



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 16 – September 17, 2009

Pat Brooks – Introductions and Committee overview
Co-Chairperson
September 16, 2009

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

Topics:

- | | |
|--|---|
| 1. ICD-10 MS-DRG Conversion Project | Pat Brooks, CMS
Janice Bonazelli, 3M
Rhonda Butler, 3M |
| Open Discussion on Freezing Code Updates | Pat Brooks, CMS
Donna Pickett, CDC |
| 2. Insertion of Drug-eluting Stent into Superficial Femoral Artery
Pages 9-11 | Ann B. Fagan
James Gardner, MD, MBA
Medical Science Officer
Cook Incorporated |
| 3. Reverse Shoulder Arthroplasty
Pages 12-14 | Mady Hue
Anand Murthi, MD
Chief of Shoulder and Elbow Service
University of Maryland
Department of Orthopaedics |

Lunch Break 12:30-1:30 p.m

- | | |
|---|---|
| 4. Bronchoscopic Bronchial Thermoplasty
Pages 15-17 | Pat Brooks
Michael E. Wechsler, MD, MMSc
Asst. Prof Harvard Medical School
Assoc. Dir. Brigham & Women's
Asthma Research Center |
| 5. Circulatory Support Devices
Pages 18-19 | Ann B. Fagan
Daniel H. Raess, MD, FACC, FACS
Medical Director
Abiomed, Inc. |
| 6. Carotid Sinus Baroreflex Activation
Device
Pages 20-22 | Amy L. Gruber
Luis Sanchez, MD
Washington University School of
Medicine
St. Louis, Missouri |
| 7. Addenda
Pages 23-27 | Mady Hue |

Registering for the meeting:

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

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

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

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

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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 17 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 16 – 17, 2009	ICD-9-CM Coordination and Maintenance Committee meeting. Those who wish to attend the ICD-9-CM Coordination and Maintenance Committee meeting must have registered for the meeting online by September 10, 2009 . You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.
October 2009	Summary report of the Procedure part of the September 16 – 17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes Summary report of the Diagnosis part of the September 16– 17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm
October 1, 2009	New and revised ICD-9-CM codes go into effect along with DRG changes. Final addendum posted on web pages as follows: Diagnosis addendum - http://www.cdc.gov/nchs/icd9.htm

Procedure addendum at -
<http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes>

October 9, 2009

Deadline for receipt of public comments on proposed code revisions discussed at the September 16-17, 2009 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on April 1, 2010.

November 2009

Any new ICD-9-CM codes required to capture new technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2010 will be posted on the following websites:

<http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes>
<http://www.cdc.gov/nchs/icd9.htm>

November 20, 2009

Deadline for receipt of public comments on proposed Code revisions discussed at the September 16-17, 2009 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2010.

January 8, 2010

Deadline for requestors: Those members of the public requesting that topics be discussed at the March 9 – March 10, 2010 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses by this date.

February 2010

Draft agenda for the Procedure part of the March 9, 2010 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 10, 2010 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 9 – March 10, 2010 ICD-9-CM Coordination and Maintenance Committee Meeting will be published.

February 12, 2010 **On-line registration opens for the March 9 – 10, 2010 ICD-9-CM Coordination and Maintenance Committee meeting at: <http://www.cms.hhs.gov/events>**

March 2010 Because of increased security requirements, **those wishing to attend the March 9 – March 10, 2010 ICD-9-CM Coordination and Maintenance Committee meeting** must register for the meeting online at:
<http://www.cms.hhs.gov/apps/events>

Attendees must register online by March 5, 2010 failure to do so may result in lack of access to the meeting.

March 9 – March 10 2010 ICD-9-CM Coordination and Maintenance Committee meeting.

April 1, 2010 Any new ICD-9-CM codes required to capture new technology will be implemented. Information on any new codes implemented on April 1, 2010 previously posted in early November 2009 will be on the following websites:
<http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes>
<http://www.cdc.gov/nchs/icd9.htm>
<http://www.cms.hhs.gov/MLNGenInfo>

April 2, 2010 Deadline for receipt of public comments on proposed code revisions discussed at the March 9-10, 2010 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2010.

