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
September 24 – September 25, 2008

Pat Brooks – Introductions and Committee overview
Co-Chairperson
September 24, 2008

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

Topics:

1. Cardiac Contractility Modulation Pages 8-10	Ann B. Fagan Daniel Burkhoff, MD, PhD VP & Chief Medical Officer Gerry Portzline Dir., Tech. Svcs. & Educ. Impulse Dynamics (USA), Inc.
2. Endovascular Bioactive Coils Pages 11-13	Ann B. Fagan Beverly Aagaard Kienitz, MD NeuroInterventional Surgery Assoc. Prof. of Radiology and Neurological Surgery Univ. of Wisc. Med School
3. Endoscopic Bronchial Valve Insertion In Single and Multiple Lobes Pages 14-16	Pat Brooks Daniel H. Sterman, MD Assoc. Prof. of Medicine, Dir. Intervent. Pulm. Prog. University of Pennsylvania Medical Center

4. Vascular Imaging Pages 17-19	Mady Hue David Pennington, Luminetx, Manager Clinical Operations Gregory J. Schears, MD Asst. Prof. of Anesthesiology Mayo Clinic College of Med.
5. Laser Interstitial Thermal Therapy (LITT) for Brain Tumors Pages 20-23	Amy L. Gruber Jim Duncan, CEO Monteris Medical Inc.
6. Intraoperative Anesthetic Effect Monitoring and Titration (IAEMT) Pages 24-26	Amy L. Gruber Marc Bloom, MD, PhD Clinical Associate Professor Dir., Neuroanesthesia Prog. New York University
7. Endoscopic Insertion of Colonic Stent Pages 27-30	Mady Hue
8. Addenda Pages 31-33	Mady Hue
10. ICD-10 update and Effect on MS-DRGs **1:30 -2:30 pm**	Rhonda Butler, 3M Pat Brooks
11. Cooperating Parties and Physicians Update on ICD-10 **2:30-4:30 pm**	Cooperating Parties: Pat Brooks, CMS Donna Pickett, CDC Nelly Leon-Chisen, AHA Sue Bowman, AHIMA
Physician Presenters: Jeffrey Linzer, MD, FAAP, FACEP Lee Hilborne, MD	

*** Open discussion of ICD-10 will follow physician presentations.**

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:

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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 September 25 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:

September 24 – 25, 2008	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 12, 2008.** You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.
October 2008	Summary report of the Procedure part of the September 24 – 25, 2008 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on the CMS homepage as follows: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes

	Summary report of the Diagnosis part of the September 24 – 25, 2008 ICD-9-CM Coordination and Maintenance Committee meeting report will be posted on the NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm
October 1, 2008	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 10, 2008	**Deadline for receipt of public comments on proposed code revisions discussed at the September 24-25, 2008 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on April 1, 2009.**
Early November, 2008	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, 2009 will be posted on the following websites: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes http://www.cdc.gov/nchs/icd9.htm
December 5, 2008	**Deadline for receipt of public comments on proposed code revisions discussed at the September 24-25, 2008 ICD-9-CM Coordination and Maintenance Committee meetings for implementation of October 1, 2009.**
January 9, 2009	Deadline for requestors: Those members of the public requesting that topics be discussed at the March 11–March 12, 2009 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses by this date.
February 2009	Draft agenda for the Procedure part of the March 11, 2009 ICD-9-CM Coordination and Maintenance Committee meeting posted on CMS homepage as follows: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes Draft agenda for the Diagnosis part of the March 12, 2009 ICD-9-CM Coordination and Maintenance Committee meeting posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm

	Federal Register notice of March 11 – March 12, 2009 ICD-9-CM Coordination and Maintenance Committee Meeting will be published.
February 15, 2009	**On-line registration opens for the March 11 – 12, 2009 ICD-9-CM Coordination and Maintenance Committee meeting at: http://www.cms.hhs.gov/events**
March 2009	Because of increased security requirements, **those wishing to attend the March 11 – March 12, 2009** 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 March 5, 2009 failure to do so may result in lack of access to the meeting**.
March 11 – March 12 2009	ICD-9-CM Coordination and Maintenance Committee meeting.
April 1, 2009	Any new ICD-9-CM codes required to capture new technology will be implemented. Information on any new codes implemented on April 1, 2009 previously posted in early October 2008 will be on the following websites: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes http://www.cdc.gov/nchs/icd9.htm http://www.cms.hhs.gov/MLNGenInfo
April 2, 2009	Deadline for receipt of public comments on proposed code revisions discussed at the March 11-12, 2009 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2007.
April 2009	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 2009	Summary report of the Procedure part of the March 11, 2009 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 12, 2009 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 2009	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
July 17, 2009	Those members of the public requesting that topics be discussed at the September 16 – 17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses.
August 1, 2009	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, 2009. This rule can be accessed at: http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp
August 2009	Tentative agenda for the Procedure part of the September 16 – 17, 2009 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 16 – 17, 2009 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 16 –17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.
August 15, 2009	**On-line registration opens for the September 16-17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting at: http://www.cms.hhs.gov/events**
September 10, 2009	Because of increased security requirements, those wishing to attend the September 16 - 17, 2009 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, 2009; failure to do so may result in lack of access to the meeting.
September 16 – 17, 2009	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, 2009.** You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.
October 2009	Summary report of the Procedure part of the September 16 – 17, 2009 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 24– 25, 2008 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, 2009	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 10, 2009	**Deadline for receipt of public comments on proposed code revisions discussed at the September 16-17, 2009 ICD-9-CM Coordination and Maintenance Committee meetings for implementation of April 1, 2009.**
November 2009	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, 2009 will be posted on the following websites: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes http://www.cdc.gov/nchs/icd9.htm
December 5, 2009	Deadline for receipt of public comments on proposed code revisions discussed at the September 16-17, 2009 ICD-9-CM Coordination and Maintenance Committee meetings for implementation of October 1, 2010.

Cardiac Contractility Modulation (CCM)

Issue: The concept of cardiac contractility modulation (CCM) is a recent discovery concerning the electrical control of the muscles of the heart. The CCM signals are non-excitatory impulses to the heart during a period of time called the absolute refractory period (ARP). Unlike a pacemaker, the CCM signals do not initiate a new heartbeat. Rather, these signals are intended to enhance the strength of the heart and overall cardiac performance. The implantation of the device may occur alone, in the presence of a pre-existing automatic implantable cardioverter/defibrillator (AICD), or in a combined implantation with an AICD. As this is a separate device, a unique code is needed to identify its implantation, especially in combination with an AICD.

