DRAFT AGENDA

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedural Coding System (HCPCS) Public Meeting Agenda for Supplies and "Other"
Tuesday, May 1, 2007, 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

8:15 a.m. Arrival and sign-in

9:00 a.m. Welcome
Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS's preliminary coding decision is provided. An overview of Medicare pricing/payment, methodology is also attached to this agenda. Preliminary decisions are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about the agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

AGENDA ITEM #1
Attachment #07.46
Request to establish 3 new codes to reflect the three components of a continuous glucose monitor system (CGM).

AGENDA ITEM #2
Attachment #07.60
Request to establish 3 new codes to reflect the three components of a continuous glucose monitor system (CGM).

AGENDA ITEM #3
Attachment #07.32
Request to establish 3 new codes to reflect the three components of a continuous glucose monitor system (CGM).

AGENDA ITEM #4
Attachment #07.62
Request to establish a code to identify blood ketone test/reagent strips, trade name: Precision Xtra™ Ketone Strips.

AGENDA ITEM #5
Attachment #07.14
Request to establish a code to identify Maternity support, Brand name: Comfy Cradle Maternity Support #3090RT

Attachment #07.15
Request to establish a code to identify Maternity support, Brand name: Mother-To-Be without insert #0055 Maternity Support #3090RT

Attachment #07.16
Request to establish a code to identify a maternity support with thermoplastic insert, Trade Name: Mother-To-Be with Insert #0050

Attachment #07.17
Request to establish a code to identify a maternity support, Trade Name: Loving Comfort Maternity Support #0230

Attachment #07.18
Request to establish a code to identify Maternity support, Brand name: Comfy Cradle Maternity Support #3090.

Attachment #07.19
Request to establish a code to identify Maternity support, Brand name: Comfy Cradle Maternity Support with insert #3091.

AGENDA ITEM #6
Attachment #07.26
Request to establish a new code to identify abdominal lifting devices. Trade Name: BabyHugger®.

AGENDA ITEM #7
Attachment #07.133
Request to establish a code to identify a pediatric medication delivery system, trade name: Medibottle.

AGENDA ITEM #8
Attachment #07.119
Request to establish a code for an integrated subcutaneous insulin deliver device, Trade Name: OmniPod

AGENDA ITEM #9
Attachment #07.23
Request to establish a new code to identify the TempTouch®, an infrared dermal thermometer that allows for the detection of inflammation in diabetics with neuropathy. General Product Name: Dermal Thermometer. Trade Name: TempTouch®.

AGENDA ITEM #10
Attachment #07.53
Request to establish a code to identify a low frequency, non-contact, non-thermal ultrasound disposable applicator for the MIST Therapy® System.

Attachment #07.54
Request to establish a code to identify a low frequency, non-contact, non-thermal ultrasound generator for the MIST Therapy® System.

AGENDA ITEM #11
Attachment #07.116
Request to establish a code to identify a foot pressure off-loading shoe, trade name: DynaWalk.

AGENDA ITEM #12
Attachment #07.137
Request to establish a new code to identify a diabetic shoe insert (multi-layer friction reducing insole), trade name: GlideSoft®.

AGENDA ITEM #13
Attachment #07.135
Request to establish a code to identify an assessment for Pervasive Developmental Disorders (PDD).

Attachment #07.136
Request to establish a code to identify dialectical behavior therapy (DBT).

AGENDA ITEM #14
Attachment #07.24
Request to establish a code to identify a custom made ankle foot orthosis. Trade name: Ulcer Healing Orthosis (UHO).

AGENDA ITEM #15
Attachment #07.66
Request to assign code L4398 to identify the ankle and foot orthosis and heel protector for non-ambulatory patients and consumers, trade name: Prevalon™ Heel Protector and Ankle-Foot Orthosis.

AGENDA ITEM #16
Attachment #07.110
Request to establish a code to identify a therapeutic foot roller, trade name: Tenderfoot.

AGENDA ITEM #17
Attachment #07.08
Request to establish a code to identify a support pad for the neck and head, trade name: Flexion/Extension MRI Device.

AGENDA ITEM #18
Attachment #07.95
Request to establish a code to identify surgical mesh, Trade Name: Surgisis ® AFP™ Anal Fistula Plug

AGENDA ITEM #19
Attachment #07.79
Request to establish a code to identify a processing kit for an ascorbic-acid enhanced platelet gel, trade name: AutoloGel™ Component Kit.

AGENDA ITEM #20
Attachment #07.39
Request to establish a new "L" code to identify non-animal stabilized hyaluronic acid/dextranomer copolymer implant material, Trade Name: Deflux® Injectable Gel.

AGENDA ITEM #21
Attachment #07.109
Request to establish a series of new codes for the full range of prosthetic devices and supplies used in the treatment of lymphedema from all causes.

AGENDA ITEM #22
Attachment #07.102
Request to establish four (4) new codes for devices used for transferring patients with limited mobility from one seat to another, trade names: 1) Small Swivel; 2) Large Swivel; 3) Swivel Jimmy Knee Support; and 4) Large Swivel w/Jimmy Knee Support.

AGENDA ITEM #23
Attachment #07.72
Request to establish a code for computer dependent external fixation struts, Trade Name: Taylor Spatial Frame (TSF) Standard and Fast FX Struts.

AGENDA ITEM #24
Attachment #07.83
Request to establish a code to identify FortaFlex® Surgical Mesh, trade name: Fortaflex.

AGENDA ITEM #25
Attachment # 07.88
Request to establish a code to identify recombinant human bone morphogenetic protein-2 and absorbable collagen sponge, trade name: INFUSE® Bone Graft.

HCPCS Meeting Agenda Item #1
May 1, 2007

Attachment: #07.46

Topic/Issue:
Request to establish 3 new codes to reflect the three components of a glucose monitor systems. Requester Suggested Language: (1) "Sensor; invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, each"; (2) "Transmitter; external, for use with interstitial continuous glucose monitoring system"; and (3) "Receiver (monitor); external, for use with interstitial continuous glucose monitoring system"

Background/Discussion:
According to the requester, RealTime Glucose Monitors help improve diabetes management by continuously monitoring interstitial glucose levels in persons with diabetes mellitus. The system captures on-going glucose values and displays them in real-time (in 5 minute averages), allowing users to identify cycles of glucose levels and to detect episodes of low and high blood glucose. Realtime consists of three components: sensor, transmitter, and receiver. The sensor is inserted subcutaneously under the skin, typically in the abdominal area or just above the buttocks. It continuously records interstitial glucose values and provides updated glucose readings every 5 minutes, up to 2888 glucose measurements per day. The transmitter connects to the glucose sensor and is secured to the skin by an adhesive patch. It collects continual glucose readings from the sensor and computes an average that is displayed on the monitor every 5 minutes. The sensor may and transmitter may be worn while showering or bathing. The receiver acts as the primary system interface with the user. Using radio frequency, the transmitter sends glucose signals from the sensor to the receiver every five minutes. Using an LCD display, the receiver displays the blood glucose values every 5 minutes for patient review. The user can program various setup options for customization such as high and low glucose alarms threshold settings. The receiver is designed to alert the patient if glucose values rise above or fall below the preset limits by sounding an alarm, vibrating, or both. It also stores up to 21 days of data for download and analysis. According to the requester, three separate codes are required for the system because the function and replacement/purchase frequency of the individual components are unique. Sensors for this particular model are indicated for use up to 72 hours and are replaced on an on-going basis, transmitters are replaced annually and monitors are a one-time purchase.

