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

Agenda
ICD-9-CM Coordination and Maintenance Committee
Department of Health and Human Services
Centers for Medicare & Medicaid Services
CMS Auditorium
7500 Security Boulevard
Baltimore, MD 21244-1850
ICD-9-CM Volume 3, Procedures
March 31 – April 1, 2005

Patricia E. Brooks
Co-Chairperson
March 31, 2005

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

Overview of Committee
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Topics:

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   American Association of Orthopaedic Surgeons

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3. Hip replacement bearing surfaces
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   University of Pittsburgh
   Department of Orthopaedic Surgery

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7. Radio Frequency Ablation of (Chronic) Total Artery Occlusion Page 26	Ann B. Fagan Geoffrey "Jeff" Hartzler, MD Founder & Vice Chair IntraLuminal Therapeutics, Inc.
8. Endovascular implant in Thoracic Aorta Page 28	Ann B. Fagan Richard Cambria, MD Massachusetts General Hosp.
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Registering for the meeting:
Information on registering online to attend the meeting can be found at:
http://www.cms.hhs.gov/paymentsystems/icd9/

ICD-9-CM Volume 3, Procedures Coding Issues:
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Summary of Meeting:
A complete report of the meeting, including handouts, will be available within one month of the meeting as follows:
Procedure issues: http://www.cms.hhs.gov/paymentsystems/icd9
Diagnosis issues: 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:

August 11, 2004	Hospital Inpatient Prospective Payment System final rule published in the Federal Register as mandated by Public Law 99-509. The rule can be accessed at: http://www.cms.hhs.gov/providers/hipps/frnotices.asp
October 1, 2004	New ICD-9-CM codes are implemented.
October 7-8, 2004	ICD-9-CM Coordination and Maintenance Committee Meeting
October 2004	Summary report of the Procedure part of the October 7-8, 2004 ICD-9-CM Coordination and Maintenance Committee meeting posted on CMS homepage at: http://www.cms.hhs.gov/paymentsystems/icd9 Summary report of the Diagnosis part of the October 7-8, 2004 ICD-9-CM Coordination and Maintenance Committee meeting report posted on NCHS homepage at: http://www.cdc.gov/nchs/icd9.htm
March 31 – April 1	ICD-9-CM Coordination and Maintenance Committee meeting.
2005	Those who wish to attend the ICD-9-CM Coordination and Maintenance Committee meeting **must have registered for the meeting online by March 25, 2005.** You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building.
April 15, 2005	Deadline for receipt of public comments on proposed code revisions discussed at the March 31 and April 1, 2005 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2005.
April 2005	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/providers/hipps/frnotices.asp
April 2005	Summary report of the Procedure part of the March 31, 2005 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows: http://www.cms.hhs.gov/paymentsystems/icd9

	Summary report of the Diagnosis part of the April 1, 2005 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 2005	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/paymentsystems/icd9
July 29, 2005	Those members of the public requesting that topics be discussed at the September 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee meeting must have their requests to CMS for procedures and NCHS for diagnoses.
August 1, 2005	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, 2005. This rule can be accessed at: http://www.cms.hhs.gov/providers/hipps/frnotices.asp
August 2005	Tentative agenda for the Procedure part of the September 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage at - http://www.cms.hhs.gov/paymentsystems/icd9 Tentative agenda for the Diagnosis part of the September 29 – 30, 2005 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 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
September 23, 2005	Because of increased security requirements, those wishing to attend the **September 29 - 30, 2005** ICD-9-CM Coordination and Maintenance Committee meeting must register for the meeting online at http://www.cms.hhs.gov/events **Attendees must register online by September 23, 2005**; **failure to do so may result in lack of access to the meeting**.
Sept 29 – 30, 2005	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 23, 2005.** You must bring an official form of picture identification (such as a drivers license) in order to be admitted to the building. **Those who wish to have a new code considered for implementation on April 1, 2006 must make this request at the**

	meeting and justify the need of the April 1 update to capture new technology.
October 1, 2005	New and revised ICD-9-CM codes go into effect along with DRG changes. Final addendum posted web pages as follows: Diagnosis addendum - http://www.cdc.gov/nchs/icd9.htm Procedure addendum at - http://www.cms.hhs.gov/paymentsystems/icd9
October 15, 2005	Deadline for receipt of public comments on proposed code revisions discussed at the September 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on April 1, 2006 to capture new technology.
October 2005	Summary report of the Procedure part of the September 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee meeting will be posted on CMS homepage as follows: http://www.cms.hhs.gov/paymentsystems/icd9 Summary report of the Diagnosis part of the September 29 – 30, 2005 ICD-9-CM Coordination and Maintenance Committee meeting report will be posted on NCHS homepage as follows: http://www.cdc.gov/nchs/icd9.htm
Early Nov., 2005	Any new ICD-9-CM codes required to capture new technology that will be implemented on April 1, 2006 will be announced. Information on any new codes to be implemented on April 1, 2006 will be posted on the following websites: Diagnoses http://www.cms.hhs.gov/paymentsystems/icd9 Procedures http://www.cdc.gov/nchs/icd9.htm Code titles http://www.cms.hhs.gov/medlearn/icd9code.asp
December 2, 2005	Deadline for receipt of public comments on proposed code revisions discussed at the March 31 and April 1, 2005 and September 29 -30, 2005 ICD-9-CM Coordination and Maintenance Committee meetings for implementation on October 1, 2006.
April 1, 2006	Any new ICD-9-CM codes required to capture new technology will be implemented. Information on any new codes implemented on April 1, 2006 was previously posted in early November 2005 on the following websites: Procedures http://www.cms.hhs.gov/paymentsystems/icd9 Diagnoses http://www.cdc.gov/nchs/icd9.htm Code titles http://www.cms.hhs.gov/medlearn/icd9code.asp

SUBTALAR JOINT ARTHROEREISIS

Issue:
There is not a unique code to capture subtalar joint arthroereisis. This procedure is performed to treat a condition known as collapsing pes valgo planus, or flexible flatfoot. The procedure is currently captured by code 81.99, Other operations on joint structure. This code does not clearly identify the procedure.

New Technology Application:
No.

Background:
There are various surgical techniques of subtalar joint arthroereisis in the treatment of flexible flatfoot. The pathologic condition of flatfoot is the most common foot deformity. In its most severe state, the foot is functionally inefficient. The deformity can lead to degenerative arthritis. Painful symptoms can cause the patient to restrict physical activities. Various approaches have been used to correct this problem. Some surgeons use bone grafts to limit excessive subtalar joint pronation, while others use various endoprosthetic devices such as the subtalar arthroereisis peg, the Silastic silicone sphere, and the Subtalar Maxwell-Brancheau arthroereisis (MBA) implant. Arthroereisis is the limitation of exogenous joint motion without complete arthrodesis. It limits excessive motion at the involved joint axis. It limits excessive valgus motion at the subtalar joint and retains the varus range of motion. Arthrodesis, by contrast, prevents all motion across the joint axis by creating a surgical fusion of the joint.

