CMS WILL NO LONGER BE PROVIDING PAPER COPIES OF HANDOUTS FOR THE MEETING. ELECTRONIC COPIES OF ALL MEETING MATERIALS WILL BE POSTED ON THE CMS WEBSITE PRIOR TO THE MEETING AT HTTP://WWW.CMS.HHS.GOV/ICD9PROVIDERDIAGNOSTICCODES/03_MEETINGS.ASP

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

Agenda
ICD-9-CM Coordination and Maintenance Committee
Department of Health and Human Services
Centers for Medicare & Medicaid Services
CMS Auditorium
7500 Security Boulevard
Baltimore, MD 21244-1850
ICD-9-CM Volume 3, Procedures
March 9 – March 10, 2010

There will be conference lines available to the first 225 participants who dial in each day of the meeting that are unable to attend in person. Individuals do not need to register on-line for the meeting if planning to dial in. This call will be available in listen-mode only. There will be an audio CD and transcript available after the call.

Please note there is a different conference ID for each day of the meeting. **Participants who do not have the Conference ID Number will not be admitted to the call**.

March 9 – **Participant Dial-In Number(s):**
US/Canada Dial-in #: (800) 603 – 1774 **Conference ID # 58092988**

March 10 - **Participant Dial-In Number(s):**
US/Canada Dial-in #: (800) 603 – 1774 **Conference ID # 58095913**

Agenda
ICD-9-CM Coordination and Maintenance Committee
Department of Health and Human Services
Centers for Medicare & Medicaid Services
CMS Auditorium
7500 Security Boulevard
Baltimore, MD 21244-1850
ICD-9-CM Volume 3, Procedures
March 9 – March 10, 2010

Pat Brooks – Introductions and Committee overview
Co-Chairperson
March 9, 2010

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

1. ICD-10 Updates — Pat Brooks, CMS; Donna Pickett, CDC

   - General Equivalence Mappings
     - 2010 updates based on industry feedback and testing
     - GEM applications and use in updating systems
     - Discussion of need for additional updates to GEMs
   - Freezing updates to ICD-9-CM & ICD-10
   - ICD-10-PCS 2010 updates
   - ICD-10-CM 2010 updates

2. Central Venous Catheter Placement Using Intra-Atrial Electrocardiographic Guidance — Pat Brooks; Peter M. Rothenberg, MD, MA, President, PacerView Technologies, San Clemente, CA

3. Closed Chest Intra-Cardiac Mitral Valve Repair — Ann B. Fagan; D. Scott Lim, MD, Virginia Children's Hospital Center, U of VA Medical Center, Assoc. Professor Pediatrics Cardiology

4. Thoracoscopic Cardiac Ablation	Ann B. Fagan Andrew S. Wechsler, MD Department of Cardiothoracic Surgery Drexel University College of Medicine
5. Fat Grafting for Reconstructive Surgery	Amy L. Gruber Steven Cohen, MD Director of FACESplus Plastic Surgery
6. Sternal Fixation with Rigid Plates	Pat Brooks Arthur T. Martella, MD Clinical Assistant Professor of Surgery University of Pennsylvania
7. Laparoscopic Hernia Repair Without Mesh	Mady Hue
8. Cranial Implantation of Neurostimulator	Amy L. Gruber Martha Morrell, MD Chief Medical Officer Neuropace, Inc. Robert Worth, MD Professor of Neurological Surgery Indiana University
9. Intralaminar Lumbar Decompression and Laminotomy with Epidurography	Mady Hue Lora Lee Brown, MD Coastal Orthopedics and Pain Management Bradenton, Florida
10. Biopsy of Soft Tissue Mass	Ann B. Fagan
11. Continuous Glucose Monitoring	Amy L. Gruber Steven D. Wittlin, MD Prof of Medicine, Univ. of Rochester Med Ctr

12. Circulating Tumor Cell Enumeration Test	Amy L. Gruber Ralph V. Bocchia, MD President and Medical Director Center for Cancer and Blood Disorders
13. Intra-operative Angiography in CABG	Mady Hue T. Bruce Ferguson, MD East Carolina Heart Institute Michael Zenn, MD Duke University Medical Center
14. Addenda	Mady Hue

Registering for the meeting:
Information on registering online to attend the meeting can be found at:
http://www.cms.hhs.gov/apps/events/

For questions about the registration process, please contact Mady Hue at 410-786-4510 or marilu.hue@cms.hhs.gov.

ICD-9-CM Volume 3, Procedures Coding Issues:
Mailing Address:
Centers for Medicare & Medicaid Services
CMM, HAPG, Division of Acute Care
Mail Stop C4-08-06
7500 Security Boulevard
Baltimore, MD 21244-1850
FAX: (410) 786-0681

Pat Brooks	E-mail: patricia.brooks2@cms.hhs.gov 410-786-5318
Ann Fagan	E-mail: ann.fagan@cms.hhs.gov 410-786-5662
Amy Gruber	E-mail: amy.gruber@cms.hhs.gov 410-786-1542
Mady Hue	E-mail: marilu.hue@cms.hhs.gov 410-786-4510

Summary of Meeting:

A complete report of the procedure part of the meeting, including handouts, will be available on CMS's homepage within one month of the meeting. The summary can be accessed at:
http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp

A summary of the diagnosis part of the meeting held on March 10 can be found at:
http://www.cdc.gov/nchs/icd9.htm

ICD-9-CM TIMELINE

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

March 9 – March 10 2010	ICD-9-CM Coordination and Maintenance Committee meeting.
April 1, 2010	There will **not** be any new ICD-9-CM codes implemented on April 1, 2010 to capture new technology.
April 2, 2010	**Deadline for receipt of public comments on proposed code revisions discussed at the March 9-10, 2010 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2010.**
April 2010	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This notice will include the final ICD-9-CM diagnosis and procedure codes for the upcoming fiscal year. It will also include proposed revisions to the DRG system on which the public may comment. The proposed rule can be accessed at: http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp
April 2010	Summary report of the Procedure part of the March 9, 2010 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes Summary report of the Diagnosis part of the March 10, 2010 ICD-9-CM Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm
June 2010	Final addendum posted on web pages as follows: Diagnosis addendum at - http://www.cdc.gov/nchs/icd9.htm Procedure addendum at – http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes
June 11, 2010	Deadline for receipt of public comments on proposed **diagnosis** code revisions discussed at the March 9-10, 2010 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on **October 1, 2011**.

July 16, 2010	**Those members of the public requesting that topics be discussed at the September 15 – 16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses.**
August 1, 2010	Hospital Inpatient Prospective Payment System final rule to be published in the Federal Register as mandated by Public Law 99-509. This rule will also include all the final codes to be implemented on October 1, 2010. This rule can be accessed at: http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp
August 2010	Tentative agenda for the Procedure part of the September 15 – 16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage at - http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes Tentative agenda for the Diagnosis part of the September 15 – 16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on NCHS homepage at - http://www.cdc.gov/nchs/icd9.htm Federal Register notice for the September 15 –16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.
August 13, 2010	**On-line registration opens for the September 15-16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting at: http://www.cms.hhs.gov/events**
September 10, 2010	Because of increased security requirements, those wishing to attend the September 15 - 16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting must register for the meeting online at: http://www.cms.hhs.gov/apps/events **Attendees must register online by September 10, 2010; failure to do so may result in lack of access to the meeting.**
September 15 – 16, 2010	ICD-9-CM Coordination and Maintenance Committee meeting. Those who wish to attend the ICD-9-CM Coordination and Maintenance Committee meeting **must have registered for the**

	meeting online by September 10, 2010. You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.
October 2010	Summary report of the Procedure part of the September 15 – 16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes Summary report of the Diagnosis part of the September 15– 16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm
October 1, 2010	New and revised ICD-9-CM codes go into effect along with DRG changes. Final addendum posted on web pages as follows: Diagnosis addendum - http://www.cdc.gov/nchs/icd9.htm Procedure addendum at - http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes
October 08, 2010	**Deadline for receipt of public comments on proposed code revisions discussed at the September 15-16, 2010 ICD-9-CM Coordination and Maintenance Committee meetings for implementation of April 1, 2011.**
November 2010	Any new ICD-9-CM codes required to capture new technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2011 will be posted on the following websites: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes http://www.cdc.gov/nchs/icd9.htm
November 19, 2010	**Deadline for receipt of public comments on proposed code revisions discussed at the September 15-16, 2010 ICD-9-CM Coordination and Maintenance Committee meetings for implementation of October 1, 2011.**

The General Equivalence Mappings

GEM Files Summary Sheet

Use the GEMs When…

- You are translating lists of codes, code tables, or other coded data
- You are converting a system or application containing ICD-9-CM codes
- You are creating a "one-to-one" applied mapping (aka crosswalk) between code sets that will be used in an ongoing way to translate records or other coded data
- You want to study the differences in meaning between the ICD-9-CM classification systems and the ICD-10-CM/PCS classification systems by looking at the GEMs entries for a given code or area of classification

Use the ICD-10-CM/PCS and ICD-9-CM Code Books When…

- You have a short list of ICD-9-CM codes with their code descriptions
- You have access to the medical record
- You have access to other forms of clinical information, such as text descriptions or clinical terms from surveys, research, or clinical software applications

Note: A medical record that will be processed and stored as ICD-10 data should always be coded directly in ICD-10-CM/PCS, using the code books or an encoder.