New Technology Application?
No.

Food & Drug Administration (FDA) Approval:
Impulse Dynamics is the parent company which has created the OPTIMIZER® III System. Impulse Dynamics has completed enrollment in its pivotal clinical study and expects to submit an original pre-market application (PMA) to the FDA in the fourth quarter of 2008. The parent company expects this technology to be approved within approximately 12 months following this submission, which would be early in the next fiscal year.

Background: The most common forms of heart failure are treated with drugs, pacing devices and other currently available methods. Available pharmacological therapies are primarily focused on restoring fluid balance (diuretics) or counteracting secondary neurohormonal derangements, which contribute to the remodeling process (ACE inhibitors, beta blockers, and aldosterone inhibitors). Biventricular pacing, for patients with more severe heart failure, has recently been introduced to the market but is applicable to only about 30-40% of the CHF population. As the severity of the heart disease increases, more aggressive alternative therapies come into play, such as the use of positive inotropic agents, ventricular assist devices, and heart transplantation.

The OPTIMIZER® III System is designed for the treatment of patients with moderate to severe heart failure (New York Heart Association functional Class III or IV) due to either ischemic or non-ischemic cardiomyopathy with left ventricular systolic dysfunction (ejection fraction ≤ 35%) and a normal QRS duration. The patient population for CCM therapy is very similar to the population indicated for AICD and Cardiac Resynchronization Therapy with back-up defibrillation (CRT-D) with the exception that the current US studies have been limited to patients with normal QRS duration. Most patients who meet criteria for an OPTIMIZER® III system will also fulfill the indications for AICD therapy. As noted above, the implantation of the

device may occur alone, in the presence of a pre-existing automatic implantable cardioverter/defibrillator (AICD), or in a combined implantation with an AICD.
Components of the system:

- Implantable Pulse Generator (IPG) – delivers CCM signals to the heart
- OMNI Programmer System – non-invasively programs the IPG parameters and telemetrically receives device performance data
- Charger – non-invasively recharges the IPG's internal rechargeable battery
- Monita Data Acquisition System – evaluates acute changes in cardiac hemodynamics during the implant of the IPG
- Extension cables and cable adaptor – used during implant to connect the leads to a test IPG
- Leads – commercially available cardiac pacing leads which deliver CCM signals from the OPTIMIZER® III to the heart, as well as to detect the heart's intrinsic electrical activity.

Procedure: The IPG generates CCM therapy signals (as opposed to "pacing signals") that are delivered to the heart through the pacemaker leads. The procedure entails the introduction of a catheter-based transducer to perform hemodynamic measurements during lead positioning. Three standard pacemaker leads are then implanted in the heart – two of them affixed to the right ventricular septum, and the third to the right atrium. These leads are connected to the IPG which is placed subcutaneously in a pectoral pocket. An external programmer system allows medical personnel to customize the IPG's programmed parameters according each patient's specific needs. The charger allows the patient to recharge the battery of the IPG at home, eliminating the need for more frequent pulse generator replacements as a result of normal battery depletion.

Implantation of the OPTIMIZER™ III System is more complex and requires more O.R. time than insertion of either pacemakers or defibrillators because of the additional testing required to ensure appropriate function. In the context of prior clinical studies, the average implant time was approximately 3 hours with dual procedures taking much longer.

Coding Options:
Option 1:
Do not create a new code for the CCM procedure.

Option 2:
Create a new subcategory and codes in Chapter 17 to describe this device.

17 Other miscellaneous procedures *(effective October 1, 2008)*

New subcategory 17. 5 Additional cardiovascular procedures

New code 17.51 Implantation of rechargeable cardiac contractility modulation, total system [CCM]

Note: Device testing during procedure – *omit code*

Implantation of CCM system includes formation of pocket, transvenous leads, including placement of leads, placement of catheter into left ventricle, intraoperative procedures for evaluation of lead signals, obtaining sensing threshold measurements, obtaining defibrillator threshold measurements

Code also any concomitant:
coronary bypass (36.01 – 36.19)
extracorporeal circulation (39.61)
insertion or replacement of automatic cardioverter/defibrillator, total system [AICD] (37.94)

Excludes: implantation of cardiac resynchronization device, total system (00.50 – 00.51)

New code

17.52 Implantation or replacement of cardiac contractility modulation (CCM) rechargeable pulse generator only (IPG)

Note: Device testing during procedure – *omit code*.

Implantation of CCM device with removal of any existing CCM device
Code also any:
revision of device pocket (37.79)
revision of lead [electrode] (37.75)

CMS Recommendation:
CMS is interested in the comments from the participants regarding coding for this device.

Interim Coding:
Clinical trial cases should include code V70.7, Examination of participant in clinical trial, to designate these cases. As there is no overarching code for system implantation, coders should use as many codes as necessary to describe the different parts, such as 37.79 for creation of the cardiac device pocket, and codes from the 37.7x category for lead insertion. There is no general code for the implantation of the pulse generator, so code 37.99, Other operation on heart and pericardium, other, is suggested.

Endovascular Bioactive Coil

Issue:
The current ICD-9-CM code 39.72, Endovascular repair or occlusion of head and neck vessels, does not differentiate between the use of bare platinum coils (BPCs) and more advanced coils that include biodegradable polymers. This new generation of coils is reported to have gained wide acceptance in the medical community for treating cerebral aneurysms. These bioactive coils have been shown to improve patient clinical outcomes (aneurysm occlusion durability) in initial trial data when compared to treatment using BPCs and coated coils. In order to track the frequency and efficacy of items and services associated with procedures that involve bioactive coils, a new procedure code is necessary to differentiate them from the bare coils captured by code 39.72.

New Technology Application?
No.

Food & Drug Administration (FDA) Approval:
The initial device of the Micrus Modified Microcoil "Cerecyte®" systems was authorized for commercial distribution by the FDA through fulfillment of the requirements in 21 C.F.R. Part 807, §E (Premarket Notification) on February 4, 2004.

