

**Centers for Medicare & Medicaid Services (CMS)  
Healthcare Common Procedure Coding System (HCPCS)  
Public Meeting Summary Report  
Supplies & Other – Day 1  
Tuesday, May 12, 2009**

**Introduction and Overview**

Approximately 25 people attended. The agenda included 26 items.

Cindy Hake, chair, CMS' HCPCS Coding Workgroup, provided an overview of the HCPCS public meeting process as it relates to the overall HCPCS coding process.

Joel Kaiser, Director, Division of DMEPOS Policy, 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>.

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](http://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/ANHCPSC/itemdetail.asp](http://www.cms.hhs.gov/HCPCSReleaseCodeSets/ANHCPSC/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](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, May 12, 2009, 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 #09.050

Request to establish a code for a temperature differential sensor, manual, trade name: TempTouch.

No Primary Speaker

**AGENDA ITEM #2**

Attachment #09.064

Request to establish a code for a plantar temperature sensing device, trade name: TempStat.

Primary Speaker: Scott Kantro of Visual Footcare Technologies, LLC

**AGENDA ITEM #3**

Attachment #09.111

Request to establish a code for Therapeutic Massaging Insoles, trade name: TMI Pharmacy insoles.

No Primary Speaker

**AGENDA ITEM #4**

Attachment #09.009

Request to establish a code for a custom foot orthotic, trade name: DIApedia TrueContour(TM).

Primary Speaker: Peter Cavanagh, M.D.

**AGENDA ITEM #5**

Attachment #09.086

Request to establish a new code for a custom made ankle foot orthosis, trade name: Ulcer Healing Orthosis (UHO).

Primary Speaker: John Rooney of DuPage Prosthetic-Orthotic Service

**AGENDA ITEM #6**

Attachment #09.041

Request to establish a code for a total contact cast system with multiple essential components, trade names: MedE-Kast, MedE-Kast Ultra, and TCC-EZ.

Primary Speaker: Jeffrey Jensen of MedEfficiency, Inc.

**AGENDA ITEM #7**

Attachment #09.070

Request to establish a code for a closed system drug transfer device (CTSD), trade name: PhaSeal® System.

Primary Speaker: Dan Pitulia of Carmel Pharma

**AGENDA ITEM #8**

Attachment #09.052

Request to establish a code for a catheter, intravascular, short-term, cannula type, trade name: i-port Injection Port.

Primary Speaker: Rusty Stein of Patton Medical Devices

**AGENDA ITEM #9**

Attachment #09.118

Request to revise the verbiage of code A4356.

No Primary Speaker

**AGENDA ITEM #10**

Attachment #09.024

Request to establish 3 codes for incontinence management devices and silicone adhesive seal, trade name: (1)GeeWhiz Incontinence Manage Device (IMD) with Integral Urine Collection Pouch; (2) GeeWhiz Incontinence Management Device (IMD) without integral collection chamber; and (3) GeeWhiz silicone adhesive GelStrip seal.

Primary Speaker: Paul Dwork of Leading Edge Innovations, Inc.

**AGENDA ITEM #11**

Attachment #09.021

Request to establish a code for a female urethral insert, non-valved, disposable, trade name: FemSoft® Insert.

Primary Speaker: Lois McGuire, R.N. of Mayo Clinic

**AGENDA ITEM #12**

Attachment #09.005

Request to establish a code for intermittent catheters that have an introducer tip and protective no-touch sleeve for insertion, trade names: Apogee Closed System and Advanced Plus Intermittent Catheter.

Primary Speaker: Deanna Eaves of Hollister Inc.

**AGENDA ITEM #13**

Attachment #09.008

Request to establish a code for an automatic urine collecting device, trade name: Care Clean 3000.

Primary Speaker: Ike Odum of Regional Medical Supplies

**AGENDA ITEM #14**

Attachment #09.077

Request to establish a code for cervical dilator, trade name: Cook Cervical Ripening Balloon (CRB).

Attachment #09.007

Request to establish a code for a silicone balloon tamponade, trade name: Cook Bakri Postpartum Balloon.

No Primary Speaker

**AGENDA ITEM #15**

Attachment #09.080

Request to establish a code for a rectal balloon system (prostate immobilizer treatment device), trade name: Radiadyne Prostate Immobilizer Treatment Device Rectal Balloon Kit (Radiadyne Classic, and ISOLOC).

Primary Speaker: Andrew Lee, M.D.

**AGENDA ITEM #16**

Attachment #09.078

Request to establish a code for a balloon catheter in 2 sizes (2mm and 3mm) used for unilateral and bilateral balloon Dacryoplasty (DCP) procedures, trade name: LacriCath Lacrimal Duct Balloon Catheter.

Attachment #09.079

Request to establish a code for a balloon catheter in 2 sizes: (5mm and 9mm) used in unilateral and bilateral Balloon Dacryocystorhinostomy (DCR) procedures, trade name: LacriCath Lacrimal Duct Balloon Catheter (DCR).

Primary Speaker: David Silbert, M.D.

**AGENDA ITEM #17**

Attachment #09.010

Request to establish 2 codes for foam dressings with silver sulfate, trade name: Restore Foam Dressing Silver, non-Adhesive with TRIACT technology.

Attachment #09.011

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

Attachment #09.013

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

Primary Speaker: Deanna Eaves of Hollister Inc.

**AGENDA ITEM #18**

Attachment #09.121

Request to establish "a proper code and reimbursement" for a polysaccharide polymer patch, trade name: Syvek Patch NT.

No Primary Speaker

**AGENDA ITEM #19**

Attachment #09.045

Request to assign an impermeable moisture barrier dressing, Aqua Guard, to existing HCPCS code A4221.

Primary Speaker: Kaye Counts of Cenorin

**AGENDA ITEM #20**

Attachment #09.032

Request to establish two codes for 100% silicone medical adhesive removers, trade names: Trio Niltac REF TR 101 50ml aerosol and 2) Trio Niltac REF TR 102 carton of 30 single-use wipes.

Primary Speaker: Ben Curtis of Trio Healthcare, Ltd

**AGENDA ITEM #21**

Attachment #09.114

Request to establish a code for superabsorbent polymer with odour and ballooning/gas controlling ingredients, trade name: Trio Diamonds with ActiveOne Odour Control.

Primary Speaker: Ben Curtis of Trio Healthcare, Ltd

**AGENDA ITEM #22**

Attachment #09.054

Request to establish 2 codes for a device used to cut holes in ostomy pouches/bags, trade name: Stomico Ostomy Pliers and Stomico Cutting Disc.

No Primary Speaker

**HCPCS Public Meeting Agenda Item #1**  
**May 12, 2009**

**Attachment: #09.050**

**Topic/Issue:**

Request to establish a code for a temperature differential sensor, manual, trade name: TempTouch

**Background/Discussion:**

According to the requester, the TempTouch is "a device for diagnosing points of inflammation on the soles of the feet of diabetic patients with neuropathy". It is specially designed temperature sensor utilizing infrared technology. TempTouch is regulated by the FDA as a "clinical electronic thermometer." It is 16 inches long with a right angle at the tip, designed for use by diabetic persons with a variety of physical limitations related to their disease. The function of TempTouch is to measure the difference in temperature between paired landmarks on the two feet of a neuropathic patient. A temperature difference of 4° F is the key data supporting a diagnosis of skin inflammation. Skin inflammation is the first stage of foot ulcers. Early diagnosis of diabetic foot ulcers via measurement of foot landmark temperature is well established in the literature.

