Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Durable Medical Equipment (DME)-Day 1
Wednesday, May 28, 2008

Introduction and Overview

Approximately 60 people attended. The agenda included 17 items.

Joel Kaiser of CMM presented an educational overview of the 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 and is also attached to this summary. For additional information, the DME payment rules are located at Section 1834 (a) of the Social Security Act. The Medicare fee schedule for DME, Prosthetics, Orthotics and Supplies, and background information, can be accessed and downloaded free of charge at: www.cms.hhs.gov/feeschedulegeninfo.

Cindy Hake provided an overview of the HCPCS public meeting process as it relates to the overall HCPCS coding process.

Prior to the Public Meetings, CMS HCPCS workgroup meets to review all HCPCS code applications, and to make 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 website at: www.cms.hhs.gov/medhcpcsgeninfo, as part of the HCPCS public meeting agendas.

Following the public meetings, CMS HCPCS workgroup reconvenes, and considers all the input provided at the Public Meetings regarding its preliminary coding recommendations. CMS also reconsiders its Medicare payment 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.

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

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/downloads/2008guidelines.pdf . 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 at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/2009_alpha.pdf. A decision tree, outlining CMS' decision-making criteria is also available at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/decisiontree.pdf.

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Durable Medical Equipment (DME)
Wednesday, May 28, 2008, 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

8:15 a.m. Arrival and sign-in

9:00 a.m. Welcome
Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS's preliminary coding decision is provided. An overview of Medicare pricing/payment methodology is also attached to this agenda. Preliminary decisions are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about the agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

AGENDA ITEM #1
Attachment #08.105
Request to establish a code for: 1) a fixed-power output radio frequency generator and transmitter, trade name: Provant Wound Therapy System and 2) disposable applicator pad cover.

Primary Speaker: Dr. Rick Isenberg of Regenesis Biomedical, Inc.

AGENDA ITEM #2
Attachment #08.41
Request to establish 7 codes to, identify an external functional neuromuscular stimulator and components, trade names: 1) WalkAide System patient kit; 2) WalkAide Control Unit; 3) WalkAide Electrode Lead Cable; 4) WalkAide System Cuff; 5) WalkAide System Electrodes® (pkg.4); 6) WalkAide System Electrodes® (case); 7) WalkAide System Patient Foot Sensor.

Primary Speaker: Dr. Conrad Kufta of Innovative Neurotronics, Inc.

AGENDA ITEM #3
Attachment #08.108
Request to establish two new codes: one for a digitally controlled acoustic airway clearance device, and a second code for the adapter ring with filter, used with this device, Trade Name: The Frequencer™.

Primary Speaker: Jean Bigoney of Springfield Metallurgical Services, Inc.

AGENDA ITEM #4
Attachment #08.71
Request to establish 3 codes for pneumatic compression appliances for the trunk or chest, trade name: Flexitouch® Chest Garment, and Flexitouch® Trunk Garment (lower and upper extremity).

Primary Speaker: Maggie Thompson of Tactile Systems Technology, Inc.

AGENDA ITEM #5
Attachment #08.20
Request to establish a code for a Wheeled Cart with Handle used with portable oxygen concentrators also know as OGPE (oxygen generating portable equipment), trade name: Eclipse Wheeled Cart with Handle.

Attachment #08.21
Request to establish a code for battery cartridges or battery packs used with portable oxygen concentrators also know as OGPE (oxygen generating portable equipment), trade name: Eclipse Battery Cartridge, 195 watt – hour

Attachment #08.22
Request to establish a code for a Desktop Battery Charger used with portable oxygen concentrators also know as OGPE (oxygen generating portable equipment, trade name: Eclipse Desktop Battery Charger with power cord.

Attachment #08.23
Request to establish a code for a DC Power Supply used with portable oxygen concentrators also know as OGPE (oxygen generating portable equipment, trade name: Eclipse DC Power Supply with outlet adaptor.

Primary Speaker: Ron Richard of Sequal Technologies, Inc.

AGENDA ITEM #6
Attachment #08.112
Request to modify the description of E1392 for portable oxygen concentrators (POC), trade name: Eclipse® Oxygen System.

Primary Speaker: Patrick Dunne of Healthcare Productions, Inc.

AGENDA ITEM #7
Attachment #08.107
Request to modify code E1392 for portable oxygen concentrators (POC), trade name: Invacare® XPO2™ Portable Oxygen Concentrator.

Primary Speaker: Cara Bachenheimer of Invacare, Inc.

AGENDA ITEM #8
Attachment #08.30
Request to establish a code for a transfilling oxygen concentrator system, trade name: Invacare HomeFill System.

Primary Speaker: Cara Bachenheimer of Invacare, Inc.

AGENDA ITEM #9
Attachment #08.86
Request to revise the verbiage of code E1392 for portable oxygen concentrators, trade name: Inogen One Portable Oxygen Concentrator (POC).

Primary Speaker: Bob Fary of Inogen, Inc.

AGENDA ITEM #10
Attachment #08.80
Request to establish a code for an auto-adjusting Continuous Positive Airway Pressure (APAP) device, trade name: Resmed S8 AutoSet Vantage.

Primary Speaker: Dr. Michael Coppola of Mercy Medical Center

AGENDA ITEM #11
Attachment #08.129
Request to establish a code for oxygen transfilling systems, trade name: DeVilbiss iFill®.

No Primary Speaker

AGENDA ITEM #12
Attachment #08.90
Request to establish a code for home oxygen liquefier and portables, trade names: VIAspire Personal Oxygen System; Model 300D, VIAspire Liquefier and Models 300P, 600P, 1200P, VIAspire Oxygen Portables.

Primary Speaker: Dan Easley of Inspired Technologies, Inc.

AGENDA ITEM #13
Attachment #08.46
Request to establish a code for an oxygen flow meter, trade name: Oxyview®.

Primary Speaker: Scott Sand of Ingen Technologies, Inc.

AGENDA ITEM #14
Attachment #08.12
Request to establish a code for the personal therapy manager, an accessory to the Medtronic SynchroMed(R) II Implantable Infusion System.

Primary Speaker: Linda Holtzman of Clarity Coding

AGENDA ITEM #15
Attachment #08.17
Request to establish a code for a steerable knee walker, trade name: Turning Leg Caddy® (TLC).

Primary Speaker: Jackie Cardinali of RAMM TLC, LLC

AGENDA ITEM #16
Attachment #08.51
Request to 1) establish a code to specify and differentiate clinical and therapeutic advantages associated with technological advances in crutch assisted walking devices during patient ambulation, trade name: Millennial In-Motion Pro Crutch or 2) assign the Millenial In-Motion Pro Crutch to existing code E0117 “CRUTCH, UNDERARM, ARTICULATING, SPRING ASSISTED, EACH”.

Primary Speaker: Ken Lester of Millennial Medical

AGENDA ITEM #17
Attachment #08.143
Request to establish 2 codes for air purification systems, trade name: Healthway 10,000 and Healthway 20,000.

