DRAFT AGENDA

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedural Coding System (HCPCS) Public Meeting Agenda for Supplies and "Other"
Wednesday, May 2, 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 #07.108
Request "proper funding" for the Para Ladder™.

AGENDA ITEM #2
Attachment #07.138
Request to establish a code to identify a patient lift, trade name: Easy Pivot™.

AGENDA ITEM #3
Attachment #07.111
Request to establish a code to identify an assistive dining device, trade name: Mealtime Partner.

AGENDA ITEM #4
Attachment #07.120
Request to establish a code to identify a portable shower, trade name: FAWSsit™.

AGENDA ITEM #5
Attachment #07.121
Request to establish a code to identify an airshower, trade name: Airsonett Airshower.

AGENDA ITEM #6
Attachment #07.122
Request to establish a code to identify a thin, flat wallet, trade name: BackSaver Wallet™.

AGENDA ITEM #7
Attachment #07.65
Request to establish 3 codes to identify hydrophilic urinary catheters, trade names: LoFric; and revise codes A4351, A4352 and A4353.

AGENDA ITEM #8
Attachment #07.22
Request to establish a code to identify Ostomy/Urological Supplies. General Product Name: Urinary Drain Bag Liner with Absorbent Polymer. Trade Name: PATHO-SORB® Absorbent-Polymer Liner.

AGENDA ITEM #9
Attachment #07.07
Request to establish 2 codes: one to identify ostomy pliers and one to identify circular cutting discs, trade names: Stomico Ostomy Pliers and Stomico Cutting Disc.

AGENDA ITEM #10
Attachment #07.68
Request to establish a single code to identify both types of low-profile gastrostomy tubes, trade names: Entristar® & NutriPort™.

AGENDA ITEM #11
Attachment #07.69
Request to establish a single code to identify both types of low-profile gastrostomy feeding tubes, Trade name: The Kimberly-Clark *MIC-KEY*.

AGENDA ITEM #12
Attachment #07.82
Request to establish a code to identify a closed CVC connector for hemodialysis, trade name: Tego™ Connector.

AGENDA ITEM #13
Attachment #07.21
Request to establish a code to identify a stoma cap/covering, Trade Name: AMpatch.

AGENDA ITEM #14
Attachment #07.73
Request to establish 3 codes: 1) gold bone marker; 2) gold soft tissue marker; and 3) gold suture type breast marker, trade name: ACCULOC® Gold Bone Marker; ACCULOC® Soft Tissue Gold Marker; and ACCULOC® Suture Type Breast Marker.

AGENDA ITEM #15
Attachment #07.42
Request to establish 3 codes to identify a flexible linear soft tissue monitor, trade name: Visicoil®. One code is intended for markers 1cm to 3cm in length; the second for markers 4cm to 6cm in length; and the third for the XL/1.1mm diameter marker.

AGENDA ITEM #16
Attachment #07.41
Request to establish a code to identify implantable radiation dosimeters and insertion tools, trade name: DVS® Dosimeter.

AGENDA ITEM #17
Attachment #07.25
Request to establish a code to identify Caphosol™, an artificial saliva formulation. Trade Name: Caphosol™.

AGENDA ITEM #18
Attachment #07.64
Request to establish a code to identify an antimicrobial dressing, trade name: Biopatch.

AGENDA ITEM #19
Attachment #07.10
Request to establish a code to identify vacuum sealed waterproof cast, bandage, PICC line, orthotic, prosthetic protectors, trade name: XeroSox and Stay Dry Pro Pump.

AGENDA ITEM #20
Attachment #07.75
Request to revise existing code A4215 "Needle, sterile, any size, each" and establish 2 new codes to make a distinction between "standard" needles, and pen injector needles and "needle systems".

AGENDA ITEM #21
Attachment #07.56
Request to establish a code to identify a closed system drug transfer device (CSTD), trade name: PhaSeal®.

AGENDA ITEM #22
Attachment #07.118
Request to establish a code to identify a multi-electrode pad, trade name: Flexible Array Electrode Pad.

AGENDA ITEM #23
Attachment #07.80
Request to establish a code to identify an impedance threshold device, trade name: ResQPOD Circulatory Enhancer®.

AGENDA ITEM #24
Attachment #07.11
Request to establish a permanent code for hyperbaric oxygen under pressure, full body chamber, per 30 minute interval, currently identified by code C1300.

AGENDA ITEM #25
Attachment #07.94
Request to establish a code to identify MimyX® Cream.

HCPCS Meeting Agenda Item #1
May 2, 2007

Attachment: #07.108

Topic/Issue:
Request "proper funding" for the Para Ladder™.

Background/Discussion:
According to the requestor, the Para Ladder is a folding, light weight, self help floor transfer aid ideally suited for patients with paraplegia. It is designed to allow safe and unassisted transfer from the floor to a wheelchair. After a paraplegic experiences a fall, the Para Ladder's function allows the person to return to their wheelchair by using their arms and hands to lift themselves up "a plurality of seats" (steps). There are handles positioned above each seat so that a person can place one's hands on the handles and lift oneself up seven and one half inches to the next highest seat, and grasp the next highest handles and lift to the next highest seat until the person is able to move from the highest seat to the wheelchair seat. It is designed to assist paraplegics possessing substantial arm and hand strength and the dexterity to lift oneself unassisted while traveling up the Para Ladder. The Para Ladder was reviewed by CMS in last years coding cycle, and it was determined that E0705 "Transfer board or device, any type, each" adequately describes this product. According to the applicant, while existing code E0705 describes this device, "the fee schedule for this code is inadequate for proper coverage. This application is to request a method of proper funding."

