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

Durable Medical Equipment

Tuesday, June 8, 2011

Introduction and Overview

Approximately 25 people attended. The agenda included 10 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 Durable Medical Equipment (DME) and Accessories
Wednesday, June 8, 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# 11.040
Request to retain the Kalypto pump and wound care set in existing Negative Pressure Wound Therapy (NPWT) codes E2402 and A6550; OR retain the Kalypto pump in E2402 and either revise the existing wound care set code A6550 or create a new wound care set code to read WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES, ACCESSORIES, *AND CANISTER OR EXUDATE COLLECTION SYSTEM.*

Primary Speaker: Philip Vierling of Kalypto Medical

AGENDA ITEM #2
Attachment# 11.099
Request to establish a new HCPCS code to identify a crutch, Trade Name: HOPE Crutch.

Primary Speaker: Philip Dickerson of CareBorne

AGENDA ITEM #3
Attachment# 11.102
Request to expand the following 3 existing HCPCS code categories: E0277 powered pressure reducing air mattress; E0185 gel or gel-like pressure pad for mattress, standard mattress length and width; and E0184 dry pressure mattress by adding 2 new codes to each of these categories. The proposed new codes would add distinctions based on width and weight capacity. Trade Names: Power-Pro Elite, Relief Care Pro, Gel Pro and similar bariatric devices.

Primary Speaker: Andrea Millstein of Nutritional Services, Sourcing and Procurement

AGENDA ITEM #4
Attachment# 11.016
Request to establish 2 codes: one code for a pressure reducing mattress with a cavity, and the other for a disposable draw sheet with attached waste collection plastic bag. These two components comprise the Incontinence Relief System (IRS).

No Primary Speaker

AGENDA ITEM #5
Attachment# 11.019
Request to establish a code for an ambulatory patient support and rehabilitation system, Trade Name: Secure Tracks.

Primary Speaker: Les Dace of Secure Tracks

AGENDA ITEM #6
Attachment# 11.098
Request to 1) Establish a new HCPCS code for a hot or cold water circulating pad, Trade Name: Hydrot -PT-5; and 2) Modify existing code E0249.

Primary Speaker: Dr. John Sanker of Sanker International, Inc.

AGENDA ITEM #7
Attachment# 11.103
Request to establish 4 new HCPCS codes to describe components of a targeted UVB phototherapy system, Trade Name: Levia® Personal Targeted Phototherapy System.

Primary Speaker: Dr. Ethan Lerner of Lerner Medical Devices, Inc.

AGENDA ITEM #8
Attachment# 11.048
Request to establish a code for a pneumatic hand traction device, Trade Name: CTRAC.

No Primary Speaker

AGENDA ITEM #9
Attachment# 11.106
Request to establish a single new code to describe lever-activated retrofitable wheelchair wheels, Trade Names: Wijit® Tetra® and Voyager® driving and braking systems (DBS®).

Primary Speaker: Darryl Sonenstein of Wijit Corporation

AGENDA ITEM #10
Attachment# 11.101
Request to establish a HCPCS code for a high efficiency/low impact wheelchair handrim, Trade Name: FlexRim.

Primary Speaker: Mark Richter of MAX Mobility

HCPCS Public Meeting Agenda Item #1
June 8, 2011

Attachment# 11.040

Topic/Issue:

Request to retain the Kalypto pump and wound care set in existing Negative Pressure Wound Therapy (NPWT) codes E2402 and A6550; OR retain the Kalypto pump in E2402 and either revise the existing wound care set code A6550 or create a new wound care set code to read WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES, ACCESSORIES, *AND CANISTER OR EXUDATE COLLECTION SYSTEM.*

Background/Discussion:

According to the requester, the Kalypto Medical NPD 1000 is an NPWT System that includes two components - the NPWT electrical pump and the wound care set. Conventional NPWT systems have three components: a pump, a dressing and a separate canister for collection of wound exudates. The Kalypto system, on the other hand, collects exudate into the wound dressing. The requester characterizes the dressing as also functioning as a canister or "exudate collection system" for wound secretions. In September 2010, the PDAC reassigned the Kalypto pump from E2402 to E1399 DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS and reassigned the Kalypto wound care set from A6550 WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES AND ACCESSORIES to A6251 SPECIALTY ABSORPTIVE DRESSING, WOUND COVER, STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING or A6252 SPECIALTY ABSORPTIVE 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. According to the requester, the newly applied codes "fail to provide accurate descriptors and create significant disruption and confusion among dealers and payors." According to the requester, existing code E2402 NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE adequately describes the Kalypto NPWT pump. More accurate HCPCS codes and appropriate reimbursement are needed to identify the Kalypto as an NPWT system and to enable efficient claims processing and equal access by Medicare patients to all NPWT systems. The recommended coding action will result in cost savings to the Medicare program.

