ICD-9 Committee Explores New Technology, Drug Codes

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This is part two in a two-part summary of proposals from the November ICD-9-CM Coordination and Maintenance Committee meeting. Part 1 was published in the March 2002 Journal of AHIMA.

The ICD-9-CM Coordination and Maintenance Committee, cosponsored by the National Center for Health Statistics (NCHS) and the Centers for Medicare and Medicaid Services (CMS), met on November 1-2, 2001, in Baltimore, MD. Donna Pickett, RHIA, from NCHS, and Patricia Brooks, RHIA, from CMS, co-chaired the meeting.

Proposed modifications to ICD-9-CM were presented and are summarized below. Unless otherwise indicated, there was general support for the proposed changes.

The summary of the Coordination and Maintenance Committee meeting is provided for information purposes only. The comment period for the proposed revisions has expired.

Proposed changes, if approved, would become effective **October 1, 2002**.

Procedures

Minutes from the procedural portion of the Coordination and Maintenance Committee meeting, as well as full details of the code proposals, can be found at the CMS Web site at www.hcfa.gov/ medicare/icd9cm.htm.

Brain Wafer Chemotherapy

Chemotherapeutic wafers are being used as an adjunct to surgery in order to prolong survival in patients with recurrent glioblastoma multiforme (GBM) for whom surgical resection is indicated. Implanted directly into the cavity that is created when a brain tumor is surgically removed, the wafer delivers anti-tumor medication to the site of the excised tumor. The number of wafers implanted is dependent on the size and location of the tumor cavity. The wafers are placed close together against the wall of the tumor cavity by forceps. Once full coverage of the surgical cavity is achieved, the neurosurgeon applies a topical, absorbable hemostatic agent to the area to secure the wafers in place.

A new code to describe implantation of chemotherapeutic agents has been proposed. It would be created in category 00, which is a newly established category for capturing new technology. The code title of the new code would be broad enough to include implantation of chemotherapeutic agents in sites other than the brain.

Therapeutic Ultrasound

Intravascular ultrasound is an interventional treatment for atherosclerotic vascular disease that uses a selective spectrum of therapeutic ultrasound energy. It has a lower frequency and higher intensity level than that used in diagnostic ultrasound applications. The intravascular ultrasound system has two components: a catheter introduced percutaneously, and a dedicated ultrasound instrument to generate and control the ultrasound therapy. Patients with coronary and peripheral vascular atherosclerotic and recurrent stenotic diseases are candidates for this procedure.

Restenosis is a process by which vascular smooth muscle cells excessively proliferate back into the lumen of the artery (neointimal hyperplasia) following balloon angioplasty or stent placement, causing restenosis of the blood vessel. By treating the revascularized lesion with ultrasound, the over-proliferative response of the vascular smooth muscle cells is regulated and may

reduce the incidence of restenosis. In addition to the anti-restenotic applications of ultrasound for coronary and peripheral vascular diseases, therapeutic ultrasound is undergoing development for other uses, such as treatment for plaque, enhancing the delivery of non-viral vector gene delivery for myocardial and peripheral vascular angiogenesis, and enhancing the delivery of DNA vaccines. It is important to note that the US Food and Drug Administration (FDA) has not yet granted approval for the use of intravascular ultrasound.

New codes in category 00 have been proposed for therapeutic ultrasound of vessels of head and neck, heart, peripheral vascular vessels, and other sites. CMS recommended that new codes be adopted after FDA approval has been granted.

Endovascular Repair of Cerebral Vessels

Effective for discharges occurring on or after October 1, 2000, new ICD-9-CM codes were created for endovascular implantation of graft in abdominal aorta and other endovascular graft repair of aneurysm. However, these revisions failed to take into consideration the endovascular approach for other vessels and sites. For example, cerebral aneurysms and cerebral arteriovenous malformations may be repaired via endovascular surgery.

It has been recommended that a new code be created for endovascular repair or occlusion of head and neck vessels and that the code description for code 39.79 be revised to state “other endovascular repair of other vessels.”

Infusion of Drotrecogin Alfa (Activated)

Drotrecogin alfa (activated) is a new biological agent to treat severe sepsis. Severe sepsis is sepsis with at least one organ failure, which could be cardiovascular, renal, respiratory, hepatic, hematological, central nervous system, or unexplained metabolic acidosis. The rate of death from severe sepsis ranges from 30 to 50 percent. The current standard of care for severe sepsis includes antibiotics, intravenous fluids, nutrition, mechanical ventilation for respiratory failure, and surgery to eradicate the source of infection. There has been an increase in the use of more potent and broader spectrum antibiotics, immunosuppressive agents, and new technologies in the treatment of inflammation, infection, and neoplastic disease. These factors will have a direct impact on severe sepsis and its incidence.

