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 27 – September 28, 2007

Patricia E. Brooks
Co-Chairperson
September 27, 2007

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

Topics:

1. Present on admission indicator (POA)	Patricia E. Brooks
2. ICD-10 Procedure Classification System (PCS) Update	Patricia E. Brooks
3. Non-invasive Positive Pressure Ventilation [NIPPV] Page 9-13	Mady Hue Neil MacIntyre, MD Division of Pulmonary and Critical Care Medicine Duke University Medical Center
4. SuperOxygenation Therapy Page 14-16	Ann B. Fagan Jack L. Martin, MD, FACC Chief of Interventional Cardiology Bryn Mawr Hospital
5. Laparoscopic Repair of Hernia Page 17-22	Patricia E. Brooks Rod Brown, MD, FAAFP Glacial Ridge Health System

6. Surgical Closure of Atrial Appendage
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Ann B. Fagan
Kathryn Barry, MPH, MSN, RN
Health Policy Specialist
Medical Education Training Assoc.

7. Bi-ventricular Replacement
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Ann B. Fagan
Bartley P. Griffith, MD
Chief, Division of Cardiac Surgery
University of Maryland Med. Center

8. Application of Surgical Gel
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Mady Hue
Alfred L. Rhyne, MD
OrthoCarolina Spine Center

9. Laparoscopic Colectomy
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Patricia E. Brooks
Pam Martin, MD, FACS
Director of Professional Education
Ethicon Endo-Surgery

10. Intra-Aneurysm Sac Pressure Measurement
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Amy L. Gruber
Sean Roddy, MD
Associate Professor of Surgery
Albany Medical Center

11. Percutaneous Vertebral Augmentation
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Amy L. Gruber
Chetan Patel, MD
Attending Surgeon, Spine Surgery
William Beaumont Hospital

12. Intravascular Pressure Measurement
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Joe Kelly, MD
Stuart Higano, MD
Mayo Clinic

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Jay Caplan, Chief Tech. Officer
InfraReDx™
Burlington, MA

14. Percutaneous Dilatational Tracheostomy — Joe Kelly, MD
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15. Repair of the Annulus Fibrosus — Mady Hue
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    Reginald J. Davis, MD, FACS
    Chief of Neurosurgery
    Greater Baltimore Medical Center

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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:
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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 28 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 27 – 28, 2007	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 21, 2007.** You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.
October 2007	Summary report of the Procedure part of the September 27 – 28, 2007 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 27 – 28, 2007 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, 2007	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 12, 2007	**Deadline for receipt of public comments on proposed code revisions discussed at the September 27-28, 2007 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on April 1, 2008.**
Early November, 2007	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, 2008 will be posted on the following websites: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes http://www.cdc.gov/nchs/icd9.htm

December 3, 2007	**Deadline for receipt of public comments on proposed code revisions discussed at the September 27-28, 2007 ICD-9-CM Coordination and Maintenance Committee meetings for implementation of October 1, 2008.**
January 18, 2008	Deadline for requestors: Those members of the public requesting that topics be discussed at the March 19–March 20, 2008 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses by this date.
February 2008	Draft agenda for the Procedure part of the March 19, 2008 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 20, 2008 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 19 – March 20, 2008 ICD-9-CM Coordination and Maintenance Committee Meeting will be published.
February 15, 2008	**On-line registration opens for the March 19 – 20, 2008 ICD-9-CM Coordination and Maintenance Committee meeting at: http://www.cms.hhs.gov/events**
March 2008	Because of increased security requirements, **those wishing to attend the March 19 – March 20, 2008** 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 12, 2008 failure to do so may result in lack of access to the meeting**.
March 19 – March 20 2008	ICD-9-CM Coordination and Maintenance Committee meeting, CMS Auditorium, Baltimore, MD.

April 1, 2008	Any new ICD-9-CM codes required to capture new technology will be implemented. Information on any new codes implemented on April 1, 2008 previously posted in early November 2007 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 11, 2008	Deadline for receipt of public comments on proposed code revisions discussed at the March 19-20, 2008 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2008.
April 2008	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 2008	Summary report of the Procedure part of the March 19, 2008 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 20, 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
June 2008	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 25, 2008	Those members of the public requesting that topics be discussed at the September 24 – 25, 2008 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses.

August 1, 2008	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, 2008. This rule can be accessed at: http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp
August 2008	Tentative agenda for the Procedure part of the September 24 – 25, 2008 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 24 – 25, 2008 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 24 – 25, 2008 ICD-9-CM Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.
August 15, 2008	**On-line registration opens for the September 24-25, 2008 ICD-9-CM Coordination and Maintenance Committee meeting at: http://www.cms.hhs.gov/events**
September 12, 2008	Because of increased security requirements, those wishing to attend the September 24 - 25, 2008 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 12, 2008; failure to do so may result in lack of access to the meeting.
September 24 – 25, 2008	ICD-9-CM Coordination and Maintenance Committee meeting, CMS Auditorium, Baltimore, MD. 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 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, 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 of April 1, 2009.**
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.

Non-invasive Positive Pressure Ventilation

Issue: Currently, ICD-9-CM procedure code 93.90, Continuous positive airway pressure [CPAP], includes non-invasive positive pressure ventilation (NIPPV). In recent years however, respiratory treatment modalities have changed and it is suggested that 1) CPAP is a form of NIPPV and therefore, NIPPV should have its own unique code and 2) NIPPV delivered via a face or nasal mask utilizes resources that are similar to invasive (mechanical) positive pressure ventilation in treating patients who are diagnosed with acute respiratory failure. Should a new procedure code be created to describe non-invasive positive pressure ventilation delivered via a face or nasal mask?

New Technology Application? No.

Background: The terms CPAP, BiPAP®, PEEP, and positive pressure ventilation can have different meanings to critical care physicians, pulmonologists and sleep specialists, as well as coders, thereby creating a level of incongruity and inconsistency in the physician documentation and code assignment. Historically, the concept of mechanical ventilation for critically ill patients invariably included the establishment of an artificial airway, invasively, either through endotracheal intubation or tracheostomy. With growing frequency, however, a significant portion of these patients can now be treated through non-invasive mechanical ventilation with the use of a face mask. There is an important body of evidence that these patients experience fewer complications and shorter length of stay, but they still require a certain level of intensive care and management to ensure appropriate care[1].

Perhaps most importantly, the devices used to treat these patients may be traditional ventilators or could be CPAP or BiPAP® type devices with appropriate alarms, setting options, etc.

CPAP – continuous positive airway pressure:
Machine delivers a constant elevated airway pressure to the patient. This pressure is the same during inspiration and expiration and thus no breathing (ventilatory) assistance is provided. CPAP is used to stabilize airway structures in obstructive sleep apnea and stabilize alveolar structures in conditions such as pulmonary edema. CPAP is most commonly delivered by a facemask but can be provided through an endotrachael tube or tracheostomy.

PPV – positive pressure ventilation:
Machine delivers a higher pressure during inspiration than during expiration to the patient. PPV thus provides breathing (ventilatory) assistance. PPV is used to provide breathing (ventilatory) assistance for patients with acute respiratory failure through either a facemask (non-invasive PPV or NPPV) or an endotracheal tube or a tracheostomy (invasive). NPPV is also sometimes used during sleep to provide breathing (ventilatory)

[1] Lightowler JV, Wedzicha JA, Elliot M, Ram SF. Noninvasive positive pressure ventilation to treat respiratory failure resulting from exacerbations of chronic obstructive pulmonary disease: Cochrane systematic review and meta-analysis. BMJ 2003; 326: 185-189.

assistance to patients with sleep apnea or chronic CO2 retention. PPV (and NPPV) can be provided with a variety of different pressure and flow configurations as well as with or without backup machine breaths (eg assist control (ACV), volume assist control (VACV), pressure assist control (PACV), pressure support (PSV), airway pressure release ventilation (APRV), and synchronized intermittent mandatory ventilation (SIMV)). **These different flow, volume, and backup rate combinations should not be used to distinguish different levels of support or intensity of support as they all can act as respiratory life support strategies. Note that the trade names BiPAP® and BILEVEL refer to devices providing PACV and PSV – usually through a facemask**.

PEEP – positive end expiratory pressure:
Machine delivers an elevated pressure during expiration to maintain stability of alveolar structures as the lung empties. PEEP is often used in conjunction with the higher inspiratory pressures and breathing (ventilatory) assistance of PPV. PEEP technically is part of CPAP except that with CPAP the elevated expiratory pressures are equal to the inspiratory pressures and thus, as described above, no breathing (ventilatory) assistance is supplied. A common mistake is to refer to "CPAP with pressure support" – what this really means is pressure support ventilation with PEEP.

Coding issue: Positive pressure ventilation can be delivered invasively or non-invasively. According to the presenter, terms associated with positive pressure ventilation (PPV) may include: assist control volume (ACV), adaptive support ventilation, airway pressure release ventilation (APRV), intermittent mandatory ventilation (IMV), pressure assist control ventilation (PACV), pressure regulated volume control, proportional assist ventilation, synchronized intermittent mandatory ventilation (SIMV), and volume assist control.

As comments are formulated, consideration should be given to determine if these terms would be helpful if included in the tabular section of the code book to assist coders who may encounter this type of documentation. However, the differentiating factor continues to be based on whether or not the patient receives invasive or non-invasive positive pressure ventilation.

Coding options:
Coding option 1: Continue to use existing codes as currently defined.