The subtalar MBA implant is an “internal orthotic” designed for correction of pediatric pes valgus and adult posterior tibial dysfunction deformity. There are five different MBA implant sizes: 6, 8, 9, 10, and 12 mm in diameter. The implant is a titanium device that is inserted into the sinus tarsi. It aims to restore the arch by blocking the anterior and inferior displacement of the talus and by preventing the foot from pronating. By doing so it allows normal subtalar joint motion. Tissue grows normally around the implant and aids in holding it in place. In adults, ancillary procedures may be performed simultaneously (e.g. an Achilles tendon lengthening if an equines deformity is present). The patient can ambulate the day after surgery in a Cam Walker for approximately 3 weeks. Thereafter, regular shoes can be worn with an ankle brace for an additional 2 to 3 weeks.

A modified subtalar arthroisis is obtained by implanting an endoprosthesis manufactured from ultrahigh molecular weight polyethylene. The implant is shaped into a peg. The peg is implanted into the dorsal surface of the calcaneus just anterior to the posterior facet of the subtalar joint and fixed with polymethylmethacrylate. The implant’s purpose is to eliminate abnormal pronation, correct heel valgus, and produce an increase of the medial longitudinal arch in growing children.

Another approach used in the treatment of planovalgus feet in children is subtalar stabilization of the planovalgus foot by staple arthroereisis. The procedure consists of subtalar stabilization (arthroereisis) with a Vitallium staple. The procedure attempts to correct alignment, restore balance, and allow continued function.

Calcaneo-stop with retrograde endorthesis implantation is another type of surgery performed to correct calcaneo valgus or flat foot, in children aged 9 to 13 years old. A retrograde endorthesis screw is placed at the level of the external opening of the tarsal sinus, a space between the talus and the exterior calcar, until it abuts at the correct length on the lateral process of the talus. The screw contains proprioceptive receptors, neuroreceptors that integrate at the medullary and spinal level a contracting reflex of the spinators that transmit the impulses required for active correction of the flat foot precisely at the phase it is needed. The retrograde endorthesis does not need to be removed since it is designed so that it is incorporated into the bone structure of the calcar during growth at the end of its function.

While this appears to be an evolving field, there is not a unique ICD-9-CM code which captures the procedure. Code 81.99, Other operations on joint structure does not indicate that an arthroereisis has been performed.

Coding Options:
Option 1: Continue capturing the procedure using code 81.99, Other operations on joint structure.

Option 2: Create the following new code to more clearly identify these procedures.

Revise	81.1	Arthrodesis of foot and ankle <u>and arthroereisis</u>
New code:	81.17	Subtalar joint arthroereisis

CMS recommendation: Option 2, create new code 81.17, Subtalar joint arthroereisis.

Interim Coding:
Continue using code 81.99, Other operations on joint structure, to describe this procedure until a new code can be created.

360 DEGREE SPINAL FUSION

Issue:
Code 81.61, 360 degree spinal fusion, single incision approach, was created on October 1, 2002. The issue of creating a new code for this procedure was discussed at the November 1, 2001 meeting of ICD-9-CM Coordination & Maintenance Committee. A complete report of this meeting can be found at: http://www.cms.hhs.gov/paymentsystems/icd9/ The creation of this new code has generated considerable confusion among coders as to when it should be used. It has been suggested that we delete code 81.61 and capture spinal fusions using codes 81.00 – 81.08 and 81.30 – 81.39, or that we make other revisions that coders can more easily understand. Coders are confused as to whether the use of an interbody fusion device means that code 81.61 should be assigned. Other coders have been instructed by surgeons to assign 81.61 when the medical record documents a posterior lumbar interbody fusion (PLIF). The code is not being used consistently and is generating considerable confusion.

New Technology Application?
No.

Background:
Medical technology has changed since physicians began performing 360-degree spinal fusions. A 360-degree spinal fusion is a fusion of both the anterior and posterior portion of the spine performed during the same operative session. Historically this procedure was performed with two incisions. One incision was made with the patient facing the surgeon and the other incision was made through the patient's back. These are called anterior and posterior approaches. Current instrumentation allows surgeons to perform fusions of the anterior and posterior portion of the spine (or 360-degree fusion) by using a single approach. This procedure gives the patient the benefits of an anterior and posterior fusion without having two incisions.

In the classic anterior approach, the procedure is performed from the front, with the patient facing the surgeon, through an incision in the neck or abdomen. The fusion is carried out from the front of the vertebrae through the anterior annulus. In the classic posterior approach, the procedure is performed through an incision in the patient’s back directly over the vertebrae. The fusion is carried out from the back of the vertebrae through the lamina, removing the spinous processes. In another approach, lateral transverse, the incision is made on the patient’s side but this is also considered a posterior approach because the patient is lying face down and the vertebrae are approached through the lamina.

A surgeon can perform both an anterior fusion and a posterior fusion during the same operative session, in which both the front and back of the vertebrae are fused. This has traditionally involved both an anterior approach and a posterior approach, accomplished by repositioning the patient and making two incisions. However, improved technology and surgical techniques allow both an anterior and a posterior spinal fusion to be accomplished through a single incision, predominantly via the lateral transverse approach. Therefore**,** in a 360 degree spinal fusion, both anterior and posterior vertebrae are fused, sometimes through both anterior and posterior approaches and sometimes through a single lateral transverse approach. Code 81.61 360 degree spinal fusion, single incision approach was created in October 2002 to capture these procedures.

Coding Options:
Option 1: Continue using code 81.61, 360 degree spinal fusion, single incision approach, to capture fusions of the anterior and posterior spine with a single incision.

Option 2: Delete code 81.61, modify code 81.08, and create the following new code to better capture PLIFs (Posterior Lumbar Interbody Fusion) and TLIFs (Transforaminal Lumbar Interbody Fusion):

Delete code	~~81.61 360 Degree spinal fusion, single incision approach~~	
	81.06	Lumbar and lumbosacral fusion, anterior technique
Add		ALIF (Anterior Lumbar Interbody Fusion)
Revise	81.08	Lumbar and lumbosacral fusion, posterior column, posterior technique
Delete		~~Posterior (interbody) technique~~
Delete		~~Posterolateral technique~~
New code	81.09	Lumbar and lumbosacral interbody fusion, posterior technique
		Inter-transverse process technique
		PLIF (Posterior Lumbar Interbody Fusion)
		TLIF (Transforaminal Lumbar Interbody Fusion)

This option would involve reporting both codes 81.09 and 84.51, which would appear to provide duplicative information on the use of an interbody fusion device.

Option 3: Delete code 81.61 and add PLIF and TLIF as inclusion terms under 81.08 and ALIF under 81.06. Coders would also assign the code for the insertion of interbody fusion device (81.51).

Delete code	~~81.61 360 Degree spinal fusion, single incision approach~~	
	81.06	Lumbar and lumbosacral fusion, anterior technique
Add		ALIF (Anterior Lumbar Interbody Fusion)
	81.08	Lumbar and lumbosacral fusion, posterior technique
Add		Inter-transverse process technique
Add		PLIF (Posterior Lumbar Interbody Fusion)
Add		TLIF (Transforaminal Lumbar Interbody Fusion)

CMS Recommendation:
CMS recommends Option 3, delete code 81.61, 360 Degree spinal fusion, single incision approach. Add inclusion terms as indicated. And continue reporting code 81.51, insertion of interbody fusion device when the device is inserted.

