Centers for Medicare & Medicaid Services (CMS)
Summary Report
HCPCS Public Meeting
Tuesday, April 25, 2006

Introduction and Overview

Denise Bailey-Jones, CMS Office of Operations Management, moderated the meeting. Approximately 80 people attended. The agenda included 23 items.

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. The 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://www.cms.hhs.gov/DMEPOSFeeSched/LSDMEPOSFEE/list.asp?filterType=none&filterByDID=0&sortByDID=3&sortOrder=descending.

Cindy Hake provided an overview of the HCPCS public meeting process and the overall HCPCS process.

Prior to Public Meetings, the CMS HCPCS workgroup meets to review the coding requests on the public meeting agenda, and to make a preliminary coding recommendations. CMS also makes preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the HCPCS world-wide web site at: www.cms.hhs.gov/medhcpcsgeninfo, as part of the HCPCS public meeting agendas.

Following the public meeting, the CMS HCPCS workgroup will use the input provided at the Public Meeting to reconsider its preliminary coding recommendations, and CMS staff will reconsider its pricing recommendations. The CMS HCPCS workgroup 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 are not CMS HCPCS workgroup meetings. Final decisions are not made at the public meetings. All requestors will be notified in writing, in November, of the 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 are posted on the official HCPCS

world wide web site at: http://cms.hhs.gov/medhcpcsgeninfo in a document entitled: "Alpha-Numeric HCPCS Coding Recommendation Format. The standard application format for requesting a modification to the HCPCS Level II Coding System, along with instructions for completion and background information regarding the HCPCS Level II coding process is available on the same web site.

Meeting Agenda Item #1
April 25, 2006
HCPCS Request #06.73

Topic/Issue:
Request to establish a code to describe a modular, contoured arm/hand positioning system for use on a wheeled mobility base, trade name: Modular Hand and Channel Forearm Pad System.

Background/Discussion:
According to the requester, this is a modular hand pad and channel forearm pad system consisting of four (4) different hand pads in various sizes and one channel forearm pad in three (3) sizes. This system provides a channel to support and position the patient's forearm, and independently mountable hand pads which attach to the front of the arm channel that support and position the hand. The forearm channels and hand pads are available in various sizes and lengths to fit a wide population of arm lengths, hand sizes and tone (contracture of the hand). The arm/hand pad system design is based on the individual's clinical condition and hand positioning needs to address individualized needs for resting hand positioning support for spasticity and contractures. The four hand pad configurations address the following:
Flat Hand Pad – allows the hand to lay flat with fingers extended.
Palm Extensor Pad – has a mild buildup over the palm for arched hand positioning.
Horn Pad – Raised palmer arch encourages slight supination for tone reduction.
Cone Pad – Build-in cone for individuals with high tone and more involved positioning needs. Encourages supination and external rotation to assist with tone reduction.

The patient's forearm rests in the arm channel. The modular hand pad is attached to the front of the channel forearm pad. This entire arm/hand positioning system is mounted to the wheelchair arm.

CMS HCPCS Workgroup Preliminary Decision:
Revise code E2209 to read: ARM TROUGH, WITH OR WITHOUT HAND SUPPORT, EACH, to clarify the intent that the hand support be included with arm trough. It is inappropriate to use code K0108 or any miscellaneous code to identify this item. No payer identified a national program operating need to isolate hand pads from existing code E2209.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 32

Primary Speaker:
On behalf of Otto Bock, the primary speaker stated that a separate code should be created to describe and reimburse the hand pads separate from the arm troughs. Otto Bock hand pads are intended to support and position the hand and fingers only; and are a separate

support surface from the arm trough, intended to support the arm only from the elbow forward. According to the speaker, the arm and hand troughs are occasionally used separately and independently, and occasionally replaced separately.

Meeting Agenda Item #2
April 25, 2006
HCPCS Request #06.75

Topic/Issue:
Request for CPM therapy device coverage on upper extremity joint procedures, and to establish a code for continuous passive motion (CPM) therapy for all upper extremity joint (shoulder, elbow, wrist, forearm, and hand) injuries/trauma or surgical procedures as prescribed by a physician, trade names: Otto Bock Healthcare's 600 Shoulder CPM, S3 Shoulder CPM, E3 Elbow CPM, PS1 Pronation/Supination CPM, W2 Wrist CPM, and the WaveFlex™ Composite Fist CPM.

Background/Discussion:
According to the requester, CPM devices are electro-mechanical devices which extend, flex, supinate or pronate any given joint through a desired range of motion without active muscle participation on the part of the patient. The devices can be controlled or programmed by the Physician, Therapist, or, under guidance, the patient. CPM units are positioned for the joint and the limb is placed on the CPM device. A programming sequence is entered into an electronic controller, which begins a physician-prescribed set of movements on the joint. The movement of the joint in question by CPM effectively pumps fluid through and away from the area of the joint, preventing further accumulation of edema in the periarticular soft tissue thus preventing the formation of granulation tissue and fibrosis. This edema reduction and fluid movement stimulates the healing and regeneration of articular tissues, as well as preventing joint stiffness which results in increased range of motion. In addition to increased range of motion, CPM has been proven to reduce pain, especially in patients over the age of 60.

CMS HCPCS Workgroup Preliminary Decision:
Establish a code:
Exxxx CONTINUOUS PASSIVE MOTION EXERCISE DEVICE FOR USE OTHER THAN KNEE. Inquiries regarding coverage are not within the purview of the HCPCS code set maintainers, and should be submitted separately to individual insurers. The establishment of a code is not a guarantee of coverage or payment by any insurer.

Medicare Payment: Pricing = 00
This item is not covered by Medicare in accordance with national coverage determination.

