

**Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Supplies & Other – Day 1
Tuesday, April 22, 2008**

Introduction and Overview

Approximately 70 people attended. The agenda included 20 items.

Joel Kaiser of CMM presented an educational overview of the methods used for setting the payment amount for items, and when the different methods are used. The overview was also provided as a written attachment to the agenda and is also attached to this summary. For additional information, the DME payment rules are located at Section 1834 (a) of the Social Security Act. The Medicare fee schedule for DME, Prosthetics, Orthotics and Supplies, and background information, can be accessed and downloaded free of charge at: <http://www.cms.hhs.gov/feeschedulegeninfo>.

Cindy Hake provided an overview of the HCPCS public meeting process as it relates to the overall HCPCS coding process.

Prior to the Public Meetings, CMS HCPCS workgroup meets to review all HCPCS code applications and makes preliminary coding recommendations. CMS also makes preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the HCPCS world-wide web site at www.cms.hhs.gov/medhcpcsgeninfo, as part of the HCPCS public meeting agendas.

Following the public meetings, CMS HCPCS workgroup reconvenes, and considers all the input provided at the Public Meetings regarding its preliminary coding recommendations. CMS also reconsiders its Medicare payment recommendations. CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

All requestors will be notified in writing, in November, of the final decision regarding the HCPCS code request(s) they submitted. At around the same time, the HCPCS Annual Update is published at:
www.cms.hhs.gov/HCPCSReleaseCodeSets/ANHCPCS/itemdetail.asp.

The process for developing agendas and speaker lists for the public meetings, and Guidelines for Proceedings at CMS' Public Meetings are posted on the official HCPCS world wide web site at:

<http://cms.hhs.gov/medhcpcsgeninfo/downloads/2008guidelines.pdf>. The standard application format for requesting a modification to the HCPCS Level II Coding System, along with instructions for completion and background information regarding the HCPCS Level II coding process is available at:

http://cms.hhs.gov/medhcpcsgeninfo/downloads/2009_alpha.pdf. A decision tree, outlining CMS' decision-making criteria is also available at:

<http://cms.hhs.gov/medhcpcsgeninfo/downloads/decisiontree.pdf>.

**Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure
Coding System (HCPCS) Public Meeting Agenda
for Supplies and “Other”
Tuesday, April 22, 2008, 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 #08.24

Request to establish 2 codes for a pediatric medication delivery system. Trade names: medibottle2 and medibottle3.

Primary Speaker: Mark Burchett of Medicine Bottle Company

AGENDA ITEM #2

Attachment #08.69

Request to establish 3 new codes for hydrophilic urinary catheters and kits, trade names: LoFric; and revise existing codes A4351, A4352 and A4353.

Primary Speaker: John Gould of Arnold & Porter, LLP

AGENDA ITEM #3

Attachment #08.59

Request to 1) establish 2 codes for intermittent urinary catheters (hydrophilic), trade name: SpeediCath and 2) revise codes A4351 and A4352.

Primary Speaker: Russell Miller of Coloplast Corporation

AGENDA ITEM #4

Attachment #08.58

Request to establish a code for surgical dressing, trade name: Interdry™ Ag Textile with Silver.

Attachment #08.57

Request to establish 6 codes for surgical dressing, trade name: Contreet® Hydrocolloid Dressing.

Primary Speaker: Russell Miller of Coloplast Corporation

AGENDA ITEM #5

Attachment #08.48

Request to establish 2 codes for antimicrobial dressings, trade name: Restore Foam Dressing, non-Adhesive with TRIACT Technology.

Attachment #08.49

Request to establish a code for contact layer silver sulfate, trade name: Restore Contact Layer Silver, with TRIACT Technology.

Attachment #08.50

Request to establish 3 codes for calcium alginate dressing with silver sodium hydrogen zirconium, trade name: Restore Calcium Alginate Dressing Silver, Sterile.

Primary Speaker: Marissa Carter, M.D.

AGENDA ITEM #6

Attachment #08.77

Request to establish a code for Active Manuka Honey Wound Dressing. Trade name: Medihoney™ Wound Dressings, which contains at least 50% Active Manuka Honey (minimum activity rating of 12) as the major portion of the dressing construction.

No Primary Speaker

AGEDNA ITEM #7

Attachment #08.19

Request to establish 3 codes for an “All-in-One” borderless absorbent foam pad bonded to a latex-free self-adherent, trade name: Coflex® Absorbent Foam Dressing (AFD).

No Primary Speaker

AGENDA ITEM #8

Attachment #08.96

Request to establish a code for a multi-layered gradient compression surgical dressing system for lower extremity.

Primary Speaker: Esther Scherb of Latham & Watkins, LLP

AGEDNA ITEM #9

Attachment #08.13

Request to establish a code “to provide cover for devices that modify the wound healing environment”, trade name: Kerraboot®.

Primary Speaker: Ian Shurville of Ark Therapeutics

AGENDA ITEM #10

Attachment #08.04

Request to reassign code A4348 to identify the condom catheter, trade name: AlphaDry.

No Primary Speaker

AGENDA ITEM #11

Attachment #08.03

Request to establish a code for a penile compression device with absorbency attachment, trade name: ActiCuf™ Compression Pouch.

Primary Speaker: Gerald Timm of GT Urological, LLC

AGENDA ITEM #12

Attachment #08.43

Request to establish a code for medical food, trade name: Baby’s Only Essentials Oral Electrolyte.

Attachment #08.44

Request to establish a code for conventional food, trade name: Baby’s Only Organic® Soy Toddler Formula.

Attachment #08.45

Request to establish a code for conventional food, trade name: Baby’s Only Organic® Dairy Toddler Formula.

No Primary Speaker

AGENDA ITEM #13

Attachment #08.47

Request to establish a code for medical food, trade name: Juven® Therapeutic Nutrition® Drink Mix.

No Primary Speaker

AGENDA ITEM #14

Attachment #08.54

Request to establish a code to identify the electromagnetic transponders used as part of the Calypso® 4D Localization System, trade name: Beacon electromagnetic transponders.

Primary Speaker: Constantine Mantz, M.D.

AGENDA ITEM #15

Attachment #08.104

Request to establish a code for a total hip resurfacing surgical total hip resurfacing/arthroplasty procedure performed on hospital inpatients.

No Primary Speaker

AGENDA ITEM #16

Attachment #08.26

Request to establish a code for radiopaque marker. Trade name: SITZMARKS

Primary Speaker: Patrice Hambleton of Konsyl Pharmaceuticals, Inc.

AGENDA ITEM #17

Attachment #08.79

Request to establish a code for Disinfected, medical-grade blowfly larvae: Phaenicia (Lucilia) sericata. Trade name: Medical Maggots.

Primary Speaker: Ronald Sherman, M.D.

AGENDA ITEM #18

Attachment #08.88

Request to revise existing code A9155 “Artificial Saliva, per 30 mL”. Generic name: Dibasic Sodium Phosphate 0.032, Monobasic Sodium Phosphate 0.009, Calcium Chloride 0.052, Sodium Chloride 0.569, Purified Water qs ad (%w/w). Trade name: Caphosol™.

Primary Speaker: Michael Manyak, M.D.

AGENDA ITEM #19

Attachment #08.103

Request to establish a code to uniquely identify Mimyx® Cream.

Primary Speaker: Jerry Wells of J.F. Wells Consulting

AGENDA ITEM #20

Attachment #08.62

Request to establish a code for a Water-Soluble Implant and Bone Hemostasis Material, trade name: Ostene.

Primary Speaker: Anna Chodakiewicz of Ceremed, Inc.

HCPCS Public Meeting Agenda #1
April 22, 2008

Attachment #08.24

Topic/Issue:

Request to establish 2 codes for a pediatric medication delivery system. Trade names: medibottle2 and medibottle3.