No Primary Speaker

HCPCS Public Meeting Agenda #1
May 28, 2008

Attachment #08.105

Topic/Issue:
Request to establish a code for: 1) a fixed-power output radio frequency generator and transmitter, trade name: Provant Wound Therapy System and 2) disposable applicator pad cover.

Background/Discussion:
According to the requester, Provant is a solid state fixed-power output radiofrequency (RF) generator and transmitter designed to induce the proliferation of fibroblasts and epithelial cells, which are keys to the healing of wounds to full closure. It is indicated for patients with chronic wounds. The Provant System emits a highly specialized radiofrequency signal that is directed at a wound. Provant transmits a fixed dose of non-ionizing, non-thermal RF energy via the treatment applicator pad that is placed adjacent to the patient's dressed wound. It applies its frequency through a proprietary Cell Proliferation Induction (CPI) technology platform. Provant utilizes the CPI signal to maximize the rate at which cells progress through the mitotic or cell replication cycle. Thus, Provant signals specific growth factors and divide wound repair genes, including genes controlling inflammation responses, granulation, matrix formation, vascularization, epithelialization, and remodeling that helps to promote natural and long lasting tissue repair. It is specifically designed for home use by the patient or care-provider. The device is used twice daily for 30 minutes, with approximately 8 – 12 hours between treatments. According to the requester, code E0769 "ELECTRICAL STIMULATION OR ELECTROMAGNETIC WOUND TREATMENT DEVICE, NOT OTHERWISE CLASSIFIED" is a general code that does not specifically identify the Provant wound therapy system. The electromagnetic spectrum described in this code includes any device emitting radiant energy with a frequency falling between 10 (6) to 10(18) waves per second. In contrast, Provant operates at a narrow frequency of 27.12 MHz. Also, unlike other electric or electromagnetic devices for wound care, because it delivers a "fixed output", the Provant device is specifically designed for home use. HCPCS code E0761 "NON-THERMAL PULSED HIGH FREQUENCY RADIOWAVES, HIGH PEAK POWER ELECTROMAGNETIC ENERGY TREATMENT DEVICE" more accurately describes the technology underlying the Provant System, but it addresses the Diapulse device, which is not intended for home use because it requires a clinician's modulation.

CMS HCPCS Preliminary Decision:
No insurer identified a national program operating need to establish a code to uniquely identify this device. Existing code E0769 "ELECTRICAL STIMULATION OR ELECTROMAGNETIC WOUND TREATMENT DEVICE, NOT OTHERWISE CLASSIFIED" is available for assignment by insurers if they deem appropriate. No insurer identified a national program operating need to identify the pad covers.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 00

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that no existing code adequately describes the Provant Wound Therapy System; that Provant's technology, mechanism of action and clinical effectiveness warrant a unique code; and that there is a substantial national program operational need to identify Provant, as evidenced by current usage and coverage patterns. According to the speaker, Provant has been lumped together with treatments considered experimental and/or of questionable benefit, limiting access to this technology.

HCPCS Public Meeting Agenda #2
May 28, 2008

Attachment #08.41

Topic/Issue:
Request to establish 7 codes to, identify an external functional neuromuscular stimulator and components, trade names: 1) WalkAide System patient kit; 2) WalkAide Control Unit; 3) WalkAide Electrode Lead Cable; 4) WalkAide System Cuff; 5) WalkAide System Electrodes® (pkg.4); 6) WalkAide System Electrodes® (case); 7) WalkAide System Patient Foot Sensor.
Applicant's suggested language (respectively, to identify the above 7 products):
xxxx1 "Programmable neuromuscular functional electrical stimulation control unit kit (includes initial patient evaluation, fitting, instruction, supervision, training and follow-up for a period of 90 days)"
xxxx2 "Programmable neuromuscular functional electrical stimulation control unit"
xxxx3 "Electrical lead cable"
xxxx4 "*Custom fit* suspension cuff"
xxxx5 "Attachable electrodes for use with custom fit suspension cuff"
xxxx6 "Attachable electrodes for use with custom fit suspension cuff (case of 10 packages of 4)
xxxx7 "Patient foot sensor"

Background/Discussion:
According to the requester, the WalkAide is a neural or smart "prosthesis" that stimulates a specific nerve to replace absent brain activity directed towards walking. It is indicated for patients with a lack of ankle dorsiflexion (foot-drop) secondary to an upper motor neuron lesion. Activity occurs through programs custom designed for individuals that utilize a unique patented Tilt Sensor process which analyzes leg movement using embedded software, combined with programmable functional electrical stimulation (FES). WalkAide sends electrical signals to the common peroneal nerve which activates the muscles in the lower extremity to raise the foot at the appropriate time during the gait cycle, thereby telling the foot when and how to move. WalkAide is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. The components of the WalkAide are all integrated elements that replace the brain and brain-to-nerve biophysical process and act on behalf of the brain to initiate normal neural activity and thereby mimic natural leg movement. During the swing phase of gait, the WalkAide electrically stimulates the coordinated contraction of muscles that cause ankle dorsiflexion, thus providing a more normal gait. According to the requester, additional benefits of the WalkAide are that it may prevent/retard disuse atrophy, increase local blood flow, facilitate muscle re-education, diminish bone loss, and maintain or increase joint range of motion. The WalkAide electrodes and cuffs are replaceable based on wear and tear. The microprocessor in WalkAide has a data logging capability of 70 days that can be used to

demonstrate patient use and compliance if clinically indicated. The system runs on a 1.5 volt AA battery which typically lasts for 30 days of daily use. According to the applicant, existing codes do not adequately describe a system that eliminates the need for external wires or conscious input from the wearer.

CMS HCPCS Preliminary Decision:

Establish Exxxx FUNCTIONAL ELECTRICAL STIMULATOR, TRANSCUTANEOUS STIMULATION OF NERVE AND/OR MUSCLE GROUPS, ANY TYPE, COMPLETE SYSTEM, NOT OTHERWISE SPECIFIED

Medicare Payment:

Based on guidance contained in a National Coverage Decision, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker presented information to support the application for a unique code in the prosthetic category. According the speaker, the WalkAide fits the HCPCS definition of a Prosthetic Device, as it "replace(s) all or part of the function of a permanently inoperative or malfunctioning internal body organ" [peripheral nervous system]. The speaker suggested that code language should not include "muscle group stimulation", as this product stimulates nerves. According to the speaker, the National Academy of Science considers the WalkAide to be a "neuroprosthetic". The speaker stated that a unique code as a prosthetic device would best describe and classify the WalkAide System, thereby making the WalkAide accessible to patients who could and with to benefit from its use.