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #3
April 25, 2006
HCPCS Request #06.79

Topic/Issue:
Request to establish a code for a wheelchair cushion with phase-change materials (PCMs) for skin protection through temperature control. Trade name: Otto Bock Temperature Management Cushion. Suggested language: "Temperature Management wheelchair cushion with Phase Change Materials, All Sizes"

Background/Discussion:
According to the requester, the OB Temperature Management Cushion is a wheelchair cushion featuring a chemical Phase Change technology to moderate skin temperature at the seat/skin interface. The OB Cushion features a unique Phase Change Material (PCM) – which was designed for NASA – that begins to absorb heat from the seat interface as the PCM approaches body temperature. This phase-change temperature management cushion exchanges enough heat to keep the seat interface temperature 10 degrees cooler on average than other standard skin protection cushions. Low melt-point phase change materials cyclically draw heat from the seat/skin interface as the body temperature rises. In the same way that gases (such as Freon) extract heat from a refrigerator as the gases move from a liquid to a gas, the PCMs in the Otto Bock Temperature Control cushion draw heat from the seat/skin interface. As the patient's body heat changes, the PCMs change from a solid to a liquid. Once heat is removed (when the wheelchair user is no longer sitting on the cushion), the PCM materials cycle back into their original solid form. They are then capable of managing rising body temperatures once again the next time the wheelchair user sits on the cushion.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify temperature management cushions. There is insufficient clinical evidence to substantiate a difference in clinical outcome as a result of use of phase change materials, when compared with non-heat mitigating cushions. For Medicare, use existing code K0669 WHEELCHAIR ACCESSORY, WHEELCHAIR SEAT OR BACK CUSHION, DOES NOT MEET SPECIFIC CODE CRITERIA OR NO WRITTEN CODING VERIFICATION FROM SADMERC. Submit cushion to SADMERC for pressure testing for alternate code assignment that recognizes pressure reduction, for use by Medicare. For coding guidance for private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 32

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #4
April 25, 2006
HCPCS Request #06.149

Topic/Issue:
Request to establish a code for a foot and ankle continuous passive motion (CPM) and continuous active motion (CAM) system, trade names: UltraMotion CPM and Legs Rock & Roll CAM.

Background/Discussion:
According to the requester, the UltraMotion CPM and Legs Rock and Roll CAM are a patented foot and ankle CPM/CAM system. This system has over 140,000 different points of movement per each single orbital revolution. UltraMotion is a continuous passive motion device that incorporates a platform that revolves in an elliptical/orbital motion that the patient places either one or both feet on. It allows for a greater and more consistent stretch of the foot and ankle due to the type of motion and range of motion than in normally achieve through either conventional CPMs or physical therapists. The Legs Rock and Roll CAM is used to reduce ligatures, increase vascular blood flow to lower extremities, reeducate and strengthen his muscles, since this device is used in a seated position. The UltraMotion CPM and Legs Rock and Roll CAM system are used in a seated position and are indicated for patients with replacement ankles, ankle fractures, ankle arthroscopy, ankle ligament/tendon reconstruction foot trauma, fractures of the foot, and trauma to the foot and ankle.

CMS HCPCS Workgroup Preliminary Decision:
Establish a code:
EXXXX CONTINUOUS PASSIVE MOTION EXERCISE DEVICE FOR USE OTHER THAN KNEE. Inquiries regarding and requests for coverage are not within the purview of the HCPCS code set maintainers, and should be submitted separately to individual insurers. The establishment of a code is not a guarantee of coverage or payment by any insurer.

Medicare Payment: Pricing = 00
This item is not covered by Medicare in accordance with national coverage determination.

Primary Speaker:
On behalf of Orbital Industries, the primary speaker agreed with the workgroup preliminary decision to establish a HCPCS code, however the speaker requests that workgroup reconsider its decision to group the ankle CPM with the other multi-planar CPMs and suggests the establishment of a code for a CPM specifically for the ankle, as opposed to “other than knee”.

Meeting Agenda Item #5
April 25, 2006
HCPCS Request #06.68

Topic/Issue:
Request to establish a code to distinguish the Liberty Cane.

Background/Discussion:
According to the requester, the Liberty Cane has been designed and engineered by a daily can user to eliminate the problems associated with all traditional canes available currently. The following features differentiate the Liberty Cane from all other canes:

- Designed for the hand
- Engineered for the body
- The handle design mirrors the inverted shape of the palm of your hand
- Non-slip proven rubber-bottomed foot
- Foot (tip) will not get stuck under self-closing doors
- Assist pin allows user to get up unassisted after a fall
- Greater traction and larger footprint allows user to walk safely over sand, gravel, grass, etc.
- Geometry and balanced weight of the handle stop the Liberty Cane from falling when leaned against anything.
- Allows the user to safely use this product all the time throughout the day as it is user friendly rather than a nuisance
- Front pocket can hold necessities to assist the user with daily activities and/or provide an enhanced level of confidence and safety

According to the requestor, existing codes "refer to the continuum of inexpensive generic canes", whereas the Liberty Cane is substantially higher in price because it is engineered differently, using medically advanced materials.

CMS HCPCS Workgroup Preliminary Decision:
Existing code E0100 CANE, INCLUDES CANES OF ALL MATERIALS, ADJUSTABLE OR FIXED, WITH TIP adequately describes a category of items that serve the same primary function as the Liberty Cane. No payer identified a national program operating need to isolate the Liberty Cane based on the characteristics reported by the applicant.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 32

Primary Speaker:
On behalf of the Coakley Cane Company, the primary speaker disagreed with the workgroup's preliminary decision and requests that the Liberty Cane not be coded under

E0100 with canes that “the world knows as Canes, adjustable/fixed with tip”. The speaker claimed that there is no other assistive cane available for comparison purposes, and requested that the Liberty Cane to be considered on its merits alone. The speaker highlighted product differences, including that the Liberty Cane has a different handle geometry and material, a non-slip rubber tip and an assist pin to aid in getting to a standing position. The speaker also stated that “people who use canes probably fall more than others” and claimed that “the incidence of falls around the home could be dramatically reduced “using the Liberty Cane”.

Meeting Agenda Item #6
April 25, 2006
HCPCS Request #06.116 A&B

Topic/Issue:
Request to establish 2 codes for specialized canes, trade names: Pilot Rolling Cane and Pilot Step-Up Cane.