93.9 Respiratory therapy

Excludes: insertion of airway (96.01-96.05)
other continuous mechanical ventilation (96.70-96.72)

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

96.7 Other continuous mechanical ventilation
Includes: Endotracheal respiratory assistance
Intermittent mandatory ventilation [IMV]
Positive end expiratory pressure [PEEP]
Pressure support ventilation [PSV]
That by tracheostomy
Weaning of an intubated (endotracheal tube) patient

Excludes: bi-level positive airway pressure [BiPAP] (93.90)
continuous negative pressure ventilation [CNP] (iron lung) (cuirass) (93.99)
continuous positive airway pressure [CPAP] (93.90)
intermittent positive pressure breathing [IPPB] (93.91)
non-invasive positive pressure (NIPPV) (93.90)
that by face mask (93.90-93.99)
that by nasal cannula (93.90-93.99)
that by nasal catheter (93.90-93.99)

Code also any associated:
endotracheal tube insertion (96.04)
tracheostomy (31.1-31.29)

Note: Endotracheal Intubation
To calculate the number of hours (duration) of continuous mechanical ventilation during a hospitalization, begin the count from the start of the (endotracheal) intubation. The duration ends with (endotracheal) extubation.

If a patient is intubated prior to admission, begin counting the duration from the time of the admission. If a patient is transferred (discharged) while intubated, the duration would end at the time of transfer (discharge).

For patients who begin on (endotracheal) intubation and subsequently have a tracheostomy performed for mechanical ventilation, the duration begins with the (endotracheal) intubation and ends when the mechanical ventilation is turned off (after the weaning period).

Tracheostomy
To calculate the number of hours of continuous mechanical ventilation during a hospitalization, begin counting the duration when mechanical ventilation is started. The duration ends when the mechanical ventilator is turned off (after the weaning period).

If a patient has received a tracheostomy prior to admission and is on mechanical ventilation at the time of admission, begin counting the duration from the time of admission. If a patient is transferred (discharged) while still on mechanical ventilation via tracheostomy, the duration would end at the time of the transfer (discharge).

96.70 Continuous mechanical ventilation of unspecified duration
Mechanical ventilation NOS

96.71 Continuous mechanical ventilation for less than 96 consecutive hours

96.72 Continuous mechanical ventilation for 96 consecutive hours or more

Coding option 2: Create new code 96.8, Other non-invasive positive pressure ventilation, make revisions to code 93.90, Continuous positive airway pressure [CPAP] and revise subcategory 96.7, Other continuous mechanical ventilation.

	93.9 Respiratory therapy
Delete exclusion term	Excludes: ~~insertion of airway (96.01-96.05)~~
	93.90 Continuous positive airway pressure [CPAP]
Delete inclusion term	~~Bi-level airway pressure~~
Delete inclusion term	~~Non-invasive positive pressure (NIPPV)~~
Add inclusion term	Includes: that delivered by: endotracheal tube face mask tracheostomy
Add code also note	Code also if performed: endotracheal tube insertion (96.04) tracheostomy (31.1-31.29)
Add exclusion term	Excludes: other non-invasive positive pressure ventilation (96.8)
	96.7 Other continuous mechanical ventilation
Revise inclusion term	~~Intermittent mandatory ventilation (IMV)~~
Revise inclusion term	~~Positive end expiratory pressure [PEEP]~~
Add inclusion term	Includes: Positive pressure ventilation
Revise exclusion term	Excludes: bi-level positive airway pressure [BiPAP] ~~(93.90)~~ (96.8)
Revise exclusion term	Excludes: other non-invasive positive pressure (NIPPV)

~~(93.90)~~ (96.8)

Create new code — 96.8 Other non-invasive positive pressure ventilation [NIPPV]
That by face or nasal mask:
Bi-level positive airway pressure
Non-invasive mechanical ventilation
Non-invasive PPV
NPPV

Excludes: continuous mechanical ventilation (96.70-96.72)
continuous positive airway pressure [CPAP] (93.90)

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Ventilation

Revise subterm — bi-level positive airway pressure ~~93.90~~ 96.8

mechanical

Add subterm — positive pressure ventilation - *see* category 96.7

Add subterm — other non-invasive [NIPPV] 96.8

Add subterm — non-invasive positive pressure (NIPPV)

Add subterm — CPAP 93.90

Add subterm — other non-invasive positive pressure 96.8

Revise subterm — other non-invasive positive pressure ~~93.90~~ 96.8

CMS Recommendation:
CMS recommends option 2; create new code 96.8, Other non-invasive positive pressure ventilation, make revisions to code 93.90, Continuous positive airway pressure [CPAP] and revise subcategory 96.7, Other continuous mechanical ventilation.

Interim coding:
Continue to use existing codes as described above in option 1.

SuperOxygenation Therapy
(Associated with the Treatment of Acute Myocardial Infarction)

Issue:
No existing ICD-9-CM procedure code adequately describes the administration of SuperOxygenation therapy or aqueous oxygen (AO) therapy to oxygen-deprived myocardial tissue in acute myocardial infarct (AMI) patients following percutaneous coronary intervention (PCI).

New Technology Application?
Yes.

Food and Drug Administration (FDA) Approval:
The enrollment phase for the pivotal AMIHOT II clinical trial was completed in May 2007. A modular application for pre-market approval (PMA) has been submitted to the FDA, except for the clinical module. Submission of the clinical module is planned by the fourth Quarter 2007, with FDA approval of the PMA application anticipated in second Quarter 2008.

Background:
There are an estimated 500,000 ST-Elevation Myocardial Infarction (STEMI) cases in the United States annually. Timely recognition and diagnosis of a STEMI event in conjunction with prompt restoration of coronary artery blood flow are critical for achieving optimal short- and long-term patient outcomes. However, even with adequate reperfusion through currently available surgical or pharmacological means, restoration of adequate blood flow to the myocardium can be compromised by microvascular damage.

SuperOxygenation therapy is a novel therapy designed to ameliorate progressive myocardial necrosis by minimizing microvascular damage in AMI patients following percutaneous intervention with coronary artery stent placement. SuperOxygenation or AO therapy refers to the creation and focal delivery of SuperOxygenated arterial blood directly to reperfused areas of myocardial tissue which may be at risk. The net effect of SuperOxygenation or AO therapy is to reduce infarct size and thus preserve heart muscle.

Treatment Options: Currently, there are several treatment options available to restore coronary artery blood flow in AMI patients. These include:

- Pharmacologic – fibrinolytic therapy (plasminogen activators) with or without glycoprotein IIb/IIIa inhibitors
- Percutaneous Coronary Intervention (PCI) – angioplasty with or without sent placement, and
- Surgical – coronary artery bypass graft (CABG)

All of these therapies intend to restore blood flow by targeting the coronary artery thrombosis that is the direct cause of the AMI.

SuperOxygenation or AO therapy is not similar to any of the above reperfusion methods; it is adjunctive to these therapies and directly treats the myocardial tissue susceptible to progressive microvascular damage after the coronary artery blood flow has been restored. This treatment strategy is in accordance with the ACC/AHA guidelines as given below:

> "[C]onstruction of an ideal reperfusion regimen in patients with STEMI not only should focus on the primary means of restoring flow in the epicardial infarct artery (pharmacological or catheter-based) but should also include adjunctive and ancillary treatments that minimize the amount of microvascular damage and protect the jeopardized MI infarct zone that contains cells in various stages of ischemia, necrosis, and apoptosis.

Description of the procedure: SuperOxygenation or AO therapy is accomplished by a cartridge-based automated system that withdraws arterial blood from the patient and mixes it with a small amount of saline, supersaturated with oxygen, to create highly oxygen-enriched blood. These oxygen concentrations cannot be realized by conventional respiratory means and the intracoronary delivery avoids risk of systemic oxygen toxicity.

SuperOxygenation or AO therapy is performed in the cardiac catheterization laboratory immediately after PCI and stent placement, using the same guide components that are already in place for arterial access. The SuperOxygenated blood is delivered directly to the stented coronary artery via an infusion catheter. This therapy requires the patient to be treated and supervised for an additional 90 minutes in the cardiac catheterization lab following the initial procedure.

Current Coding:
A generic code exists at 39.97, Other perfusion. This code has as an inclusion term 'coronary artery', and instructs the coder to code also the substance perfused (99.29, Injection or infusion of other therapeutic or prophylactic substance).

Coding Options:
Option 1: Do not create a code for this procedure. Continue to use code 39.97, Other perfusion, to describe SuperOxygenation infusion therapy. Code also the substance perfused, 99.29, Injection or infusion of other therapeutic or prophylactic substance.

Option 2: Create a unique code to describe this procedure.

	00.6	Procedures on blood vessels
New Code	00.60	SuperOxygenation infusion therapy Aqueous oxygen (AO) therapy Direct approach Code also any: Injection or infusion of thrombolytic agent (99.10) Insertion of coronary artery stent(s) (36.06, 36.07) Intracoronary artery thrombolytic infusion (36.04) Number of vascular stents inserted (00.45-00.48)

Number of vessels treated (00.40-00.43)
Procedure on vessel bifurcation (00.44)

00.66 Percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy

Add note: Code also any: SuperOxygenation infusion therapy (00.60)

39.97 Other perfusion

Add excludes note: Excludes: SuperOxygenation infusion therapy (00.60)

CMS Recommendation:
CMS recommends option 2; create a new code as described above.

Interim Coding:
Code 39.97, Other perfusion, to describe SuperOxygenation infusion therapy. Code also the substance perfused (99.29, Injection or infusion of other therapeutic or prophylactic substance).

Laparoscopic Repair of Hernia

Issue:
ICD-9-CM procedure codes do not distinguish between laparoscopic and open repairs of hernias.

New Technology Application?:
No.

FDA Approval:
The Nitinol framed polymer mesh device, Rebound HRD™, manufactured by Minnesota Medical Development, Inc., received FDA 510k clearance on August 16, 2007. This device is used in laparoscopic repairs of inguinal hernias.

Background:

"An inguinal hernia occurs when tissue pushes through a weak spot in your groin muscle. This causes a bulge in the groin or scrotum. The bulge may hurt or burn. Hernias do not heal on their own, and they tend to get worse over time. By having surgery to repair the hernia, you avoid the chance of a serious problem called strangulation. This occurs when a loop of intestine is trapped in a hernia and the blood supply is cut off, killing the tissue."[1]

Surgery is the only treatment and cure for inguinal or ventral hernias. Hernia repair is one of the most common surgeries performed in the US. Approximately 750,000 people have inguinal hernia repairs each year.[2] Approximately fifteen (15%) percent of these repairs are currently performed laparoscopically.