GEMs Files at a Glance

ICD-10-CM (diagnosis) GEM	**ICD-9-CM diagnosis GEM**	**ICD-10-PCS (procedure) GEM**	**ICD-9-CM procedure GEM**
[year]_I10gem.txt	[year]_I9gem.txt	gem_pcsi9.txt	gem_i9pcs.txt
ICD-10-CM is the code to be translated (source system)	ICD-9-CM is the code to be translated (source system)	ICD-10-PCS is the code to be translated (source system)	ICD-9-CM is the code to be translated (source system)
Contains all ICD-10-CM codes *Note:* Each GEM file contains all of the source system codes for that GEM, but not all of the target system codes	Contains all ICD-9-CM diagnosis codes *Note:* Each GEM file contains all of the source system codes for that GEM, but not all of the target system codes	Contains all ICD-10-PCS codes *Note:* Each GEM file contains all of the source system codes for that GEM, but not all of the target system codes	Contains all ICD-9-CM procedure codes *Note:* Each GEM file contains all of the source system codes for that GEM, but not all of the target system codes
Translation determined by ICD-10-CM meaning and specificity *Note:* The GEM translation is determined by the meaning and specificity of the source system code	Translation determined by ICD-9-CM meaning and specificity *Note:* The GEM translation is determined by the meaning and specificity of the source system code	Translation determined by ICD-10-PCS meaning and specificity *Note:* The GEM translation is determined by the meaning and specificity of the source system code	Translation determined by ICD-9-CM meaning and specificity *Note:* The GEM translation is determined by the meaning and specificity of the source system code
Contains ICD-9-CM clusters	Contains ICD-10-CM clusters	Contains ICD-9-CM clusters	Contains ICD-10-PCS clusters
Contains entries with no target system translation (No Map Flag is 1)	Contains entries with no target system translation (No Map Flag is 1)	All source system entries have a target system translation (No Map Flag is 0)	Contains entries with no target system translation (No Map Flag is 1)
Recommended use --Convert an existing application that uses ICD-9-CM codes to ICD-10-CM --Create a backward mapping from ICD-10-CM to ICD-9-CM --Research the translation differences between the two diagnosis code sets	***Recommended use*** --Convert stored data containing ICD-9-CM codes to ICD-10-CM --Research the translation differences between the two diagnosis code sets	***Recommended use*** --Convert an existing application that uses ICD-9-CM codes to ICD-10-PCS -- Create a backward mapping from ICD-10-PCS to ICD-9-CM --Research the translation discontinuities between the two procedure code sets	***Recommended use*** --Convert stored data containing ICD-9-CM codes to ICD-10-PCS --Research the translation discontinuities between the two procedure code sets

Using GEMs File(s) for Specific Projects

Mapping Project	GEMs File to Use	How to Use the GEMs File
Convert an existing system or application that uses ICD-9-CM codes to an ICD-10-CM/PCS based system	ICD-10-CM (diagnosis) GEM *[year]_I10gem.txt* ICD-10-PCS (procedure) GEM *gem_pcsi9.txt*	--**Re-sort** the file so that you can look up the relevant GEMs entry based on the ICD-9-CM code. (aka reverse lookup) --**Find** all translation alternatives for the ICD-9-CM code(s) in your applications list or table --**Replace** the ICD-9-CM code(s) with the ICD-10-CM/PCS translation alternatives --**Review** the translated ICD-10-CM/PCS list for relevance of the code detail to the specific use for the list and application
Convert an existing data warehouse or other stored data containing ICD-9-CM codes to ICD-10-CM/PCS (create a forward mapping)	ICD-9-CM diagnosis GEM *[year]_I9gem.txt* ICD-9-CM procedure GEM *gem_i9pcs.txt*	--**Find** all GEMs entries for every ICD-9-CM code that contains multiple ICD-10-CM/PCS translation alternatives --Based on a consistent set of rules or reference data, **choose one** ICD-10-CM/PCS mapping for each ICD-9-CM code that translates to multiple ICD-10-CM/PCS alternatives *Note:* Because of translation differences between the two systems, "one" ICD-9-CM code may map to "one" ICD-10-CM/PCS cluster
Create a "one to one" backward mapping from ICD-10-CM/PCS to ICD-9-CM for a specific purpose	ICD-10-CM (diagnosis) GEM *[year]_I10gem.txt* ICD-10-PCS (procedure) GEM *gem_pcsi9.txt*	--**Find** all GEMs entries for every ICD-10-CM/PCS code that contains multiple ICD-9-CM translation alternatives --Based on a consistent set of rules or reference data (rules that pick the correct code for a service area or the most frequently recorded ICD-9-CM code), **choose one** ICD-9-CM mapping for each ICD-10-CM/PCS code that translates to multiple ICD-9-CM alternatives *Note:* Because of translation differences between the two systems, "one" ICD-10-CM/PCS code may map to "one" ICD-9-CM cluster.
Research the translation differences between the two diagnosis code sets, for your own understanding or for planning future changes to a system or application	ICD-10-CM (diagnosis) GEM *[year]_I10gem.txt* ICD-9-CM diagnosis GEM *[year]_I9gem.txt*	--**Find** the code of interest in both GEM files --**Compare** the translation alternatives for the code of interest, when it is the source system code (the code being translated) and when it is the target system code (a translation alternative of a code in the other code set). --*Note:* The code of interest may not be

		listed as a target system alternative. This in itself is useful information, to learn that the code is not considered a plausible translation based on the meaning and specificity of the source system code.
Research the translation discontinuities between the two procedure code sets, for your own understanding or for planning future changes to a system or application	ICD-10-PCS (procedure) GEM *gem_pcsi9.txt* ICD-9-CM procedure GEM *gem_i9pcs.txt*	-- **Find** the code of interest in both GEM files --**Compare** the translation alternatives for the code of interest, when it is the source system code (the code being translated) and when it is the target system code (a translation alternative of a code in the other code set). --*Note:* The code of interest may not be listed as a target system alternative. This in itself is useful information, to learn that the code is not considered a plausible translation based on the meaning and specificity of the source system code.

Glossary

Applied mapping—distillation of a reference mapping to conform to the needs of a particular application (e.g., data quality, research)

Backward mapping—mapping that proceeds from a newer code set to an older code set

Cluster—in a combination entry, one instance where a code is chosen from each of the choice lists in the target system entry, that when combined satisfies the equivalent meaning of the corresponding code in the source system

Forward mapping—mapping that proceeds from an older code set to a newer code set

General Equivalence Map (GEM)—reference mapping that attempts to include all valid relationships between the codes in the ICD-9-CM diagnosis classification and the ICD-10-CM diagnosis classification

ICD-9-CM—International Classification of Diseases 9th Revision Clinical Modification

ICD-10-CM—International Classification of Diseases 10th Revision Clinical Modification

No map flag—attribute in a GEM that when turned on indicates that a code in the source system is not linked to any code in the target system

Reverse lookup—using a GEM by looking up a target system code to see all the codes in the source system that translate to it

Source system—code set of origin in the mapping; the set being mapped 'from'

Target system—destination code set in the mapping; the set being mapped 'to'

ICD-9-CM Coordination and Maintenance Committee

March 9, 2010—ICD-10-PCS 2011 Proposed Changes

1) Transesophageal Ultrasound
Background: PCS currently does not specify that an ultrasound of the heart was performed transesophageally (TEE).

Proposal: Add new qualifier value 4 Transesophageal to table B24 for the heart body parts.
# of codes affected: 8 codes

Section B Imaging
Body System 2 Heart
Type 4 Ultrasonography: Real time display of images of anatomy or flow information developed from the capture of reflected and attenuated high frequency sound waves

Body Part	Contrast	Qualifier	Qualifier
0 Coronary Artery, Single 1 Coronary Arteries, Multiple 4 Heart, Right 5 Heart, Left 6 Heart, Right and Left B Heart with Aorta C Pericardium D Pediatric Heart	Z None	Z None	3 Intravascular Z None **ADD** 4 Transesophageal

2a) Additional Codes for Root operation Supplement
Background: Root operation Supplement needs to be added to body system J in order to capture soft tissue supplementation procedures for specific soft tissue body parts, such as pelvic region. Currently they are coded to the general anatomical regions body systems.

Proposal: Add root operation U Supplement to table 0JU with the same choices as table 0JR for the root operation Replacement.
# of codes affected: 132 codes

ADD ALL
Section 0 Medical and Surgical
Body System J Subcutaneous Tissue and Fascia
Operation U Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part

Body Part	Approach	Device	Qualifier
0 Subcutaneous Tissue and Fascia, Scalp 1 Subcutaneous Tissue and Fascia, Face 4 Subcutaneous Tissue and Fascia, Anterior Neck 5 Subcutaneous Tissue and Fascia, Posterior Neck 6 Subcutaneous Tissue and Fascia, Chest 7 Subcutaneous Tissue and Fascia, Back 8 Subcutaneous Tissue and Fascia, Abdomen 9 Subcutaneous Tissue and Fascia, Buttock B Subcutaneous Tissue and Fascia, Perineum C Subcutaneous Tissue and Fascia, Pelvic Region + 12 other body parts (extremities)	0 Open 3 Percutaneous	7 Autologous Tissue Substitute J Synthetic Substitute K Nonautologous Tissue Substitute	Z No Qualifier

2b) Additional Codes for Root operation Supplement
Background: Root operation Supplement needs to be added to the eye body part in table 08U to more accurately code scleral buckle procedures.

Proposal: Add body parts 0 and 1 to table 08U Supplement of Eye.

# of codes affected: 12 codes

Section 0 Medical and Surgical
Body System 8 Eye
Operation U Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part

Body Part	Approach	Device	Qualifier
ADD 0 Eye, Right **ADD** 1 Eye, Left C Iris, Right D Iris, Left E Retina, Right F Retina, Left G Retinal Vessel, Right H Retinal Vessel, Left L Extraocular Muscle, Right M Extraocular Muscle, Left	0 Open 3 Percutaneous	7 Autologous Tissue Substitute J Synthetic Substitute K Nonautologous Tissue Substitute	Z No Qualifier

Central Venous Catheter Placement Using
Intra-Atrial Electrocardiographic Guidance

Issue: There is a new approach to inserting indwelling vascular catheters that involves the use of electrocardiographic guidance to assist with proper positioning of the catheter. Current ICD-9-CM codes do not allow for the clear identification of those that use the electrocardiographic guidance.

New Technology Application? No.

Food and Drug Administration (FDA) approval: Yes.

