

**Centers for Medicare & Medicaid Services (CMS)**  
**Summary Report**  
**Durable Medical Equipment (DME) Public Meeting**  
**Wednesday, June 30, 2004**

**Introduction and Overview**

Robin Williams, CMS Office of Operations Management, moderated the meeting. Approximately 45 people attended. The agenda included 15 items.

Cindy Hake provided an overview of the DME 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/default.asp](http://www.cms.hhs.gov/medicare/hcpcs/default.asp).

The DME public meetings meet the BIPA 2000 requirements that CMS permit public consultation for coding and payment determinations for new DME, as explained in the Federal Register Notice published on November 23, 2001. At these meetings, interested parties have the opportunity to make oral presentations and submit written comments regarding coding and pricing recommendations for new DME that have been submitted using the HCPCS coding modification process.

Prior to Public Meetings for new DME, the CMS HCPCS workgroup meets to review the coding requests on the public meeting agenda, and to make a preliminary coding recommendations to the HCPCS National Panel. CMS also makes preliminary recommendations 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 posted on the HCPCS world-wide web site, as part of the DME public meeting agendas.

Following the public meeting, the CMS HCPCS workgroup will use the input heard at the Public Meeting to reconsider its preliminary coding recommendations, and CMS staff will reconsider its pricing recommendations. Afterwards, the workgroup will decide on its recommendations to the HCPCS National Panel. The National Panel, (comprised of the Centers for Medicare & Medicaid Services (representing Medicare and Medicaid), America's Health Insurance Plans and the Blue Cross and Blue Shield Association), is the entity that 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.

Public Meetings for new DME are neither CMS HCPCS workgroup meetings nor HCPCS National Panel meetings. No final decisions are made at the public meetings. All requestors will

be notified in writing, in early November, of the National Panel's final decision regarding the HCPCS code request(s) they submitted.

The process for developing agendas and speaker lists for the DME public meetings, and Guidelines for Proceedings at CMS' Public Meetings for New DME 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.

At the 2004 Public Meetings for new DME, CMM staff 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>.

## **AGENDA ITEM # 1**

Attachment #04.82

Request to establish a code for devices providing Static Progressive Stretch (“SPS”) Trade Name: Joint Active Systems, Inc. (“JAS”).

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To establish a new “E” code.

E???? Multi-directional static progressive stretch shoulder device, with range of motion adjustability, includes cuffs.

**Payment:** Code E???? would fall under the capped rental payment category (HCPCS pricing indicator = 36). If covered, payment would be made on a rental basis. The rental fee schedule amounts would be gap-filled by the DMERCs.

There was no Primary Speaker for this item.

## **AGENDA ITEM # 2**

Attachment #04.119

Request to establish 3 HCPCS codes for (1) portable overhead lifter, (2) portable track system, and (3) sling, trade name: Guardian Voyager System.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To discontinue code E0625 (patient lift, kartop, bathroom or toilet), because the Kartop product is no longer on the market, and establish a new “E” code.

E???? Patient lift, electric, with ceiling track system, portable or fixed.

**Payment:** This item is not covered because it does not meet the definition of durable medical equipment prescribed under the Medicare statute; therefore, no payment determination is necessary.

There was no Primary Speaker for this item.

“5-Minute” Speaker – Jennifer Hutter, Consultant for Sunrise Medical, disagreed with the wording of the proposed code and CMS benefit category determination. She argued for “E” codes; one for a fixed system and one for a portable system. She claimed that the fixed system is for home use, and the portable system is used in facilities. She commented that standard, portable floor lifts are paid for by Medicare, and used for patients who require the assistance of a caregiver, and that her client’s product, an electric ceiling track system, should be coded separately but treated similarly, in terms of coverage and benefit category determination.

### **AGENDA ITEM # 3**

Attachment #04.122

Request to establish a code for a pneumatic compressor unit and various blanket attachments, that deliver heat, cold and compression to various injury sites trade name: ProThermo.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E1399 (durable medical equipment, miscellaneous) for the total system. It is inappropriate to use E0217, E0218, and E0650 for the purpose of billing Medicare. The HCPCS Workgroup would be happy to entertain another request when sales volume increases. There is no Medicare or Medicaid program operating need to institute a national code to identify this product.

**Payment:** If covered, claims for items billed using code E1399 (DME, Miscellaneous) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using E1399. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code E1399 is 46 for “carrier priced.”