Background/Discussion:

According to the requester, the medibottle is a baby bottle with an inner sleeve dose dispenser with a plunger used to administer liquid medication to bottle-fed patients. The Medibottle2 is a single medibottle only, packaged without instructions for use. The medibottle3 includes the medibottle, 2 oral dispensers, UBA, collar and instructions. The applicant requests a code to identify the medibottle2 for hospital and clinic use, and another code to identify the medibottle3 for outpatient/home use. The medibottle's functionality is different from all of the other known oral medication delivery devices. In the most recent study, with 76 hospitalized infants, the medibottle was proven to be 85% more likely to deliver 100% of the prescribed, bitter-tasting medication, than the industry "gold" standard oral syringe. The study concluded that infant acceptance of a single dose of bitter tasting medicine using the medibottle was superior to an oral dispenser (syringe) alone. The results of this study were presented at a regional pediatric research annual meeting and at a Pediatric Academic society annual meeting in 2007. Based on this and the results of 2 smaller studies the applicant claims that the medibottle is the only device that has been clinically proven to significantly increase compliance. According to the applicant, this compliance directly affects the infant's health and therefore demonstrates a significant therapeutic distinction when compared with other oral medication delivery devices used for infants.

CMS HCPCS 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.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision and asked that it be reversed. The speaker stated that the decision should be based not on claim activity, but on the peer-reviewed published data which indicates "that there is in fact, a rather large program need for an effective delivery device." The speaker cited a study

indicating that non-compliance to prescription regimens results in unnecessary hospitalizations and physician visits. The speaker indicated that use of the Medibottle to deliver medication will improve compliance because it is 85.7% more likely than an oral syringe to deliver 100% of the prescribed dose. This is based on a study of 76 hospitalized infants.

HCPCS Public Meeting Agenda #2
April 22, 2008

Attachment #08.69

Topic/Issue:

Request to establish 3 new codes for hydrophilic urinary catheters and kits, trade names: LoFric; and revise existing 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"; and

Add xxxx1 "Intermittent urinary catheter; straight tip, hydrophilic";

Add xxxx2 "Intermittent urinary catheter; coude (curved) tip, hydrophilic" and

Add xxxx3 "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 UTI, 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 following differential outcomes for the hydrophilic catheter, as compared to catheters made of other materials: “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” and considers all these to be examples of superior clinical outcomes. The applicant’s request for distinct codes is also based on differences in utilization rates (reusability) and price.

CMS HCPCS Preliminary Decision:

Existing codes A4351 “INTERMITTENT URINARY CATHETER; STRAIGHT TIP, WITH OR WITHOUT COATING (TEFLON, SILICONE, SILICONE ELASTOMER, OR HYDROPHILIC, ETC.), EACH”; A4352 “INTERMITTENT URINARY CATHETER; COUDE (CURVED) TIP, WITH OR WITHOUT COATING (TEFLON, SILICONE, SILICONE ELASTOMERIC, OR HYDROPHILIC, ETC.), EACH” and A4353 “INTERMITTENT URINARY CATHETER, WITH INSERTION SUPPLIES” adequately describe hydrophilic intermittent catheters used to drain the urinary bladder, depending on the description of the catheter and the insurer policy that applies (e.g., regarding sterile catheterization and reusability of catheters). Clinical information provided with this application does not demonstrate superior clinical outcomes as a result of using hydrophilic catheters, when compared with use of non-hydrophilic catheters.

Medicare Payment:

The payment rules associated with the existing codes apply to this product. Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup’s preliminary decision and objected to CMS’ conclusions that the application does not demonstrate superior clinical outcomes and that hydrophilic catheters are adequately described by existing codes. The speaker acknowledged that there are limitations to the available studies, but stated that they nonetheless demonstrate superior “outcomes, in, for instance, urinary tract infection, hematuria, pain, strictures and inflammation”. The speaker indicated that hydrophilic catheters “have different indications” and are “especially useful for patients who cannot pass a conventional catheter”. The speaker also indicated that the fee associated with existing codes has the effect of denying access to the hydrophilic catheter and overpaying for conventional catheters because of the price differential between the catheters. The speaker reiterated the request for unique codes for hydrophilic catheters.

HCPCS Public Meeting Agenda #3
April 22, 2008

Attachment #08.59

Topic/Issue:

Request to 1) establish 2 codes for intermittent urinary catheters (hydrophilic), trade name: SpeediCath and 2) revise codes A4351 and A4352. Applicant's suggested language:

Axxx1 "Intermittent urinary catheter (hydrophilic); straight tip, in sterile lubricating medium"

Axxx2 "Intermittent urinary catheter (hydrophilic); coude (curved) tip, in sterile lubricating medium"

A4351 "Intermittent urinary catheter; straight tip, with or without coating (Teflon, silicone, silicone elastomer, ~~or hydrophilic, etc.~~), each

A4352 "Intermittent urinary catheter; coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomer, ~~or hydrophilic, etc.~~), each

Background/Discussion:

According to the requester, Speedicath is a ready-to-use hydrophilic-coated catheter designed for single use for sterile intermittent catheterization in order to treat urinary incontinence. The hydrophilic-coated catheter is pre-packaged in sterile saline solution eliminating the need for additional lubricants or external water sources that could provide a source of contamination. The coating is chemically bonded and permanent to ensure that the coating is not irregular and cannot migrate off the catheter. This optimal lubrication provides low urethral friction for catheter insertion and withdrawal and increases user comfort. According to the requester, clinical research suggests that the use of hydrophilic urinary catheters significantly reduces the number of urinary tract infections in spinal cord injured patients with a neurogenic bladder-sphincter disorders. The DeRidder study demonstrated that twice as many patients randomized to treatment with hydrophilic catheters were UTI-free than were patients randomized to conventional catheter use. Although both types of catheters are used for intermittent catheterization, hydrophilic catheter use can improve clinical outcomes and reduce the cost of care for appropriate, vulnerable segments of the population. According to the requester, "new codes that distinguish sterile, hydrophilic coated catheters from catheters made of other materials will enable access and ensure appropriate patient selection for which sterile catheterization is medically necessary." In addition, the requester suggests a coding distinction between hydrophilic and non-hydrophilic catheters "for the purposes of further tracking clinical outcomes and utilization."

CMS HCPCS Preliminary Decision:

Existing codes A4351 "INTERMITTENT URINARY CATHETER; STRAIGHT TIP, WITH OR WITHOUT COATING (TEFLON, SILICONE, SILICONE ELASTOMER, OR HYDROPHILIC, ETC.), EACH", A4352 "INTERMITTENT URINARY CATHETER; COUDE (CURVED) TIP, WITH OR WITHOUT COATING (TEFLON,

SILICONE, SILICONE ELASTOMERIC, OR HYDROPHILIC, ETC.), EACH” and A4353 “INTERMITTENT URINARY CATHETER, WITH INSERTION SUPPLIES” adequately describe hydrophilic intermittent catheters used to drain the urinary bladder, depending on the description of the catheter and the insurer policy that applies (e.g., regarding sterile catheterization and reusability of catheters). Clinical information provided with this application does not demonstrate superior clinical outcomes as a result of using hydrophilic catheters, when compared to use of non-hydrophilic catheters.

Medicare Payment:

The payment rules associated with the existing codes apply to this product. Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup’s preliminary decision. The speaker stated that lubrication for the entire length of the catheter “reduces the risk of UTI’s”. The speaker claimed that there is a strong body of evidence to support a claim of significant therapeutic distinction, specifically citing the DeRidder and Stensballe studies. The speaker also referenced, but did not provide, a 2008 study that demonstrates a relationship between lubricating catheters and fewer UTI’s. And finally, the speaker indicated that the creation of codes would facilitate analysis, and that lack of distinct codes suppresses access.