Background:
Brain aneurysms are weaknesses in the wall of an artery that cause a local dilation and ballooning of a blood vessel. If not treated, the aneurysm may lead to stroke or death. A common surgical treatment currently being used is a minimally invasive procedure known as endovascular coil embolization. During endovascular coiling, a catheter is inserted into the femoral artery and guided to the aneurysm in the brain. Next, coils are placed via the catheter into the aneurysm, which blocks blood flow and prevents rupture of the aneurysm. Filling the aneurysm with microcoils disrupts the flow of blood into the aneurysm and initiates a healing response. The International Subarachnoid Aneurysm Trial found that endovascular coiling has the best overall outcomes for treatment of an aneurysm. The relative risk of death or disability at one year for patients with coils was 22.6% less than the alternate treatment, which is surgical clipping. (Source: ISAT: International SAH Aneurysm Trial – Lancet 2002; 360:1267-74)

Over the past few years, microcoils have gone through several iterations with the goal of improving the long-term durability of endovascular aneurysm occlusion. This has led to the development of several "bioactive" coils aimed at stimulating intra-aneurysm thrombus formation. There are currently two classes of coils: BPCs and bioactive coils. As the name implies, bare platinum coils are primarily bare metal, while bioactive coils include a biologically

active agent that is designed to enhance occlusion rates and thrombus formation. The initial approach to improve BPCs was to coat the outer surface of the coils with these bioactive agents. Unfortunately, these coated coils proved to have poor patient outcomes. The poor outcomes in terms of aneurysm recurrence were the result of an eventual breakdown of the bioactive agent on the outer surface of the coil. As the volume of the coating is dissipated through the bioabsorption of the bioactive agent, the packing density initially achieved rapidly declines. Under these conditions, a previously well-packed aneurysm becomes loosely packed and would be expected to recanalize. However, a new approach by which the bioactive materials are contained within the inner lumen of the microcoils has resulted in better patient outcomes compared to both BPCs and coated coils.

The Cerecyte® bioactive coil offers a new design that places a bioactive material called polyglycolic acid (PGA) into the lumen of the coil, taking advantage of PGA's ability to induce thrombus formation. PGA is a biodegradable material most commonly used in sutures that induces a tissue response that enhances neointimal proliferation and increases the inflammatory reaction in the aneurysm leading to faster clot formation. Placing PGA within the coil rather than on the exterior maintains the desirable properties of BPCs (e.g. handling characteristics, clinically relevant lengths, diameters, and shapes, etc.), which reduces risk and allows increased coil-packing density. As the PGA breaks down, there is no loss in the density of coil mass. This has led to lower re-canalization and re-treatment rates. For example, the re-treatment and re-canalization rate for aneurysms treated with BPCs have been reported in the ranges of 6-13% and 16-23% respectively. With Cerecyte® Microcoils, the re-treatment and recanalization rates may be significantly less, with ranges reported as 2-6% and 11-15% respectively.

Current Coding:
All coils are described by procedure code 39.72, Endovascular repair or occlusion of head and neck vessels.

Coding Options:
Option 1: Continue capturing coil embolization in the head and neck with code 39.72.

Option 2: Create a new code describing bioactive coils, as follows:

Revise subcategory title	39.7	Endovascular ~~repair~~ treatment of vessel(s)
Add inclusion term		Implantation
Add inclusion term		Occlusion
Add inclusion term		Repair
Revise code title	39.72	Endovascular ~~repair or occlusion~~ treatment of head and neck vessels
Revise inclusion term		Coil embolization or occlusion using bare metal coils
		Excludes:
Add exclusion term		treatment of head or neck vessels using bioactive coils (39.75)

New code	39.75	Endovascular treatment of vessel(s) of head or neck using bioactive coils Biodegradable inner luminal polymer coils Coils containing polyglycolic acid (PGA) Coil embolization or occlusion utilizing bioactive coils That for treatment of aneurysm, arteriovenous malformation (AVM) or fistula
Revise code title	39.79	Other endovascular ~~repair~~ treatment ~~(of aneurysm)~~ of other vessels
Add inclusion term		Aneurysm of vessels
		Excludes:
Add exclusion term		abdominal aortic aneurysm resection (AAA) (34.84)
Add exclusion term		endovascular implantation of graft in abdominal aorta (39.71)
Revise exclusion term		endovascular ~~repair or occlusion~~ treatment of head and neck vessels, bare metal coils (39.72)
Add exclusion term		endovascular treatment of head and neck vessels, bioactive coils, (39.75)
Add exclusion term		thoracic aortic aneurysm resection (34.85)

CMS Recommendation:
Create a new procedure code as described above in Option 2. Make additional changes to this category for clarity.

Interim Coding:
Continue to use code 39.72, Endovascular repair or occlusion of head and neck vessels, to describe treatment with bioactive coils.

Endoscopic Bronchial Valve Insertion in Single and Multiple Lobes

Issue:
The current ICD-9-CM procedure code for the insertion of a bronchial valve, 33.71, Endoscopic insertion or replacement of bronchial valve(s), does not differentiate between the resources, time, and patient populations involved when treating single vs. multiple lobes of the lung within a patient during the same procedural episode. Patients requiring treatment across multiple lobes compared to a single lobe often have different indications. More specific coding would allow for the accurate capture of data for the difference in the extent of treatment for multiple lobes compared to a single lobe.

New Technology Application?
This is possible for fiscal year 2010.

FDA Approval:
FDA clearance for the Spiration® IBV® Valve for one indication is expected by the end of 2008.

Background:
Endobronchial valve insertion is currently being investigated for two indications: the treatment of severe emphysema and the control of prolonged air leaks.

Emphysema is a progressive and chronic disease characterized by destruction of the alveolar walls and capillaries, severe loss of pulmonary elastic recoil, hyper-expansion of diseased lungs and narrowing of the airways. Progressive physical activity limitations become evident and these patients experience increasing dyspnea and poor quality of life. Emphysema is usually represented by the destruction of lung tissue in multiple lobes.

Air leaks are a complication resulting from traumatic, iatrogenic or spontaneous causes, but are most common following surgery. They are attributable to lung tissue that has not completely closed and sealed, resulting in a buildup of air in the chest that can cause breathing difficulties. As air leaks from the lung, it accumulates in the pleural cavity, making breathing difficult and interfering with normal lung expansion. While most air leaks are of small volume, are self-limited, and close naturally after a few days, in some cases they persist longer than five to seven days, at which point they typically become classified as prolonged. Prolonged air leaks can contribute to significant morbidity and mortality and affect outcomes. Prolonged air leaks are typically limited to damaged tissue in a single lobe.

The Spiration IBV Valve System

Spiration, Inc. developed the IBV Valve System as a minimally invasive approach for achieving improvement in both the health status and functions supported by the lungs with diverse applications in both acute and chronic conditions. The IBV Valve is currently being investigated in the United States for the treatment of severe emphysema and the control of prolonged air leaks.