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 insures as they deem appropriate. Inquires regarding the fee associated with HCPCS codes are 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 #2
May 2, 2007

Attachment: #07.138

Topic/Issue:
Request to establish a code to identify a patient lift, trade name: Easy Pivot™. Applicant's suggested Language: "Patient lift, manual lever actuated with thigh strap, knee pad and chest pad"

Background/Discussion:
According to the requestor, Easy Pivot is a quality pivot-type patient lift that provides the user with a fast, efficient, and secure method of transfer. EasyPivot is indicated for patients who need total assistance, for example: patients who have Multiple Sclerosis, quadriplegia due to spinal cord injury, or neurological damage due to a stroke. The EasyPivot is also useful for the frail, weak elderly or post operative patient who has paralysis or weakness that precludes or compromises their ability to stand or walk. EasyPivot lifts the patient gently and supports them with ample padding at the knees and upper chest area. The patient's own weight helps in the lifting process. The caregiver helps steady the patient and provides the small lift force needed (15% of patient's weight). EasyPivot makes it possible for a 120 lb. caregiver to lift and transfer a 300 lb. patient. The dual lift handles promote good caregiver body mechanics. According to the applicant, existing HCPCS codes for hydraulic lifts do not adequately describe this product because the EasyPivot does not operate via any hydraulic mechanisms and utilizes neither a seat nor sling. Hydraulic patient lifts employ a pump, cylinder, and a cantilever lift arm. The EasyPivot is a manually operated transfer machine that utilizes the patient's weight for leverage and a thigh strap.

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 #3
May 2, 2007

Attachment: #07.111

Topic/Issue:
Request to establish a code to identify an assistive dining device, trade name: Mealtime Partner. Suggested Language: "Powered dining device".

Background/Discussion:
According to the requestor, the Mealtime Partner is a battery-operated device that allows people who are unable to eat independently due to their illness, injury, disability, or chronic health condition, to feed themselves without using their arms or hands. Food is placed in the three bowls that come with the device. A well-rounded spoonful of food is formed by the device and the spoon is positioned very near the mouth of the user. The user must lean forward slightly and remove the food from the spoon. The user can control the device using one or two adaptive switches or the device can operate fully automatically (i.e., no switches), according to the functional and/or cognitive needs of the user. The requestor claims that this device will help to ameliorate the effects of illness, injury, disability, or chronic health condition, by allowing users to routinely provide themselves nutrition.

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 #4
May 2, 2007

Attachment: #07.120

Topic/Issue:
Request to establish a code to identify a portable shower, trade name: FAWSsit™. Requester suggested languag**e**: "Shower stall, portable, includes shower attachments, drain pan, and electric pump"

Background/Discussion:
According to the requester, the FAWSsit is a portable shower for use in the patient's home. This shower is lightweight and has a strong structural aluminum frame. It folds flat for easy storage, and has an opaque curtain for privacy. The shower comes with a drain pan with a pump to remove wastewater. Basic hygiene is necessary to maintain health and promote the patient's healing. When the patient is unable to bathe or shower in a traditional bath setting, the FAWSsit can decrease the incidence of urinary tract infections, promote circulation, promote muscle relaxation, and wound care cleanliness by allowing the patient to be able to bathe in a timely and complete fashion, unlike sponge bathing. The FAWSsit is designed for patients of all ages and types with any debilitating conditions who use a wheelchair or who are too weak or too ill to use a traditional shower/bath. The shower is large enough to make it easily accessible for caregivers to assist patients. The total weight of the standard size FAWSsit is 38 pounds, and it folds to 8 inches in depth. It is 48 inches high and 36 inches wide. The FAWSsit does not require tools to set up. It must be set up in an area where there is access to both hot and cold running water and a drain for removing the person's bath water (ex: kitchen).

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 #5
May 2, 2007

Attachment: #07.121

Topic/Issue:
Request to establish a code to identify an airshower, trade name: Airsonett Airshower.

Background/Discussion:
According to the requester, the Airsonett Airshower system consists of a filter section with HEPA filter, a cooler section, a nozzle and control and regulating equipment, all in one complete mobile unit that plugs into an ordinary wall socket. Purified air is delivered about 20 inches above a patient's head. The clean, slightly cooled air moves slowly downward due to its somewhat higher density, displacing the contaminated ambient air with negligible turbulence and mixing. This guarantees a particulate level of less than 5,000 particles/ft^3 in the breathing zone, preferable during sleep at night time. The requester suggests a code to identify an airshower with the following specifications: "Vertical laminar air displacement by controlled thermal stratification, creating a clean air zone of less than 5000 particles/ft^3 (particles with aerodynamic diameter $\geq$0.5μm) measured within a 2 in. radius from patients' nose lying down in a bed in a normal indoor environment". The measurements must be made over at least a seven (7) hour period and the mean value must not exceed 5000 particles/ft^3. To guarantee a clinical effect, the laminar airflow must displace pollutants (allergens) from the breathing zone coming from the beddings on the bed, using air-cooling and temperature measurement devices. The supplied air temperature must be lower and stable (+/-0.2 degrees Fahrenheit) compared to ambient air during the treatment periods. According to the applicant, the air purification system, high efficiency filter, cooling/heating unit and laminar air flows come together to "create the function that results in a clinical significant outcome for patients with allergic asthma"; poor asthma control despite high doses of inhaled corticosteroids (ICS); and it can be used as an alternative to dose increases of ICS or other combination treatments, such as Montelukast or Omalizumab. No clinical studies were provided with this application.

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 #6
May 2, 2007

Attachment: #07.122

Topic/Issue:
Request to establish a code to identify a thin, flat wallet, trade name: BackSaver Wallet™.