April 2010 Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This notice will include the final ICD-9-CM diagnosis and procedure codes for the upcoming fiscal year. It will also include proposed revisions to the DRG system on which the public may comment. The proposed rule can be accessed at:
<http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp>

April 2010 Summary report of the Procedure part of the March 9, 2010 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows:
<http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes>

Summary report of the Diagnosis part of the March 10, 2010 ICD-9-CM Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows:
<http://www.cdc.gov/nchs/icd9.htm>

June 2010

Final addendum posted on web pages as follows:
Diagnosis addendum at -
<http://www.cdc.gov/nchs/icd9.htm>

Procedure addendum at –
<http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes>

July 16, 2010

Those members of the public requesting that topics be discussed at the September 15 – 16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses.

August 1, 2010

Hospital Inpatient Prospective Payment System final rule to be published in the Federal Register as mandated by Public Law 99-509. This rule will also include all the final codes to be implemented on October 1, 2010.
This rule can be accessed at:
<http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp>

August 2010

Tentative agenda for the Procedure part of the September 15 – 16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage at -
<http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes>

Tentative agenda for the Diagnosis part of the September 15 – 16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on NCHS homepage at -
<http://www.cdc.gov/nchs/icd9.htm>

Federal Register notice for the September 15 –16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting will be published. This will include the tentative agenda.

October 08, 2010

Deadline for receipt of public comments on proposed code revisions discussed at the September 15-16, 2010 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on April 1, 2011.

November 2010

Any new ICD-9-CM codes required to capture new technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2011 will be posted on the following websites:

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

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

December 3, 2010

Deadline for receipt of public comments on proposed code revisions discussed at the September 15-16, 2010 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2011.

Insertion of Drug-Eluting Stent(s) of Superficial Femoral Artery

Issue:

The current ICD-9-CM code for insertion of drug-eluting peripheral vessel stent(s) encompasses all peripheral vessels and does not specifically identify insertion of a drug-eluting stent into the superficial femoral artery. Since the first drug-eluting peripheral stent is likely to be approved within the next year specifically for the superficial femoral artery, should a unique code be created to identify this?

New Technology Application?

Potentially.

Food and Drug Administration (FDA) Approval:

Submission to the FDA will take place in late 2009 or in early 2010, with FDA approval anticipated in mid-2010.

The FDA submission will be for use of the Zilver® PTX™ paclitaxel drug-eluting stent in treating lesions of the superficial femoral artery. Enrollment in the U.S. pivotal study was completed in September 2008 with one-year follow up of the last enrollee to be completed in September 2009.

Background:

Code 00.55, Insertion of drug-eluting peripheral vessel stent(s), became effective October 1, 2002. This was part of a broad-based revision to ICD-9-CM to differentiate insertion of drug-eluting and non-drug-eluting stents into coronary and peripheral vessels.

Drug-eluting stents have been FDA-approved for coronary artery indications since 2003. However, although the code for insertion of peripheral drug-eluting stents has been available since 2002, no drug-eluting stents have ever been approved by the FDA for peripheral applications in the United States.

Treatment of peripheral arteries with stents is oftentimes significantly more challenging than treatment of the coronary arteries. This is particularly the case for the superficial femoral artery. This artery begins near the groin, where the common femoral artery divides, and runs the length of the thigh before transitioning into the popliteal artery as it enters the popliteal fossa behind the knee. The superficial femoral artery is a long vessel subject to significant forces. Lesions in the superficial femoral artery tend to be heterogeneous and complex, often involving long or calcified plaque as well as total occlusions. Practice guidelines are still evolving as new evidence becomes available about how to best treat different types of lesions in this vessel. In terms of technique, the Zilver® drug-eluting stent is deployed in a similar fashion to the self-expanding bare metal stents currently in use, including the bare metal Zilver® stent.

Any drug-eluting stents currently placed in peripheral vessels are being used off-label, most likely in the small arteries of the leg below the knee.

there are no other sites approved for insertion of peripheral stents. However, we are open to comments from the audience, as well as written comments.

Interim Coding:

Continue to use existing codes 39.50, Angioplasty or atherectomy of other non-coronary vessel(s) and 00.55, Insertion of drug-eluting peripheral vessel stent(s) to describe the insertion of a drug-eluting stent in the superficial femoral artery.