Background/Discussion:
According to the requester, the Pilot Rolling Cane provides the support of a quad cane with a unique wheeled base, which gives constant ground contact. This allows the patients weight to be continuously applied, improving gait cycle. The rolling cane prevents the patient from having to lift the cane with each step. It is indicated for patients with impaired ambulation. The Pilot Step-Up cane provides the stability of a quad cane with a unique flip-up platform to move and easily step up onto curbs and stairs. According to the applicant, existing code E0105 CANE, QUAD OR THREE PRONG, INCLUDES CANES OF ALL MATERIALS, ADJUSTABLE OR FIXED, WITH TIPS identifies only basic quad canes, without wheels or a platform. Applicant suggests the following language for the 2 requested codes:
EXXXX Cane, quad rolling cane, adjustable, any material, each
EXXXX Cane, includes flip-up platform, any material, each

CMS HCPCS Workgroup Preliminary Decision:
Use existing code E0105 CANE, QUAD OR THREE PRONG, INCLUDES CANES OF ALL MATERIALS, ADJUSTABLE OR FIXED, WITH TIPS. No insurer identified a national program operating need to isolate canes with wheels or flip-up platforms from the category of canes coded at E0105.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 32

Primary Speaker:
On behalf of Full Life Products, the primary speaker stated that both Pilot canes "significantly improve MRADL's"; and are for use for a different patient group than patients who use canes coded at E0105. Specifically, Pilot canes would benefit "patients who cannot use a standard cane". According to the speaker, these canes provide patients the ability to live more independently and safely within their own home, and "delay and possibly prevent patients [from] moving to a walker". The speaker requested reconsideration for both products.

Meeting Agenda Item #7
April 25, 2006
HCPCS Request #06.102

Topic/Issue:
Request to establish three new codes to reflect the three components of the Guardian ® RT Glucose Monitoring System.

Background/Discussion:
According to the requester, the Guardian RT System helps improve diabetes management by continuously monitoring interstitial glucose levels in persons with diabetes mellitus. The system captures ongoing glucose values and displays them in real-time, allowing users to identify cycles of glucose concentrations and to detect episodes of low and high blood glucose. The system alerts the user if a glucose level falls below or rises above preset values. In addition, it stores the glucose value data for download and analysis to track patterns. There are currently no codes to represent this type of continuous glucose monitoring system or its components. Existing S codes are inadequate because they are defined as noninvasive while the Guardian RT sensors are inserted subcutaneously. In addition, existing S codes do not isolate the three components of the Guardian RT System: sensor, transmitter, and monitor. The applicants suggested language for the three new codes requested:
AXXXX Sensor, invasive (eg. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, each
EXXXX Transmitter, external, for use with interstitial continuous glucose monitoring system
EXXXX Monitor, external, for use with interstitial continuous glucose monitoring system

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish codes to identify components of this glucose monitoring system. Applicant did not present clinical evidence demonstrating superior patient outcome as a result of use of this device, when compared with traditional monitoring. For Medicare, there is no benefit category, and code A9270 NON-COVERED ITEM OR SERVICE should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:

On behalf of Medtronic, the primary speaker disagreed with the workgroup's preliminary decision and asks that three new HCPCS level II codes be created for the components of the patient use glucose monitoring system: 1) sensor, 2) transmitter, and 3) monitor. The speaker believes that there is confusion between the predicate physician-based CGM systems and current patient-use CGM. The speaker stated that CGM systems meet CMS' definition of DME and are not described by existing Level II HCPCS codes.

Meeting Agenda Item #8
April 25, 2006
HCPCS Request #06.59

Topic/Issue:
Request to **discontinue** E2101 BLOOD GLUCOSE MONITOR WITH INTEGRATED LANCING/BLOOD SAMPLE.

Background/Discussion:
According to the requester, code E2101 was created and used only to report Abbott's MediSense Sof-Tact device. Abbott has discontinued manufacturing and marketing of the Sof-Tact device, effective June 2004. The applicant believes that maintaining the code could cause confusion among suppliers and providers.

CMS HCPCS Workgroup Preliminary Decision:
Keep existing code E2101 BLOOD GLUCOSE MONITOR WITH INTEGRATED LANCING/BLOOD SAMPLE. There may be other products on the market or potential new market entrants.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product. Pricing = 32

Primary Speaker:
On behalf of Abbott, the primary speaker disagreed with the workgroup's preliminary decision to keep code E2101. The speaker claimed that E2101 was created specifically to identify Abbott's MediSense SofTact blood glucose monitor; and that Abbott has discontinued manufacturing and marketing the Sof-Tact device. The speaker is unaware of any other products that fit into this code and believes that maintaining the code might cause confusion among suppliers and providers. The speaker reiterated her request to discontinue code E2101.

Meeting Agenda Item #9
April 25, 2006
HCPCS Request #06.94

Topic/Issue:
Request to modify the current HCPCS code E0431 (Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing, trade name: HomeFill II. The applicant's suggested language: "Portable gaseous oxygen system, weighing less than 10 pounds, providing a 2 L/min equivalent flow for 4 hours or more, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing."

Background/Discussion:
According to the requester, HomeFill II is an oxygen compressor that allows patients to fill their own oxygen cylinders in their homes. The patient attaches the IOH 200 to an Invacare® Platinum XL Oxygen Concentrator, which provides the oxygen for the cylinders. The IOH 200 takes that oxygen and compresses it into the portable cylinders, which the patient uses when out of the home. While at home the patient receives oxygen from the Oxygen Concentrator and may fill cylinders with the IOH 200 while also drawing oxygen for their own use. The requestor states that the current long description does not set a weight limit on the system being used, nor does it provide for a minimum flow rate and duration, allowing for too much flexibility in interpreting the definition of a "portable gaseous oxygen system".