Background/Discussion:
According to the requester, BackSaver is a patented men's wallet used to treat "wallet sciatica". The Backsaver's unique design and construction allows it to hold as much as a regular billfold but be anywhere from 40 to 60% smaller in overall size. Sitting on your wallet will cause wallet sciatica and problems in your lower back to your neck and shoulders, not to mention the increased chance of developing DVT Syndrome. In addition to a potential sciatica problem, muscle stress from sitting on a wallet can go up the spine to the neck. All movement originates from your spine; it is the core movement axis that controls and stablilizes your body. Therefore, just like building a house, the integrity of the structure is dependent upon the integrity of the foundation. Your foundation is made up of the muscles that attach and wrap around your spine and joints. Without this "balanced" foundation your body will be unstable, subject to injury, and not able to perform to its maximum capability. An unbalanced foundation over time will cause structural wear and tear on the joints and spine starting with aches and pains and eventually affecting physical mobility.

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 #7
May 2, 2007

Attachment: #07.65

Topic/Issue:
Request to establish 3 codes for hydrophilic urinary catheters, trade names: LoFric; and revise codes A4351, A4352 and A4353. Applicant's suggested language:
Revise A4351 which currently reads: "Intermittent urinary catheter; straight tip, with or without coating (Teflon, silicone, or silicone elastomer, or hydrophilic, etc.), each" to instead read: "Intermittent urinary catheter; straight tip, with or without coating (Teflon, silicone, or silicone elastomer)"
Revise A4352 which currently reads: "Intermittent urinary catheter; coude (curved) tip, with or without coating (Teflon, silicone, or silicone elastomeric, or hydrophilic, etc.), each" to instead read: "Intermittent urinary catheter; coude (curved) tip, with or without coating (Teflon, silicone, or silicone elastomeric)
Revise A4353 which currently reads: "Intermittent urinary catheter, with insertion supplies" to instead read: "Intermittent urinary catheter, conventional, with insertion supplies"
Axxx1 "Intermittent urinary catheter; straight tip, hydrophilic"
Axxx2 "Intermittent urinary catheter; coude (curved) tip, hydrophilic" and
Axxx3 "Intermittent urinary catheter, hydrophilic, with insertion supplies"

Background/Discussion:
According to the requester, LoFric hydrophilic urinary catheters are used for intermittent catheterization. "Although hydrophilic catheters are appropriate for all patients who require intermittent catheterization, certain patients (such as those experiencing repeated UTT, pain, or difficulty passing conventional catheters) would especially benefit from hydrophilic catheters." These catheters are used by patients with neurogenic bladders, injuries to the spinal chord, or surgically-created urinary diversions. Hydrophilic catheters employ a multi-layer construction. LoFric has a core of medical-grade polyvinyl chloride (PVC) and an outermost layer of polyvinylpyrrolidone (PVP) and sodium chloride (NaCl). This outer PVP/NaCl layer is integral to the catheter and covers all external catheter surfaces that contact the urinary tract. The PVP/NaCl attracts a layer of water that uniformly adheres to all external catheter surfaces. This bound water makes the catheter extremely slippery, allowing the catheter to move in the urinary tract with minimal friction and abrasion. Since all hydrophilic catheters achieve their slipperiness through chemical binding of water instead of application of a gel, these catheters remain slippery throughout the entire process of insertion, drainage, and removal. LoFric catheters are only slippery when the osmolality of the water bound to PVP/NaCl layer is similar to that of urinary tract tissues. Hydrophilic catheters are contraindicated for persons with cognitive difficulties.

The applicant requests codes to distinguish hydrophilic catheters from catheters made from other materials based on differences "in terms of construction, function, clinical outcomes and indications for use. The applicant claims the "superior clinical outcomes" for the hydrophilic catheter, as compared to catheters made of other materials, specifically: "the ability to pass an intermittent catheter when other catheters cannot be passed"; "fewer strictures… and less inflammation and irritation"; "fewer urinary tract infections"; less hematuria"; "less bacteriuria"; "less pain"; and "improved patient satisfaction." The applicant's request for distinct codes is also based on differences in utilization rates (reusability) and price.

CMS HCPCS Workgroup Preliminary Decision:

Existing codes A4351 "INTERMITTENT URINARY CATHETER; STRAIGHT TIP, WITH OR WITHOUT COATING (TEFLON, SILICONE, SILICONE ELASTOMER, OR HYDROHILIC, ETC.), EACH" and A4352 "INTERMITTENT URINARY CATHETER; COUDE (CURVED) TIP, WITH OR WITHOUT COATING (TEFLON, SILICONE, SILICONE ELASTOMERIC, OR HYDROPHILIC, ETC.), EACH" adequately describe hydrophilic intermittent catheters used to drain the urinary bladder. Studies submitted with the 2007 application and studies submitted with prior applications do not demonstrate superior clinical outcomes as a result of using hydrophilic catheters, compared to non-hydrophilic catheters.

Medicare Payment:

The fee schedule and payment rules associated with existing codes apply to these items.
Pricing = 37

HCPCS Meeting Agenda Item #8
May 2, 2007

Attachment: #07.22

Topic/Issue:
Request to establish a new code to identify Ostomy/Urological Supplies. General Product Name: Urinary Drain Bag Liner with Absorbent Polymer. Trade Name: PATHO-SORB® Absorbent-Polymer Liner.