HCPCS Public Meeting Agenda #3
May 28, 2008

Attachment #08.108

Topic/Issue:
Request to establish two new codes: one for a digitally controlled acoustic airway clearance device, and a second code for the adapter ring with filter, used with this device, Trade Name: The Frequencer™. Applicant's suggested language: XXXX1 "High-Frequency Electro-Acoustic Airway Clearance Device" and (2) XXXX2 "Replacement Adapter Ring with Filter For Use With High-Frequency Electro-Acoustic Airway Clearance Device"

Background/Discussion:
According to the requester, the Frequencer™ device provides airway clearance by inducing oscillatory sound waves in the chest by means of an electro-acoustical transducer placed externally on the patient's chest. A Power Head is connected to a frequency generator which is capable of producing frequencies between 20 and 100Hz. The vibrations in the patient's chest created by the Power Head are effective in loosening mucus deposits and promoting bronchial drainage. The Frequencer consists of two parts, a control unit and a transducer. The user places the transducer on the area to be stimulated (normally the chest). The frequency (adjustable between 20 and 100 Hz) and the volume are adjusted in the control unit to create sympathetic resonance that can be felt in the lungs. For infection control reasons, the manufacturer recommends that each patient have their own adapter ring with filter, when multiple patients are treated using the same Frequencer unit. According to the applicant, there are significant differences between devices coded at E0480 "PERCUSSOR, ELECTRIC OR PNEUMATIC, HOME MODEL" and the Frequencer. Specifically: (1) Devices coded at E0480 deliver a low frequency pounding or striking action, similar to clapping, to a patient's chest to loosen mucus. The Frequencer does not use mechanical action. It uses higher frequency acoustic waves to excite resonance in the chest. This is gentler and in some cases, more effective, because the viscosity of the mucus is lowered by the higher frequencies, causing it to flow more readily. (2) Devices coded at E0480 are not self-contained and require a source of regulated compressed air. The Frequencer is self-contained. According to the requester, existing code E0483 "HIGH FREQUENCY CHEST WALL OSCIALLATION AIR-PULSE GENERATOR SYSTEM, (INCLUDES HOSES AND VEST), EACH" describes devices that use an air pulse generator. Since the Frequencer does not use an air pulse generator, it is not described by E0483.

CMS HCPCS Preliminary Decision:
Existing code E0480 "PERCUSSOR, ELECTRIC OR PNEUMATIC, HOME MODEL" adequately describes the frequencer device.

Existing code A9999 "MISCELLANEOUS DME SUPPLY OR ACCESSORY, NOT OTHERWISE SPECIFIED" is available for assignment by all payers, if they deem appropriate, to identify the adapter ring with filter. The reported sales volume for the adapter ring with filter was insufficient to support the request for a revision to the national code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding a new code enhances the efficiency of the system and justifies the administrative burden of adding the code.

Medicare Payment:
The payment rules associated with the existing codes apply to this product. For E0480, Pricing = 36
For A9999, Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision that code E0408 describes the Frequencer. However the speaker agreed with the workgroup's preliminary decision on the adapter ring with filter. According the speaker, code E0408 "can only be used for devices that have percussors and the Frequencer does not have a percussor". It uses acoustic vibration to clear airways and, according to the speaker, "does not use percussion". Its frequency can be adjusted to the resonant frequency of any airway. The speaker claimed that "there are significant technological and therapeutic distinctions between the products coded under E0480 and the Frequencer specifically related to use for obese and paralyzed patients, and patients that are difficult to position. Based on these comments, the speaker claimed that a unique code is warranted.

HCPCS Public Meeting Agenda #4
May 28, 2008

Attachment #08.71

Topic/Issue:
Request to establish 3 codes for pneumatic compression appliances for the trunk or chest, trade name: Flexitouch® Chest Garment, and Flexitouch® Trunk Garment (lower and upper extremity). Applicant's suggested language:
Exxx1 "Segmental pneumatic appliance for use with pneumatic compressor, chest appliance"
Exxx2 "Segmental pneumatic appliance for use with pneumatic compressor, trunk appliance-upper extremity"
Exxx3 "Segmental pneumatic appliance for use with pneumatic compressor, trunk appliance-lower extremity"

Background/Discussion:
According to the requester, Flexitouch® chest and trunk appliances are fastened to the relevant extremity appliance to provide continuous therapy from the tip of the affected limb, across the damaged lymph node region, and into the chest or trunk. Treating the trunk, chest and extremity is a proven way to move excess fluid out of the damaged area into healthy lymphatics. This garment design provides comprehensive lymphedema treatment to all affected regions. Typically, each appliance is used daily for the lifetime of the patient to deliver therapy for chronic health conditions. The chest and trunk appliances are multi-layer inflatable appliances consisting of a proprietary composite of materials designed to provide a gentle stretch against the skin to stimulate the superficial lymphatics. They are adjustable to each individual patient using hook and loop fasteners. The appliances are attached by hoses to the Flexitouch pneumatic controller. Appliance chambers inflate and deflate in a sequential pattern based on well-established manual lymphatic drainage protocol; this sequential pattern together with the gentle stretch of the skin is known to further stimulate the lymphatics. According to the applicant, existing HCPCS codes do not describe pneumatic appliances for the trunk or chest.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to separately identify chest and trunk appliances. Existing code E1399 "DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS" is available for assignment by payers if they deem appropriate.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision. According to the speaker two payer entities that identified a need for unique codes for the Flexitouch chest and trunk garments, and "this alone should represent a national program operating need". The speaker also disagrees that continued use of the E1399 miscellaneous code is a viable solution for the chest and trunk garments that accompany each order for the Flexitouch Lymphedema controller which is assigned E0652. The speaker respectfully requests to assign new codes for these garments and claimed that this is merely a request to extend current coding precedent for other areas of the body.

HCPCS Public Meeting Agenda #5
May 28, 2008

Attachment #08.20

Topic/Issue:
Request to establish a code for a Wheeled Cart with Handle used with portable oxygen concentrators also know as OGPE (oxygen generating portable equipment), trade name: Eclipse Wheeled Cart with Handle.

Background/Discussion:
According to the requester, the Wheeled Cart with Handle is an integral part of the Eclipse system and allows the patient to travel and ambulate over wide range of environments and terrain using the wheeled cart to transport the OGPE system as well as it acts as stationary crutch to rest and catch their breath from time to time. The Wheeled Cart with Handle enables the patient to use their OGPE system and extend the operation of the system via the capability of easily transporting the system from place to place with minimal effort or exertion. It enables the patients suffering from chronic lung disease to ambulate using the oxygen system. The Eclipse is the only OGPE system that can deliver continuous flow of oxygen at 31pm. The system weighs 17 pounds and can not be carried by some patients who are weak or disabled. The requester states that a code would be used when patients need to replace or purchase a wheeled cart with handle used in conjunction with their Eclipse portable oxygen generating systems. The applicant asks that the patient be allowed, if needed, to replace the Wheeled Cart with Handle once per every 12 months of use.

CMS HCPCS Preliminary Decision:
Establish Exxxx "OXYGEN ACCESSORY, WHEELED CART FOR PORTABLE CYLINDER OR PORTABLE CONCENTRATOR, ANY TYPE, REPLACEMENT ONLY, EACH"

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that the item would be paid in accordance with the payment rules that apply to inexpensive and other routinely purchased items.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with the HCPCS Workgroup preliminary decision to create a new code. The speaker respectfully requested on behalf of the patients that use the Eclipse as their sole oxygen source, that these accessory codes be created in order to better serve their needs.

