



Agenda

ICD-9-CM Coordination and Maintenance Committee
Department of Health and Human Services
Centers for Medicare & Medicaid Services
CMS Auditorium
7500 Security Boulevard
Baltimore, MD 21244-1850
ICD-9-CM Volume 3, Procedures
March 23 – March 24, 2006

Patricia E. Brooks
Co-Chairperson
March 23, 2006

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

Topics:

- | | |
|--|--|
| 1. Automated Mechanical Anastomosis
Pages 8-9 | Ann B. Fagan
Keith B. Allen, MD
Heart Center of Indiana |
| 2. Therapeutic Temperature
Management
Pages 10-12 | Ann B. Fagan
Mary Ann Peberdy, MD, FACC
Virginia Commonwealth University
Medical Center, Richmond |
| 3. Thermal Ablation of Renal Lesion or
Tissue, Liver Lesion and Lung Lesion
or Tissue
Pages 13-15 | Mady Hue
Derek Tessier, MSN, RNP
Tumor Ablation Program
Rhode Island Hospital |
| 4. Totally Endoscopic and Robot-Assisted
Transmyocardial Revascularization
Pages 16-17 | Mady Hue
Louis Brunsting, III, MD
The Heart Team, PLLC |
| 5. Endoscopic Insertion of Bronchial Valve
Pages 18-21 | Patricia E. Brooks
Douglas Wood, MD
University of Washington |

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| 6. Hip Resurfacing Arthroplasty
Pages 22-25 | Patricia E. Brooks
James Powell, MD
University of Calgary |
| 7. Hip Replacement Bearing Surfaces
Page 26 | Patricia E. Brooks |
| 8. Repair of Ventricular Septal Defect with
Prosthesis – Closed Technique
Pages 27-28 | Joe Kelly, MD |
| 9. Surgical Decompression with Insertion
of Interspinous Dynamic Stabilization
Device
Pages 29-34 | Mady Hue
Gary L. Lowery, MD, PhD
Paradigm Spine, LLC
New York, NY |
| 10. Stereotactic Placement of Intracerebral
Catheters
Pages 35-36 | Amy L. Gruber
Sandeep Kunwar, MD
University of California
San Francisco, CA |
| 11. Infusion of Cintredekin Besudotox
Pages 37-38 | Amy L. Gruber
Sandeep Kunwar, MD
University of California
San Francisco, CA |
| 12. Implantation of Visual Prosthetic Device
Pages 39-41 | Amy L. Gruber
Michael Raizman, MD
Associate Professor of Ophthalmology
Tufts University School of Medicine |
| 13. Addenda
Pages 42-45 | Mady Hue |
| 14. ICD-10 Procedure Classification System
(PCS) Update | Rhonda Butler, 3M |

Registering for the meeting:

Information on registering online to attend the meeting can be found at:

<http://www.cms.hhs.gov/apps/events/>

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

Please note this is the new website address that was effective December 15, 2005.

A summary of the diagnosis part of the meeting held on March 24 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:

December 15, 2005	CMS launched a new website redesign. Information relating to ICD-9-CM with links to the Coordination and Maintenance Committee (C&M) meetings will be posted on the CMS webpage at: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes
January 3, 2006	On-line registration opens for the March 23 – 24, 2006 ICD-9-CM Coordination and Maintenance Committee meeting at: http://www.cms.hhs.gov/events
January 23, 2006	Deadline for requestors: Those members of the public requesting that topics be discussed at the March 23 –March 24, 2006 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses by this date.

February 2006	<p>Draft agenda for the Procedure part of the March 23, 2006 ICD-9-CM Coordination and Maintenance Committee meeting posted on CMS homepage as follows: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes</p>
	<p>Draft agenda for the Diagnosis part of the March 24, 2006 ICD-9-CM Coordination and Maintenance Committee meeting posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm</p>
	<p>Federal Register notice of March 23 – March 24, 2006 ICD-9-CM Coordination and Maintenance Committee Meeting will be published.</p>
March 17, 2006	<p>Because of increased security requirements, those wishing to attend the March 23 – March 24, 2006 ICD-9-CM Coordination and Maintenance Committee meeting must register for the meeting online at: http://www.cms.hhs.gov/apps/events</p>
	<p>Attendees must register online by March 17, 2006; failure to do so may result in lack of access to the meeting.</p>
March 23 – March 24 2006	<p>ICD-9-CM Coordination and Maintenance Committee meeting.</p>
April 1, 2006	<p>There will not be any new ICD-9-CM codes implemented on April 1, 2006 to capture new technology.</p>
April 14, 2006	<p>Deadline for receipt of public comments on proposed code revisions discussed at the March 23-24, 2006 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2006.</p>
April 2006	<p>Notice of Proposed Rulemaking to be published in the <u>Federal Register</u> 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</p>
April 2006	<p>Summary report of the Procedure part of the March 23, 2006 ICD-9-CM Coordination and Maintenance</p>

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 24, 2006 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 2006

Final addendum posted on web pages as follows:

Diagnosis addendum at -

<http://www.cdc.gov/nchs/icd9.htm>

Procedure addendum at –

<http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes>

June 29, 2006

On-line registration opens for the September 28-29, 2006 ICD-9-CM Coordination and Maintenance Committee meeting at: <http://www.cms.hhs.gov/events>

July 28, 2006

Those members of the public requesting that topics be discussed at the September 28 – 29, 2006 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses.

August 1, 2006

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, 2006.

This rule can be accessed at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp>

August 2006

Tentative agenda for the Procedure part of the September 28 – 29, 2006 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 28 – 29, 2006 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 28 – 29, 2006 ICD-9-CM Coordination and Maintenance Committee

meeting will be published. This will include the tentative agenda.

September 22, 2006

Because of increased security requirements, those wishing to attend the September 28 - 29, 2006 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 22, 2006; failure to do so may result in lack of access to the meeting.

September 28 – 29, 2006

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 22, 2006**. You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.

October 2006

Summary report of the Procedure part of the September 29 – 30, 2006 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 29 – 30, 2006 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, 2006

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 13, 2006

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, 2007 will be posted on the following websites:

<http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes>

<http://www.cdc.gov/nchs/icd9.htm>

December 4, 2006

Deadline for receipt of public comments on proposed code revisions discussed at the September 28-29, 2006 ICD-9-CM Coordination and Maintenance Committee meetings for implementation of October 1, 2007.

Automated Mechanical Anastomosis

Issue:

There is no unique ICD-9-CM code describing automated mechanical anastomosis.

New Technology Application?

Yes

FDA Approval:

In a letter dated November 10, 2005, the Cardica® C-Port™ Anastomosis System was deemed substantially equivalent to legally marketed predicate devices. The intended use of this device is for the creation of anastomoses in blood vessels and grafts, including use in coronary artery bypass grafting (CABG) procedures.

Background:

According to the American Heart Association, approximately 13.2 million Americans have coronary artery disease (CAD), with approximately 653,000 people in the United States dying each year as a result of this disease. CAD, also known as atherosclerosis, is a degenerative disease resulting from the deposit of cholesterol and other fatty materials on the interior walls of blood vessels, forming a build-up known as plaque. The accumulation of plaque, usually over decades, causes the vessel to become inelastic and progressively narrows the interior of the artery, impairing its ability to supply blood and oxygen to the heart muscle. When there is insufficient blood flow to the heart muscle, injury may occur, often resulting in chest pain (angina), heart attack, or even death. CAD is caused by aging and is exacerbated by dietary and environmental factors, as well as by genetic predisposition. As patients age, the disease will typically advance and become more diffuse, compromising the coronary artery system more globally and occluding more small-diameter vessels.

There are a variety of treatments addressing CAD, including pharmaceuticals, balloon angioplasty, stenting, and CABG. The type of treatment selected often depends on the stage and severity of the disease and the age of the patient. Patients with severe and multi-vessel disease are often most effectively treated with CABG. An estimated 260,000 CABG procedures were performed in the US in 2005, and it is estimated that those procedures required approximately 1.2 million anastomoses. The Cardica® C-Port™ system is indicated for all patients requiring a vein as a conduit during CABG.

Technique: The device consists of 8 stainless steel clips and a delivery system. In preparing to deploy the C-Port™ system, the surgeon cuts the end of the bypass graft as s/he would for a hand-sewn anastomosis and attaches the graft to four small hooks situated on the base of the cartridge. The surgeon then creates a small incision in the target coronary artery and inserts the anvil, a small metal structure of one millimeter diameter. Pressing the button on the C-Port™ system handle, the surgeon lowers the cartridge with the graft attached onto the target coronary artery, and then deploys the staples through the graft and coronary artery against the anvil. The staples are formed on the anvil surface, joining the coronary artery and graft. In addition, a small knife located

inside the anvil is released to cut the coronary artery from the inside out to create an opening in the coronary wall through which the blood can flow. Following completion of the anastomosis, the surgeon removes the anvil from the coronary artery and manually stitches the small opening initially created to insert the anvil.

