then stimulates the two ventricles to contract at the same time, thereby synchronizing ventricular contraction. This optimizes filing of the left ventricle with oxygenated blood, and reduces or eliminates the backward flow of blood into the left atrium. The result is an improved cardiac output.

Although similar in concept to conventional pacemakers and internal cardioverter-defibrillators (ICDs), CRT based products are uniquely different primarily because they:

- Are designed to treat substantially different symptoms;
- Require new and more sophisticated medical devices;
- Require the implantation of a third electrode into the coronary venous system of the left ventricle;
- Require a significant amount of additional time and resources;
- Represent the next generation of cardiac electrical pacing products.

Implantation of a Cardiac Resynchronization Pacemaker (CRT-P) is currently being coded with the existing pacemaker codes. The Cardiac Resynchronization Defibrillator (CRT-D) is being coded with the AICD codes. Therefore, we are not able to tell which patients are receiving the new devices.

Options:

1. Create new ICD-9-CM procedure codes to capture implantation of CRT-Ps and CRT-Ds.

00.5 Other cardiac procedures
  00.50 Implantation of Cardiac Resynchronization Pacemaker without mention of Defibrillation, total system [CRT-P]

Biventricular pacing without internal cardiac defibrillator

Includes: Implantation of cardiac resynchronization (biventricular) pulse generator pacing device, formation of pocket, any transvenous leads including placement of lead into left ventricular coronary venous system, and intraoperative procedures for evaluation of lead signals.

Excludes: Replacement of cardiac resynchronization pacemaker pulse generator only (00.53)
Implantation of cardiac resynchronization defibrillator, total system (00.51)
Insertion or replacement of any type pacemaker device (37.80-37.87)
Replacement of cardiac resynchronization defibrillator pulse generator only (00.54)

00.51 Implantation of Cardiac Resynchronization Defibrillator, total system [CRT-D]

Biventricular pacing with internal cardiac defibrillator

Includes: Implantation of a cardiac resynchronization (biventricular) pulse generator with defibrillator (AICD), formation of pocket, any transvenous leads, including placement of lead into left ventricular coronary venous system, intraoperative procedures for evaluation of lead signals, and obtaining defibrillator threshold measurements.

Excludes: Implantation of cardiac resynchronization pacemaker, total system (00.50)
Implantation or replacement of automatic cardioverter/defibrillator, total system (AICD) (37.94)
Replacement of cardiac resynchronization defibrillator pulse generator, only (00.54)

00.52 Implantation or Replacement of Transvenous Lead (Electrode) into Left Ventricular Coronary Venous System

Excludes: Implantation of cardiac resynchronization pacemaker, total system (00.50)

Implantation of cardiac resynchronization defibrillator, total system (00.51)
Initial insertion of transvenous lead (electrode) (37.70-37.72)
Replacement of transvenous atrial and/or ventricular lead(s) (electrodes) (37.76)

00.53 Replacement of Cardiac Resynchronization Pacemaker Pulse Generator only [CRT-P]

Excludes: Implantation of cardiac resynchronization pacemaker, total system (00.50)
Insertion or replacement of any type pacemaker device (37.80-37.87)
Replacement of cardiac resynchronization defibrillator pulse generator, only (00.54)

00.54 Replacement of Cardiac Resynchronization Defibrillator pulse generator device only [CRT-D]

Excludes: Implantation of automatic cardioverter/defibrillator pulse generator, only (37.96)
Implantation of cardiac resynchronization defibrillator, total system (00.51)
Replacement of cardiac resynchronization pacemaker pulse generator, only (00.53)

37.99 Other

Add: Removal of cardiac resynchronization pacemaker and defibrillator devices, CRT-P and CRT-D

Revisions to existing codes

37.7 Insertion, revision, replacement, and removal of pacemaker leads; insertion of temporary pacemaker system; or revision of pocket

ADD: Excludes: Implantation or replacement of transvenous lead [electrode] into left ventricular cardiac venous system (00.52)