HCPCS Public Meeting Agenda #5
May 28, 2008

Attachment #08.21

Topic/Issue:
Request to establish a code for battery cartridges or battery packs used with portable oxygen concentrators also know as OGPE (oxygen generating portable equipment), trade name: Eclipse Battery Cartridge, 195 watt - hour.

Background/Discussion:
According to the requester, the Eclipse battery packs are much like those in laptop computers and inserted into the Eclipse which provide a power source to run their oxygen systems for several hours per charge. The battery allows the Eclipse system to generate oxygen up to 3 liters a minute of continuous flow or 6 different settings in the pulse flow mode. The fully charged battery pack can allow the patient to ambulate from 1.4 to 4.5 hours depending on the prescribed settings. The battery packs are an integral component of the Eclipse and patients depend on their battery packs to deliver the power they require to operate their device for many hours when away from their homes and ambulating. The battery pack can withstand repeated charge and discharge cycles (approximately 500) but the life of the battery is dependent on the operating environment, temperatures the battery is subjected and patient prescription settings.

CMS HCPCS Preliminary Decision:
Establish Exxxx "OXYGEN ACCESSORY, BATTERY PACK/CARTRIDGE FOR PORTABLE CONCENTRATOR, ANY TYPE, REPLACEMENT ONLY, EACH"

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that the item would be paid in accordance with the payment rules that apply to inexpensive and other routinely purchased items.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with the HCPCS Workgroup preliminary decision to create a new code. The speaker respectfully requested on behalf of the patients that use the Eclipse as their sole oxygen source, that these accessory codes be created in order to better serve their needs.

HCPCS Public Meeting Agenda #5
May 28, 2008

Attachment #08.22

Topic/Issue:
Request to establish a code for a Desktop Battery Charger used with portable oxygen concentrators also know as OGPE (oxygen generating portable equipment, trade name: Eclipse Desktop Battery Charger with power cord.

Background/Discussion:
According to the requester, the Eclipse Desktop Battery Charger are used with the with the OGPE system typically to re-charge a battery pack and do need periodic replacement. The Desktop Battery Charger is typically used to enable the patient to ambulate for extended periods of time with their OGPE system. The Desktop Battery Charger is an integral part of the Eclipse system and allows the patient to charge additional battery while using their system with an existing battery pack in place. An external external Desktop Battery Charger will allow the patient to charge multiple battery packs which can be used for ambulation and on long trips where DC and AC power supplies are unavailable. The applicant requests that the patient be allowed, if needed, to replace the desktop battery charger once every 12 months of use.

CMS HCPCS Preliminary Decision:
Establish Exxxx "OXYGEN ACCESSORY, BATTERY CHARGER FOR PORTABLE CONCENTRATOR, ANY TYPE, REPLACEMENT ONLY, EACH"

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that the item would be paid in accordance with the payment rules that apply to inexpensive and other routinely purchased items.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with the HCPCS Workgroup preliminary decision to create a new code. The speaker respectfully requested on behalf of the patients that use the Eclipse as their sole oxygen source, that these accessory codes be created in order to better serve their needs.

HCPCS Public Meeting Agenda #5
May 28, 2008

Attachment #08.23

Topic/Issue:
Request to establish a code for a DC Power Supply used with portable oxygen concentrators also know as OGPE (oxygen generating portable equipment, trade name: Eclipse DC Power Supply with outlet adaptor.

Background/Discussion:
According to the requester, the Eclipse DC Power Supply with outlet adaptor is typically used to enable the patient to ambulate for extended periods of time with their OGPE system. The DC Power Supply is an integral part of the Eclipse system and allows the patient to use their system in car or transportation that supports DC operation. Many airlines permit patients to bring their OGPE on board an airplane and may of them provide access to DC power outlets at each seat or with certain rows within the cabin of the plane. The DC Power Supply allows the Eclipse system to generate oxygen up to 3 liters a minute of continuous flow or 6 different settings in the pulse flow mode. The DC Power Supply allows the patient to ambulate for a number of hours while driving or traveling at their prescribed oxygen settings. The applicant asks that the patient be allowed, if needed, to replace the DC power supply once per every 12 months of use.

CMS HCPCS Preliminary Decision:
Establish Exxxx "OXYGEN ACCESSORY, DC POWER ADAPTER FOR PORTABLE CONCENTRATOR, ANY TYPE, REPLACEMENT ONLY, EACH"

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with the HCPCS Workgroup preliminary decision to create a new code. The speaker respectfully requested on behalf of the patients that use the Eclipse as their sole oxygen source, that these accessory codes be created in order to better serve their needs.

HCPCS Public Meeting Agenda #6
May 28, 2008

Attachment #08.112

Topic/Issue:
Request to modify the description of E1392 for portable oxygen concentrators (POC), trade name: Eclipse® Oxygen System. Applicant's suggested language: "Portable oxygen concentrator used both a stationary and portable oxygen delivery device, weighing less than 20 pounds, capable of delivering 85% or greater oxygen and providing at least 2 hours of remote portability at a 2 L/min prescription equivalency; includes concentrator, cannula, tubing, battery, AC/DC power supplies and cord"

Background/Discussion:
According to the requester, the POC produces >85% pure oxygen for low flow oxygen therapy applications. This oxygen production method draws and filters ambient air. To maximize oxygen efficiency and production, the POC incorporates a highly sensitive, patient triggered demand oxygen delivery technology, commonly referred to as an oxygen-conserving device (OCD). The OCD delivers a precise amount of oxygen at the optimal point of inhalation during a patient's breathing cycle. The portable oxygen concentrator (POC) is a complete oxygen system that provides needing supplemental oxygen with both stationary and portable oxygen functionality. The POC is small, lightweight oxygen concentrator capable of fulfilling low flow prescriptions for oxygen. It is designed to provide low flow oxygen to patients prescribed long term oxygen therapy (LTOT) outside of the acute care environment. Code E1392 "PORTABLE OXYGEN CONCENTRATOR, RENTAL" is currently used in conjunction with code E1390 "OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRECSCRIBED FLOW RATE", to describe this technology. The proposed revision to code E1392 would replace the current use of two codes to bill for portable oxygen concentrators. The requester proposes that the payment rate for E1392 would be equal to the current combination of E1390 and E1392, and that code E1392 be used exclusively to represent the new POC technology. According to the requester, the deficiency with the current two code system is that the E1390 base code that is used in conjunction with E1392 is also used to describe traditional stationary oxygen concentrator technology when it is not part of new oxygen technology systems. Code E1390 should be maintained and for use only with traditional stationary oxygen concentrators. According to the requester, in a final rule published November 9, 2006, CMS' new oxygen technology classification system recognizes POC technology as "oxygen generating portable equipment" (OGPE), and continued use of existing code E1390 does not enable POC technology to be distinguished from old technology.

CMS HCPCS Preliminary Decision:

Existing code E1390 "OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRESCRIBED FLOW RATE" together with E1392 "PORTABLE OXYGEN CONCENTRATOR, RENTAL" adequately describe this product. For Medicare, both codes are necessary to separately track rental periods. In addition, keeping the two existing codes retains flexibility for all insurers.