The intent of the system is to substantially improve patient outcomes by improving the durability and patency of coronary artery bypass grafts and to facilitate minimally invasive surgical approaches. It is designed to create a fully compliant end-to-side anastomosis between a vein graft and a coronary artery in less time than is required to create a hand-sewn distal anastomosis. The number of times this closure device would be deployed depends on the number of CABGs performed.

Coding Options:

Option 1:

Do not assign a new code for this type of procedure. The ICD-9-CM structure does not capture this level of detail, and closure of CABG anastomosis(es) is inherent in the CABG procedure. The most logical subcategory for this procedure, 39.3, Suture of vessel, has a clear exclusion note that instructs: Excludes: any other vascular puncture closure device – omit code. Additionally, this device has been deemed substantially equivalent to legally marketed predicate devices; we do not code those devices.

Option 2:

Create a new code as follows:

	39.3	Suture of vessel
Revise note		Excludes: any other vascular puncture closure device – omit code, <u>except automated mechanical anastomosis for CABG (39.33)</u>
New code	39.33	Automated mechanical anastomosis Note: adjunct code used for CABG procedures anastomosis delivery system with staples
	36.1	Bypass anastomosis for heart revascularization Code also:
Add note		automated mechanical anastomosis, if performed (39.33)

Recommendation:

CMS has concerns about creating a new code for this device, as it represents a confusing deviation from standard coding practice. We currently do not code intestinal anastomoses, nor do we code the use of a stapling device for any closures. Closing the operative site is inherent in the procedure. CMS welcomes comments from attendees as well as relevant, evidentiary comments via e-mail.

Interim Coding:

Do not code the use of this device, as no unique code exists to identify it. Current coding guidelines are clear that closure of vascular puncture, by any means, is not to be coded separately.

Therapeutic Temperature Management

Issue:

Current ICD-9-CM procedure codes do not provide a unique code to capture therapeutic temperature management, including both maintenance of normal temperature (i.e. fever control) and controlled induction and reversal of therapeutic hypothermia.

New Technology Application:

No

FDA Approval:

October 26, 2000: The FDA determined the Arctic Sun™ temperature management system to be substantially equivalent to other devices already in the market. The system is indicated for monitoring and controlling patient temperature between 33° C to 37° C. The indications include any condition where patient temperature control within a range covering mild hypothermia to normothermia is required.

Background:

Therapeutic temperature management is a method for induction and reversal of hypothermia and sustained patient temperature control. The purpose of this therapy is to prevent the impairment of brain function in critically ill patients who are at high risk of permanent neurological injury resulting from fever caused by cardiac arrest, stroke, or traumatic brain injury. Normothermia is the maintenance of patient temperature within the normal range (36.5-37° C). When provided as therapy, the purpose of normothermic temperature control is to prevent the impairment of brain function in critically ill patients who are at high risk of permanent neurological injury resulting from uncontrolled fever following cardiac arrest, stroke, or traumatic brain injury.

In a study of patients hospitalized with acute brain injuries, 83% of cardiac arrest patients, 70% of subarachnoid bleeding patients, and 68% of head injury patients developed fever. Several clinical studies have found that fever is an independent predictor of poor outcome following the above brain injuries. In a study of a large cohort of neurological ICU patients, after controlling for severity of illness, age, and complications, it was reported that elevated temperature was independently associated with longer ICU and hospital length of stay, higher mortality rate, and worse overall outcome.

Cardiac Arrest (Anoxic Brain Injury): Two research studies published separately in the New England Journal of Medicine detailed the benefits of inducing mild hypothermia in comatose survivors of hospital cardiac arrest. In one European study, 275 resuscitated cardiac arrest patients were randomized to standard care or to mild hypothermia for 24 hours. The hypothermia group showed a statistically significant favorable neurologic outcome compared to the normothermia group. Additionally, the hypothermia group showed a statistically significant favorable neurologic outcome as well as survival outcomes compared to the normothermia group.

Based on published evidence to date, the Advanced Life Support Task Force of the International Liaison Committee on Resuscitation (ILCOR) has made the following recommendations:

- Unconscious adult patients with spontaneous circulation after out-of-hospital cardiac arrest should be cooled to 32-34° C for 12-24 hours when the initial rhythm is ventricular fibrillation (VF).
- Such cooling may also be beneficial for other rhythms or in-hospital cardiac arrest.

These recommendations were incorporated into the American Heart Association Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiac Care.

Stroke: Mild hypothermia has been used as a method of neuroprotection in neurosurgical procedures and cardiopulmonary bypass for decades. In ischemic stroke, a central core of damage is surrounded by an area of hypoperfused and potentially salvageable tissue, known as the penumbra. With the promising clinical data on the efficacy of hypothermia post cardiac arrest, new interest has been raised in the use of hypothermia for neuroprotection in ischemic stroke patients. No pivotal clinical trials have yet been performed in this ischemic stroke population, several feasibility trials have demonstrated the ability to safely induce and reverse hypothermia in ischemic stroke patients, with encouraging trends towards reduced brain injury in patients who were cooled.

Acute Myocardial Infarction: Preclinical studies have demonstrated potential benefits of mild hypothermia in animal models with myocardial infarction. These studies have shown consistent reductions in infarct size, improvements in hemodynamics, and preserved ventricular function without an increase in potentially harmful arrhythmias. Mild hypothermia has been used to determine if the same benefit seen in animal models could be attained in randomized clinical trials.

COOL-MI was a prospective, multi-center trial to evaluate the safety and effectiveness of cooling as adjunctive therapy to primary percutaneous coronary intervention (PCI) for acute MI compared to PCI alone. The 375 patients presented to the tertiary hospital within 6 hours of symptom onset with either anterior MI or inferior MI. Patients were randomized to receive either primary PCI or primary PCI + cooling to a target temperature of 33° C maintained for a 3-hour interval, and then warming. No significant differences were seen between the treatment groups in the primary efficacy endpoint (infarct size at 30 days). However, an analysis based on infarct location found that those patients with anterior MI who were cooled to 35° C or less at the time of reperfusion had significantly smaller final infarct size than control patients with anterior MI.

The current practice of providing mild hypothermia to survivors of cardiac arrest include the available methods of packing the entire body in ice, infusion of iced saline, iced gastric lavage, and traditional water and air blankets. There is a lack of ability to control the depth of hypothermia within a reasonable degree of predictability, which may lead to overshooting of the target temperature, placing the patient at further risk of complications. Additionally, ice packs and water blankets invariably leak, leading to an

unstable patient potentially in need of defibrillation in a puddle of water. This is a safety concern for both patient and caregiver.

The key distinction in the Arctic Sun™ temperature management system is that the direct conduction of thermal energy through the unique hydrogel patient pads, combined with the feedback control of the system, results in efficient and precise temperature management unlike anything currently accomplished with existing technology.

Current Codes:

There is no ICD-9-CM code describing warming. The Index entry “hypothermia” sends coders to two codes:

- 99.81, Hypothermia (central) (local).
- 39.62, Hypothermia (systemic) incidental to open heart surgery.

Note: Both these codes are in the original ICD-9-CM procedures, adopted in 1979.

Coding Options:

Option 1:

Continue to use 99.81, Hypothermia (central) (local), and 39.62, Hypothermia (systemic) incidental to open heart surgery, as appropriate. This type of therapy can be considered an integral part of inpatient care for critically ill patients meeting clinical criteria.

Additionally, this specific device is substantially equivalent to other devices already in the market. These like-devices are not identified with a specific code. We do not believe a unique code is warranted.

Option 2:

Create a new code as follows:

	99.8	Miscellaneous physical procedures
new code	99.87	Controlled (systemic) temperature management Hydrogel contact pads for direct thermal conduction Induction, maintenance, and reversal of mild hypothermia Maintenance of normothermia

Excludes:

Hypothermia (central) (local) (99.81)
Hypothermia (systemic) incidental to open heart surgery (39.62)

CMS Recommendation:

CMS is interested in receiving comments from meeting attendees, and thoughtful, evidence-based comments in subsequent e-mail comments from the general public.

Interim Coding:

Continue to use 99.81, Hypothermia (central) (local), and 39.62, Hypothermia (systemic) incidental to open heart surgery, as appropriate, to describe temperature management.

Thermal Ablation of Liver, Lung, and Renal Lesions or Tissues

Issue: The ICD-9-CM procedure code system includes specific codes for ablation procedures, however, it does not currently contain codes that describe and differentiate the unique procedures involving thermal ablation of liver, lung and renal lesions or tissues. Should new codes be created to capture thermal ablative procedures for these specific sites?

New Technology Application?