CMS HCPCS Workgroup Preliminary Decision:
Establish the following 3 codes:
Axxx1 SENSOR; INVASIVE (E.G. SUBCUTANEOUS), DISPOSABLE, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM, ONE UNIT = 1 DAY SUPPLY
Axxx2 TRANSMITTER; EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM
Axxx3 RECEIVER (MONITOR); EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for these items.

HCPCS Meeting Agenda Item #2
May 1, 2007

Attachment: #07.60

Topic/Issue:
Request to establish 3 new codes for a continuous glucose monitoring systems. Requester Suggested Language: (1) "Sensor, invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, each"; (2) "Transmitter, external, for use with interstitial continuous glucose monitoring system"; and (3) "Receiver, external, for use with interstitial continuous glucose monitoring system"

Background/Discussion:
According to the requestor, the STS is a continuous glucose monitoring (CGM) system for people with diabetes. The STS provides patients with continuous glucose information and allow patients to continuously track trends in glucose levels, enabling them to accurately anticipate excursions and make appropriate treatment adjustments. Alarms on this CGM device immediately alert the patient when glucose levels are outside of the target range, allowing the patient to intervene and prevent acute events, such as severe hypoglycemia, which can lead to permanent damage, coma or even death. CGMs also serve to "automate" patient compliance by providing up to 288 glucose readings per day with only minimal finger stick calibration required by the patient. The STS includes a disposable sensor, a transmitter and a small cell-phones sized receiver. The STS sensor wirelessly transmits continuous glucose data at specific intervals to the handheld receiver. The receiver receives continuous glucose values data from the sensor. With a push of a button, the patient can access their current glucose value and one-, three-, and nine-hour trended data. When glucose values are inappropriately high or low, the receiver provides an audible alert or vibrates to notify the patient of the condition. The applicant indicates that some private insurers have paid for CGM and have developed policies for CGM. The STS sensor is labeled for up to 3 days use.

CMS HCPCS Workgroup Preliminary Decision:
Establish the following 3 codes:
Axxx1 SENSOR; INVASIVE (E.G. SUBCUTANEOUS), DISPOSABLE, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM, ONE UNIT = 1 DAY SUPPLY
Axxx2 TRANSMITTER; EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM
Axxx3 RECEIVER (MONITOR); EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for these items.

HCPCS Meeting Agenda Item #3
May 1, 2007

Attachment: #07.32

Topic/Issue:
Request to establish 3 new codes to describe the variety of continuous glucose monitoring systems on the market. Suggested Language: (1) "Sensor, invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, each"; (2) "Transmitter, external, for use with interstitial continuous glucose monitoring system"; and (3) "Receiver, external, for use with interstitial continuous glucose monitoring system"

Background/Discussion:
According to the requester, Freestyle Navigator, though not yet FDA approved, is similar to other products approved for marketing, and is intended for use by patients with diabetes to improve glucose monitoring, which enables better, more timely health care treatment decisions to maintain glycemic control and avoid adverse medical complications. Freestyle consists of 3 components: a sensor, transmitter and receiver. The receiver and transmitter are expected to be sold together for patient's initial use. The sensor that accompanies this requester's model is intended to be replaced every 5 days. It is attached to a plastic sensor mount with adhesive to adhere to the skin, like a patch. The sensor is placed just under the skin by a disposable self-insertion device. The transmitter is designed to snap into the sensor mount on the skin's surface; and is used to transmit information wirelessly to the receiver. The receiver receives information wirelessly from the sensor/transmitter every minute. It is designed to display glucose values, directional glucose trend arrows, and rate of change. The receiver also has high and low glucose alarms to be set at a pre-determined level by the patient and/or their health care provider. The receiver can store glucose data for analysis by the user or by a health care provider; and has a built-in blood glucose meter used in combination with test strips for calibration purposes. According to the requester, many studies have shown that frequent testing and tighter control of glucose levels can dramatically reduce the adverse consequences of diabetes in Type 1 and Type 2 diabetes. Freestyle Navigator measures glucose levels as frequently as once per minute, compared to blood glucose monitoring systems that use fingersticks to read glucose levels a few times a day.

CMS HCPCS Workgroup Preliminary Decision:
Establish the following 3 codes:
Axxx1 SENSOR; INVASIVE (E.G. SUBCUTANEOUS), DISPOSABLE, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM, ONE UNIT = 1 DAY SUPPLY
Axxx2 TRANSMITTER; EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM
Axxx3 RECEIVER (MONITOR); EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for these items.

HCPCS Meeting Agenda Item #4
May 1, 2007

Attachment: #07.62

Topic/Issue:
Request to establish a code to identify blood ketone test/reagent strips, trade name: Precision Xtra™ Ketone Strips. Applicant's suggested language: "Blood ketone test/reagent strips, per 10 strips"

Background/Discussion:
According to the requester, Precision Xtra Ketone Strips are used in connection with the Precision Xtra Advanced Diabetes Management System. The Ketone strips are necessary for the proper functioning of the meter when testing for blood ketones. Precision strips measure the level of the ketone betahydroxybutyrate in the blood. Each ketone strip contains Hydroxybutyrate Dehydrogenase, which measures betahyroxybutyrate levels. The individual inserts a Precision Xtra Ketone Strip into the Precision Xtra monitor. The monitor turns on automatically. The individual applies a small blood sample from their finger to the strip. The monitor displays the ketone measurement as a number. The ketone strip is then discarded after a single use. According to the requester, Precision Xtra's are the first FDA-approved home-use test strips designed to allow people with diabetes to test their blood for ketone levels.

CMS HCPCS Workgroup Preliminary Decision:
Establish code AXXXX BLOOD KETONE TEST OR REAGENT STRIP, EACH

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #5
May 1, 2007

Attachment: #07.14

Topic/Issue:
Request to establish a code to identify Maternity support, Brand name: Comfy Cradle Maternity Support #3090RT (Please note the 3090RT is the same product as the 3090 only in a retail (RT) package).

Background/Discussion:
According to the requester, the Comfy Cradle maternity support is an orthopedic support to be used by women during pregnancy. It provides support to the back to help relieve back pain, as well as lifting and supporting the growing abdomen which helps ease back and leg pain. The product helps supports the abdominal muscles and ligaments and helps transfer the weight of the growing abdomen to the spine where it is more efficiently carried. The maternity support is made of elastic and polyester/cotton. It can be hand laundered and air dried and is intended for repeated use. The Comfy Cradle Maternity support features an elastic abdominal front section not found on the other products. It also features a pocket in the back panel to accept a thermoplastic insert. The function of the Comfy Cradle maternity support is comparable to the other maternity supports on the market.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #5
May 1, 2007

Attachment: #07.15

Topic/Issue:
Request to establish a code to identify Maternity support, Brand name: Mother-To-Be without insert #0055 Maternity Support #3090RT (Please note the 3090RT is the same product as the 3090 only in a retail (RT) package).