Drotrecogin alfa (activated) is a biotechnology product that is a recombinant version of naturally occurring Activated Protein C (APC). APC is needed to ensure the control of inflammation and clotting in the blood vessels. In patients with severe sepsis, Protein C cannot be converted in sufficient quantities to the activated form. It appears that drotrecogin alfa (activated) has the ability to bring blood clotting and inflammation back into balance and restore blood flow to the organs.

It has been proposed that a new code be created in category 00 to classify infusion of drotrecogin alfa (activated). A number ofparticipants opposed the creation of this code because they felt this was contrary to the design and use of ICD-9-CM as a classification system that captures groups of similar services or procedures. ICD-9-CM is rarely used to capture drug-specific information. It was suggested that if new codes are to be created for drugs, they should be more generic so that the code includes a class of drugs as opposed to just a single drug. Currently, code 99.19, Injection of anticoagulant, is the appropriate code to capture administration of drotrecogin alfa (activated).

Cardiac Resynchronization Therapy

Cardiac resynchronization therapy (bi-ventricular pacing) is a new therapy designed to treat cardiac ventricular dysynchrony, common in 20 percent of patients with heart failure. It provides strategic electrical stimulation to the right atrium and both ventricles in order to re-coordinate ventricular contractions and improve cardiac output. There are two types of cardiac resynchronization devices. One is a cardiac resynchronization pacemaker, which is used to provide resynchronization therapy to patients with ventricular dysfunction who do not meet the indications for an automatic cardioverter-defibrillator device (AICD). This device contains programming and treatment algorithms, sensing and controlling features, advanced battery technology, and diagnostic functions. It is currently coded with the pacemaker codes.

A second type of device, the cardiac resynchronization defibrillator, is similar to the pacemaker, but also includes an implantable AICD. The AICD component is used to deliver high-energy shocks to prevent and treat life-threatening ventricular tachyarrhythmias. These devices are currently coded with the AICD codes. The type of device selected by the physician depends on patient indications and the risk for sudden cardiac death due to tachyarrhythmias.

The procedure for both types of devices involves the implantation of a pacemaker or AICD device and electrodes inserted through the subclavian vein and placed directly in the right atrium and right ventricle. A third electrode is inserted through the subclavian vein and is placed within the coronary vein to facilitate its attachment to the external wall of the left ventricle. This procedure often requires a left heart venogram to delineate the coronary vascular system prior to placing the left ventricular electrode. After the device senses an atrial contraction, the two ventricles are stimulated to contract simultaneously. This synchronization of the ventricular contraction sequence optimizes filling of the left ventricle with oxygenated blood and reduces the backward flow of blood into the left atrium. The result is an improved cardiac output.

Although similar in concept to conventional pacemakers and internal cardioverter-defibrillators, cardiac resynchronization therapy devices are uniquely different for the following reasons: they are designed to treat different symptoms, they represent the next generation of cardiac electrical pacing products, and they require new and more sophisticated medical devices, implantation of a third electrode into the coronary venous system of the left ventricle, and a significant amount of additional time and resources.

It has been recommended that new codes be created in category 00 for the following:

- implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system
- implantation of cardiac resynchronization defibrillator, total system
- implantation or replacement of transvenous lead (electrode) into left ventricular coronary venous system
- replacement of cardiac resynchronization pacemaker pulse generator device only
- replacement of cardiac resynchronization defibrillator pulse generator device only

The code for implantation or replacement of transvenous lead into left ventricular coronary venous system would not be assigned if a total system is implanted, and the codes for total system implantation include implantation of this third lead.

Drug-eluting Stents

There are no unique ICD-9-CM codes to describe procedures in which drug-eluting stents are implanted in arteries. Percutaneous procedures using drug-eluting stents are anticipated to have significantly different patient outcomes when compared to procedures in which conventional stents are implanted. A drug is placed on the stent with a special polymer and slowly released into the vessel wall tissue over a period of 30-45 days, thereby preventing the buildup of scar tissue that can narrow the re-opened artery. Stent-based drug therapy is an efficient method of preventing re-narrowing because it addresses both blood vessel remodeling and scar tissue build-up (neointimal hyperplasia). The FDA has not yet approved this technology.