The Spiration IBV Valve is a small umbrella shaped valve that is placed in selected regions of the bronchial tree using standard bronchoscopic techniques. The valve is designed to limit airflow to the portions of the lungs distal to the valve, while still allowing mucus and air movement in the proximal direction.

IBV Valves are available in three sizes ranging from 5mm to 7mm in diameter to accommodate the different airway sizes found in the segmental and sub-segmental bronchi. An airway sizing kit is used to determine the appropriate valve size for each airway. During the sizing process, a balloon is calibrated and then inflated at the target implant location with saline. The volume of saline required to inflate the balloon indicates the appropriate valve size to use at the measured target site. The IBV Valve is deployed into the bronchial tree using a delivery catheter passed through the working channel of a bronchoscope.

For the treatment of severe emphysema, the valve redirects air from diseased portions of the lung to healthier areas, which may improve disease-related quality of life. For this indication, physicians determine the number of valves to be placed by the extent of the disease in each lobe as assessed on CT scan and the individual patient's anatomy. The valves are intended to be permanent, but are designed to be removed if necessary. For severe emphysema, multiple lobes are typically treated during an individual procedural episode.

For the control of prolonged air leaks, the valve limits airflow to injured tissue which may enable healing. This may result in earlier hospital discharge and reduced need for additional surgery. For this indication, the valve sizing process also helps physicians determine the location of air leaks. The use of the IBV Valve for prolonged air leaks is intended to be temporary; patients return within six weeks for removal of the valve. For air leaks, it is most common for only one lobe to be treated often resulting in fewer valve placements.

Current Coding:

As stated earlier, the insertion of a bronchial valve is captured through code 33.71, Endoscopic insertion or replacement of bronchial valve(s) which was created on October 1, 2006. There is no ICD-9-CM procedure code to accurately capture the difference in the extent of treatment necessary for the different patient indications for single vs. multiple lobes of the lung through bronchial valve intervention. The clinical resources (e.g. length of anesthesia, number of valves) and the time required to perform the procedure on patients who require valve insertion in multiple lobes are greater than those needed for patients requiring single-lobe treatment.

Coding Options

Option 1: Do not create new ICD-9-CM codes for this procedure. Continue using procedure code 33.71, Endoscopic insertion or replacement of bronchial valve(s), to describe insertion of bronchial valves regardless of single or multiple lobe indications.

Option 2: Revise the current code (33.71) and create an additional code to describe the number of lobes treated:

Revise Code	33.71 Endoscopic insertion or replacement of bronchial valve(s), single lobe
Add exclusion term	Excludes: endoscopic insertion or replacement of bronchial valve(s), multiple lobes (33.72)
New Code	33.73 Endoscopic insertion or replacement of bronchial valve(s), multiple lobes
	Excludes: endoscopic insertion or replacement of bronchial valve(s), single lobe (33.71)

Recommendation:
CMS recommends option 2 as stated above. In the meantime, continue assigning code 33.71 for endoscopic insertion or replacement of bronchial valves.

Vascular Imaging

Issue: Currently, there is not a unique ICD-9-CM procedure code to adequately describe the utilization of peripheral vascular visualization imaging with direct on-anatomy projection and interpretation. Vascular visualization imaging utilizes near-infrared technologies in order to enhance the healthcare provider's ability to access venous structures. Should a new code be created to identify this technology?

New technology application? No.

FDA Approval: The VeinViewer® by Luminetx is cleared for market under 21 CFR § 880.6970 Liquid Crystal Vein Locator as a FDA Class I Exempt Device (per Product Code KZA). A liquid crystal vein locator is a device used to indicate the location of a vein by revealing variations in the surface temperature of the skin by displaying the color changes of heat sensitive liquid crystals (cholesteric esters).

Background: The VeinViewer®, a vascular imaging system, was developed to illuminate subcutaneous vasculature by imaging the vein's location on the surface of the skin. This noninvasive technology is thought to be especially useful in the hospital inpatient setting for appropriate patients who have difficult venous access (DVA). Treating patients with DVA can be challenging for healthcare providers for a number of reasons including delays in patient's access to IV therapy and/or venipuncture (blood sampling). This condition can also result in the need to request the services of a vascular access team, which can lead to further delays in patient care.

Technology: Several technologies have been introduced to attempt to improve the ability to obtain peripheral venous access with the first needlestick attempt, but only two have seriously dealt with improving vessel visualization. These technologies include ultrasound and a reflective near-infrared technology known as a vein contrast enhancer (VCE) or VeinViewer®. Both technologies have the ability to visualize vessels using very different approaches. The VCE technology utilizes a harmless, near-infrared light (NIR) that is reflected back from tissues that surround the hemoglobin in the blood. The blood itself does not reflect the light source, therefore only the surrounding tissue creates an image. This image is then captured by a digital video camera located in the head of the VeinViewer® unit. The image is processed by an image processing unit located in the base of the VeinViewer® device. Once processed, a green LED is used to add contrast to the image and Digital Light Processing (DLP) technology is utilized to project that image back onto the surface of the skin. This image is placed back onto the skin at precisely the same anatomical location of the subcutaneous vasculature just below the skin with an image depicting veins as black structures on a high-contrast green background.

VeinViewer® is a VCE mobile biomedical device developed at the University of Tennessee. A VCE takes the "guesswork" out of finding veins and gives the clinician a "roadmap" from which to work in a way that is more efficient in gaining peripheral intravenous access. The VeinViewer® is a unique device that displays the vasculature directly on the patient's skin, providing an "eyes on patient" technique, thereby providing

a visual aid to clinicians attempting to gain peripheral venous access. The resulting improved peripheral vascular access provides numerous benefits to both patients and healthcare providers. The VeinViewer® can be utilized in a number of different clinical areas and is used primarily to locate veins for venipuncture for peripheral intravenous access or phlebotomy.

This technology has demonstrated the ability to decrease the average number of needlestick attempts per successful peripheral venous access. In a 2007 hospital based study in the Baptist Health System (Jacksonville, Florida), the VeinViewer® successfully demonstrated the ability to improve peripheral venous access in several ways. Traditional methods for peripheral venous access yielded the following results:

1. 1st attempt success rate – 49.3%
2. Mean number of attempts per IV – 1.97
3. IVs initiated in < 15 minutes – 55%

The VeinViewer® assisted method which included the clinician utilizing the near-infrared technology and projection to provide vascular visualization yielded the following results:

1. Successful IV stick on first attempt – 80%
2. Mean number of attempts per IV – 1.28
3. IVs initiated in < 15 minutes – 85%

As shown above, utilization of the VeinViewer® successfully demonstrated a dramatic enhancement with regard to first stick success, number of attempts and the time needed for cannulation. Through these study results, the VeinViewer® proved to be a truly cost-effective way to enhance patient care and satisfaction.