HCPCS Public Meeting Agenda #4
April 22, 2008

Attachment #08.58

Topic/Issue:

Request to establish a code for surgical dressing, trade name: Interdry™ Ag Textile with Silver. Applicant's suggested language: Axxxx "Specialty antimicrobial dressing, without adhesive border, any width, per yard"

Background/Discussion:

According to the requester, InterDry is a skin protectant indicated for management of skin folds and other skin-to-skin contact areas. It is a polyurethane coated knitted textile with silver complex that provides effective antimicrobial action for up to five days. The textile also reduces moisture, skin-to-skin friction, and odor in skin folds. InterDry is intended for patients with skin conditions as a result of skin folds, typically between the ages of 18-90. Many of these patients are pre- and/or post-bariatric surgeries who have folds commonly located on the abdomen, under breast, legs, neck and arms. Other patients who frequently have skin conditions suitable for InterDry Ag are those who have complications associated with metabolic syndrome, contractures, folliculitis, lymphedema, diabetes and venous ulcers of the leg. According to the requester, there are no other textiles with antimicrobial ingredients that are used for skin folds. InterDry Ag textile is applied by inserting it into the skin fold, with a minimum of 5 cm of textile remaining exposed outside of the skin fold. The skin fold should be inspected and cleansed daily. It should be replaced if it becomes soiled with urine, feces, and/or excessive drainage, or in 5 days. According to the requester, there are no other textiles with antimicrobial ingredients that are used for skin folds. As such, no dedicated codes exist to describe this product. A code is requested in order to allow for automation of claims processing, specific payer and provider contract administration and utilization data gathering. Specialty absorptive dressing codes (A6251 – A6256) are specific to pads for wound covers and do not describe the per yard measurement needed to describe this product.

CMS HCPCS Preliminary Decision:

Existing code A6250 "SKIN SEALANTS, PROTECTANTS, MOISTURIZERS, OINTMENTS, ANY TYPE, ANY SIZE" adequately describe the product that is the subject of this request. Clinical information provided by the applicant does not support a claim of superior clinical outcome when this product is used, when compared with use of other products coded at A6250.

Medicare Payment:

The payment rules associated with the existing codes apply to this product. Pricing = 00

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda #4
April 22, 2008

Attachment #08.57

Topic/Issue:

Request to establish 6 codes for surgical dressing, trade name: Contreet® Hydrocolloid Dressing. Applicant's suggested language:

Axxx1 "Foam dressing, antimicrobial wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing"

Axxx2 "Foam dressing, antimicrobial wound cover, pad size more than 16 sq. in., but less than or equal to 48 sq. in., without adhesive border, each dressing"

Axxx3 "Foam dressing, antimicrobial wound cover, pad size 16 sq. in. or less, with any size adhesive border, each dressing"

Axxx4 "Foam dressing, antimicrobial wound cover, pad size more than 16 sq. in., but less than or equal to 48 sq. in., with any size adhesive border, each dressing"

Axxx5 "Hydrocolloid dressing, antimicrobial wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing"

Axxx6 "Hydrocolloid dressing, antimicrobial wound cover, pad size more than 16 sq. in., but less than 48 sq. in., without adhesive border, each dressing"

Background/Discussion:

According to the requester, Contreet wound care dressings are intended for use on patients suffering from chronic wounds that fail to progress. Contreet antimicrobial dressings work through ionic exchange, whereby the dressings release silver ions into the wound exudates as it is absorbed into the dressings. Potassium and sodium ions interact with the dressing, which liberates the silver ions to attack bacteria present in the exudates. Their mode of action, combined with the amount of silver in each dressing, provides an effective and sustained release of silver for up to 7 days, establishing the basis for an optimal healing environment. Contreet foam dressings consist of unique, 3D polymer structures within the 4.4 mm thick foam pad, designed to vertically absorb and lock wound exudates away, leading to high exudates retention and no lateral spreading. Non-adhesive dressings consist of a semi-permeable top layer of polyurethane film which allows for optimal moisture vapor transfer (MVTR), providing a moist environment for the wound to heal. Adhesive foam consists of the same components, to include a thick layer of hydrocolloid which extends beyond the foam to create a bordered, skin friendly adhesive. Adhesive dressings reduce the need for a secondary dressing. The existing HCPCS codes are unable to differentiate antimicrobial dressings from standard foam and hydrocolloid dressings, which hampers providers' and payers' ability to track the clinical effectiveness of antimicrobial dressings. According to the requester, with robust clinical and in vitro data now available, there is a need to differentiate antimicrobial dressings from standard foam and hydrocolloid dressings.

CMS HCPCS Preliminary Decision:

Existing codes A6209 “FOAM DRESSING, WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING” and A6210 “FOAM DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ. IN., BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING” (depending on size) adequately describe foam dressings without adhesive. Existing codes A6212 “FOAM DRESSING, WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, WITH ANY SIZE ADHESIVE BORDER, EACH DRESSING” and A6213 “FOAM DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITH ANY SIZE ADHESIVE BORDER, EACH DRESSING” (depending on size) adequately describe dressings with adhesive. Existing codes A6234 “HYDROCOLLOID DRESSING, WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING” or A6235 “HYDROCOLLOID DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING” (depending on size) adequately describe the hydrocolloid dressings. Clinical information provided by the applicant does not support a claim of superior clinical outcome when this product is used, when compared with use of other products coded at A6209, A6210, A6212, A6213, A6234, A6235 or A6236.

Medicare Payment:

The payment rules associated with the existing codes apply to this product. Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup’s preliminary decision and reiterated the original request for unique codes that would distinguish antimicrobial dressings. According to the speaker, silver dressings differ technologically and functionally from standard foam dressings. The speaker stated that silver dressing technology is indicated for chronic wounds, unlike standard dressings. The speaker also stated that silver dressings help wounds heal faster.

HCPCS Public Meeting Agenda #5
April 22, 2008

Attachment #08.48

Topic/Issue:

Request to establish 2 codes for antimicrobial dressings, trade name: Restore Foam Dressing, non-Adhesive with TRIACT Technology. Applicant's suggested language:
xxxx1 "Foam dressing, antimicrobial, pad size 16 sq. in. or less, without adhesive border, each dressing"

xxxxx2 "Foam dressing, antimicrobial, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing"

Background/Discussion:

According to the requester, Restore Foam Dressing Silver is a sterile, antimicrobial wound contact dressing with silver sulfate. It is non-occlusive and non-adhesive for painless removal. It is comprised of three layers: a polyester mesh impregnated with a matrix of carboxymethylcellulose hydrocolloid particles, cohesion polymers and Vaseline containing silver; a non-sensitizing, super-absorbent polyurethane foam pad; and a protective, semi-permeable polyurethane backing. The barrier functions of Restore Foam Dressing may help reduce bacterial load in moderately to highly exuding partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, donor and graft sites. The proprietary TRIACT technology specificity lies in the presence of a polymer matrix which ensures cohesion of hydrocolloid particles and petrolatum on a polyester mesh. In contact with exudates, the hydrocolloid particles combine with the matrix to form a lipidocolloidal gel, providing a moist environment that promotes healing. The dressing has also been shown to sustain antibacterial activity for up to 7 days in invitro studies. The super-absorbent foam pad ensures drainage of exudates and helps protect skin around the lesion from any maceration. According to the applicant, existing HCPCS codes do not describe the antimicrobial function provided by silver sulfate in the dressing. The applicant claims that silver sulfate kills a wide range of micro-organisms commonly found in colonized and infected wounds which confers a significant therapeutic distinction between these dressings and dressings that with silver salts. The applicant suggests a coding distinction based on therapeutic differences and also for tracking purposes.

CMS HCPCS Preliminary Decision:

Existing code A6209 "FOAM DRESSING, WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING" or A6210 "FOAM DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING", depending on size, adequately describes a category of foam dressings without adhesive border which perform a function similar to the item that is the subject of this request. Clinical information provided by the applicant does not support a claim of

superior clinical outcome when this product is used, when compared with use of other products coded at E6209 and E6210.

Medicare Payment:

The payment rules associated with the existing codes apply to this product. Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker reviewed evidence related to the use of silver dressings. The speaker stated that looking at a dressing in the realm of partial (as opposed to complete) wound healing makes more sense. The speaker indicated that “the wound care scientific community is approaching consensus” that partial wound healing endpoints should replace complete healing as the gold standard, and that the FDA definition of “complete wound healing”, “needs to be updated”. The speaker acknowledged that Meta Analysis of the effect of silver dressings on complete wound healing is inconclusive; that complete wound healing is not statistically significant in any study; and that there is better evidence for improvement of infection rates and surrogate parameters.