CMS HCPCS Preliminary Decision:

Newly established codes K0743 "SUCTION PUMP, HOME MODEL, PORTABLE, FOR USE ON WOUNDS"; K0744 "ABSORPTIVE WOUND DRESSING FOR USE WITH SUCTION PUMP, HOME MODEL, PORTABLE, PAD SIZE 16 SQUARE INCHES OR LESS"; K0745 "ABSORPTIVE WOUND DRESSING FOR USE WITH SUCTION PUMP, HOME MODEL,

PORTABLE, PAD SIZE MORE THAN 16 SQUARE INCHES BUT LESS THAN OR EQUAL TO 48 SQUARE INCHES"; and K0746 "ABSORPTIVE WOUND DRESSING FOR USE WITH SUCTION PUMP, HOME MODEL, PORTABLE, PAD SIZE GREATER THAN 48 SQUARE INCHES," (depending on size) adequately describe the Kalypto pump and wound care set.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.
For K0743, Pricing = 36
For K0744-K0746, Pricing = 34

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported the workgroup's recommendation to issue new codes. However, the speaker addressed concerns about the verbiage of the newly established "K" codes. The speaker stated that the terms "absorbent dressings" and "suction pump" do not accurately describe the Kalypto. The speaker requested that CMS issue new permanent codes that describe the Kalypto pump as an NPWT device and clarify that the Kalypto dressing is an "integrated dressing/exudates collection kit" for an NPWT pump, not an "absorptive dressing". The speaker also suggested that the dressing codes subdivide dressings based on storage volume capacity, as opposed to square inches.

HCPCS Public Meeting Agenda Item #2
June 8, 2011

Attachment# 11.099

Topic/Issue:

Request to establish a new HCPCS code to identify a crutch, Trade Name: HOPE Crutch.

Background/Discussion:

According to the requester, the HOPE Crutch is not similar to underarm crutches or forearm crutches. The HOPE Crutch is made of aluminum tubing drawn over mandrel for increased strength and durability. As such, the HOPE Crutch is a major improvement for people using a swing through crutch gait. It helps patients recover from injury faster because it is safer, more stable, comfortable and easy to use. The HOPE Crutch requires less energy output so the patient can move farther and faster with less fatigue. "The HOPE Crutch is significantly safer in non-weight bearing use." The Hope Crutch provides two points of body contact per crutch - behind the shoulder, and the hand. This design provides a significant advantage over conventional crutches because it prevents the crutch from slipping out from under the arm. The HOPE Crutch design prevents falling, saves energy, improves range and eliminates underarm irritation. Unlike conventional crutches which cause unnatural movement and associated discomfort, use of the Hope Crutch against the shoulder, with straight arms, allows the body to move like the pendulum, with no stress on the wrist, elbow or rotator cuff; and allows the spine to hang straight. The applicant claims that HOPE Crutch users experienced differences when comparing conventional crutches to the HOPE Crutch. According to the requester, existing code E0114 CRUTCHES UNDERARM, OTHER THAN WOOD, ADJUSTABLE OR FIXED, PAIR, WITH PADS, TIPS AND HANDGRIPS does not describe a crutch that uses two points of body contact: behind the shoulder and the hand. The 2 points of contact is the distinguishing design and function feature of the HOPE Crutch.