CMS HCPCS Workgroup Preliminary Decision:
Existing code E0431 PORTABLE GASEOUS OXYGEN SYSTEM, RENTAL; INCLUDES PORTABLE CONTAINER, REGULATOR, FLOWMETER, HUMIDIFIER, CANNULA OR MASK, AND TUBING adequately describes the item that is the subject of this request. No insurer identified a national program operating need to narrow the code descriptor or to isolate products based on weight or flow rate.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 33

Primary Speaker:
On behalf of Invacare Corporation, the primary speaker disagreed with the workgroup's preliminary decision. According to the speaker, the current HCPCS code language for portable oxygen does not define what is truly portable. The speaker stated that portable

can now be defined, according to the medical community, to weigh less than ten pounds, and have at least the equivalent of two liters per minute of continuous flow oxygen for four or more hours. Therefore, Invacare requests that the descriptor of code E0431 be revised: 1) to include weight limit; 2) to describe minimum liter flow rate and duration; and 3)to describe payment method as “rental”.

Meeting Agenda Item #10
April 25, 2006
HCPCS Request #06.133

Topic/Issue:
Request to establish a new code for an aerosol nebulizer, trade name: AeroTech™ II Aerosol Delivery System.

Background/Discussion:
According to the requester, the AeroTech II is a single patient use, disposable hand held nebulization device. It is designed for a single-dose delivery of viscous medications, specifically PULMINIQ™, Chiron Pharmaceuticals, Inc. grand of cyclosporine and must be disposed of immediately after use. The AeroTech II nebulizer is a specialty small particle, high output pneumatic filtered nebulizer. It incorporates a high efficiency baffling system; a closed system, dual valve mechanism for controlled inhalation and medication output and a HEPA filtered exhalation port that prevents medication and exhaled gas from entering the ambient air. The most common aerosolized drugs are normally administered with a simple nebulizer/compressor device as described by A7003 (administration set, with small volume nonfiltered pneumatic nebulizer, disposable) and E0570 (nebulizer, with compressor). The applicant suggested the following language for the requested code:
AXXXX Administration set, with small volume pneumatic nebulizer with a dual valve mechanism for controlled inhalation and medication output and a HEPA filtered exhalation port for use with inhaled cyclosporines.

CMS HCPCS Workgroup Preliminary Decision:
Existing code A7006 ADMINISTRATION SET, WITH SMALL VOLUME FILTERED PNEUMATIC NEBULIZER adequately describes the item that is the subject of this request. A7006 does not distinguish between disposable and reusable, and therefore may be used to identify either. Use of other codes, including miscellaneous codes, is inappropriate.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 32

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #11
April 25, 2006
HCPCS Request #06.42

Topic/Issue:
Request to establish a code for an integrated wheelchair handrim assembly, trade name: Natural-Fit™.

Background/Discussion:
According to the requester, the Natural-Fit is ergonomically designed to fit the hand, to relieve stress on the hands and wrists during the repetitive strain of manual wheelchair propulsion, and to reduce pain associated with Carpal Tunnel Syndrome (CTS). The intended population is manual wheelchair users who report CTS – related pain in the hand and wrist. Currently, wheelchair handrims are identified using E2205 MANUAL WHEELCHAIR ACCESSORY, HANDRIM WITHOUT PROJECTIONS, ANY TYPE, REPLACEMENT ONLY, EACH. This describes an accessory for a manual wheelchair used for mobility because of lower extremity impairment. Handrims included in E2205 do not treat pain associated with CTS. Instead, the pinch grip required by the small tube of E2205 coded handrims exacerbates CTS-related pain. Thus, the applicant feels that the E2205 descriptor is overly broad and fails to recognize the different functions that handrims serve for different sub-populations such as those experiencing CTS. The applicants suggested language for the new code is "Manual wheelchair accessory, integrated two-piece handrim system; contoured thumb slot and contoured oval".

CMS HCPCS Workgroup Preliminary Decision:
Use existing code E2205 MANUAL WHEELCHAIR ACCESSORY, HANDRIM WITHOUT PROJECTIONS, ANY TYPE, REPLACEMENT ONLY, EACH. This code adequately describes a category of wheelchair handrims which perform a function similar to the Natural Fit product. The function of all manual wheelchair handrims is to provide and accessory attachment to the wheel for hands to grip when propelling a manual wheelchair. New information submitted with application this year includes a Natural Fit customer opinion survey. Applicant has not provided scientific evidence published in peer-reviewed medical journals to substantiate claim of improved clinical outcomes for a particular patient population when the Natural Fit handrim is used, compared with other wheelchair handrims coded at E2205.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 32

Primary Speaker:

On behalf of Three Rivers Holdings, the speaker disagreed with the workgroup's preliminary decision. The speaker claimed that the Natural Fit handrim warrants a new HCPCS code because it is:

- "technologically unique as an integrated two-piece, dual surface assembly";
- "therapeutically unique as a treatment for Carpal Tunnel Syndrome (CTS)";
- "functionally unique through an ergonomic design that changes how one grips, pushes, and brakes on the handrim"; and
- "backed by peer-reviewed evidence that supports its functional and therapeutic distinction from E2205 handrims".

Meeting Agenda Item #12
April 25, 2006
HCPCS Request #06.49

Topic/Issue:
Request to revise verbiage of existing code E0986 MANUAL WHEELCHAIR ACCESSORY, PUSH ACTIVATED POWER ASSIST, EACH to add "non-programmable;" and establish a new code for a programmable power-assist for manual wheelchairs, trade name: E-motion M12. Applicant's suggested language for the new code**:** EXXXX – "Manual wheelchair accessory, push activated power assist, programmable control parameters for power, acceleration control and glide time, each," to distinguish products based on whether the therapist or end-user has programming options.

Background/Discussion:
According to the requester, the products described by E0986 are non-programmable. These power assist products are pre-programmed by the manufacturer, and do not allow the end user any programmability of the power levels. The submitter is requesting that a new code be established to identify a push-activated power assist that is programmable.