Reverse Total Shoulder Replacement

Issue: Reverse total shoulder replacement is an alternative procedure for patients whose shoulder disorder cannot be effectively managed with a conventional total shoulder replacement. Should a new ICD-9-CM procedure code be established for reverse shoulder replacement to differentiate the two procedures?

New Technology Application?

No.

Background: The shoulder is a true ball-and-socket joint. The ball is the top of the humerus and the socket is the glenoid surface of the scapula. For patients with advanced glenohumeral pathology, such as osteoarthritis and fractures of the humeral head, conservative management is often insufficient to alleviate pain and restore function. These patients may then go on to receive a total shoulder replacement, also called total shoulder arthroplasty.

In a conventional total shoulder replacement, the damaged bone and cartilage are removed and replaced with metal and plastic implants. Typically three implants are used including a ball to replace the humeral head, a stem to anchor the ball into the shaft of the humerus, and a cup to form the socket on the glenoid.

While effective for osteoarthritis, conventional total shoulder replacement is not effective for patients with certain other diagnoses. Most commonly, these are patients with a diagnosis of rotator cuff tear arthropathy.

The rotator cuff is the group of tendons and muscles that surrounds and stabilizes the shoulder joint, enabling rotation of the arm. As distinct from a rotator cuff tear, which involves damage only to the soft tissues of the tendons, rotator cuff tear arthropathy involves irreparable cuff damage which has led to degeneration of the bones themselves with severe displacement of the humeral head. The cuff damage is so extensive in some patients that the humerus is riding out of the socket. In addition to pain, these patients have severe functional deficits, including pseudoparalysis. This leaves them unable to lift their arms to perform activities of daily living such as brushing their hair and feeding themselves.

In addition to rotator cuff tear arthropathy, conventional replacement may not be indicated for patients with complex fractures and patients who had previously undergone a conventional total shoulder replacement which has failed. Reverse total shoulder replacement is a surgical option for these patients. As indicated by its name, the ball and socket implants go in opposite locations from a conventional procedure.

Procedure: In a reverse total shoulder replacement, the ball is placed on the glenoid and the socket is placed on top of the humerus. Five or more implants are typically used. A baseplate (metaglens) is screwed into the glenoid and a metallic ball (glenosphere) is then attached to the baseplate. On the other side, a metallic stem and neck (metaphysis) are implanted into the humerus to which the cup (polyethylene liner or insert) is then attached. A spacer may also be used in the humerus. Although the term “spacer” is often used in joint surgery for a temporary placeholder, here the spacer is a permanent implant to achieve proper joint tensioning.

At the beginning of the procedure, the rotator cuff is often inspected to verify that it cannot be repaired. Non-viable tissue may be resected if the damage is confirmed as irreparable. To perform the reverse total shoulder replacement, the surgeon must open the capsule to expose the joint. It is common to release the biceps tendon and also to release and later reattach the subscapularis tendon. Debridement of bone may be performed as well as bone grafting to defects in the glenoid surface. These components are integral to the reverse total shoulder replacement procedure. In some cases, transfer of nearby muscles and tendons such as the latissimus dorsi is also performed to help restore rotation and ensure stability of the joint postoperatively.

The reverse total shoulder replacement procedure takes about the same amount of time in the operating room as the conventional procedure. However, the patient populations are quite different and the techniques and implants used are distinct.

In 2008, about 61,000 shoulder replacement procedures were performed in the United States. About 27,000 were for partial shoulder replacement and about 3,000 were for shoulder resurfacing. Of the remaining cases, about 21,000 were for conventional total shoulder replacement and about 10,000 were for reverse total shoulder replacement.

In conclusion, the reverse total shoulder replacement procedure provides patients with relief from pain. Importantly, it also restores a level of shoulder function, by pressing the overlying deltoid muscle into service to compensate for the irreparable rotator cuff damage. Because it may not restore full function, the reverse procedure is often indicated in patients 65 to 70 years old and older who have lower functional needs.

Coding Options:

Option 1: Do not create a new code. Continue to use current code 81.80, Total shoulder replacement, to identify that a total shoulder replacement was performed. An inclusion term for the reverse total shoulder replacement could be added.

Option 2: Create a new code in subcategory 81.8 for reverse total shoulder arthroplasty. Add an excludes note at code 81.80, Total shoulder replacement.

