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

Orthotics & Prosthetics

Tuesday, June 7, 2011

Introduction and Overview

Approximately 25 people attended. The agenda included 10 items.

Cindy Hake, Chair, of the CMS' HCPCS Coding Workgroup, provided an overview of the HCPCS public meeting procedures as it relates to the overall HCPCS coding process.

Joel Kaiser, Director, of the Division of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy, presented an overview of the methods used for setting the payment amount for DME, prosthetics, orthotics and supplies and when the different payment categories are used. The overview was also provided as a written document to the agenda and is attached to this summary. For additional information, the DME payment rules are located at Section 1834 (a) of the Social Security Act. The Medicare fee schedule for DME, Prosthetics, Orthotics and Supplies, and background information, can be accessed and downloaded free of charge at: http:www.cms.gov/DMEPOSFeeSched/.

Prior to the Public Meetings, over the course of several months, the CMS HCPCS Coding Workgroup convene, discuss, and establish preliminary coding recommendations, on all HCPCS code applications. CMS also assigns preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the CMS HCPCS web site at http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage, as part of the HCPCS public meeting agendas.

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings and reconsiders its preliminary coding recommendation in light of any new information provided, and formulates its final coding decisions. CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

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

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as Guidelines for Proceedings at CMS' Public Meetings can be found on the CMS HCPCS web site specifically at: http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage. In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completing the application, and background information regarding the HCPCS Level II coding process is available at: http://www.cms.gov/MedHCPCSGenInfo/01_Overview.asp#TopOfPage . The application form is updated annually and posted on the CMS HCPCS web site sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: http://www.cms.gov/MedHCPCSGenInfo/Downloads/decisiontree/pdf .

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Orthotics & Prosthetics
Tuesday, June 7, 2011, 9:00 am – 5:00 pm
CMS Media Center
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

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

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

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

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

AGENDA ITEM #1
Attachment# 11.110
Request to: 1) revise existing code L6881 which currently reads: "AUTOMATIC GRASP FEATURE, ADDITION TO UPPER LIMB ELECTRIC PROSTHETIC TERMINAL DEVICE" to instead read: ADDITION TO UPPER LIMB ELECTRIC PROSTHETIC TERMINAL DEVICE, AUTOMATIC OR USER ACTIVATED GRASP FEATURE, AUTOGRASP, STALL DETECTION FEATURE, AND/OR PULSE MODULATION FEATURE, OR EQUAL, EACH; 2) establish a new code to describe voluntary control of (user-activated) grip adjustment function; and 3) issue instructions that code L6881 is intended for use with all grip adjustment features, regardless of mechanism of activating the automation. These changes to the code set are requested to describe a programmable feature that allows the user of a prosthetic hand to direct and adjust grasp to any combination of digits. Trade name: i-LIMB™ Pulse Hand.

Attachment #11.112
Request to establish a new addition code for Upper Limb Prosthesis to identify an individually motorized thumb that can be manually rotated and positioned by the user. Trade Name: ProDigits™, for use with i-LIMB and I-LIMB Pulse hands.

Attachment #11.113
Request to establish a new addition code for Upper Limb Prosthesis to identify modular, motorized electronic digits 2-4, Trade Name: ProDigits™ (for use with the i-LIMB and i-LIMB Pulse hands).

Primary Speaker: Rob Kistenberg of RSK Consulting, Inc.

AGENDA ITEM #2
Attachment# 11.116
Request to establish a code for a manual prosthetic cable control and locking system for an upper extremity prosthesis, Trade Name: Sure-Lok.

No Primary Speaker

AGENDA ITEM #3
Attachment# 11.114
Request for a new HCPCS "addition" code to identify a lower extremity silicone liner that incorporates biaxial electromagnetic shielding fabric. Trade Name: Medipro® RELAX Liner with Umbrellan® (the Medipro® RELAX Liner).

Primary Speaker: Peter Thomas of Powers Pyles Sutter & Verville PC

AGENDA ITEM #4
Attachment# 11.055
Request to reinstate code L5989 "ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL SYSTEM, PYLON WITH INTEGRATED ELECTRONIC FORCE SENSORS" with a verbiage change to delete the word “pylon” and insert the word “pyramid,” to describe the Smart Pyramid™.

Primary Speaker: David Boone of Orthocare Innovations

AGENDA ITEM #5
Attachment# 11.015
Request to establish a code for a knee extension assist (KEA), Trade Name: Townsend Design Knee Joint Extension Assist.

No Primary Speaker

AGENDA ITEM #6
Attachment# 11.117
Request to establish an "addition" code for an electronically activated knee joint used in custom-made KAFOs, Trade Name: E-MAG Active Knee Joint.

Primary Speaker: Curt Kowalczyk of Otto Bock Healthcare

AGENDA ITEM #7
Attachment# 11.115
Request to establish a code for a prefabricated ankle foot orthosis, Trade Name: Noodle AFO.

Primary Speaker: Wade Bader of Kinetic Research, Inc.

AGENDA ITEM #8
Attachment# 11.108
Request to establish a new addition code to add to existing base codes for all prosthetic feet.