Background:

Long term, indwelling vascular catheters have been in use for over twenty years in order to administer medications over a prolonged period of time and for withdrawing blood samples as an alternative to repeated venipunctures. These catheters are typically inserted into a vein in the arm and then threaded into the superior vena cava. The proper placement of the tip of the catheter is important in order to avoid complications, and as a result, the catheters are sometimes placed using fluoroscopy. More often, however, the catheter is inserted blindly, which requires that the proper position of the catheter be confirmed using a chest x-ray. The rate of catheter tip malposition may be as much as 8– 15%. Improper catheter tip positioning can lead to repeated insertion procedures and delays in catheter related therapy.

Long-term peripherally inserted central catheters are used in patients of all age groups. However, they are predominantly placed in adults greater than 18 years of age. The typical patient is one who needs vascular access for delivery of IV meds, such as antibiotics, TPN, chemotherapy, fluid replacement, pain meds, etc. for greater than 6 days. Greater than 90% of the patients admitted to hospitals today require vascular access for one of the reasons noted above.

The Sherlock 3CG TPS System is a new device that combines electrocardiography with catheter insertion in order to accurately place the catheter tip in the proper position in the superior vena cava. Using two standard exterior ECG electrodes placed on the left shoulder and the lower left abdomen, and an intravascular electrode located on the tip of the catheter, a signal is generated similar to that seen on Lead II of a standard ECG. Using a proprietary magnet technology, this signal then changes as the tip of the catheter moves towards or away from the heart, and optimal catheter tip placement can be correlated with the appearance of the ECG signal. The information provided by ECG-guided catheter tip placement technology gives the clinician rapid feedback so that catheter tip misplacements can be readily detected and corrected, if necessary.

Patients with cardiac pacemakers have been excluded from most studies using ECG guidance for vascular catheter placement. Many studies also exclude patients who have or have a history of atrial fibrillation. This technique requires the catheter to be advanced into the atrium then withdrawn, which may further exacerbate atrial flutter in these patients. Some patients (~10%) experience transient dysrhythmias while the catheter was located in the atrium.

Current Coding:

The following codes are currently used to capture this procedure:
38.93, Venous catheterization, NEC
89.52, Electrocardiogram (with ECG)

Coding options:

Option 1: Do not create a new code. Continue to assign codes 38.93 and 89.52 to capture this procedure.

Option 2: Create a new code in subcategory 38.9, Puncture of vessel, to clearly identify this procedure.

New code 38.97 Electrocardiogram guided central venous catheter placement

Recommendation: CMS recommends option 2, as outlined above.

Interim Coding:
Continue to assign codes 38.93 and 89.52 to capture this procedure.

Closed Chest Intracardiac Mitral Valve Repair

Issue:
The procedure provides a minimally invasive closed chest repair of the mitral valve in order to reduce mitral valve regurgitation (MR). This is a catheter based approach, and a unique code for mitral valve identification is being requested.

New Technology Application?
No.

Food & Drug Administration (FDA) Approval:
The Pre-Market Approval (PMA) submission to FDA is planned for the end of the first quarter of 2010. It is expected that the technology for this device, named MitraClip® and marketed by Evalve, will be reviewed by FDA and the Circulatory Systems Advisory Panel in mid-2010. PMA approval is expected in the first half of 2011.

Background:
Over 4 million Americans currently suffer from significant mitral valve regurgitation (MR). The only current therapeutic option for clinically significant MR is open heart surgery. While surgery is effective in reducing MR, there may be substantial morbidity and mortality associated with mitral valve surgery. As a result, the actual number of patients with MR who undergo surgery is only about 20-30% of newly diagnosed patients. Many patients receive medical management aimed at reducing their symptoms because the risks of surgery are not justifiable, yet long term survival is poor, especially for patients with New York Heart Association (NYHA) Functional Class III-IV symptoms. The ACC/AHA (American College of Cardiology /American Heart Association) guidelines recommend that MR should be corrected surgically before symptoms become severe, or before the onset of left ventricular dysfunction.

The MitraClip® therapy is a minimally invasive, closed chest catheter based approach for intracardiac repair of MR caused by mitral valve pathology and/or left ventricular dysfunction. The procedure is performed while the heart is beating, and is an alternative to the open chest, open heart surgical approach.

The MitraClip® procedure is conducted in the cardiac catheterization laboratory or in a hybrid operating room, often by interventional cardiologists. While the procedure does not require cardiopulmonary bypass, this less invasive valve repair procedure remains a major intracardiac intervention requiring highly trained medical personnel, substantial facility resources, and operative time similar to open heart mitral valve surgery.

Nearly 1000 patients have been treated with the MitraClip® therapy in the U.S. and Europe. Of note, the severity of MR and the degree of comorbidities in the patients treated with the MitraClip® therapy have been similar to and often worse than the patients who are typically treated with open heart surgery.

Procedure:
Since the early 1990's, the double-orifice technique has been increasingly used in the treatment of MR. Pioneered in Italy by Dr. Ottavio Alfieri, the technique involves suturing together the two leaflets of the mitral valve. The valve continues to open on both sides of the suture, allowing blood flow through the valve from the left atrium to the left ventricle, while assuring proper valve closure when blood is pumped from the left ventricle to the rest of the body.

The patient is prepared for the MitraClip® procedure similarly as for an open heart surgical mitral valve procedure. Access into the left atrium is achieved by puncture of the interatrial septum with the use of a transseptal needle and sheath under fluoroscopic and continuous transesophageal echocardiographic (TEE) guidance. Following the puncture, the patient is anti-coagulated using intravenous heparin to achieve an activated clotting time (ACT) of at least 250 seconds. A 24 French steerable guide catheter-dilator assembly of the MitraClip® system is advanced into the left atrium. The clip delivery system with the attached MitraClip® implant is inserted through the steerable guide catheter. Using the steering controls on the guide catheter and the clip delivery system under careful manipulation, the MitraClip® implant is precisely steered until it is axially aligned and centered over the origin of the regurgitant MR jet. The implant is advanced into the left ventricle and is retracted until the leaflets are grasped and then closed to bring the leaflets together. The quality of the grasp of the leaflets, valve function, and adequacy of repair (reduction of MR) are systematically and repeatedly assessed. After adequate reduction of MR has been achieved and proper leaflet insertion is confirmed, the MitraClip® implant is deployed, and the clip delivery system and guide catheter are withdrawn. Approximately 50-60% percent of patients achieve adequate reduction of their MR with a single implant, and 40-50% require a second implant.

After the procedure, the patient is recovered from general anesthesia in the cardiac intensive care unit (ICU) with appropriate monitoring of cardio-respiratory function and vascular access sites. Total procedure time from induction of anesthesia to removal of guiding catheter and clip delivery system in the cardiac catheterization laboratory or hybrid operating room varies, but on average is around 3-4 hours, with an average anesthesia time around 5-6 hours.

Current Coding:
No code exists for a catheter-based, closed chest repair of the *mitral* valve. Therefore, code 35.96, Percutaneous valvuloplasty, is recommended to describe this procedure. This advice is consistent with instruction published in Coding Clinic for ICD-9-CM, Third Quarter 2004, page 10.

Coding Options:
Option 1: Do not create a new code describing this procedure. Instead, use the available code, 35.96.

Option2: Create a new ICD-9-CM procedure code to describe this procedure, making it specific to the mitral valve.

35.9 Other operations on valves and septa of heart

	35.96	Percutaneous valvuloplasty
Add excludes note		Excludes: mitral valvuloplasty (35.97)
New code	35.97	Endovascular mitral valvuloplasty

CMS Recommendation:
Create a new code as described in Option 2, above, with corresponding changes to code 35.96.

Interim Coding:
Assign code 35.96, Percutaneous valvuloplasty, to describe this procedure.

Thoracoscopic Cardiac Ablation (maze) Procedure

Issue: The maze procedure can be performed by open, thoracoscopic or endovascular approach. Should a new ICD-9-CM procedure code be established to distinctly identify thoracoscopic maze procedures and differentiate between the three approaches?

New Technology Application? No

Food and Drug Administration (FDA) approval:
Not applicable.

Clinical Background:
The maze procedure treats atrial fibrillation by creating lesions in the tissue of the left and right atrium of the heart. These lesions are designed to interrupt the chaotic and disorganized electrical currents that characterize atrial fibrillation and to redirect them in such a manner as to restore normal sinus rhythm. Over the years, three different approaches have been developed by which the maze procedure can be performed.

Open approach

This is the oldest approach. In the open approach, a median sternotomy or occasionally a thoracotomy is made, the pericardium is opened, and the atria are usually opened for complete access to all of the target sites.

"Cut-and-sew" is the original technique for an open procedure, involving incisions into the atrial tissue followed by reconstruction of the atria. However, due to the increased difficulty and risk associated with making multiple atrial incisions, it is now more common to make a series of linear ablations. Ablation methods used to create the lesions can involve a variety of energy sources, such as radiofrequency, cryothermy, microwave, laser, and ultrasound. These energy sources are delivered by a probe or a clamp instrument applied to strategic locations within the heart and on the heart's surface. Creation of the incisions or ablation lines is directly visualized in the open approach.

The open approach is performed in an operating room by a cardiac surgeon or cardiothoracic surgeon.

Endovascular (percutaneous) approach

In the endovascular or percutaneous approach, a catheter is inserted into a peripheral vein and advanced into the right atrium. As needed, the atrial septum is punctured and the catheter is further advanced into the left atrium. Because the instrumentation is internal, no tissue dissection is needed or performed.

Incisions and clamps cannot be used in the endovascular approach. Instead, all lesions are created by a catheter-based energy source applied to the endocardial surface of the heart, i.e. from within the heart.

This approach is commonly used for ablation of other types of supraventricular tachycardia, including atrioventricular nodal reentry tachycardia. Because visualization is obviously not possible, the procedure is performed under imaging guidance (fluoroscopy). Endovascular maze is a medical procedure performed in an electrophysiology or catheterization laboratory by an electrophysiologist.