81.8 Arthroplasty and repair of shoulder and elbow

New code	81.88 Reverse total shoulder replacement Reverse ball-and-socket of the shoulder
	Excludes: conversion of prior (failed) total shoulder replacement (arthroplasty) to reverse total shoulder replacement (81.97)
Add exclusion term	81.80 Total shoulder replacement <u>Excludes: reverse total shoulder replacement (81.88)</u>

CMS Recommendation: CMS recommends option 2, create a new code in subcategory 81.8 for reverse total shoulder arthroplasty and add an excludes note at code 81.80, Total shoulder replacement for the proposed new code.

Interim coding: Continue to assign code 81.80, Total shoulder replacement, to identify a reverse total shoulder replacement.

Bronchoscopic Bronchial Thermoplasty

Issue:

Bronchial thermoplasty of airway smooth muscle is a new bronchoscopic procedure involving the application of radio-frequency (RF) based technology to the airways for the treatment of severe asthma. Bronchial thermoplasty involves ablation of airway smooth muscle in the lung. This procedure is currently identified by code 32.26, Other and unspecified ablation of lung lesion or tissue. This code does not clearly describe the procedure.

New Technology Application?

No.

Food & Drug Administration (FDA) Approval:

The U.S. Food and Drug Administration (FDA) cleared this technology (i.e. the Alair® System) for “coagulation or hemostasis in the tracheobronchial tree,” and is currently considering a premarket approval application (PMA) for a specific new use in severe asthma. FDA approval for this expanded application in asthma is expected by year’s end.

Background:

Bronchoscopic ablation of airway smooth muscle for the treatment of severe asthma, springs from the fact that airway smooth muscle plays a key role in the manifestation of many asthma symptoms. Airway smooth muscle is located within the walls of airways in the lung. Patients with asthma have significant increases in the amount of airway smooth muscle in the lungs. This increased airway smooth muscle mass has the potential to increase airway responsiveness to external stimuli, such as dust, allergens, cold air or stress, causing bronchoconstriction, which leads to asthma symptoms. The excessive and inappropriate constriction of airway smooth muscle, a predominant feature of asthma, makes it a key target for pharmacotherapy.

Current therapeutic regimens have been reasonably successful in controlling inflammation and airway muscle contraction in the majority of patients with asthma. A small proportion of patients with severe asthma continue to suffer with exacerbations of symptoms due to excessive bronchoconstriction, an integral part of an asthma “attack.” Therefore, reducing airway smooth muscle should inhibit bronchoconstriction, thus reducing asthma attacks and improving asthma quality of life, therefore providing a therapeutic benefit for patients with severe asthma.

Technology:

The Alair® System includes a catheter, a radiofrequency (RF) controller, and accessories. The catheter is a sterile, single-use, disposable device, containing heating and sensing elements designed to deliver therapeutic RF energy to the airways. The pulmonary-specific RF controller provides temperature-controlled delivery of RF energy to the catheter. The RF controller uses two accessories: a foot switch and patient return electrode. The foot switch assembly connects to the RF controller front panel and is used

to initiate the RF energy delivery. The patient return electrode is a standard, commercially available patient return electrode, which is used to complete the current path to the RF controller.

Procedure:

Bronchial thermoplasty ablation is performed through a standard flexible bronchoscope that is introduced through a patient's nose or mouth. The small diameter catheter is delivered into the airways through the bronchoscope working channel. The tip of the catheter is expanded to contact the wall of the targeted airway. Thermal energy is then delivered to reduce the presence of airway smooth muscle within the airway wall, and thereby reduce the ability of the treated airway to constrict. The bronchoscope and catheter are systematically repositioned to provide consistent and thorough treatment throughout the targeted lung region, moving from distal to proximal airways. Depending on patient anatomy, treatment is performed in 60-115 airway segments distal to the main stem bronchi down to airways of ≥ 3 mm in diameter, if reachable and within direct vision using a standard, 5mm OD bronchoscope. This includes all segmental/tertiary bronchi with the exception of the right middle lobe, and may include 1-3 generations of sub-segmental airways. Bronchial thermoplasty takes about an hour for each region of the lung being treated. These airways normally represent about 80% of the total airway resistance in humans.

Experience to date suggests that approximately 3% of procedures may be done on an inpatient basis, and available evidence suggests that bronchial thermoplasty ablation can significantly improve clinical outcomes in patients with asthma refractory to conventional medical therapy.

