Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report

Supplies and Other

Tuesday, May 24, 2011

Introduction and Overview

Approximately 60 people attended. The agenda included 17 items.

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

Joel Kaiser, Director, of the Division of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy, presented an overview of the methods used for setting the payment amount for DME, prosthetics, orthotics and supplies and when the different payment categories are used. The overview was also provided as a written document to the agenda and is 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.gov/DMEPOSFeeSched/.

Prior to the Public Meetings, over the course of several months, the CMS HCPCS Coding Workgroup convene, discuss, and establish preliminary coding recommendations, on all HCPCS code applications. CMS also assigns 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 CMS HCPCS web site at http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage, as part of the HCPCS public meeting agendas.

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings and reconsiders its preliminary coding recommendation in light of any new information provided, and formulates its final coding decisions. 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.

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

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as Guidelines for Proceedings at CMS' Public Meetings can be found on the CMS HCPCS web site specifically at: http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage. In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completing the application, and background information regarding the HCPCS Level II coding process is available at: http://www.cms.gov/MedHCPCSGenInfo/01_Overview.asp#TopOfPage . The application form is updated annually and posted on the CMS HCPCS web site sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: http://www.cms.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 24, 2011, 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# 11.079
Request to establish a code for a custom made ankle foot orthosis, Trade Name: Ulcer Healing Orthosis (U.H.O.).

Primary Speaker: John Rooney of DuPage Prosthetic-Orthotic Service

AGENDA ITEM #2
Attachment# 11.077
Request to establish 3 HCPCS codes for sterile Sodium Chloride Solution for inhalation in three concentrations, trade names: Sodium Chloride Solution USP 3%, Nebusal Sodium Chloride Solution USP 6%, and Sodium chloride Solution USP 7%.

Primary Speaker: Dr. Preston Campbell, III of Cystic Fibrosis Foundation

AGENDA ITEM #3
Attachment# 11.060
Request for a new HCPCS code to identify disposable components of the Celleration MIST Therapy™ System 5.1.

No Primary Speaker

AGENDA ITEM #4
Attachment# 11.085
Request to establish 2 codes for diabetic inserts, Trade Name: DIApedia TrueContour.

Primary Speaker: Dr. Jan Ulbecht of DIApedia, LLC

AGENDA ITEM #5
Attachment# 11.084
Request to establish two new HCPCS codes to identify the BalanceWear Devices (BWD).

Primary Speaker: Cynthia Gibson-Horn of Motion Therapeutics

AGENDA ITEM #6
Attachment# 11.031
Request to establish a code for a lower body Stabilizing Pressure Input Orthosis,
Trade Name: SPIO.

Attachment# 11.032
Request to establish a code for an upper body Stabilizing Pressure Input Orthosis, Trade Name: SPIO.

No Primary Speaker

AGENDA ITEM #7
Attachment# 11.096
Request to establish a code for a low transverse abdominal peri-incisional support undergarment,
Trade Name: C-Panty.

No Primary Speaker

AGENDA ITEM #8
Attachment# 11.124
Request to reinstate 12 codes in the L8100 series that previously identified Compression Garments. Trade Name: Mediven®.

Primary Speaker: Michael Cannon of Medi USA

AGENDA ITEM #9
Attachment# 11.056
Request to establish a code for a vocal fold medialization implant, Trade Name: RADIESSE® Voice.

Primary Speaker: Dr. Clark Rosen of University of Pittsburgh Medical School

AGENDA ITEM #10
Attachment# 11.107
Request to revise existing code L2660 "ADDITION TO LOWER EXTREMITY, THORACIC CONTROL, THORACIC BAND" to include the Zzoma Positional Device.

No Primary Speaker

AGENDA ITEM #11
Attachment# 11.080
Request to establish code for a urinary drainage bag that has a built-in cover which is fused onto the bag materials so that it is one integral unit, Trade Name: "The Fig Leaf".

Primary Speaker: Earl Christensen of SteriGear, Inc.

AGENDA ITEM #12
Attachment# 11.023
Request to establish 2 codes for a one-piece ostomy pouch with an extended wear barrier and a filter, Trade Name: Premier One-piece Ostomy Pouch.

No Primary Speaker

AGENDA ITEM #13
Attachment# 11.111
Request to establish a code for Addition to Upper Limb Electric Prosthetic Terminal Device, Control Strategy and External Feature Selection Software, Wireless Adjustability, Bluetooth or equal, Trade Name: BioSim.

No Primary Speaker

AGENDA ITEM #14
Attachment# 11.047
Request to establish 3 codes to identify the components of a disposable mechanically powered suction device Intended for Negative Pressure Wound Therapy, Trade Name: SNaP® (Smart Negative Pressure) Wound Care System.

Primary Speaker: Moshe Pinto of Spiracur, Inc.

AGENDA ITEM #15
Attachment# 11.104
Request to establish a new code for pressure ulcer prevention and treatment complete bed system, Trade Name: CircSupport™ Complete Bed System.