HCPCS Public Meeting Agenda #5
April 22, 2008

Attachment #08.49

Topic/Issue:

Request to establish a code for contact layer silver sulfate, trade name: Restore Contact Layer Silver, with TRIACT Technology. Applicant's suggested language:
Axxxx "Antimicrobial contact layer, more than 16 sq. in. but less than or equal to 48 sq. in., each dressing"

Background/Discussion:

According to the requester, Restore Contact Layer Silver is a sterile, non-occlusive, non-adhesive antimicrobial wound contact dressing composed of a polyester mesh impregnated with a matrix comprising of hydrocolloid particles (carboxymethylcellulose), cohesion polymers, petrolatum and silver designed for painless removal. The barrier functions of Restore Contact Layer Silver may help reduce infection in low to moderate exuding partial and full thickness wounds, including second degree burns, pressure ulcers, venous stasis ulcers, diabetic ulcers and graft and donor sites. This product is used as a primary dressing. It requires a secondary dressing to cover it and hold it in place. In contact with exudates, the hydrocolloid particles combine with the matrix to form a lipido-colloidal gel, providing a moist environment that promotes healing. Restore was shown to be effective against bacteria most frequently associated with wound infections. Existing HCPCS codes do not effectively describe the "antimicrobial function" provided by the silver sulfate in the dressing, which provides a significant therapeutic distinction. It effectively kills a wide range of microorganisms which are commonly found in colonized and infected wounds and continually releases silver for up to seven days. According to the requester, HCPCS code A6207 "CONTACT LAYER, MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING" does not address the antimicrobial role that the dressing plays within the wound bed. The applicant requests a code based on therapeutic differences and also for tracking purposes.

CMS HCPCS Preliminary Decision:

Existing code A6207 "CONTACT LAYER, MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING" adequately describes the product that is the subject of this request. Clinical information provided by the applicant does not support a claim of superior clinical outcome when this product is used, when compared with use of other products coded at A6207.

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker reviewed evidence related to the use of silver dressings. The speaker stated that looking at a dressing in the realm of partial (as opposed to complete) wound healing makes more sense. The speaker indicated that “the wound care scientific community is approaching consensus” that partial wound healing endpoints should replace complete healing as the gold standard, and that the FDA definition of “complete wound healing”, “needs to be updated”. The speaker acknowledged that Meta Analysis of the effect of silver dressings on complete wound healing is inconclusive; that complete wound healing is not statistically significant in any study; and that there is better evidence for improvement of infection rates and surrogate parameters.

HCPCS Public Meeting Agenda #5
April 22, 2008

Attachment #08.50

Topic/Issue:

Request to establish 3 codes for calcium alginate dressing with silver sodium hydrogen zirconium, trade name: Restore Calcium Alginate Dressing Silver, Sterile. Applicant's suggested language:

Axxx1 "Alginate or other fiber gelling dressing, antimicrobial, pad size 16 sq. in. or less, each dressing"

Axxx2 "Alginate or other fiber gelling dressing, antimicrobial, pad size more than 16 sq. in. but less than or equal to 48 sq. in., each dressing"

Axxx3 "Alginate or other fiber gelling dressing, antimicrobial filler, per 6 inches"

Background/Discussion:

According to the requester, Restore Calcium Alginate Dressing Silver is clinically indicated for use in the management of moderate to heavily exuding partial to full thickness wounds, including: post-operative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites. It is a sterile, non woven pad composed of a high G (guluronic acid) calcium alginate, carboxymethylcellulose (CMS) and ionic silver complex which absorbs wound exudates and releases silver ions in the presence of wound fluid. As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment for optimal wound healing, and allows intact removal. The silver ions protect the dressing from a broad spectrum of microorganisms over a period of up to four days, based on in vitro laboratory testing. Odor reduction results from the antibacterial effect in the dressing. The dressing is an effective barrier to penetration by microorganisms. The dressing is available in various sizes including a 2x2 inch, a 4x4.75 inch and a rope that is 1x12 inches. According to the applicant, a recently completed study "offers evidence that silver in a dressing does affect the healing rate of the wound. The applicant states that existing HCPCS codes do not effectively describe the "antimicrobial function" provided by the ionic silver complex in the dressing, which provides a significant therapeutic distinction. It effectively kills a wide range of microorganisms which are commonly found in colonized and infected wounds. The applicant requests new codes based on this distinction, and also for tracking purposes.

CMS HCPCS Preliminary Decision:

Existing code: A6196 "ALGINATE OR OTHER FIBER GELLING DRESSING WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, EACH DRESSING"; A6197 "ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ.IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING"; or A6199 "ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND FILLER, PER 6 INCHES", (based on product characteristics and size) adequately describes the products that are the subject of this request. Clinical information provided by applicant does not support a claim of superior clinical outcome

when this product is used, when compared with other products coded at A6196, A6197 and A6199.

Medicare Payment:

The payment rules associated with the existing codes apply to this product. Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker reviewed evidence related to the use of silver dressings. The speaker stated that looking at a dressing in the realm of partial (as opposed to complete) wound healing makes more sense. The speaker indicated that “the wound care scientific community is approaching consensus” that partial wound healing endpoints should replace complete healing as the gold standard, and that the FDA definition of “complete wound healing”, “needs to be updated”. The speaker acknowledged that Meta Analysis of the effect of silver dressings on complete wound healing is inconclusive; that complete wound healing is not statistically significant in any study; and that there is better evidence for improvement of infection rates and surrogate parameters.

HCPCS Public Meeting Agenda #6
April 22, 2008

Attachment #08.77

Topic/Issue:

Request to establish a code for Active Manuka Honey Wound Dressings. Trade name: Medihoney™ Wound Dressings, which contain at least 50% Active Manuka Honey (minimum activity rating of 12) as the major portion of the dressing construction.

Background/Discussion:

According to the requester, Manuka is the name of the New Zealand tea tree *Leptospermum scoparium* or *Leptospermum*. Bees harvest the nectar and other floral parts of this tree and produce the manuka honey. A standardized assay has been established to quantify the activity rating of each batch of manuka honey cultivated. This activity rating is based on the antimicrobial activity compared to a relative percentage of a known antimicrobial, phenol. An activity rating of 1 is equivalent to a 1% concentration of phenol, a rating of 10 is equivalent to 10%, and so on. The literature shows that an activity rating of at least 12 is required for the management of chronic wounds and burns. Medical-grade Active Manuka Honey is prepared purely for medical use and controlled by a rigorous set of systems and standards. All batches are first tested for their activity rating, filtered through a sophisticated filtering system, and then sterilized. It is certified that no antibiotics or other pharmacological substances were used in the hives of the bees producing the honey. This practice is only rigorously followed and certified in New Zealand and Australia.

Manuka Medical-grade Honey dressings are placed in direct contact with the wound surface as a primary dressing to protect the wound tissues and support debridement. Due to contact with wound fluids, there must be a significant level of honey in the dressings for the dressings to be effective. The normal healing process is complex with overlapping series of events that include inflammation, cell proliferation and tissue remodeling. During the early inflammatory phase, neutrophils infiltrate the injured region and remove cell debris, foreign materials and bacteria by a combination of phagocytosis and proteolytic action. Later monocytes released from damaged blood vessels differentiate and tissue macrophages dominate the wound environment. These cells digest debris and release mediators, cytokines and lipid metabolites to progress the wound to form granulation tissue. This application notes that “Derma Sciences only promotes wound environment and healing-oriented claims and not antimicrobial claims.” According to the requester, a HCPCS code for Manuka Medical-grade Honey dressings would provide a dressing option with effective wound healing and bacterial management properties.

CMS HCPCS Preliminary Decision:

Existing codes A6196 “ALGINATE OR OTHER FIBER GELLING DRESSING WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, EACH DRESSING” and A6197 “ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ.IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING”, adequately describe the pads, depending on size. Existing code A6199 “ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND FILLER, PER 6 INCHES” adequately describes rope, gel and paste products.