CMS HCPCS Workgroup Preliminary Decision:
Use existing code E0986 MANUAL WHEELCHAIR ACCESSORY, PUSH ACTIVATED POWER ASSIST, EACH. E0986 includes programmable and non-programmable devices, and adequately describes this product. In fact, the item that is the subject of this request is a predicate product for the establishment of code E0986. Use of K0108 or miscellaneous codes is inappropriate.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product. Pricing = 32

Primary Speaker:
On behalf of Frank Mobility Systems, the speaker disagreed with the workgroup's preliminary decision. The speaker believes that programmable and non-programmable should be differentiated for manual wheelchairs as it is for power wheelchairs. The speaker reiterated the original request to revise code E0986 Manual wheelchair accessory, push activated power assist, each; to add "non-programmable"; and establish a new code: "Manual wheelchair accessory, push activated power assist, programmable parameters (power control, acceleration control and glide time), each".

Meeting Agenda Item #13
April 25, 2006
HCPCS Request #06.113

Topic/Issue:
Request to establish a new code for a power add-on to a wheelchair, trade name: Viamobil.

Background/Discussion:
According to the requester, the Viamobil takes on the work of pushing uphill and braking downhill for the caregiver. It can be fitted to practically every wheelchair. The electric unit sits under the seat and is held by two quick-lock devices. The drive unit is lifted and lowered at the press of a button on the control unit making it easy to take on and off the wheelchair. The Viamobil operates using a control unit. The direction of travel is selected at the press of a button and is within easy reach while driving. Speed levels are adjusted through the dial switch located on the side of the control unit. Companions have complete control of the Viamobil at all times. There is no existing code that distinguishes a caregiver operated power add-on to a manual wheelchair. The applicant is requesting the creation of a new code as follows: EXXXX Manual wheelchair accessory, power-assist add-on, caregiver operated.

CMS HCPCS Workgroup Preliminary Decision:
This is a convenience item for use by caregiver. No insurer identified a national program operating need to establish a code to identify this product. For Medicare, there is no benefit category, and code A9270 NON-COVERED ITEM OR SERVICE should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #14
April 25, 2006
HCPCS Request #06.111

Topic/Issue:
Request to establish a new code for a footrest retractor, trade name: Wheelchair Footrest Retractor. The suggested language is "WHEELCHAIR ACCESSORY, FOOTREST RETRACTOR"

Background/Discussion:
According to the requester, the wheelchair footrest retractor is a wheelchair footplate positioning device that is medically necessary because it provides significant safety, independence and infection control benefits to wheelchair users by allowing them to raise or lower common flip up type footplates from operating handles near the brakes, thus solving several common problems. There are currently no HCPCS codes that cover this product.

CMS HCPCS Workgroup Preliminary Decision:
This is a convenience item. No insurer identified a national program operating need to establish a code to identify this product. For Medicare, there is no benefit category, and code A9270 NON-COVERED ITEM OR SERVICE should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Assistance Products, LP, the primary speaker disagreed with the workgroup's preliminary decision that this product is a convenience item. The speaker stated that the wheelchair footrest retractor is the only product on the market that allows patients to raise and lower the footplates on their wheelchair without reaching down to them. In addition, the speaker believes that the footrest retractor falls into the same category as brake handle extensions and "makes possible the safe use" of a medically necessary device, and therefore should be covered. According to the speaker, this device is "particularly beneficial" to patients under bending restrictions and unable to move the footplates, and others who cannot manipulate break extensions or footrest retractors.

Meeting Agenda Item #15
April 25, 2006
HCPCS Request #06.128

Topic/Issue:
Request to establish a new code for a wheelchair accessory designed to backup OEM brakes, trade name: Brakebuddy.

Background/Discussion:
According to the requester, the WC Brakebuddy is an accessory to manual wheelchairs designed to backup OEM brakes. The product is a solid steel device that is completely independent of the OEM brakes. The product does not restrict the wheelchair from normal everyday use. There are no protrusions or appendages on the WC Brakebuddy that would prevent equipped chairs from conventional travel. Chairs equipped with the WC Brakebuddy preserve all of the traveling capabilities provided by OEM chairs. WC Brakebuddy equipped wheelchairs can still be folded for travel or storage. Manual wheelchairs equipped with the WC Brakebuddy provide extra safety while maintaining the versatility of the wheelchair. The Brakebuddy requires minimal user interaction. The brake system will disengage when pressure is applied to the seat of the manual wheelchair, and the brake will engage as pressure is removed from the seat. The WC Brakebuddy is all-inclusive and ready for installation. The solid steel mechanism is pre-assembled and is prepped for manual wheelchairs as a bolt-on application.

CMS HCPCS Workgroup Preliminary Decision:
Use existing code K0108 WHEELCHAIR COMPONENT OR ACCESSORY, NOT OTHERWISE SPECIFIED. No insurer identified a national program operating need to establish a unique code to separately identify this product.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 46

Primary Speaker:
On behalf of WC-Brakebuddy, the primary speaker stated that DME dealers do not want to manually process paperwork for the Brake Buddy. According to the speaker, the Brake Buddy helps prevent falls and therefore saves overall program expense, however, patients do not have access to the Brakebuddy because suppliers won't provide it without a distinct code.

Meeting Agenda Item #16
April 25, 2006
HCPCS Request #06.23

Topic/Issue:
Request to establish a code for self adjusting sleep apnea system, trade name: ResMed S8 AutoSet Advantage.

Background/Discussion:
According to the requester, select payers consider APAP technology medically necessary as a second or third line alternative therapy for obstructive sleep apnea when documentation of failed CPAP is an issue. Patients may experience difficulty in using positive pressure therapy if the pressure is equal to or greater than 10cms of H20 as evidenced by an in lab technician attended CPAP titration during polysomnography. Also if the patient is intolerant of high fixed CPAP pressures despite appropriate patient education and interventions to improve comfort and compliance, APAP may be deemed medically necessary. APAP addresses issues such as positional and sleep stage induced apneas. The technology has also been reviewed as appropriate for pre and post management of bariatrics patients where dramatic changes in weight over time have a profound effect on the pressure needs of the patient once looking at long-term compliance and providing efficacious therapy to offset complications associated with apneaic patient.