Attachment# 11.105
Request to establish a code for pressure ulcer prevention and treatment mattress, Trade Name: CircSupport™ Mattress.

No Primary Speaker

AGENDA ITEM #16
Attachment# 11.097
Request to establish a code for a transfer and lift device, Trade Name: Transfer and Lift Control Unit (TLC Unit).

Primary Speaker: Gregory Burkholder of Transitions Industries

AGENDA ITEM #17
Attachment# 11.100
Request to establish a code for a Patient lift; non-mechanical, Trade Name: ErgoNurse®.

No Primary Speaker

HCPCS Public Meeting Agenda Item #1
May 24, 2011

Attachment# 11.079

Topic/Issue:

Request to establish a code for a custom made ankle foot orthosis, Trade Name: Ulcer Healing Orthosis (U.H.O.).

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 cushioned liner, posterior heel cushioned pad, plantar platform cushioned insert, rigid plantar 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 functions of the UHO include: vascularization of wound during ambulation, redistribution of plantar weight bearing, diagnostic weight bearing wound inspection, increased ambulation, unassisted ambulation, monitor wound healing, increase normal appearance of lower extremity, stabilization of the charcot joint deformity, reduced comorbidities, and aids in the complete healing of the diabetic plantar ulcerated condition. The patient dons the UHO then puts on their shoe, and ambulates. According to the requester, there are no existing codes that describe the features, functions or therapeutic benefits 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 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 24, 2011

Attachment# 11.077

Topic/Issue:

Request to establish 3 HCPCS codes for sterile Sodium Chloride Solution for inhalation in three concentrations, trade names: Sodium Chloride Solution USP 3%, Nebusal Sodium Chloride Solution USP 6%, and Sodium chloride Solution USP 7%.

Background/Discussion:

According to the requester, Sodium Chloride Solution is hypertonic saline solution used to help thin and liquefy pulmonary mucociliary/sputum for clearance or expectoration. The solution is aerosolized and inhaled and is used in conjunction with a nebulizer. Sodium Chloride Solutions are indicated for the induction of sputum production in patients with pulmonary diseases that have increased mucus or sputum production such as Cystic Fibrosis and Chronic Obstructive Pulmonary Disease (COPD). Recommended dosage is 4 ml twice daily. Sodium Chloride Solution is supplied in sterile 4 ml single use vials in boxes of 60 vials. According to the requester, existing code J7130 "HYPERTONIC SALINE SOLUTION, 50 OR 100 MEQ, 20 CC VIAL" is inadequate to describe this product because it is "inaccurate, misrepresentative, and not indicated as an inhalation solution."

CMS HCPCS Preliminary Decision:

Existing code J7130 "HYPERTONIC SALINE SOLUTION, 50 OR 100 MEQ, 20 CC VIAL" adequately describes the products that are the subject of this request.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated there are no HCPCS codes for sodium chloride solution for inhalation administered through DME. The usual dosage for Cystic Fibrosis patients is 4ml, nebulized twice a day. According to the speaker, two new codes are needed to identify the 3% and 7% solutions in single-use vials, and to differentiate these products inhaled through DME from the stronger solution identified by codes J7130, which the speaker believes is for injection only.

HCPCS Public Meeting Agenda Item #3
May 24, 2011

Attachment# 11.060

Topic/Issue:

Request for a new HCPCS code to identify disposable components of the Celleration MIST Therapy™ System 5.1. Applicant's suggested language: "Sterile single-use disposable applicator with saline reservoir for ultrasonic wound therapy".

Background/Discussion:

According to the Requester, ultrasonic wound therapy is indicated for wounds that have been determined to be non-healing after 2-4 weeks, and provides an adjunct to other wound healing modalities. Cellerations' MIST Therapy System 5.1 produces a low energy ultrasound-generated mist which provides continuous ultrasonic energy to a wound. This treatment is intended to accelerate wound healing via: 1) cellular stimulation (stimulation of fibroblast activity, protein synthesis, blood flow and tissue regeneration); 2) decreased bioburden (destruction of bacteria); 3) increased blood flow (due to vasodilation effect of ultrasound); and 4) gentle debridement (ultrasound-induced tissue sloughing loosens and clears debris). MIST Therapy is provided by qualified healthcare practitioners. According to the requester, the use of Celleration ultrasound equipment in the Home Health setting has expanded. As such, a CPT code alone is inadequate to describe this product. HCPCS codes are needed to report the disposable components: ultrasound applicator with saline reservoir. According to the requester, code A6260 "WOUND CLEANSERS, STERILE, ANY TYPE, ANY SIZE" is inadequate to describe this system because it is considered a bundled supply under the Medicare DMEPOS Fee Schedule with a $0 allowable. A specific HCPCS code will facilitate coverage and payment for patients who receive therapeutic low frequency would ultrasound in their home.