Background/Discussion:
According to the requester, the Mother-To-Be maternity support is an orthopedic support to be used by women during pregnancy. It provides support to the back to help relieve back pain, as well as lifting and supporting the growing abdomen which helps ease back and leg pain. The product helps supports the abdominal muscles and ligaments and helps transfer the weight of the growing abdomen to the spine where it is more efficiently carried. The maternity support is made of elastic and polyester/cotton. It can be hand laundered and air dried and is intended for repeated use. The Mother-To-Be features an abdominal lift pad not found on the other products. The function of the Mother-To-Be is comparable to the other maternity supports on the market.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #5
May 1, 2007

Attachment: #07.16

Topic/Issue:
Request to establish a code to identify a maternity support with thermoplastic insert, Trade Name: Mother-To-Be with Insert #0050

Background/Discussion:
According to the requester, the Mother-To-Be maternity support is an orthopedic support to be used by women during pregnancy. It provides support to the back to help relieve back pain, as well as lifting and supporting the growing abdomen which helps ease back and leg pain. The product helps supports the abdominal muscles and ligaments and helps transfer the weight of the growing abdomen to the spine where it is more efficiently carried. The maternity support is made of elastic and polyester/cotton. It can be hand laundered and air dried. The thermoplastic insert can be reshaped as needed throughout the pregnancy. The Mother-To-Be features an abdominal lift pad not found on the other products. It also features the optional thermoplastic insert for additional support if needed. The function of the Mother-To-Be is comparable to the other maternity supports on the market.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #5
May 1, 2007

Attachment: #07.17

Topic/Issue:
Request to establish a code to identify a maternity support, Trade Name: Loving Comfort Maternity Support #0230

Background/Discussion:
According to the requester, the Loving Comfort maternity support is an orthopedic support to be used by women during pregnancy. It provides support to the back to help relieve back pain, as well as lifting and supporting the growing abdomen which helps ease back and leg pain. The product helps supports the abdominal muscles and ligaments and helps transfer the weight of the growing abdomen to the spine where it is more efficiently carried. The maternity support is made of elastic and polyester/cotton. It can be hand laundered and air dried and is intended for repeated use. The Loving Comfort Maternity support features a separate abdominal lift pad not found on the other products. It also features the optional thermoplastic insert for additional support if needed. The function of the Loving Comfort Maternity support is comparable to the other maternity supports on the market.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #5
May 1, 2007

Attachment: #07.18

Topic/Issue:
Request to establish a code to identify Maternity support, Brand name: Comfy Cradle Maternity Support #3090.

Background/Discussion:
According to the requester, the Comfy Cradle maternity support is an orthopedic support to be used by women during pregnancy. It provides support to the back to help relieve back pain, as well as lifting and supporting the growing abdomen which helps ease back and leg pain. The product helps supports the abdominal muscles and ligaments and helps transfer the weight of the growing abdomen to the spine where it is more efficiently carried. The maternity support is made of elastic and polyester/cotton. It can be hand laundered and air dried and is intended for repeated use. The Comfy Cradle Maternity support features an elastic abdominal front section not found on the other products. It also features a pocket in the back panel to accept a thermoplastic insert. The function of the Comfy Cradle maternity support is comparable to the other maternity supports on the market.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #5
May 1, 2007

Attachment: #07.19

Topic/Issue:
Request to establish a code to identify Maternity support, Brand name: Comfy Cradle Maternity Support with insert #3091.

Background/Discussion:
According to the requester, the Comfy Cradle maternity support with insert is an orthopedic support to be used by women during pregnancy. It provides support to the back to help relieve back pain, as well as lifting and supporting the growing abdomen which helps ease back and leg pain. The product helps supports the abdominal muscles and ligaments and helps transfer the weight of the growing abdomen to the spine where it is more efficiently carried. The maternity support is made of elastic and polyester/cotton. It can be hand laundered and air dried and is intended for repeated use. The Comfy Cradle Maternity support with insert features an elastic abdominal front section not found on the other products. It also features thermoplastic insert that fits in the back pocket of the support for additional back support. The function of the Comfy Cradle maternity support is comparable to the other maternity supports on the market.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #6
May 1, 2007

Attachment: #07.26

Topic/Issue:
Request to establish a new code to identify abdominal lifting devices. Trade Name: BabyHugger®.

Background/Discussion:
According to the requestor, BabyHugger® is a soft cotton/lycra underpant and lifting elastic strap designed to gather and lift the pregnant belly to the shoulder girdle to relieve backache, pelvic pain and pressure, hip pain, abdominal stress, varicosities, urinary frequency, fatigue and pre-term contractions. It is described as an abdominal lifting support for maternity and bariatric patients. BabyHugger® lifts the weight of the belly from the center top, center bottom and from each side. It is designed to include only elastic straps.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #7
May 1, 2007

Attachment: #07.133

Topic/Issue:
Request to establish a code to identify a pediatric medication delivery system, trade name: Medibottle.

Background/Discussion:
According to the requester, the pediatric medication delivery system "medibottle" is designed to deliver (not just measure) extremely accurate dosages of oral liquid medication to an infant, which is willingly ingested. The medibottle's functionality is completely different from all other known "personal choice/medication dispenser" items. The effectiveness and corresponding level of compliance should be a measure of actual ingestion, not just the accurate filling of a dispenser. The medibottle's functionality translates to outcome measurements that offer a "significant therapeutic distinction". The medibottle makes use of two key fluid dynamic principles to transport the medicine from the oral dispenser to the very tip of the nipple without using any physical structure. The key result is that the medicine remains undiluted on its journey. The medibottle then utilizes the infant's natural desire to take/suck in the familiar liquid. Because the infant controls the flow, the medicine is delivered to the ideal position in the mouth for swallowing, also minimizing the residence time which in turn minimizes the chance for the infant to sense the medicine. The medibottle device is primarily and customarily used to serve the medical purpose of administering an accurate dose of a prescribed oral liquid medication to infants.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #8
May 1, 2007

Attachment: #07.119

Topic/Issue:
Request to establish a new code for an integrated subcutaneous insulin delivery device, which is one of 2 components of the OmniPod Insulin Management System. Suggested Language: "Integrated subcutaneous insulin delivery device, disposable (every 3 days), including pump mechanism, reservoir and insertion set with automated cannula insertion, each"

Background/Discussion:
According to the requestor, this insulin delivery system is a small, lightweight, self-adhesive insulin delivery device that the patient wears directly on the skin beneath clothing for up to three days and then replaces. During wear, it delivers precise, personalized doses of insulin through a small, flexible cannula inserted beneath the skin once at the beginning of wear via a fully-automated insertion process. It integrates the insulin reservoir, cannula, infusion set, inserter, motor and power source of a conventional pump into one device that can be worn directly on the skin. This system is watertight and does not need to be removed for showering, thereby eliminating the interruptions of therapy associated with disconnecting conventional insulin pumps.