CMS HCPCS Workgroup Preliminary Decision:
Existing code E0601 CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) DEVICE adequately describes a category of items by that perform the same or similar function as the item in this request. Clinical information included with this application does not demonstrate a superior clinical patient outcome when this device is used, when compared with other CPAP devices categorized at code E0601.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 36

Primary Speaker:
On behalf of ResMed, the speaker requests that the workgroup establish a unique code for auto adjusting sleep apnea (APAP) systems. The speaker stated that a unique HCPCS code will enable tracking of utilization and outcomes and enable doctors to order APAP tied to a specific reimbursement code. According to the speaker, key physician and patient groups support the request for a HCPCS code, and clinical data confirms previous findings in terms of patient preference and compliance.

Meeting Agenda Item #17
April 25, 2006
HCPCS Request #06.25

Topic/Issue:
Request to establish a code for a replacement tubing deflector for a CPAP nasal application device. The proposed language for this code is as follows:
"Tubing deflector, hose guide or elbow, for CPAP".

Background/Discussion:
According to the requester, the tubing deflector is a unique component of the nasal application device (mask or pillow type, HCPCS code A7034) for a positive airway pressure device. the tubing deflector is a rigid support that directs or angles the CPAP tubing away from the patient's body so it stays open while the patient is in sleeping positions. Tubing deflectors include both hose guides and elbow assemblies, and are individually replaceable components of the nasal application device. The addition of a unique code for a replacement tubing deflector would allow medical equipment suppliers to replace this individual component of the nasal application devices and avoid the cost of replacing the complete nasal application device, when replacement of an individual component would suffice.

CMS HCPCS Workgroup Preliminary Decision:
This item is a component of A7034 NASAL INTERFACE (MASK OR CANNULA TYPE) USED WITH POSITIVE AIRWAY PRESSURE DEVICE, WITH OR WITHOUT HEAD STRAP. It may be identified using A9900 MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE. It is not separately payable. Use of other miscellaneous codes is inappropriate. No insurer identified a national program operating need to establish a code to separately identify the item that is the subject of this request.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 32

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #18
April 25, 2006
HCPCS Request #06.26

Topic/Issue:
Request to establish a new code to describe a replacement shell for a CPAP nasal application device, trade name: Breeze Nasal Pillows Shell; DreamSeal Shell. Recommended language – AXXXX – "Shell for CPAP Interface, Replacement"

Background/Discussion:
According to the requester, the shell is a unique component of the nasal application device (mask or pillows type, HCPCS code A7034) for a positive airway pressure device. The shell is the hard plastic frame that provides rigid support for the seal (mask or nasal pillows type) and is an individually replaceable component of the nasal application device. The addition of a unique code for a replacement shell would allow replacement of this individual component of the nasal application devices and avoid the cost of replacing the complete nasal application device when replacement of an individual component would suffice.

CMS HCPCS Workgroup Preliminary Decision:
This item is a component of A7034 NASAL INTERFACE (MASK OR CANNULA TYPE) USED WITH POSITIVE AIRWAY PRESSURE DEVICE, WITH OR WITHOUT HEAD STRAP. It may be identified using A9900 MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE. It is not separately payable. Use of other miscellaneous codes is inappropriate. No insurer identified a national program operating need to establish a code to separately identify the item that is the subject of this request.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product. Pricing = 32

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #19
April 25, 2006
HCPCS Request #06.15

Topic/Issue:
Request to establish 3 codes for a mechanical intermittent compression system, disposable sleeves, and replacement battery, trade name: **A)** FlowMedic™ FM220 Intermittent Compression system Control Unit, **B)** FlowMedic FM220 Intermittent Compression System Disposable Sleeve, and **C)** FM220 Battery Replacement.

Background/Discussion:
According to the requester, the FlowMedic model FM220 is a mechanical, battery operated portable system for improving blood flow in the lower limbs through the application of pulsed compressions to the calf. The FlowMedic FM220 system combines a portable, reusable control unit with a charging adaptor for use with a disposable FM220 sleeve. The device is externally mounted by attaching it to a detachable disposable sleeve wrapped on the calf and then securing it with Velco straps. The device pulls and releases the straps periodically, thus stretching and releasing the sleeve on the limb. The applicant requested the following language:
E06XX Intermittent compression device, mechanical, for arterial insufficiency
E06XY Mechanical compression device sleeve, disposable, four sleeves, per month
E06XZ Battery, replacement, for mechanical compression device

CMS HCPCS Workgroup Preliminary Decision:
Establish code: Exxxx INTERMITTENT LIMB COMPRESSION DEVICE (INCLUDES ALL ACCESSORIES), NOT OTHERWISE SPECIFIED

Medicare Payment: Pricing = 00
This item is not covered by Medicare.

Primary Speaker:
On behalf of FlowMedic Inc., the speaker disagreed with the workgroup's preliminary decision that the FM220 sleeves should be wrapped into the code description for the base unit rather than be coded separately for the following reason:

- The FM220 Disposable Sleeve is not an optional accessory; it is essential to the operation of the device; the control unit cannot operate independently, however, the sleeves should be coded separately because it is difficult to anticipate the number of sleeves the patient will need in advance so there cannot be a consist "capture" of the number of sleeves acquired with a device by a combined code. A unique code, separate from the device code for sleeves is desired, at least for replacement sleeves.

FlowMedic reiterated its original request for 3 new codes; one for the compression system; one for disposable sleeves; and one for a replacement battery, and asked that the language for the device and sleeves specify "intermittent, non-pneumatic".

Meeting Agenda Item #20
April 25, 2006
HCPCS Request #06.151

Topic/Issue:
Request to establish a code for a Portable Pneumatic Hand-Pump Lumbar Traction Device, trade name: Homestretch.