37.8 Insertion, replacement, removal, and revision of pacemaker device

ADD: Excludes: Implantation or replacement of cardiac resynchronization pacemaker (00.50, 00.53)

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

ADD: Excludes: Implantation of cardiac resynchronization defibrillator, total system (00.51)

37.96 Implantation of automatic cardioverter/defibrillator pulse generator only

ADD: Excludes: implantation or replacement of cardiac resynchronization defibrillator, pulse generator only (00.54)

37.98 Replacement of automatic cardioverter/defibrillator pulse generator only

ADD: Excludes: replacement of cardiac resynchronization defibrillator, pulse generator only (00.54)

2. Continue coding these devices using the existing pacemaker and defibrillator codes.

Recommendation: Create new ICD-9-CM procedure codes to capture implantation of CRT-Ps and CRT-Ds as was discussed in option 1. In the meantime, continue coding these devices by assigning pacemaker codes for the cardiac resynchronization pacemakers (CRT-P) and automatic cardioverter/defibrillator codes (AICD) for the cardiac resynchronization defibrillators (CRT-D).

Drug-eluting Stents

Issue

There are no unique ICD-9 codes to describe procedures in which drug-eluting stents are implanted. Percutaneous procedures using drug-eluting stents are anticipated to have significantly different patient outcomes when compared to procedures in which conventional stents are implanted. Unique codes to identify these services are important for tracking patient outcomes.

Background

At present, coronary stents (36.06, Insertion of coronary artery stent(s)) and non-coronary stents (39.90, Insertion of non-coronary artery stent or stents) have distinct ICD-9 codes to describe their use. Stents scaffold the artery and greatly increase the vessel diameter and hence blood flow as compared to balloon angioplasty. Stents have been shown to reduce post-procedure renarrowing of the blood vessel by 33-50% versus balloon angioplasty, nonetheless the incidence of renarrowing remains high (15-30%), and is the Achilles heel of percutaneous interventional procedures.

Recently, a new, transformational technology (drug-eluting stents) has been developed to combat the problem of renarrowing. The drug is placed onto the stent with a special polymer and slowly released into the vessel wall tissue over a period of 30-45 days, thereby preventing the build-up of scar tissue that can narrow the re-opened artery. Stent-based drug therapy is an efficient method of preventing renarrowing because it addresses both blood vessel remodeling and scar tissue build-up (neointimal hyperplasia). Further, it maximizes the drug effect where it is required, minimizes the potential for systemic toxicity and allows for optimization of the time period over which the drug is released.

The results of a major prospective, double-blinded, randomized, controlled clinical trial involving 238 patients showed that Sirolimus-eluting stents completely eliminated the process of renarrowing (0% renarrowing) as compared to a 26% incidence of renarrowing for patients in the control group receiving conventional stents. This translated into the need for 22% of the patients in the control group to receive costly percutaneous revascularization procedures versus 0% patients in the drug-eluting stent group.

Coding Options

Option 1: The Food and Drug Administration (FDA) has not yet approved this technology. Therefore, do not assign new codes at this time due to space constraints in the ICD-9-CM coding structure. If the FDA approves this device prior to Spring, 2002, we will be able to incorporate new codes into use effective for discharges on or after October 1, 2002. In the meantime, code drug-eluting stents to existing codes 36.06 and 39.90.

Option 2: Create two new codes to capture this technology, as follows:

36.1 Removal of coronary artery obstruction and insertion of stent(s)

36.06 Insertion of coronary artery stent(s)

New code 36.07 Insertion of drug-eluting coronary artery stent(s)
Stent graft
Code also any:
Open chest coronary artery angioplasty (36.03)
Percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy (36.01, 36.02, 36.05)

Excludes: Insertion of coronary artery stent(s) without drug coating (36.06)

New section 00 Other Procedures

New sub-section 00.5 Other cardiac procedures

New code 00.50 Insertion of drug-eluting non-coronary artery stent(s)
Stent grafts
Code also any non-coronary angioplasty or atherectomy (39.50)

Excludes: Insertion of non-coronary artery stent(s) without drug coating (39.90)
That for aneurysm repair (39.71 - 39.79)

Recommendation
Audience participation and discussion, as this technology is not yet FDA approved.