Beginning in the late 19th century until the early 1960's the repair of hernias was based on the principal of a sutured tissue repair via an inguinal incision. With the advent of various synthetic mesh materials new techniques were developed to improve the procedure of hernia repair, and the incorporation of mesh re-enforcement of the repair gradually gained popularity from the 1960's until it was a fairly standard technique in the 1990's. Modifications in these various techniques have continued to evolve.

Laparoscopic hernia repair is similar to other laparoscopic procedures. General anesthesia is administered, and a small incision is made in or just below the navel. The

[1] http://www.webmd.com/digestive-disorders/tc/Inguinal-Hernia-Topic-Overview

[2] Harford W, Jeyarajah R (2002). Inguinal and femoral hernias (groin hernias) section of Abdominal hernias and their complications, including gastric volvulus. In M Feldman et al., eds., Sleisenger and Fordtran's Gastrointestinal and Liver Disease, 7th ed., vol. 1, pp. 375–377. Philadelphia: W.B. Saunders.

abdomen is inflated with air so that the surgeon can see the abdominal organs. A thin, lighted scope called a laparoscope is inserted through the incision. The instruments to repair the hernia are inserted through other small incisions in the lower abdomen. Mesh is then placed over the defect to reinforce the abdominal wall.[1]

In 1989 the first reports of laparoscopic hernia repairs began appearing in the medical literature. These repairs involved the placement of a piece of synthetic mesh in the pre-peritoneal space over the hernia defect as well as placing a mesh plug in the hernia defect. This procedure has evolved since then with the abandonment of the mesh plug and the fixation of the mesh to the fascia with spiral or circular tacks or sutures.

The Nitinol framed polymer mesh device was developed to overcome several of the difficulties and shortcomings of the current laparoscopic techniques. The Nitinol frame spontaneously opens the device after delivery which facilitates ease of placement. This feature also allows the mesh to remain secure after placement since the Nitinol framed polymer mesh device does not require anchoring of the device with tacks or sutures. This also eliminates the potential risk of injuring nerves or blood vessels by these anchoring devices. The nitinol frame can be visualized with a plain radiograph (x-ray) which may be helpful with the post-operative evaluation of patients.

This device is effective for direct and indirect hernias. Since this is minimally invasive surgery it requires only two five millimeter trocar sites and one ten to twelve millimeter trocar site. Bilateral hernias can be repaired with the same access as used for unilateral hernias.

Laparoscopic surgery has the following advantages over open hernia repair[2]:

- Some people may prefer laparoscopic hernia repair because it causes less pain and they are able to return to work more quickly than they would after open repair surgery.
- Repair of a recurrent hernia after open or laparoscopic surgery often is easier using laparoscopic techniques than using open surgery.
- It is possible to repair or check for a second hernia on the opposite side at the time of the operation.
- Because smaller incisions are used, laparoscopy may be more appealing for cosmetic reasons.

The super-elastic, multi-strand, Nitinol frame allows the device to be folded into a 10mm loading cannula and inserted laparoscopically through a 10 - 12mm access port. The Nitinol framed polymer mesh device is manufactured in several shapes to accommodate different anatomies and surgical preference. The Nitinol framed polymer mesh is self-

[1] McCormack K, et al. (2004). Laparoscopic techniques versus open techniques for inguinal hernia repair. Cochrane Database of Systematic Reviews (4). Oxford: Update Software.

[2] Neumayer L, et al. (2004). Open mesh versus laparoscopic mesh repair of inguinal hernia. New England Journal of Medicine, 350(18): 1819–1827.

expanding. Designed for placement between the fascia and fully closed peritoneum, it can cover the direct or indirect space, with at least a 15mm margin beyond the edges of the hernia defect.

The Nitinol framed polymer mesh device will result in shorter operating times due to elimination or reducing the time involved with unfurling and reorganizing the folded mesh, the pre-peritoneal placement of the mesh, and the anchoring of the mesh. The ability to stabilize the mesh in the proper position without the use of tacks or sutures results in less post-operative pain for patients and consequently a quicker return to unrestricted activities than is possible with other hernia repair procedures. For most patients this can be accomplished as an out-patient procedure. Post-operative restrictions after this procedure are minimal. Patients do not have any activity restrictions after the surgery; however, they should not submerge the abdominal trocar site incisions under water (no swimming, hot-tubs, or tub baths) for the first week, however, showering is permitted.

The Nitinol framed polymer mesh device was specifically designed for laparoscopic hernioplasty and this device is uniquely suited to facilitate the performance of this procedure. Using the Rebound HRD will result in shorter operating times and anesthesia exposure, decreased post-operative discomfort, a faster return to work and unrestricted activity and also eliminates the operative risk associated with anchoring the mesh with tacks and sutures. The Nitinol frame of the polymer mesh enables the surgeon to evaluate patients with a plain x-ray post-operatively in a way that is not possible with any other type of hernia repair procedure.

Lastly, the mesh-Nitinol frame assembly is easily distinguishable by standard X-ray. This aids in the identification of displacement if the patient experiences a reoccurrence of symptoms. This feature is not possible in the plastic frame with polypropylene mesh material.

Coding Issues:
Although professional component (CPT) differentiation exists between laparoscopic and open inguinal hernia repair with graft, no such delineation is noted with the current ICD-9-CM coding set. Identification of approach for this type of repair should be distinct and trackable.

Option 1: Do not modify the codes. Continue to use the codes as currently assigned. Current codes:

53 Repair of hernia
- 53.0 Unilateral repair of inguinal hernia
  - 53.00 Unilateral repair of inguinal hernia, not otherwise specified
  - 53.01 Repair of direct inguinal hernia
  - 53.02 Repair of indirect inguinal hernia
  - 53.03 Repair of direct inguinal hernia with graft or prostheses
  - 53.04 Repair of indirect inguinal hernia with graft or prostheses

53.05 Repair of inguinal hernia with graft or prostheses, not otherwise specified

53.1 Bilateral repair of inguinal hernia
- 53.10 Bilateral repair of inguinal hernia, not otherwise specified
- 53.11 Bilateral repair of direct inguinal hernia
- 53.12 Bilateral repair of indirect inguinal hernia
- 53.13 Bilateral repair of inguinal hernia, one direct and one indirect
- 53.14 Bilateral repair of direct inguinal hernia with graft or prosthesis
- 53.15 Bilateral repair of indirect inguinal hernia with graft or prosthesis
- 53.16 Bilateral repair of inguinal hernia, one direct and one indirect, with graft or prosthesis
- 53.17 Bilateral inguinal hernia repair with graft or prostheses, not otherwise specified

53.7 Repair of diaphragmatic hernia, abdominal approach

53.8 Repair of diaphragmatic hernia, thoracic approach
- 53.80 Repair of diaphragmatic hernia with thoracic approach, not otherwise specified
- 53.81 Plication of the diaphragm
- 53.82 Repair of parasternal hernia

Option 2: Modify the codes so that there are separate codes to identify laparoscopic hernia repairs.

17.1 Laparoscopic unilateral repair of hernia
Excludes: Open and other unilateral repair of hernia (53.00 – 53.05)

New code: 17.11 Laparoscopic repair of direct inguinal hernia with graft or prostheses

New code: 17.12 Laparoscopic repair of indirect inguinal hernia with graft or prostheses

New code: 17.13 Laparoscopic repair of inguinal hernia with graft or prostheses, not otherwise specified

17.2 Laparoscopic bilateral repair of hernia
Excludes: Open and other bilateral repair of hernia (53.10 – 53.17)

New code: 17.21 Laparoscopic bilateral repair of direct inguinal hernia with graft or prosthesis

New code: 17.22 Laparoscopic bilateral repair of indirect inguinal hernia

		with graft or prosthesis
New code:	17.23	Laparoscopic bilateral repair of inguinal hernia, one direct and one indirect, with graft or prosthesis
New code:	17.24	Laparoscopic bilateral inguinal hernia repair with graft or prostheses, not otherwise specified

53 Repair of hernia

Revise: 53.0 Other unilateral repair of inguinal hernia,

Add: Excludes: Laparoscopic unilateral repair of inguinal hernia (17.10 – 17.1X)

53.00		Unilateral repair of inguinal hernia, not otherwise specified
Revise:	53.01	Open repair of direct inguinal hernia
Revise:	53.02	Open repair of indirect of hernia
Revise:	53.03	Open repair of direct inguinal hernia with graft or prostheses
Revise:	53.04	Open repair of indirect inguinal hernia with graft or prostheses
	53.05	Repair of inguinal hernia with graft or prostheses, not otherwise specified

Revise: 53.1 Other bilateral repair of inguinal hernia

Excludes: Laparoscopic bilateral repair of inguinal hernia (17.21 – 17.24)

	53.10	Bilateral repair of inguinal hernia, not otherwise specified
Revise:	53.11	Open bilateral repair of direct inguinal hernia
Revise:	53.12	Open bilateral repair of indirect inguinal hernia
Revise:	53.13	Open bilateral repair of inguinal hernia, one direct and one indirect
Revise:	53.14	Open bilateral repair of direct inguinal hernia with graft or prosthesis
Revise:	53.15	Open bilateral repair of indirect inguinal hernia with graft or prosthesis
Revise:	53.16	Open bilateral repair of inguinal hernia, one direct and one indirect, with graft or prosthesis
	53.17	Bilateral inguinal hernia repair with graft or prostheses, not otherwise specified

Revise: 53.7		Repair of diaphragmatic hernia, abdominal approach
New code:	53.71	Laparoscopic repair of diaphragmatic hernia abdominal approach
New code:	53.72	Open repair of diaphragmatic hernia, abdominal approach
New code:	53.75	Repair of diaphragmatic hernia, abdominal approach, not otherwise specified

53.8		Repair of diaphragmatic hernia, thoracic approach
	53.80	Repair of diaphragmatic hernia with thoracic approach, not otherwise specified
	53.81	Plication of the diaphragm
	53.82	Repair of parasternal hernia
New code:	53.83	Laparoscopic repair of diaphragmatic hernia, with thoracic approach
New code:	53.84	Open repair of diaphragmatic hernia, with thoracic approach

CMS Recommendation: Select Option 2. Create new codes to distinguish between laparoscopic and open approaches to hernia repair. In the meantime, continue to use the existing codes for hernia repair.