This delivery system is one component of the OmniPod Insulin Management System. The OmniPod System utilizes proprietary design and technology to combine all the functionality of a conventional insulin pump with that of a blood glucose meter in a completely wireless, easy-to-use, two-part system. The other component is the personal diabetes manager (PDM), a hand-held remote controller integrating diabetes management software and a blood glucose meter which communicates wirelessly to the OmniPod. The PDM is used to program the OmniPod with personalized insulin delivery instructions and to check blood glucose using FreeStyle test strips. PDM facilitates disease management by seamlessly integrating blood glucose results into suggested bolus calculations, integrating a food reference library with over 1,000 common food items, and storing up to 5,400 carbohydrate, insulin delivery and blood glucose records. The applicant is not requesting a code for the PDM.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish code AXXXX "EXTERNAL AMBULATORY, INSULIN DELIVERY SYSTEM, DISPOSABLE, EACH, INCLUDES ALL SUPPLIES AND ACCESSORIES".
2) Existing code E0607 "HOME BLOOD GLUCOSE MONITOR" is available for use by all payers to describe the home glucose monitors.

Medicare Payment:
For AXXXX, based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

For E0607, the fee schedule and payment rules associated with existing code apply to this product. Pricing = 32

HCPCS Meeting Agenda Item #9
May 1, 2007

Attachment: #07.23

Topic/Discussion:
Request to establish a new code to identify the TempTouch®, an infrared dermal thermometer that allows for the detection of inflammation in diabetics with neuropathy. General Product Name: Dermal Thermometer. Trade Name: TempTouch®.

Background/Discussion:
According to the requestor, the TempTouch® is a handheld infrared foot probe designed for daily use to detect hot spots before these break the surface of the skin and become open wounds. This probe is designed as a daily non-invasive self-management tool for use at home to provide patients with an "early warning" of inflammation. Persons with diabetes and neuropathy are unable to feel pain or inflammation in their feet that can lead to open wounds. The TempTouch® detects inflammation at key points on the foot. A log is provided where the individual can record the temperatures and easily compare the readings from one foot to the other. The individual can "offload" and reduce their activity to prevent ulceration to the foot. The TempTouch® infrared foot probe is used to take daily foot temperature measurement depending on patient needs and physician orders. Temperature is taken by taking touching the infrared sensor tip to sites on each foot. If a temperature variance of 4º F or greater from one foot to the other is detected, the individual is armed with heightened awareness of the potential dangers. Should the hot spot continue beyond 24 to 48 hours, it is recommended that the individual contact their healthcare provider.

According to the requestor, existing codes A4931 (Oral Thermometer) and A4931 (Rectal Thermometer) do not adequately describe the TempTouch® because these codes do not apply to the infrared technology the device possesses. The two codes do not create a preventative modality that the TempTouch® establishes. Currently, there is no code that describes this item.

CMS HCPCS Preliminary Decision:
Existing code A9279 MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED, adequately describes the product that is the subject of this request.

Medicare Payment:
The fee schedule and payment rules associated with the existing code apply to this product.
Pricing = 00

HCPCS Meeting Agenda Item #10
May 1, 2007

Attachment: #07.53

Topic/Issue:
Request to establish a code to identify a low frequency, non-contact, non-thermal ultrasound disposable applicator for the MIST Therapy® System. Applicant's suggested Language: "Low frequency, non-contact, non-thermal ultrasound disposable applicator"

Background/Discussion:
According to the requester, the Mist Therapy System is a low frequency, non-contact, non-thermal ultrasound wound care system that is clinically proven to promote the healing of chronic wounds, (i.e. pressure ulcers, diabetic foot ulcers, and vascular ulcers) and dehisced surgical wounds. The MIST system uses continuous low frequency ultrasonic energy to atomize saline and deliver continuous low frequency ultrasound through the mist to the wound bed. When applied to the wound bed, the MIST Therapy System results in cavitation and acoustic microstreaming. These mechanisms of action, which are unique to this therapy, promote wound healing by stimulating tissue granulation and cell repair, as well as by reducing bioburden on the wound surface. The non-contact, non-thermal nature of the devices avoids any deleterious effects on healthy cells thus moving the wound to progress to complete closure. The MIST system consists of an equipment component (consisting of an ultrasonic generator) and a disposable component (a sterile applicator). The sterile disposable applicator is attached to the generator's transducer and has been designed to accept a pre-packaged sterile bottle of saline. The flow of saline is controlled by the disposable applicator and operates in the range of 16-20 ml/min. The applicant claims that the Mist Therapy System "is a significant clinical breakthrough for the treatment of chronic wounds" and that it "has been demonstrated to provide significant improvement in healing to promote wound closure, more rapid progression toward healing, and in the preparation of the wound bed for other interventions such as skin grafts and metabolically active skin substitutes."

CMS HCPCS Workgroup Preliminary Decision:
HCPCS Level II is not the appropriate coding jurisdiction for this item. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:
We believe payment for this item may be included in some other Medicare service or procedure.

HCPCS Meeting Agenda Item #10
May 1, 2007

Attachment: #07.54

Topic/Issue:
Request to establish a code to identify a low frequency, non-contact, non-thermal ultrasound generator for the MIST Therapy® System. Applicant's suggested language: "Low frequency, non-contact, non-thermal ultrasound generator, stationary or portable"

Background/Discussion:
According to the requester, the Mist Therapy System is a low frequency, non-contact, non-thermal ultrasound wound care system that is clinically proven to promote the healing of chronic wounds, (i.e. pressure ulcers, diabetic foot ulcers, and vascular ulcers) and dehisced surgical wounds. The MIST system uses continuous low frequency ultrasonic energy to atomize saline and deliver continuous low frequency ultrasound through the mist to the wound bed. When applied to the wound bed, the MIST Therapy System results in cavitation and acoustic microstreaming. These mechanisms of action, which are unique to this therapy, promote wound healing by stimulating tissue granulation and cell repair, as well as by reducing bioburden on the wound surface. The non-contact, non-thermal nature of the devices avoids any deleterious effects on healthy cells thus moving the wound to progress to complete closure. The MIST system consists of an equipment component (consisting of an ultrasonic generator) and a disposable component (a sterile applicator). According to the requester, the MIST system has been found to be effective on patients suffering from non-healing wounds persisting for weeks to years. The requester also indicates that clinical evidence has demonstrated that the utilization of the MIST system shortens the healing time in patients suffering from diabetic foot ulcers, venous insufficiency ulcers of the lower extremity, arterial insufficiency ulcers, pressure ulcers, and surgical wounds not progressing toward healing. The applicant claims that the Mist Therapy System "is a significant clinical breakthrough for the treatment of chronic wounds" and that it "has been demonstrated to provide significant improvement in healing to promote wound closure, more rapid progression toward healing, and in the preparation of the wound bed for other interventions such as skin grafts and metabolically active skin substitutes."

CMS HCPCS Workgroup Preliminary Decision:
HCPCS Level II is not the appropriate coding jurisdiction for this item. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:
We believe payment for this item may be included in some other Medicare service or procedure.

HCPCS Meeting Agenda Item #11
May 1, 2007

Attachment: #07.116

Topic/Issue:
Request to establish a code to identify a foot pressure off-loading shoe, trade name: DynaWalk. Requester Suggested Language: "Pressure off-loading system, includes metatarsal bars, triple layer heat-moldable insole, and rigid sole, each".