In another data trial performed at Cardinal Glennon Childrens Medical Center (St. Louis, MO) in early 2008, similar results were realized with the utilization of VeinViewer® technology:

Traditional Method (48 pediatric patients: M/S, ED, Pre-Op/SDS, Rehab, Ortho, PICU):

1. Successful IV stick on first attempt – 31%
2. Mean number of attempts per IV – 2.08
3. Mean time per IV – 17.06 minutes
4. Average patient satisfaction score – 1.85*

VeinViewer® Assisted Method (40 pediatric patients: M/S, ED, Pre-Op/SDS, Rehab, Ortho, and PICU):

1. Successful IV stick on first attempt – 83%
2. Mean number of attempts per IV – 1.18
3. Mean time per IV – 6.60 minutes
4. Average patient satisfaction score – 4.07*

**Patient satisfaction scores were based on a 1-5 scale (1–very unsatisfied, 2-unsatisfied, 3-neutral, 4-satisfied, 5-very satisfied).*

The VeinViewer® can also be utilized to avoid the cost and potential complications of an unnecessary central venous catheter (CVC). In early 2008 at Anne Arundel Medical Center (Baltimore, MD), the implementation of the VeinViewer® technology demonstrated the ability to decrease the need for CVC placement in many patients. Over the course of 3 months, 50 CVCs were avoided as a result of utilizing the VeinViewer® technology to enhance vascular visualization and ultimately, place peripheral IVs that otherwise might have been impossible to initiate.

Coding Options:

Option 1: Do not create a new code. Assign procedure code 88.90, Diagnostic imaging, not elsewhere classified, to identify the use of the VeinViewer® technology.

Option 2: Create a new code to identify the VeinViewer® technology for vascular imaging.

00.9 Other procedures and interventions

New code 00.95 Near-infrared (peripheral) vascular imaging
Visualization of veins or arteries directly on surface of skin

Excludes: diagnostic procedures on blood vessels (38.21-38.22, 38.29)
intravascular imaging of blood vessels (00.21-00.25, 00.28-00.29)
other diagnostic imaging (88.90-88.98)
thermography (88.81-88.86, 88.89)

Recommendation: CMS believes the technology provides an overall improvement to patient care; however, we are interested in hearing comments from the audience regarding the proposal.

Interim coding: Assign procedure code 88.90, Diagnostic imaging, not otherwise specified, to identify the use of the VeinViewer® technology.

Laser Interstitial Thermal Therapy (LITT) For Brain Tumors

Issue: Laser Interstitial Thermal Therapy (LITT) under real time MRI guidance has been developed for use in ablating tumors in the brain. Should a new ICD-9-CM procedure code be established for this new technology for LITT of the lesion or tissue of the brain under MRI guidance?

New Technology Application?
Yes. The requestor is recommending an implementation date of April 2009 for a new code, if approved.

FDA Approval: 510K clearance is anticipated in October/Early November 2008 for the AutoLITT™ System technology developed and produced by Monteris Medical, Inc.

Background: There are more than 187,000 newly diagnosed cases of malignant brain cancer in the US each year. Malignant brain tumors have a high mortality rate and are extremely debilitating in terms of patient quality of life. Ten (10%) percent of brain tumors that originate in the brain include: glioblastoma multiforme (GBM) which has a median life expectancy of <12 months and anaplastic astrocytoma (AA) which has a life expectancy of 24-36 months. The remaining ninety percent (90%) of brain tumors are metastatic tumors that originate in distant sites such as lung, breast, prostate, colon, kidney and others and then spread to the brain. There are limited treatment options available today for treating brain cancer. These options include: surgical resection, stereotactic radiosurgery (SRS) [e.g. Gamma Knife®], radiation both external beam and intracranial (e.g. Gliasite®, IMRT]), and chemotherapy. Typically a patient with brain cancer will receive various combinations of these treatments.

All of these treatment options have limitations including:

- Risk to nearby healthy, functional tissue
- Failure to kill/neutralize the tumor
- Ineffectiveness/unsuitability for some tumors due to size, type, or location
- Toxic side effects
- Difficulty in targeting the tumor and/or therapeutic dosing
- High expense
- High morbidity/mortality

The use of Laser Interstitial Thermal Therapy (LITT) under guidance (e.g. MRI, ultrasound) has been evaluated in the clinical literature since the early 1990's. These early feasibility studies demonstrated that the use of LITT effectively destroys or reduces the size of tumors in the brain, head and neck, thyroid, lung, breast, liver, bone, prostate, uterus, and rectum. More recent studies over the past 5 years have evaluated the clinical efficacy and cost effectiveness of LITT plus MRI in the treatment of cancer. A large portion of the published literature has focused on its use on brain, head/neck and liver malignancies, and on benign neoplasms.

The key components of all systems for MR-guided LITT for brain applications include a laser (generally operating at 980-1062nm wavelength), a probe to deliver the laser energy, an apparatus

to cool the probe so as to reduce adjacent tissue temperature, a means of guiding the probe and various software, displays and controls to monitor and control the thermal lesioning process in real time.

The AutoLITT™ System procedure begins with the patient positioned in a standard 1.5T MRI scanner. The neurosurgeon inserts a unique, side-firing MRI-compatible laser probe through a guide attached to the cranium and through a small (1cm) cranial burr hole. The probe is then advanced into the tumor and positioned under MRI guidance. Because the probe is very thin (3mm), it temporarily displaces brain tissue rather than cutting it, thereby reducing tissue damage as it is inserted.

The side-firing nature of the laser probe, combined with gas cooling within the probe tip, enables the surgeon to focus the laser energy on the targeted tumor tissue, while largely avoiding damage to surrounding healthy tissue in part because the cooled tip of the probe acts as a heat sink that reduces thermal injury to non-targeted tissue.

The neurosurgeon observes this process in real time using a monitor at the AutoLITT™ workstation in the MRI control room. During the firing of the laser, the surgeon observes the progression of thermal "isodose" lines to monitor the degree to which he has treated the tumor. The thermal isodose lines represent the cumulative amount of thermal energy (i.e. joules of energy) absorbed by the tissue, and they correlate with permanent tissue destruction. A yellow line on the screen defines the region beyond which no damage has occurred and a white line indicates the region within which 100% of the tissue is dead or dying. A blue line is the center of the transition zone between dead and healthy tissue. The distance between the white (dead) and yellow (undamaged) lines typically ranges no more than 1-2 millimeters, thereby enabling the physician to treat the tumor with approximately the same precision he could achieve with surgical resection by observing the relationship of the lines to one another. If necessary, the probe can be repositioned in order to access and treat different areas of the tumor, and at the end of treatment the probe is withdrawn and the burr hole is closed.