Interim coding: Continue to use existing codes as described in option 1.

Surgical Closure [Exclusion] of the Left Atrial Appendage

Issue:
There is currently no specific code which uniquely identifies the surgical closing [exclusion] of the left atrial appendage (LAA) by clipping, stapling, or oversewing.

New Technology Application?
No.

Background:
In patients with atrial fibrillation (AF), exclusion or closure of the left atrial appendage by oversewing, clipping, or stapling is routinely performed by cardiovascular surgeons during a major cardiovascular procedure, such as CABG, mitral valve repair, or maze procedure. As patients age, the risk of developing AF increases. Consequently, prophylactic left atrial appendage removal or exclusion is recommended whenever the chest has been opened for another cardiovascular procedure. Closure or exclusion is performed to prevent future strokes. The LAA topic was discussed at the April 1, 2004 C&M meeting, with subsequent creation of code 37.90, Insertion of left atrial appendage device. We also recently discussed the maze procedure, and made addenda changes effective October 2003 for codes 37.33, Excision or destruction of other lesion or tissue of heart, open approach, and 37.34, Excision or destruction of other lesion or tissue of heart, other approach.

AF is the most commonly occurring cardiac arrhythmia. It affects more than 2.2 million people in the United States, and its prevalence rises with the age of the population. In terms of clinical significance, AF is known to lead to irreversible heart damage, increased risk of stroke, and decreased quality of life. Patients with AF are five times more likely to suffer a thromboembolic stroke than patients in normal sinus rhythm. Symptoms include unpredictable episodes of palpitations, decreased exercise tolerance, and dyspnea.

The first line of therapy for AF is pharmacologic; however, chronic anti-coagulation is associated with a myriad of known side effects. When effective oral anticoagulation is not feasible, surgical intervention is the next consideration. In patients with AF, the most common place of thrombus formation is the left atrial appendage (LAA), which is derived from the left wall of the primary atrium. It lies within the confines of the pericardium in close relation to the free wall of the left ventricle. The clinical significance of closing off (excluding) the LAA demonstrate that 90-100% of thrombus coming from the atrium originate from the LAA in non-rheumatic AF patients. Based on these findings, occlusion of the LAA has become a standard surgical practice used to reduce the incidence of stroke. As patients age and develop AF, prophylactic appendage removal whenever the chest is open is suggested as a method to prevent future strokes.

Appropriately selected patients for surgical closing (exclusion) of the LAA include patients who:

- Have persistent AF symptoms despite drug compliance
- Have documented drug resistance

- Are intolerant of, or contraindicated for chronic anti-arrhythmic drug therapy
- Are intolerant of, or contraindicated for chronic oral anticoagulation therapy.

Surgical exclusion of the LAA is not appropriate:

- As a first-line treatment of atrial fibrillation
- In the absence of drug resistance, intolerance, and/or contraindication
- In asymptomatic patients.

Description of the Surgical Procedure: The LAA is a discrete and accessible anatomic structure. To surgically close (exclude) the LAA, the surgeon can use either a surgical stapler, can clip, or can oversew with suture. The technique requires the surgeon to mechanically approximate the walls of the LAA to permanently and completely close the opening into the LAA from the left atrium. The staple and clip devices are non-absorbable permanent implants. Both occlude the target tissue structure, but typically do not cut out the tissue being occluded. The occluded tissue heals normally at the site of approximation and atrophies distally to it.

Current Coding:
The most appropriate current code would be 37.33, Excision or destruction of other lesion or tissue of heart, open approach. This code includes ablation by any means, such as cryoablation, laser, microwave, electrocurrent, etc. It also includes the maze procedure. Additionally, code 37.90, Insertion of left atrial appendage device, would describe closure, but only via a device designed to remain in the left atrial appendage which would then scar over, effecting the closure.

Coding Options:
Option 1: Do not create a new code for this procedure. Use existing code 37.33, Excision or destruction of other lesion or tissue of heart, open approach, to describe surgical closing (exclusion) of the left atrial appendage.

Option 2: Revise existing code 37.33, Excision or destruction of other lesion or tissue of heart, open approach, as follows:

	37.3	Pericardiectomy and excision of lesion of heart
	37.33	Excision or destruction of other lesion or tissue of heart, open approach
Add term		Clipping, stapling, or oversewing of the left atrial appendage
Add term		Surgical exclusion, left atrial appendage

Option 3: Create a new code in the same subcategory, as follows:

	37.3	Pericardiectomy and excision of lesion of heart
New code	37.36	Excision or destruction of left atrial appendage (LAA), open approach
		Clipping of left atrial appendage

Exclusion of left atrial appendage by any open technique
Oversewing of left atrial appendage
Stapling of left atrial appendage

CMS Recommendation:
CMS is requesting audience input on this topic, both today at the meeting and by e-mail prior to the close of the comment period.

Interim Coding:
Use code 37.33, Excision or destruction of other lesion or tissue of heart, open approach, to describe surgical closing (exclusion) of the left atrial appendage.

Biventricular Replacement – Artificial Heart

Issue:
Coding clarification for the implantation and removal of biventricular mechanical heart assist devices, also known as an artificial heart.

New Technology Application?
No.

Food & Drug Administration (FDA) Approval:
SynCardia Systems, Inc.'s CardioWest™ temporary Total Artificial Heart (TAH-t) was approved by the FDA in 2004 for use as a bridge to transplantation in cardiac transplant eligible candidates at risk of imminent death from biventricular failure. Abiomed's™ AbioCor® Implantable Replacement Heart received designation as an humanitarian device exemption (HDE) in 2006 for use in certain patients who are not candidates for heart transplantation.

Coverage:
CMS has a longstanding noncoverage policy regarding the use of artificial hearts when used as a permanent replacement for the human heart or as a temporary replacement for patients awaiting heart transplantation. However, on August 1, 2007, CMS' Coverage and Analysis Group (CAG) issued a national coverage analysis (NCA) for artificial hearts when used for bridge to heart transplantation and for destination therapy. The formal coverage request is to remove the current noncoverage for artificial heart and to cover this technology for Medicare beneficiaries when used in accordance with its FDA approval. The NCA completion date is scheduled for May 1, 2008.

As defined in CAG's NCA, an artificial heart is an implanted prosthetic device that replaces the heart. As part of the artificial heart implantation, a substantial part or all of the biological heart is removed. The artificial heart differs from a ventricular assist device (VAD) which is attached to the intact native heart at the ventricle. Because the heart remains intact it is possible for the native heart to recover its function after being assisted by a VAD. Since the artificial heart requires resection of the ventricles, the native heart is no longer intact and recovery of the native heart is not possible.

Background:
In 1969, Dr. Denton Cooley performed the first implantation of a temporary total artificial heart, and this primitive device sustained the patient for almost three days until a donor heart was procured for transplant. In 1982, Dr. William DeVries implanted the Jarvik 7 total artificial heart into Dr. Barney Clark. Through a series of business dealings, the Jarvik 7 artificial heart exists today, and is marketed as the CardioWest™ TAH-t.

Biventricular replacement devices, depending on the type of model, replace much of the patient's native heart, including both ventricles, but may not replace the heart in its entirety. It may not replace the native atria. This type of biventricular replacement

device is **not** a ventricular assist device (VAD), because when the device is implanted, there is very little of the native heart left for the device to assist.

Background TAH-t: The TAH-t is composed of implantable artificial ventricles and valves connected by drivelines to an external pneumatic driver. The device is sewn to the patient's remaining atria (the top half of the heart). The design of the TAH-t arose from the clinical need for a system capable of completely restoring systemic and pulmonary blood circulation and organ perfusion in patients with failed circulatory systems resulting from irreversible biventricular dysfunction.

The TAH-t is an orthotopic, pneumatically-driven, pulsatile pump, consisting of two separate 70cc polyurethane chambers that replace the patient's native diseased ventricle and valves. The patient's total cardiac output is provided by the TAH-t, which pumps blood through both the pulmonary and systemic circulations. The device can be set to meet the unique cardiac output needs of each patient.

Each artificial ventricle consists of a semi-rigid polyurethane shell that houses four flexible polyurethane diaphragms. These diaphragms allow the blood chamber of the ventricle to fill passively and then eject blood when the diaphragms are compressed by air that is pumped into the air chamber side of the diaphragms by the external driver. Drivelines connect the pneumatic output of the external driver to the TAH-t cannulae. Where the cannulae traverse the chest wall, a 9.75" length of velour covers the external surface to promote tissue adherence and minimize the risk of infection. Mechanical heart valves that control the direction of blood flow are mounted in the inflow and outflow ports of each artificial ventricle.

Current Coding:
A code exists at 37.52, Implantation of total replacement heart system. The inclusion terms include "Artificial heart" and "Implantation of fully implantable total replacement heart system, including ventriculectomy".

Coding Options:
Option 1: There is an existing code (37.52, Implantation of total replacement heart system) which adequately identifies implantation of an artificial heart. Do not make any changes to this code.

Option 2: Modify code 37.52, and create a code for explantation of this device.

37.5 Heart Replacement Procedures

Revise title	37.52	Implantation of ~~total~~ internal biventricular heart replacement ~~heart~~ system
Add note		Note: This procedure includes substantial removal of part or all of the biological heart. Both ventricles are resected, and the native heart is no longer intact. Ventriculectomy is included in this procedure; do not code separately.