CMS HCPCS Preliminary Decision:

Existing code E0114 "CRUTCHES UNDERARM, OTHER THAN WOOD, ADJUSTABLE OR FIXED, PAIR, WITH PADS, TIPS AND HANDGRIPS" adequately describes the crutches that are the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker pointed out differences between the Hope crutch and "conventional" crutches. Specifically, the Hope Crutch design allows for a second point of body contact behind the shoulder, requiring no locking of joints. The point of body contact behind the shoulder becomes the pivot point enabling the user to float through like a pendulum with great stability (longer, smoother gait, easier gait initiation). The Hope Crutch has a bigger bottom tip and minimizes slipping and is therefore safer (than other crutches). According to the speaker, use of the Hope Crutch allows for cost savings in that it "can drastically improve the recovery and lives for thousands of patients who face the agony and terror of using underarm crutches". The speaker offered feedback from Hope crutch users as validation that the Hope Crutch is more stable, much safer, helps prevent the crutch from slipping, and reduces stress on the wrist, elbow, rotator cuff, and spine.

HCPCS Public Meeting Agenda Item #3
June 8, 2011

Attachment# 11.102

Topic/Issue:

Request to expand the following 3 existing HCPCS code categories: E0277 POWERED PRESSURE REDUCING AIR MATTRESS; E0185 GEL OR GEL-LIKE PRESSURE PAD FOR MATTRESS, STANDARD MATTRESS LENGTH AND WIDTH; and E0184 DRY PRESSURE MATTRESS by adding 2 new codes to each of these 3 categories, (6 new codes in all). The proposed new codes would add distinctions based on width and weight capacity. Trade Names: Power-Pro Elite, Relief Care Pro, Gel Pro and similar bariatric devices. Applicant's suggested language:

Exxx1 Powered press-reducing air mattress, heavy duty, extra wide, with a weight capacity greater than 350 pounds, but less than or equal to 750 pounds

Exxx2 Powered pressure-reducing air mattress, extra heavy duty, extra wide, with a weight capacity greater than 750 pounds, but less than or equal to 1000 pounds

Exxx3 Dry pressure mattress, heavy duty, extra wide, with a weight capacity greater than 350 pounds, by less than or equal to 750 pounds

Exxx4 Dry pressure mattress, extra heavy duty, extra wide, with a weight capacity greater than 750 pounds, but less than or equal to 1000 pounds

Exxx5 Gel pressure overlay, heavy duty, extra wide, with a weight capacity greater than 350 pounds, but less than or equal to 750 pounds

Exxx6 Gel pressure overlay, extra heavy duty, extra wide, with a weight capacity greater than 750 pounds, but less than or equal to 1000 pounds

Background/Discussion:

According to the requester, bariatric pressure-reducing mattresses and overlays differ from products currently coded at HCPCS codes E0277, E0184 and E0185 in width, weight capacity, construction and cost to manufacture. The requester comments that other HCPCS code categories for DME have distinguished products based on weight capacity, and pressure reducing mattresses should be similarly distinguished but have been "overlooked". The requester states that "Medicare typically identifies bariatric version of the standard as E1399 "DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS"." Medicare has not issued any such direction regarding bariatric mattresses or overlays.

CMS HCPCS Preliminary Decision:

Existing code E0277 "POWER PRESSURE-REDUCING AIR MATTRESS" adequately describes the Power-Pro Elite Mattress; Existing code E0184 "DRY PRESSURE MATTRESS" adequately describes the Relief Care Mattress; and existing code E0185 "GEL OR GEL-LIKE PRESSURE PAD FOR MATTRESS, STANDARD MATTRESS LENGTH AND WIDTH," adequately describes the Gel-Pro overlay. Bariatric mattresses are included in existing codes E0277, E0184, and E0185. A national program operating need was not identified by Medicare, Medicaid or the Private Sector insurers to establish codes to separately identify bariatric mattresses.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.
For E0184, Pricing = 32
For E0185, Pricing = 32
For E0277, Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that if extra wide hospital beds are coded independently then the required mattresses for use with the beds should also be coded separately. The speaker requested the creation of a code for bariatric support surfaces for the following reasons: 1) Bariatric surfaces are functionally and mechanically different than the standard size surfaces, in that they use higher grade materials for durability, and require a high output blower system to support added weight and moisture control. 2) There are clinical indications for the larger surface in clinical practice. There are increased skin/wound care problems with surfaces that are inappropriately sized. 3) Providing bariatric sized equipment is the standard of care in current clinical practice. 4) The national program operating need should reflect the level of quality care that this ever increasing population demands. 5) Coding precedent has been set for bariatric products in other product sectors, as well as the fact that the PDAC currently has bariatric support surface coded as E1399 on their classification lists. The speaker claimed that construction features and costs for structurally sufficient bariatric mattresses were not considered when the existing codes were established. The speaker also mentioned “discrimination against obese patients”.