According to the requester, existing code A9279 (MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED) is inadequate to describe a device such as TempTouch because A9279 describes monitoring devices, and TempTouch is not a monitoring device. "While the line between monitors and diagnostic devices may not always be clear, it should be clear that a statistically demonstrated improvement linking the use of the device with improved patient health outcomes establishes the device as diagnostic."

**CMS HCPCS Preliminary Decision:**

A national program operating need to establish a unique code to identify the TempTouch sensor was not identified by Medicare, Medicaid or the Private Insurance Sector.

Existing code A9279 "MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED" is available for assignment by insurers as they deem appropriate.

**Medicare Payment:**

The payment rules associated with the existing code 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 Item #2**  
**May 12, 2009**

**Attachment: #09.064**

**Topic/Issue:**

Request to establish a code for a plantar temperature sensing device, trade name: TempStat

**Background/Discussion:**

According to the requester, Tempstat is a plantar temperature sensing device that facilitates daily self-examination for signs of inflammation and other damage to the soles of the feet. TempStat is used in the home by the beneficiary to identify impending inflammatory changes before they become open wounds or ulcers. It provides a graphic representation of increased skin and subcutaneous tissue temperature differences, comparing one area of the foot relative to other areas of the foot. Tempstat is intended for use by diabetic patients with peripheral neuropathy. Tempstat consists of a three section plastic panel with a 2X convex mirror in the center third section and two polycarbonate plastic pads on either side of the mirror. The plastic pads are constructed of liquid crystalline cholesteric esters that react to skin surface temperature and change to a specific color relative to that level of temperature. According to the requester, TempStat is new technology and there are no HCPCS codes to describe a device that accurately depicts comparative temperature differentials indicative of inflammation of the feet.

**CMS HCPCS Preliminary Decision:**

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

**Medicare Payment:**

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

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker disagreed with the workgroup's preliminary coding decision and with the Medicare Benefit Category information. The speaker feels the equipment has clearly been demonstrated to be DME. The speaker stated that while the primary purpose of the TempStat device is to predict (and thereby prevent) ulcerative breakdown, it can also be used to follow the progress of treatment interventions. The speaker stated that physicians are using the TempStat in their offices. It is also used by patients in their in homes. The TempStat is a cost effective "self-management" adjunctive device for use with other coded products, like shoe inserts and

Blood Glucose Monitors for diabetics. The speaker believes it should be considered DME and coded as such.

**HCPCS Public Meeting Agenda Item #3**  
**May 12, 2009**

**Attachment: #09.111**

**Topic/Issue:**

Request to establish a code for Therapeutic Massaging Insoles, trade name: TMI Pharmacy insoles.

**Background/Discussion:**

According to the requester, TMI insoles turn any shoe into a diabetic shoe. TMI insoles are designed with Foot Reflexology to stimulate all of the 7000 nerve endings in the foot that correspond to every part of the human body. They are intended to increase blood flow throughout the entire body. These insoles have Glycerin in the core. The user receives foot reflexology with every step as the glycerin moves back and forth, promoting an increase in blood flow. The insole conforms to the person's foot. It can be removed and placed into any shoe. TMI insoles can be machine or hand washed. This trim-able insole is available in 9 different sizes. According to the requester, this insole differs from similar products because they are thinner, and the glycerin provides benefits of foot reflexology, such as reduced swelling and increased blood flow. HCPCS codes L3003 "FOOT, INSERT, REMOVABLE, MOLDED TO PATIENT MODEL, SILICONE GEL, EACH" and A5510 "FOR DIABETICS ONLY, DIRECT FORMED, COMPRESSION MOLDED TO PATIENT'S FOOT WITHOUT EXTERNAL HEAT SOURCE, MULTIPLE-DENSITY INSERT(S) PREFABRICATED, PER SHOE" are not appropriate HCPCS codes for this product given the descriptive definitions.

**CMS HCPCS Preliminary Decision:**

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

**Medicare Payment:**

The payment rules associated with the existing code apply to this product. Pricing = 38

**Summary of Primary Speaker Comments at the Public Meeting:**

There was no primary speaker for this item. The applicant submitted a written comment agreeing that existing code A5510 describes TMI Pharmacy Insoles.

**HCPCS Public Meeting Agenda Item #4**  
**May 12, 2009**

**Attachment: #09.009**

**Topic/Issue:**

Request to establish a code for a custom foot orthotic, trade name DIApedia TrueContour(TM). Applicant's suggested language: "For plantar-pressure reduction, multiple density insert, custom molded from a digital image combining the three-dimensional shape of the patient's foot with dynamic pedobarographic data of the patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore A 35 durometer or higher, includes arch filler and other shaping material, custom fabricated, each".

**Background/Discussion:**

According to the requester, TrueContour(TM) therapeutic inserts are the only inserts individually designed based on both foot shape and plantar pressure. Measurements of the patient's foot shape and dynamic plantar pressure are collected and transmitted to the manufacturer. A custom pressure-reducing insert is designed and fabricated using computer assisted design and computer assisted manufacturing techniques. According to the requester "DIApedia's researchers have shown that this product reduces areas of high pressure in the metatarsal-head region of the plantar surface of the patient's foot better than other "standard-of-care" products currently on the market." TrueContour(TM) inserts are specifically designed to address diseases where high plantar pressure has adverse consequences for patients, with the two conditions most relevant being plantar ulceration in diabetic patients and ambulation-limiting pain in patients with rheumatoid arthritis. Although insoles coded at A5513 may in some instances reduce high plantar pressure, their use is limited to patients with diabetes whose primary care physicians have certified them to be at-risk for plantar ulceration. The requester believes that code A5513 is inadequate for addressing the needs of most patients and that the fee associated with A5513 does not capture the technology and resources used in making these inserts.

**CMS HCPCS Preliminary Decision:**

Existing code A5513 "FOR DIABETICS ONLY, MULTIPLE DENSITY INSERT, CUSTOM MOLDED FROM MODEL OF PATIENT'S FOOT, TOTAL CONTACT WITH PATIENT'S FOOT, INCLUDING ARCH, BASE LAYER MINIMUM OF 3/16 INCH MATERIAL OF SHORE A 35 DUROMETER (OR HIGHER), INCLUDES ARCH FILLER AND OTHER SHAPING MATERIAL, CUSTOM FABRICATED, 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 = 38

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that while TrueContour™ insoles may appear similar to other insoles coded at A5513, fundamentally different design and production methods are used to manufacture them. Specifically, the TrueContour™ insole is designed based on shape and pressure, and it has been demonstrated (in a 20-patient Cleveland Clinic experiment) to provide significantly better off-loading. For these reasons, the speaker feels that a new HCPCS code should be created to accommodate the use of this new technology.