Medicare Payment:

The payment rules associated with the existing codes apply to this product. Pricing =33

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the preliminary decision and reiterated the original request to modify existing code E1392 with the exception of a revision to change the text "85 percent or greater oxygen" to instead read "90 percent or greater oxygen" on the basis that "90 percent is what most manufacturers ascribe to".

HCPCS Public Meeting Agenda #7
May 28, 2008

Attachment #08.107

Topic/Issue:
Request to modify code E1392 for portable oxygen concentrators (POC), trade name: Invacare® XPO2™ Portable Oxygen Concentrator. Applicant's Suggested Language: "Portable oxygen concentrator used as both a stationary and portable oxygen delivery device, weighing less than 20 pounds, capable of delivering 85% or greater oxygen and providing at least 2 hours of remote portability at a 2 L/min prescription equivalency; includes concentrator, cannula, tubing and AC/DC power cord and adapter."

Background/Discussion:
According to the requester, the POC produces >85% pure oxygen for low flow oxygen therapy applications. This oxygen production method draws and filters ambient air. To maximize oxygen efficiency and production, the POC incorporates a highly sensitive, patient triggered demand oxygen delivery technology, commonly referred to as an oxygen-conserving device (OCD). The OCD delivers a precise amount of oxygen at the optimal point of inhalation during a patient's breathing cycle. The portable oxygen concentrator (POC) is a complete oxygen system that provides needing supplemental oxygen with both stationary and portable oxygen functionality. The POC is small, lightweight oxygen concentrator capable of fulfilling low flow prescriptions for oxygen. It is designed to provide low flow oxygen to patients prescribed long term oxygen therapy (LTOT) outside of the acute care environment. Code E1392 "PORTABLE OXYGEN CONCENTRATOR, RENTAL" is currently used in conjunction with code E1390 "OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRECSCRIBED FLOW RATE", to describe this technology. The proposed revision to code E1392 would replace the current use of two codes to bill for portable oxygen concentrators. The requester proposes that the payment rate for E1392 would be equal to the current combination of E1390 and E1392, and that code E1392 be used exclusively to represent the new POC technology. According to the requester, the deficiency with the current two code system is that the E1390 base code that is used in conjunction with E1392 is also used to describe traditional stationary oxygen concentrator technology when it is not part of new oxygen technology systems. Code E1390 should be maintained and for use only with traditional stationary oxygen concentrators. According to the requester, in a final rule published November 9, 2006, CMS' new oxygen technology classification system recognizes POC technology as "oxygen generating portable equipment" (OGPE), and continued use of existing code E1390 does not enable POC technology to be distinguished from old technology.

CMS HCPCS Preliminary Decision:
Existing code E1390 "OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRESCRIBED FLOW RATE" together with E1392 "PORTABLE OXYGEN CONCENTRATOR, RENTAL" adequately describe this product. For Medicare, both codes are necessary to separately track rental periods. In addition, keeping the two existing codes retains flexibility for all insurers.

Medicare Payment:
The payment rules associated with the existing codes apply to this product. Pricing =33

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The speaker is not averse to maintaining a two code billing system, however a new code is needed to replace E1390 to describe the stationary functionality of portable oxygen concentrators. According to the speaker, a new code is required to reflect the myriad technological advances associated with portable oxygen concentrators, which is markedly different from older, traditional stationary and portable oxygen delivery systems.

HCPCS Public Meeting Agenda #8
May 28, 2008

Attachment #08.30

Topic/Issue:
Request to establish a code for a transfilling oxygen concentrator system, trade name: Invacare HomeFill System. Applicant's suggested language: "Home oxygen transfilling system, complete: includes stationary device capable of delivering 85 percent of greater oxygen concentration at the prescribed flow rate, and portable gaseous oxygen system, home compressor used to fill portable oxygen cylinders; includes portable container/tanks, regulator, flowmeter, humidifier, cannula or mask and tubing; system may be single integrated unit or multiple unit transfill oxygen device"

Background/Discussion:
According to the requester, HomeFill is a component system, which includes a specific and unique oxygen concentrator connected directly to the Invacare IOH200 HomeFill compressor. It allows the patient to breath their prescribed flow of oxygen (i.e., 2 liters per minute) directly from the concentrator while simultaneously, a portion of the unused oxygen is diverted to the IOH200 transfill compressor, where it is safely compressed into any size, specially configured portable cylinders, which the patient may then use to ambulating in and out of the home. The HomeFill system supports the patient's stationary and portable oxygen needs, and allows the patient and/or their caregiver to fill their own portable oxygen cylinders in their homes as often as needed to meet their clinical and lifestyle needs. The oxygen concentrator supplies oxygen to the patient via cannulas (tubing), and the oxygen compressor component allows patients to fill their own high-pressure oxygen cylinders from a concentrator. The HomeFill compressor unit is a multi-stage pump that simply and safely compresses oxygen from a specially equipped INvacre HomeFill compatible 5-liter or 10-liter concentrator into oxygen cylinders in sizes M2, ML4, ML6, M6, M9C and D. The oxygen transfilling system is currently being billed under codes E1390 "OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRESCRIBED FLOW RATE" and K0738 "PORTABLE GASEOUS OXYGEN SYSTEM, RENTAL; HOME COMPRESSOR USED TO FILL PORTABLE OXYGEN CYLINDERS; INCLUDES PORTABLE CONTAINERS, REGULATOR, FLOWMETER, HUMIDIFIER, CANNULA OR MASK, AND TUBING". The recommended new code would replace the current use of two HCPCS codes to bill for oxygen transfilling units.

CMS HCPCS Preliminary Decision:
Revise existing code K0738 which currently reads: "PORTABLE GASEOUS OXYGEN SYSTEM; RENTAL" to instead read: "PORTABLE GASEOUS OR LIQUID OXYGEN SYSTEM; RENTAL" effective. 1/1/09. Revised code K0738 together with existing code E1390 "OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE

PRESCRIBED FLOW RATE" adequately describe this product. For Medicare, both codes are necessary to separately track rental periods. In addition, keeping the two existing codes retains flexibility for all insurers.

Medicare Payment:
The payment rules associated with the existing codes apply to this product. Pricing = 33

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. A unique code should be created to replace E1390 to distinguish homefill from older technology and to describe the stationary functionality of innovative new home oxygen transfilling technologies that support the patient's stationary and portable needs, and allow the patient and/or their caregiver to fill their own portable oxygen cylinders in their homes. According to the speaker, the proposed new code could be used together with K0738.