Primary Speaker – Tony Quisenberry of ThermoTek, Inc. described the ProThermo product as one that allows heat, cold, compression and contrast therapy in one container, which makes it unique. The blanket is washable and recyclable. He estimated that they have shipped up to 300 units per month.

“5-Minute” Speaker - Deborah Mills, CPT Coding Consultant for Thermotek and ProThermo, discussed the sales volume and stated that there has been a significant increase in the past three to four months, since their application was submitted, primarily in nursing homes and extended care facilities.

### **AGENDA ITEM # 4**

Attachment #04.80

Request to establish a code for a pressure redistribution support surface, trade name: Tempur-Med Therapeutic Mattress.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E0184 dry pressure mattress. Insufficient substantiating, peer reviewed, clinical evidence of a difference in function or patient outcome as a result of use of this device.

**Payment:** Code E0184 falls under the payment category for inexpensive or routinely purchased items (HCPCS pricing indicator = 32). The national, purchase fee schedule ceiling for E0184 is currently \$194.70 and the floor is \$165.50. The national, monthly rental fee schedule ceiling for E0184 is currently \$24.57 and the floor is \$20.88.

Primary Speaker – Rick Fontaine of Tempur Pedic Inc. describes this product as different from any other regular support mattress because of its “peak pressure” pressure management element, which “appears as a solid, but is a fluid”. According to Mr. Fontaine, this system redistributes weight and is equivalent with low air loss mattresses.

“5-Minute” Speaker – Dr. Eric Flan of the University of Medicine and Dentistry, New Jersey studied standard foams and three different TempurPedic materials with an instrument developed under an NIH research grant with sensors embedded at the bony interface. He compared TempurPedic to polyurethane foam. According to Dr. Flan, TempurPedic “behaves like a fluid.” It allows movement, and then stabilizes. It has “fluid-like behavior”, and behaves as if it had a fluid-like component.

#### **AGENDA ITEM # 5**

-Attachment #04.84

Request to establish a code for a chondrogenesis system, Trade Name: BioniCare® Stimulator, Model BIO- 1000™.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E1399 (durable medical equipment, miscellaneous), due to low volume of documented use. Volume has not increased since their 1998 request. Insufficient peer reviewed clinical evidence to substantiate claim of chondrogenesis. There is no Medicare or Medicaid program operating need to institute a national code to identify this product.

**Payment:** If covered, claims for items billed using code E1399 (DME, Miscellaneous) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using E1399. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code E1399 is 46 for “carrier priced.”

-Attachment #04.85

Request to establish a code for replacement supplies for the for BioniCare® Stimulator, Model BIO- 1000™.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code A9999 (miscellaneous DME supply or accessory, not otherwise specified), due to low volume of documented use and insufficient peer reviewed clinical evidence of effect on humans or stimulation of cartilage repair. There is no Medicare or Medicaid program operating need to institute a national code to identify this product or its related replacement components.

**Payment:** If covered, claims for items billed using code A9999 (Miscellaneous DME Supply or Accessory) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded

using A9999. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code A9999 is 46 for “carrier priced.”

-Attachment #04.86

Request to establish a code for a replacement battery for the BioniCare® Stimulator, Model BIO- 1000™.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code A9999 miscellaneous DME supply or accessory, not otherwise specified.

**Payment:** If covered, claims for items billed using code A9999 (Miscellaneous DME Supply or Accessory) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using A9999. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code A9999 is 46 for “carrier priced.”

-Attachment #04.87

Request to establish a code for replacement supplies for a replacement Knee Signal Applicator use with the BioniCare® Stimulator, Model BIO- 1000™.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code A9999 miscellaneous DME supply or accessory, not otherwise specified.

**Payment:** If covered, claims for items billed using code A9999 (Miscellaneous DME Supply or Accessory) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using A9999. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code A9999 is 46 for “carrier priced.”

Primary Speaker – Dr. Thomas Zizic, MD of Johns Hopkins, and President and CEO of Bionicare, stated that the product was launched last fall. In his opinion, there is substantiating evidence supporting the manufacturer’s claim that the product stimulates chondrogenesis. He added that they have shipped 314 of the devices. According to Dr. Zizic, FDA has approved this product for the treatment of osteoarthritis of the knee.

#### **AGENDA ITEM # 6**

Attachment #04.96

Request to establish a code for a radiofrequency signal induction wound closure system, trade name: Provant® Wound Closure System.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: There is no Medicare or Medicaid program operating need to institute a

national code to identify this product. The current volume of use does not justify the administrative burden of instituting a new national code. We will be happy to entertain another application once volume increases. In the meantime, use existing code E1399 (durable medical equipment, miscellaneous).