Interim Coding
Code insertion of drug-eluting stents to existing stent codes, using either 36.06, Insertion of coronary artery stent(s), or 39.90, Insertion of non-coronary artery stent or stents, as appropriate by site.

Injection or Infusion of Human B-type Natriuretic Peptide (hBNP)

Issue:
Should a new code be created to capture the injection or infusion of Human B-type Natriuretic Peptide (hBNP)?

Background:
Human B-type natriuretic peptide (hBNP) is indicated for the treatment of patients with acutely decompensated congestive heart failure who have dyspnea at rest or with minimal activity. The use of this treatment reduces pulmonary capillary wedge pressure and improves dyspnea.

Nesiritide is the generic name for recombinant human B-type natriuretic peptide. The properties of this drug, which represents a new class of agents, include a balanced arterial and venous vasodilatation and a marked natriuresis and diuresis. Human BNP binds to the particulate guanylate cyclase receptor of vascular smooth muscle and endothelial cells, leading to increased intracellular concentrations of guanosine 3'5'-cyclic monophosphate (cGMP) and smooth muscle cell relaxation. Cyclic GMP serves as a separate messenger to dilate veins and arteries.

Natrecor® (nesiritide), the first FDA approved drug (August 2001) in the hBNP class, the first natriuretic peptide commercially released in the United States as a pharmaceutical agent, has been shown to relax isolated human arterial and venous tissue preparations that were pre-contracted with either endothelin-1 or the alpha-adrenergic agonist, phenylephrine. Nesiritide is administered intravenously by infusion or bolus. The primary adverse event reported in the use of this drug is hypotension.

Options:

1. Continue to code the administering of hBNP (nesiritide) to code 99.29, Injection or infusion of other therapeutic or prophylactic substance.

2. Create a new code to capture the injection or infusion of human B-type natriuretic peptide (hBNP).

New code 00.13 Injection or infusion of human B-type natriuretic peptide (hBNP).
Nesiritide

3. Create a new code to capture the injection or infusion of nesiritide.

New code 00.13 Injection or infusion of nesiritide
Human B-type natriuretic peptide (hBNP).

CMS Recommendation:

Option 3. Create a new code to capture the injection or infusion of nesiritide.

New code 00.13 Injection or infusion of nesiritide
Human B-type natriuretic peptide (hBNP).

In the interim, continue to code this treatment to code 99.29, Injection or infusion of other therapeutic or prophylactic substance.

Antibiotic - Oxazolidinone

Issue
There is no specific ICD-9-CM code describing administration of an oxazolidinone, the first class of antibiotics with an entirely new mechanism of action in more than 35 years.

Background
The drug, brand name Zyvox™ (linezolid injection), is currently the only agent in the oxazolidinone class; therefore, hospitals need a mechanism to track the use of this agent. A specific code for administration of an oxazolidinone supports cooperative research, allowing researchers to identify cases where the product has been used, and to review and improve patient outcomes and utilization patterns.

Zyvox™, approved by the Food and Drug Administration (FDA) on April 18, 2000, is the first antibiotic in the oxazolidinone class and is widely used by hospitals in the United States and other countries against the medically significant gram-positive bacteria, including those that are resistant to other therapies. Gram-positive bacterial infections have become increasingly prevalent in recent years, most commonly implicated in infections in the lower respiratory tract, skin and soft tissue, bone and bloodstream, and in meningitis. Significant morbidity and mortality trends are associated with such pathogens in hospitalized patients with serious hospital-and community-acquired infections and continued exposure to nosocomial risks.