		Artificial heart
Delete term		~~Implantation of fully implantable total replacement heart system, including ventriculectomy~~
		Excludes: implantation of heart assist system [VAD] (37.62, 37.65, 37.66, 37.68)
Revise title	37.53	Replacement or repair of thoracic unit of (total) replacement heart system
Revise title	37.54	Replacement or repair of other implantable component of (total) replacement heart system
New code	37.55	Removal of internal biventricular heart replacement system Explantation of artificial heart Code also any concomitant procedure, such as heart transplantation (37.51), combined heart-lung transplantation (33.6) or implantation of a replacement biventricular heart replacement system (37.52) Excludes: explantation [removal] of heart assist system (37.64) explantation [removal] of percutaneous external heart assist device (97.44) nonoperative removal of heart assist system (97.44) that with replacement or repair of biventricular heart replacement system (37.53, 37.54)

CMS Recommendation:
Option 2 – modify existing codes 37.52, 37.53, and 37.54 as described above. Create code 37.55 to describe explantation of this device.

Interim Coding:
Use existing code 37.52 to describe implantation of total replacement heart system or artificial heart.

Oxiplex® Adhesion Barrier Surgical Gel

Issue:
Effective October 1, 2002, ICD-9-CM procedure code 99.77, Application or administration of adhesion barrier substance, was created to describe the use of a variety of products to assist in the prevention or reduction of adhesions following surgery. A technology known as Oxiplex® is presently indicated (in a clinical trial) for a reduction in back and leg pain, including any associated neurologic symptoms, due to a posterior discectomy, laminectomy, or laminotomy. Should a unique procedure code be created to identify the use of Oxiplex® for this indication?

New technology application?
Unknown. Oxiplex/SP® Gel Adhesion Barrier for Spine is described as only being approved for use outside of the US and is designed to act as a protective coating to prevent post-surgical adhesions from forming; however, the US pivotal trial did not assess Oxiplex® for use in adhesion prevention. An IDE study with 352 patients has been completed. PMA of the technology as indicated is expected by second quarter 2008.

Background: Failed back surgery syndrome (FBSS) has a myriad of possible surgical and non-surgical etiologies. It is an imprecise term encompassing a diverse group of disorders that have similar pain symptoms in common following surgery. Nerve root damage, resulting from dissection and retraction required in this surgery, often leads to edema, ischemia, and cellular injury of the nerve root. The post surgical site contains blood products including fibrin, wound exudates, and inflammatory mediators which can lead to compression, inflammation and chemical irritation. Oxiplex® provides an environment that reduces nerve root exposure to these elements. As a result, and as shown in the pivotal study, nerve root-related postoperative pain and related symptoms following surgery can be significantly reduced by using Oxiplex®.

Oxiplex® is an absorbable, viscoelastic gel made of carboxymethylcellulose (CMC) and polyethylene oxide (PEO) that is surgically implanted during a posterior discectomy, laminotomy or laminectomy. The gel reduces the potential for inflammatory mediators that injure, tether, or antagonize the nerve root in the epidural space by creating an acquiescent, semi- permeable environment to protect against localized debris. It is a unique material in that it coats tissue such as the nerve root in the epidural space to protect the nerve root from the effects of inflammatory mediators originating from either the nucleus pulposus or from blood derived inflammatory cells or cytokines during the healing process.

Oxiplex® can be used as an adjunct to posterior discectomy, a laminectomy or laminotomy for the reduction of pain, radiculopathy, and lower extremity weakness and incidence, extent and severity. It is used during a discectomy, a laminectomy or laminotomy to protect the dura from pro-inflammatory mediators secreted by spinal disks. These pro-inflammatory mediators, phospholipase A and nitric oxide induced or extruded by intervertebral discs, may be responsible for increased pain during these

procedures. It is applied around exposed tissues and remains at the site of application for a period of time, providing a protective environment during the healing process.

Patient outcomes include reduction of pain, radiculopathy, and lower extremity weakness and incidence, extent and severity.

Coding Options:

Option 1:

Do not create a new code. Currently, Oxiplex® is only approved for use as an adhesion barrier for spine surgery outside the United States. Existing code 99.77, Application or administration of adhesion barrier substance, adequately describes the use of Oxiplex® if it were to be approved in the US.

Option 2:

Create a new code at subcategory 84.5, Implantation of other musculoskeletal devices and substances, to describe the application and insertion of Oxiplex® as follows:

New code	84.50 Insertion of absorbable, viscoelastic gel
	Code also primary procedure performed: excision of intervertebral disc (80.51) laminectomy (03.09) laminotomy (03.02)

Recommendation:

CMS recommends option 1, do not create a new code. Currently, Oxiplex® is only approved for use as an adhesion barrier for spine surgery outside the United States. Existing code 99.77, Application or administration of adhesion barrier substance, adequately describes the use of Oxiplex®.

Interim coding :

In the interim, use code 99.77, Application or administration of adhesion barrier substance, since this code adequately describes Oxiplex® as an adhesion barrier substance, regardless of the indication.

Laparoscopic Colectomy

Issue:
The current ICD-9-CM procedure codes do not distinguish between open and laparoscopic colo-rectal surgery (removal of portions of the large bowel and rectum). The lack of specificity for these codes makes it very difficult to track what type of surgical approach was used. Furthermore, separate laparoscopic ICD-9-CM procedure codes already exist for many other procedures including: cholecystectomy, appendectomy, and hysterectomy.

New Technology Application:
No.

Background:
Colectomy is a surgical treatment for patients who suffer from colon cancer or other diseases of the colon that may require surgery a treatment option. Other non-cancerous diseases include ulcerative colitis and Crohn's disease. The colectomy procedures remove portions of the large intestine in order to treat the disease. The procedure can be performed both open as well as laparoscopically.

Open Surgery:
During traditional "open surgery," the surgeon makes an incision up to 16 inches long from the upper to lower abdomen to view the colon and remove the diseased portions. Because of the nature of this highly invasive procedure, patients often face a long and difficult healing process that results in a hospital stay of at least a week, with recovery time ranging from six to eight weeks.

Laparoscopic Surgery:
During "minimally invasive," or laparoscopic, colon surgery, the surgeon makes a series of small incisions, from one-fourth inch to four inches, in the patient's abdomen. A small video camera or "scope" is placed in one of the incisions, providing the surgeon with a magnified view of the patient's internal organs on a television monitor. Surgical instruments are placed in the other incisions via portals called trocars allowing the surgeon to work inside the body cavity and ultimately remove portions of the colon.

Studies show laparoscopic colon surgery to be as safe and as effective as open surgery, while offering many benefits over the open procedure. These benefits include:

- Less pain and scarring
- Quicker recovery time
- Shorter hospital stay
- Better cosmetic results

Current coding:

The following codes capture these procedures, but do not identify the approach:
45.71 Multiple segmental resection of large intestine
45.72 Cectomy
45.73 Right hemicolectomy
45.74 Resection of transverse colon
45.75 Left hemicolectomy
45.76 Sigmoidectomy
45.79 Other partial excision of large intestine
45.8 Total intra-abdominal colectomy
48.49 Other pull-through resection of the rectum
48.5 Abdominoperineal resection of the rectum

Options:

Option 1: Do not modify the codes. Continue using the existing codes to capture the procedures.

Option 2:
Create new codes that specifically capture the laparoscopic approach. Modify the existing codes to capture open and other types of approaches.

	17.3	Laparoscopic partial excision of large intestine
New code:	17.31	Laparoscopic multiple segmental resection of large intestine
New code:	17.32	Laparoscopic cecectomy
New code:	17.33	Laparoscopic right hemicolectomy
New code:	17.34	Laparoscopic resection of transverse colon
New code:	17.35	Laparoscopic left hemicolectomy
New code:	17.36	Laparoscopic sigmoidectomy
New code:	17.39	Other laparoscopic partial excision of large intestine

Revise:	45.7	Open and other partial excision of large intestine
		Excludes: Laparoscopic partial excision of large intestine (17.31 – 17.39)
Revise:	45.71	Open and other multiple segmental resection of large intestine
Revise:	45.72	Open and other cecectomy
Revise:	45.73	Open and other right hemicolectomy
Revise:	45.74	Open and other resection of transverse colon
Revise:	45.75	Open and other left hemicolectomy
Revise:	45.76	Open and other sigmoidectomy
Revise:	45.79	Other and unspecified partial excision of large intestine

45.8 Total intra-abdominal colectomy

New code: 45.81 Laparoscopic total intra-abdominal colectomy
New code: 45.82 Open total intra-abdominal colectomy
New code: 45.83 Other and unspecified total intra-abdominal colectomy

48.4 Pull-through resection of rectum

New code: 48.40 Pull-through resection of rectum, not otherwise specified
48.41 Soave submucosal resection of rectum
New code: 48.42 Laparoscopic pull-through resection of rectum
New code: 48.43 Open pull-through resection of rectum
48.49 Other pull-through resection of the rectum

48.5 Abdominoperineal resection of the rectum

New code: 48.50 Abdominoperineal resection of the rectum, not otherwise specified
New code: 48.51 Laparoscopic abdominoperineal resection of the rectum
New code: 48.52 Open abdominoperineal resection of the rectum
New code: 48.59 Other abdominoperineal resection of the rectum

Recommendation:
CMS recommends option 2. Create unique codes for the laparoscopic approach. In the meantime, continue to assign the existing procedure codes to capture these procedures.

Intra-Aneurysm Sac Pressure Measurement

Issue:
There is no unique ICD-9-CM procedure code that identifies the procedure of measuring intra-aneurysm sac pressure during endovascular aneurysm repair (EVAR) of abdominal aortic aneurysms (AAA) and thoracic aortic aneurysms (TAA).

New Technology Application:
No.

FDA Approval:
CardioMEMS' The EndoSure® Wireless Pressure Measurement System received 510(k) clearance on October 28, 2005 for measuring intra-aneurysm sac pressure during EVAR of AAA. It also received 510(k) clearance on March 15, 2007 for measuring intra-aneurysm sac pressure during EVAR of TAA.