**Payment:** If covered, claims for items billed using code E1399 (DME, Miscellaneous) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using E1399. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code E1399 is 46 for “carrier priced.”

Primary Speaker – Mary Ritz of Regenesis Biomedical, stated that since the application was submitted, four states have approved use in skilled nursing facilities and for home health. The product can be used by a number of patients in the same facility. Only the infection control cover separately billed. The expectation is that 100 patients will be treated this year. She described the product as one that provides radiofrequency dose controlled signals to speed tissue regeneration/wound healing, which is dose monitored and constantly regulated. She claims that the product is unique because the dosage does not vary and it creates DNA in 8 hours as opposed to 16.

#### **AGENDA ITEM # 7**

Attachment #04.76

Request to establish a code for a cranial electrotherapy stimulation device, trade name: Alpha-Stim 100 and Alpha-Stim SCS.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code A9270 non-covered item or service. Product is statutorily not covered by Medicare as per CIM 35-18. There is no need for a national code for Medicaid.

**Payment:** This item is not covered; therefore, no payment determination is necessary.

There was no Primary Speaker for this item.

#### **AGENDA ITEM # 8**

Attachment #04.70

Request for a code for a heated humidification system for ventilatory and respiratory assist applications, trade name: MR850 Heated Humidification System, and codes for the required system parts used in the initial patient set-up and as replacements.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To revise E0562 which currently reads (humidifier, heated, used with positive airway pressure device), to instead read: Humidifier, heated, non-servo controlled, used with positive airway pressure device or ventilator.

and establish new “E” code:

E????Humidifier heated servo controlled, used with positive airway pressure device or ventilator.

**Payment:** Code E0562 falls under the payment category for inexpensive or routinely purchased items (HCPCS pricing indicator = 32). The national, purchase fee schedule ceiling for E0562 is currently \$301.22 and the floor is \$256.04. The national, monthly rental fee schedule ceiling for E0562 is currently \$30.11 and the floor is \$25.59. Code E???? would fall under the payment category for inexpensive or routinely purchased items (HCPCS pricing indicator = 32). If covered, payment would be made on a rental basis. The rental fee schedule amounts would be gap-filled by the DMERCs.

Primary Speaker – Steve Moore of Fisher & Paykel Healthcare, Inc., agrees with the recommendation to establish a new code, however he requested a description change for A7046 to include “ventilator;” new codes for replacement parts; and a new A code for heated wire circuits.

#### **AGENDA ITEM # 9**

Attachment #04.77

Request to establish a code for a high flow humidification system, trade name: Vapotherm.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E0550 humidifier, durable for extensive supplemental humidification during IPPB treatments or oxygen delivery. CMS HCPCS Workgroup requested literature to substantiate the clinical benefits of the therapy.

**Payment:** Code E0550 falls under the capped rental payment category (HCPCS pricing indicator = 36). The national, monthly rental fee schedule ceiling for E0550 for the first 3 rental months is currently \$50.13 and the floor is \$42.61. The rental fee schedule amounts for months 4 through 15 are reduced by 25 percent.

There was no Primary Speaker for this item.

#### **AGENDA ITEM # 10**

Attachment #04.72

Request to revise the description of code E0454 to include ventilators providing responsive triggering using other technologies in place of flow triggering, trade name: Newport HT50 Ventilator.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To discontinue E0454 (pressure ventilator with pressure control, pressure support and flow triggering features) to revise E0450 which currently reads (volume ventilator, stationary or portable, with backup rate feature, used with invasive interface (e.g. tracheostomy tube) to instead read: Volume control ventilator, without pressure support mode, may include pressure control mode, used with invasive interface (e.g. tracheal tube).

Revise E0461 which currently reads (volume ventilator, stationary or portable, with backup rate feature, used with non-invasive interface), to instead read: Volume control ventilator, without pressure support mode, may include pressure control mode, used with non-invasive interface (e.g. mask).

To establish the following “E” code:

E???1 Pressure support ventilator with volume control mode, may include pressure control mode, used with invasive interface (e.g. tracheal tube).

To establish the following “E” code:

E???2 Pressure support ventilator with volume control mode, may include pressure control mode, used with non-invasive interface (e.g. mask).

Use code E???1 or E???2 to describe the product, whichever is appropriate, depending on whether it is used with an invasive or non-invasive interface.