No

Background:

In 2005, the American Cancer Society estimated there would be approximately 17,550 new cases of liver cancer, 172,570 new cases of lung cancer and 36,160 new cases of kidney cancer.¹

Thermal ablative procedures that use heat to destroy liver, lung, or renal lesions apply energy to a specific lesion for the purpose of achieving lesion destruction. Energy derived from the radiofrequency bandwidth originates from a base generator and is transmitted through the ablation device causing lesion cell death via coagulation necrosis. Active ablation generally lasts ten to fifteen minutes but it can be longer depending on the number of lesions being treated.²

Thermal ablation can be performed by one of three methods: open, laparoscopic, and percutaneous. Prior to the procedure the patient receives general anesthesia or conscious sedation. Once sedated, the patient is positioned to provide the best angle necessary for accurate device placement.

The *open* or surgical approach to thermal ablation involves the physician creating an incision to provide greater visual identification for ablation device placement. After the ablation generator is activated and has completed its cycle, the physician removes the device and closes the incision via traditional methods.

Laparoscopic thermal ablation involves the physician inserting the ablation device into the lesion with the assistance of the laparoscope, and imaging guidance, if necessary. After the ablation generator is activated and has completed its cycle, the physician removes the device and closes the small incisions with a few sutures.

Percutaneous thermal ablation involves the physician inserting the ablation device through the skin and into the lesion. To achieve accurate device placement, the physician will employ ultrasound or computed tomography guidance. After the ablation generator is activated and has completed its cycle, the physician removes the ablation device and places a bandage over the insertion point.

Coding Options:

Option 1:

Continue to use existing codes:

50.29, Other destruction of lesion of liver

32.28, Endoscopic excision or destruction of lesion or tissue of lung

32.29, Other local excision or destruction of lesion or tissue of lung

55.39, Other local destruction or excision of renal lesion or tissue

Option 2:

Create 4 new codes in subcategory 50.2, as follows:

New code	50.23	Open thermal ablation of liver lesion or tissue
New code	50.24	Percutaneous thermal ablation of liver lesion or tissue
New code	50.25	Laparoscopic thermal ablation of liver lesion or tissue
New code	50.26	Other and unspecified thermal ablation of liver lesion or tissue

50.29 Other destruction of lesion of liver

Add exclusion term *Excludes: thermal ablation of liver lesion (50.23-50.26)*

Create 4 new codes in subcategory 32.2, as follows:

New code	32.23	Open thermal ablation of lung lesion or tissue
New code	32.24	Percutaneous thermal ablation of lung lesion or tissue
New code	32.25	Endoscopic thermal ablation of lung lesion or tissue
New code	32.26	Other and unspecified thermal ablation of lung lesion or tissue

32.29 Other local excision or destruction of lesion or tissue of lung

Add exclusion term *Excludes: thermal ablation of lung lesion or tissue (32.23-32.26)*

Create 4 new codes in subcategory 55.3, as follows:

New code	55.32	Open thermal ablation of renal lesion or tissue
New code	55.33	Percutaneous thermal ablation of renal lesion or tissue
New code	55.34	Laparoscopic thermal ablation of renal lesion or tissue
New code	55.35	Other and unspecified thermal ablation of renal lesion or tissue

55.39 Other local excision or destruction of renal lesion or tissue

Add exclusion term *Excludes: thermal ablation of renal lesion or tissue (55.32-55.35)*

Recommendation:

CMS recommends option 2, create new codes as described above to differentiate among the various approaches. We would also like to hear from the audience regarding the option to consider revising the titles of the subcategories to include the term “ablation.”

Interim Coding:

Use codes identified in Option 1 as follows:

Use code 50.29, Other destruction of lesion of liver for thermal ablation of lesion of liver

Use code 32.28, Endoscopic excision or destruction of lesion or tissue of lung

Use code 32.29, Other local excision or destruction of lesion or tissue of lung for thermal ablation of lesion or tissue of lung

Use code 55.39, Other local destruction or excision of renal lesion or tissue for thermal ablation of renal lesion or tissue

¹ American Cancer Society
<http://www.cancer.org>

² National Institutes of Health; Radiofrequency Ablation: Frequently Asked Questions.
<http://clinicalcenter.nih.gov/drd/rfa/frame-faq.html>

Totally Endoscopic and Robot-Assisted Transmyocardial Revascularization

Issue: ICD-9-CM captures transmyocardial revascularization (TMR) with procedure code 36.31 for open chest TMR and code 36.32 for percutaneous, thoracoscopic, and other TMR approaches. Should new codes be created to differentiate between the percutaneous and endoscopic approaches currently captured in code 36.32?

New Technology Application?

No

Background:

Transmyocardial revascularization (TMR) is indicated as an isolated procedure in patients who have been diagnosed with NYHA Class III – IV angina and are not suitable candidates for percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) surgery. This group of patients normally exhibits a left ventricular ejection fraction (LVEF) of > 25% and has mild to nonexistent congestive heart failure. It is hypothesized that TMR creates channels in the left ventricular myocardium inducing angiogenesis (the formation of new vessels from preexisting vessels via cellular outgrowth) and partial cardiac denervation.

The traditional approach to TMR is through an anterolateral thoracotomy. TMR is a surgical technique which uses a laser to bore holes through the myocardium of the heart in an attempt to restore perfusion to areas of the heart not being reached by diseased or clogged arteries. This technique is used as a late or last resort for relief of symptoms of severe angina in patients with ischemic heart disease not amenable to direct coronary revascularization interventions, such as angioplasty, stenting, or open coronary bypass. Studies indicate that sole therapy TMR results in reduced pain, shorter hospitalization, and improved long-term survival.

The totally endoscopic technique offers a minimally invasive approach and improved visualization. Patients are placed in the right lateral decubitus position under general anesthesia with independent lung ventilation. Four thoracoscopic ports are placed through < 3 cm incisions. Visualization takes place through the endoscope using a single channel for thoracoscopic (2-D vision) and dual channel for robotic (3-D vision). If pleural adhesions are present, they are lysed. The pericardium is opened and scar tissue divided to expose the surface of the heart. Next, transmyocardial channels are created in the left ventricular free wall with laser energy. Once hemostasis is achieved, drains are placed, the endoscopic equipment removed, and the port sites closed. This method allows for a broader patient selection, such as those who were not candidates for sternotomy or thoracotomy approaches. Studies demonstrate that patients who undergo the totally endoscopic technique have a shorter recovery period as well.

Some physicians utilize robotics in performing TMR procedures. ICD-9-CM does not currently differentiate between procedures performed with or without robotics.

Endoscopic Insertion of Bronchial Valve

Issue

The current ICD-9-CM codes do not clearly describe the endoscopic insertion of a bronchial valve, which is a new therapy used in the treatment of chronic obstructive pulmonary disease. The endoscopically placed bronchial valve closes during inspiration and opens during expiration, helping to reduce air trapping and hyperinflation, and it is a less invasive alternative to lung volume reduction surgery and/or lung transplant. This procedure is currently captured with codes 33.22, Fiber-optic bronchoscopy, and 96.05, Other intubation of respiratory tract. These codes do not capture the fact that a valve was inserted into the bronchial tree.

New Technology Application

Planning for an application for FY2008 (October 2006 submission).

FDA Approval

FDA approval for the Spiration IBV™ Valve for treatment of chronic air leak associated with lung disease is expected in mid-2006. FDA approval for the Emphasys Medical Zephyr™ EBV™ Valve for severe emphysema is expected by 2008 and the Spiration IBV™ Valve for the additional indication of severe emphysema is expected by 2008.

Background

It is estimated that 16 million people suffer from chronic obstructive pulmonary disease (COPD) in the United States alone. COPD is a family of lung diseases characterized by a combination of chronic bronchitis and emphysema that leads to obstruction of airflow during exhalation. It is the fourth leading cause of death in the United States and the fifth leading cause of death in the world.

Emphysema is a progressive disease characterized by destruction of the alveolar walls and capillaries, severe loss of pulmonary elastic recoil, hyper-expansion of diseased lungs and narrowing of the airways. Progressive physical activity limitations become evident and these patients experience increasing dyspnea and poor quality of life. Despite the seriousness and prevalence of the disease, treatment of emphysema has been generally unsatisfactory because it has traditionally been non-curative.

Only a small percentage of the patient population with emphysema and COPD is eligible for lung transplant surgery or lung volume reduction surgery (LVRS). Lung transplant and LVRS are both invasive surgical procedures and have significant associated morbidity and mortality. Approximately 80% of selected patients referred for LVRS are ineligible for this surgical treatment. Although this is sometimes due to issues with the indications, the great majority of these fragile patients are ineligible because of concerns about morbidity associated with the surgical procedure.

There are no approved, minimally invasive procedures or devices for this patient population. The vast majority of this patient population currently receives only medical

therapy and/or pulmonary rehabilitation and experiences a gradual, uninterrupted decline in pulmonary function, exercise tolerance and quality of life.