Patient Population:

Bronchial thermoplasty delivered by the Alair® System is currently being investigated for treatment of severe persistent asthma in patients 18 years or older.

There are approximately 2 million adults with severe asthma in the U.S. In order to qualify for bronchial thermoplasty, patients must remain symptomatic despite use of current medication. Further, patients must be willing and able to undergo a bronchoscopic procedure.

Current Coding: Code 32.26, Other and unspecified ablation of lung lesion or tissue, is currently used to identify this procedure.

Coding options:

Option 1: Do not create a new code. Continue to assign code 32.26, Other and unspecified ablation of lung lesion or tissue, to capture this procedure.

Circulatory Support Devices

Issue:

There is an amazing proliferation of new cardiac devices as well as subsequent generations of existing devices for which there may or may not be codes to adequately describe them. Today we're discussing two temporary circulatory assist devices that rely on an internal impeller to provide increased cardiac output in patients with acute heart failure.

New Technology application?

Unknown.

Food and Drug Administration (FDA) approval:

Abiomed, Inc. has received 510(k) clearance for its Impella® 5.0 and Impella® LD (“left direct”) circulatory support devices effective April 16, 2009. Both devices are part of a larger family of small circulatory support devices.

Background:

Similar to the Impella 2.5® device, the Impella 5.0® and Impella LD® devices are small continuous circulatory assist devices that use an internal impeller to provide continuous high blood flow rates. An impeller is a rotating component of a centrifugal pump which transfers energy from the motor that drives the pump to the fluid (in this case, blood) being pumped by accelerating the blood outwards from the center of rotation.

The 5.0® device is inserted using a catheter inserted into the femoral artery, and the LD® device is inserted directly into the heart during open cardiac surgery. Both devices have one end inside the left ventricle and the other end in the ascending aorta, with the body of the pump connecting the two ends by crossing the aortic valve. Blood is withdrawn from the left ventricle, through the impeller and then ejected into the aorta, thereby augmenting cardiac output.

Current Coding:

The addenda effective for October 1, 2009 (FY 2010) directs all Impella® percutaneous external heart assist devices to code 37.68, Insertion of percutaneous external heart assist device. This code includes, but is not limited to:

- Circulatory assist device
- Extrinsic heart assist device
- pVAD
- Percutaneous heart assist device

Coding Options:

Option 1. Do not create a new ICD-9-CM code; rather code percutaneous circulatory support devices of this kind to existing code 37.68, Insertion of percutaneous external heart assist device.

Due to some confusion created when we attempted to clarify this subcategory of codes last year, code 37.62, Insertion of temporary non-implantable extracorporeal circulatory assist device, will be modified as follows:

37.62 Insertion of temporary non-implantable extracorporeal circulatory assist device

Delete inclusion term ~~Acute circulatory support device~~

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

Existing at 37.62 is a note excluding use of code 37.66, Insertion of implantable heart assist system. Code 37.66 includes the word “pulsatile” which could lead to more confusion, however pulsatile is a term which simply indicates *rhythmic pulsation* which describes the pumping action of the heart.

Option 2. Create a new code for this type of device for tracking purposes:

New code 37.69 Insertion of impeller pump circulatory support device
Note: includes both percutaneous and open approaches
Catheter based
Left direct (LD) impeller pump

Excludes:

Insertion of heart assist system NOS (37.62)
Insertion of implantable heart assist system (37.66)
Insertion of temporary circulatory assist device (37.62)

Index

Revise term

Impella®

Add term

2.5® external heart assist device 37.68

Add term

5.0® impeller pump circulatory support device 37.69

Add term

LD® (left direct) impeller pump circulatory support device 37.69

CMS Recommendations:

- Create a new code at 37.69 as shown above in Option 2.
- Make corrections to the Tabular under code 37.62 as shown above in Option 1.
- CMS is requesting industry input – should code 37.62 be deleted entirely because it is unclear what devices are actually assigned here, as opposed to code 37.68?

Interim Coding:

Code Impella 5.0® and Impella LD® cardiac support devices to 37.68, Insertion of percutaneous external heart assist device.

Carotid Sinus Baroreflex Activation Device

Issue: Should new codes be created to uniquely identify procedures involving the implantation of an implantable device on the carotid sinus?