Thoracoscopic approach

The thoracoscopic approach is the most recently developed technique.
Most commonly, what is referred to as the thoracoscopic approach is more accurately termed thoracoscopically-assisted. The thoracoscope is used for illumination and visualization only, while the surgical and ablation instruments are inserted via a (mini)thoracotomy or a subxiphoid incision rather than through the scope itself. More recently, however, a total thoracoscopic approach has been developed.

As with the open approach, the thoracoscopically-assisted and total thoracoscopic techniques require opening the pericardium. Significant dissection of the pericardial sinuses and other vital structures is necessary to gain access to the target sites of the heart. In addition, as with the open technique, incisions can be made into the atria thoracoscopically but linear ablations are most commonly used. The same energy sources are used as with the open technique.

Creation of the lesions is visualized via the thoracoscope. Similar to the open procedure, the thoracoscopic approach must be performed in an operating room by a cardiac or cardiothoracic surgeon.

Coding Background

There are currently two ICD-9-CM codes for excision or destruction of other lesion or tissue of heart, which includes the maze procedure:

- Code 37.33, Excision or destruction of other lesion or tissue of heart, open approach, has an inclusion term for "modified maze procedure, trans-thoracic approach"
- Code 37.34, Excision or destruction of other lesion or tissue of heart, other approach, has inclusion terms for "via peripherally inserted catheter" and "endovascular approach".

When codes 37.33 and 37.34 were last revised in 2003, the thoracoscopic approach had not yet been developed for the maze procedure. As the thoracoscopic approach later came into use, Coding Clinic for ICD-9-CM (3rd Q 2006, p. 13) advised that it be coded to 37.33 based on the inclusion note for "trans-thoracic approach".

More recently, an addendum was proposed at the September 2009 meeting of the ICD-9-CM Coordination and Maintenance Committee to add an inclusion term for "thoracoscopic (endoscopic) approach" to code 37.34 instead. This change was not made as CMS wanted to review pertinent coded data first.

Coding Options

Option 1:

Make no changes to this section of the coding book. Classify the thoracoscopic approach to procedure code 37.33 as is currently done.

Option 2:

Revise codes 37.33 and 37.34 as proposed in the Addenda at the September 2009 meeting of the ICD-9-CM Coordination and Maintenance Committee. This approach would have moved the thoracoscopic procedure out of code 37.33 and into 37.34. In this option, it would not be possible to differentiate endovascular maze procedures from surgical thoracoscopic maze procedures in the encoded data.

Option 3:

Create a new code for thoracoscopic maze procedure with accompanying revisions to existing codes 37.33 and 37.34. This will allow all three approaches to be distinctly identified and tracked in the data.

37.33 Excision or destruction of other lesion or tissue of heart, open approach

Revise inclusion term	Ablation or incision of heart tissue (cryoablation) (electrocautery) (laser) (microwave) (radiofrequency) (resection) (ultrasound), open chest approach
	Cox-maze procedure
	Modified maze procedure
Delete inclusion term	~~Modified maze procedure, trans-thoracic approach~~
Add inclusion term	That by median sternotomy
Add inclusion term	That by thoracotomy without use of thoracoscope
Revise exclusion term	Excludes: ablation, excision or destruction of lesion or tissue of heart, endovascular approach (37.34) or thoracoscopic approach (37.37) excision or destruction of left atrial appendage (LAA) (37.36)

Revise code title	37.34 Excision or destruction of other lesion or tissue of heart, ~~other~~ endovascular approach
Revise inclusion term	Ablation of heart tissue (cryoablation) (electrocautery) (laser) (microwave) (radiofrequency) ~~(resection)~~ (ultrasound), via peripherally inserted catheter
Revise inclusion term	Modified maze procedure, ~~endovascular~~ percutaneous approach

Add exclusion term		Excludes: ablation, excision or destruction of lesion or tissue of heart, open approach (37.33) or thoracoscopic approach (37.37)
New code	37.37	Excision or destruction of other lesion or tissue of heart, thoracoscopic approach Ablation or incision of heart tissue (cryoablation) (electrocautery) (laser) (microwave) (ultrasound) (radiofrequency) (resection), via thoracoscope Modified maze procedure, thoracoscopic approach That via thoracoscopically-assisted approach (with thoracotomy) (with sub-xiphoid incision) (with port access) Excludes: ablation, excision or destruction of lesion or tissue of heart, open approach (37.33) or endovascular approach (37.34) thoracoscopic excision or destruction of left atrial appendage (LAA) (37.36)

CMS Recommendation:
Create a new code as shown in Option 3, above. Make corresponding changes to existing codes 37.33 and 37.34 in the Tabular and Index.

Interim Coding:
Assign these procedures to existing code 37.33, Excision or destruction of other lesion or tissue of heart, open approach.

Fat Grafting for Reconstructive Surgery

Issue:
ICD-9-CM does not have specific codes for harvesting or placing fat grafts used in reconstructive surgery. Should new ICD-9-CM procedure codes be established to distinctly identify these procedures?

New Technology Application?
No.

Background:
Fat grafting is a technique in which prepared fat cells are injected to correct soft tissue defects. Fat grafts are commonly used in reconstructive procedures, particularly in the breast following lumpectomy and as an adjunctive procedure with post-mastectomy reconstruction. Fat grafts are also used in cosmetic procedures, such as augmenting lips and filling in facial wrinkles.

The fat used for grafting is always autologous. Fat is harvested by liposuction from elsewhere on the patient's body, typically an unobtrusive area such as the abdomen, flanks or thighs. After injecting tumescent fluid, a standard liposuction cannula is placed subcutaneously and adipose tissue is then aspirated. The volume of fat taken varies with the amount needed for reconstruction.

Before being used as a graft, the lipoaspirate must be processed to concentrate the number of fat cells. This is performed as a back table procedure during the same operative encounter. Conventionally, the standard is to filter the fat by centrifuging it. This procedure removes the extra fluid and leaves a more concentrated graft, consisting mostly of adipocytes along with a small volume of adipose progenitor cells. This technique has been in use for many years. Unfortunately, results have been variable and unpredictable because fat cells are subject to ischemia after grafting. This can often lead to cell atrophy and recurring soft tissue defects. To overcome these complications, new techniques have been developed to enrich the fat graft with more adipose progenitor cells, also called adipose-derived stem and regenerative cells. Because the regenerative cells are thought to encourage neoangiogenesis and prevent cell death, this enriched material is likely to enhance graft survival. Enrichment starts by dividing the lipoaspirate into two aliquots. One aliquot is biochemically "digested" to render the adipose stem cells and other regenerative precursor cells. These are then mixed with the remaining portion of lipoaspirate to create a progenitor-enriched fat graft with a far greater concentration of stem and regenerative cells.

The technique for placement in the recipient area is the same for conventional and enriched fat grafts. The graft material is loaded into a syringe. The needle or cannula is inserted into the subcutaneous tissues at the site of the defect and small droplets of fat are injected. The needle is passed though many layers and in many directions ("fanning") to ensure even distribution and maximal surface area of the fat grafts. This, in turn maximizes exposure of the fat grafts to the surrounding native tissue to increase availability of oxygen and nutrients until the graft establishes a new blood supply (until the graft "takes"). For breast reconstruction, the fat grafts

are placed into the layers around the mammary glands to obtain contour and texture complementary to the remaining native breast.

Fat grafting of the breast can be performed as a solo procedure. It is also commonly done during the same operative episode as other reconstruction, such as myocutaneous flaps e.g. TRAM, breast implants, and mammoplasty for revision of previously reconstructed breasts.

Total operative time for conventional fat grafting in breast reconstruction is about 1½ to 2½ hours. Because of the preparation, total operative time for enriched grafts is about 3 to 4 hours.

Coding Options:
Option 1. Continue to assign 85.99, Other operations on the breast, for fat grafting to the breast. If grafting is preformed with total reconstruction of breast, continue to assign codes for the total reconstruction of breast (85.70-85.79). For liposuction to harvest the fat graft, continue to assign code 86.83, Size reduction plastic operation.

Option 2. Create new codes for: a) fat graft of breast, b) fat graft of other subcutaneous sites, and c) harvesting fat for grafting for a total of 5 new codes.

85.5 Augmentation mammoplasty

85.51 Unilateral injection into breast for augmentation

Add exclusion term — Excludes: injection of fat graft of breast (85.55-85.56)

85.52 Bilateral injection into breast for augmentation

Add exclusion term — Excludes: injection of fat graft of breast (85.55-85.56)

New code — 85.55 Fat graft to breast without use of enriched graft
Includes: extraction of fat for autologous graft
Autologous fat transplantation or transfer
Fat graft to breast NOS
Micro-fat grafting
Excludes: fat graft to breast with use of enriched graft (85.56)

New code — 85.56 Fat graft to breast with use of enriched graft
Includes: extraction of fat for autologous graft
Cell-enriched fat grafting
That enriched with:
adipose-derived (regenerative) (stem) cells
adipose progenitor cells
Excludes: fat graft to breast without use of enriched graft (85.55)

85.9 Other operations on the breast

85.92 Injection of therapeutic agent into breast

Revise exclusion term — Excludes: that for augmentation of breast (85.51-85.52, 85.55- 85.56)

86.8 Other repair and reconstruction of skin and subcutaneous tissue

86.83 Size reduction plastic operation
Liposuction
Reduction of adipose tissue of:
abdominal wall (pendulous)
arms (batwing)
buttock
thighs (trochanteric lipomatosis)

Add exclusion term

Excludes: liposuction to harvest fat graft (86.90)

New code

86.87 Fat graft without use of enriched graft
Includes: extraction of fat for autologous graft
Autologous fat transplantation or transfer
Fat graft NOS
Micro-fat grafting
Excludes: fat graft to breast (85.55)
fat graft with use of enriched graft (86.88)

New code

86.88 Fat graft with use of enriched graft
Includes: extraction of fat for autologous graft
Cell-enriched fat grafting
That enriched with:
adipose-derived stem cells
adipose progenitor cells
Excludes: fat graft to breast (85.56)
fat graft without use of enriched graft (86.87)

86.9 Other operations of skin and subcutaneous tissue

New code

86.90 Extraction of fat for graft or banking
Harvest of fat for extraction of cells for future use
Liposuction to harvest fat graft
Excludes: that with graft at same operative episode (85.55-85.56, 86.87-86.88)

CMS Recommendation:
Option 1. Continue to assign 85.99, Other operations on the breast, for fat grafting to the breast. If grafting is preformed with total reconstruction of breast, continue to assign codes for the total reconstruction of breast (85.70-85.79). For liposuction to harvest the fat graft, continue to assign code 86.83, Size reduction plastic operation.