Clinical studies are underway which focus on an endobronchial approach to emphysema treatment. This approach involves the use of a one way endobronchial valve that blocks air from going into a diseased segment but allows air to escape. The device is either a small umbrella shaped valve or a reinforced duckbill valve that is placed in the bronchial tree using standard bronchoscopic techniques. Its intent is to limit the ventilation of targeted sections of the lung while still allowing trapped air and normal secretions to flow out. By limiting ventilation in part of the diseased lungs, the remaining healthier portions of lung may function with better efficiency. (The intent of LVRS is similar in that it improves the functioning of healthy tissue by excising diseased portions of the lung.)

Typically, multiple valves are placed during an operative episode. Physicians determine the number of valves to be placed by the extent of the disease as assessed on CT scan. On average, between 6 and 7 valves are placed during a procedure. The valves are intended to be permanent, but are designed to be removed for displacement, malfunction or other complication, if necessary.

The valves are also being studied for use in the treatment of chronic air leaks. Patients can experience persistent air leaks as a result of traumatic, iatrogenic or spontaneous causes. These patients are typically managed with chest tubes, Heimlich valves and surgery, or combinations of all three. These persistent air leaks cause patients to be at increased risk for other complications and prolonged hospitalization. The use of the airflow redirection valves may allow patients to be managed without external catheters and allow for earlier hospital discharge.

Current Coding Issues

As stated earlier, there is no ICD-9-CM code to capture the endoscopic insertion of a bronchial valve. To capture this procedure, one must assign the following:

33.22, Fiber-optic bronchoscopy

96.05, Other intubation of respiratory tract

These codes do not clearly describe the procedure since it is performed for therapeutic, not diagnostic purposes. Subcategory 33.2 contains diagnostic procedures on the lung and bronchus. However, there is no other ICD-9-CM code that clearly describes the fact that a valve is inserted in the bronchus. A more precise means of identifying the insertion of these devices is needed.

The removal of these devices is captured through code 97.49, Removal of other device from thorax. While this code captures the fact that a device was removed, it does not clearly identify that the device was a valve within the bronchial tree.

Coding Options

1. Do not create new ICD-9-CM codes for this procedure. Continue using codes 33.22 and 96.05 to capture the insertion of the endoscopic insertion of the bronchial airflow valve and code 97.49 for the removal of the valve.
2. Create a new subcategory for therapeutic, endoscopic insertion of devices in the bronchus or lung.

New subcategory	33.7	Endoscopic insertion, replacement and removal of therapeutic device in bronchus or lung endobronchial airflow redirection valve intra bronchial airflow redirection valve Excludes: insertion of tracheobronchial stent (96.05)
New code	33.70	Endoscopic insertion or replacement of bronchial valves, not otherwise specified
New code	33.71	Endoscopic insertion or replacement of 1 to 3 bronchial valves
New code	33.72	Endoscopic insertion or replacement of 4 to 6 bronchial valves
New code	33.73	Endoscopic insertion or replacement of 7 or more bronchial valves
New code	33.74	Endoscopic removal of bronchial valve(s)
New code	33.79	Endoscopic insertion of other bronchial devices
Add exclusion term	33.2	Diagnostic procedures on lung and bronchus Excludes: endoscopic insertion or replacement of bronchial valve (33.70-33.73)
Add exclusion term	96.05	Other intubation of respiratory tract Excludes: endoscopic insertion or replacement of bronchial valve (33.70-33.73)

- Add exclusion term 97.49 Removal of other device from thorax
Excludes:
Endoscopic removal of bronchial valve (33.74)
- Add exclusion term 98.15 Removal of intraluminal foreign body from trachea and
bronchus without incision
Excludes:
Endoscopic removal of bronchial airflow redirection
valve (33.74)

Recommendation:

CMS recommends option 2, create new codes for the endoscopic insertion and removal of bronchial valves. In the meantime, continue capturing the insertion of bronchial valves with codes 33.22 and 96.05. Capture the removal of the bronchial valves with code 97.49.

Hip Resurfacing Arthroplasty

Issue:

Currently there is no ICD-9-CM code that adequately describes the hip resurfacing arthroplasty procedure. This procedure is different from traditional hip replacement which involves resection of the head and the majority of the neck of the femur. Hip resurfacing involves grinding away the worn surfaces of the femoral head and acetabulum and the placement of new bearing surfaces. This procedure is currently captured through code 81.52, Partial hip replacement when only one of the surfaces is replaced and code 81.51, Total hip replacement, when both the femur and acetabulum surfaces are replaced. The codes do not accurately reflect the procedure.

New Technology Application: No.

FDA Status:

The PMA (P040033) for the Birmingham Hip Resurfacing System is currently under review by FDA. The FDA's Orthopaedic and Rehabilitation Devices Panel met on September 8, 2005 to review the Birmingham Hip Resurfacing System PMA, and the Panel voted for approval of the PMA with the condition that a post-approval study be conducted.

Background:

Hip resurfacing is intended as a primary joint replacement for patients who are at risk of requiring more than one hip joint replacement over their lifetimes. Factors that increase the risk of revision surgery include younger age and/or a high activity level. Hip resurfacing can delay total hip replacement and potentially eliminate the need for a revision. Evidence suggests that it will become the procedure of choice for patients who wish to maintain a relatively active lifestyle.

The PMA submission to the FDA reported on results of 2,385 procedures. The primary effectiveness measurement was implant survival. The all patient 5 year survivorship was 98.4%.¹ Comparable survivorship is seen in patients 65 years of age and older.²

The hip resurfacing procedure is distinct from traditional hip replacement. Traditional total hip replacement (THR) dictates resection of the head and the majority of the neck of the femur and reconstruction with a stem and replacement head as shown in diagram 1. On the acetabular side the socket requires reaming to fit the shape of the metal / titanium shell which is press fit or cemented into the reamed cavity. This shell usually requires a bearing surface insert which articulates with the head.

In contrast, resurfacing utilizes instruments that machine or grind away just the worn surfaces on the femoral head, retaining the femoral neck and majority of the femoral head. Then a cobalt chrome cap is placed over the machined surfaces of the femoral head (Diagram 2) which articulates with a metal shell press fitted into a reamed acetabulum. The technique on the acetabular side is almost identical to that of uncemented THR except that there is no insert into the shell. That is, the articulation is metal on metal.