Background/Discussion:
According to the requester, pressure off-loading of the foot is appropriate as part of a diabetic foot ulcer management program to promote faster healing of the ulcer and injured structures. Pressure off-loading is done through the use of metatarsal bars that can be precisely positioned to off-load either the forefoot or the rear foot. The system also includes a triple-density heat moldable insole to help distribute pressures more evenly and off-load pressure sensitive areas, allowing a faster healing cycle. The triple-density heat moldable insert can be used for the treatment of foot biomechanics abnormalities. The support is adjusted to minimize shearing forces. The footplate is rigid so as to provide a solid platform on which motion to the foot is significantly minimized.

The DynaWalk™ product line is an integral part of the treatment process, and is not to be considered as a preventative measure to decrease further damage of the affected site. The DynaWalk™ product line allows the clinician to precisely adjust the metatarsal bars location and off-load the pressure. Currently there are no existing codes to identify a device that off-loads the area of an ulcer to allow healing.

CMS HCPCS Workgroup Preliminary Decision:
Establish code Axxxx FOOT PRESSURE OFF LOADING/SUPPORTIVE DEVICE, ANY TYPE, EACH. It is inappropriate to bill an orthotic code to identify this product.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #12
May 1, 2007

Attachment: #07.137

Topic/Issue:
Request to establish a new code to identify a diabetic shoe insert (multi-layer friction reducing insole), trade name: GlideSoft®.

Background/Discussion:
According to the requestor, the GlideSoft is a multi-layer friction (or shear) reducing insole designed for use by people with diabetes. The GlideSoft is designed to alleviate stress in the forefoot area by reducing the vertical pressure and reducing the friction force. It consists of a bottom cushion layer made from polyurethane or ethyl vinyl acetate (EVA) at least 3/16 inch thick. In the forefoot, a paper thin layer of low friction material (woven fiberglass sheet coated with Teflon) is layered between a second cushion layer which creates a total thickness at least 3/16 inch thick. The forefoot layers are held together with elastic bindings that are sewn around the perimeter of the forefoot area. These bindings will stretch and retract in response to normal walking activities, which will allow slight movements of the insole's top layer thereby reducing the friction force on the foot. This reduction of friction reduces the stress and trauma on the skin, which helps prevent ulcerations. According to the requester, the GlideSoft insole has been successfully tested in a two-arm randomized trial consisting of 299 diabetic patients at high-risk for foot complications. The trial was funded by the National Institutes of Health (NIH) and managed by Xilas Medical. Based on differences in construction, (multi-layer) design intended to reduce vertical pressures as well as sheer friction force), the applicant believes that existing code A5512 does not adequately describe the GlideSoft.

CMS HCPCS Workgroup Preliminary Decision:
Existing code A5510 "FOR DIABETICS ONLY, DIRECT FORMED, COMPRESSION MOLDED TO PATIENT'S FOOT WITHOUT EXTERNAL HEAT SOURCE, MULTIPLE-DENSITY INSERT(S), PREFABRICATED, PER SHOE adequately describes the product that is the subject of your request.

Medicare Payment:
The fee schedule and payment rules associated with existing code apply to this product.
Pricing = 38

HCPCS Meeting Agenda Item #13
May 1, 2007

Attachment: #07.135

Topic/Issue:
Request to establish a code to identify an assessment for Pervasive Developmental Disorders (PDD). Requestor's Suggested Language: HXXXX "Applied Behavioral Analysis (ABA) treatment, per 30minutes".

Background/Discussion:
According to the requestor, Pervasive Developmental Disorders include autistic disorder, Rett's disorder, childhood disintegrative disorder, Asperger's disorder, and pervasive developmental disorder not otherwise specified. They are cognitive and neurobehavioral disorders characterized by impairments in three core areas: social interactions, verbal and/or nonverbal communication, and restricted, repetitive patterns of behavior. There is very little scientific evidence supporting specific treatment programs for pervasive developmental disorders. Therefore, treatment must follow the practice parameters and policy statements set forth by the organizations nationally recognized for their expertise in assessment and treatment of PDD. The service itself is medical in nature. It is a combination of therapies, customized to the patient, whose purpose is to teach adaptive behavior to individuals with autism and other developmental disabilities. Intervention at an early age is key in working with individuals with these diagnoses. This service is rendered only for a PDD diagnosed patient.

CMS HCPCS Workgroup Preliminary Decision:
HCPCS Level II is not the appropriate coding jurisdiction for this professional service. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:
If payment were made for this service, we believe it may be included in some other Medicare service or procedure.

HCPCS Meeting Agenda Item #13
May 1, 2007

Attachment: #07.136

Topic/Issue:
Request to establish a code to identify dialectical behavior therapy.
Requestor's Suggested Language: HXXXX "Dialectical Behavioral Therapy (DBT), per 30 minutes".

Background/Discussion:
According to the requestor, Dialectical Behavior Therapy (DBT) was developed for treatment of chronically suicidal patients. It is a principal-based comprehensive treatment for borderline personality disorder, and is based on adaptations made to standard cognitive-behavioral therapy. A number of randomized, controlled studies have demonstrated its efficacy in significantly decreasing all of the following: suicidal and parasuicidal episodes, numbers of hospitalizations and lengths of stay, levels of rage, and medical treatments. Dialectical behavior therapy is associated with increasing rates of employment. The service itself is medical in nature. It is a combination of therapies, rendered in a group setting. DBT is an on-going treatment whose purpose is to teach new skills over long period of time. This service is rendered only for a behaviorally ill patient.

CMS HCPCS Workgroup Preliminary Decision:
HCPCS Level II is not the appropriate coding jurisdiction for this professional service. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:
If payment were made for this service, we believe it may be included in some other Medicare service or procedure.

HCPCS Meeting Agenda Item #14
May 1, 2007

Attachment: #07.24

Topic/Issue:
Request to establish a code to identify a custom made ankle foot orthosis. Trade name: Ulcer Healing Orthosis (UHO).

Background/Discussion:
According to the requester, the Ulcer Healing Orthosis is a custom made ankle foot orthosis, plastic or other, rigid proximal anterior support section, attached laterally, via flexible plastic hinge, with cushioned liner, posterior proximal section cushioned liner, corrugated mid section alignment guide, medial lateral ankle section cushioned lined, posterior heel cushioned pad, plantar platform cushioned insert, rigid planar platform hollow, plantar platform dynamic alignment wedges, used with a modified diabetic shoe, internally and externally modified for acceptance of orthosis, nylon sheath prior to donning, ridged clear plastic platform check fitting.

The UHO functions: Restoration of the ulcerated plantar platform, Rigid protection of plantar ulcer during ambulation, Vascularization of wound during ambulation, redistributes plantar weight bearing, diagnostic weight bearing wound inspection, increase ambulation, unassisted ambulation, monitor wound healing, increase normal appearance of lower extremity, stabilizes the charcot joint deformity, reduce co morbidities and aid in the complete healing of the diabetic plantar ulcerated condition.

CMS HCPCS Workgroup Preliminary Decision:
Establish code Axxxx FOOT PRESSURE OFF-LOADING/SUPPORTIVE DEVICE, ANY TYPE, EACH

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #15
May 1, 2007

Attachment: #07.66

Topic/Issue:
Request to assign code L4398 to identify the ankle and foot orthosis and heel protector for non-ambulatory patients and consumers, trade name: Prevalon™ Heel Protector and Ankle-Foot Orthosis.