Background/Discussion:
According to the requestor, the PATHO-SORB® Absorbent-Polymer Liner is a liner for a urinary drainage bag. The liner is a closed bag made of non-woven materials; the liner contains 35 grams of cross-linked anionic polyacrylamide potassium salt co-polymer in the form of crystals. The liner is made to fit the urinary drain bag. The polymer in the liner absorbs urine. As fluid (urine, blood) comes in contact with the polymer a gel is formed. The gel is enclosed in the non-woven liner; the liner is inside the urinary drainage bag. The liner is changed daily. Liner capacity is 2000 ml. The urine is transformed by antimicrobial polymer into a gel. The gel is self-contained in the Polymer Liner. The liner is removed from the drainage bag and disposed of in regular organic waste disposal system. According to the applicant, encapsulation of urine destroys or inhibits growth of microorganisms; reduces the risk of migration of microorganisms from drainage bag to the urinary tract system; and reduces exposure risk by improving safety for all persons who come in contact with patient, urinary drainage system or environment.

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 #9
May 2, 2007

Attachment: #07.07

Topic/Issue:
Request to establish 2 codes: one for ostomy pliers and one for circular cutting discs, trade names: Stomico Ostomy Pliers and Stomico Cutting Disc.

Background/Discussion:
According to the requester, Stomico ostomy pliers simplify and speed up the changing process of the ostomy pouches/bags and reduces concern over irritation, infection, and proper fit as they consistently make the correct size hole for the stoma in regular, convex, and extended wear adhesive skin barriers/wafers/flanges/appliances. The screw-on circular cutting disc is available in 1 mm size increments from 17mm-43mm. Ostomy pliers eliminate the learning curve and resulting mis-cut wafers and appliances. According to the requester, these pliers present a potential cost savings by eliminating the replacement of scissor mis-cut, wasted wafers and appliances. They are quicker and easier than scissors and offer a more custom fit than pre-cuts. Stomico ostomy pliers will cut most wafers/flanges and some one-piece appliances.

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 these items.

HCPCS Meeting Agenda Item #10
May 2, 2007

Attachment: #07.68

Topic/Issue:
Request to establish a single code to encompass both types of low-profile gastrostomy tubes, trade names: Entristar® & NutriPort™.

Background/Discussion:
According to the requester, a gastrostomy tube is a device that is placed through a patient's abdominal and stomach walls to permit delivery of enteral formula directly into the stomach. NutriPort is a type of low-profile gastrostomy tube that utilizes an inflatable balloon for keeping the feeding tube within the stoma tract. It is constructed of silicone and has a proximally located anti-reflux valve. Entristar is a non-balloon type that requires an obturator to place the device into the patient's tract. It is constructed of polyurethane material that is designed to withstand the gastric environment for prolonged periods and increase flow rates. The external retention bolster helps hold the tube and stomach in position. The bolster is fitted with "feet" to allow a minimal contact area and optimize ventilation and wound healing. Access to the stomach is through the feeding/compression port via the extension tubes. Both products contain an internal proximal anti-reflux valve in the uppermost portion of the tube, directly below the point where the cap sits. The valve helps prevent stomach contents from spilling out on the patient. Connecting a feeding extension set causes the valve to open during feeding or when decompression is desired.

According to the requester, a new code is necessary since the codes currently used to bill the low profile G-tube are inadequate. Specifically, B4086 is too broad of a code category since it includes standard, low profile gastrostomy and jejunostomy tubes. Use of Miscellaneous codes creates administrative and financial burdens in prior approval, rate establishment, claims payment and expenditure tracking. Use of Modifiers is unworkable since every state Medicaid agency uses modifiers in different ways and for different products or services, and their use causes cost reporting problems. According to the applicant, a low-profile G-tube is the treatment of choice for pediatric patients. There are "technical design" differences between standard and low-profile tubes. The applicant also claims that there are clinical benefits resulting from the use of the low-profile design although no clinical studies were provided with the application. The applicant also claims that reimbursement amounts are inadequate for the low-profile tubes.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue B4086 "GASTROSTOMY/JEJUNOSTOMY TUBE, ANY MATERIAL, ANY TYPE, (STANDARD OR LOW PROFILE), EACH
2) Establish BXXX1 "GASTROSTOMY/JEJUNOSTOMY TUBE, STANDARD, ANY MATERIAL, ANY TYPE, EACH
3) Establish BXXX2 "GASTROSTOMY/JEJUNOSTOMY TUBE, LOW PROFILE, ANY MATERIAL, ANY TYPE, EACH
Proposed code BXXX2 adequately describes the item that is the subject of your request.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that the items would be paid in accordance with the payment rules that apply to Parenteral and Enteral Nutrition.
Pricing = 39

HCPCS Meeting Agenda Item #11
May 2, 2007

Attachment: #07.69

Topic/Issue:
Request to establish a single code to encompass both types of low-profile gastrostomy feeding tubes, Trade name: The Kimberly-Clark *MIC-KEY*.