Medicare Payment:

The payment rules associated with the existing codes apply to this product. Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda #7
April 22, 2008

Attachment #08.19

Topic/Issue:

Request to establish 3 codes for an “All-in-One” borderless absorbent foam pad bonded to a latex-free self-adherent, trade name: Coflex® Absorbent Foam Dressing (AFD).

Applicant’s suggested language:

xxxx1 “Combination foam dressing/self-adherent bandage 10 sq in w/o bdr/2.5 yd Bandage”

xxxx2 “Combination foam dressing/self-adherent bandage 20 sq in w/o bdr/2.5 yd Bandage”

xxxx3 “Combination foam dressing/self-adherent bandage 20 sq in w/o bdr/7.5 yd Bandage”

Background/Discussion:

According to the requester, Coflex is borderless absorbent foam pad bonded to a latex-free self-adherent cohesive bandage. It is used for the treatment of venous leg ulcers, arterial ulcers, pressure ulcers, traumatic wounds, diabetic foot ulcers, non-healing surgical incisions, lower extremity wounds, skin tears, burns, tracheotomies, donor sites and chronic wounds. It includes a hydrophilic absorbent foam pad (which draws in exudates while keeping the wound site moist and clean) and waterproof film of web adhesive which attaches the dressing to the Ace-wrap-type bandage. When applied, the foam pad expands to conform to the wound cavity, managing exudates and reducing maceration around the wound bed. The pad protects delicate granulating tissue and avoids trauma during dressing changes, thus promoting wound closure and natural healing. The product is designed to absorb blood and stop bleeding. It is described in product literature both as an “All-in-One Foam Pad Dressing and Cohesive Bandage” and as an “All-in-One Emergency Bandage System”. Coflex removes the need to use several products in treating a wound; stays in place while transporting patients to and from different units; and easier for caregivers and patients to use. It is available in six sizes. Three codes are requested, based on size categories. According to the requester although existing HCPCS codes separately describe foam and bandages, there are no existing codes that describe the combination of components in this bandage system.

CMS HCPCS Preliminary Decision:

Existing codes A6209 “FOAM DRESSING, WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING” and A6453 “SELF-ADHERENT BANDAGE, ELASTIC, NON-KNITTED/NON-WOVEN, WIDTH LESS THAN THREE INCHES, PER YARD” or A6210 “FOAM DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ. IN., BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING” and A6454 “SELF-ADHERENT BANDAGE, ELASTIC, NON-KNITTED/NON-WOVEN, WIDTH GREATER THAN OR EQUAL TO THREE INCHES AND LESS THAN FIVE

INCHES, PER YARD”, (depending on size) adequately describe the components in this bandage system.

Medicare Payment:

The payment rules associated with the existing codes apply to this product. Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda #8
April 22, 2008

Attachment #08.96

Topic/Issue:

Request to establish a code for a multi-layered gradient compression surgical dressing system for lower extremity. Trade Name: CircAid® Medical Products T-3 M™.
Applicant's suggested language: "Multi-layered gradient compression surgical dressing system for lower extremity with built-in gradient pressure system, non-elastic, below knee, 30-50 mmHg, each"

Background/Discussion:

According to the requester, the T-3 M is a multi-layered surgical dressing system that provides gradient compression using adjustable adherent nonelastic bands that fasten to achieve therapeutic compression levels. The product is used on the lower extremity to treat venous disease, including active venous stasis ulcers and lymphedema. The compression layer is comprised of a nonelastic binder that is secured at the prescribed level of compression (i.e., 30 to 50 mmHg) using a Built-In-Pressure System ("BPS"), which allows the user to align markers on the neoprene strip that runs along the posterior aspect of the device with a calibration card that is provided with the product. Existing code A4465 ("nonelastic binder for extremity"), does not adequately describe the design and therapeutic abilities of the T-3 M. Specifically, the gradient pressure levels are not contemplated. Nor is the current code restricted to products that are placed on the lower extremities or for products used for the treatment of venous stasis ulcers. The first layer is an elastic knit stocking that covers the leg from the toes up to just below the knee and is usually applied over the primary wound dressing. This stocking pads the leg and creates a barrier between the compression layer and the primary wound dressing. The second layer, or compression layer, consists of three components: (1) the leg wrap or "legging" made of multiple nonelastic straps connected by a neoprene strip; (2) the BPS calibration card; and (3) an ankle-foot wrap. The leg wrap's neoprene strip is at the center of the device and is flanked on either side of the nonelastic straps. According to the applicant, products currently identified using A4465 do not use the BPS component to achieve selected levels of sustained gradient compression, and "for this reason, it is appropriate to develop a new code that specifically takes into account this feature of gradient compression at the recognized 30-50 mmHg levels".

CMS HCPCS Preliminary Decision:

Establish Axxxx GRADIENT COMPRESSION WRAP, NON-ELASTIC, BELOW KNEE, 30 - 50 mmHg, EACH

Medicare Payment:

Based on guidance contained in an informal benefit category determination, we believe that the item would be paid in accordance with the payment rules that apply to surgical dressings.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported the workgroup's preliminary decision to establish a code. The speaker asked that the language: "with measurable pressure" be added to the new code to reflect an inelastic wrap that is designed to achieve clinical therapeutic measures. Elastic dressings identify only the measures, not the *measurability* component.

HCPCS Public Meeting Agenda #9
April 22, 2008

Attachment #08.13

Topic/Issue:

Request to establish a code “to provide cover for devices that modify the wound healing environment”, trade name: Kerraboot®. Applicant’s suggested language: “Dressing, wound, wound environment modifying”

Background/Discussion:

According to the requester, Kerraboot® is an innovative wound healing system designed to completely enclose the lower leg and modify the environment of the wound, the wound bed and surrounding tissue. Kerraboot is indicated for use on wounds of the lower leg, including light, moderate or heavily exudating delayed or non-healing diabetic, neuropathic, venous, and arterial foot ulcers and etc. It consists of a super absorbent pad, a non-slip sole, an occlusive multi-layer film and retaining strap and is designed to be as easy to apply as a stocking. Kerraboot increases the temperature of the lower leg and in response the body increases blood perfusion of wound and of tissue adjacent to the wound site. It also: allows free drainage of chronic wound exudates away from the wound bed; locks wound exudates into an integral super absorbent pad and so removes negative growth factors from contact with the wound; creates and maintains a moist healing environment around the wound surface encouraging autolytic debridement; and ensures odor containment. Kerraboot is comprised of five-layer co-extruded film, absorbent insole/pad, cuff liner, non-slip sole and a Velcro strap. It is supplied as a single sterile dressing and is available in four sizes. It is available in an opaque white or clear format depending on the need to visualize the wound. A typical patient may use Kerraboot for up to two months while the wound is undergoing debridement and re-epithelialization. The frequency of dressing change varies from daily to 3 times per week. According to the requester, existing codes, including A6253 SPECIALTY ABSORPTIVE DRESSING, WOUND COVER, PAD SIZE MORE THAN 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING do not adequately identify the components of this product or describe a product which both protects the wound and also modifies the wound healing environment. In addition, reimbursement for A6253 “makes it very difficult to sell” this product. Product literature claims that use of the Kerraboot, as compared with standard care, result in: greater reduction in slough, increased granulation tissue and greater patient independence.

CMS HCPCS 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:

Payment for any covered items will be based on the carrier's individual consideration of the claim since no specific code or fee schedule has been established for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that the decision not to establish a code contradicts a prior SADMERC decision to assign this product to existing code A6253. The speaker stated that Kerraboot acts as a primary and secondary dressing, not just a protectant. It removes exudates from the wound bed and maintains a warm moist environment to inhibit healing, while allowing the patient to remain mobile. According to the speaker, code A6253 ignores film as a fundamental aspect of Kerraboot's design, and limits use to only large dressings. The speaker believes that a miscellaneous code is appropriate but the product warrants a unique code.

HCPCS Public Meeting Agenda #10
April 22, 2008

Attachment #08.04

Topic/Issue:

Request to reassign code A4348 to identify the condom catheter, trade name: AlphaDry.

