Centers for Medicare & Medicaid Services (CMS)
HCPCS Public Meeting Summary Report for:
Durable Medical Equipment (DME)
June 23, 2005

Public Meeting Introduction and Overview

Michael Barron, CMS Office of Operations Management, moderated the meeting. Approximately 65 people attended. The agenda included 26 items.

Cindy Hake provided an overview of the public meeting process and the overall HCPCS process. She also discussed the survey of stakeholders regarding needed changes to the HCPCS process, the nature of responses to the survey, and the nature of changes already made, as well as pending changes, included in the reformation of the HCPCS process. Monitor the HCPCS world-wide website for announcement of changes to the HCPCS coding process at www.cms.hhs.gov/medicare/hcpcs.

Joel Kaiser presented an educational overview of the variety of methods used for setting the payment amount for items, and when the different methods are used. This overview was also provided as a written attachment to the agenda. 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://cms.hhs.gov/providers/pufdownload/default.asp#dme.

CMS HCPCS Public Meetings provide an opportunity for CMS to share its preliminary coding decisions and payment recommendations, and an opportunity for interested parties to make oral presentations and submit written comments in reaction to CMS' these coding and pricing recommendations.

Prior to the Public Meetings the CMS HCPCS workgroup meets to review the coding requests on the public meeting agenda, and to make a preliminary coding decision. CMS also makes preliminary decisions regarding the applicable 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 included in the public meeting agendas.

Following the public meeting, the CMS HCPCS workgroup will reconsider its preliminary coding decisions based on the input heard at the Public Meetings. Afterwards, the workgroup will decide on its final recommendations. CMS maintains the permanent HCPCS level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

HCPCS Public Meetings are not workgroup meetings. No final decisions are made at the public meetings. All requestors will be notified in writing, in early November, of the workgroup's final decision regarding the HCPCS code request(s) they submitted.

The process for developing agendas and speaker lists for the public meetings, and Guidelines for Proceedings at CMS' Public Meetings for new supplies are posted on the official HCPCS world wide web site at: http://cms.hhs.gov/medicare/hcpcs/default.asp. The standard application form for requesting a modification to the HCPCS Level II Coding System, along with instructions for completion and background information regarding the HCPCS Level II coding process is available on the same web site.

Public Meeting Summary

The following information includes a detailed summary of each request on the Public Meeting Agenda, along with CMS' preliminary decisions and rationale, and summaries of presentations made by primary speakers.

Meeting Agenda Item #1
June 23, 2005
HCPCS Request #05.156

Background/Discussion:
Ken Lester of Millennial Medical Equipment, LLC submitted a request that CMS either assign existing code E0117 for use to identify the Millennial Crutch; or modify an existing code or create a new code to describe the unique features of Millennial Crutch and assign it "a reimbursement range that reflects its added value to the user over existing standard crutches". Existing code E0117 reads: "CRUTCH, UNDERARM, ARTICULATING SPRING ASSISTED, EACH". According to the requester, the Millennial Crutch operates the same way traditional crutches do. They are placed slightly below the armpit with the tip touching the ground in front of the user. Grasping the handle the user moves in a forward direction supporting his or her weight on the hands and arms and steps or swings taking the weight off of the involved leg. Millennial Crutch has a spring shock-absorbing/power assist feature which compresses as the crutch is planted ahead of the user, and as he or she steps through, releases the tension of the spring positively to help him or her propel forward. This requires less energy of the user than it would with conventional crutches. Millennial crutch is adjusted to the height of the user and to proper arm angle and gripping position. The crutch also detaches at the mid-section so that it can be collapsed or folded.

CMS HCPCS Workgroup Preliminary Decision: Use existing code E0116 Crutch, underarm, other than wood, adjustable or fixed, with pads, tips and handgrips.

An existing code, E0116, adequately describes a category of crutches which performs a function similar to the item in this coding request. There are no significant therapeutic distinctions between the category of items described in this code and the item in the coding request. No insurer identified a national program operating need to alter the existing code set to separately identify this product. The item that is the subject of this request contains a shock absorber, and does not provide spring assistance, therefore, it is in appropriate to use code E0117 to identify this product. It is not within the jurisdiction of HCPCS code set maintainers to assign fees to codes. Any concerns or inquires regarding reimbursement rates should be submitted to the insurer. For Medicare, please contact CMS' Inherent Reasonableness Authority. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Primary Speaker- Brad J. Larson, M.D. of Millennial Medical respectfully refutes the preliminary decision to use existing code E0116 and offered the following comments:
We recommend a new code be established to adequately describe the objective and therapeutic advantages of the Millennial Ergonomic Crutch. Traditional axillary crutches have not changed in design, only in composition in the last hundreds of years. The medical literature is full of articles and examples detailing the harmful effects these crutches cause.

These range from compressive neuropathies, vascular compromise, stress fractures, and even osteoarthritis.

The Millennial Erogomic Crutch offers significant therapeutic distinctions from the traditional crutch. The crutch is designed ergonomically, from the underarm cradle to the cushioned tip. Features include: single vertical strut, ergonomic underarm design, collapsible, unique ergonomic hand grip, and a spring assist and shock absorbing component.

The therapeutic advantages, design, and proven ergonomics place the category by itself. We propose that a new code will clearly set this assistive device apart from the others.

Meeting Agenda Item #2
June 23, 2005
HCPCS Request #05.02

Background/Discussion:
Bill Niland of Vapotherm, Inc. submitted a request to establish a code for a high flow humidification system, trade name: Vapotherm 2000h. According to the requester, The Vapotherm 2000h is the only device available that can comfortably and adequately deliver breathing gas flows of up to 40 liters per minute directly to a nasal cannula, or other small-tube respiratory interfaces, without a supplemental air source. This system consists of the base driver unit and a series of accessories for single patient use in the patient's home. Vapotherm used membrane transfer technology to saturate a stream of air and/or oxygen to generate a high flow of warm and sterile vapor. High flow is indicated for numerous chronic lung diseases, acute respiratory insufficiency, apnea of prematurity, respiratory compromise where gas exchange in the respiratory tract needs improvement and where work of breathing needs to be reduced.

CMS HCPCS Workgroup Preliminary Decision: Use existing code E0550 humidifier, durable, glass or autoclavable plastic bottle type, for use with regulator or flowmeter.

Existing code E0550 is available for use by all payers, and adequately describes a category of humidifiers for use with a regulator or flowmeter which perform a function similar to the Vapotherm 2000h. The study provided with the application does not support a claim of therapeutic distinctions between the category of items described by E0550 and the Vapotherm 2000h. No insurer identified a national program operating need to distinguish the Vapotherm 2000h from other items coded at E0550 based on different pressures or efficiency. Code assignment is made by the insurer in whose jurisdiction a claim would be filed. For Medicare, use code E0550; use of miscellaneous codes to identify this product is inappropriate. For private insurance sector, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

There was no Primary Speaker for this item.

Meeting Agenda Item #3
June 23, 2005
HCPCS Request #05.120

Background/Discussion:
Ron Billingsley of Respironics, Inc. submitted a request assign a HCPCS code to the Prodose Adaptive Aerosol Delivery System and requests that the code descriptor state that the device is specifically for use with Ventavis. According to the requester, the Prodose AAD system represents a unique technology to deliver a predefined amount of aerosol to the patient's lungs. AAD was designed to minimize the variability of the delivered dose, to minimize the waste of aerosol to the environment and to improve the patients' adherence to their treatment and compliance with the user specification of the device. AAD systems adapt delivery of aerosol to the patient's breathing patterns, eliminating the greatest source of variability in drug delivery associated with conventional jet and ultrasonic nebulizers. The timing of the pulse of aerosol to be delivered to the patient is determined by the analysis of the breathing pattern. AAD systems analyze the pressure changes of the airflow of the first three breaths, to ascertain the correct starting point for aerosol delivery. It also provides the patient with feedback on how to effectively use the AAD system during the treatment, which improves adherence to treatment and compliance with device. Prodose uses the AAD disc to control drug delivery. The Prodose system consists of a compressor connected to a self-powered hand piece fitted with a liquid crystal display.

CMS HCPCS Workgroup Preliminary Decision: To establish a new "E" code.