HCPCS Public Meeting Agenda #9
May 28, 2008

Attachment #08.86

Topic/Issue:
Request to revise the verbiage of code E1392 for portable oxygen concentrators, trade name: Inogen One Portable Oxygen Concentrator (POC). Applicant's suggested language: "Portable oxygen concentrator used as both a stationary and portable oxygen delivery device, weighing less than 20 pounds, capable of delivering 85% or greater oxygen and providing at least 2 hours of remote portability at a 2 L/min prescription equivalency; includes concentrator, cannula, tubing and AC/DC power cord and adapter"

Background/Discussion:
According to the requester, a single HCPCS code should be used to replace the current use of a two-code system. Portable oxygen concentrators are currently billed by using HCPCS code E1390 "OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRESCRIBED FLOW RATE" and E1392 "PORTABLE OXYGEN CONCENTRATOR, RENTAL". The deficiency with the current two code system is that the E1390 base code that is used in conjunction with E1392 is also used to describe traditional stationary oxygen concentrator technology when it is not part of new oxygen technology systems. Code E1392 should be used alone, and the Medicare payment amounts for both codes should be "shifted" under the one code. The E1390 HCPCS code needs to be maintained for use only with traditional stationary oxygen concentrators that are being deployed alone or in conjunction with traditional portable systems and not when considered components of an integrated, patient oriented and cost-effective OGPE system. The POC is a complete oxygen system that provides patients needing supplemental oxygen with both stationary and portable oxygen functionality. The POC is a small, lightweight oxygen concentrator capable of fulfilling low flow prescription at an equivalent rate of 1-5 liters per minute. The POC produces >85% pure oxygen for low flow oxygen therapy applications. It works on the principles of pressure-swing-adsorption (PSA), common to all oxygen concentrators, which draws and filters ambient air. To maximize oxygen efficiency and production, the POC incorporates a highly sensitive, patient triggered demand oxygen delivery technology, commonly referred to as an oxygen-conserving device (OCD). The OCD delivers a precise amount of oxygen at the optimal point of inhalation during a patient's breathing cycle

CMS HCPCS Preliminary Decision:
Existing code E1390 "OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRESCRIBED FLOW RATE" together with E1392 "PORTABLE OXYGEN CONCENTRATOR, RENTAL" adequately describe this product. For Medicare, both codes are necessary to separately track rental periods. In addition, keeping the two existing codes retains flexibility for all insurers.

Medicare Payment:
The payment rules associated with the existing codes apply to this product. Pricing = 33

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated a 24-hour use portable concentrators are an innovative and patient preferred option for Medicare beneficiaries. The speaker supported a 2-code system, however he stated that the portable component is represented by the E1392 code, but the stationary aspect is not properly represented, as the E1392 code is the code used for stationary concentrators that are in no way portable. According to the speaker, CMS should create a new code to replace E1390 that will represent the stationary-use component of a 24-hour use portable concentrator. The speaker stated this is necessary to ensure beneficiary access and proper tracking and reimbursement of the innovative devices.

HCPCS Public Meeting Agenda #10
May 28, 2008

Attachment #08.80

Topic/Issue:
Request to establish a code for an auto-adjusting Continuous Positive Airway Pressure (APAP) device, trade name: Resmed S8 AutoSet Vantage. Applicant's suggested language: "Auto-adjusting positive airway pressure (APAP) device"

Background/Discussion:
According to the requester, S8 AutoSet is an auto-adjusting positive airway pressure (APAP) delivery system used to treat patients suffering from a chronic disease commonly referred to as obstructive sleep apnea (OSA). APAP devices can be the primary treatment for patients with obstructive sleep apnea because the device automatically delivers necessary airway pressure, the device does not require manual titration. APAP devices can be used instead of manual titration to choose and deliver a long-term therapy pressure. APAP devices can also be used on a permanent basis to adjust to a patient's changing pressure needs over time, such as from weight or behavior changes (alcohol or medication). The S8 AutoSet Vantage has the ability to provide pre-emptive therapy and monitor treatment validity on a breath-by-breath basis: essentially performing every night a new titration study. The device produces varying levels of pressure based on measuring the flow required to maintain a patent upper airway while normalizing the patient's apnea hypopnea index (AHI). It responds to these various parameters: snoring, flow limitation, or any combination of the aforementioned breathing patterns. The newest generation of APAP devices incorporates flow sensors and pressure sensors that examine changes in airflow, air pressure and vibration. APAP technology can be used as a part of a comprehensive approach in the diagnostic process. According to the requester, S8 AutoSet Vantage is recognized by physicians and commercial and public payers as technologically distinct and significantly more sophisticated in its applicability than a standard fixed CPAP device. Therefore, existing code E0601 "CONTINUOUS AIRWAY PRESSURE (CPAP) DEVICE" does not describe this product because the technology does not perform in the same manner as fixed CPAP devices currently coded as E0601. The expected design life for the device is five plus years.

CMS HCPCS Preliminary Decision:
Existing code E0601 "CONTINUOUS AIRWAY PRESSURE (CPAP) DEVICE" adequately describes the product that is the subject of this request. No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to differentiate APAP from other CPAP devices currently coded at E0601.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision. According to the speaker there is no code that reflects the technological distinction of the self-adjusting sleep apnea breathing therapy devices. The lack of a distinct code limits Medicare beneficiary access to technology. The speaker stated that clinical studies support the technology and efficacy of the auto-adjust devices' impact on sleep quality. Existing code E0601 does not adequately describe the APAP technology. APAP should be distinguished from other CPAP technology with its own unique code. According to the speaker, auto-titration capabilities are an important component of home sleep testing. Also according to the speaker, private payers "recognize APAP".

HCPCS Public Meeting Agenda #11
May 28, 2008

Attachment #08.129

Topic/Issue:
Request to establish a code for oxygen transfilling systems, trade name: DeVilbiss iFill®. Applicant's suggested language: "Home oxygen transfilling system, including stationary device capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, and portable gaseous oxygen system, home compressor used to fill portable oxygen cylinders; includes portable container/tanks, regulator, flowmeter, humidifier, cannula or mask and tubing; may be single integrated unit or multiple unit device"

Background/Discussion:
According to the requester, the DeVilbiss iFill Home Oxygen Transfilling System is an oxygen compressor that allows patients to fill their own oxygen cylinders in their homes. The DeVilbiss iFill is comprised of an oxygen concentrator that extracts oxygen from room air and fills a portable oxygen cylinder with gaseous oxygen at greater than 90% purity. The device may be used to fill most common size oxygen cylinders for home use. The iFill can be used with any manufacturer's stationary oxygen concentrator system. According to the requester, one code should be created for oxygen transfilling systems, whether the system is a single integrated unit or is composed of multiple components. The single new code would replace the current use of two HCPCS codes: E1390 "OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRESCRIBED FLOW RATE" and K0738 "PORTABLE GASEOUS OXYGEN SYSTEM, RENTAL; HOME COMPRESSOR USED TO FILL PORTABLE OXYGEN CYLINDERS; INCLUDES PORTABLE CONTAINERS, REGULATOR, FLOWMETER, HUMIDIFIER, CANNULA OR MASK, AND TUBING". Code E1390 needs to be maintained for use with traditional stationary oxygen concentrators that are being deployed alone or in conjunction with traditional portable systems and not when considered components of an integrated, patient oriented and cost-effective oxygen generating portable equipment (OGPE) system. According to the requester, a single new code is necessary to reflect changes in technology; to facilitate competitive bidding and Medicare's new payment for home oxygen therapy; to segment new technology from traditional oxygen devices; and to replace the cumbersome process of billing for oxygen transfilling systems using two codes.