The audience generally favored waiting until FDA approval had been received before implementing new codes for drug-eluting coronary and non-coronary artery stents. Some audience members felt that new codes are unnecessary because use of drug-eluting stents may become standard practice in the future, which would mean that the existing stent codes would be adequate.

Injection or Infusion of Human B-type Natriuretic Peptide (hBNP)

Human B-type natriuretic peptide (hBNP) is indicated for the treatment of patients with acutely decompensated congestive heart failure who have dyspnea at rest or with minimal activity. The use of this treatment reduces pulmonary capillary wedge pressure and improves dyspnea.

A new code has been proposed in category 00 to capture the injection or infusion of hBNP. Participants generally opposed this proposal because they felt that creating codes for specific drugs is an inappropriate use of ICD-9-CM. The existing ICD-9-CM procedure codes for drugs are used infrequently.

Administration of Oxazolidinone

Oxazolidinone is a new class of antibiotics used to treat gram-positive bacteria, including those that are resistant to other therapies. Gram-positive bacterial infections have become increasingly prevalent in recent years, most commonly implicated in infections in the lower respiratory tract, skin and soft tissue, bone and bloodstream, and in meningitis. Currently, only one drug exists in this class of antibiotics.

A new code in category 00 describing injection or infusion of the oxazolidinone class of antibiotics has been proposed. Participants opposed the creation of a new code because they felt it was unnecessary to have a unique code for such a specific class of drugs. A comment was made that ICD-9-CM is not a "drug-naming" coding system. If a facility wishes to collect ICD-9-CM data on the administration of antibiotics code 99.21, Injection of antibiotic can be assigned.

Implantation of Anal Neosphincter

The anal neosphincter currently available is composed of a cuff that is placed around the anal canal, a pressure-regulating balloon, and a control pump that is placed in the scrotum or labia. Tubing connects the cuff to the control pump. Separate tubing connects the control pump to the reservoir balloon. The patient returns for activation of the device six weeks after surgery. Patients who are candidates for this artificial anal sphincter have intractable fecal incontinence due to anorectal trauma (obstetrical, surgical, or accidental), congenital malformations (spina bifida or imperforate anus), or neurological disorders (neuropathy or myasthenia gravis) and have failed conventional management of their fecal incontinence.

Two new codes have been proposed to describe implantation or revision of artificial anal sphincter and removal of artificial anal sphincter. The code for removal of the device would be for those instances when the device is removed without being replaced.

360-Degree Spinal Fusion

In the anterior approach to performing a spinal fusion, the procedure is performed from the front, 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 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 the lateral transverse approach, 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. Both an anterior and posterior fusion can be performed during the same operative session, whereby 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. Improved technology and surgical techniques now 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. Operations in which both an anterior and posterior fusion are performed are clinically more complex and require significantly higher resources, including operative time, implantable devices, and recovery time, than when a fusion is performed on only one part of the spine.

It was recommended that a unique code be created for 360-degree spinal fusion performed through a single approach. This code would be reported in addition to the current fusion (81.0x) and refusion (81.3x) codes, which would identify the approach as well as the level of the spine involved. Participants expressed concern about this "double coding" and recommended the creation of codes for 360-degree spinal fusion that include the level of spine fused so that one code would fully describe the procedure.

Insertion of Interbody Spinal Fusion Device

ICD-9-CM does not currently capture spinal fusion devices such as the interbody spinal fusion device. Interbody fusion devices, also known as interbody fusion cages, Bak cages, and titanium cages, were designed to stabilize and fuse the degenerative disc spaces. They were designed to provide an immediately stable segment to allow fusion and relief of symptoms. The procedure utilizes small, threaded metal cylinders to restore the degenerated disc space to its original height, relieving pressure on the nerves. During surgery, the physician removes portions of the disc and vertebral bones to allow the implants to be inserted into the disc space. Bone grafts are not always used, but when they are, they are packed inside the implant. The devices may be implanted from a posterior or anterior approach. Multiple fusion devices may also be implanted. Although these devices were originally used for patients with no previous fusions, they are now being used during refusion procedures as well.

The current ICD-9-CM codes capture the level and approach for both fusions and refusions. It has been recommended that a new code be created to show that an interbody fusion device was inserted. This code would be reported in addition to the appropriate spinal fusion or refusion code.

Bone Morphogenetic Proteins

Bone morphogenetic proteins (BMPs) have been isolated and shown to have the capacity to induce new bone formation. Using recombinant techniques, some BMPs (referred to as rhBMPs) can be produced in large quantities, leading the way for their potential use in a variety of clinical applications such as in delayed unions, nonunions, and spinal fusions. The FDA has not yet approved any of the BMP products, but BMPs are under investigation for several applications.