Primary Speaker: Kurt Collier of Freedom Innovations

AGENDA ITEM #9
Attachment# 11.053
Request to establish a HCPCS "addition" code for endoskeletal ankle foot systems to describe the Hydraulic (Fluid) dampening capabilities of the Echelon foot.

Primary Speaker: Alan Kercher of Endolite

AGENDA ITEM #10
Attachment# 11.109
Request to: 1) establish a new HCPCS code to describe a prosthetic foot/ankle system, trade name: The Motion Foot;
2) broaden the language of existing codes L5810, L5988 and L5999 to include the functions of this prosthesis, so that these codes may also be applied to the Motion Foot: Revise L5810 which currently reads: ADDITION, ENDOSKELETAL KNEE-SHIN, SINGLE AXIS, MANUAL LOCK to instead read: Addition, endoskeletal knee-shin *or ankle*, single axis, manual lock; Revise code L5988 which currently reads: ADDITION TO LOWER LIMB PROSTHESIS, VERTICAL SHOCK-REDUCING PYLON FEATURE to instead read: Addition to lower limb prosthesis, shock-reducing pylon *or ankle*; Revise L5990 which currently reads: ADDITION TO LOWER EXTREMITY PROSTHESIS, USER ADJUSTABLE HEEL HEIGHT to instead read: Addition to lower extremity prosthesis, user *automatic or* adjustable heel height *and plantarflexion/dorsiflexion hydraulic alignment*; and
3) also assign existing codes L5981 and L5968 to the Motion Foot; and
4) also permit use of code L5999 to describe other individual functions of the Motion Foot functions, such as dynamic and toe motion, multi-axial motion with active dorsiflexion, automatic heel height adjustment, shock absorption, and manual lock.

No Primary Speaker

HCPCS Public Meeting Agenda Item #1
June 7, 2011

Attachment# 11.110

Topic/Issue:

Request to: 1) revise existing code L6881 which currently reads: "AUTOMATIC GRASP FEATURE, ADDITION TO UPPER LIMB ELECTRIC PROSTHETIC TERMINAL DEVICE" to instead read: ADDITION TO UPPER LIMB ELECTRIC PROSTHETIC TERMINAL DEVICE, AUTOMATIC OR USER ACTIVATED GRASP FEATURE, AUTOGRASP, STALL DETECTION FEATURE, AND/OR PULSE MODULATION FEATURE, OR EQUAL, EACH; 2) establish a new code to describe voluntary control of (user-activated) grip adjustment function; and 3) issue instructions that code L6881 is intended for use with all grip adjustment features, regardless of mechanism of activating the automation. These changes to the code set are requested to describe a programmable feature that allows the user of a prosthetic hand to direct and adjust grasp to any combination of digits. Trade name: i-LIMB™ Pulse Hand.

Background/Discussion:

According to the requester, i-LIMB's multi-articulating prosthetic hand and partial hand technology utilizes individually motorized, modular digits which proportionally control motor speed and strength via an on board microprocessor. Each of the modular, motorized digits employees a stall when moderate grip force has been applied to reach a predetermined resistance. The programmable microprocessor offers an opportunity to select a user-adjustable grasp enhancing "Pulse feature" to any combination of digits which in turn allows improvement to grasps required in everyday living. When the multi-articulating prosthetic hand closes on an object, the programmable feature allows the user the option to activate the pulsing effect via a short sustained closing signal initiated from the user for improved grip strength and user-controlled grasp. The sustained closing signal by the user results in the activation of a timed, rapid and repeatable, high-frequency electronic pulse to the assigned digit motors, driving the motor to close the digit more securely around an object. The combination of stall detection and the non-backdrivable gear box design in each digit allows for a moderate grasp to be maintained while an input signal is active, or also when an input signal has been terminated. Initiating a moderate grip when first grasping an object allows for reasonable initial compliant grip control much like that of a human hand with articulating fingers. The built-in stall detection of individual digits regulates sufficient grip on an object resulting in termination of power to that specific digit or digits. Each individual digit locks into position until the patient triggers an open signal allowing the hand to open. This stall feature allows for a conforming grasp that offers functional capabilities (such as allowing a user to type, point and shake hands) and a safety enhancement that prevents the user from inadvertently applying "crushing" force. According to the requester, existing code L6881 applies to the use of a sensor that detects a change in the center of gravity automatically activating the grasp feature. That methodology is different than technology employed by the i-LIMB Pulse. There are no codes that describe voluntary control of the grip adjustment function.

Attachment# 11.112

Topic/Issue:

Request to establish a new addition code for Upper Limb Prosthesis to identify an individually motorized thumb that can be manually rotated and positioned by the user. Trade Name: ProDigits™, for use with i-LIMB and I-LIMB Pulse hands. Applicant's suggested language: "Addition to Upper Limb Prosthesis, Modular, Articulating, Individually Motored, Manually Positionable Thumb."