CMS HCPCS Preliminary Decision:

CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:

If payment were made for these services, 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 #4
May 24, 2011

Attachment# 11.085

Topic/Issue:

Request to establish 2 codes for diabetic inserts, Trade Name: DIApedia TrueContour®. Applicant's suggested language:
Code 1 - "For diabetics only, modification of a custom molded multiple density insert creating a customized metatarsal support along a pressure contour line(s) of the foot constructed from the combination of a model of the patient's foot and a quantified dynamic plantar pressure contour map of the patient's foot, each"

Code 2 - "For diabetics only, modification of a custom molded multiple density insert creating a customized metatarsal relief for the foot constructed from the combination of a model of the patient's foot and a quantified dynamic plantar pressure contour map of the patient's foot, each"

Background/Discussion:

According to the requester, TrueContour® 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 the TrueContour® diabetic insert with customized modifications 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." The target population for TrueContour® inserts is diabetic patients who have been certified by their treating physician to be in need of therapeutic shoes, inserts and/or modifications. According to the requester, inserts coded at A5513 are modeled on the shape of the patients' foot and reduce pressure at high pressure areas only by supporting the full foot surface equally, whereas the TrueContour® inserts are specifically designed with customized surface modifications to additionally transfer pressure away from regions of the forefoot which are susceptible to plantar ulcer development. While the TrueContour® meets the A5513 specification, it also features key and functionally critical modifications that are not described by A5513.

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 products

that are the subject of this request. A national program operating need to establish a code to separately identify the metatarsal support was not identified by Medicare, Medicaid or the Private Insurance Sector.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker claimed that A5513 does not capture the addition of pressure-based functional modifications to therapeutic shoe inserts. According to the primary speaker the TrueContour™ incorporates customized modifications that off-load beyond the effects of molding [as evidenced in a 20-subject study funded by the applicant]. The speaker claimed that TrueContour™ insoles are not in total contact with patient's foot [as code A5513 indicates]. The speaker claimed a new HCPCS code is needed to allow patients consistent access to these custom modified orthotics.

HCPCS Public Meeting Agenda Item #5
May 24, 2011

Attachment# 11.084

Topic/Issue:

Request to establish two new HCPCS codes to identify the BalanceWear Devices (BWD). Applicant's suggested language:

Code 1 - "Balance-based proprioceptive neuromuscular strategic weighting full torso support device including fitting"

Code 2 - "Balance-based proprioceptive neuromuscular strategic weighting lower torso support device including fitting".

Background/Discussion:

According to the requester, BalanceWear Devices (BWDs) are noninvasive therapeutic support devices with strategically placed weights. They are indicated for use by patients with balance dysfunction to correct proprioceptive alignment and physical balance. The treatment involves placing small amounts of weight in a garment on a person's torso, in strategic locations, to address directional impairment(s). The BW300 vest stabilizes the full torso over the hip in both static and dynamic conditions. The BW350 belt is for lower torso control, with weights strategically placed in the lumbar, sacral, hip or waist areas. Both devices are intended to improve postural control, reduce leaning and the possibility of falls, without restricting body movement or ability. BWDs provide immediate benefit to elderly patients and those with neurological disease who exhibit postural control impairment or loss of balance. The BWDs include balanced-based proprioceptive neuromuscular strategic weighting garment, flexible rubberized weights in 1/4 and 1/2 pound increments, instructions for use, body chart, instructions for laundering, and indicators on the device for documentation of position and relocation of weight. The garment is made from laminated material that contains Lycra Spandex on one side, thin foam in the middle, and unbroken loop nylon on the other side. The requester claims that the BW300 and BW350 are semi custom garments but are custom fitted to the patient size and exact weight location according to the findings of the balanced-based torso-weighting (BBTW) assessment. The clinician determines wear times based on the patient's responsiveness to initial application and carry over ability. In general, clients can start using the garment for 1 to 2 hours per day during upright activities, however, some can benefit from all day wear. According to the requester, there are no existing codes to identify the BW300 or BW350.

CMS HCPCS Preliminary Decision:

Existing code E0700 "SAFETY EQUIPMENT, DEVICE OR ACCESSORY, ANY TYPE" adequately describes the products that are the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to these products.
Pricing = 00

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker claimed that BalanceWear products treat balance and mobility disorders and stated that patients deserve products that make improvements and reduce the risks of falls. The speaker requested that the Balance-wear devices either be placed in a “billable code” or be assigned to a miscellaneous code or a new code with a pricing indicator of 45 or 46.

HCPCS Public Meeting Agenda Item #6
May 24, 2011

Attachment# 11.031

Topic/Issue:

Request to establish a code for a lower body Stabilizing Pressure Input Orthosis, Trade Name: SPIO.