Interim Coding:
Continue assigning code 81.61, 360 Degree spinal fusion, single incision approach, to capture 360 degree spinal fusion, single incision approach until the code is deleted and new inclusion terms are added.

HIP REPLACEMENT BEARING SURFACES

Issue:
ICD-9-CM does not capture information on the types of bearing surfaces used in hip replacement prostheses. While there are a number of procedure codes that describe the replacement and revisions of hip joints, the type of bearing surface is not included. A manufacturer requested that we create codes that would capture the type of bearing surface including a new type of surface, ceramic-on-ceramic.

New Technology Application?
Yes.

FDA Approval:
The Trident™ Ceramic Acetabular System was approved by the Food and Drug Administration (FDA) in February 2003. This is a two-piece hip implant comprised of alumina ceramic-on-ceramic material.

Background:
We discussed major revisions to the ICD-9-CM procedure codes for revision of hip and knee replacements. Information on this topic can be found in the Summary Report of the ICD-9-CM Coordination and Maintenance Committee meeting, October 7-8, 2004 at www.cms.hhs.gov/paymentsystems/icd9. These codes did not provide information on the type of bearing surface used in the hip replacements or revisions. Hospitals code the type of joint procedures performed. These Total Hip Arthroplasty (THA) procedures are being performed on a wider patient population including a younger and more active patient population. THAs currently last approximately 10-15 years before they need to be replaced. The devices have component loosening, fractures, and surface wear.

Efforts have been made to find bearing materials that will prolong the life of these devices and that will allow a high level of function. Currently, most of these devices use either a metal-on-metal or metal on polyethylene bearing surface. A new bearing surface, ceramic-on-ceramic, offers the possibility of a extending the life of these devices by reducing the amount of friction and providing a less biologically reactive material than is provided by polyethylene or metal surfaces. New codes describing the type of wearing surface may provide better data on patient outcome.

Comparison of Bearing Materials used in Total Hip Arthroplasty

In past decades, surgeons focused on achieving excellent implant fixation during THA because a good initial fixation generally was considered to be a reliable predictor of the future performance of a device. In the 1990s, it became clear that polyethylene wear debris generated with time by the articulating bearing surface of a hip implant was associated with the occurrence of osteolysis, often leading to reoperation and possibly shortening the useful life of an implant. As average life expectancy continues to increase and younger and more active patients have THAs, limiting the amount of wear debris could help extend the average life expectancy of an implant.

Ceramic –on-Ceramic Bearings

Alumina ceramic offers several theoretical advantages: it is extremely hard and scratch resistant; it has a low coefficient of friction and excellent wear resistance; it is more hydrophilic than either polyethylene or metal and provides improved lubrication; there is no potential for metal ion release; and alumina particulate debris is less bioreactive than either polyethylene or metal debris.

Metal-on- Metal Bearings

Metal-on-metal bearings have extremely low wear compared with metal-on-polyethylene bearings. Although good clinical results have been reported with metal-on-metal bearings, the long-term effect of accumulated metal ions in otherwise healthy tissue is unknown. Negative effects of elevated metal ion levels in people with compromised kidney function have been reported.

Metal on Polyethylene Bearings

To address the problem of polyethylene wear and subsequent debris mediated osteolysis, polyethylenes with improved wear performance have been developed. Crosslinking of the polyethylene material has been shown in the laboratory to decrease the polyethylene wear rates up to 90% over conventional polyethylene. Cross-linked polyethylenes with enhanced resistance to wear now are in use clinically, but long-term results still are unknown.

Bearing	Strengths	Weaknesses
Ceramic on Ceramic	• Superior wear in laboratory compared to MOM or M/P • Extreme hardness and scratch resistance • Hydrophilic=improved lubrication • Highly biocompatible • 7 years clinical experience with modern designs • Allows use of larger femoral heads which may contribute to stability of construct	• Risk of component fracture; estimated 1 to 3 in 10,000 components implanted (0.01%-0.03%) with modern designs.[willman, 2003 8th Biolox Symposium] • Audible noise from hip joint in small number of cases
Metal on metal (MOM)	• Superior wear in laboratory compared to M/P • No risk of device fracture • 10+ years of clinical history	• Long term metal ion exposure with reports of high serum chromium levels. [Jacobs et al Metasul Hans Huber, Bern 1999]

	• Allows use of larger femoral heads which may contribute to stability of construct	• Hypersensitivity to metal • Run-in wear reported • Audible noise from hip joint in small number of cases
Metal on Polyethylene(M/P)	• No risk of catastrophic fracture • No metal ion effect • 5 year experience with cross linked polyethylenes	• Potential for polyethylene particle release / osteolytic reaction • Manufacturing process associated with cross linking has the potential to affect mechanical properties; reports of component breakage with some designs • Head size is limited by minimum acceptable polyethylene thicknesses.

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2. Hellman EJ, Capello WN, Feinberg JR: Omnifit cementless total hip arthroplasty: A 10-year average follow-up. Clin Orthop 364:164-174, 1999.
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6. Capello WN, D'Antonio JA, Feinberg JR, Manley MT: Ten-year results with hydroxyapatite-coated total hip femoral components in patients less than fifty years old. J Bone Joint Surg 85A:885-889, 2003.
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13. D'Antonio J, Capello W, Manley M. Alumina ceramic bearings for total hip arthroplasty. Orthopedics. 2003 Jan;26 (1):39-46.
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17. Stea S, Visentin M, Granchi D, et al: Wear debris and cytokine production in the interface membrane of loosened prostheses. J Biomater Sci Polym Ed 10:247-257, 1999.

Coding Options:

1. **Do not create codes to capture the type of hip replacement bearing surfaces. Continue to code the procedure performed.**

2. **Create new codes as follows to describe the type of bearing surface:**

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

Code also notes would then be placed under the codes for hip replacement and revisions (00.70 – 00.73, 81.51 – 81.53,) as follows:

Code also type of bearing surface, if known (00.74-00.78)

CMS Recommendation:
CMS recommends option 2, create new codes to describe the type of bearing surface for total hip arthroplasties.

Interim Coding:
In the interim, there are not codes that capture the type of bearing surface. Continue to code the type of procedure performed.

Implantation of Interspinous Process Decompression Device

Issue:
Current ICD-9-CM procedures codes do not provide a unique descriptor identifying posterior approach interspinous process decompressive (IPD) implantable devices that are non-fusion in nature. This procedure is currently captured under code 84.59, Insertion of other spinal devices. As technological improvements are made and adopted, there is no adequate methodology for appropriate coding or tracking of such device(s). Should new codes be created to uniquely capture such devices?

New Technology Application?
No.

FDA Approval:
The X STOP interspinous process decompressive (IPD) implantable device is currently being implanted under clinical trials at 12 sites in the US. The company anticipates FDA approval in the second quarter of 2005 (April – June 2005).