Background:
An aneurysm is a bulge or balloon that forms in the wall of a blood vessel due to weakening and thinning of the layers of the vessel wall. Over time, the weakness of the wall progresses and the force of normal blood pressure in the aneurysm can lead to rupture. Abdominal aortic aneurysms (AAA) form in the portion of the aorta that lies in the abdomen, and thoracic aortic aneurysms (TAA) form in the segment of the aorta that lies in the thorax.

Endovascular aneurysm repair of AAA and TAA includes the placement of a stent graft inside the aneurysmal vessel without surgically opening the tissue surrounding the diseased vessel. The stent graft excludes the aneurysm from the functional lumen of the blood vessel. However, one potential complication during the EVAR procedure is an endoleak, or the leaking of blood around the graft and into the aneurysm sac. An endoleak causes continued pressurization of the aneurysm sac and may leave the patient at risk for subsequent aneurysm rupture. Standard clinical practice includes the use of imaging to determine if endoleaks are present at time of graft placement.

Another method used to detect endoleaks in conjunction with imaging is to evaluate sac pressure within the aneurysm. A successful endovascular aneurysm repair of AAA results in considerable pressure reduction in the aneurysm sac. The EndoSure® Wireless Pressure Measurement System provides intra-aneurysm sac pressure during EVAR. The System is comprised of two components: a miniaturized, wireless implantable sensor and an external electronics module. The external electronics module wirelessly communicates with the sensor to deliver sac pressure. The sensor is powered by RF energy transmitted from the electronics module, and provides real-time data without batteries.

The EndoSure® sensor comes pre-loaded in a one-piece 14 French delivery system that enables the physician to insert the sensor endovascularly during EVAR procedure. The sensor location can be viewed on angiography or CT scans. Pressure measurements are recorded prior to deployment of the stent graft, and are again recorded once the graft has

been placed. The surgeon is able to use the difference in pressure measurements to help determine if an endoleak is present. The EndoSure® sensor is intended to be a permanent implant in the aneurysm sac. Pressure measurements are not utilized in every EVAR procedure.

Options:

Option 1: Continue to code the intra-aneurysm sac pressure measurement to code 89.61, Systemic arterial pressure monitoring. Add inclusion term under code 89.61.

89.61 Systemic arterial pressure monitoring

Add inclusion term Insertion of intra-aneurysm sac pressure monitoring device (intraoperative)

Option 2: Create a new procedure code to uniquely capture the implantation of a wireless pressure sensor measurement system. Add code also note under code 39.71, Endovascular implantation of graft in abdominal aorta and code 39.73, Endovascular implantation of graft in thoracic aorta, to code this measurement system in addition to the endovascular aneurysm repair. Add exclusion note under code 89.61 to exclude this monitoring system.

New Code 00.58 Insertion of intra-aneurysm sac pressure monitoring device (intraoperative)
Insertion of pressure sensor during endovascular repair of abdominal or thoracic aortic aneurysms

39.71 Endovascular implantation of graft in abdominal aorta

Add code also note Code also intra-aneurysm sac pressure monitoring (intraoperative) (00.58)

39.73 Endovascular implantation of graft in thoracic aorta

Add code also note Code also intra-aneurysm sac pressure monitoring (intraoperative) (00.58)

89.61 Systemic arterial pressure monitoring

Add exclusion term Excludes: intra-aneurysm sac pressure monitoring (intraoperative) 00.58

CMS's Recommendation:

Option 2: Create a new procedure code to uniquely capture the implantation of a wireless pressure sensor measurement system. Add code also note under code 39.71, Endovascular implantation of graft in abdominal aorta and code 39.73, Endovascular implantation of graft in thoracic aorta, to code this measurement system in addition to the endovascular aneurysm repair. Add exclusion note under code 89.61 to exclude this monitoring system.

New Code 00.58 Insertion of intra-aneurysm sac pressure monitoring device (intraoperative)
Insertion of pressure sensor during endovascular repair of abdominal or thoracic aortic aneurysms

39.71 Endovascular implantation of graft in abdominal aorta
Add code also note Code also intra-aneurysm sac pressure monitoring (intraoperative) (00.58)

39.73 Endovascular implantation of graft in thoracic aorta
Add code also note Code also intra-aneurysm sac pressure monitoring (intraoperative) (00.58)

89.62 Systemic arterial pressure monitoring
Add exclusion term Excludes: intra-aneurysm sac pressure monitoring (intraoperative) 00.58

Interim Coding:
Continue to code the intra-aneurysm sac pressure measurement to code 89.61, Systemic arterial pressure monitoring.

Percutaneous Vertebral Augmentation

Issue: Code 81.66, Kyphoplasty, was effective on October 1, 2004. The code was created to differentiate this procedure for augmenting and stabilizing diseased vertebrae from conventional vertebroplasty which is identified under code 81.65, Vertebroplasty. Should the code title and inclusion terms for code 81.66 be modified to incorporate other comparable methods of vertebral augmentation?

New Technology Application:
No.

Background:

Both conventional vertebroplasty and vertebral augmentation are percutaneous procedures that treat fractured or otherwise diseased vertebrae using cement or other fillers.

Conventional vertebroplasty is a single step procedure in which bone cement, or polymethylmethacrylate (PMMA), is percutaneously injected into the vertebrae under imaging guidance. The cement hardens and stabilizes the vertebrae, preventing further progression of the fracture or vertebral collapse, thereby, reducing the associated pain. Vertebroplasty does not otherwise address the underlying vertebral collapse.

In contrast, vertebral augmentation is a two step procedure. Using a variety of techniques and devices, an attempt is made to mechanically augment or increase the vertebral body height, prior to injecting the cement filler. Kyphoplasty, for example, uses a technique that involves using an inflatable balloon to create a cavity or void into which cement is then injected. Other techniques involve inserting a jack, tamp, or other shaping tool to create spaces by displacing bone, then injecting cement or other fillers. In one technique, Spineoplasty, a space is created with a shaping tool and then filled with a mesh bag contain the filler. In another technique, thin implants are stacked on top of each other within the vertebral body prior to introducing the cement. Although a goal of augmenting the vertebrae may be to restore vertebral height, there is clinical uncertainty over whether height restoration is an established outcome.

The current definition of code 81.66 is “kyphoplasty”. According to the requestor, this term is considered proprietary as it specifically refers to the performance of a vertebral compression fracture repair using a particular balloon product. The existing inclusion note cites other devices but the definition restricts this. Also, because the manufacturer considers the creation of “cavities” or “voids” proprietary to its product, no other techniques use these terms.

The description “percutaneous vertebral augmentation” is already in common use as a generic nomenclature for the two step procedures; this is the term used in CPT.

Options:

Option 1. Continue to assign code 81.65, Vertebroplasty, for vertebroplasty procedures and code 81.66, Kyphoplasty, for procedures that augment the vertebrae to reestablish the height of the vertebrae.

Option 2. Revise the code titles and inclusion terms under code 81.66 to encompass all techniques of vertebral augmentation. The code title for code 81.65 would also be revised.

Revise code title	81.65	Percutaneous vertebroplasty
		Injection of bone void filler (cement) (polymethylmethacrylate) (PMMA) into the diseased or fractured vertebral body
Revise exclusion note		Excludes: ~~kyphoplasty~~ percutaneous vertebral augmentation (81.66)
Revise code title	81.66	~~Kyphoplasty~~ Percutaneous vertebral augmentation
Revise inclusion term		Insertion of inflatable balloon, bone tamp, or other device displacing (removing) (compacting) bone to create a space (cavity) (void) ~~for partial restoration of height of diseased or fractured vertebral body~~ prior to the injection of bone void filler (cement) (polymethylmethacrylate) (PMMA) to revise and stabilize diseased or fractured vertebrae (for partial restoration of height)
Add inclusion term		Kyphoplasty
Add inclusion term		Spineoplasty
		Excludes: percutaneous vertebroplasty (81.65)

Option 3. Collapse codes 81.65 and 81.66 into one code due to the clinical uncertainty over height restoration and the lack of consensus from the spine community on the differentiation between these various methods of vertebroplasty and vertebral augmentation.

Revise code title 81.65 Percutaneous vertebroplasty and percutaneous vertebral augmentation

Add inclusion term Kyphoplasty

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

Interim Coding:
Continue to assign code 81.65, Vertebroplasty, for vertebroplasty procedures and code 81.66, Kyphoplasty, for procedures that augment the vertebrae to reestablish the height of the vertebrae.

Flow Reserve and Intravascular Pressure Measurement

Issue: Fractional Flow Reserve (FFR) is a type of intracoronary pressure measurement which is currently assigned to code 89.69, Monitoring of coronary blood flow. However, listed under code 89.69 is an inclusion term, Coronary blood flow monitoring by coincidence counting technique, which does not fully capture the use of FFR. In addition, coding for coronary flow reserve measurement does not capture the use of intravascular pressure measurement outside of the heart. In some instances, intravascular pressure measurement may be viewed as adjunct to other procedures—*e.g.*, angiography and might not be coded at all. Distinct procedure codes for analogous intravascular ultrasound procedures (IVUS) have been created to address the same coding concerns. Should new procedure codes be created for FFR in coronary vessels and intravascular pressure measurement in non-coronary vessels?

New Technology Application:
No.

Background:
Fractional Flow Reserve (FFR) is a technique developed to assess the severity of coronary artery stenoses that might otherwise not be accurately measured by conventional angiography. FFR involves using a pressure sensitive catheter to compare the intravascular pressure distal to a coronary lesion to the mean aortic pressure proximal to the lesion at maximum hyperemia in order to develop a ratio between the two, which can then be used to assess the functional severity of the lesion in terms of limitation of blood flow. It is usually done in conjunction with other diagnostic coronary artery procedures in order to help determine the most appropriate therapeutic intervention, i.e. stenting or angioplasty. Fractional Flow Reserve also allows physicians to better diagnose more complex disease such as serial stenoses, diffuse disease and patients with multi-vessel disease. Such intravascular pressure measurements are also valuable after treatment in order to determine whether or not an intervention is successful, and they have also found utility in non-coronary vessels for similar clinical benefits.