**HCPCS Public Meeting Agenda Item #5**  
**May 12, 2009**

**Attachment: #09.086**

**Topic/Issue:**

Request to establish a new code for a custom made ankle foot orthosis, Trade Name: Ulcer Healing Orthosis (UHO)

**Background/Discussion:**

According to the requester, "the Ulcer Healing Orthosis (UHO) is a custom made ankle foot orthosis, plastic or other, rigid proximal anterior support section, attached laterally, via flexible plastic hinge, with cushioned liner, posterior proximal section cushioned liner, corrugated mid section alignment guide, medial lateral ankle section cutinized lined, posterior heel cushioned pad, plantar platform cushioned insert, rigid planar platform hollow, plantar platform dynamic alignment wedges, used with a modified diabetic shoe, internally and externally modified for acceptance of orthosis, nylon sheath prior to donning, ridged clear plastic platform check fitting. The UHO functions: To control the alignment and motions of the joints of the foot and ankle associated with diabetes, i.e. Calanevalgus, Equinovarus, charcot joint mid-foot collapse. Additionally providing a custom designed plantar platform, that addresses the excessive plantar forces that are symptomatic upon weight bearing due to the bullet head shaped protuberance of charot joint collapse of the mid foot, causing the devascularization of skin, the UHO allows revascularization to occur while ambulating. In review of existing HCPCS codes, in the orthotic device category, no descriptions are found that are similar to the UHO, additionally no similar functional or therapeutic equivalent is presented, when identifying the following features: rigid plantar platform hollow section, insert cushioned lined, diagnostic rigid clear plastic plantar check fitting platform, rigid proximal anterior support section, cushioned lined, laterally hinged to posterior section, cushioned lined, with medial Velcro closure, plantar platform alignment wedges, used with modified diabetic shoe, and internal and external adjustment for orthotic acceptance, nylon sheath donned prior to orthotic donning, digital photo journal accompaniment, documented superior therapeutic significance, in aiding the medical condition diabetic plantar ulceration." No existing code describes the features, functions or therapeutic significance of the UHO.

**CMS HCPCS Preliminary Decision:**

Existing code A9283 "FOOT PRESSURE OFF LOADING/SUPPORTIVE DEVICE, ANY TYPE, EACH" adequately describes the product that is the subject of this request. The UHO is the predicate product for which code A9283 was established.

**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:**

The primary speaker disagreed with the workgroup's preliminary coding decision and with the Medicare payment information.

**HCPCS Public Meeting Agenda Item #6**  
**May 12, 2009**

**Attachment: #09.041**

**Topic/Issue:**

Request to establish a code for a total contact cast system with multiple essential components, trade names: MedE-Kast, MedE-Kast Ultra, and TCC-EZ.

**Background/Discussion:**

According to the request, Total contact casting (TCC) for neuropathic foot wounds has long been considered the "Gold Standard" for off-loading and reducing frictional forces assisting the healing process. By casting in full contact with a patient's lower limb, pressure from the bottom surface of the foot is redistributed over more surface area including the entire foot, ankle and lower leg. With the redistribution over a greater surface area including the leg, the pressure at the wound site is reduced, allowing the wound to heal more quickly. TCC is indicated for patients with neuropathy and wounds or post-operative incisions, in addition to patients with Charcot Neuroarthropathy. The TCC system is comprised of: protective felt to prevent abrasions on bony areas, stockinette and protective layers to prevent the synthetic materials from adhering to the patients' skin, and synthetic materials which are applied when soft and then harden to create a protective cast in intimate contact with the lower leg and foot. According to the requester, existing code Q4038 (CAST SUPPLIES, SHORT LEG CAST, ADULT (11 YEARS +), FIBERGLASS) does not describe the multiple layers, synthetic materials, and additional specialized protective materials provided by the TCC.

**CMS HCPCS Preliminary Decision:**

Existing code A9283 "FOOT PRESSURE OFF LOADING/SUPPORTIVE DEVICE, 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 = 00

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker disagreed with the workgroup's preliminary coding decision and with the Medicare Payment information. The speaker stated that the cost of supplies are not reimbursed by Medicare, making the economics of total contact casting difficult at best. The speaker claimed that off-loading is only one factor in the ulcer healing process, and that it is often overlooked or underestimated. The speaker indicated that "lack of payment leads to underutilization", because "clinicians provide care based on reimbursement pathways" "how

reimbursement” for TCC translates into no incentive to use it. The speaker requested “support” for TCC “with reimbursement for supplies used”.

**HCPCS Public Meeting Agenda Item #7**  
**May 12, 2009**

**Attachment: #09.070**

**Topic/Issue:**

Request to establish a code for a closed system drug transfer device (CTSD), trade name: PhaSeal® System.

**Background/Discussion:**

According to the requester, PhaSeal is a closed system drug transfer device used to contain hazardous drugs throughout preparation, transportation, administration, and disposal. This technology has the potential for use in a variety of sites of services where chemotherapy drugs or other potentially hazardous drugs are prepared and administered. PhaSeal consists of three components: a protector, an injector, an infusion adaptor and a connector. All components of the system have thermoplastic elastomer (TPE) membranes that meet to form a dry connection and self-seal when the components are disconnected. The protector attaches to the drug vial to form an airtight seal and has a sealed expansion chamber that captures any aerosols or vapors while simultaneously maintaining equal pressure in the vial. The injector is used both during preparation and administration of the hazardous drugs. One end of the injector is luer-locked onto a syringe while the opposite end provides for a dry connection at the cannula's access point. The infusion adaptor provides a closed access point for spiking and priming the bag as well as a dry connection to the injector. The connector or y-site connector with a standard luer-lock fitting and dry membrane is available for use when the drug is to be infused by standard IV push, once again providing a dry double membrane connection to the injector and a reduction of hazardous drug contamination at the site of patient administration. An infusion clamp is also available to secure the connection between the injector luer lock and the connector at the hub of the IV line. Together these components form a system that eliminates hazardous drug interactions with the environment. According to the requester, customers are not using separate codes to bill for the PhaSeal System. It is Carmel Pharma's understanding that providers have avoided the use of miscellaneous codes due to the unfavorable reaction of health benefit plans to the use of such codes and the attending difficulty in processing claims using these codes. Establishing a new code would alleviate the problem for both providers and payers. There are no existing codes that specifically represent closed system drug transfer technology such as the PhaSeal system.

**CMS HCPCS Preliminary Decision:**

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

**Medicare Payment:**

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

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that the efficacy of the device is the program justification for coding it. The closed-system drug transfer device (CSTD) technology does not fit into current HCPCS coding terminology therefore there is no way to capture information regarding whether the CSTD was paid for or what the reimbursement amount was, and a HCPCS code is needed in order to obtain that data. The speaker added that PhaSeal System meets both the NIOSH and ISOPP definitions for closed-system drug transfer device.

**HCPCS Public Meeting Agenda Item #8**  
**May 12, 2009**

**Attachment: #09.052**

**Topic/Issue:**

Request to establish a code for a catheter, intravascular, short-term, cannula type, trade name: i-port Injection Port. Applicant's suggested language "Catheter, Intravascular, short term, cannula type"

**Background/Discussion:**

According to the requester, the i-port Injection Port is a disposable, low profile, injection port through which physician prescribed medications, including insulin, can be injected subcutaneously from a standard syringe needle, pen or alternative manual injection device. The i-port Injection Port is a single use product cleared for up to 72 hour use and 75 individual injections. This results in approximately ten devices for each thirty days of use. The i-port Injection Port is packaged in boxes of ten (a one month supply). It is indicated for patients who administer, or to whom is administered, multiple daily subcutaneous injections of physician prescribed medication, including insulin. The i-port functions as a medication delivery channel directly into the subcutaneous tissue. When applying the i-port, an insertion needle guides a soft cannula (a small, flexible tube) under the skin. Once applied, the insertion needle is removed and only the soft cannula remains below the skin, acting as the gateway into the subcutaneous tissue. Current codes do not describe a catheter, intravascular, short term, cannula type product.