Background:
Lumbar spinal stenosis (LSS) is a condition involving any type of narrowing of the spinal canal or neural foramina. The most common form of LSS is degenerative stenosis, which occurs as a result of the natural process of aging. Stenosis patients usually present with pain, numbness and tingling in the lower extremities. These symptoms are relieved in flexion or sitting and are exacerbated in extension. Patients develop chronic low back pain and weakness in the legs that limit walking to brief duration and short distance, restricting their ability to carry out the basic activities of daily life – work, social, and recreational.

Decompressive surgery with or without fusion is the 'gold standard' treatment for moderate to severe symptomatic LSS. This treatment however requires a long recovery time and many elderly patients are unable to undergo general anesthesia due to co-morbid conditions and health risks. Thus minimally invasive procedures like IPD's, provide great potential benefit to this group of LSS sufferers.

LSS is now the most common diagnosis leading to lumbar spinal surgery in adults older than 65 years of age. Patients requiring surgical intervention undergo a decompressive laminectomy, sometimes accompanied by fusion. Other types of decompressive surgery to treat LSS include laminotomy, foraminotomy, and medial facetectomy. These procedures require invasive surgery with multiple hospital days for recuperation. Close to 300,000 days of care were required in non-federal hospitals alone in the treatment of LSS in 2002. Success rates of approximately 60% are expected, and the morbidity rate ranges from 12-20% for this invasive surgery.

The X STOP IPD was designed to treat patients with lumbar spinal stenosis (LSS) who normally experience pain and tingling in their legs while standing or extending, and experience pain relief while sitting or flexing their lumbar spine. The X STOP is placed between the lumbar spinous processes of the stenotic level(s) and the design rationale is to limit extension of the stenotic level(s). Biomechanical testing has demonstrated that X STOP placement significantly increased

the spinal canal and neural foramina areas of the treated level(s) during extension, and did not significantly affect the areas of the untreated level(s). The spinal canal and neural foramina are widely believed to be the source of neural compression and subsequent pain in LSS patients. Additional biomechanical testing has demonstrated that X STOP placement significantly decreased the intervertebral disc pressure and facet loading at the treated level(s), and did not significantly affect the pressure or loading of untreated levels.

What it does and how it is used:

There are several benefits to the patient who has an X STOP implantation over current surgical alternatives. The X STOP is implanted under local anesthesia with light intravenous sedation, with the patient in the lateral decubitus position. A posterior, two- to four-inch midline incision is made exposing the spinous processes at the appropriate disc level, which is confirmed radiographically. The supraspinous ligament is preserved. The interspinous ligament is dilated and the IPD implant is inserted and secured. Generally speaking, implantation of the X STOP IPD can be completed in approximately one hour for a single-level implant.

Research has been conducted to answer questions regarding the biomechanical impact of implanting IPD devices in the spine, and to understand the mechanism by which the IPD's allow patients to resume their normal posture symptom-free postoperatively. In vitro data have demonstrated that IPD devices have several biomechanical effects on the implanted and adjacent spinal levels:

> Kinematics: The IPD limits extension at the treated level during flexion-extension, and preserves the range of motion in axial rotation and lateral bending; it does not affect the flexion-extension, axial rotation, and lateral bending rages of motion at adjacent levels.

Patient Population:

LSS is becoming increasingly common as the American population ages, representing a hidden neurological epidemic. Patients at risk for LSS are increasing in numbers as the population ages, since 'almost all adults have narrowing in their spinal canals and are potential candidates for lumbar spinal stenosis.

> Low back problems are among the most frequent complaint expressed by patients during primary care office visits.
>
> Spine surgery ranks third among all surgical procedures.
>
> > *Anderson GBJ. Epidemiology of spinal disorders. In: Frymoyer JW, ed. The Adult Spine. New York, NY: Raven Press, 1991:107-146.*
>
> Approximately 80 percent of Americans report low back problems at some time during their lives.

Damkot DK, Pope MII, Lord J, Frymoyer JW. The relationship between work history, work environment and low back pain in men. Spine. 1984;9:395-399.

At any given time, about 1 percent of the U.S. population is chronically disabled due to back problems and another 1 percent is temporarily disabled.

Kelsey JL, White AA III. Epidemiology and impact on low back pain. Spine. 1980; 5(2):133-142.

FDA approval information:
St. Francis Medical Technologies, responsible for the development and manufacturing of the X STOP IPD device, is anticipating FDA approval for its device and subsequent release in the second quarter of 2005. Currently, there are multiple Continued Access Programs (CAP) beyond the initial clinical trials whereby the X STOP continues to be implanted. The X STOP is CE marked, and currently in use in many countries around the world.

Overview of Existing Surgical Alternatives:
Once the diagnosis of LSS has been confirmed treatment begins with a regimen of non-operative care, consisting of conservative therapy and epidural steroid injections. Non-operative modalities represent the standard of care for patients with mild to moderate symptoms of LSS. Decompressive surgery is the next therapeutic option and may be considered for patients with more severe symptoms or those patients who are dissatisfied with the outcomes of non-operative therapies. Decompressive surgery is absolutely indicated in patients at risk of irreversible neurological damage from canal compromise such as cauda equina syndrome; however, this represents a very small percentage of LSS patients.

The reported complications from decompressive laminectomy include death, pain, infection, dural tears, bleeding, neurological deficit, re-operations and functional disability. The incidence of morbidity and mortality from surgery increases with the presence of co-morbid conditions, which are frequently present in the elderly patient population at risk for LSS. The overall rate of complications for laminectomy procedures alone and with fusion was reported by Deyo:

Postoperative complications, by procedure, from 18,122 hospitalizations*

OPERATION:	**Complications while hospitalized**	**Mean duration of hospitalization**
Laminectomy*	**13.9%**	**7.2 days**
Laminectomy with arthrodesis (fusion)*	**19.6%**	**8.0 days**
X STOP IPD	**< 1%**	**1 day**

The procedure is currently being performed in 12 sites in the US. It is being performed in an inpatient and outpatient setting. While the initial procedures may be performed predominately as an inpatient, clinical trials indicated that eventually it will be primarily an outpatient procedure.

Current Codes:
Currently, the insertion of Interspinous Process Decompression devices is captured in code 84.59, Insertion of other spinal devices.

Coding Options:

Option 1
Continue capturing this procedure with code 84.59, Insertion of other spinal devices. Since this procedure may predominantly be performed in an outpatient setting, a unique code is not needed.

Option 2
Initially, the procedure will be performed for the most part as an inpatient procedure. However, it could be performed on either an inpatient or outpatient basis. More accurate data is needed to track this procedure.

Revise: 84.5 Implantation <u>or removal</u> of other musculoskeletal devices and substances

New code: 84.56 Implantation of interspinous process decompression device
Excludes: fusion of spine (81.00-81.08, 81.30-81.39)

New code: 84.57 Removal of spinal device

CMS Recommendation:
CMS recommends Option 2, create new codes for:
84.56 Implantation of interspinous process decompression device
84.57 Removal of spinal device

Interim Coding:
Continue capturing the insertion of this device using code 84.59, Insertion of other spinal devices.

External Fracture Fixation Devices

Issue:
ICD-9-CM does not differentiate between the different types of fracture fixation devices.