Background/Discussion:
According to the requester, the Prevalon Heel Protector and AFO deliver the clinical value of both a brace and a pressure ulcer prevention device. Prevalon is semi-rigid; maintains the foot in a fixed position; is designed to reduce the risk of plantar flexion; is designed for the non-ambulatory patient; and has a soft interface. Prevalon helps minimize pressure, friction and shear on the feet, heels and ankles of non-ambulatory patients. It is pre-fabricated, one size fits all, enables fitting and adjustment, and floats the heel while reducing the risk of Foot Drop. Prevalon works by floating the heel while maintaining the foot in place through adjustable Velcro straps, spandex fabric, pontoon design, and a unique adjustable 'foot drop' strap that limits undue pressure and rough edges on the skin. It can be used in conjunction with the Prevalon Foot and Leg Stabilizer Wedge to address even greater risk of lateral foot and leg rotation that can result in plantar heel from the mattress surface. It keeps the heel open for easy skin assessment without removing the device. According to the requester, existing code E0191 as currently assigned by Medicare, is inappropriate when you consider the clinical value delivered by Prevalon; and the current low payment by Medicare is grossly under-serving. The applicant is therefore requesting reassignment of this product to a different, existing code.

CMS HCPCS Workgroup Preliminary Decision:
Existing code E0191 "HEEL OR ELBOW PROTECTOR, EACH", adequately describes the product that is the subject of this request. Insurers have the necessary flexibility to assign individual products to codes as they deem appropriate in accordance with their policies and program operating needs. Requests for coding guidance or assignment of this product to another existing code should be submitted directly to the insurer in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agengy in which a claim would be filed. For Medicare, contact the Medicare contractor. Similarly, inquiries regarding the fee associated with this product are not within the jurisdiction of the HCPCS Workgroup and should be submitted directly to insurers.

Medicare Payment:
The fee schedule and payment rules associated with existing code apply to this product.
Pricing = 32

HCPCS Meeting Agenda Item #16
May 1, 2007

Attachment: #07.110

Topic/Issue:
Request to establish a code to identify a therapeutic foot roller, trade name: Tenderfoot.

Background/Discussion:
According to the requester, Tenderfoot is designed for relief of foot pain. The Tenderfoot therapeutic foot roller consists of an aluminum cylinder machined to specific dimensions and finished so as to ensure cleanliness and traction to prevent slippage when in use. The patient uses the product by rolling their foot over the roller, with the roller placed on an appropriate floor surface such as a carpet or rug. The patient exercises appropriate pressure on sensitive areas by shifting their weight to different areas of the foot and of the roller. The patient only needs to roll their foot on the product for a short period of time, typically less than 5 minutes, once or twice a day. Tenderfoot works by allowing deep stretching of the foot muscles and tendons and deep massaging of scars and bone spurs.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

HCPCS Meeting Agenda Item #17
May 1, 2007

Attachment: #07.08

Topic/Issue:
Request to establish a code to identify a support pad for the neck and head, trade name: Flexion/Extension MRI Device.

Background/Discussion:
According to the requester, the Flexion/Extension MRI Device supports the head and neck of a supine patient during medical imaging procedures such that the cervical vertebrae are disposed in flexion or extension as desired. The pads are formed of a material that is invisible or non-interfering to the imaging equipment to avoid formation of image artifact. The pads are provided as a set, one for flexion and one for extension positioning. This product is designed for use in closed an open MRI systems. The Flexion/Extension Device is indicated when hyper flexion/extension with neck pain, and/or radicular symptoms occur, when conventional scan findings do not correlate with physician's clinical findings, and when radiographs on flexion/extension indicate subluxation or hyper-mobility of the cervical spine.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify imaging equipment. For coding guidance, please submit an inquiry to the American Medical Association (AMA) practice expense advisory committee regarding inclusion of the flexion/extension MRI device when it is used in the procedure.

Medicare Payment:
We believe payment for this item may be included in some other Medicare service or procedure.

HCPCS Meeting Agenda Item #18
May 1, 2007

Attachment: #07.95

Topic/Issue:
Request to establish a code to identify surgical mesh, Trade Name: Surgisis ® AFP™ Anal Fistula Plug. Requester's suggested language**:** JXXXX **"**Fistula plug, porcine small intestine submucosa, lyophilized bioabsorbable xenograft implant" (long descriptor), "Fistula Plug" (short description).

Background/Discussion:
According to the requester, the Surgisis ® AFP™ Anal Fistula Plug is a biologically derived, conically shaped biodegradable collagen plug made from the submucosa layer (SIS) in the small intestine of the domestic pig. The submucosa is mechanically separated from the adjoining layers to remove the serosal, mucosal and muscular elements. Once isolated, it is chemically cleaned, decellularized, freeze-dried and terminally sterilized. It then undergoes a viral inactivation and is validated using parvovirus, reovirus, pseudorabies virus and leukemia retrovirus as the test viruses. It is used to repair anal and anorectal fistulae in a procedure that does not damage the sphincters. The plug is implanted into the high pressure area of the fistula, producing a mechanically stable system where the higher pressures within the anal canal, in conjunction with suturing, tend to maintain the plug in place. Following implantation, the tissues adjacent to the Surgisis ® AFP™ Anal Fistula Plug begin to deliver cells and nutrients that rapidly invade it. Capillary growth follows and more nutrients enter the matrix. The plug is gradually replaced as the patient's system rebuilds the weakened site. The patient's body tissue grows completely into the surgical site while the Surgisis ® AFP™ Anal Fistula Plug maintains needed tissue support, until is subsequently resorbed by the body's own tissues.

CMS HCPCS Workgroup Preliminary Decision:
HCPCS Level II is not the appropriate coding jurisdiction for this item. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:
We believe payment for this item may be included in some other Medicare service or procedure.

HCPCS Meeting Agenda Item #19
May 1, 2007

Attachment: #07.79

Topic/Issue:
Request to establish a code to identify a processing kit for an ascorbic-acid enhanced platelet gel, trade name: AutoloGel™ Component Kit. Requestor's suggested language: AXXXX "Processing kit for an ascorbic-acid enhanced platelet gel" for the treatment of open cutaneous wounds.

Background/Discussion:
According to the requestor, the AutoloGel™ Component Kit is a medical and surgical supply kit to derive AutoloGel™. AutoloGel™ is autologous platelet-rich-plasma (PRP) gel containing multiple growth factors and a fibrin matrix for the treatment of open, cutaneous wounds. The process for deriving AutoloGel™ includes drawing blood from the patient, separating the PRP from the patient's blood through the use of a specially calibrated centrifuge, and mixing activator/reagents with the PRP that cause the release of growth factors involved in tissue repair and the formation of fibrin matrix scaffold to support new tissue growth. The activated PRP also changes from a liquid to a gelatinous consistency and is applied to the wound bed. The area is then covered with a dressing. The AutoloGel™ Component Kit contains the items necessary for drawing the patient's blood, preparing the PRP gel, and applying the PRP gel to the wound, including phlebotomy supplies, mixing chamber and applicator-processing syringes, contact dressing, and a biohazard removal pouch. The specially –calibrated centrifuge and the activator/reagents are not included in the AutoloGel™ Component Kit; however, the ascorbic-acid enhanced platelet gel cannot be made without them. Code A4649 "Surgical Supply; Miscellaneous" has been used to describe this product.