**CMS HCPCS Preliminary Decision:**

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

**Medicare Payment:**

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

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker disagreed with the workgroup's preliminary decision. The speaker requested reconsideration and specifically, requested that the product be assigned to existing code A4221 "SUPPLIES FOR MAINTENANCE OF DRUG INFUSION CATHETER, PER WEEK (LIST DRUG SEPARATELY). The speaker claimed, like an infusion set, the i-port acts as an infusion cannula (i.e. catheter), providing a gateway for medication to be delivered into the subcutaneous tissue. The speaker also claimed patients would be more likely to administer their

injections regularly if a product such as the i-port was available to ease the pain and discomfort of shots.

**HCPCS Public Meeting Agenda Item #9**  
**May 12, 2009**

**Attachment: #09.118**

**Topic/Issue:**

Request to revise the verbiage of code A4356 which currently reads: "EXTERNAL URETHRAL CLAMP OR COMPRESSION 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), package of 10".

**Background/Discussion:**

According to the requester, the ActiCuf Compression Pouch is designed for the male patient to treat and manage light to moderate urinary incontinence. It minimizes urinary incontinence by mechanical compression of the urethra eliminating urine leakage and allowing the bladder to fill. If there is breakthrough of leakage from the urethra, the moisture is confined to the disposable pouch. According to the requester, the descriptor "each" in HCPCS code A4356 makes this code inappropriate for use, because a patient typically uses one ActiCuf per day and the cost is approximately \$3.99 each. The fee schedule for each under A4356 pays between \$36 and \$56, increasing the opportunity for over billing. ActiCuf is sold in a package of 10. The allowable for this code would be appropriate if the billing unit of "each" were to be changed to a "package of 10".

**CMS HCPCS Preliminary Decision:**

Establish code: Axxxx DISPOSABLE EXTERNAL URETHRAL CLAMP OR COMPRESSION DEVICE, WITH PAD AND/OR POUCH, 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 orthotics, prosthetics devices and vision services.

**Summary of Primary Speaker Comments at the Public Meeting:**

There was no primary speaker for this item. The applicant submitted a written comment asking to have the word "disposable" stricken from the text of the new code.

**HCPCS Public Meeting Agenda Item #10**  
**May 12, 2009**

**Attachment: #09.024**

**Topic/Issue:**

Request to establish 3 codes for incontinence management devices and silicone adhesive seal, trade name: (1)GeeWhiz Incontinence Manage Device (IMD) with Integral Urine Collection Pouch; (2) GeeWhiz Incontinence Management Device (IMD) without integral collection chamber; and (3) GeeWhiz silicone adhesive GelStrip seal.

**Background/Discussion:**

According to the requester, the GeeWhiz IMD is an external urine collection device (catheter/sheath) for males which utilizes a silicone gel technology to provide a conformable adhesive GelStrip seal that adheres to the penile shaft in the correct position prior to the application of the sheath and one that will not cause skin irritation. It includes an outer SecureStrip wrap that accommodates the daily changes in penis diameter by maintaining a light positive pressure on the shaft. The users of the GeeWhiz IMD with and without Integrated Urine Collection Chamber are generally the elderly diagnosed with urinary incontinence. Other users are those who have lost urine control due to spinal cord injury, cerebral palsy, Parkinson's disease, multiple sclerosis, interstitial cystitis, enlarged prostate or prostatectomy's as well as other neurological diseases. According to the applicant, although existing code A4326 MALE EXTERNAL CATHETER WITH INTEGRAL COLLECTION CHAMBER, ANY TYPE, EACH "defines the exact parameters of the GeeWhiz IMD with integral urine collection pouch," it does not capture improvements and enhancements to the GeeWhiz system which "set a new standard in the industry," and therefore the GeeWhiz system ought to be uniquely coded. The GeeWhiz without the Integral Urine Collection Pouch also requires a unique, product specific code. The design, features and demonstrated overall benefits and performance of the GeeWhiz IMD versus generic condom catheters place the GeeWhiz IMD in a different category than all other catheter products available for male external urine collection. The silicone adhesive GeeWhiz seal has no current classification number with Medicare and requires a new code for the Gelatinous Silicone Gel Seal.

**CMS HCPCS Preliminary Decision:**

Existing code A4349 "MALE EXTERNAL CATHETER, WITH OR WITHOUT ADHESIVE, DISPOSABLE, EACH" adequately describes the Incontinence Management Device; and code A4358 "URINARY DRAINAGE BAG, LEG OR ABDOMEN, VINYL, WITH OR WITHOUT TUBE, WITH STRAPS, EACH" adequately describes the collection pouch. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector) to separately code the adhesive strip.

**Medicare Payment:**

The payment rules associated with the existing codes apply to these products.

Pricing = 37

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker disagreed with the workgroup's preliminary decision. The speaker asked if a new code is not established, whether in that case the GeeWhiz could be assigned to existing code A4326 "MALE EXTERNAL CATHETER WITH INTEGRAL COLLECTION CHAMBER, ANY TYPE, EACH. The speaker claimed that GeeWhiz IMD meets the definition for A4326. The speaker stated that the state of California assigned the Gee Whiz to code A4326.

**HCPCS Public Meeting Agenda Item #11**  
**May 12, 2009**

**Attachment: #09.021**

**Topic/Issue:**

Request to establish a code for a female urethral insert, non-valved, disposable. Trade name: FemSoft® Insert. Applicant's suggested language: AXXXX "Female urethral insert, non-valved, disposable"

**Background/Discussion:**

According to the requester, the FemSoft® Insert is a self-inserted, single-use, disposable intra-urethral device that returns immediate control to women suffering from mild to severe stress urinary incontinence (SUI). SUI is marked by the involuntary loss of urine during coughing, laughing, sneezing, lifting, exercising or other activities that increase the pressure on the bladder. The small, latex-free insert provides women an effective and discreet, non-surgical option for controlling wetness and odor. The FemSoft® Insert consists of a narrow silicone tube entirely encased in a soft, thin, mineral oil-filled sleeve. The silicone sleeve forms a balloon at the internal tip and a soft, oval-shaped, external retainer at the opposite end. To facilitate easy insertion, the device is packaged on a disposable applicator. When a woman advances the FemSoft® Insert into her urethra, fluid within the device moves toward the external retainer to facilitate passage into the urethra. As the insert tip enters the bladder, fluid returns to fill the balloon, creating a seal at the bladder neck and urethra and securing the device in place. No manipulation of the insert or balloon inflation is required. Once the insert is in place, the applicator is withdrawn and thrown away. A woman removes the insert for urination by grasping the external retainer and slowly pulling the device out of her body. If continued protection is desired, a new device is inserted after her bladder has been emptied. The FemSoft® Insert is available in three diameter sizes (16, 18 and 20 Fr) and two lengths (3.5 and 4.5 cm). None of the existing female urinary incontinence HCPCS codes appropriately recognize an intra-urethral device for women seeking an effective and discreet, non-surgical option for managing stress urinary incontinence (SUI). There are four HCPCS codes specific to devices for female urinary incontinence. Two codes are specific to female incontinence appliances and care supplies: A4327 & A4328. Two codes are specific to female additional miscellaneous supplies that may be used to address urinary incontinence: A4561 & A4562. These codes are not appropriate to the FemSoft Insert in terms of either the defined anatomical interface during device use or the number of

devices used.