New Technology Application?
No.

Background:
External fixation is an external scaffold designed to secure bone fragments with temporary percutaneous implants. The purpose is to provide a stable healing environment for the restoration and healing of bone and soft tissue.

Hippocrates (460-370 BC) described a method of external fixation as a means of immobilizing fractures. He was 2,000 years ahead of his time. The development of the more modern external fixator has continued to evolve partly because of the need to treat serious war injuries. The philosophy of external fixation has changed dramatically over the last few decades. Wide usage in the early part of the 1800s, often for inappropriate indications, coupled with the lack of appreciation of the biomechanics of fracture healing, served to highlight the problems which could be associated with the technique when transfixing pins and multi-bar constructs causing uncompromising rigidity.

Better understanding of the physiology of fracture healing has resulted in a change in the way the external fixator has been utilized. We have learned over time that compression of the fracture site encourages healing as well as creating an osteosynthesis for an arthrodesis of a joint or healing a non-union of a fracture. Concepts of elastic fixation have been developed and micro movement has been shown to promote bony union at fresh fracture sites. Dynamization, toward the end of fracture healing, strengthens the callus, speeds up consolidation, and allows early removal of the fixator.

External fixators may be applied to function in one of three ways:
1. Neutralization – Holding the limb out to length; protecting the fracture site from loading (neutralizing the load)
2. Compression – Compressing the fracture fragments together in an effort to increase stability and facilitate the healing of fresh fractures and non-unions.
3. Distraction – Pulling the fracture or osteotomy apart so that bone will regenerate, and thus lengthen the limb.

In addition to healing fractures and non-unions, external fixation has been used for deformity correction across all patient age groups. Preserving the blood supply to the bone is the main benefit in using external fixation. Keeping the periosteum intact and performing a closed reduction limits the chance of infection. Contraindications to external fixation include patients with severe osteoporosis, HIV infection, patients who may be uncooperative or predictably difficult, and patients with severe, poorly-controlled diabetes mellitus.

Current Coding:
Fixation devices can currently be coded as follows:

Index:

Application
external fixation device (bone) 78.10
fourth digits of [0-9] are used to specify site

Fixation
bone
external, without reduction 93.59
with fracture reduction – *see* Reduction, fracture

Reduction
fracture (bone) (with cast) (with splint) (with traction device) (closed) 79.00
with internal fixation 79.10
fourth digits of [0-9] are used to specify site

Tabular:

78 Other operations on bones, except facial bones
78.1 Application of external fixation device
[0-9] Minifixator with insertion of pins/wires/screws into bone
Excludes other immobilization, pressure, and attention to wound (93.51-93.59)

79 Reduction of fracture and dislocation
Includes application of cast or splint
reduction with insertion of traction device (Kirschner wire) (Steinmann pin)
Code also any application of external fixation device (78.10-78.19)
Excludes external fixation alone for immobilization of fracture (93.51-93.56, 93.59)
79.1 Closed reduction of fracture with internal fixation
[0-9] are fourth digits used to indicate site

93 Physical therapy, respiratory therapy, rehabilitation, and related procedures
93.5 Other immobilization, pressure, and attention to wound
93.51, plaster jacket; 93.52, neck support; 93.53, other cast; 93.54, splint; 93.55, dental wiring; 93.56, pressure dressing
93.59 Other immobilization, pressure, and attention to wound

Coding Option(s):
1. Continue to use the established structure, as outlined above. The use of more than one code may be necessary to completely describe the case. The diagnosis code will identify the indication for use of the device.

2. The applicant has suggested the following modifications to the existing coding system.

	78	Other operations on bones, except facial bones
Revise code title	78.1	Application of external fixation device, monoplanar
Revise includes note	[0-9]	~~Minif~~Fixator with insertion of pins/wires/screws into bone

Minifixator(s)

Add excludes note Excludes: ring system (17.0x)

NEW CHAPTER

3A. Other Procedures and Interventions, Not Elsewhere Classified (17)

17 Other procedures and interventions, not elsewhere classified

The following fourth-digit subclassification is for use with categories in section 17.0 and 17.1 to identify the site. Valid fourth-digit categories are in [brackets] under each code.

0 unspecified site
2 humerus
3 radius and ulna
5 femur
7 tibia and fibula
8 tarsals and metatarsals
9 other
pelvic bones
phalanges [of foot] [of hand]
vertebrae

New code 17.0 Application of external fixation device, ring system [0, 2-3, 5, 7-9]
Sheffield type
Excludes: monorail system (78.1x)
other multiplanar system (17.1x)

New Code 17.1 Application of external fixation device, other multiplanar [0, 2-3, 5, 7-9] system
Hybrid system using both ring and monoplanar devices
Excludes: ring system (17.0x)
monoplanar (78.1x)
monorail (78.1x)

79 Reduction of fracture and dislocation

Revise note Excludes ~~external fixation alone for immobilization of fracture~~ other external fixation such as casts, support, splints, or wiring (93.51-93.56, 93.59)

CMS Recommendation: CMS recommends coding option 1.

Interim Coding: Continue to use existing codes found at categories 78, 79, and 93 to describe fixation of fractures.

Infusion of Liquid Radioisotope

Issue:
Should new procedure codes be created to capture the three integral parts of infusion of liquid radioisotope? There is no specific ICD-9-CM code describing infusion of a liquid radioisotope into the brain. The current ICD-9-CM does not differentiate between the placement of different types of radioelements. This issue was discussed at the October 7, 2004 ICD-9-CM Coordination and Maintenance Committee meeting and is being revisited.

New Technology Application?
No.

Background:
Iotrex™ is an organically bound liquid form of Iodine-125 used in intracavitary brachytherapy with the GliaSite® Radiation Therapy System (RTS). Iotrex™ is a single non-encapsulated (liquid) radioactive source. Iotrex™ I-125 liquid radioisotope was cleared for marketing in April 2001. The liquid is a solution of sodium 3-(125I) iodo-4-hydroxybenzenesulfonate and is used in a breakthrough approach to deliver brachytherapy for treatment of brain cancer. The I-125 solution is nontoxic, nonpyrogenic and water-soluble. Iotrex™ comes in a one ml glass vial. Each one ml dose provides ~195 mCi of radiation.

The delivery system for I-125 Iotrex™ is a unique cavity conforming balloon catheter. The liquid Iotrex™ is administered via injection through a self-sealing port into the primary lumen of the barium-impregnated catheter that leads to the balloon reservoir. Various sizes of balloons are available.

<u>What it does and how it is used:</u>
After the malignant brain tumor has been resected, a balloon catheter (GliaSite® catheter) is implanted temporarily inside the cavity. The patient is released from the hospital. After a period of 3 days to 3 weeks, the patient is readmitted. At this time, the liquid I-125 (Iotrex™) is infused into the special catheter and intracavity radiation is delivered to the target area. The emitted gamma radiation from Iotrex™ is delivered directly to the margins of the tumor bed. Because the radiation dose rapidly decreases beyond the tumor site, there is minimal damage to surrounding healthy tissue. This approach allows the physician to maximize total radiation to the target area. After 3 to 7 days, the liquid I-125 Iotrex™ is removed.