E???? Controlled dose inhalation drug delivery system.

Medicare Payment:
This item falls under the capped rental DME payment category. The allowed rental payment amounts for this device will be based on the contractor's individual consideration of each claim until fee schedule amounts can be established for this new code.

Primary Speaker – Ron Billingsley, of Respironics, Inc. offered the following comments: "We strongly support the Workgroup's preliminary decision to establish a new "E" code, and we strongly support the coding language proposed by the Workgroup (Controlled Dose Inhalation Drug Delivery System) for the Prodose Adaptive Aerosol Delivery System.

We urge the Workgroup to reconsider the statement in the draft agenda suggesting that this device will fall within the capped rental payment category under Medicare. In this brief presentation, we provide the HCPCS Panel with additional information that is directly relevant to the assignment of a payment category under Medicare.

The Prodose Adaptive Aerosol Delivery System is a technologically sophisticated device that provides precision dosing for prescription drugs delivered via inhalation. This requires the device to adapt to the breathing patterns of each patient. At this time, the Prodose Adaptive Aerosol Delivery System is approved by the FDA for the delivery of one prescription drug (iloprost, trade name "Ventavis").

The potential risk to the beneficiary's health due to interruptions in this therapy is reflected in the FDA's labeling, which requires patient access to a back-up Prodose device when this drug is administered. Although this equipment is durable, it may only be used by a single patient. For these and additional reasons, we urge the Workgroup to reconsider and withdraw its reference to the capped rental category".

Meeting Agenda Item #4
June 23, 2005
HCPCS Request #05.121

Background/Discussion:
Terry O'Brien of Omron Healthcare, Inc. submitted a request to have the NE-U22 Micro-Air vibrating mesh nebulizer reclassified from under current HCPCS code E0574 ULTRASONIC/ELECTRONIC AEROSOL GENERATOR WITH SMALL VOLUME NEBULIZER to E0571 AEROSOL COMPRESSOR, BATTERY POWERED, FOR USE WITH SMALL VOLUME NEBULIZER. According to the requester, NE-U22 is a small volume electronic nebulizer that operates on 2 "AA" batteries and has an AC power option. It produces a breathable aerosol by breaking solution medications into small aerosol particles that can be inhaled into the lungs. The nebulization takes place by forcing medication from the medication bottle through a mesh plate containing 6,000 holes. Nebulized medication then passes from the top of the mesh through either a mouthpiece or mask to the user, which is then inhaled into the lungs. NE-U22 is used by any patient who suffers from respiratory conditions that require medications that are delivered to the lungs. NE-U22 provides relief of airway disease and can be used in any setting provided that the patient has access to their medication and device.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E0574 ultrasonic/electronic aerosol generator with small volume nebulizer.

Existing code E0574 adequately describes a category of nebulizers that perform a function similar to the item that is the subject of this request, and is available for use by all payers. Assignment of codes to individual products is made by the insurer in whose jurisdiction a claim if filed. For Mediccare, as long as the patient meets the criteria in medical policy, the product is paid for using the fee assigned to E0574. Based on its policy, Medicare may downcode based on medical necessity. The method of breaking up the solution is not an issue. The item is essentially AC powered, but can have batteries. It is not primarily battery powered. The battery is a back up to the AC power source. The setting of fees and reimbursement rates associated with codes is outside the jurisdiction of the code set maintainers. If you have a concern regarding the fee associated with E0574, please submit your inquiry directly to the insurer. For Medicare, please contact CMS' Inherent Reasonableness Authority. For private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Primary Speaker – Terry O'Brien, of Omron Healthcare, Inc., disagreed with the preliminary decision. To summarize:

- Omron is asking that the NE-U22 be grouped with E0571 with regard to the modality of operation.

- CMS' position on aerosol generation and therapy does not differentiate regarding compressor/nebulizers and electronic nebulizers.
- CMS allows for battery operation with regard to compressor/nebulizers and has defined the specification for battery operated devices in E0571:
    - It must have a battery or DC power capability and may have an AC power option.
- Omron's NE-U22 meets the specifications established by CMS for battery operated devices and is sold as a battery operated nebulizer. It should be grouped with E0571 and the code descriptor modified to reflect the distinctions of the NE-U22.
- The NE-U22 benefits persons who are ambulatory and require aerosol therapy.

Meeting Agenda Item #5
June 23, 2005
HCPCS Request #05.122

Background/Discussion:

Beth Guevara of Respironics, Inc. submitted a request to establish a separate code for a therapy data management system for positive airway pressure devices, trade name: Respironics SleepLink™ Modem System and Encore® Pro SmartCard® Technology. The SleepLink and SmartCard are used with continuous positive airway pressure (CPAP) devices and bi-level respiratory devices. In addition, the SleepLink can be used with XPOD® oximetry device to provide oxygen saturation data. Both products are use by patients who are diagnosed with obstructive sleep apnea that utilize CPAP and bi-level technology in the treatment of their condition. Compliance and event monitoring information associated with the use of these devices is essential to the effective treatment of sleep-related conditions. The SleepLink and SmartCard are two technologies that provide efficient ways to monitor sleep therapy compliance and event data by offering in-depth information for analysis. SmartCard is a removable data recorder card that is installed into the side of a compatible PAP device. It can then be downloaded for review by the patient's physician or homecare provider through the use of Encore Data Management Software. SleepLink is a data recorder system like the Smartcard with the addition of a modem device that allows home care providers to transmit data for review and interpretation by the treating physician. The SleepLink allows the option to download compliance data only or compliance data and oximetry information simultaneously.

CMS HCPCS Workgroup Preliminary Decision: Use existing code A9900 miscellaneous DME supply, accessory, and/or service component of another HCPCS code.

This product was originally cleared for marketing as a component to a BiPAP and CPAP device, and is included in the code that describes the BiPAP or CPAP device. Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, A9900 is the appropriate code. No insurer identified a national program operating need to alter the existing code set to describe this item. E1399 or other miscellaneous codes should not be used to identify this item on a Medicare claim.

Medicare Payment : There is no separate payment for this DME component since payment for all necessary components of DME is included in the payment for the DME (i.e., CPAP or respiratory assist device).

Primary Speaker – Michael Stanchina, M.D., of the Rhode Island Hospital, Brown Medical School, spoke on behalf of Responics, and disagreed with the preliminary decision Dr. Stanchina offered the following comments: The CMS HCPCS Workgroup preliminary decision is to use the existing miscellaneous code A9900. We urge the Workgroup to reconsider this decision and establish a new, unique HCPCS code for therapy data management systems for positive airway pressure (PAP) devices.

This technology allows PAP devices, both continuous positive airway pressure (CPAP) and bi-level, to function substantially differently from standard, less advanced PAP devices. The current coding system does not account for the significant difference in function provided by PAP devices combined with therapy data management systems.

The clinical literature demonstrates the value, both clinically and economically, of PAP device therapy adherence. Obstructive sleep apnea (OSA) left under- or untreated may result in significant co-morbidities, such as cardiovascular disease, stroke and hypertension. In addition, the link between OSA and diabetes has also been established. Successful PAP treatment can be fostered and monitored through the use of this technology.

Therapy data management systems can play an integral role in the current strategies for improving the management of chronic disease, including the application of compliance and adherence initiatives, disease management interventions, pay-per-performance programs and the use of electronic medical records systems. All of which can lead to improved patient care and outcomes as well as a reduction in healthcare expenditures.

A new, unique HCPCS code would facilitate recognition of this important technology by Medicare and in addition, would allow third party payers who are interested in promoting its use to incorporate it into their disease management programs.

Meeting Agenda Item #6
June 23, 2005
HCPCS Request #05.123

Background/Discussion:
Martha Christian of the Princeton Reimbursement Group submitted a request to establish a code for auto or self-adjusting positive airway pressure devices (APAP), trade name: AutoSet Spirit System. According to the requester, AutoSet Spirit is a flow-based auto-adjusting respiratory device used in the treatment of Obstructive Sleep Apnea. It employs sophisticated sensors and microprocessors not present in standard CPAP machines. The device's unique mode of action allows the device to respond to these various parameters: flow limitation, snoring, hypopnea, complete obstruction or any combination of the aforementioned breathing patterns. AutoSet's mode of action delivers varying levels of pressures based on the detected sleep disordered breathing events and may change pressure on a breath-to-breath basis. This device is only used when the patient has failed on a standard CPAP.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E0601 continuous airway pressure (CPAP) device.