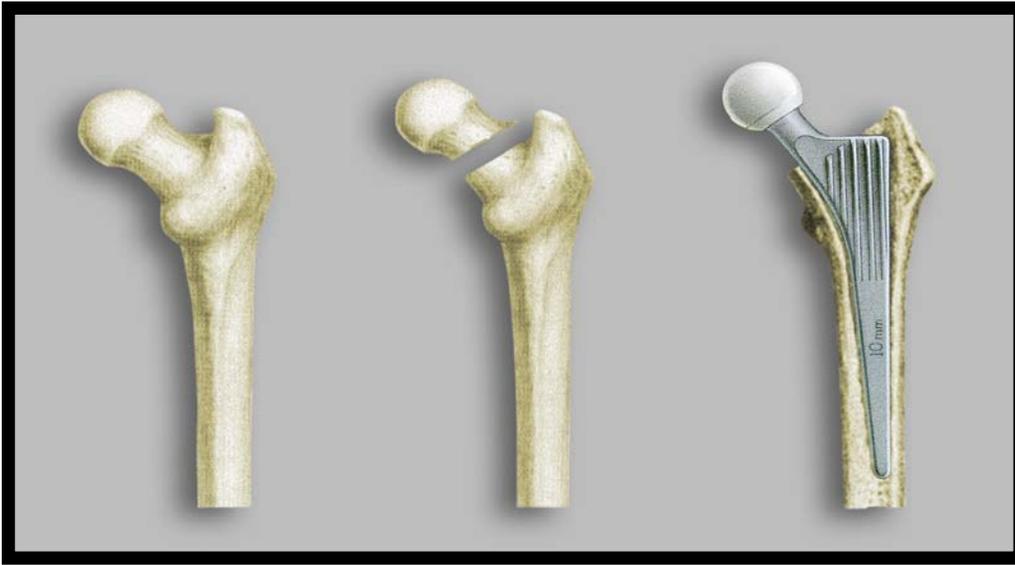


DIAGRAM 1. Traditional Hip Replacement

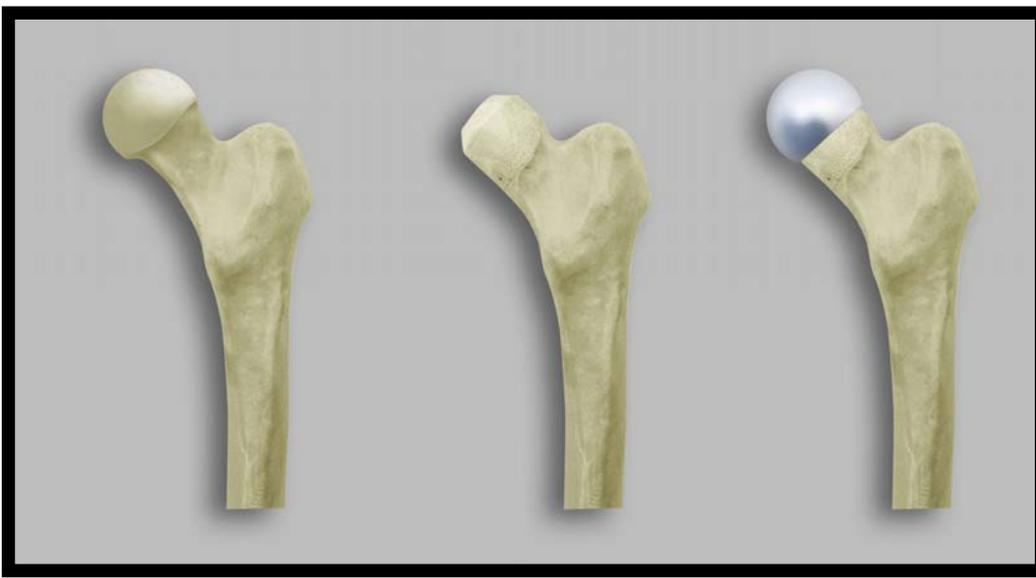


DIAGRAM 2. Hip Resurfacing

While there are many similarities between the two operations, the procedures have some important differences. They both can be done via the posterior approach. However, the resurfacing procedure is far more soft tissue aggressive. This is required to obtain adequate exposure to perform the reaming of the acetabulum without resection of the femoral head and neck. The incision is usually larger, the gluteus maximus insertion onto the femoral shaft is released and a circumferential capsulotomy is required. These releases are not usually required in a standard THR exposure.

Perhaps the most technically demanding step in the operation is the insertion of the guide wire into the femoral head that dictates the eventual positioning of the femoral component. If this is not done exactly, it can lead to varus placement or notching of the femoral neck. The guide wire position then dictates the pivot point over which you sleeve cut, plane and ream the head to a shape that fits the cemented femoral component.

The hip resurfacing can involve a resurfacing of only the femoral head. In this case it is referred to as a partial or hemi-resurfacing. The indications for partial resurfacing is Ficat stage II or early stage IV osteonecrosis of the femoral head. The acetabular cartilage would be minimally diseased. A total resurfacing involves the resurfacing of both the femoral and acetabular surfaces. The indications for total resurfacing are end-stage degenerative joint disease, regardless of cause, when there is satisfactory proximal femoral bone stock and anatomy to allow resurfacing. The majority of patients undergoing a total hip resurfacing have osteoarthritis with about 10% having osteonecrosis (advanced Ficat stage IV).

Partial resurfacing with the currently available implants has relatively unpredictable pain relief and is not recommended as a treatment for osteoarthritis or any inflammatory disease. Although mechanical failure of partial resurfacing is rare, unsatisfactory pain relief can lead conversion of the partial resurfacing to a total hip replacement within 5 years (removing the femoral head and neck with the femoral resurfacing component and then inserting a conventional total hip stem, ball and socket).

With the current generation of resurfacing implants, some painful hemi-resurfacings may be converted to a total resurfacing. This involves retaining the femoral side implant and inserting an acetabular component that mates to it. Total hip resurfacing has consistently good pain relief.

Total resurfacing involves inserting components into the femur and the acetabulum while the partial or hemi-resurfacing involves only the femoral side. However, as stated earlier, a patient may undergo a partial resurfacing of the femoral side and then later require a resurfacing of the acetabular component.

References:

1. Smith & Nephew BHR Orthopaedic and Rehabilitation Devices Panel Meeting Presentations, September 8, 2005.
2. Smith & Nephew data on file.

Options:

1. Do not create a new code for this procedure. Continue assigning code 81.52, Partial hip replacement, to capture partial hip resurfacing arthroplasty and 81.51, Total hip replacement, to capture total hip resurfacing arthroplasty..
2. Develop a new code to clearly identify hip resurfacing arthroplasty as follows:

Add:	81.51 Total hip replacement Excludes: Hip resurfacing, total (00.85)
Add:	81.52 Partial hip replacement Excludes: Hip resurfacing, partial (00.86 – 00.87)
Revise	00.8 Other knee <u>and hip</u> procedures
New code	00.85 Resurfacing hip, total, acetabulum and femoral head Hip resurfacing arthroplasty, total
New code	00.86 Resurfacing hip, partial, femoral head Hip resurfacing arthroplasty, partial, femoral head Excludes: that with resurfacing of acetabulum (00.85)
New code	00.87 Resurfacing hip, partial, acetabulum Hip resurfacing arthroplasty, partial, acetabulum Excludes: that with resurfacing of femoral head (00.85)

Recommendation:

CMS recommends Option 2, create new codes to clearly identify hip resurfacing. In the meantime, continue to assign 81.52, Partial hip replacement to capture partial resurfacing and code 81.51, Total hip replacement, for total hip resurfacing.

Hip Replacement Bearing Surfaces

Issue: Three new codes were created on October 1, 2005 to capture specific types of hip replacement bearing surfaces. We have received a request to add two more types of bearing surfaces, metal-on-ceramic and ceramic-on-polyethylene.

New Technology: No.

Background: The topic of hip replacement bearing surfaces was discussed at the March 31, 2005 ICD-9-CM Coordination and Maintenance Committee meeting. A summary report of this meeting can be found at: www.cms.hhs.gov/ICD9ProviderDiagnosticCodes. As a result of comments received from the public, three new codes were created to capture the most common types of hip replacement bearing surfaces. The following three codes went into effect on October 1, 2005:

00.74 Hip replacement bearing surface, metal on polyethylene
00.75 Hip replacement bearing surface, metal-on-metal
00.76 Hip replacement bearing surface, ceramic-on-ceramic

We have received requests to add two additional types of bearing surfaces, metal-on-ceramic and ceramic-on-polyethylene. The metal-on-ceramic bearing surface is not yet approved by the FDA and is several years away from approval.

Options:

1. Do not create new bearing surface codes. Continue to capture information on only the three types for which codes were created. Do not assign codes to hip replacements that use other types of bearing surfaces.
2. Create the following new codes:

New code: 00.77 Hip replacement bearing surface, metal-on-ceramic
New code: 00.78 Hip replacement bearing surface, ceramic-on-polyethylene

3. Create one new code:

New code: 00.77 Hip replacement bearing surface, ceramic-on-polyethylene

Do not create a new code for the metal-on-ceramic bearing surface until it is closer to FDA approval.

Recommendation:

CMS recommends option 3, create the following new code for bearing surfaces:

New code: 00.77 Hip replacement bearing surface, ceramic-on-polyethylene

In the meantime, continue to capture information on the three types of bearing surfaces for which codes exist.

Repair of Ventricular Septal Defect with Prosthesis, Closed Technique

Issue:

Currently ICD-9-CM procedure code 35.53, Repair of ventricular septal defect with prosthesis, does not distinguish between an open technique and closed technique. Should a new procedure code be created to uniquely capture the repair of ventricular septal defect with prosthesis using the closed technique?

New Technology Application:

No.

FDA Approval:

The FDA is currently considering at least one Percutaneous Ventricular Septal Defect Device for marketing approval in the United States.

Background:

Ventricular Septal Defect is a congenital heart defect characterized by a hole in the wall, or septum, which separates the right and left ventricles. If the defect is small enough it may close spontaneously, but if it is larger it can allow blood to be shunted from the left ventricle with its high pressure into the right ventricle causing pulmonary hypertension and ultimately to inadequate oxygenation and death. Historically, repair of a ventricular septal defect has involved major open heart surgery in order to place a patch or graft over the defect, but a number of catheter based interventional techniques are now available to place a variety of prostheses over the defect that have the distinct advantage of avoiding an open heart procedure.

Options:

1. Continue to code this procedure to code 35.53, Repair of ventricular septal defect with prosthesis.
2. Create a new procedure code to capture the repair of ventricular septal defect with prosthesis using the closed technique.

Revise code title 35.53 Repair of ventricular septal defect with prosthesis,
open technique

New code 35.55 Repair of ventricular septal defect with prosthesis, closed technique

CMS Recommendation:

Option 2. Create a new procedure code to capture the repair of ventricular septal defect with prosthesis using the closed technique.

Revise code title 35.53 Repair of ventricular septal defect with prosthesis,
open technique

New code 35.55 Repair of ventricular septal defect with prosthesis, closed
technique

In the interim, continue to code this procedure to 35.53, Repair of ventricular septal defect with prosthesis.

Surgical Decompression with Insertion of Interspinous Stabilization Device

Issue:

At the March 31, 2005 ICD-9-CM Coordination & Maintenance Committee Meeting, implantation of interspinous process decompression device was discussed. Effective October 1, 2005, procedure code 84.58 was created to describe that procedure. Presently, there is no unique ICD-9-CM procedure code to identify a *surgical* decompression of the spine with insertion of a dynamic interspinous stabilization device. Should new codes be created to capture this procedure?

New Technology Application?