CMS HCPCS Preliminary Decision:
Revise existing code K0738 which currently reads: "PORTABLE GASEOUS OXYGEN SYSTEM; RENTAL" to instead read: "PORTABLE GASEOUS OR LIQUID OXYGEN SYSTEM; RENTAL" effective 1/1/09. Revised code K0738 together with existing code E1390 "OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRESCRIBED FLOW RATE" adequately describe this product. For Medicare, both

codes are necessary to separately track rental periods. In addition, keeping the two existing codes retains flexibility for all insurers.

Medicare Payment:
The payment rules associated with the existing codes apply to this product. Pricing =33

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda #12
May 28, 2008

Attachment #08.90

Topic/Issue:
Request to establish a code for home oxygen liquefier and portables, trade names: VIAspire Personal Oxygen System; Model 300D, VIAspire Liquefier and Models 300P, 600P, 1200P, VIAspire Oxygen Portables. Applicant's suggested language: "Portable liquid oxygen system, rental"

Background/Discussion:
The VIAspire Liquefier converts gaseous oxygen from any concentrator to liquid. It is capable of creating up to 5 L/day from a concentrator, generator or a wall/tank source. The liquefier also stores two liters, so liquid oxygen is always available. Typically the unit runs for four hours per day, liquefying enough oxygen for two fills, or 12 -16 hours ambulatory use and the portables full in minutes. This technology is intended as an accessory to an oxygen concentrator and liquid oxygen storage system, for use as an aid or adjunct to delivering supplemental oxygen therapy in the home. The portables provide all day usage for the patient with no need to run tubing through the house. The two smaller portables provide the SmartDose technology feature that helps to maintain higher patient saturation levels during ambulation, supporting greater patient activity. According to the requester, the VIAspire Liquid Portable's design is similar to the standard cryogenic designs in today's portables with a significant difference in a clinically validated superior dosing algorithm. Conserving devices in the market today do not follow any standard for the volume of oxygen delivered per breath (the dose), therefore patients may receive (substantially) less oxygen per breath than the physician expects or prescribes. This gap is further compounded when the patient attempts to ambulate which increases their breath rate and oxygen requirements. The Inspired Technologies, Inc algorithm is responsive to the patient's activity level by monitoring their respiratory rate and supplements the dose as the patient's activity requires. According to the requester, no existing codes define making liquid oxygen in the home, or incorporating smart dose technology in portable units to adjust oxygen dose during elevated breath rates to promote higher saturation during exercise.

CMS HCPCS Preliminary Decision:
Revise existing code K0738 which currently reads: "PORTABLE GASEOUS OXYGEN SYSTEM; RENTAL" to instead read: "PORTABLE GASEOUS OR LIQUID OXYGEN SYSTEM; RENTAL" effective 1/1/09. Revised code K0738 together with existing code E1390 "OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRESCRIBED FLOW RATE" adequately describe this product. For Medicare, both codes are necessary to separately track rental periods. In addition, keeping the two existing codes retains flexibility for all insurers.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 33

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that liquid is different than gas. He discussed "smart dose" technology and a monitoring card that is part of the system that records information for later review of compliance. This unique portable Oxygen system allows the patient the light weight option for liquid; plus the clinical efficacy of the self adjusting pulse flow and the superiority over continuous flow in various lung types. The VIAspire Oxygen System eliminates the need for deliveries. The speaker offered the following additional comments in support of a new code: 1) the liquefier is a unique technology; 2) separate codes will "assist to identify the ambulatory patient group that need to use liquid oxygen"; and 3) the smart dose technology of the liquid portable and companion concentrator create a non-divisible system.

HCPCS Public Meeting Agenda #13
May 28, 2008

Attachment #08.46

Topic/Issue:
Request to establish a code for an oxygen flow meter, trade name: Oxyview®.

Background/Discussion:
According to the requester, Oxyview is an oxygen flow meter designed to monitor oxygen flow at the site of the patient. The device is adapted to be engaged between the nose/mouth mounted cannula and a compressed oxygen supply delivered to the cannula through a flexible conduit. Conventional flow meters typically employ a ball which translates up and down that is dependent of gravity, and must maintain a vertical position for accuracy and functionality. Oxyview, on the other hand, can be mounted "in-line" anywhere between the regulator and patient mask or breathing section of the cannula. Since Oxyview can be mounted close to the patient and "in-line" with the oxygen tubing, it enables the patient/caregiver to more easily identify the correct oxygen flow, leaks or malfunction in the regulator or respiratory equipment. According to the requester, the Oxyview device should be differentiated from other oxygen flow meters because Oxyview monitors flow rate at the destination, rather than the source and the Oxyview flow meter is not gravity dependent.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Payment for any covered items will be based on the carrier's individual consideration of the claim since no specific code or fee schedule has been established for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker provided written comments requesting recognition of flow meters as an important aspect of oxygen therapy and suggested that direct patient sales indicate a need for this device in the home oxygen therapy setting.

HCPCS Public Meeting Agenda #14
May 28, 2008

Attachment #08.12

Topic/Issue:
Request to establish a code for the Personal Therapy Manager (PTM), an accessory to the Medtronic SynchroMed® II Implantable Infusion System.

Background/Discussion:
According to the requester, the Personal Therapy Manager (PTM) is an external, battery powered, handheld device that communicates with the SynchroMed® II Progammable Infusion Pump system vial telemetry. The PTM is the first patient-activated device that empowers chronic pain patients with Medtronic SynchroMed II implantable drug pumps to treat their severe pain in their homes by administering supplemental doses of physician prescribed pain medication at the touch of a button. This device is intended for patients with implantable programmable infusion pumps who have chronic intractable pain and who experience episodes of intermittent pain, unpredictable pain that cannot be alleviated through the pump's pre-set release of medication, and inadequate pain relief or intolerable side effects from supplemental pain medications. The anticipated useful life of the PTM is equivalent to the life of the implanted device, approximately 7 years. The PTM is operates with AAA batteries.

CMS HCPCS Preliminary Decision:
This product is included as a component of existing code E0783 "INFUSION PUMP SYSTEM, IMPLANTABLE, PROGRAMMABLE (INCLUDES ALL COMPONENTS, E.G., PUMP, CATHETER, CONNECTORS, ETC.)". If this item is replaced, existing code A9900 "MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE" is available for assignment by insurers if they deem appropriate in accordance with their programs and policies. For HOPPS, report the procedure code with C1772 "INFUSION PUMP, PROGRAMMABLE (IMPLANTABLE)".

Medicare Payment:
The payment rules associated with the existing codes apply to this product.
For E0783, Pricing = 32
For A9900, Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The Programmer enables patient to deliver supplemental doses of pain medication. It also is used to treat unpredictable episodes of severe breakthrough pain outside of the pump's pre-set schedule. According to the speaker, the programmer is new; pump system code E0783 was not designed and is not intended to include the patient programmer; and not all programmers are assigned at the time the pump is implanted.