Infusion of liquid radioisotope into a special cavity-conforming balloon catheter allows the precise delivery of local radiotherapy to the tumor margins where recurrence is most likely to occur. The delivery of a high dose of radiation locally at a continuous rate may better spare normal brain tissue from adverse radiation effects.

<u>Patient Population:</u>
The American Cancer Society estimates that 17,000 U. S. patients will be diagnosed this year with malignant primary brain tumors. Surgical resection plus radiation is the most effective treatment available today for these patients.

Overview of Conventional Insertion of Radioactive Element:
Brachytherapy has historically involved the use of small, encapsulated radioactive sources (seeds) implanted short distances apart within a malignant tumor. Radioactive seeds are used to treat multiple tumor types (breast, prostate, and in some cases, brain). Seed brachytherapy involves the invasive placement of radioactive seeds via multiple (up to 20) steel needles into the tumor tissue. In placing these multiple radiation sources, the radiation dose is frequently non-uniform with the potential for hot and cold spots. Consequently, when traditional brachytherapy is used for brain tumors, additional surgery may be needed to remove necrotic brain tissue which results from a non-uniform delivery of radiation. This complication associated with using seed brachytherapy has limited its widespread use in treating brain cancer, despite studies showing improved survival.

Infusion of Liquid Radioisotope for Treatment of Brain Cancer:
A new intracavity-conforming balloon catheter was developed to avoid some of the problems inherent with the use of seed brachytherapy for treatment of brain cancer. The device is the GliaSite® catheter and the treatment involves the infusion of a new liquid I-125 radioisotope (trade name Iotrex™). The catheter is inserted at the time that the tumor is resected. Subsequently, the I-125 is infused, placing the radioactive source in direct contact with the resection-cavity wall and providing a dose distribution that is highly conformal with the target tissue around the cavity.

The use of this single intracavitary applicator positioned inside the tumor resection cavity during the initial surgery (in place of seed implant) provides several clinical benefits which are described below.

Significantly improved dose delivery as compared to conventional brachytherapy. Infusion of I-125 (Iotrex™) facilitates the delivery in a single application the same radiation dose that requires implantation of multiple (up to 125) radioactive seeds.

More conformal/predictable dose delivery. The conformal catheter facilitates the delivery of radiation to the target tissue in a uniform manner and therefore, preclude "hot spots" and the subsequent need to re-operate to excise necrotic tumor/tissue. In comparative testing with seed implants, liquid I-125 Iotrex™ delivered via the GliaSite® catheter provides a more conformal therapy with no target tissue under-dosing, less target tissue overdosing and no healthy tissue 'hot spots'.

Coding Options:
Option 1. Continue to code this procedure to code 92.28, Injection or instillation of radioisotopes. To capture the removal of the catheter, code 86.09, Other incision of skin and subcutaneous tissue, should be assigned.

Option 2. Create three new procedure codes for the insertion of the catheter, infusion of liquid brachytherapy radioisotope, and removal of the catheter. Add exclusion terms under codes 92.27, Implantation or insertion of radioactive elements, and 92.28 to exclude this procedure.

New code 01.26 Insertion of catheter into cranial cavity

New code 01.27 Removal of catheter from cranial cavity

New code 92.20 Infusion of liquid brachytherapy radioisotope
I-125 radioisotope
Intracavitary brachytherapy
Includes: removal of radioisotope

CMS Recommendation:
Option 2. Create three new procedure codes for the insertion of the catheter, infusion of liquid brachytherapy radioisotope, and removal of the catheter. Add exclusion terms under codes 92.27, Implantation or insertion of radioactive elements, and 92.28 to exclude this procedure.

New code 01.26 Insertion of catheter into cranial cavity

New code 01.27 Removal of catheter from cranial cavity

New code 92.20 Infusion of liquid brachytherapy radioisotope
I-125 radioisotope
Intracavitary brachytherapy
Includes: removal of radioisotope

Interim Coding:

Continue to code this procedure to code 92.28, Injection or instillation of radioisotopes. To capture the removal of the catheter, code 86.09, Other incision of skin and subcutaneous tissue, should be assigned.

Radio Frequency Ablation of (Chronic) Total Artery Occlusion

Issue:
Current ICD-9-CM procedure codes do not provide a means of identifying when the specific procedure of crossing a chronic total occlusion must be carried out along with an angioplasty and stent placement. This ablation can take place in both coronary and peripheral arteries.

New Technology Application?
Yes.

FDA Approval:
510K clearance of the IntraLuminal Therapeutics Safe-Cross® Total Occlusion Crossing System for native coronary and peripheral arteries, except for carotid arteries.

Background:
Chronic total occlusion (CTO) is defined as coronary or peripheral artery occlusion of more than one month duration. Between 10 -20 percent of patients currently undergoing percutaneous interventions in major cath labs have CTOs. Successful opening of CTOs improves anginal status, increases exercise capacity, and reduces the need for bypass surgery. Opening a CTO is a major challenge for the physician, as the plaque tends to be very hard, fibrotic, and calcified, blocking the flow of imaging contrast used to visualize the path of the artery. Threading a guidewire through a CTO creates risk of vessel perforation if the guidewire can even penetrate the blockage, since the path of the artery cannot be seen. Historically, patients with CTO have not been treated by angioplasty because the anatomical condition of total blockage complicates the procedure. This condition is the most common reason that a patient is referred for bypass surgery from the cath lab.

The predominant reason for failure to open CTOs with percutaneous coronary interventions has been failure to cross the lesion with a guidewire (80 percent) and failure of a balloon to track along the guidewire (15 percent) through the very hard lesion. Many types of guidewires and devices have been tried, but successful recanalization has remained at about 60 percent of the highly selective cases. One of the problems has been difficulty in visualizing the vessel path. Another problem is the hardness of the lesion, so that the guidewire cannot be forced through or is deflected into side branches or the subintimal space, resulting in arterial dissection.

The Safe-Cross® System was designed to solve these problems, and is the first FDA–cleared guidewire device specifically labeled for the purpose of crossing CTOs. With an optical fiber embedded into the guidewire, the system is able to provide guidance feedback to the operactor through optical coherence reflectometry. Specifically, it recognizes the vessel wall and alerts the operator to steer the wire away to prevent subintimal passage or perforation. Additionally, the Safe-Cross ® device is able to deliver radio frequency energy (vaporization) to micro-ablate a small hole into a CTO of an artery to facilitate passage of the guidewire. Only after a guidewire is across the occlusion can angioplasty and often, the insertion of a stent, take place.

Coding Option(s), Coronary Vessel(s):
1. Continue to code this angioplasty to the established codes. Use one of the following codes to describe percutaneous transluminal coronary angioplasty (PTCA);
36.01, Single vessel … without mention of thrombolytic agent
36.02, Single vessel … with thrombolytic agent
36.05, Multiple vessel … with or without thrombolytic agent.
Code also any stent insertion: 36.06 (non-drug-eluting) or 36.07 (drug-eluting).