An existing code E0601, adequately describes a category of items which are functionally similar to the item in this coding request. As stated in the National Coverage decision for CPAP, the device's clinical function is to prevent the collapse of the oropharyngeal walls and then obstruction of airflow during sleep, which occurs in obstructive sleep apnea. Although changes in operating technology may exist, there are no related changes in clinical function or patient outcome. Additionally, there are no significant therapeutic distinctions between the category of items described in this code and the item in the coding request. The evolutionary enhancements of AutoSet Spirit do not change its core function. Even with auto-adjustments (as opposed to mechanical adjustments), the product affects inspirational breath only, and its core function is to prevent obstructive sleep apnea, which makes it a CPAP device.

Isolation of a product from similar products in an existing HCPCS code category based on improved patient outcome, unique clinical indications or benefits for a specific subset of patients is a matter that should be considered in relation to the individual insurer' coverage policies. When substantiating clinical evidence becomes available, the appropriate mechanism for requesting to distinguish the AutoSet Spirit from other, similar products on the basis of difference in clinical function or patient outcome is to approach individual insurers for reconsideration of coverage and policy. For Medicare, such requests are submitted to CMS's Coverage and Analysis Group, along with required substantiating documentation. More information regarding their National Coverage Determination process can be found at http://www.cms.hhs.gov/coverage.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Primary Speaker - Martha Christian of the Princeton Reimbursement Group spoke at the public meeting regarding this application and summarized her presentation as follows: "We are respectfully requesting reconsideration of the preliminary decision regarding auto-adjusting positive airway pressure devices. We believe that the devices do in fact provide a clinically meaningful treatment difference as evidenced by the fact that many private payers do cover the device as a unique treatment intervention for OSA patients that are intolerant of CPAP. There is clinical evidence to support this use as well. Inconsistent application of a standard of similarities in "core-function" to determine code necessity is neither fair nor appropriate. Other products with the same core function as others with codes were granted codes in this cycle. Secondly, if a core function comparison is made, then it should be compared to bi-level devices not CPAP. This raises the final issue, applying definitions from Medicare policy, the device is actually a bi-level device since it does in fact adjust pressures within the breath cycle.

APAP devices represent a significant difference in functional and mechanical operation over CPAP devices. These differences are recognized by the FDA, ISO, and private payers. Thus the device should be granted a new and unique code or if not, should be assigned to the Bi-level code E0470."

Meeting Agenda Item #7
June 23, 2005
HCPCS Request #05.124

Background/Discussion:
Nicholas Macmillan of DeVilbiss submitted a request to establish 2 codes A) 1 code for the modem and B) 1 code for the subscription fee of an electronic positive airway pressure monitoring device, trade name: eCompliance. According to the requester, eCompliance is an electronic compliance tracking system that is comprised of three elements: smart track modem, internet processing software and PAP device (CPAP, bilevel or AutoAdjust). eCompliance is a system that electronically monitors a patient's PAP usage and automatically notifies those responsible for therapeutic management, i.e. physician, sleep technologist, home medical equipment provider, of low usage. The system works with standard CPAP, bilevel and auto-adjusting devices. Objective and quantitative parameters monitored include daily hours of use, on/off data and pressure. The PAP device is set up in a patient's home. The SMLink 300 is connected to the PAP device and to the patient's telephone line. SMLink quietly calls the DeVilbiss IPS server during the night and transmits the previous day's information. The call frequency is the first 7 days and every 3 days thereafter. Patient PAP information is available via the secure, password protected IPS server, 24/7.

CMS HCPCS Workgroup Preliminary Decision: Use existing code A9900 miscellaneous DME supply, accessory, and/or service component of another HCPCS code.

This product was originally cleared for marketing as a component of a BiPAP and CPAP device, and is included in the code that describes the BiPAP or CPAP device. Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, A9900 is the appropriate code. No insurer identified a national program operating need to alter the existing code set to describe this item. E1399 or other miscellaneous codes should not be used to identify this item on a Medicare claim. Inquires regarding the appropriateness of separately billing a CPT code for interpretation should be submitted directly to the insurer in whose jurisdiction a claim would be filed.

Medicare Payment: There is no separate payment for this DME component since payment for all necessary components of DME is included in the payment for the DME (i.e., CPAP or respiratory assist device).

Primary Speaker – Dr. Dennis B. Liotta of the HIP Health Plan of New York spoke on behalf of DeVilbiss and summarized his presentation as follows: DeVilbiss disagreed with this preliminary HCPCS coding decision and believes that new codes need to be established since there is a national program operating need by private insurers. While there may not be a need for Medicare to establish new codes for this device, the private insurance companies have been covering and paying for this device and establishing new codes will help in claims processing so the technology can be identified. Private insurance companies cover and pay for the compliance monitoring technology since:

- It is important for the physician to know whether the patient is compliant with their CPAP usage and the compliance monitoring devices are one method to determine if the patient is compliant with his therapy.
- There is a desire to utilize compliance due to their findings that it increases the potential for a positive clinical outcome.
- The insurance companies experience an overall savings in healthcare costs using this compliance technology.

Meeting Agenda Item #8
June 23, 2005
HCPCS Request #05.125

Background/Discussion:
Steve Moore of Fisher & Paykel Healthcare, Inc. submitted a request to establish a code for a CPAP system with heated CPAP delivery tubing, trade name: HC604JHU Integrated Humidified CPAP with ThermoSmart Heated CPAP tubing. According to the requester, the HC604JHU Integrated Humidified CPAP is a CPAP device with an inbuilt heated humidifier. It utilizes a proprietary algorithm and an internal power supply to provide the power to run a heated breathing circuit known as 900HC522 ThermoSmart heated CPAP delivery tubing. The HC604 and ThermoSmart tubing combine to deliver positive airway pressure with optimal humidity, condensation free to CPAP patients. ThermoSmart is used in the home for patients that require heated humidification with positive airway pressure therapy. This form of PAP is primarily prescribed to patients with Obstructive Sleep Apnea.

CMS HCPCS Workgroup Preliminary Decision: To establish a new code "A" code.

A???? Tubing with integrated heating element for use with positive airway pressure device.

Medicare Payment:
This item falls under the inexpensive or routinely purchased DME payment category. Fee schedule amounts are established by the DMERCs in accordance with CMS gap-filling instructions.

Primary Speaker – Steve Moore of Fisher & Paykel Healthcare. Fisher & Paykel Healthcare agreed with the CMS HCPCS Work Group's preliminary recommendation for this item.

Meeting Agenda Item #9
June 23, 2005
HCPCS Request #05.126

Background/Discussion:
Steve Moore of Fisher & Paykel submitted a request to establish a code for a heated humidification system, trade name: MR850 Heated Humidification System. According to the requester, the MR850 heated humidification system is stand-alone "durable medical equipment" that consists of a heated humidifier and all of the necessary components required to deliver optimal humidity in a variety of applications. The MR850 is a new generation auto set dual servo controlled humidifier that offers invasive (trached) or noninvasive (mask or cannula) at the push of a button. In the invasive mode, the MR850 conditions gases to core temperature saturated and in the noninvasive mode, the MR850 conditions gases to match normal inspiratory levels. The MR850 is used for ventilation (invasive and noninvasive), respiratory assist (with and without back-up rate), positive airway pressure (noninvasive positive pressure ventilation), and continuous flow (humidified gas therapy and high flow oxygen therapy).

CMS HCPCS Workgroup Preliminary Decision: To use existing code E0562 humidifier, heated, used with positive airway pressure device.

Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, if used with a ventilator, humidification is included in cost of ventilator rental and should not be separately billed. If used with CPAP, code E0562 should be used. No insurer identified a national program operating need to alter the existing code set to separately identify this item.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Primary Speaker – Steve Moore of Fisher & Paykel Healthcare. Fisher & Paykel Healthcare respectfully disagreed with the preliminary coding recommendation of the CMS HCPCS Work Group. He summarized his presentation as follows: "When heated humidification is prescribed for a ventilatory application, homecare companies pay out-of-pocket. Not all ventilator patients are prescribed heated humidification, some are prescribed a Heat & Moisture Exchanger (HME) (A4483: Moisture exchange filter, each). A unique code should be established which describes: "Humidifier heated, servo controlled used in ventilatory and respiratory assist applications."

Meeting Agenda Item #10
June 23, 2005
HCPCS Request #05.128

Background/Discussion:
Joseph Lewarski of Inogen, Inc. submitted a request to establish a code for an oxygen concentrator, trade name: Inogen One Oxygen Concentrator. According to the requester, the Inogen One is a small, lightweight oxygen concentrator capable of fulfilling low flow prescriptions for oxygen while functioning as both a stationary and portable oxygen delivery device. It produces more then 90% pure oxygen for low flow oxygen therapy applications. Inogen One works on the principles of pressure-swing-adsorption, common to all oxygen concentrators. This oxygen production method draws and filters ambient air from the room by passing it through a filter system composed of a superior molecular sieve material. The sieve separates the oxygen from the nitrogen in the air, accumulates it and then pressurizes it in a reservoir. The oxygen-enriched gas is supplied to the patient via a standard nasal cannula in accordance with a physician prescription. Inogen One provides the prescribed oxygen to the patient at an equivalent rate of 1 to 5 liters per minute in increments of 0.5 liters per minute for a total of nine settings. Inogen is used by patients who are prescribed long term oxygen therapy (LTOT) outside of the acute care environment. Language proposed by applicant: EXXXX PORTABLE OXYGEN CONCENTRATOR USED AS A PORTABLE OXYGEN DELIVERY DEVICE, WEIGHING LESS THAN 10 POUNDS, CAPABLE OF DELIVERING 85% OR GREATER OXYGEN AND PROVIDING AT LEAST 2 HOURS OF REMOTE PORTABILITY AT A 2 LPM PRESCRIPTION EQUIVALENCY; INCLUDES CONCENTRATOR, CANNULA, TUBING AND AC/DC POWER CORD AND ADAPTER.

CMS HCPCS Workgroup Preliminary Decision: To use newly established code K0671 portable oxygen concentrator, rental (effective 4/1/2005).

Medicare Payment:
Portable oxygen equipment add-on fee and payment rule apply to this device.

There was no primary speaker for this item

Meeting Agenda Item #11
June 23, 2005
HCPCS Request #05.09

Background/Discussion:
Richard Weston of BlueSky Medical Group Inc. submitted a request to establish a code for powered suction pump, trade name: Versatile 1 Wound Vacuum System. According to the requester, Versatile is a portable suction device that can be powered by an internal battery pack, wall current or 12 volt input via optional cigarette lighter adaptor. The pump can be used for removal of surgical fluids, tissues, gases, bodily fluids or infected materials during surgery or from a patient's airway or respiratory support system. Versatile can also be used to create localized topical negative pressure when used with the Chariker-Jeter accessory kits to promote wound healing and drainage of fluids and infected materials from the wound into a disposable or reusable canister. Versatile consists of a medium sized housing that contains a vacuum pump and control system with a location for a fluid canister system. Accessories include a vehicle power adaptor and a Mobil stand. Versatile is indicated for promotion of wound healing or for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials from a patient's airway or respiratory support system either during surgery or at the patient's bedside.

CMS HCPCS Workgroup Preliminary Decision: Existing codes E1399 (durable medical equipment, miscellaneous) and E2402 (negative pressure wound therapy electrical pump, stationary or portable) are available for assignment by insurers.

Code assignment is made by the insurer in whose jurisdiction a claim would be filed. For Medicare, E1399 must be used to describe the item that is the subject of this request, as per existing policy, pending the outcome of a technology assessment. For the private insurance sector, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
Deferred for technology assessment

Primary Speaker – Richard Weston, of BlueSky Medical Group, Inc., partially agreed with the preliminary decision. The BlueSky presentation included a discussion on general background, the special challenges of acquiring evidence based studies, Russian based information on vacuum therapy, hyperemia, and NPWT. Mr. Weston summarized as follows:

- We would ask your assistance in rapidly assigning Medicare coding to the Versatile 1 (other than the E1399).
- If a new code is assigned, we ask that this be the primary code used before any other Vacuum therapies.
- Insure that kit components not cause issues of problems in the wound itself.

Meeting Agenda Item #12
June 23, 2005
HCPCS Request #05.131

Background/Discussion:
David Hintzman of Bodypoint, Inc. submitted a request to establish a code for a dynamic pelvic stabilization device, trade name: Bodypoint Hip Grip. According to the requester, Bodypoint is a pelvic stabilization device equipped with variable resistance springs that assists the wheelchair user to maintain pelvic stability while allowing functional pelvic movements. Hip Grip incorporates rear, front, and side support of the pelvis in an adjustable unit, which allows the pelvis to pivot forward about the hip joint within a specified range. It reduces undesired pelvic movement and provides variable resistance to bring the pelvis back into its neutral posture after allowing movement. The combination of pelvic positioning and dynamic pelvic movement improves functional activities and enhances sitting posture. Bodypoint is used primarily by those patients with cerebral palsy and spinal cord injury. The pivot mechanism of Bodypoint incorporates an elastic resistance band that allows forward pelvic movement within range depending on the person's flexibility, balance and feedback. The quick release wheelchair attachment hardware combination assures the greatest compatibility with a wide range of wheelchairs and the ability to remove it for folding the wheelchair when necessary.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E0978 wheelchair accessory, positioning belt/safety belt/pelvic strap, each.

Existing code E0978 adequately describes a category for pelvic positioning devices that perform a function similar to the Hip Grip device described in your application. Sufficient evidence has not been provided to demonstrate a distinction in terms of stability or dynamic stability, as a result of the use of this product compared with other items included in E0978. No insurer identified a national program operating need to alter the existing code set to uniquely identify the Bodypoint Hip Grip.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Primary Speaker – **Primary Speaker** – Allen Sieckman, consultant for Bodypoint, Inc. Bodypoint respectfully disagreed with the preliminary decision. He commented that there are functional and design differences between the Hip Grip and other products coded at E0978 and asked that the Hip Grip be assigned to either a new code or K0108 or broken down into component parts and coded as such.

Meeting Agenda Item #13
June 23, 2005
HCPCS Request #05.134

Background/Discussion:
David Boninger of Three Rivers submitted a request to establish a code for wheelchair propulsion and braking assembly, trade name: Natural-Fit™. According to the requester, Natural Fit is a wheelchair propulsion and braking assembly ergonomically designed to fit the hand and reduce stress on the hands, wrists, and arms when propelling a manual wheelchair, thereby treating the pain associated with Carpal Tunnel Syndrome (CTS). The Natural Fit is an assembly because it has two separately coated components, a smooth oval surface for the palm of the hand and a higher friction contoured slot for the thumb. The assembly of these two components is designed to create an ergonomic grip for the hand and to provide separate surfaces for propulsion and braking. The contoured trough provides a surface area between the rim and tire to increase the contact area for the thumb to apply propulsion forces. By adding the trough, the gap between the tire and standard handrims is eliminated which enhances safety (e.g., fingers can no longer get caught in the gap). The ergonomic grip provided by the combination of the contoured trough and the oval component of the Natural Fit reduces finger tip loading, pinch gripping, and excessive activation of the finger flexors during wheelchair propulsion.

CMS HCPCS Workgroup Preliminary Decision: Existing code E2205 (manual wheelchair accessory, handrim without projections, any type, replacement only, each), is available for use by all payers.