Interim Coding:
Continue to assign 85.99, Other operations on the breast, for fat grafting to the breast. If grafting is preformed with total reconstruction of breast, continue to assign codes for the total reconstruction of breast (85.70-85.79). For liposuction to harvest the fat graft, continue to assign code 86.83, Size reduction plastic operation.

Sternal Fixation with Rigid Plates

Issue: There is not a unique ICD-9-CM code to capture the internal fixation of the sternum using rigid plates. Currently this procedure is captured in a more generic code, 78.51 Internal fixation of bone without fracture reduction, scapula, clavicle, and thorax [ribs and sternum]. This code is too general for tracking purposes because it describes a variety of locations as well as orthopedic procedures that employ internal fixation. Therefore, it is not possible to track outcome results for the prevention of sternal dehiscence (SD) and deep sternal wound infections (DSWIs) after cardiothoracic surgery.

New Technology Application? No.

FDA Status: The Synthes TSFS was cleared by the FDA in 2001 (510(k) K010943) for the following intended use: "primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion."

Background:
The conventional approach to sternal closure after cardiothoracic surgery is sternal wiring. However, in obese patients and others at higher risk for SD, certain studies demonstrate that rigid plate fixation of the sternum significantly reduces the incidence of SD in this select population of patients undergoing cardiothoracic surgery.

This request is for a new ICD-9-CM procedure code to describe the fixation of the sternum with rigid plates for the prevention of sternal dehiscence (SD) and deep sternal wound infections (DSWIs) after cardiothoracic surgery. Sternal dehiscence is a complete or partial separation of the sternum following a median sternotomy for cardiothoracic surgery. Patients with SD have an increased incidence of DSWI, and the risk of hospital death in patients with DSWI ranges from 10 to 25 percent. Risk factors for SD and DSWI after cardiothoracic surgery are obesity, diabetes mellitus, COPD, renal failure, steroid use, and tobacco use.

The Synthes Titanium Sternal Fixation System (TSFS) is a type of rigid plate fixation system that is used in the procedure. It consists of implants and instruments dedicated for sternal closure and reconstruction. The system provides rigid fixation using locking plate technology that functions like an "external fixator," but it is applied internally to the sternum. This procedure is performed along with cardiothoracic surgery in the inpatient setting. Plates link the two sternal halves, and screws link the plates to the sternum and the ribs. The primary procedure steps for fixation of the sternum with rigid plates using the Synthes TSFS are summarized as follows:

1. Exposure of the ribs laterally, if necessary for plate application;
2. Measurement of bone thickness for appropriate screw selection;
3. Reduction of the sternum with reduction forceps;
4. Cutting and contouring of the plates, if necessary;
5. Drilling of the screw holes on the sternum and ribs (for self tapping screws only);
6. Selection and insertion of the appropriate screw;
7. Drilling and application of the remaining screws;

8. Insertion of remaining plates for adequate stability (3 plates are recommended);
9. Closure of soft tissue and postoperative considerations.

The purpose of this code request is to establish a distinct code for sternal fixation with sternal plates. This code would allow tracking of the use of this new technology, in particular in the population at high risk for SD after cardiothoracic surgery. As described further below, CMS has considerable interest in the prevention of surgical wound infections and DSWIs in particular. This proposed new code could be used to track and measure on an ongoing basis the use and effect of sternal fixation with rigid plates in preventing SD and DSWIs.

It will be important to track the use of and the results from sternal fixation with rigid plates with an appropriate ICD-9-CM procedure code. The U.S. Department of Health and Human Services, in the *HHS Action Plan to Prevent Healthcare-Associated Infections* (January 2009), identified surgical site infections as one of the "four categories of infections [that] account for approximately three quarters of HAIs in the acute care hospital setting." This Action Plan includes many initiatives to improve the prevention of surgical site infections.

CMS has designated selected surgical site infections, e.g., mediastinitis after CABG surgery and those after certain orthopedic procedures and bariatric surgery, as hospital acquired conditions (HACs), meaning that in some cases hospitals are paid a reduced amount to treat these infections unless the infections are present on admission. The HAC payment reduction is designed to motivate hospitals to prevent these surgical site infections. CMS has also included several quality measures related to prophylactic antibiotics and infection prevention within the Surgical Care Improvement Project (SCIP) part of the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program, in which hospitals must report certain quality measures in order to avoid a payment reduction. All of these initiatives demonstrate the importance of surgical site infections and reflect the commitment of HHS and CMS to addressing the problem by promoting policies aimed at preventing these infections. Synthes plans to contribute to these efforts by performing a study of sternal plating versus wiring in high-risk groups. To assess the technology's use and effect in SD and DSWI prevention, proper tracking with a specific ICD-9-CM procedure code will be critical.

Almost 700,000 cardiothoracic (open heart) surgeries were performed in the U.S. in 2006 and 98.5% of these procedures were performed through a median sternotomy. Sternotomy closure is usually performed via sternal wiring. Due to various factors, the significant complications of SD and DSWI occur more often in certain high risk patients, e.g., patients with obesity, diabetes mellitus, COPD, renal failure, steroid use, and tobacco use. Several studies have discussed sternal fixation with rigid plates or demonstrated the effectiveness of sternal fixation with rigid plates instead of sternal wiring in preventing SD and DSWI in high risk patients.

A more extensive randomized controlled trial of sternal fixation with rigid plates versus sternal wiring has been proposed by Synthes. It is intended to advance the clinical evidence for the prevention of these potentially devastating complications in this population of patients with significant risk factors and comorbidities. The availability of more precise codes to capture this use of sterna fixation with rigid plates would be provide more accurate data for outcome studies.

Current Coding: Currently code 78.51, Internal fixation of bone without fracture reduction, scapula, clavicle, and thorax [ribs and sternum] is assigned to capture this procedure.

Coding Options:
Option 1: Do not create a new code. Continue to assign code 78.51 to capture this procedure.

Option 2: Create a new code in category 84.9, Other operations on musculoskeletal system to clearly identify this procedure.

New code:	84.94	Insertion of sternal fixation device with rigid plates
	78.5	Internal fixation of bone without fracture reduction
Revise		Excludes: insertion of sternal fixation device with rigid plates (84.94)

Recommendation: CMS recommends option 2.

Interim coding: Continue to assign code 78.51 to capture this procedure.

Laparoscopic Hernia Repair Without Graft or Prosthesis

Issue: We currently do not have ICD-9-CM procedure codes to identify laparoscopic incisional, inguinal or ventral hernia repair *without* graft or prosthesis. Although the frequency in which these procedures have been performed is low, we received a request to propose new codes.

New Technology Application? No

Coding options:

1. Do not create new codes to describe laparoscopic incisional, inguinal and ventral hernia repairs without graft or prosthesis. Continue to use the following codes:

   53.5 Repair of other hernia of anterior abdominal wall (without graft or prosthesis)
   - 53.51 Incisional hernia repair
   - 53.59 Repair of other hernia of anterior abdominal wall (ventral)

   These codes do not describe the laparoscopic approach; however, they indicate that a graft or prosthesis was not used.

   An inclusion term could also be added at code 53.59 to identify a laparoscopic hernia repair performed without the use of a graft or prosthesis.

2. Create new codes to describe laparoscopic incisional, inguinal and ventral hernia repairs without graft or prosthesis. Exclusion notes would be placed appropriately.

   17.1 Laparoscopic unilateral repair of inguinal hernia
   - New code 17.14 Laparoscopic repair of direct inguinal hernia without graft or prosthesis
   - New code 17.15 Laparoscopic repair of indirect inguinal hernia without graft or prosthesis
   - New code 17.16 Laparoscopic repair of inguinal hernia without graft or prosthesis, not otherwise specified

   17.2 Laparoscopic bilateral repair of inguinal hernia
   - New code 17.25 Laparoscopic bilateral repair of direct inguinal hernia without graft or prosthesis
   - New code 17.26 Laparoscopic bilateral repair of indirect inguinal hernia without graft or prosthesis
   - New code 17.27 Laparoscopic bilateral repair of inguinal hernia, one direct and one indirect, without graft or prosthesis

   53.5 Repair of other hernia of anterior abdominal wall (without graft or prosthesis)
   - New code 53.52 Laparoscopic incisional hernia repair
   - New code 53.57 Laparoscopic repair of other hernia of anterior abdominal wall

Revise code 53.51 Other and open ~~I~~incisional hernia repair
Revise code 53.59 Other and open ~~R~~repair of other hernia of anterior abdominal wall

Recommendation: CMS recommends option one as stated above since the volume in which these procedures are performed is so low. CMS would like to hear input as to whether an inclusion term would be helpful at code 53.59.

Interim coding: Continue to use code 53.59 to describe laparoscopic incisional, inguinal, or ventral hernia repairs without graft or prosthesis.

Cranial Implantation of Neurostimulator

Issue:
There are procedure codes to identify the implantation or replacement of neurostimulator pulse generators that are subcutaneously implanted. There is a new procedure in which the leads and neurostimulator pulse generator are implanted in the cranium. Should new procedure codes be created to identify the neurostimulator pulse generators that are cranially implanted?

New Technology Application?
There was no application received for consideration for FY 2011.