Background/Discussion:
According to the requester, the Homestretch is a portable, pneumatic powered lumbar traction device designed for use in the clinic or home. It consists of a traction bed, an air pressure hand pump, 2 straps (lumbar & chest), carrying case, a copy of "You Back for Life" book, and instruction manual. The patient uses it by lying on the bed with legs bent in a 90/90 angle. The chest and lumbar belts are applied tightly and the lumbar belt is attached to an extension bar at the end of the bed. A hand pump is utilized to pump up the device, thereby extending the bar and applying traction to the low back. Patients have total control over the amount of traction applied. A pressure release valve is opened to release the pressure. Traction can only be applied if the patient is completely relaxed. As the patient feels a slight stretch in the back they must discontinue inflating the unit until the muscles completely relax and they no longer feel a stretch. They can then continue pumping the hand pump and start over again per instructed by a physician. According to the applicant, code E0947 "Fracture frame, attachments for complex pelvic traction" has been used for years, but does not adequately describe the Homestretch device.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this item. It is not primarily medical in nature. And, there is no way to regulate therapeutic application. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #21
April 25, 2006
HCPCS Request #06.152

Topic/Issue:
Request for reclassification of the code assigned or establish a new code for a Portable Cervical Traction Device, trade name: Pronex. The current code E0855 "Cervical traction equipment not requiring additional stand or frame" is no longer the closest description because of improvements over the years. The applicant suggests that the Pronex is now adequately described by E0849 "Traction equipment, cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible".

Background/Discussion:
According to the requester, the Pronex is a pneumatic cervical traction device that weighs 5 lbs and contains a lightweight carrying case, headstrap, flexion wedge, and instruction manual. It is available in 3 different sizes based on the circumference of the patient's neck. Pronex cradles the reclining patient's head and neck on two soft foam cushions. One cushion supports the occiput and the other rests against the upper trapezious. An air-inflated bellows between them provides up to 35 pounds of continuously adjustable traction. Pronex, pneumatic powered cervical traction device provides static and/or intermittent traction while supporting the natural curve of the cervical spine. It can be used in the home or in a clinical setting. Glacier Cross is requesting that a new code be given to the Pronex. The code E0855 no longer adequately describes the Pronex due to improvement of the device. A flexion wedge has been added to provide optional flexion treatment to patients. The Pronex has also been professionally engineered to provide up to 35 lbs of traction. There has been confusion in the marketplace as to which code to bill the Pronex since these changes have been made.

CMS HCPCS Workgroup Preliminary Decision:
The Pronex is adequately described by existing code E0855 "CERVICAL TRACTION EQUIPMENT NOT REQUIRING ADDITIONAL STAND OR FRAME". It is inappropriate to bill E0849 "TRACTION EQUIPMENT, CERVICAL, FREE-STANDING STAND/FRAME, PNEUMATIC, APPLYING TRACTION FORCE TO OTHER THAN MANDIBLE", and does not meet the definition of code E0849.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 32

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #22
April 25, 2006
HCPCS Request #06.80

Topic/Issue:
Request to establish three codes for a bariatric mattress replacement system, trade name: ULTRA-CARE XTRA.

Background/Discussion:
According to the requester, the Ultra-Care Xtra system provides pressure relief for patients up to 1000 pounds. The system comes in three sizes; 39 inch, 42 inch and 48 inch. Due to the fact that bariatric patients require deeper air cell support, the mattress is ten inches deep providing additional support to the patient. The low air loss therapy replacement mattress has a patented cell-in-cell design that allows the inflation and deflation of air cells to be achieved in the shortest amount of time while providing good pressure relief. This design also reduces the risk of bottoming out when the bed is articulated. The inner cell also offers a sufficient weight support during a power failure. The existing code E0277 (powered pressure-reducing air mattress) identifies the standard size low air loss mattress. Pyramid Industries is requesting three similar codes for the bariatric population, which would mirror the codes for the heavy duty hospital beds.
Applicant's suggested language:
EXXXX Powered pressure-reducing air mattress, heavy duty, with a weight capacity greater than 350 pounds, but less than or equal to 650 pounds
EXXXX Powered pressure-reducing air mattress, heavy duty, extra wide, with a weight capacity greater than 650 pounds, but less than or equal to 750 pounds
EXXXX Powered pressure-reducing air mattress, extra heavy duty, extra wide, with a weight capacity greater than 750 pounds, but less than or equal to 1000 pounds

CMS HCPCS Workgroup Preliminary Decision:
Existing code E0277 POWERED PRESSURE-REDUCING AIR MATTRESS adequately describes a category of items that perform the same function. No payer identified a national program operating need to differentiate based on patient size or weight.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 36

Primary Speaker:
On behalf of Pyramid Industries, the primary speaker disagreed with the workgroup's preliminary decision and respectfully requested that the workgroup establish new codes for bariatric powered alternating low air loss mattress replacement systems. According to the speaker, these items have different clinical indications for obese patients than the other powered, pressure-reducing air mattresses described by existing code E0277. In

addition, the speaker claimed that patients on equipment that is too narrow are more prone to skin ulcers. The speaker stated that previous Medicare decisions "to cover other obese problems, for example, gastric bypass surgery" sets a precedent for distinct coding for other bariatric items, specifically, hospital beds.

Meeting Agenda Item #23
April 25, 2006
HCPCS Request #06.110

Topic/Issue:

Request to establish three new codes for negative pressure wound therapy (NPWT) pumps, canisters and dressings which provide wound site pressure feedback. Applicant's suggested codes and language are as follows:
EXXXX Negative pressure wound therapy electrical pump with wound site pressure feedback, stationary or portable
AXXXX Canister set with isolyzer gel for use with negative pressure wound therapy electrical pump with wound site pressure feedback.
AXXXX Foam dressing set, any size or shape, for use with negative pressure wound therapy electrical pump with wound site pressure feedback.