Existing code E2205, adequately describes a category of wheelchair handrims which perform a function similar to the Natural Fit product. Testimonials and summaries of articles provided by the applicant do not demonstrate a significant therapeutic distinction between the category of items described by E2205 and the item in the coding request. Code assignment is made by the insurer in whose jurisdiction a claim would be filed. For Medicare, E2205 is the appropriate code, and it is not appropriate to use K0108 or other miscellaneous codes to identify the item that is the subject of this request. For private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Primary Speaker – David Boninger, of Three Rivers Holdings, LLC, disagrees with the preliminary decision and offered the following basis for disagreement: "The statement that there is no "significant therapeutic distinction" between the Natural-Fit and wheelchair handrims covered by the E2205 code disregards substantial peer-reviewed scientific evidence presented in our application- evidence that was not based on testimonials. We summarized over 30 peer-reviewed scientific studies that repeatedly supported the following conclusions:

- Carpal Tunnel Syndrom is prevalent among wheelchair users

- Ergonomic modification is recognized as an effective non-invasive treatment of CTS
- Ergonomic modification in wheelchair handrims changes how people push their wheelchairs
- The ergonomic design of the Natural-Fit treats CTS-related pain
- E2205 handrims are not designed to treat CTS and do not treat CTS

The Natural-Fit was specifically designed to treat CTS by providing an ergonomic grip that reduces pressure on the carpal tunnel. The therapeutic significance of this is underscored by the fact that NIH has peer-reviewed and funded two Natural-Fit Grants because E2205 handrims are inadequate for treating pain. The evidence we have provided that supports the above bulleted points meets CMS requirements for issuing a new code by demonstrating that the Natural-Fit is:

- Technologically unique as an integrated two-piece, dual surface assembly
- Functionally unique as an ergonomic design that changes how one grips, pushes and brakes on the handrim
- Therapeutically unique as a treatment for CTS
- Backed by peer-reviewed evidence of its functional and therapeutic distinction from E2205 handrims

The intended patient population for the Natural-Fit is manual wheelchair users who report CTS-related pain in the upper extremities (e.g., wrist and hand). This population pushes on their handrims an average of 2500 times a day and those suffering from CTS-related pain deserve a non-invasive option for treating their pain. CTS-related pain that is left untreated will lead to outlays for surgery and/or the prescription of a power wheelchair. Instead, the establishment of a new "E" code is clearly merited. Its wording and associated fee calculations must take into account the Natural-Fit's integrated two-piece, dual surface assembly. A proposed working for a new "E" code descriptor may be: "Manual wheelchair accessory, integrated two-piece handrim system; contoured thumb slot and contoured oval."

Meeting Agenda Item #14
June 23, 2005
HCPCS Request #05.135

Background/Discussion:
Robert Fulton III of Glance Wheels, LLC submitted a request to establish a unique code to differentiate rear wheels for manual wheelchairs that are maintenance free, extended life, high durability from other rear wheels currently coded at K0069, K0070 or K0108. According to the applicant, Glance wheels are no maintenance, high durability, high strength aircraft quality aluminum rear wheels. These wheels are intended for long term and active use. Glance wheels are intended to never be replaced and can have an extended and continuous "life". Thus Glance Wheels are resistant to usual "wear and tear" common with active disabled users of manual wheelchairs. These wheels do not require "spoke tuning" or "truing" of the wheel rim. Glance wheels are used by paraplegics, quadriplegics, amputees and other individuals using a manual wheelchair for over 4 hours per day with a continued wheelchair use to exceed one year. Current codes do not specify a high endurance, long life, no maintenance product for active users of manual wheelchairs.

CMS HCPCS Workgroup Preliminary Decision: Existing codes K0069 (rear wheel assembly, complete, with solid tire, spokes or molded, each) and K0070 (rear wheel assembly, complete, with pneumatic tires, spokes or molded, each), are available for use by all payers, and adequately describe rear wheel assemblies (solid or pneumatic).

Use existing code K0069 or K0070 as appropriate,based on whether the tires are solid or pneumatic. Use of K0108 (wheelchair component or accessory, not otherwise specified) is not appropriate. No insurer identified a national program operating need to distinguish wheels products based on degree of durability. Products either meet durable medical equipment standards or they don't. This product does not offer significant therapeutic distinctions from other wheels, and it performs a function for the patient similar to the function of other wheels.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

There was no Primary Speaker for this item.

Meeting Agenda Item #15
June 23, 2005
HCPCS Request #05.136

Background/Discussion:
Greg Howard of Independence Technology, LLC submitted a request to establish a code for a mobility system, trade name: Independence iBot 3000 Mobility System. According to the requester, iBot is a sophisticated mobility system with patented iBalance technology enabling users to climb and descend stairs, navigate surfaces, ascend curbs and balance the seat user at a "standing" eye-level height. iBot is an integrated combination of mechanical, electronic, sensor, and software components that is customized to the user's size, weight and center of gravity. The iBalance technology is comprised of six solid-state gyroscopes, three tilt sensors, three computer processor systems and multiple sensors. This technology is integrated with a cluster of two, interconnected, 12-inch wheels on each side of the device as well as two smaller caster wheels in the front of the device. The device automatically adjusts wheel and/or frame position in reaction to changes in pitch, wheel velocity, wheel position, seat height and other parameters based on a complex series of computerized sensors and software algorithms. iBot is powered by two, 72-volt rechargeable nickel-cadium batteries that can power the device all day on a single charge depending on usage.

CMS HCPCS Workgroup Preliminary Decision: Use existing K0011 STANDARD - WEIGHT FRAME MOTORIZED/POWER WHEELCHAIR WITH PROGRAMMABLE CONTROL PARAMETERS FOR SPEED ADJUSTMENT, TREMOR DAMPENING, ACCELERATION CONTROL, AND BRAKING

Existing code K0011 adequately describes a category of motorized wheelchairs that perform a function similar to the chair component of the iBOT.

The entire power wheelchair and accessory code series has recently been revised after considerable input and cooperation from stakeholders. No insurer identified a national program operating need to identify the power chair component of the iBOT, combined with separately codeable accessories, as a distinct chair type. Code assignment for the chair and accessories are made by the insurer in whose jurisdiction a claim is filed. For Medicare, use Code K0011 STANDARD - WEIGHT FRAME MOTORIZED/POWER WHEELCHAIR WITH PROGRAMMABLE CONTROL PARAMETERS FOR SPEED ADJUSTMENT, TREMOR DAMPENING, ACCELERATION CONTROL, AND BRAKING with the KF modifier ITEM DESIGNATED BY FDA AS CLASS III DEVICE to describe the power chair component of the iBOT; use code E2300 POWER WHEELCHAIR ACCESSORY, POWER SEAT ELEVATION SYSTEM to describe the elevating feature; and use code A9270 NON-COVERED ITEM OR SERVICE to describe the stair climbing feature, which is not covered by Medicare. For coding guidance for

power wheelchair accessories for private insurance systems, contact the individual private insurance contractor. For Medicaid systems, contact the Medicaid agency in the state in which a claim would be filed.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Primary Speaker – Greg Howard, of Independence Technology, LLC., took exception to CMS' preliminary decision claiming that it fails to recognize the breakthrough nature of this technology. Mr. Howard offered the following summary of his presentation: "Evidence of the need for a separate code are indicated by the fact that it is the only mobility device categorized by the FDA as a Class III medical device and the unique treatment of the iBOT Mobility System by other payers. The Veterans Administration, New Jersey and California Medicaid, and various state Workers Compensation and Vocational Rehabilitation programs have all treated the iBOT separate from other mobility devices in their coverage and payment decisions.

Significantly new, breakthrough technology requires a new code. Current coding options do not address the design and structural differences between the iBOT Mobility System and other mobility devices. Nor do current codes address the functional needs only an Interactive Balancing Mobility System (IBMS) meets. The current codes are insufficient to accommodate a computer-based gyroscope mobility system and gyroscopes that provide interactive balancing in a dynamically mobile system. IBMS is fundamentally different than a power chair's statically stable system. There are four key functions of an IBMS including balance, stair, four wheel and standard functions. The first three functions use gyroscopes to replicate upright balance, enable stepping up and down flights or stairs, and level negotiation of inclines and obstacles.

The current coding options also fail to recognize the importance of integrating multiple functions into a single device. The iBOT Mobility System is set apart from traditional power chairs in its extensive functionality and the interdependent nature of the functions. This integration facilitates participation and performance of MRADLs. It engages functions as needed, allowing the user to overcome obstacles as encountered and reducing the need for many transfers, improving safety, efficacy, and independence.