**CMS HCPCS Preliminary Decision:**

Establish Axxxxx INCONTINENCE SUPPLY, URETHRAL INSERT, ANY TYPE,  
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 orthotics, prosthetics devices and vision services.

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker agreed with the workgroup's preliminary decision. The speaker stated she would like to applaud CMS for the recommendation to assign a new HCPCS code. The speaker claimed that stress urinary incontinence (SUI) is the most common type of incontinence in women younger than 60 years and accounts for at least half of incontinence in all women.

**HCPCS Public Meeting Agenda Item #12**  
**May 12, 2009**

**Attachment: #09.005**

**Topic/Issue:**

Request to establish a code for intermittent catheters that have an introducer tip and protective no-touch sleeve for insertion, trade names: Apogee Closed System and Advanced Plus Intermittent Catheter. Applicant's suggested language: "Intermittent urinary catheter, with introducer tip and no-touch sleeve (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each".

**Background/Discussion:**

According to the requester, the Advanced Plus intermittent catheter and Apogee Closed systems are "sterile, closed, stand-alone catheter systems that have an introducer tip and an attached collection bag which also serves as a no-touch sleeve for insertion." Lubricant for the catheter is contained in the bag. To insert the catheter, the user removes the protective cap from the introducer tip, inserts the introducer tip into the urethra then slides the pre-lubricated, sterile catheter through the introducer tip directly into the urinary tract and into the bladder, while bypassing the critical distal 15mm of the urethra where the most harmful bacteria reside. Once the bladder is drained, the catheter is withdrawn from the body and disposed of with the bag, after the collected urine is emptied. The entire system can be used without the catheter being touched before or during the procedure. These catheters are used for patients without adequate nerve function to void the bladder (spinal cord injured, spina bifida, multiple sclerosis, etc.) Catheters with introducer tips and no-touch sleeves offer a distinct advantage over straight intermittent catheters without these features, by providing a protective barrier for hygienic catheter insertion. The applicant claims that the incidence of urinary tract infection is decreased upon switching to a "closed intermittent catheter." The applicant also claims that existing codes describe catheters that "must be inserted through the bacterially compromised 15mm zone of the distal urethra, and that require insertion supplies, and therefore existing codes do not describe the systems or the "additional protective benefits" of the catheter systems that are the subject of this application.

**CMS HCPCS Preliminary Decision:**

Existing code A4353 "INTERMITTENT URINARY CATHETER, WITH INSERTION SUPPLIES" adequately describes the product that is the subject of this request.

**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 the use of A4353 code is inconsistent with DME policy that specifies certain supplies which are not included with this product. The speaker claimed that the catheters that are the subject of this request do not contain all of these items. Specifically, they do not include gloves, drapes or antiseptic swabs. The speaker also commented that use of code A4353 is not consistent with Medicaid policy in two states, for these reasons, it is not appropriate to use A4353 with the type of product. The speaker reiterated the request to create a new HCPCS code for a No-Touch intermittent catheter (with a no-touch sleeve and introducer tip), but proposed language somewhat different than that proposed in the original application.

**HCPCS Public Meeting Agenda Item #13**  
**May 12, 2009**

**Attachment: #09.008**

**Topic/Issue:**

Request to establish a code for an automatic urine collecting device, trade name: Care Clean 3000.

**Background/Discussion:**

According to the requester, Care Clean is a non-invasive, battery operated, self-contained urine-collecting device with bidet. It is suggested as an alternative to catheters or diapers for patient who are unconscious; whose mobility is restricted; or who are on long distance air travel. The Care Clean device is packaged with a male and female cup. The cup is held in place with elastic straps. The collecting cup attaches to a hose and a vacuum collection device with a reservoir. A photo sensor automatically operates the unit when the patient voids. The device also includes a "bidet" that rinses with heated water. Care Clean eliminates rashes and pressure sores associated with long term use of diapers, and eliminates infections associated with catheter usage. Care Clean also reduces care-giver burden, and it promotes a safe environment by eliminating disposal from catheters and diapers. The requester states that this product was previously evaluated by the SADMERC in May 2008 and assigned code A9270 "NON-COVERED ITEM OR SERVICE" which has no reimbursement. "Therefore, this request is for evaluation of the product and the issuance of a new code that would meet reimbursement requirements."

**CMS HCPCS Preliminary Decision:**

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

**Medicare Payment:**

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

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated the Care Clean meets "uniqueness" criteria. The Care Clean could be used as an alternative to a diaper or a catheter. It could be considered an "electric diaper". The speaker has indicated that

the Care Clean 3000 might eliminate UTI as a complication of catheterization, (e.g., if it were used as an alternative to catheterization). The speaker has asked that the coding decision be reconsidered.

**HCPCS Public Meeting Agenda Item #14**  
**May 12, 2009**

**Attachment: #09.077**

**Topic/Issue:**

Request to establish a code for cervical dilator, trade name: Cook Cervical Ripening Balloon (CRB).

**Background/Discussion:**

According to the requester, the Cervical Ripening Balloon (CRB) is an all silicone double balloon used for dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction. The CRB is 18 French in size, 40 centimeters in length, and each balloon has an 80mL volume. The CRB has two ports, one for uterine and one for vaginal. This allows the balloons to be filled and drained independently of each other. Ripening and dilation is accomplished by the balloons' gentle and constant pressure at the level of the cervix from both the internal and external ostia. According to the requester, CRB is safe device engineered to naturally and gradually dilate the cervix and facilitate labor induction without the potential side effects of other ripening methods. The requester states that there are no similar products. Foley catheters have been used in a similar fashion, but cervical ripening by Foley catheter is an off-label use of the device. According to the requester, CPT code 59200 "INSERTION OF CERVICAL DILATER (E.G., LAMINARIA, PROSTAGLANDIN) (SEPARATE PROCEDURE)" describes the procedure. "However, no good code exists for the device itself, for device specific reimbursement."

**CMS HCPCS Preliminary Decision:**

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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:**

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:**

There was no primary speaker for this item. The applicant submitted written comment disagreeing with the workgroup's preliminary decision and expressing concerns about reimbursement. The applicant claims that the cost of this balloon is "not adequately addressed" in the RVU for CPT code 59200, therefore "lack of a separately identifiable HCPCS Level II code with separate payment for this device prevents physicians from obtaining adequate reimbursement for the placement of this device in a physician's office setting".

**HCPCS Public Meeting Agenda Item #14**  
**May 12, 2009**

**Attachment: #09.007**

**Topic/Issue:**

Request to establish a code for a silicone balloon tamponade, trade name: Cook Bakri Postpartum Balloon.

**Background/Discussion:**

According to the requester, the Bakri Postpartum silicone balloon tamponade is indicated for temporary control or reduction of postpartum hemorrhage when conservative management of uterine bleeding is warranted. The Bakri is positioned in the patient's uterus and inflated with sterile liquid. It conforms to the shape of the uterus. It produces hemostatis by the internal instillation of water through a double-lumen catheter, into a controlled space past the cervical canal and internal ostium and expands the internal balloon to create pressure and stop uterine bleeding. The Bakri can be used for both vaginal and cesarean deliveries as a potential way to avoid an unwanted hysterectomy. Maximum indwell time is 24 hours. According to the applicant, customers are asking for a level II HCPCS code to uniquely identify this device, for use on medical claims.