Background/Discussion:

According to the requester, SPIO lower body orthoses are prefabricated compression orthoses made from a blend of lightweight, breathable, elastic materials that allows for multi-directional stretch. These orthoses are designed to provide uniform compression to both the trunk and the lower extremities. The deep pressure produced by these orthoses has been linked to tone reduction, balance/proprioception improvements, improved oral-motor function, improvements in respiration, decrease in dynamic scoliosis, and a reduction in sensory-related behavioral abnormalities. SPIO orthoses are indicated for people with hyper/hypotonic muscle patterns. SPIO orthotics are mainly used by, but not limited to, children who have developmental delays related to abnormal muscle tone. For example: Cerebral Palsy, down's Syndrome, Anglemans Syndrome, Prader Willie Syndrome, disautonomia, and Autism. The requester is seeking a new code for SPIO lower body orthoses because the existing codes available for compression orthoses are designed to address issues of edema and burn scarring. In contrast, SPIO lower extremity compression orthoses address neuro-motor impairments including decreased balance, movement control, body awareness and stability. They also support core muscular activation, postural control, balance and respiration.

CMS HCPCS Preliminary Decision:

Existing code A4466 GARMENT, BELT, SLEEVE OR OTHER COVERING, ELASTIC OR SIMILAR STRETCHABLE MATERIAL, ANY TYPE, EACH adequately describes the device that is the subject of this application.

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 #6
May 24, 2011

Attachment# 11.032

Topic/Issue:

Request to establish a code for an upper body Stabilizing Pressure Input Orthosis, Trade Name: SPIO.

Background/Discussion:

According to the requester, SPIO upper body orthoses are prefabricated compression orthoses made from a blend of lightweight, breathable, elastic materials that allow for multi-directional stretch. These orthoses are designed to provide uniform compression to both the trunk and the upper extremities. The deep pressure produced by these orthoses has been linked to tone reduction, balance/proprioception improvements, improved oral-motor function, improvements in respiration, decrease in dynamic scoliosis, and a reduction in sensory related behavioral abnormalities. SPIO orthoses are indicated for people with hyper/hypotonic muscle patterns. They are mainly used by children who have developmental delays related to abnormal muscle tone. SPIO upper body orthoses are primarily designed to support core muscle activation, alignment and active balance for improved trunk, limb and head movement control function. SPIO compression has proved helpful in persons with muscle hypotonia to improve active stability, balance and smooth grading of movement. This includes persons with compensatory hypertonus, spasticity and/or dystonia related to instability, sensory awareness deficits and motor control impairments. The requester is seeking a new code for SPIO upper body orthoses because the existing codes used for compression orthoses are designed to support vascular and lymphatic impairments such as edema, or are designed for severe burn and tissue management. There are other codes for devices designed to alleviate minor spinal problems like lower back pain, but no codes exist for orthoses that are specifically designed to improve balance, active stability and movement control. In addition, SPIO orthoses address problems with neuro-muscular deficits and there are no specific codes for compression orthoses that address these issues.

CMS HCPCS Preliminary Decision:

Existing code A4466 GARMENT, BELT, SLEEVE OR OTHER COVERING, ELASTIC OR SIMILAR STRETCHABLE MATERIAL, ANY TYPE, EACH adequately describes the device that is the subject of this application.

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 #7
May 24, 2011

Attachment# 11.096

Topic/Issue:

Request to establish a code for a low transverse abdominal peri-incisional support undergarment, Trade Name: C-Panty.

Background/Discussion:

According to the requester, C-Panty is an elastic undergarment that provides targeted peri-incisional support at the low transverse abdominal incision area to reduce post-surgical swelling and support tissues after surgery and during recovery. The low transverse abdominal incision approach is commonly used for Cesarean delivery and open hysterectomies. According to the requester, existing codes refer to orthoses or dressings and do not adequately describe the C-Panty and, given the number of low transverse abdominal incisions performed each year, a code is warranted.

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 our preliminary benefit category analysis, 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 #8
May 24, 2011

Attachment# 11.124

Topic/Issue:

Request to reinstate 12 codes in the L8100 series that previously identified Compression Garments. Trade Name: Mediven®.

Background/Discussion:

The requester is seeking to reinstate codes in the L8100 series that previously identified compression garments. These codes were discontinued and replaced with codes in the A6500 series, effective January 1, 2006. According to the requester, the A-codes identify garments and dressings used in the treatment of burns, venous stasis ulcers, and surgical prevention. They do not properly identify compression garments used in the treatment of Lymphedema. Lymphedema results when a "malfunctioning internal body organ" (Lymphatics system) results in blockage, partial removal or fibrosing of lymphatics. Compression replaces part of the function of the lymphatic system. Recognition of the function of compression bandage systems, compression garments and compression devices used in the treatment of lymphedema as "prosthetic devices" warrants assignment with L-Codes and coverage by Medicare under§1861(s)(8). The requester is seeking Medicare coverage of compression garments as prosthetic devices and placement of compression garments in the prosthetic code series.