No existing HCPCS code describes the device. It is revolutionary technology that is not a wheelchair. It provides extensive functions not available in any other single device and it relies on multiple microprocessors and gyroscopes not included in any other mobility device. There is no "like" product currently coded under K0011. A new HCPCS code is required. CMS should rescind its preliminary recommendation and create a new HCPCS code for IBMS so that CMS and other payers can determine coverage policy for select users."

Meeting Agenda Item #16
June 23, 2005
HCPCS Request #05.05 A&B

Background/Discussion:
Jessica Lurz of Dynasplint Systems, Inc. submitted a request to A) establish a modifier to distinguish between extension and flexion dynamic adjustable joint stretch devices and B) establish a code to identify a dynamic adjustable metacarpo-phalangeal (MCP) joint stretch device. According to the requester, Dynasplint systems are joint stretch devices that provide a low-load prolonged-duration stretch for shortened connective tissue, thus relieving joint stiffness and regaining lost range of motion caused by injury, surgery, trauma or disease. Each unit is made of stainless steel that will withstand an extensive refurbishment process and soft interface material that comes in contact with the body. These MCP units are designed to be worn at rest or while sleeping for 8-10 hours to give patients several hours of therapy while sleeping. Each unit comes complete with a tensioning tool to either increase of decrease the force applied to the joint, according to the patient's comfort.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E1825 (dynamic adjustable finger extension/flexion device, includes soft interface material) for both A & B.

Existing code E1825 includes flexion and extension, and adequately identifies a category of devices that perform a function similar to the devices described in this application. Separation of flexion and extension could result in billing confusion or inadvertent duplicate billing. No insurer identified a national program operating need to alter the existing HCPCS code set to separate flexion and extension or to isolate finger joints.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

There was no Primary Speaker for this item.

Meeting Agenda Item #17
June 23, 2005
HCPCS Request #05.26

Background/Discussion:
Frank Joutras of Inverse Technology Corporation submitted a request to establish a code for a functional neuromuscular control device, trade name: Protonics. Requester claims that instruction to code E1810 is inappropriate because the product is not being used for what E1810 was originally intended; Protonics is not a spring-loaded device or intended for non-functional use after surgery. Requester claims this is causing confusion to third party payers. Therefore requester is seeking a new E code. According to the requester, Protonics is an external limb component that is added to, or part of an orthosis. This device is used only while the patient is functioning to control neuromuscular activation of certain muscle groups during motion allowing the device to influence joint kinematics and contact areas associated with the pelvis, femur and patella resulting in increased function and decreased pain during activities. Protonics uses a patented and unique form of functional resistance to influence certain neuromuscular activity only while the patient is walking or performing functional movements. Usage of the device needed on a daily basis is patient dependent, but most patients will need to use the device extensively over the first few months, and then periodically based on their activity level.

CMS HCPCS Workgroup Preliminary Decision: Existing code E1810 dynamic adjustable knee extension/flexion device, includes soft interface material is available for assignment by insurers and adequately describes the item that is the subject of this request.

Items previously coded under L1885 (knee orthosis, single or double upright, thigh and calf, with functional active resistance control, prefabricated, includes fitting and adjustment), were crosswalked to new code E1810 (dynamic adjustable knee extension/flexion device, includes soft interface material), at the time L1885 was discontinued. The item that is the subject of this request was a predicate product for the original establishment of L1885. It is appropriately crosswalked to and adequately described by E1810, and performs a similar function to products coded at E1810. There is no significant therapeutic distinction between this item and other products identified by code E1810. All items are used as physical therapy equipment and not separated as orthotics. These products can no longer be purchased as rental items. This product is used to build up muscle, not reduce contracture, and functions like a dynamic splint. Code assignment is made by the insurer in whose jurisdiction a claim would be filed. For Medicare, use existing code E1810. For private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this device.

Primary Speaker – Frank Joutras, of Inverse Technology Corporation, respectfully disagreed with the preliminary decision. Mr. Joutras agreed with CMS' assessments in general, and agreed that the Protonics device could probably fit under code E1810 because

it is general enough, but he claimed that there are functional and therapeutic distinctions as follows:

1. Functional Neuromuscular Control Devices are used as an orthosis to facilitate ambulation, and are not a passive piece of physical therapy equipment like a dynamic splint. This is because of the type of programmable concentric-only resistance applied through the subject device, which is substantially different than spring-loaded devices.
2. Compared to a dynamic splint, only a Functional Neuromuscular Control Device can stimulate muscle-energy techniques performed manually in the clinic.
3. Unlike dynamic splints using E1810, Functional Neuromuscular Control Devices sometimes need to be purchased (not to build muscle, but) to inhibit improper neuromuscular activity of over-active muscles during ambulation.

Actions suggested to remedy the problem:

To avoid confusion within the Medicare/Medicaid System and to third party payers, it is essential that the CMS-HCPCS workgroup acknowledge the differences between Functional Neuromuscular Control Devices and dynamic splints within their final decision.

It is respectfully suggested, that in lieu of creating a completely new E code, that the current descriptor for reimbursement code E1810 be modified to add the following language; “with or without functional neuromuscular control attached”, and that the CMS-HCPCS workgroup indicate the therapeutic differences between Functional Neuromuscular Control Devices and dynamic splints using E1810 in their final decision.

Meeting Agenda Item #18
June 23, 2005
HCPCS Request #05.127

Background/Discussion:
Lance Matthews of CANADALEG Inc. submitted a request for an "L" code for a mobility rehabilitation device, Trade Name: IWALKFree. According to the requester, the IWALKFree is a rehabilitation device that can also be used as a temporary prosthetic, orthotic or brace. It replaces a missing lower leg or a lower leg that has been injured and is in need of rehabilitation. It allows weight to be transmitted through the flexed knee resulting in no weight being borne by the tibia, ankle, or foot. The device is made of a fiber reinforced injection molded knee tray with adjustable fitting positions that is attached to an extruded single piece aluminum shaft. Hypoallergenic foam is used on the knee tray, which allows bare skin and wounds to be attached directly to the tray. A three-point attachment system ensures stability. It is set off center, with rounded rubber foot, which replicates normal walking motion.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E0118 crutch substitute, lower leg platform, with or without wheels, each.

The product that is the subject of this request is, in fact, one of the predicate products considered in originating code E0118. The product is not an orthotic or a prosthetic. Specific inquiries regarding processing Medicare claims or "down-coding", as raised in your application, should be submitted directly to the Regional DMERC in whose jurisdiction the claim was filed.

Medicare Payment:
Coverage and payment based on contractor discretion.

Primary Speaker – Lance Matthews, of CANADALEG, Inc., disagreed with the preliminary decision and offered the following comments: "The preliminary decision stated that the IWALKFree was the predicate product for the development of E0118. This is true, but it was not what we requested. We requested an L code. The decision also stated that this product was not an orthotic or a prosthetic. In fact, the IWALKFree is a preparatory prosthetic used with amputees and should be placed under an L code. There are significant therapeutic distinctions between a crutch and our preparatory prosthesis. The presentation covered the following topics: review of technical similarities to a preparatory prosthesis, review of therapeutic modalities, and suggested code verbiage. Physicians are currently using this device as a prosthetic, and therefore it should be coded as such. We are requesting that E0118 be deleted and an new code added as follows: Lxxxx—Preparatory, Below Knee, interim prosthesis Non-alignable, shaft, No Cover, rubber foot, Prefabricated, Adjustable Open Knee Tray."