Coronary blood flow monitoring, as coded under 89.69, covers coronary blood flow monitoring by another method known as coincidence counting technique. FFR measurement is clinically distinguishable from monitoring by coincidence counting technique. Whereas coincidence counting relies on measurements of radioactive tracers to estimate blood flow, FFR assesses blood flow using comparative pressure measurements, and FFR is the only method which has been proven in peer review clinical journals to be 100% specific for identification of ischemia-causing lesions.

As such, FFR has a unique role as a therapeutic adjunct, and it has been shown to provide a more reliable assessment of the functional severity of coronary lesions than that obtained with angiography alone.

Professional societies have long recognized that FFR is an effective modality for assessment of ischemia inducing lesions. The Society for Coronary Angiography and Intervention, American College of Cardiology, and American Heart Association have all acknowledged the importance of FFR in providing empirical data for use in clinical

decision making and have issued scientific statements describing its use, but because FFR does not have unique coding options to date there has been no way to track its use.

For analogous procedures such as IVUS, procedure codes 00.21 -00.29 have already been established. Intravascular pressure measurement and IVUS are similar in terms of resource utilization requirements: Intravascular pressure and IVUS provide different types of diagnostic data about the same underlying conditions. Both types of procedures provide data for assessing the need for either coronary or non-coronary vascular interventions. The services are comparably invasive and utilize comparable methodologies (i.e., guidewires and/or catheters) to obtain such data, but IVUS provides an anatomical assessment rather than a functional physiological assessment. Clinical research supports roles for both techniques in clinical decision-making and evaluation of interventional outcomes.

The rationale for distinct intravascular pressure codes is the same as for the IVUS codes that have already been implemented: utilization will be better tracked through hospital data to facilitate the analysis of resource alignment and procedure costs; Medicare will benefit from more accurate data on costs related to intravascular pressure measurement; providers will benefit for improved tracking or revenue and resource utilization; and clearer coding options will facilitate more accurate coding by providers.

Options:
Option 1. Continue to assign code 89.69, Monitoring of coronary blood flow, for FFR of coronary arteries. Continue to assign code 89.61, Systemic arterial pressure monitoring, for intravascular pressure measurement of intrathoracic and peripheral arteries. Continue to code 89.62, Central venous pressure monitoring, for intravascular pressure measurement of venous system.

Option 2. Create 1 new code under subcategory 00.5, Other Cardiovascular Procedures, and 3 new codes under 00.6 Procedures on Blood Vessels, describing the multiple uses of intravascular pressure measurements. Intravascular pressure measurements can be used to measure blood flow in a number of different arteries throughout the body, not just the coronary arteries.

00.5 Other Cardiovascular Procedures
New code 00.59 Intravascular pressure measurement of coronary arteries
Includes: fractional flow reserve (FFR)
Code also any synchronous diagnostic or therapeutic procedures

00.6 Procedures on Blood Vessels
New code 00.67 Intravascular pressure measurement of intrathoracic arteries
Assessment of:
aorta and aortic arch

Code also any synchronous diagnostic or therapeutic procedures

New code 00.68 Intravascular pressure measurement of peripheral arteries
Assessment of:
other peripheral vessels
renal vessels
vessels of arm(s)
vessels of leg(s)
Code also any synchronous diagnostic or therapeutic procedures

New code 00.69 Intravascular pressure measurement, other specified and unspecified vessels
Code also any synchronous diagnostic or therapeutic procedures

89.69 Monitoring of coronary blood flow
Add exclusion term Excludes: intravascular pressure measurement of coronary arteries (00.59)

Option 3. Revise the inclusion term under code 89.69 to include FFR.

89.69 Monitoring of coronary blood flow
Revise inclusion term Coronary blood flow monitoring by intravascular pressure measurement, fractional flow reserve (FFR) or coincidence counting technique

Option 4. Create a new code under subcategory 36.9, Other operations on vessels of heart. This option will allow FFR to be captured with a code that is accurately classified with other procedures on vessels of the heart and recognizes the invasive nature of FFR.

36.9 Other operations on vessels of heart

New code 36.92 Intravascular pressure measurement of coronary arteries
Fractional flow reserve (FFR)
Code also any:
Coronary angiography (88.50-88.58)
Intracoronary artery thrombolytic infusion (36.04)
Intravascular brachytherapy (92.27)
Percutaneous transluminal coronary artery angioplasty or atherectomy (00.66)

CMS's Recommendation: Option 2. As stated above.

Interim coding:
Continue to assign code 89.69, Monitoring of coronary blood flow, for FFR of coronary arteries. Continue to assign code 89.61, Systemic arterial pressure monitoring, for intravascular pressure measurement of intrathoracic and peripheral arteries. Continue to code 89.62, Central venous pressure monitoring, for intravascular pressure measurement of venous system.

Intravascular Spectroscopy

Issue:
There is no ICD-9-CM procedure code which is able to identify near infrared (NIR) spectroscopy.

New Technology Application?
Yes.

FDA Approval:
The fiber optic, catheter-based, near infrared (NIR) spectroscopy system is designed to characterize the composition of coronary plaques in patients undergoing cardiac catheterization. Presently, the NIR system is being evaluated by the Food & Drug Administration (FDA) in a clinical study for use in the detection of lipid rich coronary plaques. The manufacturer is hopeful that FDA clearance for this indication in early 2008.

Background:
InfraReDx™ has developed a fiber-optic, catheter-based NIR spectroscopy system designed for use in the detection of lipid rich coronary plaques, which would assist interventional cardiologists in determining the most appropriate type of stent to utilize depending on the presence, location, and amount of lipid rich plaque.

Visual interpretation of plaque type has been demonstrated with angioscopy as this technology allows for direct visualization inside the artery. However, angioscopy requires a blood-free field for proper imaging and this has relegated its use solely as a research tool. The NIR system overcomes this limitation because it can accurately detect this type of plaque through blood without the need to flush or occlude the artery. The system consists of a laser light source, an automated pullback and rotation device, a small fiber optic catheter, and the InfraReDx console. The intravascular Chemography (IVCG) catheter is a single use device that is similar to an intravascular ultrasound catheter, although it provides an optical signal rather than an ultrasonic signal.

The system is used during a coronary stenting procedure. The physician will use the NIR system to interrogate “plaques of interest”, usually after having addressed the culprit lesion causing symptoms. The imaging catheter is loaded onto a .014 inch guidewire then introduced through a 6 French guide catheter. The catheter has distal tip radio-opaque markers that the physician uses to select the optimal position for scanning the coronary artery. Once in position, the physician enables the rotation and pullback of the scanning probe inside the catheter by activating the pull-back and rotation device to which the catheter is attached, and the scan begins. It takes a couple of minutes for the entire scanning process to finish. The data collected is analyzed by the algorithms to produce a visual interpretation of the findings in the form of an intravascular chemogram. The catheter is then withdrawn and disposed of, while the console is wheeled from the procedure room and stored for the next case. Physicians will use the chemogram to aid their clinical judgment about the most appropriate patient care.

InfraReDx™ has developed an algorithm to analyze the spectral signals obtained through the catheter which crates a chemical map of spectra reflected by lipid rich plaques in coronary arteries. The map is interpreted by the interventional cardiologist during the procedure, and can be used to aid in the determination of the appropriate stent (drug eluting vs. bare metal) to implant and how to treat other lipid rich plaques of interest in the coronary arteries.

The detection of lipid rich plaques is believed to have a number of important clinical benefits. A number of issues have arisen with regard to the use of stents in the treatment of coronary artery disease, as recently discussed at the American College of Cardiology annual meeting. It was noted that drug eluting stents have been associated with late stent thrombosis and that stenting has not been shown to prevent subsequent myocardial infarction and cardiac death. The ability to detect lipid rich plaques can assist in determining whether it is appropriate for drug-eluting stent(s) to be implanted rather than bare metal stent(s). Studies have shown that thrombosis was much more frequent when a drug-eluting stent, compared to a bare metal stent, was implanted over a lipid rich plaque. Additionally, since lipid rich plaques are suspected of causing secondary events after stenting, understanding whether other present, but not stented plaques are lipid rich can influence the choice of treatment of such other plaques – aggressive medical therapy, stenting, surgery, or a combination thereof.

Coding Options:
Option 1: Do not create a new code. Continue to use codes in subcategory 00.2, Intravascular imaging of blood vessels.

Option 2: Create a new ICD-9-CM procedure code as follows:

	38.2	Diagnostic procedures on blood vessels
New code	38.23	Intravascular spectroscopy Includes imaging of both coronary and peripheral vessels Intravascular chemography Near infrared (NIR) spectroscopy

Option 3:
Create a new ICD-9-CM procedure code as follows:

	88.9	Other diagnostic imaging
New code	88.99	Intravascular spectroscopy Includes imaging of both coronary and peripheral vessels Intravascular chemography Near infrared (NIR) spectroscopy

CMS Recommendation:
Option 2; create new code 38.23, Intravascular Spectroscopy, as described above.

Interim Coding:
In the absence of a specific code, use codes in subcategory 00.2, Intravascular imaging of blood vessels.

Percutaneous Dilatational Tracheostomy

Issue:
Current ICD-9-CM coding does not distinguish between performing a tracheostomy using the traditional surgical approach, typically done in the Operating Room, from a newer approach called Percutaneous Dilatational Tracheostomy (PDT), which is typically performed at the bedside.

New Technology Application:
No.