HCPCS Public Meeting Agenda Item #4
June 8, 2011

Attachment# 11.016

Topic/Issue:

Request to establish 2 codes: one code for a pressure reducing mattress with a cavity, and the other for a disposable draw sheet with attached waste collection plastic bag. These two components comprise the Incontinence Relief System (IRS).

Background/Discussion:

According to the requester, the IRS is a mattress with a cavity combined with a disposable draw sheet with an attached waste collection plastic bag. It is indicated for use by incontinent patients. Application of the IRS device involves placing the disposable draw sheet with attached waste collection plastic bag onto the mattress and extending the plastic bag through the mattress cavity. "The patient lies comfortably on the mattress while the fecal and urine wastes are collected in the bottom of the plastic bag." Additionally, the patient experiences zero pressure in a critical area of the buttock due to the 10" long x 5" wide x 8" deep mattress cavity. Thus, the product works by effectively separating the patient's skin from their fecal and urine wastes and providing zero pressure in the buttock area, including the sacrum. The combination of these two benefits provides an extremely effective means to treat and prevent pressure ulcers. According to the requester, there are no existing codes to adequately describe the IRS because it is the only medical product available that can effectively separate the immobile, incontinent patient's skin from their fecal and urine wastes. The mattress can be placed onto any hospital bed.

CMS HCPCS Preliminary Decision:

Existing E0184 "DRY PRESSURE MATTRESS" adequately describes the mattress. A national program operating need to establish a code for the waste collection bag was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance for the bag, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

For the mattress, the payment rules associated with the existing code apply to this product if covered. Pricing = 32
Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for the waste collection plastic bag.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item. The applicant submitted written comments disagreeing with CMS' preliminary decision and discussing the medical benefit associated with having a cavity in a dry pressure mattress for passing waste. The applicant reiterated the request to distinguish dry pressure mattresses with and without a cavity via separate HCPCS codes.

HCPCS Public Meeting Agenda Item #5
June 8, 2011

Attachment# 11.019

Topic/Issue:

Request to establish a code for an ambulatory patient support and rehabilitation system, Trade Name: Secure Tracks. Applicant's suggested language: "Ambulatory patient support system consisting of overhead track and patient support frame for patient fall prevention and improved outcomes during rehabilitation therapy."

Background/Discussion:

According to the requester, Secure Tracks is a patient support system designed to help ambulatory patients recover faster, with less pain and without the fear of falling. The System uses an adjustable U-shaped support frame attached to a pivoting trolley that glides along an overhead mounted track. The patient is secured into the adjustable support frame, holds the handgrips, and walks along a prescribed path, defined by the overhead track. Secure Tracks is intended for any patient recovering from stroke, heart attack, joint surgery, amputation, pulmonary disease or any disease requiring temporary rehabilitation therapy. It can assist with gait training, strengthening, flexibility and functional movement, especially for patients learning to use a prosthesis after amputation. According to the requester, Secure Tracks is not simply a piece of safety equipment, as existing code E0700 "SAFETY EQUIPMENT, DEVICE OR ACCESSORY, ANY TYPE" would suggest. It is sophisticated DME technology. The lack of reimbursement associated with code E0700 does not compensate for the "improvement in patient outcomes and safety "associated with use of Secure Tracks.

CMS HCPCS Preliminary Decision:

Existing code E0700 "SAFETY EQUIPMENT, DEVICE OR ACCESSORY, ANY TYPE" adequately describes this product.

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 CMS' preliminary decision. The speaker reiterated the original request to establish a code for Secure Tracks. According to the speaker, Secure Tracks: improves patient outcomes; prevents falls and decreases complications; saves the health care

system significant costs; and sets an entirely new standard of care for post-operative rehabilitation.