Food and Drug Administration (FDA) Approval:
NeuroPace, Inc. plans to submit a Premarket approval (PMA) application to the FDA in the 2nd quarter of 2010. FDA approval is anticipated in early 2011. The FDA submission is for use of the RNS® System in treating adults with localization-related (focal) (partial) epilepsy[1] whose seizures have not been adequately controlled with medication.
Enrollment in a U.S. randomized, controlled pivotal trial of the RNS System was completed in November 2008. Subjects completing either the pivotal trial or preceding feasibility study are eligible to enroll in a subsequent study designed to capture an additional five years of safety and efficacy data.

Background:
Epilepsy is a chronic neurological condition affecting individuals of all ages and is characterized by abnormal electrical activity in the brain resulting in seizures. According to the Epilepsy Foundation, almost three million people in the United States have active epilepsy.[2] Despite treatment, more than one-third of people with epilepsy continue to have seizures.[3] Risks for people with uncontrolled seizures include injury, depression, and cognitive disability.

Individuals with uncontrolled seizures originating from one or two areas in the brain would be candidates for treatment using the RNS System.

Technology:
The RNS System, designed for the treatment of medically refractory localization-related (focal) (partial) epilepsy, includes implantable and external products. Implantable components include the RNS neurostimulator as well as depth leads and cortical strip leads. The RNS neurostimulator is a small curved device designed to fit within the skull. It is a programmable, battery powered, microprocessor-controlled device that delivers short bursts of mild electrical pulses to the brain through implanted leads. In treating epilepsy, the RNS neurostimulator is designed to continuously monitor brain electrical activity and detect abnormal electrical activity that indicates a seizure is about to start. After detecting such electrical activity, the device responds by delivering brief and mild electrical stimulation to normalize brain activity before the

[1] In localization-related (focal) (partial) epilepsy, seizures originate from one or more localized areas of the brain.
[2] http://www.epilepsyfoundation.org/about/statistics.cfm
[3] Epilepsy—At a Glance, 2009. Centers for Disease Control and Prevention.

patient experiences seizure symptoms. This type of therapy is called responsive neurostimulation. Stimulation is delivered only when needed. Typically, patients receive no more than one to two minutes of stimulation in total over the course of a day.

The neurostimulator is implanted within the skull and connected to one or two leads that are implanted near the patient's seizure focus or foci. Approximately the same thickness as the skull, the neurostimulator is designed so that it is anchored into place and does not protrude on either side of the skull when implanted.

External products include a physician programmer and a patient remote monitor. Both products use proprietary software that enables communication with an implanted RNS neurostimulator. Physicians use the programmer to non-invasively program the detection and stimulation parameters of an implanted device specifically for individual patients. Additional features of the programmer include the ability to view the patient's brain electrical activity (electrocorticogram or ECoG) in real-time. Patients use the remote monitor at home (or elsewhere) to transmit ECoGs and other information that has been stored in the RNS neurostimulator to a secure data repository. Physicians can review and analyze information about device operation and the patient's health over the internet between the patient's office appointments to enhance patient management.

Procedure:

Implantation

The RNS neurostimulator and leads are implanted during a single surgical procedure in the hospital inpatient setting. First, the leads are implanted through burr holes and/or a craniotomy in the area(s) of seizure onset in the brain. Then the RNS neurostimulator is implanted in the patient's skull.

To implant the neurostimulator, the neurosurgeon makes an incision to expose the skull, and then creates an outline on the skull for a craniectomy using a template. A burr hole is made in the skull along the outline and a portion of the skull is removed to complete the craniectomy. An accessory product called a "ferrule" (tray into which the neurostimulator fits) is placed in the skull where the bone was removed and is anchored to the skull with bone screws. The purpose of the ferrule is to provide support to the implanted neurostimulator. Next, the implanted intracranial leads are connected to the neurostimulator and the neurostimulator is placed in the ferrule and secured. The scalp is replaced over the skull, covering the implanted neurostimulator, and the surgical site is sutured closed.

The entire procedure is performed in the hospital inpatient setting with patients under general anesthesia and takes approximately three hours to complete.

This single stage procedure differs from the current practice of implanting intracranial leads and subcutaneous neurostimulator pulse generators, commonly used for deep brain stimulation (DBS) for Parkinson's disease. The DBS leads and neurostimulator are typically implanted in two separate procedures. First, the leads are implanted in a hospital inpatient procedure with the

patient under conscious sedation. Later, the neurostimulator is implanted in a separate hospital outpatient procedure with the patient under general anesthesia.

The DBS neurostimulator is implanted in the chest through an incision below the clavicle. A pocket is formed between the subcutaneous fat and muscle for the device. The previously implanted leads are "tunneled" down the neck to the neurostimulator implant site in the chest, and the leads are connected to the neurostimulator. The neurostimulator is placed in the chest pocket, and the incision site is sutured closed.

As described above, there are clear differences in implant site and surgical techniques for implantation of subcutaneous neurostimulators and cranially implanted neurostimulators. There would be value in having unique ICD-9-CM procedure codes in order to differentiate between these distinct neurostimulator implant procedures.

Replacement

Both cranially implanted neurostimulators and subcutaneous neurostimulators need to be replaced periodically due to battery depletion (in both cases, the intracranial leads are not replaced). The battery life of a cranially implanted neurostimulator is expected to average approximately three years. Replacement of a cranially implanted neurostimulator can take place in either an inpatient or an outpatient procedure, under either general or local anesthesia.

Removal

Infrequently, it may be medically necessary to remove a neurostimulator without replacement. Removal of a cranially implanted neurostimulator may involve removal of the ferrule and repair of the craniectomy defect (where a portion of the skull was removed) using cranioplasty techniques. This procedure would typically occur in the inpatient setting under general anesthesia, and would differ in many ways from removal of a subcutaneous neurostimulator in the chest.

Coding Options:

Option 1. Continue to assign code 02.93, Implantation or replacement of intracranial neurostimulator lead(s) and code 86.95, Insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable, for the cranial implantation or replacement of the neurostimulator. Continue to assign code 86.05, Incision with removal of foreign body or device from skin and subcutaneous tissue, for the removal of the pulse generator.

Option 2. Create two new codes for the cranial implantation or replacement of the neurostimulator pulse generator and removal of the pulse generator under category 01.2, Craniotomy and craniectomy. There will be revisions to the code also note under code 02.93 and the exclusion terms under the neurostimulator pulse generator codes.

New code 01.20 Cranial implantation or replacement of
neurostimulator pulse generator
Code also any associated lead implantation (02.93)

New code 01.29 Cranial removal of neurostimulator pulse generator

CMS Recommendation:

Option 2. As stated above.

Interim Coding:

Continue to assign code 02.93, Implantation or replacement of intracranial neurostimulator lead(s) and code 86.95, Insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable, for the cranial implantation or replacement of the neurostimulator. Continue to assign code 86.05, Incision with removal of foreign body or device from skin and subcutaneous tissue, for the removal of the pulse generator.

Intralaminar Lumbar Decompression and Laminotomy with Epidurography and Image Guidance

Issue: There is no specific ICD-9-CM procedure code that describes an intralaminar lumbar decompression and laminotomy with epidurography and image guidance. Currently, code 03.09, Other exploration and decompression of spinal canal, is used to identify when a lumbar decompression (laminectomy/laminotomy) is performed.

New Technology? No.

FDA status: The *mild*® technology that is used for the Intralaminar Procedure was cleared for marketing by the Food and Drug Administration (FDA) on December 19, 2006. The first date of sale was in April of 2008.

Background: Intralaminar lumbar decompression and laminotomy with epidurography and image guidance (the Intralaminar Procedure) is a surgical treatment for lumbar spinal stenosis (LSS). The Intralaminar Procedure removes the bone or tissue causing the pressure on the nerves through a minimally invasive approach.

Technology: The Vertos *mild*® Devices are specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions. They are a sterile, single-use system of surgical tools consisting of one each of the following components:
1. *mild* Tissue Sculpter Device - 8.5 Gauge, 8.5" (21.59 cm) working length
2. *mild* Trocar and Handle – 7 Gauge, 6.5" (16.51 cm) working length
3. *mild* Portal – 6 Gauge, 6.5" (16.51 cm) working length
4. Surgical Clamp – 14" (35.56 cm) length
5. Accessory Guide
6. *mild* Bone Sculpter Rongeur (forward)
7. Back Plate

Procedure: The Intralaminar Procedure devices are designed to access the intralaminar space from the posterior lumbar spine to enable the user to preferentially resect thickened ligamentum flavum. Surgical access begins at the inferior lumbar segment and is lateral to the spinous process margin. The tissue access device is advanced through the back muscle and tissue to the inferior vertebral segment lamina, toward the border of the intralaminar space. The portal accepts the tissue sculpter, which is advanced into the intralaminar space, toward the inferior border of the adjacent lamina for ligamentous tissue resection.

Initially, the Anterior-Posterior (AP) projection for identifying the target region and guiding device placement for tissue resection is recommended for the Intralaminar Procedure. This projection positions the fluoroscopic imaging head substantially parallel to the surface of the laminae to enable an unobstructed imaging trajectory into the intralaminar space and ligamentum flavum. Additionally, the contralateral-oblique imaging plane is required to assess the posterior-anterior depth, viewed from the lamina to the epidural space. This aids to

determine the relative position of the tissue sculpter within the ligamentum flavum.

The injection of non-ionic contrast media to perform epidurography prior to device insertion is recommended. Following epidurography, image-guided cephalad placement of the portal to the laminar surface of the inferior vertebral segment is initially completed. The tissue sculpter is then introduced through the portal and advanced into the intralaminar space toward the superior vertebral segment. The open tip of the tissue sculpter is directed to the ventral surface of the superior lamina, remaining superior to the epidural space. This procedure selectively places the device within the ligamentum flavum to retract, grasp and excise tissue.