No

FDA Approval:

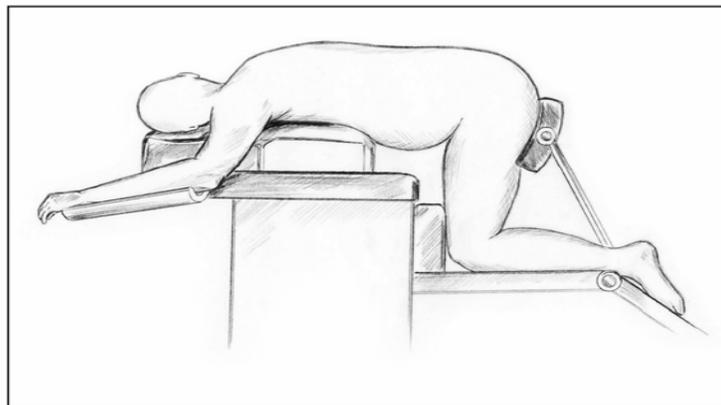
Paradigm Spine is planning to submit for an Investigational Device Exemption (IDE) in the first quarter of 2006. They anticipate beginning clinical trials in June 2006.

Background:

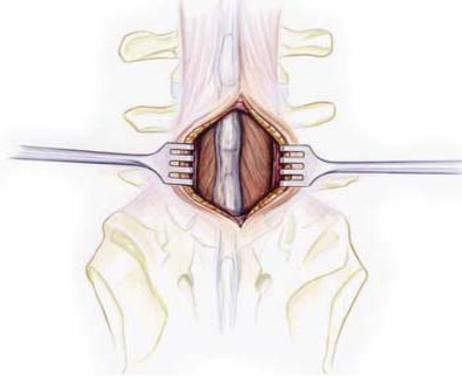
The coflex™ interspinous stabilization procedure is intended to reduce low back pain in patients with spinal stenosis. Stabilization after surgical decompression of compromised neural elements eliminates the neurogenic claudication these patients can experience. The device preserves foraminal height, restores stability, and maintains motion at a vertebral segment. It is indicated for use in patients with moderate to severe spinal stenosis (not precluding all severity levels of spinal stenosis) at a single level, or two contiguous lumbar levels from L1 to L5 with a stable spondylolisthesis of Grade 1 or less. The coflex interspinous stabilization procedure is performed as an inpatient procedure.

Procedure:

The patient is placed in prone position on a surgical frame avoiding hyperlordosis of the spinal segment(s) to be operated upon. A neutral position or a slight kyphosis may be advantageous for surgical decompression.

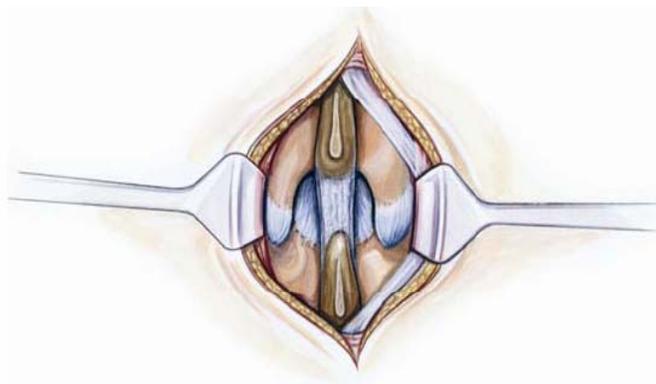


A routine (midline) skin incision is performed. The muscle is sharply dissected lateral to the supraspinous ligament preserving the entire thickness of the supraspinous ligament.

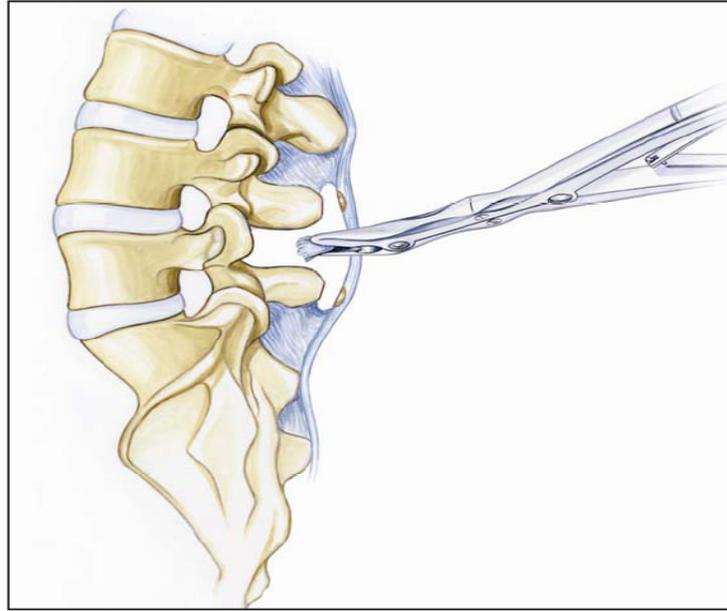


Paraspinal muscles are stripped off the laminae while preserving the facet capsules. The supraspinous ligament is dissected subperiostally and preserved as a thick cuff and retracted laterally. If possible, a small portion of the bony tip can be resected together with the supraspinous ligament. This will aid in faster healing after reconstruction of the ligament.

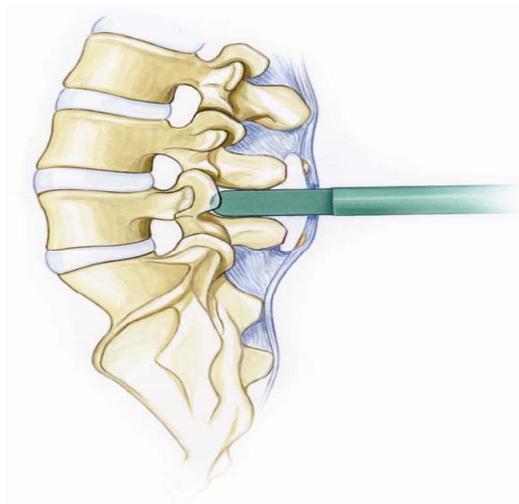
Note: Dependent on the pathology, a microsurgical unilateral decompression can be preformed and then the supraspinous ligament together with the fascia and muscle from the opposite side can be mobilized together. Completion of the microsurgical decompression can then be performed.



The interspinous ligament is sacrificed and any bony overgrowth of the spinous process that may interfere with insertion is resected.

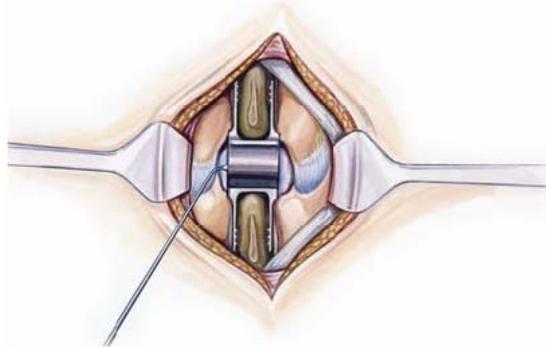


Ligamentum Flavum is resected and microsurgical decompression is performed, relieving all points of neural compression. Trials are utilized to define appropriate implant size. Trial instrument is placed to evaluate proper contact with spinous process and amount of interspinous distraction. Some bony resection of the spinous process may be needed to ensure proper contact of the implant.



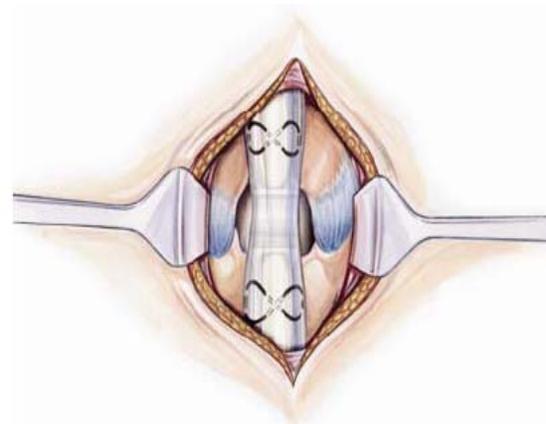
To ensure proper depth of implant insertion a small portion of the laminar surface may need partial resurfacing. Implant is introduced via impaction utilizing a mallet. If the wings are not having sufficient bony contact after insertion, additional stability can be achieved by slightly crimping the wings.

Proper depth is determined if a beaded tip probe can be passed freely leaving 3-4 mm separation from the dura. If the implant is not seated appropriately further resurfacing or slightly more impaction force may be utilized.

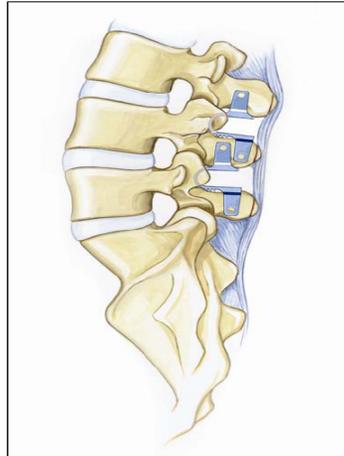


In case of ligament reconstruction a Figure of 8 suture through two bone holes in the spinous process and through the supraspinous ligament is performed. A surgical drain may be placed as per surgeon preference. Paraspinal muscles are reattached to the supraspinous ligament. Skin is closed in the usual manner.