HCPCS Public Meeting Agenda Item #6
June 8, 2011

Attachment# 11.098

Topic/Issue:

Request to 1) Establish a new HCPCS code for a hot or cold water circulating pad, trade name: Hydrot -PT-5. Applicant's suggested language: "HYDROT-PT-5 water circulating five modality unit" (when used for regulating blood flow locally); and 2) Modify existing code E0249 which currently reads: "Pad for Water Circulating Heat Unit, for Replacement Only," to instead read "Pad for water circulating Hydrot-Pt-5 Unit, for replacement."

Background/Discussion:

According to the requester, the Hydrot-PT-5 unit houses a hot and a cold reservoir, switches, and LCD readouts for temperature controls. The System also includes tubing and a pad. The Hydrot-PT-5 system revolutionizes healing, prevention and maintenance by regulating blood locally and stimulating the manufacture of red and white blood cells in bone marrow. The system uses a 5 minute cycling process which automates the following five modalities combined scientifically through a single pad: 1) hot, 2) neutral, 3) cold, 4) intermittent compression, and 5) continuous heart rhythm directional message. The hot stimulates the central nervous system to rush blood to the local area in an attempt to bring it back to the body's temperature. The neutral zone signals the central nervous system to relax the local area and allow an increased blood flow. The cold cycle stimulates the volume of blood flow provided by the neutral zone. In the compression intermittent cycle, the pad compresses externally with the internal compression of the cold physiological response. The continuous directional message cycle regulates the blood flow as the heart polls beating rate, regulating blood flow locally. The Hydrot-PT-5 assists in restoration in less than one third the time of conventional applications, and works even when conventional applications fail. The pad is placed over the affected area. All five modalities are automated for consistency and removing the human error. The requester claims that existing codes E0217, E0218 and E0249 do not, individually or collectively, regulate blood flow locally as the Hydrot-pt-5 does, and that this process of regulating blood "cures gangrene" and "prevents amputation." According to the requester, existing code E1399 "DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS" is inadequate to describe this product because it requires cumbersome documentation and follow-up.

CMS HCPCS Preliminary Decision:

Existing code E0217 "WATER CIRCULATING HEAT PAD WITH PUMP;" E0218 "WATER CIRCULATING COLD PAD WITH PUMP;" or E0249 "PAD FOR WATER CIRCULATING HEAT UNIT, FOR REPLACEMENT ONLY," depending on what is supplied, 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 if covered.
For E0217, Pricing = 32
For E0218, Pricing = 36
For E0249, Pricing = 32

We believe that contractors are not covering this durable medical equipment.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that the Hydrot-PT-5 is 5 therapeutic modalities in one machine. According to the speaker, the Hydrot-PT-5: regulates the blood flow locally by controlling the hot/cold timing variable temperature; creates a physical and physiologic effect moving fresh blood in and stale blood out; creates a physiological response resulting in relaxation; and creates a physical and physiologic effect restraining the swelling. The speaker also claimed that the Hydrot-PT-5 heals gangrene and prevents amputations.

HCPCS Public Meeting Agenda Item #7
June 8, 2011

Attachment# 11.103

Topic/Issue:

Request to establish 4 new HCPCS codes to describe components of a targeted UVB phototherapy system, Trade Name: Levia® Personal Targeted Phototherapy System. Applicant's suggested language:

Exxx1 Ultraviolet B, targeted light therapy, table top treatment system, includes lamp, optical filters, programming console, eye protection and beam delivery attachments to treat multiple small area (3 cm^2) increments of skin and scalp psoriasis

Axxx1 Treatment programming module (programmed USB flash memory drive)

Axxx2 Replacement, lamp, targeted therapy

Axxx3 Replacement, calibration light meter.

Background/Discussion:

According to the requester, the Levia® Personal Targeted Phototherapy System is used in the home to treat psoriasis, vitiligo, atopic dermatitis and seborrheic dermatitis. Levia® delivers precisely calibrated UVB light therapy directly to the affected area of the scalp and the body. The internal control module in Levia® calculates automatically the exposure time needed to deliver the prescribed energy per unit area. The system includes a treatment console and connected handpiece, a scalp psoriasis treatment attachment with quartz fiber-optic bristles, and a general skin treatment attachment. On initial issue, the patient receives a console with handpiece and light meter, 1 litebrush, 1 litespot, 1 treatment programming module, power cord, user manual, carrying case, 1 pair of UV goggles, protective gloves, brush cleaner, and mineral oil applicator. Phototherapy is typically administered every second or third day for a total of three times per week. Dosage can be adjusted as prescribed by the physician. In typical home use, the lamp will need to be replaced once every 5 years and the light meter is specified for annual calibration. According to the requester, existing codes describe older cabinet or panel phototherapy systems and their replacement lamps, and do not adequately describe the Levia® Personal Targeted Phototherapy System and its components. Levia® utilizes fundamentally different technology from these older systems and requires separate coding to reflect the distinctions. There are no table top targeted phototherapy systems similar to Levia® specifically designed for home use.

CMS HCPCS Preliminary Decision:

Existing code E0691 "ULTRAVIOLET LIGHT THERAPY SYSTEM PANEL, INCLUDES BULBS/LAMPS, TIMER AND EYE PROTECTION; TREATMENT AREA 2 SQUARE FEET OR LESS" adequately describes the table top treatment system. Existing code A4633 "REPLACEMENT BULB/LAMP FOR ULTRAVIOLET LIGHT THERAPY SYSTEM, EACH" adequately describes the replacement bulb. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to establish a code to identify the program module or the calibration light meter.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For E0691, Pricing = 32
For A4633, Pricing = 32

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for the programming module.

Routine regulation/maintenance of equipment is not covered so there would be no separate Medicare payment for the calibration light meter.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that targeted phototherapy involves a fundamentally different principle of light generation technology leading to important treatment distinctions. The speaker also claimed that targeted phototherapy is a different treatment modality and it is effective for scalp psoriasis. According to the speaker, panels as described in existing code E0691 do not provide targeted therapy. The speaker stated that a new HCPCS code for targeted phototherapy devices will provide symmetry with CPT codes, which do make a distinction between targeted and non-targeted treatment modalities.

HCPCS Public Meeting Agenda Item #8
June 8, 2011

Attachment# 11.048

Topic/Issue:

Request to establish a code for a pneumatic hand traction device, Trade Name: CTRAC.

Background/Discussion:

According to the requester, CTRAC is a pneumatic hand traction device indicated for the treatment of Carpal Tunnel Syndrome (CTS) in patients who have not had Carpal Tunnel Release (CTR) surgery. CTRAC consists of a "C" shaped plastic frame with a thumb opening; an air bladder that attaches by velcro on the inside of the device (at the back of the hand); a manometer for measuring mmHg pressure; a bulb with a nozzle used to inflate/deflate the air bladder; and a hose that attaches the bulb to the manometer. The device is placed on the hand by inserting the hand in the frame. Once the device is in place, the bladder is inflated to a pressure of 180 mm HG - 200 mmHg for 2 minutes. After 2 minutes, the bladder is deflated to provide 1 minute of rest, then it is inflated again for 2 more minutes to complete the treatment. This treatment is repeated 3 times a day for 4 to 6 weeks. This treatment stretches the Carpal Ligament and increases the area of the Carpal Tunnel. Increasing the area of the Carpal Tunnel decreases the symptoms of CTS by decreasing the pressure on the Median Nerve. CTRAC has not been formally tested in people that have had CTR surgery. According to the requester, there are no codes in the existing HCPCS code set that describe a pneumatic hand traction 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 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 #9
June 8, 2011

Attachment# 11.106

Topic/Issue:

Request to establish a single new code to describe lever-activated retrofitable wheelchair wheels, Trade Names: Wijit® Tetra™ and Voyager™ driving and braking systems (DBS®). Applicant's suggested language: "Retrofitable wheelchair accessory, bi-manual, lever-activated, hub-based gear driven brake and reversible clutch transmission wheel, each."