CMS HCPCS Preliminary Decision:

Existing HCPCS Level II codes for Gradient Compression Stockings, A6530 through A6549 adequately describe the products that are the subject of this request, based on compression range.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.
For codes A6530, A6533 -A6541, and A6544-A6549, Pricing = 00
For codes A6531 & A6532, Pricing =35

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that they are asking for specific custom codes and specific materials (circular vs. flat knit) that are not represented in code range A6530-A6549. According to the speaker circular knitting is primarily suitable for manufacturing support stockings, stockings for prophylaxis, and Class1-3 compression stockings. The flat -knit process is suitable for custom-made products, especially

for higher compression classes (3and 4). The speaker commented that there is a lack of codes to identify custom upper limb garments used in the treatment of Lymphedema. The speaker asked CMS to recognize compression garments as reasonable and necessary for treatment of diagnosed lymphedema. The speaker also asked CMS to reconsider its preliminary decision, and reinstate the 12 L codes for compression garments.

HCPCS Public Meeting Agenda Item #9
May 24, 2011

Attachment# 11.056

Topic/Issue:

Request to establish a code for a vocal fold medialization implant, trade name: RADIESSE® Voice. Applicant's suggested language: "Injectable bulking agent, synthetic implant for vocal fold medialization, 1 ml syringe, includes shipping and necessary supplies".

Background/Discussion:

According to the requester, RADIESSE® Voice is an injectable, synthetic laryngeal implant which is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue bulking agent. It augments the size of the displaced or deformed vocal fold so that it may meet the opposing fold at the midline for improved phonation. The principle component of RADIESSE® Voice is synthetic calcium hydroxylapatite, the primary mineral constituent of bone and teeth. The gel structure of RADIESSE® Voice is formed by the addition of a small amount of sodium carboxymenthylcellulose (USP). The gel is dissipated in vivo and replaced with soft tissue growth, while the calcium hydroxylapatite remains at the site of injection. The result is long-term restoration and augmentation. RADIESSE® Voice 1 cc has a particle size range of 25 -45 microns and can be injected with a 26 gauge or larger diameter thin-wall needle with a standard Luer fitting. Injection volume varies on a patient by patient basis; however, injections range between .5cc and 1.5 cc and average about .7 cc. RADIESSE® Voice is supplied in a pre-filled single use syringe containing 1.0 cc. According to the requester, existing code C1878 "MATERIAL FOR VOCAL CORD MEDIALIZATION, SYNTHETIC (IMPLANTABLE)" is not valid for use in the physician office setting and code Q2026 "INJECTION, RADIESSE, 0.1 ML" describes Radiesse® dermal filler, therefore, a new code is needed to describe RADIESSE® Voice for use in a physician's office for vocal fold medialization.

CMS HCPCS Preliminary Decision:

Existing code Q2026 INJECTION, RADIESSE, 0.1 ML adequately describes the product that is the subject of this request.

Medicare Payment:

Based on guidance contained in Chapter 1, Part 4, Section 250.5 of the Medicare National Coverage Determinations manual, 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 CMS' preliminary decision. The speaker stated that the existing code for RADIESSE® (Q2026) has narrow payment indications. RADIESSE® Voice, on the other hand, is an injectable, synthetic laryngeal implant which is indicated for vocal fold medialization and vocal fold insufficiency. The speaker commented that RADIESSE® Voice should be coded as a prosthetic implant as are the urologic bulking agents using L-codes specific to the indication.

HCPCS Public Meeting Agenda Item #10
May 24, 2011

Attachment# 11.107

Topic/Issue:

Request to revise existing code L2660 "ADDITION TO LOWER EXTREMITY, THORACIC CONTROL, THORACIC BAND" to include the Zzoma Positional Device. Applicant's suggested language: "Thoracic control device designed to restrict and/or eliminate undesired patient motion (side to supine motion during sleep)."

Background/Discussion:

According to the requester, the Zzoma is a Positional Device consisting of a 12" x 5.5" x 4" foam wedge encased in nylon material with an associated belt with velcro straps. The Zzoma fastens around the patient's torso. It is worn while in bed to prevent side to supine movement (rolling over onto back) during sleep. It is indicated for the treatment of diagnosed mild to moderate positional obstructive sleep apnea (OSA). The requester claims that the Zzoma is clinically proven to deliver therapy results equivalent to continuous Positive Airway Pressure (CPAP) for positional OSA at a fraction of the cost. The product is warranted for 180 days of use, (two devices should be used per year). According to the requester, Zzoma operates similarly to orthotic products listed under code L2660, in that it restricts movement and stabilizes the body. As such, the requester is seeking to expand the language of this code to also describe the Zzoma positioning device, and to place the Zzoma in an orthotic code.

CMS HCPCS Preliminary Decision:

Existing code E0190 "POSITIONING CUSHION/PILLOW/WEDGE, ANY SHAPE OR SIZE, INCLUDES ALL COMPONENTS AND ACCESSORIES" 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 = 00

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #11
May 24, 2011

Attachment# 11.080

Topic/Issue:

Request to establish code for a urinary drainage bag that has a built-in cover which is fused onto the bag materials so that it is one integral unit, Trade Name: "The Fig Leaf". The applicant suggests that the new HCPCS code include the language of "cover that is fused or welded onto the bag".