Clinical Use: Infections are a major clinical problem, particularly in the inpatient setting, and Zyvox™ offers improved clinical efficacy in treating difficult infections in patients for whom no other adequate therapy is available. Zyvox™ is indicated for the treatment of adult patients with one of the following infections caused by susceptible strains of the designated microorganisms:

- Vancomycin-Resistant *Enterococcus faecium* infections, including cases with concurrent bacteremia
- Nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and –resistant strains), or *Streptococcus pneumoniae* (penicillin-susceptible strains only)
- Complicated skin and skin structure infections caused by *Streptococcus pyogene*s, or *Streptococcus agalactia*e.
- Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible strains only) or *Streptococcus pyogene*s.
- Community-acquired pneumonia caused by *Streptococcus pneumoniae* (penicillin-susceptible strains only, including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible strains only).

Zyvox's™ coverage of resistant gram positive pathogens, notably methicillin-resistant Staphylococcus *aureus (MRSA)* and Vancomycin-resistant

Enterococcus faecium (VRE) has led to its usage typically after the first or second course of treatment with other classes of antibiotics. As few antibiotics treat these serious infections involving pathogens resistant to most antibiotics, physicians typically reserve their use of Zyvox™ for the most medically significant, often life-threatening, infections. Since its launch in April 2000, the majority of use of this drug is in short-term, acute care general medicine hospitals. The importance of this drug in treating medically significant infections is noted by its role in treatment and the pathogens treated.

Role in Treatment

Physicians typically do not use Zyvox™ until they have confirmed the pathogen they are treating is resistant to other antibiotics. The majority of Zyvox™ usage is for a proven methicillin-resistant *Staphylococcus aureus* or a Vancomycin-Resistant *Enterococcus faecium* infection. Because a culture may take 48 to 72 hours to obtain, physicians will often initiate antibiotic therapy to treat the infection until a resistant pathogen infection is proven. A proven resistant pathogen often necessitates a change in therapy. Depending upon the severity of the patient's illness, physicians may begin treatment with Zyvox™ before the resistant pathogen is proven.

About 60% of Zyvox™ usage is after the first course of treatment with another (or other) antibiotic(s); another 20% is after two prior courses of treatment with other antibiotics; and 5% is after three prior courses. About one in six patients (15%) are treated with Zyvox™ initially.

Pathogens Treated

The most common use of Zyvox™ is to treat patients whose infections have progressed to the bloodstream and are caused by resistant pathogens. These infections account for 32% of Zyvox™ use in 2001. The next most common use is for patients with hospital-acquired pneumonia, or ventilator associated pneumonia and who are at high risk or have a proven resistant gram-positive infection. These patients with respiratory illnesses account for 18%% of use. The remainder of Zyvox™ use is primarily in a variety of skin and soft tissue illnesses, with resistant gram-positive infections. These infections include post-surgical wounds, traumatic wounds, and moderate to severe cellulite.

Options

Option 1: Do not assign a new code for this product. Continue to identify the administration of an antibiotic using code 99.21, Injection of antibiotic. This code includes, however, all antibiotics, and is therefore not specific to this new class of drugs.

Option 2: Create a new code as follows:

New chapter	00	Other Procedures

New subchapter	00.1	Pharmaceuticals
New code	00.14	Injection or infusion of oxazolidinone class of antibiotics Linezolid injection That for methicillin-resistant pathogens *Excludes:* *Injection of antibiotic (99.21)* *Injection of other anti-infective (99.22)*

Recommendation
We recommend the adoption of Option 2, creation of a new code, as outlined above.

Interim Coding
In the meantime, capture use of this antibiotic by using code 99.21, Injection of antibiotic.

Proposed Addenda

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	Cholecystotomy 51.04
Add subterm	percutaneous 51.01
Add term	Kasai portoenterostomy 51.37
Add term	Portoenterostomy (Kasai) 51.37

Tabular List

	51.01 Percutaneous aspiration of gallbladder
Add inclusion term	Percutaneous cholecystotomy

51.37 Anastomosis of hepatic duct to gastrointestinal tract

Add inclusion term Kasai portoenterostomy