Background/Discussion:
According to the requester, the MIC-KEY is intended primarily as a replacement tube for use in an established gastrostomy. The MIC-KEY is a skin-level replacement gastrostomy feeding tube made of pure medical grade silicone that allows the intake of food, water, and medications for individuals requiring long-term enteral nutrition and designed to be inserted into a well-established gastrostomy stoma. The MIC-KEY is available in a variety of French sizes and standard shaft (fixed stoma) lengths. According to the requester, providers are currently billing B4086 "Gastrostomy/jejunostomy tube, any material, any type, (standard or low profile), each", however, a new code is necessary because this code is inadequate. Specifically, B4086 is too broad of a code category since it includes standard, low-profile gastrostomy and jejunostomy tubes. Use of Miscellaneous codes creates administrative and financial burdens in prior approval, rate establishment, claims payment and expenditure tracking. Use of Modifiers is unworkable since every state Medicaid agency uses modifiers in different ways and for different products or services, and their use causes cost reporting problems. According to the applicant, a low-profile G-tube is the treatment of choice for pediatric patients. There are "technical design" differences between standard and low-profile tubes. The applicant also claims that there are clinical benefits resulting from the use of the low-profile design although no clinical studies were produced with the application. The applicant also claims that reimbursement amounts are inadequate for the low-profile tubes.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue B4086 "GASTROSTOMY/JEJUNOSTOMY TUBE, ANY MATERIAL, ANY TYPE, (STANDARD OR LOW PROFILE), EACH
2) Establish BXXX1 "GASTROSTOMY/JEJUNOSTOMY TUBE, STANDARD, ANY MATERIAL, ANY TYPE, EACH
3) Establish BXXX2 "GASTROSTOMY/JEJUNOSTOMY TUBE, LOW PROFILE, ANY MATERIAL, ANY TYPE, EACH
Proposed code BXXX2 adequately describes the item that is the subject of your request.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that the items would be paid in accordance with the payment rules that apply to Parenteral and Enteral Nutrition.
Pricing = 39

HCPCS Meeting Agenda Item #12
May 2, 2007

Attachment: #07.82

Topic/Issue:
Request to establish a code to identify a closed CVC connector for hemodialysis, trade name: Tego™ Connector.

Background/Discussion:
According to the requestor, the Tego Connector is a needle-free, one-piece connector that establishes a completely closed system for those patients specifically requiring a Central Venous Catheter (CVC) for hemodialysis treatment as ordered by their physician. The Tego creates a mechanically and microbiologically closed system only when attached to the hub of a CVC, thereby eliminating the need to manipulate the hub when attaching or removing blood lines. The result is a reduction in the risk of catheter related bloodstream infection (CRBSI) otherwise caused by repeat exposure to the catheter with each "opening" or manipulation. The Tego Connector is a single-patient use connector with a useful life of one week. It has been designed to withstand multiple accesses via the blood tubing for hemodialysis treatment and standard syringes for flushing during the one-week period. It is recommended that the connector remain in place on the central venous catheter for one week to provide access to the catheter for all necessary hemodialysis treatments. After one week, the Tego should be replaced with a new device to ensure that adequate functional requirements are met.

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. A4913 "MISCELLANEOUS DIALYSIS SUPPLIES, NOT OTHERWISE SPECIFIED" is available for assignment by insurers as they deem appropriate.
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:
For Medicare, payment is subject to the regulations that apply to the method two home patient monthly payment cap. Payment for this item is bundled in a dialysis facility. It is not separately billable in an inpatient setting.

HCPCS Meeting Agenda Item #13
May 2, 2007

Attachment: #07.21

Topic/Issue:
Request to establish a code to identify a stoma cap/covering, Trade Name: AMpatch. Applicant's suggested language: "Stomal Seal".

Background/Discussion:
According to the requester, the AMpatch is designed for a person with a continent intestinal reservoir (CIR). The AMpatch Stoma/Cap/Covering/Seal collects and retains the mucous that is secreted from the stoma, 24 hours a day, 7 days a week, and keeps the peristomal skin area free of moisture so that breakdown of skin does not occur. The requestor claims there are vast differences in the construction and maintenance of a CIR (which include ileostomies, sigmoid colostomies, and urostomies) and a conventional colostomy. A5055 "Stoma Cap" is the code that is currently used to bill this product, as advised by the SADMERC. According to the requester, "code A5055 does not allow CIR patients adequate management of their medical condition…"

CMS HCPCS Workgroup Preliminary Decision:
Existing code A6219 GAUZE, NON-IMPEGNATED, PAD SIZE 16 SQ. IN. OR LESS, WITH ANY SIZE ADHESIVE BORDER, EACH DRESSING, adequately describes the item that is the subject of your request.

Medicare Payment:
The fee schedule and payment rules associated with existing code apply to this product.
Pricing = 35

HCPCS Meeting Agenda Item #14
May 2, 2007

Attachment: #07.73

Topic/Issue:
Request to establish 3 codes: 1) gold bone marker; 2) gold soft tissue marker; and 3) gold suture type breast marker, trade name: ACCULOC® Gold Bone Marker; ACCULOC® Soft Tissue Gold Marker; and ACCULOC® Suture Type Breast Marker.

Background/Discussion:
According to the requester, ACCULOC gold markers are used with Image-guided Radiation Therapy (IGRT) to provide a permanent method for quick and accurate daily tumor alignment. The implanted markers are intended to assist in the localization of targets for radiotherapy treatments acting as visible landmarks referencing tumor location. IGRT uses implanted markers, pre-treatment images, and localization software to provide advanced tumor targeting accuracy for radiotherapy. Accurate targeting is essential to resolve daily tumor location changes due to internal organ motion and body position variation on the treatment couch. IGRT increases radiation to the tumor and spares normal surrounding tissue.

The ACCULOC markers are provided for bone, soft tissue and in a suture. In most cases, two to three markers are implanted for IGRT. Implant is generally performed in the outpatient setting or the physician office. Image guidance is utilized based upon the site of the implant to determine the target and market location that will help develop an effective, patient unique treatment plan. HCPCS Code A4649 "surgical supply; miscellaneous" and CPT code 99070 are currently being used to bill for services associated with the ACCULOC over and above those usually included with a visit. According to the applicant, use of these codes requires supporting documentation. A HCPCS Level II code is requested to facilitate "accurate reporting" of the product and to "streamline reimbursement".

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.

C1879 maybe used to identify these products when used in HOPPS.