Background/Discussion:

According to the requester, although these products are currently classified under existing NPWT codes, other products recently assigned to those codes are so different in design, function, benefits, and costs from products listed in this application, that coding differentiation is required. The improved efficacy of these products is reflected in the strengthening of the 2003 FDA clearance language going from "may promote wound healing" to "help promote wound healing: with Wound Site Pressure Feedback (WSPF). Neither the position of the unit in relation to the wound nor patient movement prevents the NPWT pump with WSPF from providing the prescribed range of negative pressure. These pumps also sense and alarm while canisters are full or when tubing is blocked. WSPF requires tubing with double lumen: one to draw fluid and other materials away from the wound, and the other to monitor and send pressure readings from the wound site through the dressing and canister back to the pump. Only foam dressings can be used with pumps providing WSPF because of the hydrophobic properties of foam and because the foam is still 80% air when compressed.

CMS HCPCS Workgroup Preliminary Decision:

Existing code E2402 NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE adequately identifies the NPWT pump. This product is the predicate product for the original establishment of E2402. Alterations to accommodate WSPF do not alter the primary function of the device. Applicant did not provide scientific evidence demonstrating a difference in clinical outcome. Existing code A7000 CANISTER, DISPOSABLE, USED WITH SUCTION PUMP, EACH adequately identifies the canister set. The added tube and sensor does not alter the primary function of the product. Existing code A6550 WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES AND ACCESSORIES adequately identifies the dressing/wound care set, including foam products.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 36/32/34

Primary Speaker:
There was no Primary Speaker for this item.

PAYMENT FOR DMEPOS

DMEPOS

The term DMEPOS, which stands for durable medical equipment (DME), prosthetics, orthotics and supplies, is used in the Medicare program to describe a set of Medicare Part B device and supply benefits for which claims are processed by four DME Regional Carriers (DMERCs). The Part B device benefits covered by this term include:

- DME – equipment used in the home which can withstand repeated use, is primarily and customarily used to serve a medical purpose, and is generally not useful in the absence of an illness or injury;
- Prosthetic Devices – devices that replace all or part of an internal body organ, including ostomy, tracheostomy and urological supplies, parenteral and enteral nutrients, equipment and supplies (PEN), intraocular lenses (IOLs), and one pair of conventional eyeglasses or contact lenses after each cataract surgery;
- Prosthetics – artificial legs, arms, and eyes;
- Orthotics – rigid or semi-rigid leg, arm, back, and neck braces;
- Home Dialysis Supplies and Equipment
- Surgical Dressings
- Therapeutic Shoes and Inserts

Depending on the item or the setting in which the item is furnished, Medicare claims for some of these items may also be processed by local carriers and fiscal intermediaries (e.g., claims for DME implanted in an ambulatory surgical center are processed by local carriers). Claims for DME and ostomy, tracheostomy and urological supplies furnished by a home health agency are processed by Regional Home Health Intermediaries (RHHIs).

Fee Schedule Payments

Prior to January 1, 1989, payment for most DMEPOS items and services was made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment is still made on a reasonable charge basis for home dialysis supplies and equipment and for IOLs inserted in a physician's office. There is a monthly limit per beneficiary on payments for home dialysis supplies and equipment. Payment for most of the other DMEPOS items and services is based on the lower of the actual charge for the item or a fee schedule amount. The Part

B deductible and 20 percent coinsurance both apply to the DMEPOS items and services described above.

The Social Security Act requires that the DMEPOS fee schedule amounts be established based on average reasonable charges made during a base period (e.g., July 1, 1986 thru June 30, 1987 for prosthetic devices, prosthetics and orthotics). The fee schedule amounts are increased by annual update factors. Because the reasonable charge data required by the law in establishing fee schedule amounts does not exist for new DMEPOS items, the fee schedule amounts for new DMEPOS items are "gap-filled" using fees for comparable items, supplier price lists, manufacturer suggested retail prices, or wholesale prices plus a markup. The gap-filling methodology is used to estimate the average reasonable charge for the item from the base period.

DMEPOS Payment Categories/HCPCS Pricing Indicators

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicators in the HCPCS identify which major payment category a code falls under. The pricing indicators applicable to DMEPOS are as follows:

- **Pricing = 00 Service Not Separately Priced**
  Items or services described by the HCPCS codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

- **Pricing = 31 Frequently Serviced Items**
  Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health.

- **Pricing = 32 Inexpensive and Other Routinely Purchased Items**
  Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of $150 or less, are generally purchased 75 percent of the time or more, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or intermittent assist device with continuous airway pressure device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

- **Pricing = 33 Oxygen and Oxygen Equipment**
  Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. An additional payment is made for those beneficiaries who require portable oxygen. The beneficiary takes over ownership of the equipment after the 36th monthly payment is made, after which payment for delivery of contents continues for patient owned gaseous or liquid systems.

- **Pricing = 34 Supplies Necessary for the Effective Use of DME**
  Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

- **Pricing = 35 Surgical Dressings**
  Payment is made on a purchase fee schedule basis for surgical dressings.

- **Pricing = 36 Capped Rental Items**
  Payment is made on a monthly rental fee schedule basis. For items furnished on or after January 1, 2006, the beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. Power wheelchairs can be purchased in the first month.

- **Pricing = 37 Ostomy, Tracheostomy and Urological Supplies**
  Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

- **Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)**
  Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

- **Pricing = 39 Parenteral and Enteral Nutrition (PEN)**
  Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

- **Pricing = 45 Customized DME**
  Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The

payment amount is based on the carrier's individual consideration of the item.

- **Pricing = 46 Carrier Priced Item**
  For items falling under codes for miscellaneous or not otherwise classified items, the fee schedule or reasonable charge payment amount, whichever is applicable, is based on the carrier's individual consideration of the item.

- **Pricing = 52 Reasonable Charges**
  Payment continues to be made on a reasonable charge basis in accordance with Medicare regulations at 42 CFR 405.500 for splints, casts, and other devices used to reduce a fracture or dislocation, dialysis supplies and equipment, and intraocular lenses (IOLs) inserted in physician's offices.