New Technology Application?

No.

FDA Approval:

As of June 30, 2009, the Rheos carotid sinus baroreflex activation system™, developed by CVRx, Inc., has been implanted in 64 patients in Europe in hypertension and heart failure clinical trials, and in 205 patients in the United States under feasibility and pivotal hypertension clinical trials. The current Phase III IDE pivotal trial for hypertension is expected to complete enrollment of 300 U.S. patients in 2009. In addition to the hypertension indication, a 540 patient Phase III IDE Pivotal Heart Failure clinical trial has been approved by the FDA in May 2009 and is expected to commence in the fall of 2009.

Background:

The Rheos carotid sinus baroreflex activation system™ is an implantable medical device designed to electrically activate the baroreflex, the system that helps regulate cardiovascular function. The Rheos System™ is currently the only surgical procedure that implants a medical device to treat patients with primary hypertension. These patients are also being treated simultaneously with several medications. This system contains one implantable pulse generator, bilateral carotid sinus leads and one computer programming system. When activated by the Rheos system™, signals are sent to the brain which are interpreted as a rise in blood pressure. The brain works to counteract this perceived rise by modulating the nervous system and body hormones to dilate blood vessels to allow blood to flow more freely, reduce the heart rate and influence fluid handling by the kidneys. The intended result is a reduction in excessive blood pressure, a reduction in workload by the heart, improved circulation, and a more optimal neurohormonal balance.

The Rheos™ implantable pulse generator provides control and delivery of the activation energy through the carotid sinus leads. The leads conduct activation energy from the implantable pulse generator to the left and right carotid sinus, which are two main blood pressure control points. The programmer system provides the ability to non-invasively communicate with the pulse generator.

A surgical implant procedure is used to place the pulse generator in a subcutaneous pocket in the pectoral region below the collarbone. The electrodes are placed bilaterally on the carotid sinuses and the leads run under the skin and are connected to the pulse generator in the chest. The procedure is performed in the hospital inpatient department under general anesthesia and takes approximately 2 - 3 hours to complete. The Rheos™

implant is not expected to compromise the patient's anatomy. It is removable and revisable.

Potential complications of chronic carotid sinus baroreflex activation therapy include:

- Hypotension – a decrease in systolic and diastolic blood pressure below normal that could potential result in dizziness, fainting, and/or falls
- Stimulation of extravascular tissues – any event that results in localized tissue/nerve stimulation (muscle twitching, hoarseness, pain, tingling, oral sensations) that would not otherwise occur
- Stimulation of cranial nerves – any event that results in cranial nerve activity that would not otherwise occur
- Vascular injury including carotid artery rupture – injury that results in the lack of integrity of the vessel wall leading to hemorrhage or stenosis

Additionally, patients receiving the carotid sinus baroreflex activation device will be exposed to operative and post-operative risks similar to related surgical procedures involving the neck and medical device implantation.

Coding Options:

Option 1. Continue to code the implantation or replacement of carotid sinus baroreflex activation device to code 39.8, Operations on carotid body, carotid sinus and other vascular bodies. Code 04.92, Implantation or replacement of peripheral neurostimulator lead(s), should be assigned for implantation or replacement of the carotid sinus lead(s) only. Code 86.96, Insertion or replacement of other neurostimulator pulse generator, should be assigned for the insertion or replacement of the pulse generator only. Code 86.05, Incision with removal of foreign body or device from skin and subcutaneous tissue, should be assigned for the removal of carotid sinus baroreflex activation device.

Option 2. Create new procedure codes to uniquely identify the implantation or replacement, or removal of carotid sinus baroreflex activation device.

New category	39.8	Operations on carotid body, carotid sinus and other vascular bodies
New code	39.81	Implantation or replacement of carotid sinus baroreflex activation device, total system Implantation of carotid sinus stimulator and lead(s) Includes: carotid explorations Excludes: implantation or replacement of carotid sinus lead(s) only (39.82) implantation or replacement of carotid sinus pulse generator only (39.83)
New code	39.82	Implantation or replacement of carotid sinus lead(s) only Excludes: implantation or replacement of carotid sinus baroreflex activation device, total system (39.81)

New code	39.83	Implantation or replacement of carotid sinus pulse generator only Excludes: implantation or replacement of carotid sinus baroreflex activation device, total system (39.81)
New code	39.84	Removal of carotid sinus baroreflex activation device, total system
New code	39.85	Removal of carotid sinus lead(s) only
New code	39.86	Removal of carotid sinus pulse generator, only
New code	39.89	Other and unspecified operations on carotid body, carotid sinus and other vascular bodies Chemodectomy Denervation of: aortic body carotid body Glomectomy, carotid Excludes: excision of glomus jugulare (20.51)

CMS's Recommendation:

Option 2. As stated above.