The AutoLITT System itself consists of capital equipment and single-use, disposable devices:

- Laser Probe. 3mm diameter, MRI-compatible, gas-cooled, side-firing. Delivers controlled thermal energy confined to the treatment target site. Disposable.

- Probe Driver. Manipulates the probe to the precise treatment position and orientation determined by the neurosurgeon and the AutoLITT control software. Maintains position during treatment. MRI compatible. Disposable.

- Patient-Probe Interface. Frameless stereotaxy trajectory guide used to establish probe trajectory and maintain rigid stability during alignment, insertion and treatment. MRI compatible. Disposable.

- Equipment Rack. Central processor computers; software for planning, monitoring and controlling the procedure; cooling apparatus; safety apparatus. Capital equipment. (MRI equipment room)

- Workstation. Monitoring screens and user interface for direct and remote controls for the entire procedure. Capital. (MRI control room)

- Thermometry Software. Converts MRI signals to thermal images overlaid on anatomical images of tumor, brain, etc. Feeds back treatment information to the neurosurgeon to monitor and control the procedure. (Rack computers-MRI equipment room)

- Laser. 1064nm diode laser. Capital. (MRI control room)

- Accessories. Various disposable and capital items necessary for positioning the patient, patient fixation, MRI imaging, treatment planning, calibrating location, interfacing with different MRI tables, etc.

- VizApp™. The VizApp software overlays and merges the images of heat dosage and thermal damage threshold ("kill zone") with the anatomical images of brain, tumor, and the physical image of the probe. The neurosurgeon is able to visualize all aspects of the procedure in quasi-real-time magnified images, enabling them to control treatment precisely within the tumor.

Coding options:

Option 1. Continue to code this procedure to code 01.59, Other excision or destruction of lesion or tissue of brain.

Option 2. Create a new category with codes for the MRI-guided LITT of lesion or tissue of brain and other sites. Add exclusion terms under appropriate ablation and destruction codes to exclude this procedure.

New category 17.6 MRI-guided laser interstitial thermal therapy (LITT)
Focused Laser Interstitial Thermal Therapy LITT (f-LITT) under MRI guidance

New code 17.61 MRI-guided laser interstitial thermal therapy (LITT) of lesion or tissue of brain

New code 17.62 MRI-guided laser interstitial thermal therapy (LITT) of lesion or tissue of head and neck

New code 17.63 MRI-guided laser interstitial thermal therapy (LITT) of lesion or tissue of lung

New code 17.64 MRI-guided laser interstitial thermal therapy (LITT) of lesion or tissue of breast

New code	17.65	MRI-guided laser interstitial thermal therapy (LITT) of lesion or tissue of liver
New code	17.66	MRI-guided laser interstitial thermal therapy (LITT) of lesion or tissue of prostate
New code	17.69	MRI-guided laser interstitial thermal therapy (LITT) of lesion or tissue of other and unspecified site

CMS's Recommendation:
Option 2. Create a new category with codes for the MRI-guided LITT of lesion or tissue of brain and other sites as outlined above.

Interim Coding:
Continue to code MRI-guided LITT of lesion or tissue of brain to code 01.59, Other excision or destruction of lesion or tissue of brain.

Intraoperative Anesthetic Effect Monitoring and Titration (IAEMT)

Issue: Intraoperative Anesthetic Effect Monitoring and Titration (IAEMT) involves the use of brain monitoring technology by anesthesia professionals to guide anesthesia care. Should a new ICD-9-CM procedure code be established for a continuous electroencephalogram (EEG) monitoring during surgery?

New Technology Application?
No.

FDA Approval: Bispectral Index (BIS) technology received initial 510(k) clearance in 1996.

Background: Intraoperative Anesthetic Effect Monitoring and Titration (IAEMT) uses brain monitoring technology by anesthesia professionals to guide anesthesia care. IAEMT is performed by anesthesia professionals (anesthesiologists, certified registered nurse anesthetists) to assess – monitor - the hypnotic component of anesthetic effect, and to adjust – titrate - the level of anesthetic medications to achieve an optimal or desired level of anesthetic effect.

IAEMT is performed by the application of an electrode sensor array to a patient's forehead used to acquire the patient's electroencephalogram (EEG). Specialized IAEMT devices utilizing advanced signal processing methodology rapidly analyze the EEG and determine a measure of anesthetic effect that is displayed for clinician viewing. IAEMT devices typically scale anesthetic effect from 100 (representing an awake patient, no anesthetic effect) to 0 (representing an isoelectric or flatline EEG, maximal anesthetic effect). During general anesthesia, an ideal range of anesthetic effect (e.g. anesthetic effect score of 40-60) is used as the target zone for maintaining anesthetic effect during the surgical procedure. Utilization of IAEMT is documented on the anesthesia record where the anesthesia professional typically records the average value every 5-15 minutes.

IAEMT has been performed for more than 10 years. Multiple FDA-approved IAEMT devices are available in the United States. The most widely available and commonly used IAEMT device is the BIS Monitoring System (Aspect Medical Systems, Norwood MA).

The substantial clinical value of IAEMT has been demonstrated with some, but not all, available IAEMT devices. The BIS monitoring system has the largest number of clinical investigations. BIS-based IAEMT has been compared to standard practice methods of anesthetic administration in 30 prospective randomized trials. Published and on-line meta-analyses of these studies have found: approximately 20% reduction in primary anesthetic administration, significant reductions in time required to achieve emergence and recovery milestones, and a substantial reduction in the occurrence of intraoperative awareness.

In addition, recent research suggests that IAEMT may offer substantially more important benefit to patients undergoing general anesthesia for inpatient surgical procedures. Several investigations have associated deep levels of anesthesia (as measured by excessively low BIS values during surgery) with increased risk of mortality during the first year following surgery. Although a preliminary analysis found an association of improved outcome (one-year survival) at hospitals with an apparent high-frequency use of IAMET (measured by institutional use of BIS monitoring), this research was limited by the lack of a specific ICD-9-CM code to identify the patients in whom IAEMT had been performed.