Note: Alternatively the fascia and the supraspinous ligament can be closed in one layer over the spinous processes.



If a two level decompression is mandated the implants must be sequentially placed to the appropriate depth avoiding any overlap (contact) of one pair of wings upon the other.



The coflex device can be removed (if necessary) while preserving the patient's anatomy.

Coding Options:

Option 1:

Continue to use code 84.59, Insertion of other spinal devices. Several non-fusion spinal stabilization devices are currently in development or in use through clinical trials, awaiting FDA approval. There is also a significant degree of varying terminology to describe the numerous types of non-fusion spinal stabilization devices or systems in the marketplace. Additionally, there is debate about the term "stabilization" and if these newly developed devices truly stabilize. Evidence suggests that only fusion can stabilize the spine. Once FDA approval is received for this category of devices, consideration can be given towards creating a unique set of ICD-9-CM codes.

Option 2:

Create a new subcategory to capture non-fusion spinal stabilization devices.

84.8 Implantation and revision of non-fusion spinal stabilization devices

Excludes: fusion of spine (81.00-81.08, 81.30-81.39)

New code 84.80 Insertion of interspinous dynamic stabilization device
Code also any synchronous surgical decompression
(03.09)

Excludes:

*implantation of interspinous process decompression
device (84.58)*

New code 84.81 Revision of interspinous dynamic stabilization device

*An excludes note could be placed at code 84.58 as well.

Option 3:

Create a new subcategory to capture non-fusion spinal stabilization devices.

84.8 Implantation and revision of non-fusion spinal stabilization devices

Excludes: fusion of spine (81.00-81.08, 81.30-81.39)

New code	84.80	Insertion of interspinous dynamic stabilization device Code also any synchronous surgical decompression (03.09) <i>Excludes:</i> <i>implantation of interspinous process decompression device (84.58 84.82)</i> <i>posterior insertion of flexible pedicle screw stabilization device or system (84.84)</i>
New code	84.81	Revision of interspinous dynamic stabilization device <i>Excludes:</i> <i>revision of interspinous process decompression device (84.83)</i> <i>revision of flexible pedicle screw stabilization device or system (84.85)</i>
New code	84.82	Implantation of interspinous process decompression device
New code	84.83	Revision of interspinous process decompression device
New code	84.84	Posterior insertion of flexible pedicle screw stabilization device or system <i>Excludes:</i> <i>internal fixation of bone without fracture reduction (78.59)</i>
New code	84.85	Revision of flexible pedicle screw stabilization device or system

Procedure code 80.09, Arthrotomy for removal of prosthesis would be assigned for the removal of these non-fusion spinal stabilization devices.

Recommendation:

CMS recommends option 1, continue to use code 84.59, Insertion of other spinal devices, for the reasons cited above. Also, there are numerous non-fusion spinal stabilization devices currently under development or in clinical trials (M-Brace, Dynesys, Wallis, TOPS, TFAS, DSS) and standardized terminology is not consistently utilized to describe the technology (motion preserving, non-fusion stabilization, dynamic stabilization). Once FDA approval has been received, we can explore the creation of a unique set of codes.

Stereotactic Placement of Intracerebral Catheters via Burr Hole for Delivery of Therapeutic Agents

Issue:

Currently there is no specific ICD-9-CM procedure code that describes the stereotactic placement of intracerebral catheters for the delivery of therapeutic agents. A new delivery technique called convention enhanced delivery (CED), involves the microinfusion of therapeutic agents through catheters that are strategically placed directly into the target brain tissue. Should a new ICD-9-CM procedure code be created to capture the stereotactic placement of intracerebral catheters for delivery of therapeutic agents?

New Technology Application:

No application has been submitted for FY 2007. However, it is anticipated that an application for the novel therapeutic being administered through the stereotactically-placed intracerebral catheters will be submitted in the near future.

FDA Approval:

The catheter, tubing and pump have already received FDA clearance for marketing.

Background:

The poor prognosis associated with malignant primary brain tumors treated with conventional therapies has led investigators to develop new approaches. While novel, targeted antineoplastics have been developed for brain tumors, however, their administration is hampered by the blood brain barrier which prevents the passage of large molecules. A new approach called convention enhanced delivery (CED) provides a means of administering small and large molecules to the brain. CED involves the stereotactic placement through cranial burr holes of two to four catheters into tumor cell-infiltrated brain parenchyma and the subsequent microinfusion of an antineoplastic agent. Because of the need to achieve homogenous distribution of the antineoplastic agent throughout the tumor infiltrated tissue, the catheters cannot be placed in any previous resection cavity. When the patient is stable, approximately two weeks following craniotomy with tumor resection, the antineoplastic is administered through the catheters by means of a microinfusion pump over 96 hours. Once the infusion is complete, the catheters are removed and the patient is discharged.

Patients are expected to have a separate hospital admission (apart from any admission for tumor resection) for CED catheter placement and microinfusion of the therapeutic agent.

CED is a drug delivery technique that could be used with a wide range of agents, not just antineoplastics. This delivery system has been used in the treatment of Alzheimer's disease and epilepsy. Any large molecule compound needed to treat brain tissue could be administered by CED.

Options:

1. Continue to code this procedure to code 01.26, Insertion of catheter into cranial cavity. Modify the code title to: Insertion of catheter(s) into cranial cavity and/or tissue. Add inclusion terms: burr hole and stereotactic method.

Infusion of Cintredekin Besudotox

Issue:

Infusion of cintredekin besudotox is a novel cytotoxin-based therapy used in the treatment of recurrent glioblastoma multiforme. ICD-9-CM procedure code 99.28, Injection or infusion of biological response modifier (BRM) as an anti-neoplastic agent, is not specific enough to identify the use of cintredekin besudotox. Code 99.28 is used to code therapies such as low-dose IL-2, anti-neoplastic immunotherapy, and tumor vaccine. Usage and provision of these products can be very dissimilar, and the use of a single code to describe them does not allow for differentiation of the varied courses of treatment required. Should a unique ICD-9-CM procedure code be created to distinguish cintredekin besudotox from the other BRMs, and facilitate accurate data capture for this therapy?

New Technology Application:

No application has been submitted for FY 2007 consideration. However, it is anticipated that an application will be submitted in the near future.

FDA Approval:

The registration Phase III trial for cintredekin besudotox has completed enrollment and an interim efficacy analysis is scheduled for mid 2006. Cintredekin besudotox has been granted Fast track development designation by FDA. As a Fast track product, cintredekin besudotox could be approved in early 2007.

Background:

Glioblastoma multiforme is the most common adult brain tumor with a median survival of 5 to 7 months upon recurrence. Despite aggressive therapy that currently includes tumor resection, radiation therapy, and chemotherapy, the majority of patients with glioblastoma multiforme often relapse due to infiltrating tumor. Therapies that target both the solid tumor and infiltrating tumor are necessary to improve overall survival of patients with this disease.

Cintredekin besudotox is a novel recombinant protein consisting of a single molecule composed of two parts: a tumor-targeting molecule (Interleukin-13, or IL13) and a cytotoxin (Pseudomonas Exotoxin, or PE). IL13 receptors are present in appreciable numbers on malignant glioma cells, but only to a minimal amount on healthy brain cells. The IL13 portion of the molecule binds to receptors on tumor cells like a key fits into a lock. The cancer cell latches onto and absorbs the IL13 and the attached PE, causing destruction of the cancer cell. Healthy brain cells appear to be unharmed because they do not internalize the molecule.

As a large molecule that cannot cross the blood brain barrier, cintredekin besudotox is delivered via a novel drug delivery system by convection enhanced delivery (CED) using catheters placed following tumor resection, in areas of microscopic tumor spread or at risk of tumor spread around the tumor resection cavity. These catheters are placed by neurosurgeons following a complex plan that takes into account the location of residual non-resectable tumor, brain anatomy, and fluid dynamics. Anywhere from two to four catheters are placed during multihour

Implantation of Visual Prosthetic Device

Issue:

Should a new ICD-9-CM procedure code be created to capture the implantation of a visual prosthetic device such as implantable miniature telescope for macular degeneration?

New Technology Application:

No.

FDA Approval:

VisionCare Ophthalmic Technologies expects FDA approval in June 2006.