Background/Discussion:

According to the requester, "The Fig Leaf" is a urinary drainage bag with an integrated cover. The purpose of the cover is to "protect the privacy and dignity of the patient, and to provide a better environment for care-givers and visitors by hiding urine." It is indicated for patients with urinary catheters. The applicant states that existing code: A4357 "BEDSIDE DRAINAGE BAG, DAY OR NIGHT, WITH OR WITHOUT ANTI-REFLUX DEVICE, WITH OR WITHOUT TUBE, EACH" "does not describe a drainage bag that provides for the privacy and dignity of patient." Therefore, the applicant requests a new code and reimbursement schedule for "The Fig Leaf".

CMS HCPCS Preliminary Decision:

Existing code A4357 "BEDSIDE DRAINAGE BAG, DAY OR NIGHT, WITH OR WITHOUT ANTI-REFLUX DEVICE, WITH OR WITHOUT TUBE, 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 if covered.
Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The Fig Leaf is a unique urinary drain bag that has a built-in privacy cover which hides bodily fluids from view. The speaker claimed that urinary drainage bags identified by code A4357 do not have a built-in cover, therefore they do not provide for the privacy and dignity of the patient and as such, "HCPCS reimbursement policy is in conflict with the CFR" rules protecting patient dignity. The speaker stated that a code providing for a drain bag with a built-in cover such as "The Fig Leaf", would meet with applause from patients, their families and caregivers everywhere.

HCPCS Public Meeting Agenda Item #12
May 24, 2011

Attachment# 11.023

Topic/Issue:

Request to establish 2 codes for a one-piece ostomy pouch with an extended wear barrier and a filter, Trade Name: Premier One-piece Ostomy Pouch. Applicant's suggested language:

Code 1 - "Ostomy pouch, drainable, with extended wear barrier attached, with filter (1 piece), each"

Code 2 - "Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity, with filter (1 piece), each".

Background/Discussion:

According to the requester, the Premier One Piece Ostomy pouch with extended wear barrier and a filter is a pouch used to collect effluent from a stoma. The pouch is attached to an extended wear barrier (one version is flat and the other is convex) that is attached to the peristomal skin around the stoma. The pouch is drainable and contains a filter. The filter is protected from fluid and therefore remains viable throughout the life of the extended wear barrier. According to the requester, existing codes A4388 "OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, (1 PIECE), EACH" and "A4390 OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT IN CONVEXITY (1 PIECE), EACH" do not adequately describe this product because they do not include the filter. The filter is a technological breakthrough that provides the option of longer wear times coupled with the benefits of odor and gas management offered by a filter. Other HCPCS codes that define filtered products in the ostomy line include the language "with filter" making it very clear that it is a filtered product.

CMS HCPCS Preliminary Decision:

Establish A43x1 "OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH FILTER, (1 PIECE), EACH"
A43x2 "OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY, WITH FILTER, (1 PIECE), EACH"

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that the items would be paid in accordance with the payment rules that apply to Ostomy, Tracheostomy and Urological Supplies if covered.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant provided comments in support of CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #13
May 24, 2011

Attachment# 11.111

Topic/Issue:

Request to establish a code for Addition to Upper Limb Electric Prosthetic Terminal Device, Control Strategy and External Feature Selection Software, Wireless Adjustability, Bluetooth or equal, Trade Name: BioSim.

Background/Discussion:

According to the requester, BioSim is a software tool set for use by clinical practitioners to access to a range of programmable features and settings. Designed for use with the i-LIMB™ Pulse and ProDigits™, Touch Bionics' unique BioSim software allows the devices to be connected via Bluetooth to a personal computer while the wearer is actively using their device. With plug and play auto recognition, BioSim's Bluetooth communication is established via a PC-USB connector. This specialized Bluetooth-enabled software enables prosthetists, and users, in a more limited way, the ability to select and modify features and control strategies that work best for a specific individual. The software allows a range of possible grip patterns and other gestures to be activated or deactivated, including the pulsing grip strength feature. BioSim also allows the pre-selection of various control strategies including dual- and single-site options, as well as the ability to view and monitor real-time myoelectric impulses during the assessment and training phase of a user's muscle signal assessment. BioSim is available in three versions: BioSim - for Accredited i-LIMB ™ Practitioners that have not completed BioSim training; BioSim Professional for Accredited i-LIMB™ Practitioner that have completed BioSim training and MyBioSim for i-LIMB Pulse™ and ProDigits™ users. The current code set does not include a code that identifies the connectivity capability such as Bluetooth connection.