CMS HCPCS Workgroup Preliminary Decision:
Existing code A4550 "SURGICAL TRAYS" adequately describes the product that is the subject of this request.

Medicare Payment:
The fee schedule and payment rules associated with the existing code apply to this product.

HCPCS Meeting Agenda Item #20
May 1, 2007

Attachment: #07.39

Topic/Discussion:
Request to establish a new "L" code to identify non-animal stabilized hyaluronic acid/dextranomer copolymer implant material, Trade Name: Deflux® Injectable Gel.

Background/Discussion:
According to the requestor, Deflux® is a dextranomer/hyaluronic acid copolymer implant material. It is a sterile, viscous gel of dextranomer microspheres (50mg/ml) in a carrier gel of non-animal, stabilized hyaluronic acid (NASHA 17mg/ml) constituting a biocompatible and biodegradable implant. It is used to treat Vesicoureteral reflux (VUR), common childhood anomaly of the urinary tract system that ranges in severity from grade I (mild) to grade V (severe). VUR can result in permanent damage to the kidneys if not corrected and can impact a child's life through dysfunction of the bladder. Deflux® is injected submucosally into the bladder wall near or beneath the ureter, or into the lower distal portion of the ureter where it intersects with the bladder wall. The implant corrects the angulations of the ureter thereby allowing correct functioning of the ureter. This prevents reflux of urine from the bladder up the ureters back to the kidneys. Applicants recommended language for code: L860X - Injectable bulking agent, dextronomer/hyaluronic acid, urinary tract, 1ml syringe, includes shipping and necessary supplies. The requester acknowledged a previous decision for application 06.04 to code Deflux, specifying that no payer had a national program operating need to code Deflux. In this application, the requester notes that some private insurers and some states are providing coverage for Deflux.

CMS HCPCS Workgroup Preliminary Decision:
HCPCS Level II is not the appropriate coding jurisdiction for this item. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:
We believe payment for this item may be included in some other Medicare service or procedure.

HCPCS Meeting Agenda Item #21
May 1, 2007

Attachment: #07.109

Topic/Issue:
Request to establish a series of new codes for the full range of prosthetic devices and supplies used in the treatment of lymphedema from all causes. This request encompasses compression bandaging or binding systems, compression garments, compression devices and directional flow pads and garments. This request is to add more than 100 new codes for items used in the treatment of lymphedema and to identify them as "prosthetic devices and supplies" (LXXXX codes). It is to restore the lymphedema lower limb compression stockings to the prosthetic devices grouping, from which they were recently removed. The applicant also asks that CMS recode the lymphedema upper limb compression sleeves from "uncovered codes" S8420-S8431 to a "coverable" LXXXX code.

Background/Discussion:
According to the requester, medical items commonly prescribed in the compression therapy for lymphedema include compression bandaging or binding systems, compression garments, compression devices for producing the prescribed compression pressure and directional flow pads and garments used in conjunction with compression devices. Some of these items are already listed in the HCPCS code set, but are categorized in benefit categories that do not apply to the medical function served in their treatment of lymphedema. The items already listed include various bandage types covered as surgical dressings and graduated compression stockings, covered as secondary surgical dressings, both under §1861 (s)(5). The applicant is asking for new codes to identify the full range of products used, and further, that CMS reassign the associated Medicare Benefit Category.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish unique codes to distinguish all the products listed in this application. Existing codes adequately describe the array of products available. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor and also refer to the published article regarding Lymphedema treatment on the Palmettogba.com website.

Medicare Payment:
The fee schedule and payment rules associated with the existing codes apply to these products.

HCPCS Meeting Agenda Item #22
May 1, 2007

Attachment: #07.102

Topic/Issue:
Request to establish four (4) new codes for devices used for transferring patients with limited mobility from one seat to another, trade names: 1) Small Swivel; 2) Large Swivel; 3) Swivel Jimmy Knee Support; and 4) Large Swivel w/Jimmy Knee Support.

Background/Discussion:
According to the requester, the Swivel products are all units used for transferring patients with limited mobility from one seat to another.

- Small Swivel: 12"x12" steel plates with 51 industrial grade steel ball bearings sandwiched between, allowing the unit to turn 360 degrees in either direction. Steel brackets, securely screwed into the top plate, have "hook and fastener" straps which the patient's feet firmly in place. The bottom plate has a non-skid rubber pad. Handhold cut in bottom plate is lined with rubber insert for easy, comfortable portability. Supports up to 500 lbs.
- Large Swivel: 16"x18" steel plates with 81 industrial grade steel ball bearings. All other features same as above.
- Swivel Jimmy Knee Support: An add-on for Large Swivel. Securely attaches 30, 60 or 120lb gas shock which gently press patient's knees into locked position, allowing patient to stand upright and bear weight for duration of transference.
- Large Swivel w/Jimmy Knee Support: Combination of large swivel with Jimmy knee support with castors added for safe, easy portability.

According to the applicant, existing code E0705 "Transfer board or device, any type, each", does not recognize the superior design, engineering, and quality of materials used in manufacturing the Swivel. In our experience it has proven indestructible. Thus replacement and/or repair are NOT anticipated. This fact alone justifies the higher cost and necessity for new codes. Additionally, when properly used, the Swivel reduces the number of people needed to effect transfer and reduces the incidence of injury to both patient and caregiver.

CMS HCPCS Workgroup Preliminary Decision:
Existing code E0705 "TRANSFER BOARD OR DEVICE, ANY TYPE, EACH" adequately describes the item that is the subject of this request and is available for assignment by insurers as they deem appropriate. No insurer identified a national program operating need to distinguish these products from other products code at E0705 based on materials of manufacture or degree of durability. Inquires regarding the fee associated with HCPCS codes is not within the jurisdiction of the HCPCS workgroup and should be submitted to the insurer in whose jurisdiction a claim would be filed.

Medicare Payment:
The fee schedule and payment rules associated with existing code apply to this product.
Pricing = 32

HCPCS Meeting Agenda Item #23
May 1, 2007

Attachment: #07.72

Topic/Issue:
Request to establish a code for computer dependent external fixation struts, Trade Name: Taylor Spatial Frame (TSF) Standard and Fast FX Struts. Requester's suggested language: LXXXX "Computer dependent external fixation struts, each".

Background/Discussion:
According to the requester, the TSF is the only external fixation system that also includes computer software that assists physicians in calculating a prescription for strut adjustment and replacement that allows gradual correction of fractures and deformities. This software transforms measurements of a patients fracture or deformity into a prescription for: 1) when and how much a patient should lengthen or shorten their struts; and 2) when a patient should come into a doctors office to have one of their struts replaced. Codes currently available to describe this item include L8699 "Prosthetic Implant, Not Otherwise Specified" and A4649 "Surgical Supply; Miscellaneous". The requestor claims that these codes cannot be processed electronically and therefore require inefficient paper and manual processing, which is burdensome for physicians and carriers.

CMS HCPCS Workgroup Preliminary Decision:
HCPCS Level II is not the appropriate coding jurisdiction for this item. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:
We believe payment for this item may be included in some other Medicare service or procedure.