Benefits: According to the requestor, the nature of the Intralaminar Procedure enables shorter in-patient therapy and recovery compared to other open surgical treatment options, such as laminotomy, laminectomy and spinal fusion for LSS. Patients who undergo the Intralaminar Procedure are typically discharged the day following the procedure. The Intralaminar Procedure also can be performed with fluoroscopic guidance in an outpatient setting under local anesthesia or MAC support. Initial clinical data for the procedure indicates an average 75 percent reduction in pain and greater than 70 percent increase in mobility. In addition, most patients can decrease use of narcotics or pain medication at 6 weeks.

Coding options:

1. Do not create a new code. Continue to use existing codes 03.09, Other exploration and decompression of spinal canal, and a code from subcategory 87.2, X-ray of spine, to describe an intralaminar lumbar decompression and laminotomy with epidurography and image guidance.

2. Create a new code to describe intralaminar lumbar decompression and laminotomy with epidurography and image guidance.

New code	03.03	Intralaminar lumbar decompression and laminotomy with epidurography image guidance Image-guided intralaminar lumbar decompression with epidurography
Revise	03.09	Other <u>and open</u> exploration and decompression of spinal canal
Add exclusion term		Excludes: <u>intralaminar lumbar decompression and laminotomy with epidurography image guidance (03.03)</u>

Recommendation: CMS recommends option 2 as stated above.

Interim advice: Continue to assign code 03.09, Other exploration and decompression of spinal canal, and a code from subcategory 87.2, X-ray of spine, to describe an intralaminar lumbar decompression and laminotomy with epidurography and image guidance.

Biopsy of Soft Tissue Mass

Issue:
This topic was brought to CMS' attention because it appeared to be an error of omission in the procedure coding system, thereby causing confusion. Coding currently exists to describe closed biopsies of other sites. Should conforming changes be created for existing code(s) for soft tissue biopsy?

New Technology Application?
No.

Food & Drug Administration (FDA) Approval:
Not applicable.

Current Coding:
Closed diagnostic biopsy procedures, including percutaneous and needle biopsies, exist in several chapters of the classification system. Examples include:

- 07.11, Closed [percutaneous] [needle] biopsy of adrenal gland
- 33.26, Closed [percutaneous] [needle] biopsy of lung
- 41.32, Closed [aspiration] [percutaneous] biopsy of spleen
- 85.11, Closed [percutaneous] [needle] biopsy of breast

Coding Options:
Option 1
Do not create a new code. The Index directs coders to use soft tissue NEC (83.21) to describe this procedure. This code is located in the subcategory 83.2, Diagnostic procedures on muscle, tendon, fascia, and bursa, including that of hand. There is an excludes note at 83.21 directing coders to use 86.11 for biopsy of skin and subcutaneous tissue.

Option 2
Create a new code in subcategory 83.2 to match the other closed diagnostic procedure codes. Add conforming language to code 86.11.

	83.2	Diagnostic procedures on muscle, tendon, fascia, and bursa, including that of hand
Revise title	83.21	Open ~~B~~biopsy of soft tissue
Add exclusion term		Excludes: closed percutaneous or needle biopsy of muscle, tendon, fascia or bursa, including hand (83.22)
New code	83.22	Closed [percutaneous] [needle] biopsy of soft tissue Excludes: percutaneous or needle biopsy of soft tissue mass (86.11)
	86.1	Diagnostic procedures on skin and subcutaneous tissue
Revise code	86.11	Closed [percutaneous] [needle] ~~B~~biopsy of skin and subcutaneous tissue

CMS Recommendation:
Create a new code to describe a closed, percutaneous, or needle biopsy of soft tissue.

Interim Coding:
Code 83.21, Biopsy of soft tissue, as directed by the procedure Index.

Continuous Glucose Monitoring

Issue:
There are multiple codes for monitoring various physiologic parameters and metabolic levels, such as continuous intra-arterial blood gas monitoring, intravascular pressure measurements, and intracranial oxygen and temperature monitoring. Currently, coders do not assign any code to capture blood tests, such as continuous monitoring of glucose levels. Furthermore, there are no codes to capture a variety of laboratory tests. Glycemic control has become an important standard in hospital care. Should new ICD-9-CM procedure codes be established to identify inpatient techniques for continuous glucose monitoring?

New Technology Application?
No.

Background:
Multiple studies have shown that hospitalized patients can be at a higher risk of infection and other complications if their blood glucose levels are elevated for prolonged periods. Conventionally, clinicians manage patients' glucose levels by manually drawing intermittent blood samples over the course of the stay. However, the test results are necessarily limited to a snapshot at each point in time and may not present the entire picture of patients' glucose levels.

More recently, methods for continuous glucose monitoring have been developed which provide on-going readings. This provides clinicians with a more comprehensive picture of trends in glucose levels and allows them to proactively manage glucose levels to within more tightly targeted ranges.

There are two techniques, both invasive, being developed for continuous glucose monitoring in the hospital. The first technique uses a probe (sensor) placed within a dedicated vascular catheter to directly measure blood glucose values. The second technique uses a probe (sensor) inserted in the subcutaneous tissues, of the abdomen for example, to measure glucose values from the interstitial fluids. Interstitial glucose concentrations are known to correlate closely with blood glucose concentrations. In both techniques, continuous values are displayed on a monitor against the targeted range. Trends in glucose values over time are also displayed. Alarms can be triggered by values that are outside of pre-determined thresholds.

Control of glycemic levels in hospitalized patients has taken on particular prominence in recent years. Postoperative metabolic derangement, specifically including diabetic glycemic disturbance, is among AHRQ's Quality Indicators-Patient Safety Indicators as an adverse patient event that is potentially preventable. Starting with FY 2009, manifestations of poor glycemic control have been designated as hospital-acquired conditions under IPPS. The RHQDAPU (Reporting Hospital Quality Data for Annual Payment Update) program includes cardiac surgery patients with controlled 6AM postoperative blood glucose as part of the Surgical Care Improvement Project (SCIP) for FY 2010 and FY 2011. Postoperative metabolic derangement is also being considered as an inpatient Quality Measure in reporting FY 2012 hospital quality data to promote improved patient care.

Coding Options:

Option 1. Continue not to code for continuous glucose monitoring as there is no code.

Option 2. Create new codes for continuous glucose monitoring under category 00.9, Other procedures and interventions.

New code	00.95 Continuous glucose monitoring, blood
	That by insertion of intravenous probe (sensor)
	Excludes: continuous glucose monitoring, interstitial (00.96)
New code	00.96 Continuous glucose monitoring, interstitial
	That by insertion of subcutaneous probe (sensor)
	Excludes: continuous glucose monitoring, blood (00.95)

CMS Recommendation:

Option 1. As stated above.

Interim Coding:

Continue not to code for continuous glucose monitoring as there is no code.

Circulating Tumor Cell Enumeration Test

Issue:
Circulating tumor cells ("CTC") in peripheral blood have emerged as an accurate and valuable method to monitor patient response to treatment in a variety of cancer populations. Should a new procedure code be created to identify the testing for the enumeration of circulating tumor cells?

New Technology Application?
No.

Food and Drug Administration (FDA) Approval:
The CellSearch® CTC test was granted de novo 510(k) review in January 2004 based on its unique technology and data from a metastatic breast cancer clinical study, thereby creating a new device classification (21 C.F.R. § 866.6020, Immunomagnetic circulating cancer cell selection and enumeration system). The CellSearch® Test was cleared for predicting progression free survival and overall survival of metastatic breast cancer (MBC) patient at baseline and first follow-up. In October 2005, the indication for use was expanded to include testing at any time point during therapy. In December 2006, indication for use was expanded to include serial monitoring of metastatic breast cancer patients and use as an adjunct to imaging. This included 50 months of clinical follow-up data.

In November 2007, indication for use was expanded to include serial monitoring of metastatic colorectal cancer (MCRC) patients and use as an adjunct to imaging. This prospective study included 430 metastatic colorectal cancer patients. In February 2008, indication for use was expanded to include serial monitoring of metastatic prostate cancer (MPC) patients and use as an adjunct to PSA testing. This prospective study included 231 metastatic prostate cancer patients.

Background:
The CellSearch® Circulating Tumor Kit is intended for the enumeration of circulating tumor cells of epithelial origin (CD45-, EpCAM+, and cytokeratins 8, 18+, and/or 19+) in whole blood. The presence of CTC in peripheral blood is associated with decreased progression free survival and decreased overall survival in patients treated for metastatic breast, colorectal, or prostate cancer. Serial testing of CTC is used in conjunction with other clinical methods for monitoring metastatic breast, colorectal and prostate cancer. Evaluation of CTC at any time during the course of disease allows assessment of patient prognosis and is predictive of progression free survival and overall survival.

It is important to distinguish the CellSearch® CTC Test from chemo-sensitivity and resistance assays (CSRA). Mainly, CSRAs are performed prior to the administration of a chemotherapeutic agent to determine which drug may be most effective in treating a patient; the CellSearch® CTC test is performed at baseline, and during, the administration of therapy to determine patient prognosis and to predict progression free survival and overall survival independent of the type of therapy. Serial monitoring of patients under therapy for the Indicated

Cancers with the CellSearch® CTC test allows assessment of prognosis at any time point, and can be used by physicians to make more informed patient care decisions.

Coding Options:

Option 1. Continue to code 90.59, Microscopic examination of blood, other microscopic examination, for this testing.

Option 2. Create a new code for the circulating tumor cell enumeration, immunomagnetic.

New code 00.97 Circulating tumor cell enumeration, immunomagnetic

CMS Recommendation:

Option 1. Continue to code 90.59, Microscopic examination of blood, other microscopic examination, for this testing.

Interim Coding:

Continue to code 90.59, Microscopic examination of blood, other microscopic examination, for this testing.