Meeting Agenda Item #19
June 23, 2005
HCPCS Request #05.129 A&B

Background/Discussion:
James Boswell of King & Spalding LLP submitted a request to A) either suggest that the Statistical Analysis Durable Medical Equipment Regional Carriers (SADMERC) reassign the Nasal Pap Freestyle Cushions from A7033 REPLACEMENT PILLOWS FOR NASAL APPLICATION DEVICE, PAIR to A7032 REPLACEMENT CUSHION FOR NASAL APPLICATION DEVICE, EACH; or establish a new code for the Nasal Pap freestyle Cushions and B) to either suggest that the SADMERC reassign the Nasal-Aire II Cushion from A9999 to A7032 or to establish a new code for the Nasal-Aire II Cushion. According to the requester, Nasal Pap cushions are rough cylindrical cushions made with a soft medical grade silicone. These cushions are used in conjunction with a CPAP device for the treatment of patients with obstructive sleep apnea and related disorders. A pair of the Nasal Pap cushions is inserted into each nasal cavity and connected to tubing and a swivel connection and then to the CPAP positive air pressure machine. Nasal Pap cushions channel air with a laminar flow from the CPAP machine to the patient's nose, providing patients with breathing assistance. Nasal Aire II consists of a connected pair of cylindrical nasal inserts to be used in conjunction with a CPAP device for the treatment of patients with obstructive sleep apnea and related disorders. The cushion's nasal inserts are inserted into each nasal cavity and forms an air seal with each nasal cavity. Nasal Aire II cushion channels air with a luminar flow from the CPAP machine to the patient's nose, providing breathing assistance.

CMS HCPCS Workgroup Preliminary Decision:
#05.29A
Use code A7033, which we expect to revise effective 1/1/06 to read as follows:
PILLOW FOR USE ON NASAL CANNULA TYPE INTERFACE, REPLACEMENT ONLY, PAIR. The current language reads:
REPLACEMENT PILLOWS FOR NASAL APPLICATION DEVICE, PAIR.

A7033 adequately describes the item that is the subject of your request (nasal PAP Freestyle Cushions), therefore a new code is not necessary to describe this product and would be duplicative of revised code A7033. The product distinctions described in your application are not significant therapeutic distinctions from other items in the same code category, and Nasal PAP Freestyle cushions function similar to other items in the same category.

#05.29B
Use code A7032, which we expect to revise effective 1/1/06 to read as follows:
CUSHION FOR USE ON NASAL MASK INTERFACE, REPLACEMENT ONLY, EACH. The current language reads:
REPLACEMENT CUSHION FOR NASAL APPLICATION DEVICE, EACH.

A7032 adequately describes the item that is the subject of your request (Nasal Air II Cushion), therefore a new code is not necessary to describe this product and would be duplicative of existing code A7032. The product distinctions described in your application

are not significant therapeutic distinctions from other items in the same code category, and Nasal Air II cushions function similar to other items in the same category.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these devices.

Primary Speaker – Tom Hawk, of King & Spalding, and counsel to Innomed spoke on behalf of Innomed. Mr. Hawk commented that his client supports the preliminary decision for #05.129B, regarding the Nasal Aire II replacement cushion. We believe the working group made the appropriate decision to revise the HCPCS code A7032's language and recommend that code A7032 be used for the Nasal Aire II replacement cushions.

Innomed does not support HCPCS Working Group's preliminary decision with respect to Request #05.129A, regarding the Nasal Pap Freestyle cushions and claims that there are important differences in design and functionality between the Nasal Pap Freestyle cushion and standard nasal pillows on the market. The Nasal Pap Freestyle cushions are designed to form an air seal with the inside of each nostril. In addition, the Nasal Pap Freestyle cushions have an air exhalation port to allow a patient's exhaled air to flow out of the cushion (reducing condensation). The heavier and more durable nature of the Nasal Pap Freestyle cushion enables the Nasal Pap Freestyle CPAP device to deliver air at a greater pressure than CPAP machines that use pillows. Because of these design and functional distinctions, Nasal Pap Freestyle replacement cushions have a different appearance. Given these fundamental differences, we request and recommend that the CMS HCPCS Working Group issue a new code which better represents the Nasal Pap Freestyle replacement cushions and similar products. We recommend a new code with the following (or similar language): "Individual Cushion for Use with Individual Nostril Interface Mask with Exhalation Port, Pair."

Meeting Agenda Item #20
June 23, 2005
HCPCS Request #05.130

Background/Discussion:
James Koeneman of Kinetic Muscles, Inc. submitted a request to establish a code for a repetitive active motion device, trade name: Hand Mentor. According to the requester, Hand Mentor is a device designed primarily for rehabilitation therapy for those having suffered a stroke. This device is primarily used for Active-Assist stroke therapy where the patient is encouraged to move as much as possible and then the device completes the motion for the patient. An artificial pneumatic muscle provides the coordinated motion. In addition, the device measures the electrical activity of selected muscle groups through surface electromyographic electrodes and the resistance of spastic muscles and feeds back this information to the patient to encourage maximum effort.

CMS HCPCS Workgroup Preliminary Decision: To use existing code E1399 (durable medical equipment, miscellaneous).

To revise code E0935 to read (continuous passive motion exercise device for use on knee only), to clarify that this product is not included in the E9035 code category.

No insurer identified a national program operating need to alter the existing code set to identify this item. Your reported sales volume was insufficient to support your request for a revision to the national codes (28 units sold since market introduction in March 2003). There must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity for non-drug products, so that the adding of a new or modified code enhances the efficiency of the system and justifies the administrative burden of adding or modifying a code. CMS invites the applicant to reapply when sales volume increases substantially. HCPCS code E0935 has been revised to clarify that the Hand Mentor is *not* included in the E0935 code category. The Hand Mentor does not fit the criteria for any Medicare Benefit Category. Also, it is not covered under the National Coverage decision for passive motion exercise for the knee only, for which E0935 was developed. For Medicare, the Hand Mentor should be coded using E1399. For coding guidance for private insurance systems, contact the individual insurance contractor. For Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment: This device is not covered.

There was no Primary Speaker for this item.

Meeting Agenda Item #21
June 23, 2005
HCPCS Request #05.132A-D

Background/Discussion:

#05.132A

Jonathan Cabral of Bionicare Medical Technologies, Inc. submitted a request to establish a code for a knee signal applicator used with the BioniCare Stimulator, Model BIO-1000. According to the requester, the knee signal applicator is a "noninvasive arthritis treatment device that is worn outside of the body on the joint requiring treatment". BioniCare Signal Generator delivers a specific electrical output to contact elements that are held in place by this knee signal applicator system that accurately positions and applies a special treatment contact element to the surface of the knee and a special return contact element to the surface of the thigh. Bionicare's knee signal applicator is worn on the knee when an adjunctive therapy is used to reduce the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation. The knee signal applicator is applied using a fastener system of Velcro materials, a support belt, and suspension strap. Both right and left knee applicators and support belts are manufactured in three sizes, small, medium, and large. The knee signal applicator is designed for use eight to ten hours daily for periods up to two years. It can survive up to 350 hand-washing cycles. Code description recommended by applicant: E07XX SIGNAL APPLICATOR DEVICE, KNEE; FOR USE WITH ARTHRITIS TREATMENT DEVICE.

#05.132B

Jonathan Cabral of Bionicare Medical Technologies, Inc. submitted a request to establish a code for a replacement battery use with the BioniCare Stimulator, Model BIO-1000. According to the requester, the battery is part of BioniCare's Stimulator, Model BIO-1000 System, which is a noninvasive arthritis treatment device that is worn outside of the body on the joint requiring treatment. The rechargeable battery is required for continued operation of the electronic signal generator. Battery life is dependent on patient use patterns. Under normal use conditions, it is anticipated that a replacement battery will be required after 12 months. Code description recommended by applicant: A46XX REPLACEMENT BATTERY FOR ARTHRITIS TREATMENT DEVICE ELECTRONIC SIGNAL GENERATOR, EACH

#05.132C

Jonathan Cabral of Bionicare Medical Technologies, Inc. submitted a request to establish a code for replacement supplies used with the BioniCare Stimulator, Model BIO-1000. According to the requester, the replacement supplies are part of the BioniCare Stimulator Model BIO-1000 that is worn outside of the body on the joint requiring treatment. This code request is specific to report a kit of replacement supplies, including 2 contact elements/electrodes and 6 (8.5oz) supplementary gel tubes. The quantity of supplies is expected to last 2-3 months under typical product use conditions for one signal applicator. A second set of supplies would be required if a patient were using two signal applicators. Code description recommended by applicant: A4xxx ARTHRITIS TREATMENT DEVICE SUPPLY KIT, EACH.