According to the requestor, current prospective research is investigating IAEMT utilization on both survival outcomes as well as Hospital Acquired Complications (e.g., wound infection, delirium). These research efforts may be facilitated by a unique ICD-9-CM code to identify the patient and procedure-specific utilization of IAEMT.

In the hospital diagnostic environment, neurologic testing and responses from the patient are compared to those of a control group and interpretation regarding the type of any abnormality typically provided within 24 hours of the study. However, in the case of IAEMT, the diagnostic or monitoring elements are performed continuously during the entire surgical procedure in order to detect anesthetic effect levels outside of the desired range. This information is then incorporated immediately in real-time by the anesthesia professional so that adjustments in anesthetic dosing can be taken to optimize the level of anesthetic effect. In addition, the complexity of obtaining, interpreting and responding to IAEMT information in the anesthetized patient during surgery makes it necessary that only anesthesia professionals with training and experience perform IAEMT.

The current codes do not indicate that the procedure is performed during surgery, or that the procedure involves the real-time adjustment of anesthetic administration based upon the ongoing test values. Because of the unique situation between the practice and clinical implementation in the intra-operative anesthetic situation and other inpatient diagnostic environments, a new code may be warranted.

Since the manner in which the IAEMT procedure is performed in the operating room, and the unique demands of IAEMT by the anesthesia professional staff performing the procedure are quite different, a unique ICD-9-CM code would allow identification of surgical procedures utilizing IAEMT. The presence of an ICD-9-CM procedure code describing IAEMT will allow for epidemiologic and statistical studies tracking the utilization of this procedure, and relationship to surgical outcomes, hospital acquired complications, and inpatient resource utilization.

Coding options:

Option 1. Continue to code IAEMT to code 89.14, Electroencephalogram.

Option 2. Create a new code for Intraoperative Anesthetic Effect Monitoring & Titration (IAEMT) under category 00.9, Other procedures and interventions. Add an exclusion term under code 89.14 to exclude IAEMT.

New Code 00.96 Intraoperative anesthetic effect monitoring and titration (IAEMT)
Continuous intraoperative electroencephalogram (EEG) monitoring
Excludes: electroencephalogram (89.14)

CMS's Recommendation:
CMS would be interested in hearing from the audience on this topic, both today and via written comments.

Interim coding:
Continue to code IAEMT to code 89.14, Electroencephalogram.

Endoscopic Insertion of Colonic Stent

Issue: The ICD-9-CM volume 3, procedure classification does not have a unique code to identify the endoscopic insertion of a colonic stent. In the AHA's *Coding Clinic® for ICD-9-CM*, Third Quarter, 2007, advice regarding the coding of colonic stenting recommended assigning procedure code 46.85, Dilation of intestine. Should new ICD-9-CM codes that describe a colonoscopy with stent insertion be created?

New Technology Application? No.

Background: The American Cancer Society estimates that in 2008 there will be approximately 1.4 million new cases of cancer diagnosed.[1] Of these, twenty percent will be cancers of the colon and rectum. It is anticipated that cancers of the colon and rectum will be among the most frequently diagnosed sites in men and women, following the prostate, breast and lung. Colonic obstruction routinely presents in the late stages of the cancer, often indicative of an advanced and perhaps incurable lesion. The standard protocol for these patients is to try and relieve the obstructive symptoms (which may include abdominal pain, vomiting, bloating, etc.) followed by surgery if they are a candidate.

It has also been reported that malignant colonic obstruction is the number one cause for emergency large-bowel surgery, accounting for as much as 85% of such procedures. As an alternative to emergency surgery, patients with acute malignant colonic obstruction can be effectively treated with a colonic stent insertion via colonoscopy or other non-endoscopic means followed by subsequent elective surgical resection and anastomosis. Over the last couple of years, the use of self-expandable metal stents (SEMS) for the relief of malignant or benign colonic obstruction as an alternative or bridge-to-surgery has become more acceptable.

Technology: There are currently three FDA approved self-expandable colonic stents in the U.S as shown below and in Table 1.[2]

- Colonic Z-Stent® (Wilson-Cook Medical)
- Enteral Wallstent® (Microvasive Corporation/Boston Scientific)
- Ultraflex™ Precision Colonic stent (Microvasive Corporation/Boston Scientific)

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[1] Ahmedin Jemal, Rebecca Siegel, Elizabeth Ward, Yongping Hao, Jiaquan Xu, Taylor Murray, and Michael J. Thun. Cancer Statistics, 2008; CA Cancer J Clin 2008; 58: 71-96.

[2] Baron, Todd H. MD; Colonic Stenting: Technique, Technology, and Outcomes for Malignant and Benign Disease. Gastrointestinal Endoscopy Clinics of North America 2005;15(4):757-771

Table 1. FDA approved self expanding metal stents available for colonic obstruction

	Colonic Z-Stent®	**Enteral WallStent®**	**Ultraflex™ Precision Colonic Stent**
Material	Stainless steel wire	Elgiloy monofilament wire, braided in a tubular mesh	Nitinol wire, diamond configuration
Delivery method	OTW/non-TTS, deployment from proximal end	OTW/TTS, deployment from proximal end	OTW, non-TTS, deployment from distal end
Features	Flared ends, coaxial design	No flared ends, coaxial design	Flared proximal end, coaxial design
Diameter—predeployment	30 Fr	10 Fr	16 Fr
Diameter—postdeployment	30-mm flared ends 25-mm body	20 and 22 mm	30-mm flared proximal end, 25-mm body

Abbreviation: OTW, over the wire.

Procedure: Stents can be placed radiographically (fluoroscopically), endoscopically, or with a combined technique.[3]

- In the instance of non-endoscopic, fluoroscopic stent insertion, a patient undergoes sedation, monitoring (heart rate, blood pressure, oxygenation) and receives IV antibiotics. Next, an angiography catheter is inserted into the anus and advanced to the level of obstruction. Following this, a water-soluble radiographic contrast is injected to identify the obstruction, and a guidewire is placed through the catheter beyond the level of obstruction. After removal of the angiography catheter, the stent delivery system is inserted over the guidewire. (It is recommended that the length of the stent be at least 4 cm longer than the obstruction to allow a 2-cm overlap at either end). Finally, the stent is deployed and contrast is injected to rule out any perforation.