**CMS HCPCS Preliminary Decision:**

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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:**

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:**

There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #15**  
**May 12, 2009**

**Attachment: #09.080**

**Topic/Issue:**

Request to establish a code for a rectal balloon system (prostate immobilizer treatment device), trade name: Radiadyne Prostate Immobilizer Treatment Device Rectal Balloon Kit (Radiadyne Classic, and ISOLOC). Applicant's suggested language: "Prostate Immobilizer Treatment Device, With or Without Rectal Gas Releaser".

**Background/Discussion:**

According to the requester, the Radiadyne Prostate Immobilizer Treatment device is a rectal balloon system used to immobilize the prostate gland during radiation treatment to maximize dosing to the tumor while minimizing exposure of healthy surrounding structures. A new immobilization device is placed prior to each radiation treatment fraction. The endorectal balloon is placed in the proper location and is filled with a prescribed volume of air/fluid to immobilize the prostate. After treatment, the balloon is deflated, removed, and discarded. According to the requester, Radiadyne differs from similar products because it has a multi-chamber balloon, allowing for a more consistent shape to be produced with each balloon to allow for consistent dosing patterns across treatment fractions. Physicians are able to customize the fill volume with the Radiadyne device. In addition, in February 2009, a new Prostrate Immobilizer will be available that will incorporate fiducial markers as well as allow the physician to displace gas that has accumulated in the rectum. A visible fiducial marker allows a measure of quality assurance regarding the depth of balloon insertion and the relative pitch of the prostate gland to the pelvic anatomy. It can also be used with image-guided techniques to maximize treatment accuracy. Reducing gas prior to and during treatment allows tighter treatment margins. There are no existing codes to describe this prostate immobilizer treatment device.

**CMS HCPCS Preliminary Decision:**

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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:**

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 claimed that there is no Level I or Level II code describing this procedure. The speaker indicated that HCPCS code C9275 is not appropriate because products coded there do not immobilize the prostate and claims C9275 is not intended for use to identify products used with high intensity brachytherapy. The speaker claimed a clinical advantage to using the Immobilizer Treatment Device in that it defines the target and therefore reduces treatment margins. The speaker reiterated the request that a new HCPCS code be established for this rectal balloon system.

**HCPCS Public Meeting Agenda Item #16**  
**May 12, 2009**

**Attachment: #09.078**

**Topic/Issue:**

Request to establish a code for a balloon catheter in 2 sizes (2mm and 3mm) used for unilateral and bilateral balloon Dacryoplasty (DCP) procedures, trade name: LacriCath Lacrimal Duct Balloon Catheter.

**Background/Discussion:**

According to the requester, LacriCath is a balloon catheter used in Dacryoplasty (DCP) procedures to dilate the lacrimal sac and lacrimal duct to treat cases of partial nasolacrimal duct obstruction in adults and children. The LacriCath device is passed through the superior punctum, canaliculus, sac and into the nasolacrimal duct down to the nasal floor of the nose. The balloon is filled with sterile water and deflated by releasing the lock mechanism on the inflation device. The balloon is then pulled proximally and positioned within the lacrimal sac and nasolacrimal duct junction. It is inflated and deflated once more. According to the requester, there are other devices on the market to resolve issues in the lacrimal drainage system, but none are comparable to the LacriCath device in design or utilization. DCP procedures performed with the LacriCath device are therapeutically superior to the convention methodology of silicone tubes and secondary lacrimal probing. CPT codes 68815 "PROBING OF NASOLACRIMAL DUCT, WITH OR WITHOUT IRRIGATION; WITH INSERTION OF TUBE OR STENT" and 68816 "PROBING OF NASOLACRIMAL DUCT, WITH OR WITHOUT IRRIGATION; WITH TRANSLUMINAL BALLOON CATHETER DILATION" "are strictly procedure codes" and they do not report or specifically describe the LacriCath device. Also, the reimbursement associated with these CPT codes is appropriate for the procedure, but does not account for the cost of the device.

**CMS HCPCS Preliminary Decision:**

CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance for hospital in-patient use. For HOPPS or ASCs, report using C1726 "CATHETER, BALLOON DILATATION, NON-VASCULAR".

**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 code C1726 is "not workable" due to poor compensation which forces the procedure to be done in the HOPPS setting. The majority of utilization is not Medicare. The speaker indicated

that a unique code is needed for accurate reporting and proper reimbursement. The speaker also claimed that code A4649 is insufficient because the reimbursement is widely variable.

**HCPCS Public Meeting Agenda Item #16**  
**May 12, 2009**

**Attachment: #09.079**

**Topic/Issue:**

Request to establish a code for balloon catheter in 2 sizes: (5mm and 9mm) used in unilateral and bilateral Balloon Dacryocystorhinostomy (DCR) procedures, trade name: LacriCath Lacrimal Duct Balloon Catheter (DCR).

**Background/Discussion:**

According to the requester, the LacriCath Lacrimal Duct Balloon Catheter (DCR) is used to create a new tear flow path between the lacrimal sac and the nose. It is indicated for use in procedures to treat patients with nasolacrimal duct obstruction, functional or complete obstruction, epiphora and dacryocystitis. The balloon catheter is inserted into the nose. The catheter is filled with sterile water or saline at 8 atm for 20 seconds, then deflated by releasing the locking mechanism on the inflation device. A second dilation is performed at 8 atm for 20 seconds. The device is then deflated and withdrawn. If a good opening has not been achieved, the balloon is repositioned and re-dilated.

According to the requester, there are instruments and devices on the market to resolve issues in the lacrimal drainage system but none are comparable to the LacriCath device in design or utilization. DCR procedures performed with the LacriCath device are therapeutically superior to the incision method due to their minimally invasive nature and the reduced likelihood of the potential complications. CPT codes 31239

"NASAL/SINUS ENDOSCOPY, SURGICAL; WITH DACRYOCYSTORHINOSTOMY" and 68720 "DACRYOCYSTORHINOSTOMY (FISTULIZATION OF LACRIMAL SAC TO NASAL CAVITY)" describe the related procedures, but there is no code to report the use of the device. Reimbursement associated with these CPT codes does not account for the cost of the device.

**CMS HCPCS Preliminary Decision:**

CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance for hospital in-patient use. For HOPPS or ASCs, report using C1726 "CATHETER, BALLOON DILATATION, NON-VASCULAR".

**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 code C1726 is "not workable" due to poor compensation which forces the procedure to be done in the HOPPS setting. The majority of utilization is not Medicare. The speaker indicated

that a unique code is needed for accurate reporting and proper reimbursement. The speaker also claimed that code A4649 is insufficient because the reimbursement is widely variable.