#05.132D
Jonathan Cabral of Bionicare Medical Technologies, Inc. has submitted a request to establish a code for an arthritis treatment device, Trade Name: BioniCare® Stimulator, Model BIO-1000™. According to the requestor, the BioniCare Stimulator, Model BIO-1000™ is a non-invasive arthritis treatment device that is worn outside of the body on the joint requiring treatment. It is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation and an adjunctive therapy in reducing the level of pain and stiffness from rheumatoid arthritis of the hand. The device is worn for 8 +/- 2 hours every day, usually at night but can be worn during the day. Clinical experience indicates a range of use from one to 51 months. The average length of use in a long term study was 11 months. Description recommended by applicant: E07xx ARTHRITIS TREATMENT DEVICE, ELECTRICAL, NONINVASIVE.

CMS HCPCS Workgroup Preliminary Decision: To establish a new "E" code:

E???? Transcutaneous electrical joint stimulation device system, includes all accessories.

This new code would be used to identify the system, including the stimulator, knee signal applicator, batteries and related supplies.

Medicare Payment:
This item falls under the capped rental DME payment category. Fee schedule amounts are established by the DMERCs in accordance with CMS gap-filling instructions.

Primary Speaker – Thomas Zizic, M.D., of Bionicare Medical Technologies, Inc., supports the preliminary decision to establish a new and distinct code for Transcutaneous Electrical Joint Stimulation Device Systems and discussed Bionicare's interpretation of the proposed descriptor, "Transcutaneous Electrical Joint Stimulation Device System", and the Clinical outcomes necessary for designation as a TEJS.

Meeting Agenda Item #22
June 23, 2005
HCPCS Request #05.167

Background/Discussion:
Kirk MacKenzie of Snug Seat has submitted a request to establish 2 codes: 1) pediatric dynamic stander and three way stander, Trade Name: Pediatric Dynamic Stander – Rabbit Mobile Stander (Snug Seat) and 2) Pediatric Three-Way Stander, angle adjustable, permits prone, supine, and vertical standing – Gazelle P/S Standing Frame (Snug Seat). According to the requestor, a pediatric dynamic stander is a device that places a child who cannot stand independently, in an upright or prone position and allows him to self-propel. The stander angle accommodates a range from upright to > 20 degrees prone. It differs from a basic simple standing frame in that the simple standing frame serves one single purpose – upright standing, prone standing, or supine standing, while the pediatric dynamic stander is a standing device that provides the child with independent mobility.

CMS HCPCS Workgroup Preliminary Decision:
1) To use code E0638.

2) To revise E0638 which currently reads standing frame system, any size, with or without wheels, to instead read: standing frame system, any size, any type, with or without wheels.

E0638 adequately describes standing frames. The descriptor will be revised to add the words "any type", to clarify that the code category is intended to describe the variety of devices on the market. No insurer representative of the CMS HCPS Workgroup identified a national program operating need to alter existing code set to distinguish dynamic and 3-way standers.

Medicare Payment:
Standing frames and standing tables do not meet the definition of DME.

Primary Speaker – Ginny Paleg, P.T., consultant to Snug Seat, disagreed with the preliminary decision. Standers qualify as DME and passive standing is an evidenced based practice for children and adults with gross motor dysfunction. Additionally, there is a programmatic need for unique HCPCS codes in order to reduce claims processing costs to Medicaid programs and to ensure consumer access.
Recommended coding categories:

- Single Position Stander (E0638)—upright, supine or prone.
- Three-way Stander (multi-positional)—upright, supine or prone.
- Mobile—has wheels that child can propel.
- Otherwise not categorized.

Meeting Agenda Item #23
June 23 2005
HCPCS Request #05.92

Background/Discussion:
Sara Christine Oxton of Otto Bock Health Care has submitted a request to establish a code for a wheelchair cushion with phase change materials (PCMs) for skin protection through temperature control, Trade Name: ComforT Cushion. According to the requestor, the ComforT is a wheelchair cushion made with phase change materials for skin protection. The requestor claims that lab studies prove that the ComforT absorbs enough heat to keep the seat interface temperature 10-degrees cooler on average than standard skin protection systems. This cooler temperature blocks moisture formation, which is a key contributor to skin breakdown and pressure sore formation. The PCMs also serve to slow metabolic activity in the seat interface area. The ComforT is used by people whose primary mobility device is a wheelchair. Indications for use include high need for skin protection, or strong propensity toward heat build up while sitting.

CMS HCPCS Workgroup Preliminary Decision: To use existing code K0108 wheelchair component or accessory, not otherwise specified.

The SADMERC is in the process of developing testing standards for adjustable cushions. New codes may be established when the testing criteria is finalized and released. Such codes if established would be available for potential use by all payers. In the meantime, K0108 should be used to identify this item. There is no medical evidence to support a therapeutic distinction based on phase change materials or other heat mitigation factors. No payer has identified a national program operating need to alter the existing code set at this time, to distinguish cushions based on temperature control factors.

Medicare Payment:
Local fee schedule amounts are established by DMERCs for items covered under codes for items not otherwise specified.

There was no Primary Speaker for this item.

Meeting Agenda Item #24
June 23, 2005
HCPCS Request #05.133

Background/Discussion:
Patty Curoe of Medtronic Diabetes submitted a request to establish a code for The Pathway™ Program, separately purchased software that allows patients to upgrade their insulin pumps, rather than purchasing an entirely new pump. Applicant suggests the following language for the requested new code: Exxxx SOFTWARE UPGRADE, EXTERNAL AMBULATORY INFUSION PUMP. According to the requester, Paradigm is software that is used to upgrade existing insulin pumps. This accelerates patient access to ongoing clinical advancements, without incurring repeated pump replacement costs or long delays in technology advances during pump warranty periods. Pathway can be used to update earlier versions of insulin pumps to obtain the calculator feature. In addition, other innovations such as radio frequency transmitted blood glucose values from meters to pumps are available without incurring the full costs of a replacement pump. Future advances that are expected to be a part of Pathway include an upgrade to accept and display real time glucose readings from an external glucose sensor and transmitter.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

This item is considered in-warranty software, and it is not - in and of itself - primarily medical in nature. Code assignment is made by the insurer in whose jurisdiction a claim would be filed. For Medicare, A9270 NON-COVERED ITEM OR SERVICE is the appropriate code. For coding guidance for private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed. No insurer identified a national program operating need for a code to identify this item.

Medicare Payment: This device is not covered.

Primary Speaker – Linda Holtzman, of Clarity Coding, respectfully disagreed with the preliminary decision and asked that a new HCPCS II code be created for the software upgrade for the external ambulatory infusion pump. In summary, Ms. Holtzman offered the following key points:

- Medtronic MiniMed manufactures the external insulin pumps and Pathway software. This software upgrade was created to make new technology available to patients with diabetes.
- Technology continues to evolve and in the past, patients would have to purchase an entire new pump as new technology became available. Now patients can upgrade their pump with the latest technology for a nominal fee compared to a new pump. For example, the Bolus Calculator is now available that provides recommended insulin dosages based on blood sugar level, insulin already taken, and patient food intake.
- Some patients would not be able to afford this technology if they had to purchase an entirely new insulin pump.

- The upgrade is considered medical. It requires a physician prescription and is used only in conjunction with a medical item, ambulatory infusion pumps, and it delivers medical features, such as a bolus calculator.
- Medtronic is the DME supplier for the insulin pump and payers must have a way to accept claims and track utilization via a code.
- Continued growth in pump usage and development of new clinical features adds urgency to the need for a code.

Closing Remarks

In light of new information provided at CMS' HCPCS Public Meetings, the HCPCS workgroup will reconsider its preliminary coding recommendations, CMS staff will reconsider payment methodology recommendations, and the workgroup will formulate its final recommendation. By mid November 2005, the HCPCS workgroup will mail letters to every requestor of its final decision. The 2006 HCPCS Level II Annual Update, including any coding changes, will be effective January 1, 2006, and will be published at: www.cms.hhs.gov/providers/pufdownload/anhcpcdl.asp by mid November, 2005.

Cindy Hake of CMS thanked the participants for their very valuable input at the meeting, and for all the time and effort that was spent on the presentations.

Robin Williams also thanked the audience for their participation, and officially adjourned the meeting.