Background:

The implantable miniature telescope (IMT) is a visual prosthetic device intended to treat patients with moderate to profound visual impairment due to end-stage age-related macular degeneration (AMD). The American Macular Degeneration Foundation reports that macular degeneration is the leading cause of blindness for those over 55 years old. It currently affects more than 10 million Americans. The majority of these patients are “legally blind” from central vision loss due to:

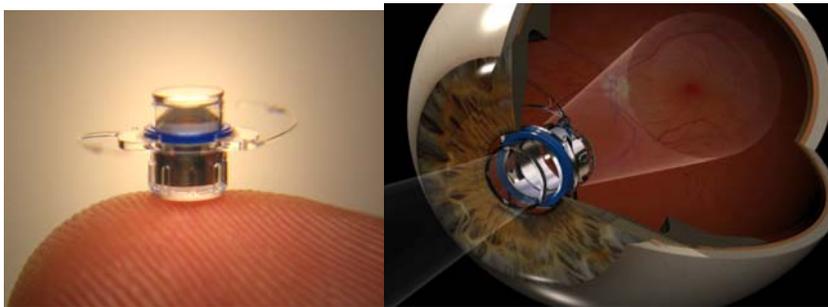
- Dry AMD (geographic atrophy), for which there is no treatment available
- Stable wet AMD (disciform scar due to choroidal neovascularization), which typically involves patients who have completed all laser/drug treatments for bleeding in and around the macula.

The implanted miniature telescope functions as a fixed focus telephoto quartz optical device comprising multiple wide-angle micro-optics. The device will improve visual function for individuals with AMD by allowing them to recognize and respond to visual images as necessary for activities of daily living. The device is implanted in one of the patient’s eyes, providing central vision, while the non-implanted eye can continue to provide peripheral vision for orientation and mobility.

This AMD device is surgically placed inside the eye in a unique and complex ocular surgery. The device and the procedure involve the removal of the patient’s lens material and the implantation of this new visual prosthetic device. Physicians must carefully insert the prosthesis while simultaneously avoiding mechanical trauma to the ocular tissues. This requires a different skill set than other procedures because the visual prosthesis is larger, heavier, more fragile, and less flexible than any other item that has ever been implanted in the eye. Moreover, the device has unique geometrical considerations, such as dimensions, weight and configuration and is a solid structure, not amenable to folding or injector systems.

The following is required for implantation:

- Large 12 mm outer limbal incision
- Large 7 mm capsule incision to accommodate device dimensions
- Multiple and specific viscoelastics to protect ocular tissues
- Skilled insertion with specific angulation, posterior pressure, and manipulation to avoid trauma to intraocular structures such as the corneal endothelium, capsule, and zonules
- Precise orientation and positioning along visual axis for image clarity
- Multiple sutures for wound management (6 to 8)
- Post-operative suture removal for astigmatic management



One-year clinical outcomes from the prospective, 28-center pivotal trial are summarized and highlighted below:

- Vision: 90% (172/192) of patients met or exceeded the study's protocol-specified visual acuity endpoint.
- Quality of life: Patients' vision-related quality of life improved significantly from baseline in 7 of 8 relevant subscales on the National Eye Institute 25-item Visual Function Questionnaire.
- Safety: The IMT device was well tolerated in the eye.
- Preservation of vision was achieved in 95% of patients, exceeding the 90% protocol-specified target.
- The most common complications included temporary increased intraocular pressure, transient corneal edema, iris prolapse, and endothelial cell loss.

Options:

1. Continue to code this procedure to code 13.9, Other operations on lens.

2. Create a new ICD-9-CM procedure code for the implantation of visual prosthetic device.

New category 13.9 Other operations on lens
New code 13.90 Operation on lens, Not Otherwise Specified
New code 13.91 Implantation of visual prosthetic device
Includes: with removal of lens, any method
Implantable miniature telescope

CMS Recommendation:

Option 2. Create a new ICD-9-CM procedure code for the implantation of visual prosthetic device.

New category 13.9 Other operations on lens
New code 13.90 Operation on lens, Not Otherwise Specified
New code 13.91 Implantation of visual prosthetic device
Includes: with removal of lens, any method
Implantable miniature telescope

In the interim, continue to code this procedure to code 13.9, Other operations on lens.

Proposed Addenda

Index

Add term	<u>Activase® 99.10</u>
	Administration (of) – <i>see also</i> Injection
Add subterm	<u>Activase® 99.10</u>
Add subterm	<u>Alteplase (tPA, generic) 99.10</u>
Add subterm	<u>Anistreplase (tPA, generic) 99.10</u>
Add subterm	<u>DrotAA 00.11</u>
Add subterm	<u>Eminase® 99.10</u>
Add subterm	<u>Retepase (tPA, generic) 99.10</u>
Add subterm	<u>Retavase® 99.10</u>
Add subterm	<u>Streptase® 99.10</u>
Add subterm	<u>Streptokinase (tPA, generic) 99.10</u>
Add subterm	<u>Tenecteplase (tPA, generic) 99.10</u>
Add subterm	<u>TNKase™ 99.10</u>
Add subterm	<u>Xigris® 00.11</u>
Add term	<u>Alteplase (tPA, generic) 99.10</u>
Add term	<u>Anistreplase (tPA, generic) 99.10</u>
	Application
	external fixator device (bone) 78.10
Add subterm	<u>computer assisted (dependent) 84.73</u>
Add subterm	<u>strapping (non-traction) 93.59</u>
Add term	<u>Corpectomy 80.99</u>
Add subterm	<u>with diskectomy 80.99</u>
	Debridement
	skin and subcutaneous tissue (burn) (infection) (wound)
	pocket
Add subterm	<u>cardiac device NEC 37.79</u>
Add subterm	<u>VersaJet™ 86.28</u>
	Diskectomy
Add subterm	<u>with corpectomy 80.99</u>
Add term	<u>Dynesys® 84.59</u>
	Embolectomy 38.00
Add subterm	<u>arteriovenous shunt or cannula 39.49</u>

Add subterm bovine graft 39.49
Add subterm pulmonary (artery) (vein) 38.05

Add term Eminase® 99.10

Add subterm Fistulogram
specified site NEC 88.49

Add subterm Fixation
external (without manipulation for reduction)
strapping (non-traction) 93.59

Add subterm Fixator, external
computer assisted (dependent) 84.73

Add subterm Immobilization (by)
strapping (non-traction) 93.59

Add subterm Instillation
thoracic cavity 34.92

Add subterm Nailing, intramedullary
internal (without fracture reduction) 78.50
Add subterm with fracture reduction – see Reduction, fracture
internal fixation

Add subterm Plethysmography
CaverMap™ 89.58

Add term Reteplase (tPA, generic) 99.10

Add term Retevase® 99.10

Add subterm Stimulation
CaverMap™ 89.58

Revise subterm nerve
Add subterm CaverMap™ 89.58
Add subterm penile 89.58
Add subterm peripheral or spinal cord, transcutaneous 93.39

Add term Strapping (non-traction) 93.59

Add term Streptase® 99.10

Add term Streptokinase (tPA, generic) 99.10

Add term Tenecteplase (tPA, generic) 99.10

Add subterm Thrombectomy
Add subterm arteriovenous shunt or cannula 39.49
Add subterm bovine graft 39.49

Add term TNKase™ 99.10

Add term VersaJet™ 86.28

Add term Xigris™ 00.11

Tabular

Revise code title 01.26 Insertion of catheter(s) into cranial cavity or tissue

Revise code title 01.27 Removal of catheter(s) from cranial cavity or tissue

Add inclusion term 14.74 Other mechanical vitrectomy
Posterior approach

Add inclusion term 34.92 Injection into thoracic cavity
Instillation into thoracic cavity

Add 2nd note 37.66 Insertion of implantable heart assist system
Note: This device can be used for either destination therapy (DT) or bridge-to-transplant (BTT)

Revise exclusion term 38 Incision, excision, and occlusion of vessels
Excludes: that of coronary vessels (00.66 (~~36.01–36.99~~) 36.03, 36.04, 36.09, 36.10–36.99)

Add inclusion term 38.4 Resection of vessel with replacement
Partial resection with replacement

Revise code title 68.39 Other and unspecified subtotal abdominal hysterectomy

Revise code title 68.59 Other and unspecified vaginal hysterectomy

Add exclusion term 80.51 Excision of intervertebral disc
Excludes:
corpectomy (80.99)

	80.99 Other excision of joint
	Excludes:
Add exclusion term	<u>excision of intervertebral disc (80.51)</u>
	84.73 Application of hybrid external fixator device
Add inclusion term	<u>Computer (assisted) (dependent) external fixator device</u>
	86.28 Nonexcisional debridement of wound, infection, or burn
Add inclusion term	<u>Water scalpel (jet)</u>
	93.11 Assisting exercise
Revise exclusion term	Excludes: assisted exercise in pool (93.31)
	93.59 Other immobilization, pressure and attention to wound
Add inclusion term	<u>Strapping (non-traction)</u>
	99.10 Injection or infusion of thrombolytic agent
Add inclusion term	<u>Alteplase</u>
Add inclusion term	<u>Anistreplase</u>
Add inclusion term	<u>Retepase</u>
Add inclusion term	<u>Tenecteplase</u>