Background/Discussion:

According to the requester, AlphaDry is a condom catheter used by males who are incontinent. The reservoir is built into the condom portion making one piece, and tucked in underwear. Urine is collected in the reservoir and drained as needed. AlphaDry is reusable and the lowest cost method of managing incontinence. It is made from high quality latex and is designed to be used 15 times over 15 days. According to the requester, prior to January 1, 2007 AlphaDry was coded at A4348, and after January 1, 2007 is coded at A4326. In addition, the requester stated that A4326 is inadequate to describe AlphaDry because it is a “collection chamber” and A4348 describes a “collection compartment” which does not require a leg bag and tube. The collection compartment is attached to the condom catheter. Code A4348 also included the words “extended wear”. Therefore A4348 describes AlphaDry. According to the requester, AlphaDry saved Medicare \$22.67/month over condom catheter/leg bag systems prior to the code change in January 2007.

CMS HCPCS Preliminary Decision:

Existing code A4326 “MALE EXTERNAL CATHETER WITH INTEGRAL COLLECTION CHAMBER, ANY TYPE, EACH” adequately describes the product that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda #11
April 22, 2008

Attachment #08.03

Topic/Issue:

Request to establish a code for a penile compression device with absorbency attachment, trade name: ActiCuf™ Compression Pouch.

Background/Discussion:

According to the requester, ActiCuf™ is a penile compression device designed for the male patient to treat and manage light to moderate urinary incontinence. The ActiCuf clamping design minimizes urinary incontinence by mechanical compression of the urethra eliminating urine leakage and allowing the bladder to fill. If there is some leakage from the urethra, the moisture is confined to the disposable pouch. This protects the surrounding skin of the inner thigh, scrotum, perineum and perianal areas from irritating urine. According to the requester, existing codes cover compression devices alone or absorbency products alone. The ActiCuf Pouch combines the advantages of these two options into one easy to use disposable device. ActiCuf can be used several times if the user is careful to compress the base of the penis before removal to urinate.

PRELIMINARY DECISION:

Revise code A4356 which currently reads: “EXTERNAL URETHRAL CLAMP OR COMPRESSIVE DEVICE (NOT TO BE USED FOR CATHETER CLAMP), EACH” to instead read: “EXTERNAL URETHRAL CLAMP OR COMPRESSION DEVICE (NOT TO BE USED FOR CATHETER CLAMP), ANY TYPE, 90-DAY SUPPLY”

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup’s preliminary decision and reiterated the original request for a unique code. The speaker discussed the general need for incontinence solutions. This product combines a clamp and a pad and is intended for use for stress, not urge continence. The speaker indicated that policy surrounding existing code A4356 allows replacement too infrequently.

HCPCS Public Meeting Agenda #12
April 22, 2008

Attachment #08.43

Topic/Issue:

Request to establish a code for medical food, trade name: Baby's Only Essentials Oral Electrolyte.

Background/Discussion:

According to the requester, Baby's Only Essentials is an oral electrolyte solution made with organic ingredients, serves the hydration needs of children and adults with chemical sensitivities, (such as gluten sensitivities). It is scientifically formulated to contain properly balanced levels of electrolytes, water and carbohydrates to replace fluid loss and maintain proper hydration. Baby's Only Essentials electrolytes help prevent dehydration due to diarrhea, vomiting and fever. The electrolytes contained in Baby's Only Essentials are sodium, potassium, and chloride. Sodium in combination with the carbohydrates (organic dextrose and organic white grape juice concentrate) aid the absorption of water from the intestinal tract into the body and helps to retain fluids in the body to prevent dehydration. Sodium works with potassium and chloride to conduct electrical currents in the body and keep tissue fluids in balance. Potassium works with sodium to regulate the body's waste balance, transmit nerve impulses, and regulate muscle contraction including the heart muscles. It is essential for metabolism and the release of insulin. Chloride helps to maintain the acid-base balance of the body fluids, prevent acidosis and is also a component of the stomach juices needed for digestion of foods. Baby's Essentials should be added to a baby, child or adult's diet immediately upon symptoms of dehydration. It can also be used in the treatment of food poisoning, rotavirus, flu, viral gastroenteritis, or Norovirus. Baby's Essentials can be used every 1-4 hours or as directed by a doctor. The requester claims that this product differs from other products in that it does not contain non-organic dextrose, fructose or artificial fruit flavors or sweeteners such as acesulfame potassium and sucralose. According to the requester, there is not a code currently being used to identify this product at this time.

CMS HCPCS Preliminary Decision:

Existing code B4103 "ENTERAL FORMULA, FOR PEDIATRICS, USED TO REPLACE FLUIDS AND ELECTROLYTES (E.G. CLEAR LIQUIDS), 500 ML = 1 UNIT", adequately describes the product that is the subject of this request. On Medicare claims, code B4103 should be used with modifier BO "ORALLY ADMINISTERED NUTRITION, NOT BY FEEDING TUBE".

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda #12
April 22, 2008

Attachment #08.44

Topic/Issue:

Request to establish a code for conventional food, trade name: Baby's Only Organic® Soy Toddler Formula.

Background/Discussion:

According to the requester, Baby's Only Organic is a certified organic soy based formula that is free of lactose, dairy, corn, wheat, peanuts, fluoride, MSG and gluten. It can be fed orally or via naso-gastric tube. Organic brown rice syrup is used instead of corn syrup as its carbohydrate source. The product also contains linolenic and linoleic essential fatty acids, which convert to DHA and ARA fatty acids in the body. Organic soy protein concentrate is the protein source. Baby's Only Organic is used by toddlers ages 1 to 3 years as a nutritional beverage and to compliment a diet that includes table foods. It can also be used to supplement breast milk or as a milk replacement. For infants less than 12-months of age it is used as directed by a healthcare professional. Many use Baby's Organic as a sole source of nutrition before solid foods are introduced or as a source of enteral nutrition in medical situations where a complete nutritional soy product is needed. Baby's Only has also been prescribed by doctors as a sole source of enteral nutrition for children who suffer from corn, gluten and dairy allergies, palm olein oil, chemical or other food sensitivities. According to the applicant, other soy formulas contain corn, sucrose or cane sugar, non-organic oils, and some contain palm olein oil and may be processed with chemicals. According to the requester, this is the only soy formula on the U.S. market that contains organic brown rice syrup instead of corn syrup as its carbohydrate source. The applicant states that there is not a code currently being used to identify this product.

CMS HCPCS Preliminary Decision:

Existing code B4159 "ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY COMPLETE SOY BASED WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER AND/OR IRON, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT", adequately describes the product that is the subject of this request. On Medicare claims, code B4159 should be used with modifier BO "ORALLY ADMINISTERED NUTRITION, NOT BY FEEDING TUBE".

Medicare Payment:

The fee schedule and payment rules associated with the existing code apply to this product. Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda #12
April 22, 2008

Attachment #08.45

Topic/Issue:

Request to establish a code for conventional food, trade name: Baby's Only Organic® Dairy Toddler Formula.

Background/Discussion:

According to the requester, Baby's Only Organic Dairy Toddler Formula is a certified organic dairy based formula that is free of lactose, dairy, corn, wheat, peanuts, fluoride, MSG and gluten. Organic brown rice syrup is used instead of corn syrup as its carbohydrate source. Baby's Only Organic consists of 40% organic brown rice syrup and 60% naturally occurring lactose. The product also contains linolenic and linoleic essential fatty acids, which convert to DHA and ARA fatty acids in the body. Organic soy protein concentrate is the protein source. Baby's Only Organic is used by toddlers ages 1 to 3 years as a nutritional beverage and to compliment a diet that includes table foods. It can also be used to supplement breast milk or as a milk replacement. For infants less than 12-months, it is used as directed by a healthcare professional. Many use Baby's Organic as a sole source of nutrition before solid foods are introduced or as a source of enteral nutrition in medical situations where a complete nutritional soy product is needed. Baby's Only has also been prescribed by doctors as a sole source of enteral nutrition for children who suffer from corn, gluten and dairy allergies, palm olein oil, chemical or other food sensitivities. The requester claims that this is "the only dairy formula on the U.S. market that contains organic brown rice syrup as opposed to other formulas that use carbohydrates from sources that are allergen or known to cause food sensitivities (lactose)."