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

HCPCS Meeting Agenda Item #15
May 2, 2007

Attachment: #07.42

Topic/Issue:
Request to establish 3 codes for a flexible linear soft tissue monitor, trade name: Visicoil®. One code is intended for markers 1cm to 3cm in length; the second for markers 4cm to 6cm in length; and the third for the XL/1.1mm diameter marker.

Background/Discussion:
According to the requester, Visicoil markers are general-purpose implanted fiducial markers indicated for use to radiographically mark the prostate, liver, lung, pancreas, and kidney for future therapeutic procedures. They are used to localize organs, tumors and tumor beds for image-guided radiation therapy (IMRT) and conformal radiation therapy (CRT). These soft tissue markers allow for accurate tumor localization which provides higher doses to the tumor and periphery; accurate patient positioning; dose escalation in a given session; real-time targeting of tumors and tumor beds; image-fusion between various visualization modes; and on-line treatment planning procedures/protocols. Visicoil is inserted into the targeted site by a fine needle, resulting in a less traumatic procedure for the patient. Existing code A4649 "surgical supply; miscellaneous", accurately describes linear soft tissue markers. According to the requester, a specific code would facilitate accurate reporting of the product and streamline reimbursement for providers.

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 the CPT coding guidance. For Hospital Outpatient PPS, continue to use existing C1879 Tissue marker (implantable) to identify this item. It is included 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 #16
May 2, 2007

Attachment: #07.41

Topic/Issue:
Request to establish a code to identify implantable radiation dosimeters and insertion tools, trade name: DVS® Dosimeter.

Background/Discussion:
According to the requester, the telemetrically powered, implantable dosimeter measures the real time radiation dose delivered to a patient in vivo utilizing two metal oxide semiconductor field effect transistors. The dosimeter is an integral part of the Dose Verification System (DVS). The DVS measures the in vivo dose of radiation to the target site. The system is comprised of five components: 1) implantable radiation dosimeters; 2) a telemetric reader for obtaining dose measurements which includes base station and reader wand; 3) insertion tools; 4) plan and review software; and 5) a bar code scanner. The DVS dosimeter is packaged with two radiation dosimeters and two insertion tools. The insertion tools are used for percutaneous implantation of the dosimeter and consist of a cannula, trocar, and plunger. This assembly is covered by a removable polyester surgical mesh for handling, suturing, or fixating the device in vivo. The assembly is subsequently sterilized by ethylene oxide. Physicians implant the dosimeter in patients scheduled to undergo radiation therapy for a malignant tumor at the start of therapy, before the delivery of any radiation treatments. Then the system compares the daily and cumulative dose at the dosimeter to the planned dose. Although daily dose changes are to be avoided, changes to the treatment plan and dose adjustments or corrections are recommended. As such, the dosimeter is an integral part of accurate treatment planning and dosimetry. According to the requester, "this is the first and only implantable dosimeter that provides this type of information, there are no existing HCPCS Level II codes that adequately describe this device, leaving providers and payers with no mechanism with which to report the use of the DVS dosimeter."

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 #17
May 2, 2007

Attachment: #07.25

Topic/Discussion:
Request to establish a new code to identify an artificial saliva formulation. General Product Name: Artificial Saliva (Dibasic Sodium Phosphate 0.032, Monobasic Sodium Phosphate 0.009, Calcium Chloride 0.052, Sodium Chloride 0.569, Purified Water qs ad (5w/w)). Trade Name: Caphosol™.

Background/Discussion:
According to the requestor, Caphosol™ is an electrolyte solution resembling human saliva, designed in part to replace the normal ionic and pH balanced in the oral cavity. It is intended as a mouth rinse to moisten, lubricate and clean the oral cavity including the mucosa of the mouth, tongue and throat. It is intended for the dryness of the mouth or throat (hyposalivation, xerostomia), regardless of the cause or whether the condition is temporary or permanent. Oral mucositis is an inflammation and ulceration of the lining of the mouth most commonly associated with chemotherapy or radiotherapy for cancer. Caphosol™ is an aqueous solution which is prepared using two separately packaged aqueous solutions: a phosphate solution (Caphosol A) and calcium solution (Caphosol B). When both ampoule solutions are combined in equal volumes, a solution supersaturated with respect to both calcium and phosphate icon is formed. There are no products currently available with the same active ingredients. A specific code for Artificial Saliva would facilitate accurate reporting of the product and streamline reimbursement for providers.

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 #18
May 2, 2007

Attachment: #07.64

Topic/Issue:
Request to establish a code to identify an antimicrobial dressing, trade name: Biopatch. Applicant's suggested language: "Antimicrobial foam dressing < 16 sq inches"

Background/Discussion:
According to the requester, Biopatch is an absorptive hydrophilic polyurethane foam impregnated dressing with chlorhexidine gluconate (CHG). CHG is a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity. The foam material absorbs up to eight times its own weight in fluid while the CHG incorporated into the dressing inhibits bacterial growth under the dressing. Biopatch is a primary dressing that fits around the percutaneous device at the insertion site and is used in combination with either a semi-occlusive or non-occlusive secondary dressing. In the presence of exudates, the Biopatch absorbs and exudates and blood, and releases CHG to the surrounding skin. According to the applicant, existing HCPCS codes describe only the function of the foam material, and do not describe the "antimicrobial barrier function" of Biopatch dressings, which protects the wound from environmental contamination and minimizes cross-contamination from the wound to the environment, a significant therapeutic distinction. It effectively kills a wide range of microorganisms (including antibiotic-resistant strains) which are commonly found on the skin and in colonized and infected wounds. Biopatch continually releases chlorhexidine gluconate for seven days. Biopatch is indicated for use to cover wounds caused by the use of vascular and non-vascular percutaneous devices.