Background:
Percutaneous dilatational tracheostomy is a type of tracheostomy that is usually done at the bedside. It involves making an incision in the skin over the tracheal cartilage and inserting a needle into the trachea through which a guidewire is inserted, and then using a dilator or dilators to create an opening by sliding them into the trachea over the guidewire. When the opening is large enough a standard tracheostomy tube is inserted and secured to the neck in standard fashion. Bronchoscopy is often, but not always, performed at the same time in order to visualize and confirm the placement of the needle, the guidewire and the dilators. The primary difference between percutaneous tracheostomy and the traditional open tracheostomy is that in the traditional procedure an opening is made in the trachea with a scalpel after it is surgically exposed, whereas in the percutaneous tracheostomy an opening is made in the trachea with dilators that are passed over a guidewire, making the procedure less invasive and allowing it to be performed at the bedside. An additional difference is the fact that in the case of percutaneous tracheostomy a bronchoscopy may be performed simultaneously to confirm the proper anatomical placement of the guidewire and dilators. Advantages of percutaneous dilatational tracheostomy are primarily related to the benefits of performing the procedure at the bedside rather than requiring the use of an operating room and to the fact that it is less invasive, although it is also possible to perform a traditional tracheostomy in a non-OR setting.

Current ICD-9-CM procedure codes available for tracheostomy are as follow:

31.1 Temporary tracheostomy
31.21 Mediastinal tracheostomy
31.29 Other permanent tracheostomy
31.74 Revision of tracheostomy

Code 31.29, Other permanent tracheostomy is currently used to capture percutaneous dilatational tracheostomy. The requestor does not believe this code adequately describes the approach and by association, the setting in which the tracheostomy was performed.

Coding options
Option 1: Continue using code 31.29, Other permanent tracheostomy, to identify Percutaneous Dilatational Tracheostomy. Revise this code by adding an inclusion term for percutaneous dilatational tracheostomy and a code also note for bronchoscopy, if performed.

	31.29 Other permanent tracheostomy
Add inclusion term	Percutaneous dilatational tracheostomy [PDT]
Add code also note	Code also any synchronous bronchoscopy, if performed (33.22 – 33.27)

Option 2: Create the following new code:

New code:	31.22 Percutaneous dilatational tracheostomy [PDT]
	Code also any synchronous bronchoscopy, if performed (33.22 – 33.27)

CMS Recommendation:
CMS recommends Option 1; continue using existing code 31.29, Other permanent tracheostomy and add the inclusion term to describe Percutaneous dilatational tracheostomy [PDT] with a code also note to assign a bronchoscopy code, if performed. Do not create a new code since the differences between the procedures are relatively small.

Interim coding:
Continue to assign existing code 31.29, Other permanent tracheostomy.

Repair of the Annulus Fibrosus

Issue:
Following a surgical discectomy, an open pathway or hole is left in the annulus fibrosus of the disc. Traditionally, the defect has primarily been left to heal. Not repairing this annular defect may contribute to recurrent disc herniation, a higher rate of reoperation, and poor patient outcomes. Today, surgeons are beginning to repair the annulus fibrosus by various techniques; however, there is not a unique ICD-9-CM code to describe this repair. Should a new code be created to identify repair of the annulus fibrosus?

New Technology Application?
No.

Background:
Discectomies are the most frequently performed spinal surgery. HCUP data shows that the majority of lumbar discectomies are performed in the inpatient hospital setting. Lumbar discectomy for the treatment of a herniated disc is a well-accepted surgical procedure with a proven track record. This surgery involves removal of protruding or extruding disc fragments that are compressing on the nerve root potentially giving rise to pain, numbness and/or weakness. However, there remains room to improve clinical outcomes and to reduce reoperation rates. Several clinical studies have reported that 28% of patients will continue to suffer from back or leg pain following a lumbar discectomy procedure. These patients will either continue with conservative medical treatment or will require a reoperation to relieve symptoms of pain. Large population-based studies report that reoperation rates after lumbar discectomy can range from 6 to 20% within 5 years.

Although the repair of residual open defects is common during most types of surgery, options have only recently become available for repair of the annulus fibrosus following lumbar discectomy surgery. Repairing and sealing the annulus fibrosus after a lumbar discectomy procedure for a herniated disc may reduce reoperations and improve patient outcomes by:

- Closing the annular defect to restrict nuclear material from re-extruding and compressing on the nerve root causing pain.
- Reducing inflammation and scar formation of the nerve root and surrounding tissues.
- Enabling less extensive disc material removal during the discectomy procedure allowing for better patient outcomes including lower back pain, faster return to work, less narcotic usage, and higher patient satisfaction.

Procedure:
Currently, surgeons have various options to repair the annulus fibrosus following a lumbar discectomy procedure including microsurgical suture repair, soft tissue re-approximation repair utilizing tension bands, and surgical mesh repair.

Microsurgical Suture Repair:
Microsurgical suture repair of the annulus fibrosus following lumbar discectomy is a technically difficult and time consuming procedure for which there are different variations of the technique. The most well documented technique provides closure of the annular defect by using two or three 4-0 absorbable sutures on half-circle needles that are placed through the annular tissue spanning the slit below the outer surface of the annulus and equidistant along the slit anulotomy incision. During the procedure, intraoperative assessment is performed to ensure tissue integrity. Additionally, an autograft can be used to augment the strength of the anuloplasty. When fascial autograft is used, a 10 by 4mm approximately sized autograft is harvested from the lumbodorsal fascia and positioned below the outer surface of the annulus and placed within the loops of two or more sutures. Each suture is then tied in succession, securing the autograft in place. After anular closure, the incision is irrigated thoroughly with normal saline solution containing bacitracin.

Soft Tissue Re-approximation Repair:
Soft tissue re-approximation repair of the annulus fibrosus following lumbar discectomy may currently be facilitated with the Xclose™ Tissue Repair System. This system consists of two sterile, disposable delivery tools containing polyester (polyethylene terephthalate) tension bands constructed of tension lines and T-anchor assemblies.

Physicians using the Xclose™ tissue repair device will perform a thorough intraoperative assessment of the annulus fibrosus to determine if the patient is an appropriate candidate. This evaluation will require assessment of the anular defect or slit anulotomy as well as tissue integrity. Following intraoperative assessment, the needle of the delivery tool is inserted into the anular tissue to deploy the first T-anchor assembly below the outer surface of the annulus. The delivery tool is then removed from the outer surface of the annulus, repositioned across the defect, and reinserted through the anular tissue on the opposite side of the defect. A second T-anchor assembly is then deployed below the surface of the annulus. The delivery tool is then removed and a knot pusher is used to secure the pre-tied knot against the outer surface of the annulus to close the defect by re-approximation of soft tissue. The trailing lines are then trimmed. This technique is usually repeated with a second tension band pre-loaded on a delivery tool.

Surgical Mesh Repair
Surgical mesh repair of the annulus fibrosus following lumbar discectomy may currently be facilitated with the Inclose™ Surgical Mesh System. This system consists of a polyester (polyethylene terephthalate) mesh and two anchor band assemblies pre-loaded on sterile, disposable delivery tools.

Physicians using the Inclose™ Surgical Mesh will perform a thorough intraoperative assessment of the annulus fibrosus to determine if the patient is an appropriate candidate. This evaluation requires assessment of the sub-tissue cavity constraint, size of the protrusion, and size of the defect opening. Following intraoperative assessment, the mesh pre-loaded on its delivery tool is placed below the surface of the annulus prior to being deployed. Following mesh deployment, the first anchor band delivery tool is inserted through the annular tissue and then through the mesh below the surface of the annulus. The anchor band is then deployed affixing the mesh to the annulus. The second anchor band is then inserted and deployed in a similar manner. The mesh delivery tool is then removed from the mesh and the trailing anchor band lines are trimmed to appropriate length.

Coding options:
Option 1: Do not create a new code.

Option 2: Create two new codes as follows:

New code 81.67 Repair of the annulus fibrosus with graft or prosthesis
Anular disc repair
Closure (sealing) of the annulus fibrosus defect

Includes: microsurgical suture repair with fascial autograft
soft tissue re-approximation repair with tension bands
surgical mesh repair

Code also any:
application or administration of adhesion barrier substance, if performed (99.77)
intervertebral discectomy, if performed (80.51)
locally harvested fascia for graft (83.43) ***Code updated since meeting.***

New code 81.68 Other and unspecified repair of the annulus fibrosus
Anular disc repair
Closure (sealing) of the annulus fibrosus defect
Microsurgical suture repair without fascial autograft
Percutaneous repair of the annulus fibrosus

Code also any:
application or administration of adhesion barrier substance, if performed (99.77)
intervertebral discectomy, if performed (80.51)

CMS Recommendation:
CMS recommends option 2; create two new codes as described above.

Interim coding: Continue to use code 03.99, Other operations on spinal cord and spinal canal structures, Other.

Addenda

Tabular

48.7 Repair of rectum
Excludes: repair of:
Revise exclusion term vaginal rectocele (70.50, 70.52, 70.53, 70.55)

70.50 Repair of cystocele and rectocele
Add exclusion term Excludes: repair of cystocele and rectocele with graft or prosthesis (70.53)

70.51 Repair of cystocele
Add exclusion term Excludes: repair of cystocele and rectocele with graft or prosthesis (70.53)
Add exclusion term repair of cystocele with graft or prosthesis (70.54)

70.52 Repair of rectocele
Posterior colporrhaphy
Add exclusion term Excludes: repair of cystocele and rectocele with graft or prosthesis (70.53)
Add exclusion term repair of rectocele with graft or prosthesis (70.55)

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Administration (of) - *see also* Injection
Add subterm Proleukin® (low-dose) 99.28
Add subterm high-dose 00.15

Arthrodesis
Revise subterm ~~plantar~~ pantalar 81.11

Debridement
Add subterm tendon 83.31

Embolization (transcatheter)
artery (selective) 38.80
Add subterm uterine (transcatheter) 99.29

Infusion (intra-arterial) (intravenous)

Add subterm interleukin-2

Add subterm high-dose 00.15

Add subterm low-dose 99.28

Add term Interleukin-2, infusion

Add subterm high-dose 00.15

Add subterm low-dose 99.28

Revise term VAD (vascular access device) - ~~*see* Implant, heart assist system~~
see vascular access device, totally implantable 86.07

Add term VAD (ventricular assist device) – *see* Implant, heart assist system