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 our preliminary benefit category analysis, 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 #14
May 24, 2011

Attachment# 11.047

Topic/Issue:

Request to establish 3 codes to identify the components of a disposable mechanically powered suction device Intended for Negative Pressure Wound Therapy, Trade Name: SNaP® (Smart Negative Pressure) Wound Care System. Applicant's suggested language:

Axxxx1 NON-POWERED NEGATIVE PRESSURE WOUND THERAPY SUCTION APPARATUS, EACH

Axxxx2 HYDROCOLLOID SPECIALTY DRESSING, MULTI-LAYER, STERILE, FOR NON-POWERED NEGATIVE PRESSURE WOUND THERAPY, EACH DRESSING SET

Axxxx3 HOLSTER WITH STRAP FOR USE WITH NON-POWERED NEGATIVE PRESSURE WOUND THERAPY, EACH

Background/Discussion:

According to the requester, the SNaP™ Wound Care System is a non-electrically powered device for negative pressure wound therapy (NPWT) for the treatment of acute and chronic wounds. It SNaP promotes healing by delivering controlled levels of negative pressure to wounds and collecting wound exudate. The negative pressure is achieved by a reduction in the density of air molecules within an enclosure. With the SNaP system this enclosure is created by sealing a wound with a specialized hydrocolloid dressing which is then connected to the SNaP Cartridge to apply the negative pressure. The SNaP system is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing and for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions and flaps. The system consists of a cartridge; a hydrocolloid dressing layer with integrated nozzle and tubing; a cartridge holster with strap; and an antimicrobial gauze wound interface layer. All components work as an integrated system and are applied for a single use. After the wound is cleaned and debrided, moistened antimicrobial gauze is gently packed into the wound bed and the hydrocolloid dressing with integrated nozzle and tubing are placed over the moistened gauze. Next, the tubing is cut and connected to the cartridge nozzle. The disposable cartridge is currently produced with three different pre-set pressure levels (-75mmHg, -100mmHg, and -125mmHG) and is strapped to the patient's leg, arm, or belt under clothing. It is left in place for 3-4 days and typically changed on a bi-weekly basis. The cartridge may be applied by the patient and sometimes may need to be replaced more frequently than the other materials in highly exudative wounds. The requester claims that existing HCPCS codes for NPWT systems are for devices that are DME. The SNaP device is not DME, rather it falls within Medicare's Surgical Dressing benefit category. In addition, the requester claims that the

hydrocolloid dressing differs from "the standard polyurethane dressings used by every other NPWT device or the market today." As such, the requester believes that existing HCPCS codes do not adequately describe the components of the SNaP 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 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 our preliminary benefit category analysis, 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 CMS' preliminary decision. The speaker stated that a "national program operating need" does exist, and no existing codes adequately describe the SNaP® Wound Care System. The speaker also claimed extensive clinical studies establish the safety and efficacy of the SNaP® System. According to the speaker, specific codes are needed to identify the product. The speaker made comments regarding product safety and efficacy and compared the SNaP® device to NPWT systems. The speaker commented that certain private insurers have incorporated the SNaP® device into their policy. Also, not related to coding, the speaker voiced an opinion that Medicare should cover the SNaP® under the surgical dressing benefit.

HCPCS Public Meeting Agenda Item #15
May 24, 2011

Attachment# 11.104

Topic/Issue:

Request to establish a new code for a pressure ulcer prevention and treatment complete bed system, Trade Name: CircSupport™ Complete Bed System.

Background/Discussion:

According to the requester, the CircSupport Complete Bed System is a pressure ulcer prevention and treatment complete bed system. The mattress component is comprised of aluminum frames (one for torso and one for lower body), non-stretch harness straps, roller motors, a timer and controls. It is constructed like a patio chase lounge with straps running perpendicular to the long axis of the body. Every 5 minutes, alternate straps slacken and retighten for up to 20 seconds for pressure relief, moisture and heat dissipation. The bed portion of the system is expected to be a standard, full-electric hospital type bed, modified to: 1) eliminate the "knee-up" positioning (there is no knee-level articulation in the CircSupport mattress); 2) replace springs with flat panels to support the mattress system; and 3) enable the mattress system to be secured on the bed. More detailed specifications were not reported. The CircSupport Complete Bed System is indicated for patients who have or are at risk for developing pressure ulcers. According to the requester, existing HCPCS codes are inadequate to describe the CircSupport System because no other bed system on the market functions the same way.

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 insurer in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, 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 #15
May 24, 2011

Attachment# 11.105

Topic/Issue:

Request to establish a code for pressure ulcer prevention and treatment mattress, Trade Name: CircSupport™ Mattress.