**HCPCS Public Meeting Agenda Item #17**  
**May 12, 2009**

**Attachment: #09.010**

**Topic/Issue:**

Request to establish 2 codes for foam dressings with silver sulfate, trade name: Restore Foam Dressing Silver, non-Adhesive with TRIACT technology. Applicant's suggested language: Axxx1 "Foam dressing, antimicrobial, pad size 16 sq. in. or less, without adhesive border, each dressing" and Axxx2 "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, petrolatum and silver sulfate; a non-sensitizing, super absorbent polyurethane foam pad; and a protective, semi-permeable polyurethane backing. The barrier functions of Restore Foam Dressing may help to reduce bacterial load in moderately to high 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, codes A6209 and A6210 describe only the materials with which this dressing is comprised. They do not address the antimicrobial role that the dressing plays within the wound bed (the primary therapeutic reason for using the dressing). The applicant claims that silver protects the dressing from a broad spectrum of microorganisms, including MRSA, and it is important that it be offered as an option to fighting virulent bacteria strains. The applicant also claims that a silver-releasing lipidocolloid contact layer promotes sustained increase in closure rates of venous leg ulcers presenting inflammatory signs suggesting high bacterial load. The applicant also claims that the fee associated with codes A6209 and A6210 is insufficient to cover the cost of products that contain silver.

**CMS HCPCS Preliminary Decision:**

Existing code A6209 "FOAM DRESSING, WOUND COVER, STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING" or A6210 "FOAM DRESSING, WOUND COVER, STERILE, 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.

**Medicare Payment:**

The payment rules associated with the existing codes apply to these products.

Pricing = 35

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker disagreed with the workgroup’s preliminary decision. The speaker stated that: 1) there is a difference in function and mechanism of action (silver antimicrobial to reduce bioburden vs: no antibacterial); 2) there is a significant therapeutic distinction (control of bioburden allows wound-healing to re-engage); 3) there is a difference in approved FDA indications for use: and 4) the FDA definition of wound-healing is out-dated [and therefore should not be used to gauge efficacy or comparative efficacy]. The speaker cited the Lazareth study, stating the findings show that silver impregnated dressings do impact wound size reduction. And finally, the speaker has requested a series of six new HCPCS codes for antimicrobial surgical dressings for tracking purposes, and to ensure continuity of care and “appropriate reimbursement”.

**HCPCS Public Meeting Agenda Item #17**  
**May 12, 2009**

**Attachment: #09.011**

**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: "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 comprised 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 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 and 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 lipidocolloidal gel, providing a moist environment that promotes healing. Restore was shown to be effective against bacteria most frequently associated with wound infections. The applicant claims that Restore Contact Layer has been shown in in-vitro studies to kill a wide range of microorganisms which are commonly found in colonized and infected wounds. It continually releases silver for up to seven days. According to the requester, code A6207 "CONTACT LAYER, STERILE, MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING" describes only the materials with which this dressing is comprised. It does not address the antimicrobial role that the dressing plays within the wound bed. The applicant claims that a silver releasing lipidocolloid contact layer promotes a sustained increase of closure rates of venous leg ulcers presenting [inflammatory signs suggesting] a high bacterial load. The applicant also claims that payment associated with code A6207 is not sufficient to cover the cost of products that contain silver.

**CMS HCPCS Preliminary Decision:**

Existing code A6207 "CONTACT LAYER, STERILE, 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.

**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 disagreed with the workgroup's preliminary decision. The speaker stated that: 1) there is a difference in function and mechanism of action (silver antimicrobial to reduce bioburden vs: no antibacterial); 2) there is a significant therapeutic distinction (control of bioburden allows wound-healing to re-engage); 3) there is a difference in approved FDA indications for use: and 4) the FDA definition of wound-healing is out-dated [and therefore should not be used to gauge efficacy or comparative efficacy]. The speaker cited the Lazareth study, stating the findings show that silver impregnated dressings do impact wound size reduction. And finally, the speaker has requested a series of six new HCPCS codes for antimicrobial surgical dressings for tracking purposes, and to ensure continuity of care and "appropriate reimbursement".

**HCPCS Public Meeting Agenda Item #17**  
**May 12, 2009**

**Attachment: #09.013**

**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 seven 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 applicant claims that this dressing kills a wide range of microorganisms which are commonly found in colonized and infected wounds and releases ionic silver for up to seven days. 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 requester, codes A6196, A6197 and A6199 describe only the materials with which the dressing is comprised. These codes do not address the antimicrobial role that the dressing plays within the wound bed. The applicant claims that silver ions protect the dressing from a broad spectrum of microorganisms. The applicant also claims that the fee schedule for alginate dressings is low compared to the cost of alginate dressing with silver.

**CMS HCPCS Preliminary Decision:**

Existing code: A6196 "ALGINATE OR OTHER FIBER GELLING DRESSING

WOUND COVER, STERILE, PAD SIZE 16 SQ. IN. OR LESS, EACH DRESSING”; A6197 “ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND COVER, STERILE, 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, STERILE, PER 6 INCHES”, (based on product characteristics and size) adequately describes the products that are the subject of this request.

**Medicare Payment:**

The payment rules associated with the existing codes apply to these products.  
Pricing = 35

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker disagreed with the workgroup’s preliminary decision. The speaker stated that: 1) there is a difference in function and mechanism of action (silver antimicrobial to reduce bioburden vs: no antibacterial); 2) there is a significant therapeutic distinction (control of bioburden allows wound-healing to re-engage); 3) there is a difference in approved FDA indications for use: and 4) the FDA definition of wound-healing is out-dated [and therefore should not be used to gauge efficacy or comparative efficacy]. The speaker cited the Lazareth study, stating the findings show that silver impregnated dressings do impact wound size reduction. And finally, the speaker has requested a series of six new HCPCS codes for antimicrobial surgical dressings for tracking purposes, and to ensure continuity of care and “appropriate reimbursement”.

**HCPCS Public Meeting Agenda Item #18**  
**May 12, 2009**

**Attachment: #09.121**

**Topic/Issue:**

Request to establish "a proper code and reimbursement" for a polysaccharide polymer patch, trade name: Syvek Patch NT.

**Background/Discussion:**

According to the requester, the Syvek Patch NT is a sterile, non-woven 3 x3 pad made of polysaccharide polymer attached to a medical grade foam backing. It is used as a topical dressing to promote rapid control of bleeding. The polymeric fiber has a three-dimensional structure that presents a vast array of bonding sites for the natural clotting agents in blood, accelerating hemostasis. The ability of this material to provide hemostatic action is related to the way the polymer is organized in the fibers. The Syvek Patch employs three inter-related components of hemostasis: vasoconstriction, red blood cell functions and platelet/coagulation factor activation. It is indicated for the promotion of rapid control of bleeding in patients following hemodialysis and in patients on anticoagulant therapy. It is also indicated for use in the local management of bleeding wounds, such as vascular access sites, percutaneous catheter or tube sites or surgical debridement. According to the requester, the patch is applied by the patient or by a healthcare provider. There are no existing codes to describe this product.

**CMS HCPCS Preliminary Decision:**

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

**Medicare Payment:**

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

**Summary of Primary Speaker Comments at the Public Meeting:**

There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #19**  
**May 12, 2009**

**Attachment: #09.045**

**Topic/Issue:**

Request to assign an impermeable moisture barrier dressing, Aqua Guard, to existing HCPCS code A4221 "Supplies for maintenance of drug infusion catheter, per week."