CMS HCPCS Workgroup Preliminary Decision:
Existing code A6209 "FOAM DRESSING, WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESVIE BORDER, EAHC DRESSING" adequately describes this product and is available for assignment by insurers when this product is used with a PEG Tube. The applicant did not submit clinical studies to demonstrate superior patient clinical outcome as a result of use of Biopatch, when compared with other products coded in the A6209 category. A4221 "SUPPLIES FOR MAINTENACE OF DRUG INFUSION CATHETER, PER WEEK (LIST DRUG SEPARATELY)" is available for assignment by insurers when this product is used at a drug infusion catheter site.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to this product.
For A6209, Pricing = 35
For A4221, Pricing = 34

HCPCS Meeting Agenda Item #19
May 2, 2007

Attachment: #07.10

Topic/Issue:
Request to establish a code to identify vacuum sealed waterproof cast, bandage, PICC line, orthotic, prosthetic protectors, trade name: XeroSox and Stay Dry Pro Pump. Suggested language: "Vacuum-sealed waterproof body, cast, dressing, bandage, PICC line, orthotics, and prosthetic protector"

Background/Discussion:
According to the requester, the Xero Sox and Stay Dry pro pump function to keep casts, bandages, PICC lines, and prosthetics completely dry. These products enable patients to swim and undergo hydrotherapy without worry of infection or getting the area wet. They are constructed of a natural rubber that is shaped in the form of a mitten and booty. There is a one-way valve near the opening and a pump for vacuum sealing the Stay Dry pro pump to the limb. The patient slips the Stay Dry pro pump over their cast or bandage, pumps out all of the air until the pump is flat, removes the pump and enters the water. Once finished, they simply pull the top of the Stay Dry pro pump out to the side to let the air back in and slip it off.

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 #20
May 2, 2007

Attachment: #07.75

Topic/Issue:
Request to 1) revise code A4215 "Needle, sterile, any size, each" to read "Needle for use with standard single use or reusable syringe, sterile, any size, each", 2) establish A42XX " Needle for use with pen injector, any size, sterile, each", and 3) establish A42XX "Needle system for use with pen injector, with automated safety cover, any size, sterile, each".

Background/Discussion:
According to the requestor, the NovoFine® 30 Needle, NovoFine® 31 Needle, and NovoFine® AutoCover® Needles are grouped within "generic" needle categories, despite health care cost-effectiveness demonstrated for such pens as compared to syringes. The requestor claims that by failing to differentiate NovoFine® and other pen needles, there is no means of administering differential coverage and payment policies relative to these distinct needle systems, thereby discouraging use of the cost-effective insulin injection pens which these needle products were intended to support. Currently, A4215 describes all sterile needles, regardless of needle design, application or intended use, and cost. According to the applicant, inclusion of Pen injector needles in code A4215: 1) fails to provide for a cost differential; 2) creates a disincentive to promote safety by inadequately reimbursing for specialty needles; and 3) does not promote competitive pricing. The applicant also claims "better patient" outcomes through use of injector systems based on a claim of "increased patient compliance with insulin therapy." No clinical studies were provided with this application.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a unique code to identify this product. Existing code A4215 "NEEDLES, STERILE, ANY SIZE, EACH" adequately describes the product that is the subject of this request, and is available for assignment by all payers as they deem appropriate.

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

HCPCS Meeting Agenda Item #21
May 2, 2007

Attachment: #07.56

Topic/Issue:
Request to establish a code to identify a closed system drug transfer device (CSTD), trade name: PhaSeal®.

Background/Discussion:
According to the requester, PhaSeal is a closed system drug transfer device used to contain hazardous drugs throughout preparation, transportation, administration, and disposal. This technology has the potential for use in a variety of sites of services where chemotherapy drugs or other potentially hazardous drugs are prepared and administered. PhaSeal consists of a protector, injector, infusion adapter, y-site and connector. For the preparation of hazardous drugs using a true CSTD, a protector is first attached to the drug vial to form an airtight seal. This component has a sealed expansion chamber that captures any aerosols or vapors while simultaneously maintaining equal pressure in the vial. All components of the CSTD system, including the protector, have thermoplastic elastomer (TPE) membranes that meet to form a dry connection and self-seal when the components are disconnected. The second component of the system, the injector, is used both during compounding and administration of the hazardous drugs. One end of injector is luer-locked onto a syringe while the opposite end provides for a dry connection at the cannula's access point. The injector is connected to the protector by pushing the two membranes together and locking the system into position. The design of the injector ensures complete enclosure of the cannula. After the drug is drawn from the vial into the syringe; the injector is disconnected from the protector. Because of the double membrane system this area remains dry and free of contamination. The protector is attached to the vial and this portion of the system can be safely disposed. Finally, a connector or a y-site connector luer-lock fitting and dry membrane is available for use when the drug is to be infused by standard IV push, membrane connection to the injector and a reduction of hazardous drug contamination at the site of patient administration.

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 #22
May 2, 2007

Attachment: #07.118

Topic/Issue:
Request to establish a code to identify a multi-electrode pad, trade name: Flexible Array Electrode Pad. Requester Suggested Language: "Electrodes, multiple, integrated, non-disposable, with low impedance sensing mechanism".