Background/Discussion:

According to the requester, the Wijit® Tetra™ and Voyager™ Driving and Braking Systems (DBS®) are activated by a lever mounted to the rear wheel hub that contains the transmission, gears and braking system. By pulling the levers inward towards the body, the brakes will engage. The Wijit Driving and Braking System (DBS) is a totally mechanical alternative propulsion system for manual wheelchairs. This driving and braking system is fully integrated into the wheel and attached to the wheelchair through its unique axle. The Wijit enables users to negotiate slopes and inclines, uneven terrain, and environmental obstacles and resistant surfaces. When compared to use of traditional push-rim wheels, the Wijit DBS fundamentally alters the interface between operator and wheel, providing tremendous increases in torque supplied to the wheels through leverage and gearing. Operators of the Wijit do not have to reach out and follow the push rim while attempting to grab and release a moving wheel. As such, their bodies remain upright most of the time, avoiding upper extremity injuries endemic within push-rim manual wheelchair users. According to the requester, current codes do not address the use and transforming effects of the DBS system.

CMS HCPCS Preliminary Decision:

Existing code E0958 "MANUAL WHEELCHAIR ACCESSORY, ONE-ARM DRIVE ATTACHMENT, EACH," billed twice, adequately describes this product.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that the Wijit is an integrated lever, transmission, brake and wheel combination that allows for forward and reverse propulsion and has a gear reduction drive transmission for braking. A separate Wijit is installed on each side of a manual wheelchair. Both handles are used for directional control

and braking, as such, it is not a one-arm drive attachment. According to the speaker, the description of E0958 does not reflect the capabilities of the Wijit. The speaker requested that CMS either consider revising code E0958 or assign the Wijit to existing code E2227. The speaker also commented that reimbursement of the Wijit as a capped rental item is inconsistent with the treatment of other similar products, and the Wijit should be reimbursed as a lump sum.

HCPCS Public Meeting Agenda Item #10
June 8, 2011

Attachment# 11.101

Topic/Issue:

Request to establish a HCPCS code for a high efficiency/low impact wheelchair handrim, Trade Name: FlexRim. Applicant's suggested language: "Manual Accessory, High-Efficiency and Low-Impact Handrim."

Background/Discussion:

According to the requester, the FlexRim is the world's first low-impact wheelchair handrim. The FlexRim features a high-friction rubber membrane that connects the tubular aluminum handrim to the outer surface of the wheel. The membrane is contoured to match the shape of the hand and, because it spans the entire gap between the rim and the wheel, it provides a large, continuous gripping surface. Since the membrane is deformable, it allows the FlexRim to absorb some of the impact force imparted by the hand during each push. Because pushing a manual wheelchair is an inefficient method of movement, users are susceptible to fatigue and fatigue-induced overuse injuries. Wheelchair propulsion is also characterized by repetitive high-impact loading, which has been associated with carpal tunnel syndrome. The FlexRim accomplishes the goal of both increasing propulsion efficiency and decreasing impact loading through the use of a patented high-friction rubber interface that provides superior engagement with the hand. The FlexRim is appropriate for all manual wheelchair users and is used the same way as any other wheelchair handrim. Therapeutic improvements in performance can help prevent the development of secondary injuries. Users who already suffer from upper extremity pain can use the FlexRim as a means to provide relief to their pain during propulsion, since it reduces the effort required to push the wheelchair. According to the requester, there are no existing coded products that address these problems facing manual wheelchair users. The requester is therefore seeking a new HCPCS code to acknowledge the unique functional capabilities of the FlexRim, a high-efficiency, low-impact wheelchair handrim.

CMS HCPCS Preliminary Decision:

Existing code E2205 "MANUAL WHEELCHAIR ACCESSORY, HANDRIM WITHOUT PROJECTIONS (INCLUDES ERGONOMIC OR CONTOURED), ANY TYPE, REPLACEMENT ONLY, EACH" adequately describes this product.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision that existing code E2205 adequately describes the FlexRim. According to the speaker, all handrims codes at E2205 have both a rigid grip surface and a rigid connection to the wheel. The speaker claimed that while the FlexRim functions the same as products identified by code E2205, it operates differently in that it: 1) conforms to the shape of the hand when gripped to provide a surface to push against and reduce the physical effort required for propulsion, and 2) is able to absorb impact loading during propulsion to protect the user from median nerve damage. The speaker stated that the therapeutic benefits of the FlexFim have been published in two peer-reviewed journals. The speaker also claimed that without a unique HCPCS code to distinguish FlexRim from other handrims, the availability of the FlexRim is limited. The speaker reiterated the request for a new code but requested different wording than originally suggested, specifically, that the new code read “conforming grip, shock absorbing handrim”.

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.