Intra-operative Angiography in Coronary Artery Bypass Graft Surgery

Issue: Currently, there is not a unique ICD-9-CM code that identifies intra-operative coronary angiography versus those that are not performed intra-operatively. Effective October 1, 2007, procedure code 88.59, Intra-operative fluorescence vascular angiography (IFVA), was created to specifically describe the IFVA or SPY technology. Code 88.59 is used in both coronary and non-coronary surgical procedures. Because IFVA and coronary angiography are used for intra-operative assessment of coronary vessels during the course of coronary artery bypass graft surgery, a code was requested to specifically identify intra-operative coronary angiography. In addition, codes are requested to report intra-operative angiography in non-coronary applications including, breast cancer surgery and tissue reconstruction procedures.

New Technology Application? No.

FDA Status: The Novadaq® SPY® Intra-operative Imaging System (SPY System), device model SP2000, received initial Food and Drug Administration (FDA) Premarket Notification 510(k) clearance for market for use during coronary artery bypass graft surgery in January 2005 (K042961). Subsequent 510(k) clearance was obtained in May 2006 (K060867) for a labeling change to inject the imaging agent ICG directly through a catheter into a bypass graft, followed by a clearance for use in plastic, micro- and reconstructive surgery in January 2007 (K063345). Clearances for use of an alternative brand of fluorescent ICG agent (Pulsion) in coronary artery bypass surgery and plastic, micro-, and reconstructive surgery were obtained in May 2007 (K071037) and September 2007 (K072222), respectively. A labeling change to broaden the use of the SPY System in cardiovascular surgical procedures was cleared in November 2007 (K071619). The SPY System, device model SP2001, was subsequently cleared for use in plastic, micro- and reconstructive surgery in January 2008 (K073088) and for organ transplant surgeries in January 2008 (K073130). A submission to clear the SPY System for use in pediatric populations is currently under review by the FDA, (K093839). In January 2010, an application was submitted to the FDA to review the use of the SPY System in gastrointestinal surgery applications.

Background: Completion angiography has been demonstrated to be effective in detecting technical errors at the time of CABG surgery. Data from several large, randomized clinical trials, define the incidence of peri-operative MI within CABG to be greater than 9% and graft failure at one year at 29%. Intra-operative completion coronary angiography is performed within the operating room at the time of CABG surgery to identify and immediately correct bypass graft defects in 4-12% of CABG patients. In some instances, Intra-operative Angiography replaces and eliminates the need for Post-operative Angiography.

Two technologies are used to perform intra-operative "completion" coronary angiography in CABG surgery: 1.) X-ray Coronary Angiography with Cardiac Catheterization and Fluoroscopy and 2.) Intra-operative Fluorescence Vascular Angiography (IFVA).

Clinical utility for IFVA or SPY Angiography is to assess function of venous and arterial vessels and blood perfusion in tissues and organs without the patient safety risks associated with

radiation and traditional X-Ray Angiography while in the setting of surgical intervention when defects can be identified and corrected. Currently, hybrid facilities provide Intra-operative X-Ray Angiography in cardiac and vascular procedures. Pre-operative MRI and CT, which has been used to identify perforator vessels in abdominal tissue flaps, is sometimes replaced with IFVA in reconstructive breast surgery.

Intra-operative angiography provides surgeons with the opportunity to proactively manage risks of anastomotic defect, leaks, necrosis, thrombus, surgical site infection and graft/flap injury and/or failure associated with poor vascular function and micro-vascular perfusion. Patients with co-morbidities including; prior radiation, history of smoking, diabetes, congestive heart failure, peripheral vascular disease, low body weight, obesity and advanced age are at increased risk for complications due to poor vascularization. Fluorescence Angiography is safe for patients with or at risk for renal insufficiency and who are contra-indicated for X-Ray Angiography.

Conclusion:
A broad number of applications for Angiography are currently recognized and include surgical procedures during which anastomoses are constructed between two co-joined vessels and where there is the potential to inadvertently occlude a vessel or construct bypass grafts that interfere with blood flow in native vessels and/or create competitive flow. IFVA is distinguished by the ability to perform angiography at the time of surgery without exposing patients to risks associated with toxic dye required for x-ray angiography.

Coding options:

Option 1. Do not create new codes. Continue to use code 88.59, Intra-operative fluorescence vascular angiography (IFVA), which was created in October 2007 to identify that intra-operative fluorescence vascular angiography was performed on both coronary and non-coronary arteries. Use one of the appropriate coronary arteriography codes to capture coronary arteriography.

Option 2. Create new codes to distinguish intra-operative coronary angiography from those angiographies that are not performed in conjunction with surgery. Create similar new codes to distinguish intra-operative non-coronary angiography versus those not performed in conjunction with surgery.

Revise code	88.59	Non-coronary ~~I~~intra-operative fluorescence vascular angiography
Revise inclusion term		Non-coronary ~~I~~intra-operative laser arteriogram (SPY)
Revise inclusion term		SPY non-coronary arteriogram
Revise inclusion term		SPY non-coronary arteriography

Add exclusion term — Excludes: Intra-operative fluorescence coronary angiography (88.57)

Revise code 88.57 Other and unspecified coronary arteriography
Add inclusion term: Intra-operative coronary angiography
Add inclusion term: Intra-operative fluorescence coronary arteriography
Add inclusion term: SPY coronary angiography
Add — Excludes: Non-coronary intra-operative fluorescence vascular angiography (88.59)

***** Option 2 establishes one code (88.59) for Intra-operative fluorescence vascular angiography in non-coronary applications and assigns Intra-operative fluorescence coronary angiography and Intra-operative coronary X-ray Angiography also known as Coronary Artery Bypass Completion Angiography to the existing 88.57 "Other and Unspecified Coronary Arteriography"

Option 3: Create a new code for coronary artery bypass completion angiography

New code XX.XX Coronary artery bypass completion angiography
Intra-operative coronary angiography
Intra-operative fluorescence coronary angiography
SPY coronary angiography

Revise code: 88.59 Non-coronary intra-operative fluorescence vascular angiography
Intra-operative laser arteriogram (SPY)
SPY angiography
Add: Excludes: Intra-operative fluorescence coronary angiography

***** Option 3 establishes one code (88.59) for Intra-operative fluorescence vascular angiography in non-coronary applications and assigns Intra-operative fluorescence coronary angiography and Intra-operative coronary X-ray angiography also known as Coronary Artery Bypass Completion Angiography to a new code "Coronary Artery Bypass Completion Angiography"

CMS Recommendation: Option one. Do not disrupt thirty years of data on angiography by differentiating the location of the procedure.

Interim Coding: Continue to use code 88.59, Intra-operative fluorescence vascular angiography (IFVA). Use one of the appropriate coronary arteriography codes to capture coronary arteriography.

Addenda

Tabular

37.62 Insertion of temporary non-implantable extracorporeal circulatory assist device

Delete inclusion term ~~Acute circulatory support device~~

Delete inclusion term ~~Short-term circulatory support (up to six hours)~~

81.0 Spinal fusion

Add note Note: Spine fusion is classified by the anatomic portion (column) fused and the technique (approach) used to perform the fusion.

For the anterior column, the body (corpus) of adjacent vertebrae are fused (interbody fusion). The anterior column can be fused using an anterior, lateral, or posterior technique

For the posterior column, posterior structures of adjacent vertebrae are fused (pedicle, lamina, facet, transverse process, or "gutter" fusion). A posterior column fusion can be performed using a posterior, posterolateral or lateral transverse technique.

Revise code title 81.02 Other cervical fusion of the ~~,~~ anterior column, anterior technique

Arthrodesis of C2 level or below:

Revise inclusion term Anterior ~~(~~interbody ~~technique)~~ fusion

Revise code title 81.03 Other cervical fusion of the ~~,~~ posterior column, posterior technique

Arthrodesis of C2 level or below:

Delete inclusion term ~~Posterior (interbody) technique~~

Revise code title 81.04 Dorsal and dorsolumbar fusion of the ~~,~~ anterior column, anterior technique

Arthrodesis of thoracic or thoracolumbar region:

Revise inclusion term Anterior ~~(~~interbody ~~technique)~~ fusion

Add inclusion term Extracavitary technique

Revise code title 81.05 Dorsal and dorsolumbar fusion of the ~~,~~ posterior

column, posterior technique
Arthrodesis of thoracic or thoracolumbar region:
Delete inclusion term ~~Posterior (interbody) technique~~

Revise code title 81.06 Lumbar and lumbosacral fusion of the ~~,~~ anterior column, anterior technique
Arthrodesis of lumbar or lumbosacral region:
Revise inclusion term Anterior ~~(~~interbody ~~technique)~~ fusion
Add inclusion term Retroperitoneal
Add inclusion term Transperitoneal
Add inclusion term Axial lumbar interbody fusion [AxiaLIF]
Add inclusion term Direct lateral interbody fusion [DLIF]
Add inclusion term EXtreme lateral interbody fusion [XLIF]

81.07 Lumbar and lumbosacral fusion of the ~~,~~ posterior column, posterior ~~or lateral transverse process~~ technique
Add inclusion term Facet fusion
Add inclusion term Posterolateral technique
Add inclusion term Transverse process technique

Revise code title 81.08 Lumbar and lumbosacral fusion of the ~~,~~ anterior column, posterior technique
Arthrodesis of lumbar or lumbosacral region:
Revise inclusion term Posterior ~~(~~interbody~~) technique~~ fusion
Delete inclusion term ~~Posterolateral technique~~

Index

Angiography (arterial) – *see also* Arteriography 88.40
Add subterm by magnetic resonance – *see* Imaging, magnetic resonance, by site

Destruction
lesion
heart
by open approach 37.33
Add subterm by other approach 37.34
Add subterm tissue of heart -*see* Excision, lesion, heart

	Excision
	lesion
Revise subterm	heart ~~37.33~~ 37.34
Add subterm	Cox-maze, open 37.33
Add subterm	maze, modified, endovascular 37.34
Add subterm	maze, modified, open 37.33
Add subterm	open 37.33
Add subterm	other approach, closed 37.34

Add term	Maze procedure
Add subterm	Cox-maze, open 37.33
Add subterm	maze, modified, endovascular 37.34
Add subterm	maze, modified, open 37.33