**Payment:** Proposed codes E???? and E???? would fall under the payment category for items requiring frequent and substantial servicing (HCPCS pricing indicator = 31). If covered, payment would be made on a rental basis. The rental fee schedule amounts would be gap-filled by the DMERCs.

Written comments were received from Jay Nash of Newport Medical Instruments, agreeing with CMS’ preliminary recommendations and in particular, supporting the recommendation to separate ventilators that provide pressure support from those that do not.

“5-Minute” Speaker – Angela King, a neonatal clinician and salaried employee for Pulmonetics, disagrees with the workgroups recommendation and feels the code should include pressure control or flow triggering. She added that most pediatric hospitals utilize pressure control and that flow triggering is the standard of care. She suggested modifiers that would differentiate “invasive” versus “uninvasive” although no such request was submitted to the HCPCS National Panel. She agrees with the recommendations to discontinue E0454 and revise E0461.

“5-Minute” Speaker – Marsha Nusgart supported Angela’s verbiage request and reiterated the point made regarding pressure control working best.

## **AGENDA ITEM # 11**

Attachment #04.92

Request to establish a code for an automatic, self-adjusting sleep apnea breathing therapy device, trade name: AutoSet Spirit™ auto adjusting respiratory device.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E0601 (continuous airway pressure (CPAP) device) which adequately describes this product.

**Payment:** Code E0601 falls under the capped rental payment category (HCPCS pricing indicator = 36). The national, monthly rental fee schedule ceiling for E0601 for the first 3 rental months is currently \$111.71 and the floor is \$94.95. The rental fee schedule amounts for months 4 through 15 are reduced by 25 percent.

#### **AGENDA ITEM # 12**

Attachment #04.93

Request to establish a code for an automatic, self-adjusting sleep apnea breathing therapy device, trade name: GoodKnight® 420 Evolution auto adjusting respiratory device.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E0601 (continuous airway pressure (CPAP) device) which adequately describes this product.

**Payment:** Code E0601 falls under the capped rental payment category (HCPCS pricing indicator = 36). The national, monthly rental fee schedule ceiling for E0601 for the first 3 rental months is currently \$111.71 and the floor is \$94.95. The rental fee schedule amounts for months 4 through 15 are reduced by 25 percent.

#### **AGENDA ITEM # 13**

Attachment #04.94

Request to establish a code for an automatic, self-adjusting sleep apnea breathing therapy device, trade name: DeVilbiss AutoAdjust LT.

**Coding Recommendation:** CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E0601 (continuous airway pressure (CPAP) device) which adequately describes this product.

**Payment:** Code E0601 falls under the capped rental payment category (HCPCS pricing indicator = 36). The national, monthly rental fee schedule ceiling for E0601 for the first 3 rental months is currently \$111.71 and the floor is \$94.95. The rental fee schedule amounts for months 4 through 15 are reduced by 25 percent.

Primary Speaker - for Agenda Item's 11, 12 & 13 Dr. Peter Gay, MD of the Mayo Clinic, Rochester, MN, supported the request for a unique code for Auto CPAP.

“5-Minute” Speaker – James O’Brien, MD, who specializes in sleep disorders, stated that a CPAP is not the same as an APAP. APAP is unique and necessary for some patients. According

to Dr. O’Brien, requirements vary with sleep stages and positions and changes over time, for instance, when alcohol is consumed. He claimed that AutoPap makes sense for patients having difficulty on CPAP and BIPAP.

“5-Minute” Speaker – Steve Stranne yielded his time to the moderator.

## **Closing Remarks**

In light of new information provided at the DME 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 to the HCPCS National Panel. Sometime by November 2004, the HCPCS National Panel will mail letters to every requestor of its final decision. The 2005 HCPCS Level II Annual Update, including any coding changes, will be effective January 1<sup>st</sup> 2005, and will be published at: [www.cms.hhs.gov/providers/pufdownload/anhpcddl.asp](http://www.cms.hhs.gov/providers/pufdownload/anhpcddl.asp).

There are no additional DME Public Meetings scheduled for 2004. The dates of the 2005 Public Meetings have not been established, but will be published in a Federal Register Notice in Spring, 2005.

On September 1, 2004 a special meeting to discuss proposed recommendations on coding and payment for power wheelchairs will be held. This meeting provides a forum for interested parties to hear various proposals presented to CMS regarding changes to wheelchair coding. The meeting will be held in CMS Auditorium from 1:00 p.m. through 5:00 p.m. You can register at [www.cms.hhs.gov/medicare/hcpcs/default.asp](http://www.cms.hhs.gov/medicare/hcpcs/default.asp).

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.