Interim Coding:

In the interim, continue to code the implantation or replacement of carotid sinus baroreflex activation device to code 39.8, Operations on carotid body, carotid sinus and other vascular bodies. Code 04.92, Implantation or replacement of peripheral neurostimulator lead(s), should be assigned for implantation or replacement of the carotid sinus lead(s) only. Code 86.96, Insertion or replacement of other neurostimulator pulse generator, should be assigned for the insertion or replacement of the pulse generator only. Code 86.05, Incision with removal of foreign body or device from skin and subcutaneous tissue, should be assigned for the removal of carotid sinus baroreflex activation device.

Addenda

Tabular

Add inclusion term	01.59 Other excision or destruction of lesion or tissue of brain <u>Amygdalohippocampectomy</u>
Revise inclusion term	33.24 Closed [endoscopic] biopsy of bronchus Transbronchoscopic needle aspiration [TBNA] of <u>bronchus</u>
Add inclusion term	33.27 Closed endoscopic biopsy of lung <u>Transbronchoscopic needle aspiration [TBNA] of lung</u>
Add inclusion term Add inclusion term	33.73 Endoscopic insertion or replacement of bronchial valve(s), multiple lobes <u>Endobronchial airflow redirection valve</u> <u>Intrabronchial airflow redirection valve</u>
Revise code also note	37.3 Pericardiectomy and excision of lesion of heart Code also cardiopulmonary bypass [extracorporeal circulation] [heart-lung machine], <u>if performed</u> (39.61)
Delete inclusion term Add inclusion term	37.33 Excision or destruction of other lesion or tissue of heart, open approach Modified maze procedure, trans-thoracic approach <u>That by median sternotomy</u>
Revise inclusion term	37.34 Excision or destruction of other lesion or tissue of heart, other approach Ablation of heart tissue (cryoablation) (electrocurrent) (laser) (microwave) (radiofrequency) (resection), via peripherally inserted catheter
Revise inclusion term	Modified maze procedure: endovascular approach
Add subterm Add subterm	<u>endovascular approach</u> <u>thoracoscopic (endoscopic) approach</u>

Add inclusion term	40.11 Biopsy of lymphatic structure <u>Transbronchoscopic needle aspiration [TBNA] of lymph node</u>
	81.0 Spinal fusion
Add note	<u>Note: An interbody fusion is a fusion of the anterior column of the spine. The anterior column can be fused using an anterior, lateral, posterior, combined (anterolateral) (posterolateral) or a percutaneous technique. A posterior column fusion can be performed using a posterior, percutaneous, posterolateral or lateral transverse technique.</u>
Revise code title	81.02 Other cervical fusion <u>of the ; anterior column,</u> anterior technique
Revise code title	81.03 Other cervical fusion <u>of the ; posterior column,</u> posterior technique
Delete inclusion term	Arthrodesis of C2 level or below: Posterior (interbody) technique
Revise code title	81.04 Dorsal and dorsolumbar fusion <u>of the ; anterior column,</u> anterior technique
Add inclusion term	<u>Posterolateral technique</u>
Revise code title	81.05 Dorsal and dorsolumbar fusion <u>of the ; posterior column,</u> posterior technique
Delete inclusion term	Arthrodesis of thoracic or thoracolumbar region: Posterior (interbody) technique
Delete inclusion term	Posterolateral technique
Revise code title	81.06 Lumbar and lumbosacral fusion <u>of the ; anterior column,</u> anterior technique
Add inclusion term	Arthrodesis of lumbar or lumbosacral region: <u>Direct lateral interbody fusion [DLIF]</u>
Add inclusion term	<u>EXtreme lateral interbody fusion [XLIF]</u>
Add inclusion term	<u>Retroperitoneal</u>
Add inclusion term	<u>Transperitoneal</u>