Background/Discussion:
According to the requester, the InterX Flexible Array Electrode pad is a non-disposable product consisting of 16 small stainless steel electrodes encapsulated in a biomedical grade silicone rubber. These electrodes are arranged such that adjacent electrodes are of opposite polarity. There is no power to the InterX Flexible Array Electrode unless it is connected to an interactive electrostimulation device, the InterX 1000. The InterX Flexible Array Electrode is placed directly onto unbroken skin and does not use any conductive gels. Unlike the Flexible Array, standard electrodes only treat one small area of pain. The Flexible Array, with the use of 16 integrated electrodes, can treat a much larger area of pain at one time and multiple areas over a treatment period. Due to the number of electrodes and the product design, the Flexible Array focuses more energy to low impedance sites as compared to 2 and 4 lead electrodes in pairs. It also allows the user to self-treat, even in hard to reach areas such as the back.

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 #23
May 2, 2007

Attachment: #07.80

Topic/Issue:
Request to establish a code to identify an impedance threshold device, trade name: ResQPOD Circulatory Enhancer®.

Background/Discussion:
According to the requester, ResQPOD is a small device used to enhance circulation during CPR that can attach a variety of airway adjuncts, including a facemask and endotracheal tube. Its primary function is to enhance circulation during CPR by passively lowering intrathoracic pressure below normal physiological parameters during the chest wall recoil phase of CPR. The negative intrathoracic pressures are increased by means of an airway impedance mechanism within the device that is placed in series within the respiratory circuit. The increase in negative pressure pulls more blood back into the chest, providing greater venous return to the heart. ResQPOD prevents unnecessary air from entering the chest during CPR. When air is prevented from rushing into the lungs as the chest wall recoils, the vacuum or negative pressure in the thorax is increased. This enhanced vacuum pulls more blood back to the heart, improving blood flow during CPR. According to the requester, studies have shown that this mechanism increases cardiac output, blood pressure and survival rates for patients in cardiac arrest. Patient ventilation and exhalation are not restricted in any way. The device selectively impedes inspiratory gas exchange during the decompression phase of CPR, lowers the intrathoracic pressure and enhances venous blood return ResQPOD is used by patients who can benefit from an increase in blood flow or perfusion, for example, patients suffering from sudden cardiac arrest, trauma, heat stroke and fainting.

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 #24
May 2, 2007

Attachment: #07.11

Topic/Issue:
Request to establish a permanent code for hyperbaric oxygen under pressure, full body chamber, per 30 minute interval, currently identified by **C1300** Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval.

Background/Discussion:
According to the requester, hyperbaric oxygen is a treatment during which a patient breathes 100 percent oxygen while inside a treatment chamber at a pressure higher than sea level. Existing code C1300 HYPERBARIC OXYGEN UNDER PRESSURE, FULL BODY CHAMBER, PER 30 MINUTE INTERVAL was created at a time when there was no other HCPCS code for the facility/technical services associated with the provision of hyperbaric oxygen therapy. The requestor feels that this is now a well-established procedure and no longer requires special designation. According to the requester, hyperbaric oxygen therapy is provided in numerous outpatient settings in addition to hospital outpatient departments. The requester is concerned that, to the extent code C1300 is recognized as specific to hospital services, there may be confusion regarding how to bill for the same services provided by a non-hospital outpatient facility, particularly on the part of non-Medicare insurers. The requestor proposes a "permanent national HCPCS code" to replace C1300 to facilitate industry-wide use of a single code to describe the service in all settings.

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 physician service. It is identified in an existing CPT code, although code C1300 is reportable when the service is provided in an outpatient setting. CMS recommends that the applicant contact the American Medical Association (AMA) CPT Editorial Panel for CPT coding guidance.

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

HCPCS Meeting Agenda Item #25
May 2, 2007

Attachment: #07.94

Topic/Issue:
Request to establish a code to identify MimyX® Cream.

Background/Discussion:
According to the requestor, MimyX® Cream is a new class of steroid-free maintenance therapy indicated to manage the burning and itching associated with atopic dermatitis (AD) and other types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. It is available by prescription and is primarily applied in the patient's home by the patient. MimyX® Cream contains PEA, which is endogenous fatty acid deficient in skin of individuals with AD. PEA has anti-inflammatory properties and is released when the skin is stressed, thereby helping to modulate the release of inflammatory chemicals. MimyX® Cream replenishes atopic skin with an optimal lipid mixture that mimics the composition of skin phospholipids and the layered structure of the physiologic skin-lipid barrier. The unique formulation of MimyX® Cream mimics healthy skin composition to repair and restore the disrupted skin barrier, which helps to reduce water loss. MimyX® is applied to affected skin areas 3 times a day and is massaged gently into the skin. It is supplied in a 140 gram tube. A6250 "Skin sealants, protectants, moisturizers, ointments, any type, any size" is the only similar code, however the requestor states that this code is generally either not paid or is inadequately reimbursed by payers.

According to the applicant, code A6250 "SKIN SEALANTS, PROTECTANTS, MOISTURIZERS, OINTMENTS, ANY TYPE, ANY SIZE," is too broad in that it includes over the counter and non-prescription creams. Also, according to the applicant, "State Medicaid agencies are no longer able to cover MimyX® under the pharmacy benefit" as a consequence of CMS' determination that MimyX® "does not meet the definition of a covered outpatient drug". The applicant believes that a HCPCS code is necessary "to allow access under the medical benefit".

Preliminary Decision:
No insurer identified a program operating need to establish a code to identify this product. Existing code A6250 "SKIN SEALANTS, PROTECTANTS, MOISTURIZERS, OINTMENTS, ANY TYPE, ANY SIZE" adequately describes the product that is the subject of this request. Inquiries regarding payment should be directed to the insurer in whose jurisdiction a claim would be filed. 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:
The fee schedule and payment rules associated with existing code apply to this product.
Pricing = 00

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.