One product, rhBMP-2, is being studied for use in place of a bone graft during spinal fusions. It is applied through use of an absorbable collagen sponge or in an interbody fusion device that is then implanted at the fusion site. During a spinal fusion, the product is placed at the fusion site to promote bone growth. This is done instead of the more traditional use of a bone graft from the iliac crest.

Other BMPs are being studied for use in promoting healing for long bone fractures. The BMP product must be surgically implanted. Only long bone fractures that are open or require open surgical management are considered potential candidates for this product.

It was proposed that a new code be created to capture insertion of BMPs during an orthopedic procedure. CMS recommended waiting to create a new code until a BMP product has received FDA approval. While the audience generally supported this recommendation, some participants felt that no code should be created even after FDA approval has been received, because BMPs represent a specific product used in the performance of a surgical procedure. These participants felt that insertion of BMPs should be considered an inherent part of the surgical procedure.

Intraoperative Magnetic Resonance Imaging

Intraoperative magnetic resonance imaging allows the surgeon to scan real-time pictures during surgery, providing guidance and stereotactic navigation, increasing accuracy, and improving the effectiveness of surgical procedures in the operating room. Participants generally supported creation of a single code to describe this service, rather than multiple site-specific codes. It was felt that information concerning the anatomic site could be obtained via the surgical procedure code.

Application of Adhesion Barrier

A proposal was submitted for a new code to describe application of an adhesion barrier used in the prevention of postoperative adhesions following abdominopelvic procedures. The adhesion barrier is a temporary bioresorbable membrane used during the primary surgical procedure. It is used to reduce the incidence, extent, and severity of postoperative adhesions between the abdominal wall and the underlying viscera such as omentum, small bowel, bladder, and stomach, and between the uterus and surrounding structures such as tubes and ovaries, large intestine, and bladder.

The procedure for placing the adhesion barrier prior to closure of the operative site requires a significant change in operative technique and use of operating room resources. The product is customized to fit the desired application site. Once the product is prepared, it is necessary to retract the abdominal wall and organs from the desired site of application. The product is placed at the site of trauma. The average procedure requires the preparation and placement of multiple adhesion barriers.

While some participants supported the creation of a new code to describe this procedure, others opposed it because they felt that the application of a substance should be considered inherent to the procedure. These individuals noted that grafts and patches are not specifically coded when performed as part of the closure of an operative wound.

Extracorporeal Immunoadsorption

Extracorporeal immunoadsorption (ECI) is the removal of antibodies from plasma with protein A columns. ECI has demonstrated efficacy in removing coagulation factor inhibitors in patients with congenital hemophilia who are either bleeding

or waiting for elective surgery. By removing the inhibitor, factor replacement therapy is again effective and hemostasis is achieved. ECI is also used to induce immune tolerance in these same patients in an effort to suppress formation of the inhibitor. Another use of ECI is in certain patients with end-stage renal failure.

Creation of a new code for extracorporeal immunoadsorption was proposed. A participant suggested adding an Excludes note for this procedure under code 99.79, Other therapeutic apheresis. Until a new code is implemented, this procedure should continue to be assigned code 99.79.

Administration of Inhaled Nitric Oxide

Inhaled nitric oxide is a potent pulmonary vasodilator used to treat pulmonary hypertension in patients with respiratory failure and hypoxia from a number of different causes. It is used in the treatment of term and near-term neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. It improves oxygenation and reduces the need for extracorporeal membrane oxygenation (ECMO). ECMO is an intensive and invasive means to oxygenate blood outside of the body.

It has been recommended that a new code be created for administration of inhaled nitric oxide. Nitric oxide therapy is currently an inclusion term under code 93.98, Other control of atmospheric pressure and composition.

Addenda

Proposed October 2002 addenda changes were reviewed. The proposed revisions include:

- addition of an inclusion term for “percutaneous cholecystotomy” under code 51.01, Percutaneous aspiration of gallbladder (participants suggested re-titling code 51.01 to state “percutaneous cholecystotomy for drainage” and adding inclusion terms for “that by needle” and “that by catheter”)
- addition of Index entry for Kasai portoenterostomy (51.37)

The comment period for the proposed revisions has expired. The next meeting of the ICD-9-CM Coordination and Maintenance Committee is scheduled for **April 18–19, 2002**.

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