CMS HCPCS Preliminary Decision:

Existing code B4158 "ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY COMPLETE WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER AND/OR IRON, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT", adequately describe the product that is the subject of this request. On Medicare claims, code B4158 should be used with modifier BO "ORALLY ADMINISTERED NUTRITION, NOT BY FEEDING TUBE".

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda #13
April 22, 2008

Attachment #08.47

Topic/Issue:

Request to establish a code for medical food, trade name: Juven® Therapeutic Nutrition® Drink Mix. Applicant's suggested language: "Enteral formula, nutritionally incomplete nutritional for special metabolic needs, includes a unique therapeutic ingredient or a unique combination of therapeutic ingredients, administered through an enteral feeding tube or by oral consumption"

Background/Discussion:

According to the requester, Juven is a unique therapeutic nutrition product in the form of a powdered drink mix that contains β -hydroxy- β -methylbutyrate (HMB), along with the amino acids arginine and glutamine. Each day, the human body converts a very small amount of dietary leucine to HMB. During times of stress, the body may not make enough HMB to keep the cell wall strong, therefore increasing the risk of protein breakdown and loss of lean mass. Juven has been clinically shown to help build lean body mass in cancer cachexia and HIV/AIDS wasting, and to enhance collagen synthesis needed to support wound healing. The three components of Juven are HMB, arginine and glutamine. HMB, naturally found in the body and produced in the membrane of cells, is the ingredient unique to Juven. HMB serves as a precursor for muscle cells to synthesize cholesterol, which is necessary for muscle membrane structure and integrity. It has also been shown to down-regulate protein degradation pathways causing a net gain in protein synthesis. Arginine is a conditionally essential amino acid that is key to muscle tissue synthesis, immune cell development, and wound healing. Glutamine is a conditionally essential amino acid that is key to muscle tissue synthesis and provides fuel for immune cells and gastrointestinal cells. Glutamine has also been shown to upregulate collagen gene transcription. Juven can be fed orally or via tube. Two servings each day are recommended to help build lean body mass and support wound healing. Each packet/serving of Juven provides 7g of arginine, 7g of glutamine, and 1.2g of HMB. According to the requester, existing code B4155 "ENTERAL FORMULA, NUTRITIONALLY INCOMPLETE/MODULAR NUTRIENTS, INCLUDES SPECIFIC NUTRIENTS, CARBOHYDRATES (E.G. GLUCOSE POLYMERS), PROTEINS/AMINO ACIDS (E.G. GLUTAMINE, ARGININE), FAT (E.G. MEDIUM CHAIN TRIGLYCERIDES) OR COMBINATION, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNITS" does not describe Juven because it contains HMB, which is not included in the code descriptor. Also, the applicant is concerned that the 100 calories = 1 unit descriptor in B4155 does not easily translate to Juven, which is commonly administered orally at 156 calories daily.

CMS HCPCS Preliminary Decision:

Existing code B4155 "ENTERAL FORMULA, NUTRITIONALLY INCOMPLETE/MODULAR NUTRIENTS, INCLUDES SPECIFIC NUTRIENTS,

CARBOHYDRATES (E.G. GLUCOSE POLYMERS), PROTEINS/AMINO ACIDS (E.G. GLUTAMINE, ARGININE), FAT (E.G. MEDIUM CHAIN TRIGLYCERIDES) OR COMBINATION, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT”, adequately describes the product that is the subject of this request. Doses that exceed 1 unit can be billed using multiples in the “units” column on the claim form. There is insufficient evidence in this application that the inclusion of HMB confers a significant therapeutic distinction when compared to use of other items coded at B4155.

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 39

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda #14
April 22, 2008

Attachment #08.54

Topic/Issue:

Request to establish a code to identify the electromagnetic transponders used as part of the Calypso® 4D Localization System, trade name: Beacon electromagnetic transponders. Applicant's suggested language: "Electromagnetic transponders, permanently implantable, package of three"

Background/Discussion:

According to the requester, Beacon electromagnetic transponders are implanted passive resonant circuits, encapsulated in a hermetically sealed, medical grade biocompatible glass capsule. These miniature electrical circuits are comprised of a copper coil, ferrite rod and capacitor. Each electromagnetic transponder is approximately the size of a small grain of rice. Beacon transponders are activated by the Calypso® 4D Localization System when the transponders are positioned directly under the system's electromagnetic array. The Calypso System is an electromagnetic tumor target positioning technology used in radiation therapy delivery. The electromagnetic transponders emit a unique electromagnetic signal which is detected, measured, and used by the Calypso System to determine the location of the tumor target relative to the linear accelerator beam. Electromagnetic transponders are implanted into the tumor target tissue prior to the delivery of radiation therapy. This technology provides clinicians with continuous position information of a tumor target during external beam radiation therapy with sub-millimeter accuracy. Use of this tumor target position information can improve radiation treatment accuracy, thereby reducing the likelihood of radiation induced complications and improving the effectiveness of radiation therapy. According to the requester, there are no existing HCPCS codes or combinations of codes that describe, either technologically or functionally, the Beacon electromagnetic transponders.

CMS HCPCS Preliminary Decision:

Existing code A4648 "TISSUE MARKER, IMPLANATABLE, ANY TYPE, EACH" adequately describes the product that is the subject of this request. Clinical information provided by the applicant does not support a claim of a superior clinical outcome when this product is used, when compared with other markers coded at A4648. For HOPPS, report using C1879 "TISSUE MARKER (IMPLANTABLE)".

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 57

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that electromagnetic transponders are the only devices that track treatment movement during radiation therapy and enable accurate delivery. Therefore, they are

clinically, functionally and structurally unique compared to gold seeds and other tissue markers. According to the speaker, real-time tracking also lends tremendous clinical significance in that it facilitates delivery of an increased dose and reduces the total number of treatments needed.

HCPCS Public Meeting Agenda #15
April 22, 2008

Attachment #08.104

Topic/Issue:

Request to establish a code for a total hip resurfacing surgical total hip resurfacing/arthroplasty procedure performed on hospital inpatients. Trade name: Total hip resurfacing/arthroplasty. Applicant's suggested language: "Resurfacing hip, total, acetabulum and femoral head, Hip resurfacing arthroplasty, total."

Background/Discussion:

According to the requestor, total hip resurfacing/arthroplasty is a procedure intended to reduce or relieve pain and/or improve hip function in non-Medicare patients who wish to maintain their active lifestyle. It is a bone-conserving alternative to conventional total hip replacement/arthroplasty. Currently, CPT codes exist only for total hip replacement/arthroplasty. Total hip resurfacing/arthroplasty is a relatively new procedure that requires accurate tracking with respect to performance and patient outcomes. Unlike total hip replacement/arthroplasty, total hip resurfacing/arthroplasty does not involve the removal of the femoral head and neck nor removal of bone from the femur. Rather, the head, neck and femur bone are preserved in an effort to preserve bone that will enable them to be revised to a primary procedure if revision is required. According to the applicant, there is not an existing CPT code that describes a total hip resurfacing/arthroplasty procedure. Consequently, physicians cannot adequately describe this procedure when billing 3rd party payers. Billing under unlisted procedures causes delays in claims processing and payment which, in turn, affects patient access. Establishment of a HCPCS code would alleviate these delays; clarify confusion surrounding billing and payment; and enable tracking of clinical outcome data and utilization.