HCPCS Meeting Agenda Item #24
May 1, 2007

Attachment: #07.83

Topic/Issue:
Request to establish a code to identify FortaFlex® Surgical Mesh, trade name: Fortaflex.

Background/Discussion:
FortaFlex® consists of laminated sheets of porcine intestinal collagen, approximately 0.18 – 0.25 mm in thickness. The collagen matrix is primarily Type I porcine collagen (>95%) in its native three-dimensional form, with less than 1% lipids and undetectable levels of glycosaminoglycans and DNA. The device is cross-linked with carbodiimide, and is free of cells and cell remnants. The product is supplied hydrated and sterile in sheet form. It is intended for use in reinforcement of soft tissues repaired by sutures or suture anchors, during tendon repair surgery including rotator cuff, patellar, achilles, biceps, and quadriceps tendons. It is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, achilles, biceps, and quadriceps tendons. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to the bone, provide biomechanical strength for tendon repair. FortaFlex is supplied sterile in sheet form (6.5x 9cm).

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For Medicare, contact the Medicare carrier or, when used in HOPPS, use C1781 "MESH (IMPLANTABLE)" for tracking, although payment is packaged in the procedure code.

Medicare Payment:
We believe payment for this item may be included in some other Medicare service or procedure.

HCPCS Meeting Agenda Item #25
May 1, 2007

Attachment: #07.88

Topic/Issue:
Request to establish a code to identify recombinant human bone morphogenetic protein-2 and absorbable collagen sponge, trade name: INFUSE® Bone Graft.

Background/Discussion:
According to the requestor, Infuse is a bone graft substitute based on bone morphogenetic protein engineered through recombinant techniques. It is used to treat tibial fractures by promoting improved union. Infuse is implanted at the fracture site, following internal fixation of the fracture with an intramedullary nail and management of the open wound (cleaning the wound, treating any infection and preparing the wound for closure). It consists of two components, a solution containing recombinant human bone morphogenetic protein-2 (rhBMP-2), which induces bone formation in fracture sites, and an absorbable collagen sponge (ACS) matrix which serves as the carrier for the rhBMP-2 at the fracture site and as a scaffold for the new bone that the protein stimulates. The two components, rhBMP-2 and ACS must be used together. At the time of definitive wound closure , the rhBMP-2 is reconstituted at a concentration of 1.50 mg/ml by adding 8 ml sterile water to 12 mg of the protein, then soaking a 7.5x10.0-cm ACS with the solution, and finally implanting the impregnated ACS as an overlay of the entire fracture site. Infuse reduces the frequency and severity of secondary procedures to promote bone healing; reduces the rate of non-union; increases the chance of fracture healing; and it reduces the incidence of infection in severe open fractures.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
We believe payment for this item may be included in some other Medicare service or procedure.

PAYMENT FOR DMEPOS

DMEPOS

The term DMEPOS, which stands for durable medical equipment (DME), prosthetics, orthotics and supplies, is used in the Medicare program to describe a set of Medicare Part B device and supply benefits for which claims are processed by four DME Regional Carriers (DMERCs). The Part B device benefits covered by this term include:

- DME – equipment used in the home which can withstand repeated use, is primarily and customarily used to serve a medical purpose, and is generally not useful in the absence of an illness or injury;
- Prosthetic Devices – devices that replace all or part of an internal body organ, including ostomy, tracheostomy and urological supplies, parenteral and enteral nutrients, equipment and supplies (PEN), intraocular lenses (IOLs), and one pair of conventional eyeglasses or contact lenses after each cataract surgery;
- Prosthetics – artificial legs, arms, and eyes;
- Orthotics – rigid or semi-rigid leg, arm, back, and neck braces;
- Home Dialysis Supplies and Equipment
- Surgical Dressings
- Therapeutic Shoes and Inserts

Depending on the item or the setting in which the item is furnished, Medicare claims for some of these items may also be processed by local carriers and fiscal intermediaries (e.g., claims for DME implanted in an ambulatory surgical center are processed by local carriers). Claims for DME and ostomy, tracheostomy and urological supplies furnished by a home health agency are processed by Regional Home Health Intermediaries (RHHIs).

Fee Schedule Payments

Prior to January 1, 1989, payment for most DMEPOS items and services was made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment is still made on a reasonable charge basis for home dialysis supplies and equipment and for IOLs inserted in a physician's office. There is a monthly limit per beneficiary on payments for home dialysis supplies and equipment. Payment for most of the other DMEPOS items and services is based on the lower of the actual charge for the item or a fee schedule amount. The Part B deductible and 20 percent coinsurance both apply to the DMEPOS items and services described above.

The Social Security Act requires that the DMEPOS fee schedule amounts be established based on average reasonable charges made during a base period (e.g., July 1, 1986 thru June 30, 1987 for prosthetic devices, prosthetics and orthotics). The fee schedule amounts are increased by annual update factors. Because the reasonable charge data required by the law in establishing fee schedule amounts does not exist for new DMEPOS items, the fee schedule amounts for new DMEPOS items are "gap-filled" using fees for comparable items, supplier price lists, manufacturer suggested retail prices, or wholesale prices plus a markup. The gap-filling methodology is used to estimate the average reasonable charge for the item from the base period.

DMEPOS Payment Categories/HCPCS Pricing Indicators

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicators in the HCPCS identify which major payment category a code falls under. The pricing indicators applicable to DMEPOS are as follows:

- **Pricing = 00 Service Not Separately Priced**
  Items or services described by the HCPCS codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

- **Pricing = 31 Frequently Serviced Items**
  Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health.

- **Pricing = 32 Inexpensive and Other Routinely Purchased Items**
  Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of $150 or less, are generally purchased 75 percent of the time or more, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or intermittent assist device with continuous airway pressure device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

- **Pricing = 33 Oxygen and Oxygen Equipment**
  Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. An additional payment is made for those beneficiaries who require portable oxygen. The beneficiary takes over ownership of the equipment after the 36th monthly payment is made, after which payment for delivery of contents continues for patient owned gaseous or liquid systems.

- **Pricing = 34 Supplies Necessary for the Effective Use of DME**
  Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

- **Pricing = 35 Surgical Dressings**
  Payment is made on a purchase fee schedule basis for surgical dressings.

- **Pricing = 36 Capped Rental Items**
  Payment is made on a monthly rental fee schedule basis. For items furnished on or after January 1, 2006, the beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. Power wheelchairs can be purchased in the first month.

- **Pricing = 37 Ostomy, Tracheostomy and Urological Supplies**
  Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

- **Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)**

Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

- **Pricing = 39 Parenteral and Enteral Nutrition (PEN)**
  Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

- **Pricing = 45 Customized DME**
  Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item.

- **Pricing = 46 Carrier Priced Item**
  For items falling under codes for miscellaneous or not otherwise classified items, the fee schedule or reasonable charge payment amount, whichever is applicable, is based on the carrier's individual consideration of the item.

- **Pricing = 52 Reasonable Charges**
  Payment continues to be made on a reasonable charge basis in accordance with Medicare regulations at 42 CFR 405.500 for splints, casts, and other devices used to reduce a fracture or dislocation, dialysis supplies and equipment, and intraocular lenses (IOLs) inserted in physician's offices.