Background/Discussion:

According to the requester, the CircSupport™ Mattress is a pressure ulcer prevention and treatment mattress. It is comprised of 2 independently operating aluminum frames (one for torso and one for lower body), non-stretch harness straps, roller motors, a timer and controls. It is constructed much like a patio chaise lounge with straps running perpendicular to the long axis of the body. Each strap can be easily removed from the frame which allows for selective pressure relief on sensitive areas. Every 5 minutes, alternate straps slacken and retighten for up to 20 seconds for pressure relief, moisture and heat dissipation. The requester claims that the CircSupport mattress will fit on any hospital bed, or on a twin bed frame. However, the CircSupport mattress does not have knee-level articulation, therefore it is recommended that "knee raise" function of a hospital bed not be engaged. According to the requester, existing HCPCS codes are inadequate to describe the CircSupport mattress because no other mattress on the market functions the same way. The SADMERC assigned HCPCS code E1399 DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS to the mattress model JB7K in 2008.

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 Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, 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 #16
May 24, 2011

Attachment# 11.097

Topic/Issue:

Request to establish a code for a transfer and lift device, trade name: Transfer and Lift Control Unit (TLC Unit). Applicant's suggested language: "Combination supine to stand independent patient lift and transfer device with an integrated hospital bed system".

Background/Discussion:

According to the requester, the TLC unit incorporates a multipositional patient support system, a patient seat lift, and a hospital bed/sleeping surface. The deck rotates between a supine position and an upright position using patient accessible hand operated electronic, programmable controls. A foot plate/footboard assembly allows full weight bearing when deck is in the full upright position, accommodating full or partial weight bearing transfers and providing a patient support surface while the patient is being lifted from a supine to a standing upright position. Using actuators, the upper deck tilts up to 65 degrees, and the entire deck assembly tilts up to 87 degrees to support safe transfer and lifting. The TLC supports the patient so they can transfer independently and safely out of bed in order to ambulate or transfer to a mobile device. Use of the TLC unit also improves blood circulation; decreases incidence of pressure sores; and reduces or eliminates injuries from falling or unsafe transfers. "The TLC is clinically indicated for the independent patient whom the physical therapist deems qualified through their appropriate score on the Tinetti" balance assessment tool. According to the requester, this includes patients who are obese or have certain neurological or musculoskeletal disease, such as Parkinson's, Multiple Sclerosis, Muscular Dystrophy or who have had CVA or spinal trauma. Additional clinical indications listed in the application include: decreased gross motor function, partial paralysis, reduced ability to perform physical activities, edema, chronic lung/bronchial infections, intermittent claudication & rest pain, numbness, atrophy, inflammation, pain, fatigue, muscle & joint stiffness, loss of certain motor function, vasculitis, necrosis, hip & vertebra fractures, shortness of breath, dizziness, tremors, history of falls, difficulty transferring & ambulating, severe muscle cramps in feet and legs, surgical hip and knee replacement, spinal surgery, and de-conditioning of muscle strength and bulk due to inactivity. The TLC unit is supplied in several models, respectively accommodating patient weights up to 350; 600; and 1000 pounds. According to the requester, because the TLC unit merges 3 DME devices into one unique device there is no existing code that adequately describes it.

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 our preliminary benefit category analysis, 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 CMS' preliminary decision. The speaker claimed that the Transfer and Lift Control Unit can withstand repeated use; is primarily and customarily used to serve a medical purpose; generally is not useful to a person in the absence of an illness or injury; and is appropriate for use in the home and therefore feels that this product should be considered to be durable medical equipment (DME). The speaker is requesting a unique HCPCS code; inclusion under the DME benefit category; and Medicare coverage.

HCPCS Public Meeting Agenda Item #17
May 24, 2011

Attachment# 11.100

Topic/Issue:

Request to establish a code for a Patient lift; non-mechanical, Trade Name: ErgoNurse®.

Background/Discussion:

According to the requester, the ErgoNurse is a patient lift system consisting of a metal frame on wheels, straps and sheet clamps. The frame is wheeled over the bed. The straps attach the frame to the sheet clamps. The sheet clamps attach to the patients' sheets, which support the patients weigh as they are repositioned. The ErgoNurse system can be used to pull the patient to the head of the bed; turn a patient from side to side; center the patient on the bed; and lift the patient for linen changes or to position a sling (for use with a different lift device). It can be used in the hospital, nursing home or home healthcare setting. It is independent of the bed and can be moved from room to room. The Ergo Nurse system can be operated by one person. According to the requester, existing HCPCS codes E0630 "Patient lift, hydraulic or mechanical, includes any seat, sling, strap(s) or pad(s);" identifies similar products that use either a manual or electrical pump. The ErgoNurse is a non-mechanical system that does not require the use of a pump. It is therefore not described by existing codes.

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 our preliminary benefit category analysis, we believe that there would be no separate Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

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, fiscal intermediaries and A/B MACs(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)and A/B MACs.

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 36th monthly payment is made, after

which payment for the ongoing 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 other than power wheelchairs 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. Effective for items furnished on or after January 1, 2011, the rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Effective for items furnished on or after January 1, 2011, only complex rehabilitative 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 blood products, transfusion medicine, splints, casts, and other devices used to reduce a fracture or dislocation, and intraocular lenses (IOLs) inserted in physician's offices.