CMS HCPCS 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 procedure.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda #16
April 22, 2008

Attachment #08.26

Topic/Issue:

Request to establish a code for radiopaque marker. Trade name: SITZMARKS

Background/Discussion:

According to the requester, SITZMARKS Radiopaque polyvinyl chloride markers impregnated with Barium Sulfate min. 30% are used for the analysis of bowel motility and transit time in the chronically constipated patient with otherwise negative GI evaluations. SITZMARKS are to be dispensed only by physician for oral intake with confirmation by office observation. SITZMARKS consists of a size 00 vegetable gelatin capsule containing 245 radiopaque polyvinyl chloride O rings (1mm x 4.5mm) impregnated with min. 30% barium sulfate. Ten capsules are blister pack sealed in a PVC lid with foil back and placed in a carton. Patient takes one capsule orally (day 1) and refrains from laxative, enema and suppository use for 5 days. Once ingested, the gelatin dissolves and releases the O rings. As the O rings move through the GI system, the diagnostician can evaluate bowel motility via x-ray and placement of the rings. A flat plate abdominal x-ray is taken on day 5 to determine the location and extent of elimination of the markers. According to the applicant this product is not described by existing HCPCS Level II codes.

CMS HCPCS Preliminary Decision:

No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to separately identify this product which is included in the procedure. When used in the course of a hospital inpatient procedure, it is included in the DRG payment. When used in an outpatient procedure, it is included in the facility payment. Inquiries regarding inclusion of SITZMARKS O rings when used in GI evaluation procedures should be separately submitted to the American Medical Association (AMA) practice expense advisory committee.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that our recommendations were based on a belief that current CPT codes are accepted for this capsule, when in practice, CPT code 99070 is often denied.

HCPCS Public Meeting Agenda #17
April 22, 2008

Attachment #08.79

Topic/Issue:

Request to establish a code for Disinfected, medical-grade blowfly larvae: Phaenicia (Lucilia) sericata. Trade name: Medical Maggots.

Background/Discussion:

According to the requester, Medical Maggots are laboratory-reared germ-free larvae of the blowfly, Phaenicia (Lucilia) sericata, tested for safety and efficacy. They are used for debriding non-healing soft-tissue wounds, such as pressure ulcers, diabetic foot ulcers, and non-healing wounds in patients who are high-risk candidates for surgery and/or anesthesia. Necrotic tissue, infectious exudates and debris are removed by the maggots' mechanical, enzymatic, and irrigating actions over 48-72 hours. The recommended dose is 5-10/cm² of wound surface area. Medical Maggots are supplied in air-permeable, germ-free vials containing 250+ larvae. Because they are highly perishable, they are shipped in temperature-controlled containers via overnight courier for immediate use.

Medical Maggots are applied to non-healing wounds with increasing frequency because they safely and effectively treat many wound problems of the elderly and infirmed; because many wound care referral centers and opinion leaders are now using them; and because maggots can perform continuous and precise debridement of devitalized tissue at a fraction of the cost of hospitalization, surgery, or even simple but prolonged wound dressings. There is no existing HCPCS Level II code that identifies this product.

CMS HCPCS Preliminary Decision:

No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a HCPCS Level II code to identify Medical Maggots. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision and requested reconsideration. The speaker stated that medical maggots are safe and effective; FDA-cleared with specific indications for use; used nationwide; and that the cost of the product with the treatment is greater than the fee assigned to debridement procedure code. The speaker indicated that maggots are self-administered in the homecare setting, but that maggot therapy is sometimes not considered as a treatment option due to lack of HCPCS coding and reimbursement.

HCPCS Public Meeting Agenda #18
April 22, 2008

Attachment #08.88

Topic/Issue:

Request to revise existing code A9155 “Artificial Saliva, per 30 mL”. Generic name: Dibasic Sodium Phosphate 0.032, Monobasic Sodium Phosphate 0.009, Calcium Chloride 0.052, Sodium Chloride 0.569, Purified Water qs ad (%w/w). Trade name: Caphosol™. Applicant’s suggested language: “Caphosol, per 30mL dose” or “Supersaturated calcium phosphate rinse, per 30mL dose”

Background/Discussion:

According to the requester, Caphosol has multiple indications and this has created confusion for providers when reporting the new HCPCS code (A9155) for indications other than artificial saliva. Caphosol (supersaturated calcium phosphate rinse) is an electrolyte solution designed in part to replace the normal ionic and pH balance in the oral cavity. Caphosol is indicated for the following conditions:

- Dryness of the mouth or throat (hyposalivation, xerostomia), regardless of the cause or whether the condition is temporary or permanent.
- As an adjunct to standard oral care in treating the mucositis that may be caused by radiation or high dose chemotherapy; and
- Dryness of the oral mucosa due to drugs such as antihistamines or atropine or other anticholinergic agents that suppress salivary secretion.

For use during high dose chemotherapy or radiation treatment, the recommended dosage is 4 doses per day from the onset of the cancer treatment; up to 10 doses per day if pain from mucositis is experienced. Use for the duration of the treatment or as instructed by physician. For relief of dry mouth the recommended dosage is 2-10 times per day or as instructed by physician.

CMS HCPCS Preliminary Decision:

Existing code A9155 “ARTIFICIAL SALIVA, 30 ML” adequately describes the product that is the subject of your request. Caphosol is the predicate product for which A9155 was established.

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 57

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup’s preliminary decision. The speaker claimed that the current code descriptor is too “broad” and does not cover the multiple indications of Caphosol. Specifically, the speaker stated that the term “artificial saliva” is a clinical indication, and that this terminology excludes other uses, such as radiation

chemotherapy-induced mucositis and hyposalivation (xerostoma). The speaker reiterated the original request to revise the language of code A9155.

HCPCS Public Meeting Agenda #19
April 22, 2008

Attachment #08.103

Topic/Issue:

Request to establish a code to uniquely identify Mimyx® Cream. Applicant's suggested language: "nonsteroidal, anti-inflammatory cream containing palmitoylethanolamide (PEA), any size tube."

Background/Discussion:

According to the requestor, Mimyx® Cream is a 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. PEA binds to CB₂ receptors on mast cells. These receptors play a role in modulating the immune response to triggers. Mimyx® Cream increases PEA level in treated skin. 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 lipid components of Mimyx® Cream interact with the natural lipids of the stratum corneum and remain in the stratum corneum, where they can most effectively influence transepidermal water loss (TEWL) and barrier function. According to the applicant, there is not a HCPCS code that represents this product.

CMS HCPCS Preliminary Decision:

Existing code A6250 "SKIN SEALANTS, PROTECTANTS, MOISTURIZERS, OINTMENTS, ANY TYPE, ANY SIZE" adequately describe the product that is the subject of your request.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision and reiterated the original request for a unique code to describe Mimyx Cream. The speaker stated that the 2007 final decision (that Mimyx is not described by A6250) should be reinstated because code A6250 does not adequately describe their product. The speaker stated that pulmitamide in Mimyx differentiates it from other products coded at A6250.

HCPCS Public Meeting Agenda #20
April 22, 2008

Attachment #08.62

Topic/Issue:

Request to establish a code for a Water-Soluble Implant and Bone Hemostasis Material, trade name: Ostene.

Background/Discussion:

According to the requester, Ostene is a water-soluble surgical implant material and it provides for control of bleeding from bone. It is a sterile mix of water-soluble alkylene oxide copolymers, derived from ethylene oxide derived from ethylene oxide and propylene oxide. It is used during surgery to control of bleeding from bone surface where a non-inflammatory material that does not interfere with bone healing is required. Also, Ostene achieves local hemostasis of the bone by acting as a mechanical barrier. It does not act biochemically. Ostene dissolves from the site of application within 48 hrs and is excreted from the body unchanged. According to the requester, there are no existing codes that adequately describe Ostene or for a water-soluble implant and bone hemostasis material.

CMS HCPCS Preliminary Decision:

No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a HCPCS Level II code to identify this surgical supply item. When used in the course of a hospital inpatient procedure, it is included in the DRG payment. When used in an outpatient procedure, it is included in the facility payment.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision and reiterated the original request for a code to identify Ostene. The speaker stated that Ostene, a product used to stop bleeding in surgically cut bone, is not identified in the current HCPCS code set, and there is no recognition of the added Medical benefits of Ostene "over other equivalent bone hemostasis materials". The speaker added that Ostene may be used when other materials are not indicated. The speaker stated that the difference in materials and price should be recognized, and "the lack of separate recognition makes it difficult for doctors to argue for this product.

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 Medicare Administrative Contractors (DME MACs). 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.