Add inclusion term	81.07 Lumbar and lumbosacral fusion of the <u>posterior column, posterior or lateral transverse process technique</u> <u>Transverse process technique</u>
Revise code title	81.08 Lumbar and lumbosacral fusion; <u>anterior column, posterior technique</u> Arthrodesis of lumbar or lumbosacral region: Posterior (interbody) technique <u>Axial lumbar interbody fusion [AxiaLIF]</u>
Delete inclusion term Add inclusion term	81.83 Other repair of shoulder Revision of arthroplasty of shoulder
Delete inclusion term	81.97 Revision of joint replacement of upper extremity <u>Revision of arthroplasty of shoulder</u>
Add inclusion term	81.97 Revision of joint replacement of upper extremity <u>Revision of arthroplasty of shoulder</u>
Revise code title	99.14 Injection or infusion of gamma globulin <u>immunoglobulin</u>
Add inclusion term	<u>Injection or infusion of gamma globulin</u>

Index

Revise subterm	Ablation lesion heart by peripherally inserted catheter 37.34 maze procedure (Cox-maze)
Revise subterm	open (trans-thoracic) approach 37.33
Add subterm	<u>other approach 37.34</u>
Add subterm	<u>thoracoscopic (endoscopic) approach 37.34</u>
Delete subterm	trans-thoracic approach 37.33
Add subterm	<u>peripherally inserted catheter 37.34</u>
Add subterm	<u>other approach 37.34</u>
Add subterm	<u>thoracoscopic (endoscopic) approach 37.34</u>
Add term	<u>Amygdalohippocampectomy 01.59</u>

Creation – *see also* Formation
conduit

Add subterm apical-aortic (AAC) 35.93

Embolization (transcatheter)
artery (selective) 38.80

by
endovascular approach 39.79
head and neck vessels 39.72

coil, endovascular 39.79

head and neck 39.75

Formation
conduit

Add subterm apical-aortic (AAC) 35.93

Fusion

Revise subterm spinal, NOS (with graft) (with internal fixation) (with instrumentation) 81.00

Add subterm axial lumbar interbody fusion [AxiaLIF®] 81.08
cervical (C2 level or below) NEC 81.02

Revise subterm anterior column (interbody), anterolateral technique 81.02

Revise subterm posterior column (~~interbody~~), posterolateral technique 81.03

Add subterm direct lateral interbody fusion [DLIF] 81.06

dorsal, dorsolumbar NEC 81.05

Revise subterm anterior column (interbody), anterolateral technique 81.04

Revise subterm posterior column (~~interbody~~), posterolateral technique 81.05

Add subterm extreme lateral interbody fusion [XLIF®] 81.06

lumbar, lumbosacral NEC 81.08

Revise subterm anterior column (interbody), anterolateral technique 81.06

Revise subterm posterior (~~interbody~~), posterolateral technique 81.08

Revise subterm lateral transverse process technique (posterior column) 81.07

Add subterm posterior column, posterior (posterolateral) technique 81.07

Add subterm	Implantation <u>chemotherapeutic agent 00.10</u>
Add subterm	Infusion (intra-arterial) (intravenous)
Add subterm	<u>IgG (immunoglobulin) 99.14</u>
Add subterm	<u>immunoglobulin (IgG) (IVIG) (IVIg) 99.14</u>
Add subterm	<u>IVIG (immunoglobulin) (IVIg) 99.14</u>
Add subterm	Injection (into) (hypodermically) (intramuscularly)
Add subterm	(intravenously) (acting locally or systemically)
Add subterm	<u>IgG (immunoglobulin) 99.14</u>
Add subterm	<u>immunoglobulin (IgG) (IVIG) (IVIg) 99.14</u>
Add subterm	<u>IVIG (immunoglobulin) (IVIg) 99.14</u>
Add subterm	Lavage
Add subterm	bronchus NEC 96.56
Add subterm	diagnostic (endoscopic)
Add subterm	bronchoalveolar lavage (BAL) 33.24
Add subterm	<u>mini-bronchoalveolar lavage (mini-BAL) 33.29</u>
Add subterm	Wang needle aspiration biopsy
Add subterm	<u>lung 33.27</u>