HCPCS Public Meeting Agenda #15
May 28, 2008

Attachment #08.17

Topic/Issue:
Request to establish a code for a steerable knee walker, trade name: Turning Leg Caddy® (TLC).

Background/Discussion:
According to the requester, the TLC is a steerable knee walker used as a crutch alternative by non-weight bearing patients or people with below-the-knee amputations as a mobility assistive device and for therapeutic healing. This device is useful for physical therapy and has a wide range of medical benefits for a wide array of medical issues. The patient places the knee of their injured foot or ankle, or the amputated limb on the knee platform and propels the unit with their uninjured leg. TLC is steerable, allowing the patient to maneuver turns and navigate with eases. The 8" wheels allow the patient to maneuver over most terrains. As a steerable device, the TLC eliminates secondary injuries that occur when crutches or the non-steerable models are used, including muscle strain in the upper back, neck and under arm areas that occur with short or long term use of crutches, or the non-steerable knee walkers. In addition, it improves cardiovascular fitness during recovery since patients can be more active and mobile. According to the requester, TLC is distinguishable from the generic classification used under HCPCS code **E0118** "CRUTCH SUBSTITUTE, LOWER LEG PLATFORM, WITH OR WITHOUT WHEELS, EACH"; and codes **E0116** "CRUTCH, UNDERARM, OTHER THAN WOOD, ADJUSTABLE OR FIXED, WITH PAD, TIP, HANDGRIP, WITH OR WITHOUT SHOCK ABSORBER, EACH", and **E0117** "CRUTCH, UNDERARM, ARTICULATING, SPRING ASSISTED, EACH", for underarm crutches also do not describe the TLC.

CMS HCPCS Preliminary Decision:
Existing code E0118 "CRUTCH SUBSTITUTE, LOWER LEG PLATFORM, WITH OR WITHOUT WHEELS, EACH" adequately describes the product that is the subject of this request.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. According to the speaker, many people cannot use crutches and for those people, the Turning Leg Caddy is a much better alternative than a wheelchair.

HCPCS Public Meeting Agenda #16
May 28, 2008

Attachment #08.51

Topic/Issue:
Request to 1) establish a code to specify and differentiate clinical and therapeutic advantages associated with technological advances in crutch assisted walking devices during patient ambulation, trade name: Millennial In-Motion Pro Crutch or 2) assign the Millenial In-Motion Pro Crutch to existing code E0117 "CRUTCH, UNDERARM, ARTICULATING, SPRING ASSISTED, EACH".

Background/Discussion:
According to the requester, Millennial Crutch is an axillary crutch that encompasses technological features of spring assist and impact absorption, anatomical and ergonomic handle design, with an overall improvement in the design and structure to assist injured persons to continue to ambulate without causing further injury. Millennial crutch has spring assisted technology which includes a suspension to reduce impact and return energy. There is also an appropriate handle design to protect the carpal tunnel and vital nerve conduction of the ulna and median nerve systems. This design protects the wrist from the impact of the radius bone when the wrist is in a cocked and unnatural position. Millennial crutch can be used to provide support and balance. It can also be used in three point and four point gaits. Millennial crutch can be used in many ways as an assisted walking device. This would include, not only post surgical, or in rehabilitation, but also as a device to assist the bariatric population to ambulate more on their own, and get away from wheelchairs and walkers. Because of the impact absorption features, heavier patients can tolerate the impact and use the crutch as a device to assist in daily ambulation. Millennial crutch allows the user to maintain mobility, reduce the incidence of cumulative trauma injuries to the upper extremity, and to lessen the energy expenditure requirements. According to the requester, existing codes E0114 "CRUTCHES UNDERARM, OTHER THAN WOOD, ADJUSTABLE OR FIXED, PAIR, WITH PADS, TIPS AND HANDGRIPS" and E0116 "CRUTCH, UNDERARM, OTHER THAN WOOD, ADJUSTABLE OR FIXED, WITH PAD, TIP, HANDGRIP, WITH OR WITHOUT SHOCK ABSORBER, EACH", lack language to describe any therapeutic value associated with advances in crutch technology. Crutches that lack the functions of spring assisted technology function similar to the traditional crutch and do not provide clinical solutions to crutch palsy or other clinically related crutch injuries. Code E0117 is off the mark for usable technology. An articulating crutch has never become available for use of clinical resolutions. Code E0110 "CRUTCHES, FOREARM, INCLUDES CRUTCHES OF VARIOUS MATERIALS, ADJUSTABLE OR FIXED, PAIR, COMPLETE WITH TIPS AND HANDGRIPS" is for a forearm crutch, and does not cover axillary crutches.

CMS HCPCS Preliminary Decision:
Existing code E0116 "CRUTCH, UNDERARM, OTHER THAN WOOD, ADJUSTABLE OR FIXED, WITH PAD, TIP, HANDGRIP, WITH OR WITHOUT SHOCK ABSORBER, EACH" adequately describes the product that is the subject of this request.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. According to the speaker, existing code E0116 does not describe the therapeutic advantages, distinct design and proven ergonomics of the Millennial Crutch. Specifically, the speaker discussed differences in ambulation speed, energy expense, wrist extension angle and peak kinetic force.

HCPCS Public Meeting Agenda #17
May 28, 2008

Attachment #08.143

This particular item was inadvertently omitted from the "Supply/Other" Public Meeting agenda, and we placed it on the next available outgoing Public Meeting Agenda to ensure an opportunity for Public input.

Topic/Issue:
Request to establish 2 codes for air purification systems, trade name: Healthway 10,000 and Healthway 20,000. Applicant's suggested language: "Air purification system with EMF technology that 1) destroys 94-100% of bacteria, viruses, fungi and 2) cleanses the air of a minimum of 99.99% particulates at .3 microns 3) removes Volatile Organic Compounds"

Background/Discussion:
According to the requester, Healthway is an advanced air cleaner system indicated for patients with respiratory difficulties to include: asthma, allergies, chronic lung disease, and reduced immune deficiency difficulties. Healthway has a guaranteed efficiency of 99.99% at.3 microns of respiratory contaminating particulates (pollens, dust particles, etc.). It has a kill rate of up to 94-100% of bacteria, viruses and fungi. Healthway also removes harmful volatile organic compounds (VOCs) from the air. Healthway creates laminar air flow and the humidity/moisture entering Healthway is 'cleansed' with a high energy field prohibiting bacterial growth. It deprives medial filter of nutrients necessary for survival of bacteria, fungi, and viruses. The low level of irradiation contained within a specific zone not only prevents moisture buildup in media but has been shown to kill mold, viruses, and bacteria surrogates. The 20,000 series is highly efficient with removal of VOCs. It is used in residential and commercial settings to provide a cleaner environment. According to the requester, pleated media filter particulate containment of 99.99% and microorganisms destruction of 94-100% surpasses HEPA filtration systems.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

PAYMENT FOR DMEPOS

DMEPOS

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

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

Depending on the item or the setting in which the item is furnished, Medicare claims for some of these items may also be processed by local carriers 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.