**Background/Discussion:**

According to the requester, Aqua Guard is a polyethylene film moisture barrier that serves to protect infusion sites and primary wound dressings against waterborne bacterial contamination. It consists of a clear polyethylene film coated on both sides with a non-sensitizing acrylic pressure-sensitive adhesive. The adhesive is protected by a white, polyethylene coated draft release liner coated on two sides with silicone. The primary function of Aqua Guard is to provide additional integrity to the primary dressing during the process of bathing, showering and personal hygiene routines to reduce the risk of infection that occurs with each dressing change and/or air and waterborne contamination. It is also indicated as a primary cover over post-operative wounds, surgical incisions, stitches, staples, shunts, dialysis catheters, heparin locks, surgical drains, vascular access sites and PICC lines. The applicant believes that existing code A4221 describes this product.

**CMS HCPCS Preliminary Decision:**

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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, this item is not separately billable.

**Medicare Payment:**

Based on guidance contained in an informal benefit category determination, we believe that 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. The speaker reiterated the original request to include the Aqua Guard dressing under existing code A4421. The speaker discussed clinical utility of Aqua Guard, patient safety, and CDC guidelines not to submerge a PICC line under water. And finally, the speaker indicated it has proven cost/savings benefits.

**HCPCS Public Meeting Agenda Item #20**  
**May 12, 2009**

**Attachment: #09.032**

**Topic/Issue:**

Request to establish two codes for 100% silicone medical adhesive removers, trade names: 1) Trio Niltac REF TR 101 50ml aerosol and 2) Trio Niltac REF TR 102 carton of 30 single-use wipes.

**Background/Discussion:**

According to the requester, Niltac is a new type of medical adhesive remover, providing rapid, sting-free and atraumatic removal of adhesive products from skin surfaces. The new silicone technology employed in the formulation of Niltac provides many additional clinical and patient benefits over alcohol and petroleum based adhesive removers, "rendering fair comparison impossible." The action of the blended 100% silicone formulation is significantly different. The requester specifically cites differences in "speed, efficacy and economical delivery systems resulting in sting-free removal...that in turn leads to maintenance of healthy skin." Niltac tracks quickly between the adhesive and the skin, temporarily disabling the adhesive. Evaporation is rapid and complete (with no residue), enabling fast re-application of dressings and appliances. Atraumatic adhesive removal dramatically reduces/prevents iatrogenic wound healing delay. Current HCPCS coding (for Medical Adhesive Removers) does not provide sufficient reimbursement for this new silicone technology. The applicant therefore requests new coding for 100% Silicone Medical Adhesive Removers. The existing code relates to alcohol/oil based pricing and does not reimburse the costs and clinical benefits associated with new, all silicone technology. "The silicone fluids are more expensive than alcohol by a factor of 10."

**CMS HCPCS Preliminary Decision:**

- 1) Discontinue code A4365
- 2) Establish Axxxx ADHESIVE REMOVER, WIPES, ANY TYPE, EACH Existing code A4455 "ADHESIVE REMOVER OR SOLVENT (FOR TAPE, CEMENT, OR OTHER ADHESIVE), PER OUNCE" adequately describes the aerosol.

**Medicare Payment:**

Based on guidance contained in an informal benefit category determination, we believe that the new code would be paid in accordance with the payment rules that apply to ostomy, tracheostomy and urological supplies. The payment rules associated with the existing code, A4455, apply to the aerosol product. Pricing = 37

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker discussed clinical benefits of 100% Silicone Medical Adhesive Remover (MRA), as opposed to non-silicone technologies, particularly to ostomy and Epidermolysis

Bullosa (EB) patient communities. The speaker also commented that raw material and manufacturing costs are significantly higher for silicone technologies, and as a consequence, the benefits of Silicone MRAs cannot be provided to patients in the U.S. under existing code A4455.

**HCPCS Public Meeting Agenda Item #21  
May 12, 2009**

**Attachment: #09.114**

**Topic/Issue:**

Request to establish a code for superabsorbent polymer with odour and ballooning/gas controlling ingredients, trade name: Trio Diamonds with ActiveOne Odour Control.

**Background/Discussion:**

According to the requester, Trio Diamonds with Odour Control are sachets used for improving the quality of life of ileostomates, and colostomates with liquid/loose stools. They provide a system for controlling the liquid fecal body fluid output collected in the stoma pouch. The dissolvable sachet is placed into the ileostomy pouch through the pouch outlet. The sachet dissolves on contact with the fluid stool releasing the formulation that absorbs the fluid, reduces/eliminates odors, and helps to reduce/eliminate pouch ballooning. According to the requester, existing codes A4422 "OSTOMY ABSORBENT MATERIAL (SHEET/PAD/CRYSTAL PACKET) FOR USE IN OSTOMY POUCH TO THICKEN LIQUID STOMAL OUTPUT, EACH" and A4394 "OSTOMY DEODORANT, WITH OR WITHOUT LUBRICANT, FOR USE IN OSTOMY POUCH, PER FLUID OUNCE" relate separately to absorbent material (leakage protection) and odor control. However these codes do not reimburse the costs or recognize the clinical benefits of reducing/eliminating pouch ballooning related to excess flatus (gas). The new code would incorporate all 3 key features.

**CMS HCPCS Preliminary Decision:**

Existing code A4422 "OSTOMY ABSORBENT MATERIAL (SHEET/PAD/CRYSTAL PACKET) FOR USE IN OSTOMY POUCH TO THICKEN LIQUID STOMAL OUTPUT, EACH" adequately describes the entire Trio Diamonds product. The odor control mechanism of action used in TrioDiamonds does not meet the criteria for separate coding at A4394: "OSTOMY DEODORANT, WITH OR WITHOUT LUBRICANT, FOR USE IN OSTOMY POUCH, PER FLUID OUNCE".

**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. The speaker stated that code A4394 recognizes only "ostomy deodorant" whereas Diamonds™ is proven to eliminate malodours associated with ostomy pouch use. The speaker indicated that most significantly, there is no code for products that eliminate "ballooning". Diamonds is the first product to reliably achieve this breakthrough.

**HCPCS Public Meeting Agenda Item #22**  
**May 12, 2009**

**Attachment: #09.054**

**Topic/Issue:**

Request to establish 2 codes for a device used to cut holes in ostomy pouches/bags, trade name: Stomico Ostomy Pliers and Stomico Cutting Disc.

**Background/Discussion:**

According to the requester, Stomico ostomy pliers simplify and speed up the process of changing ostomy pouches/bags and reduces concern over irritation, infection, and proper fit. Ostomy pliers consistently make the correct size hole for the stoma in regular, convex, and extended wear adhesive skin barriers/wafers/flanges/appliances. Pliers are easier to use than scissors, particularly for rheumatoid arthritis sufferers and the visually impaired, and will not lead to long term use potential injuries such as carpal tunnel and tendonitis. Ostomy pliers eliminate the learning curve and resulting mis-cut wafers and appliances. Therefore, these pliers present a potential cost savings eliminating the replacement of scissor mis-cut, wasted wafers and appliances. They also offer a more custom fit than pre-cuts. Stomico ostomy pliers will cut most wafers/flanges and some one-piece appliances. According to the requester, there are no existing codes to describe this product.

**CMS HCPCS Preliminary Decision:**

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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:**

There was no primary speaker for this item. The applicant submitted a written comment emphasizing the efficacy and viability of the pliers and cutting disc (as per product reputation and information in the code application), and stressed the importance of a decision to provide product reimbursement for the Stomico Medical Equipment Ostomy Pliers and Cutting Disc.

## 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. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36<sup>th</sup> monthly payment is made, after

which monthly payments for the ongoing delivery of contents continue for 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 13<sup>th</sup> 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.