2. Create a new code to describe this technology.

	00.6	Procedures on blood vessels
New code	00.66	Radiofrequency crossing of total vessel occlusion(s) Code also any: Coronary vessel stent insertion (36.06, 36.07) PTCA or coronary atherectomy (36.01, 36.02, 36.05) PTA or peripheral atherectomy (39.50) Peripheral vessel stent insertion (00.55, 39.90)

Coding Option(s), Peripheral Vessel(s):
1. Continue to code this angioplasty to the established codes. Use the following code to describe percutaneous transluminal angioplasty (PTA):
39.50, Angioplasty or atherectomy of other non-coronary vessel(s)
Code also any peripheral stent insertion: 00.55 (drug eluting) or 39.90 (non-drug eluting)

2. As above, use the newly created code to describe radiofrequency crossing of total vessel occlusion(s).

CMS Recommendation:
Create a new code at 00.66, as described above.

Interim Coding:
Use established codes as described above for coronary and peripheral sites of angioplasty, atherectomy, and stent insertion. It has come to our attention that coders may be using 36.09, Other removal of coronary artery obstruction, to describe angioplasty or atherectomy via radiofrequency ablation. However, there is an excludes note at 36.09, which "Excludes that by percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy (36.01, 36.02, 36.05).

It has also come to our attention that coders may be using 39.59, Other repair of vessel, or 39.99, Other operations on vessels, to describe angioplasty or atherectomy of peripheral vessels via radiofrequency ablation. This is incorrect coding which may result in upcoding of the case, as well as subsequent investigation or review.

Endovascular Implant in Thoracic Aorta

Issue:
There is no specific ICD-9-CM code that will capture the endovascular insertion/implantation of graft in the thoracic aorta (EIGTA). A non-specific code is currently recommended for capturing this procedure: 39.79, Other endovascular repair (of aneurysm) of other vessels.

New Technology Application?
Yes.

FDA Approval:
A letter from the FDA Panel recommending approval was dated January 8, 2005.
A letter recommending final approval was received March 23, 2005.

Background:
A defect of the thoracic aorta, whether caused by structural weakness of the aortic wall (aneurysm, dissection), trauma, or a complication of previous surgery is a potentially life threatening condition. Traditional treatment requires open surgical repair of the damaged portion of the thoracic aorta, often under urgent or emergent conditions. Despite improved patient management strategies, surgery and recovery for these patients remains challenging due to the thoracotomy required to access the thoracic aorta behind the heart and lungs. In addition, the frequent presence of comorbid conditions such as coronary artery disease, chronic heart failure, and diabetes adds to the complexity of the case. In-hospital mortality rates for patients undergoing surgical repair ranges from 3-20 percent. Operative and postoperative complications can significantly increase the risk of extended hospital stay. These major adverse events can include neurologic complications, renal failure, low cardiac output, pulmonary insufficiency, myocardial infarction, postoperative hemorrhage, pulmonary embolism, and sepsis. Return to normal activity for these patients averages 3-4 months, and sometimes longer.

Endovascular stent-grafting of the thoracic aorta provides a minimally invasive and less hazardous treatment alternative for many patients requiring thoracic aortic repair, whether on an elective or emergency basis. The endoprosthesis is a conduit constructed of ultra-thin graft material with an integrated, self-expanding metallic stent-graft. The function of the endoprosthesis is to internally reline the damaged portion of the thoracic aorta, excluding it from the blood circulation. (Envision an internal sleeve isolating the native tissue from the blood flow.)

Endovascular grafting is accomplished through a small incision, normally in the patient's leg or groin, providing access to the femoral or iliac artery. Using image guided, catheter-based techniques, the endoprosthesis is maneuvered through the peripheral vasculature and abdominal aorta, and is positioned in the damaged section of the thoracic aorta. Following deployment, imaging is used to confirm proper position in the aorta. Balloon touch-up is then utilized to ensure proper fit of the device to the aortic wall. In some cases, an additional device may be deployed to assure coverage of the entire segment to be treated, and or to better accommodate irregular anatomy. Following complete exclusion of the damaged segment, catheters and sheaths are removed, and the access incision is closed in standard fashion.

Coding Option:

1. Create a new code for this procedure, as follows:

	39.7	Endovascular repair of vessel
New code	39.73	Endovascular implantation of graft in thoracic aorta Endograft(s) Endovascular graft(s) Endovascular repair of defect of thoracic aorta with graft(s) Stent graft(s) That for repair of aneurysm, dissection, or injury
	39.79	Other endovascular repair (of aneurysm) of other vessels
Add excludes note		Excludes: endovascular implantation of graft in thoracic aorta (39.73)

CMS Recommendation:

Adopt the above coding structure in order to specifically recognize this specific procedure.

Interim Coding:

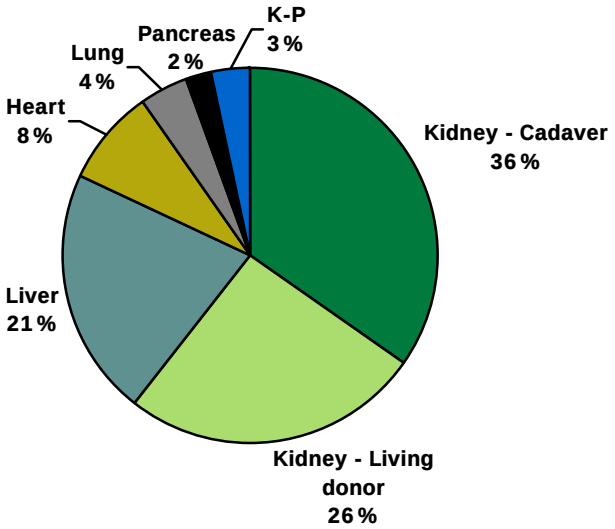
Continue to use code 39.79, Other endovascular repair (of aneurysm) of other vessels, to describe this procedure until a new code can be created.

Infusion of Immunosuppressive Antibody Therapy at the Time of Transplantation

Issue:
No specific existing ICD-9-CM procedure code describes the intravenous infusion of immunosuppressive antibody therapy during the induction phase of solid organ transplantation. One of the companies that manufactures immunosuppressive antibody therapy and physicians who use these drugs have brought this concern to the committee's attention principally because there is no way of tracking the use of these drugs through the ICD-9-CM procedure coding and their impact on the patient stay and outcome. The procedure is currently captured through code 99.29, Injection or infusion of other therapeutic or prophylactic substance.

New Technology Application?
No.

Background:
In 2003, 25,000 solid organ transplantations (SOTs) were performed in the United States. The kidney is the most commonly transplanted organ (62%), followed by the liver, heart, lung, and pancreas.[1]



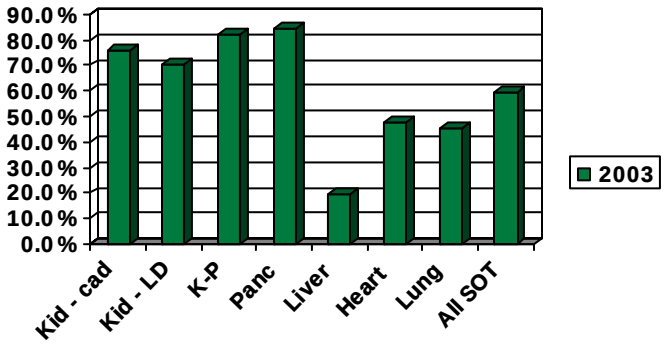
Patients can receive renal transplants from living or deceased donors. Patient survival rates are greater for kidneys that are transplanted from living donors; however, the majority of transplants are acquired from cadaver donors. Renal transplantation has become a well-established treatment in patients with end-stage renal disease. Compared to renal dialysis, renal transplantation is associated with improved quality of life, increased survival rates, and lower health care costs.