[3] Beck, D. Advances in Gastrointestinal Endoscopic Techniques. Surgical Clinics of North America, 86, (4): 849 - 865

- In the case of endoscopic stent insertion, which can also involve the use of fluoroscopy, after the patient is sedated and monitored (similar to the fluoroscopic technique described above) an endoscope is inserted until the obstruction is visualized. The length of the obstruction is measured with the endoscope. If it is determined that the endoscope will not pass through the lesion, radiographic contrast is injected by way of a biliary or angiography catheter placed through the scope. A guidewire is then placed through the scope and beyond the level of the obstruction. If the stent is designed to fit through the colonoscope, it is inserted over the guidewire into position. Radiographic markers are used to identify the location of the proximal portion of the stent. Finally, the stent is deployed under endoscopic visualization of its distal end with fluoroscopic confirmation.

    - If the stent is not designed to fit through the endoscope, the endoscope is removed (leaving the guidewire in place), and the stent is inserted over the guidewire through the obstruction. The endoscope is reinserted to the distal portion of the obstruction and the stent is deployed under endoscopic visualization. Once the stent is deployed, contrast is injected to verify appropriate placement and detect any colonic perforation.

Benefits: One study evaluated the clinical aspects and cost-effectiveness of SEMS used in the treatment of colonic obstruction for either palliation or as a bridge-to-surgery.[4] The costs of the patients treated with stents were compared to the costs of the patients treated surgically at the same facility. Results demonstrated shorter hospitalizations, reduced costs and a lower complication rate for those patients treated with the stents.

Potential adverse events include (but are not limited to) the usual complications associated with conventional stents and endoscopic procedures such as stent misplacement or migration, tumor ingrowth/overgrowth, infection, and perforation.

In summary, insertion of a colonic stent to relieve malignant or benign obstruction provides the patient with an alternative treatment to pain relief.

Coding Options:
Option 1: Do not create new codes. Continue to assign procedure code 46.85, Dilation of intestine, for the insertion of a colonic stent.

Option 2: Create two new codes to identify the insertion of a colonic stent and revise code 46.85 by adding an exclusion term for the two new codes.

[4] Binkert, C.A. Acute colonic obstruction: Clinical aspects and cost-effectiveness of preoperative and palliative treatment with self-expanding metallic stents - A preliminary report. Radiology, 1998; 206(1): 199-204

New code	46.86 Endoscopic insertion of colonic stent(s) Colonoscopy (flexible) (through stoma) with transendoscopic stent placement Stent endoprosthesis of colon Excludes: other insertion of colonic stent (46.87)
New code	46.87 Other insertion of colonic stent(s) Includes: that by: fluoroscopy Excludes: endoscopic insertion of colonic stent (46.86)
	46.85 Dilation of intestine Dilation (balloon) of duodenum Dilation (balloon) of jejunum Endoscopic dilation (balloon) of large intestine That through rectum or colostomy
Add exclusion term	Excludes: with insertion of colonic stent (46.86-46.87)

CMS Recommendation: CMS recommends option 2, as stated above.

Interim coding: Continue to use code 46.85, Dilation of intestine, to describe the insertion of a colonic stent as advised by AHA's *Coding Clinic® for ICD-9-CM*, Third Quarter, 2007.

Addenda

Tabular

Revise code title	00.56 Insertion or replacement of implantable pressure sensor (lead) for intracardiac or great vessel hemodynamic monitoring
	13.2 Extracapsular extraction of lens by linear extraction technique
Add code also note	Code also any synchronous insertion of pseudophakos (13.71)
	13.3 Extracapsular extraction of lens by simple aspiration And (irrigation) technique
Add code also note	Code also any synchronous insertion of pseudophakos (13.71)
	13.4 Extracapsular extraction of lens by fragmentation and aspiration technique
Add code also note	Code also any synchronous insertion of pseudophakos (13.71)
	33.24 Closed [endoscopic] biopsy of bronchus
Add inclusion term	Transbronchoscopic needle aspiration [TBNA]
	37.79 Revision or relocation of cardiac device pocket
Revise inclusion term	Removal of the implantable hemodynamic presssure sensor (lead) and monitor device
	39.50 Angioplasty or atherectomy of other non-coronary vessel(s)
	Code also any:
Add code also note	insertion of drug-eluting peripheral vessel stent (00.55)
Revise code also note	insertion of non- ~~coronary~~ drug-eluting peripheral vessel stent(s) or stent graft(s) (39.90)
Revise code title	80.0 Arthrotomy for removal of prosthesis without

replacement

81.5 Joint replacement of lower extremity

Add inclusion term — Includes: removal of prior prosthesis – *do not code separately*

81.54 Total knee replacement

Add inclusion term — Partial knee replacement

81.84 Total elbow replacement

Add inclusion term — Partial elbow replacement

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Arthroplasty (with fixation device) (with traction) 81.96
elbow 81.85

Revise subterm — with prosthetic replacement (partial) (total) 81.84

Biopsy
bronchus NEC 33.24

Add subterm — Wang needle (transbronchoscopic) 33.24

Formation

Revise subterm — anus, artificial - *see ~~also~~* Colostomy ~~46.13~~
Revise subterm — ileostomy - *see ~~also~~* Ileostomy ~~46.23~~
Revise subterm — colostomy - *see ~~also~~* Colostomy ~~46.13~~
fistula
Revise subterm — mucous - *see ~~also~~* Colostomy ~~46.13~~
Revise subterm — mucous fistula - *see ~~also~~* Colostomy ~~46.13~~

Graft, grafting
skin (partial-thickness) (split-thickness) 86.69
free (autogenous) NEC 86.60

Add subterm — breast
Add subterm — deep inferior epigastric artery perforator (DIEP) flap, free 85.74
Add subterm — gluteal artery perforator (GAP) flap, free 85.76
Add subterm — superficial inferior epigastric artery (SIEA) flap, free 85.75
Revised subterm — transverse rectus abdominis musculocutaneous (TRAM) flap, free 85.73

	Insertion
	sensor (lead)
Revise subterm	intracardiac or great vessel hemodynamic monitoring 00.56
Add subterm	shunt – *see* Shunt
	spine
Revise subterm	bone void filler ~~84.55~~
	Monitoring
	cardiac output (by)
Revise subterm	intracardiac or great vessel hemodynamic sensor (lead) 00.56
	Replacement
	sensor (lead)
Revise subterm	intracardiac or great vessel hemodynamic monitoring 00.56
	Shunt – *see also* Anastomosis and Bypass, vascular
	ventricular (cerebral) (with valve) 02.2
	to
Add subterm	peritoneal 02.34
	Suture (laceration)
	obstetric laceration NEC 75.69
Add subterm	periurethral 75.69
Add term	Wang needle aspiration biopsy
Add subterm	bronchus 33.24