Although allograft survival rates have improved over the past decades, allograft rejection remains a barrier to both short- and long-term allograft survival. When a new organ is introduced into the body, the human immune system naturally reacts against the foreign tissue by

1 United Network for Organ Sharing.

initiating a cell-mediated immune response. Approximately 25-60% of all patients receiving renal transplants experience rejection in the first year following transplantation.[2]

Immunosuppressive antibody therapies immunomodulate and prevent the immunologic activity against foreign antigens present on the transplanted organ. Immunosuppression is used in solid organ transplantation to prevent rejection in the induction phase as well as a maintenance phase and can be used to reverse an ongoing rejection episode. Of the 25,000 total SOTs performed annually, approximately 15,000 receive immunosuppressive induction therapy. Below is a graphic created from data collected by UNOS (United Network for Organ Sharing) that shows the percentage of patients that receive immunosuppressive antibody induction therapy broken down by organ transplanted:



The induction phase occurs prior to, during, or immediately after surgical transplantation. Immunosuppressive antibody therapies contain antibodies that preferentially bind to antigens expressed on lymphocytes, specifically T-cells that are responsible for allograft rejection. As a result, T-cells may be depleted, proliferation is inhibited, and cell surface antigens are immunomodulated leading to T-cell clearance from the blood and peripheral lymphoid tissues.

Currently available therapies used during the induction phase of transplantation to prevent renal rejection include the following monoclonal and polyclonal antibody therapies:

Monoclonal antibodies

- Novartis' Simulect® (basiliximab) received FDA approval in 1998 for the prophylaxis of acute organ rejection in patients receiving renal transplantation when used as part of an immunosuppressive regimen that includes cyclosporine and corticosteroids.

- Ortho Biotech/Johnson and Johnson's Orthoclone OKT3® (muromonab CD3), approved in 1986, is indicated for the treatment of acute allograft rejection in renal transplant patients and for the treatment of steroid-resistant acute allograft rejection in cardiac and hepatic transplant patients.

[2] Gaber AO, First MR, Tesi RJ, et al. Results of the double-blind, randomized, multicenter, phase III clinical trial of thymoglobulin versus Atgam in the treatment of acute graft rejection episodes after renal transplantation. Transplantation, 1998; 66: 1.

- Roche's Zenapax® (daclizumab) was FDA approved in 1997 for the prophylaxis of acute organ rejection in patients receiving renal transplants when used as part of an immunosuppressive regimen that includes cyclosporine and corticosteroids.

Polyclonal antibodies

- Genzyme's Thymoglobulin® (anti-thymocyte globulin [Rabbit]) was FDA approved in 1998 for the treatment of renal transplant acute rejection in conjunction with concomitant immunosuppression.

- Pfizer's Atgam® (anti-thymocyte globulin) received approval in 1986 for the prevention and/or treatment of renal allograft rejection as an adjunct to other immunosuppressive therapy.

Immunosuppressive antibody therapies used during the induction phase of transplantation are typically administered via the peripheral or central vein of renal transplant patients. In contrast to maintenance therapy, which requires stable doses over a long period of time, induction therapy is administered in short courses during the initial hospital stay. The cost of therapy depends on the total dose delivered and can range from $2,800 to as high as $7,100 or more during a single hospital stay, resulting in hospital charges as reported to Medicare of twice those amounts.

The clinical efficacy of immunosuppressive antibody therapies has been demonstrated in randomized clinical studies. In a 1998 study, patients who received Thymoglobulin® or Atgam® during the induction phase of transplantation experienced acute graft rejection reversal rates of 88% and 65%, respectively.[3] Another study investigated the use of Atgam® and OKT3® to treat acute steroid-resistant rejection episodes in kidney transplant patients and found high survival rates between both groups of patients within three months of transplantation.[4] In particular, renal rejection occurred in 3% of patients receiving Atgam® and in 10% of patients receiving OKT3®.

The number of institutions that perform SOTs is relatively small, approximately 262. They are readily identified and can be easily contacted for their support in implementing a new procedure code.

Current ICD-9-CM procedure codes exist for the transplant procedures themselves:

- 33.50 – 33.52, Transplant of lung
- 37.51, Transplant of heart
- 52.80 – 52.86, Transplant of pancreas
- 50.51 & 50.59, Transplant of liver
- 55.61 & 55.69, Transplant of kidney

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[3] Gaber AO, et al. 1998;
[4] Mariat C, Alamartin E, Diab N, et al. A randomized prospective study comparing low-dose OKT3 to low-dose ATG for the treatment of acute steroid-resistant rejection episodes in kidney transplant recipients. Transplantation International, 1998: 11.

However, they do not distinguish between those patients who receive immunosuppressive induction therapy and those who do not.

The 99.1X section (Injection or infusion of therapeutic or prophylactic substance) and the 99.2X section (Injection or infusion of other therapeutic or prophylactic substance) have no available codes left. The 00.1X section (Pharmaceuticals) has two codes available (00.18 and 00.19) that may be appropriate.

Coding Options:

Option 1.
Do not create a new code. Continue to capture this procedure through code 99.29, Injection or infusion of other therapeutic or prophylactic substance.

Option 2.
Create a new procedure code that captures the intravenous infusion of immunosuppressive antibody therapy during the induction phase of transplantation:

New Code	00.18	Infusion of immunosuppressive antibody therapy during the induction phase of solid organ transplantation

CMS Recommendation:
Adopt option 2, create new code 00.18, Infusion of immunosuppressive antibody therapy during the induction phase of solid organ transplantation.

Interim Coding:
Continue to use code 99.29, Injection or infusion of other therapeutic or prophylactic substance, to describe this procedure until a new code can be created.

Proposed Addenda

Index

	Endarterectomy (gas) (with patch graft) 38.10 intracranial (open) NEC 38.11
Delete subterm	percutaneous approach, precerebral (extracranial) vessel(s) 00.61
Add term	STARR (stapled transanal rectal resection) 70.52
	Test, testing (for) fetus, fetal
Change code	nonstress (fetal activity acceleration determinations) ~~75.35~~ 75.34

Tabular

	00.2	Intravascular imaging of blood vessels
Add Note		Note: real-time imaging of lumen of blood vessel(s) using sound waves
Add excludes note		Excludes Magnetic resonance imaging (MRI) (88.91-88.97)
		03.53 Repair of vertebral fracture
Change code		Excludes: kyphoplasty ~~(78.49)~~ (81.66)
Change code		vertebroplasty ~~(78.49)~~ (81.65)