Background/Discussion:

According to the Requester, the user-positionable thumb paired with modular, motorized electronic articulating digits allows the user the ability to rotate the thumb to select numerous combinations of grip and grasp prehensile patterns which improve and enhance functional and aesthetic movements. A multi-articulating prosthetic hand's five individually motorized digits are able to perform using variable speed and strength via an onboard microprocessor utilizing proportional control. With the addition of a user positionable thumb, the hand is able to grip around objects and the motorized electronic digits stall when sufficient grip force has been applied - just like a real hand. The ability to respond to myoelectric signals is the only similarity between this item and the hands made by other manufacturers. None of the traditional "three jaw chuck" prosthetic hands include a user-positionable thumb. The "three jaw chuck" design hand only offers gross grasp and "three jaw pinch" (index, middle finger and thumb). Individuals using this type device are not able to perform ADL's which require fine motor skills (such as buttoning shirts), as proficiently, without the use of additional adaptive equipment. Crucial to the enhanced functionality of multi-articulating prosthetic hands is the manually positionable, modular, articulating, individually motorized thumb. The incorporation of the user-positionable thumb allows patients to utilize the six fundamental grasps found in the actual human hand while the "three jaw chuck" design only provides two. The existing code for a myoelectric hand, L7007, states only that the hand is "switch or myoelectric controlled". There is no existing code for a myoelectric, modular, articulating, individually motored, user-positionable thumb. This thumb is currently billed using code L7499 "UPPER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED".

Attachment# 11.113

Topic/Issue:

Request to establish a new addition code for Upper Limb Prosthesis to identify modular, motorized electronic digits 2-4, Trade Name: ProDigits™ (for use with the i-LIMB and i-LIMB Pulse hands). Applicant's suggested language: "Addition to Upper Limb Prosthesis, Individually motorized, modular, multi-articulating, external powered, electronic digit, i-LIMB™, i-LIMB™ Pulse, ProDigits™ or equal, each."

Background/Discussion:

According to the requester, modular, motorized electronic digits are individually powered units providing enhanced functionality, overcoming the functional limitations of other electromechanical terminal devices which employ one motor and a single grasping pattern with one actuated degree of freedom. Miniaturization of the motor and packaging of wiring, gearbox and drive belt combine to provide two interdependent active movements per digit. Movement at the MCP joint via a gear box accounts for one "actuated degree of freedom" coupled with a second dependent "single degree of freedom" movement at the PIP joint via a drive belt. In all, the motorized digits of the i-LIMB and i-LIMB Pulse hand combine for a total of 9 degrees of freedom (2 each in the multi-articulating fingers and 1 in the articulating thumb). The motorized electronic digit, when used independently or in various combinations, is capable of providing versatile grip and grasp prehensile patterns which include cylindrical, spherical, hook, lateral and tip pinch. The exoskeleton structure of each motorized electronic digit is manufactured using high-strength, lightweight industrial plastics and incorporating lightweight metals for strength. Control signals supplied from the user are the source of i-LIMB™, i-LIMB Pulse™, and ProDigits™ input allowing direct control to the digits with minimal physical effort. According to the requester, this new multi-articulating hand technology has distinctive features that are not described in existing code L7007. Specifically, the motors housed in hands identified by code L7007 are housed in the chassis of the hand. In contrast, the i-Limb includes 5 independently driven motors housed in the articulating and multi-articulating digits which feature a user-positionable thumb. These features enhance function by enabling 6 fundamental grip patterns, 4 of which are not possible using "earlier generation" hands described by L7007. As such, a new code is warranted.

CMS HCPCS Preliminary Decisions pertaining to 11.110, 11.112 and 11.113:

Existing codes L7007 "ELECTRIC HAND, SWITCH OR MYOELECTRIC CONTROLLED, ADULT" and L6882 "MICROPROCESSOR CONTROL FEATURE, ADDITION TO UPPER LIMB PROSTHETIC TERMINAL DEVICE," used together adequately describe the whole hand plus the myoelectric feature. The grasp feature, as intended in existing code L6881 "AUTOMATIC GRASP FEATURE, ADDITION TO UPPER LIMB ELECTRIC PROSTHETIC TERMINAL DEVICE" does not apply to this product. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to

establish codes to identify the manual rotating thumb. The thumb is inherently included in the base code for the terminal device whether or not it is actually used, and it is therefore not separately billable. One to five digits (including the thumb) are included in existing codes L6025 TRANSCARPAL/METACARPAL OR PARTIAL HAND DISARTICULATION PROSTHESIS, EXTERNAL POWER, SELF-SUSPENDED, INNER SOCKET WITH REMOVABLE FOREARM SECTION, ELECTRODES AND CABLES, TWO BATTERIES, CHARGER MYOELECTRIC CONTROL OF TERMINAL DEVICE for partial hand on initial issue. The thumb or other individual digits are therefore not separately billable. Existing repair code L7510 REPAIR OF PROSTHETIC DEVICE, REPAIR OR REPLACE MINOR PARTS and labor code L7520 REPAIR PROSTHETIC DEVICE, LABOR COMPONENT, PER 15 MINUTES are available for assignment by insurers when a finger is replaced.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.
For L7007, Pricing = 38
For L6882, Pricing = 38
For L6025, Pricing = 38
For L7510, Pricing = 46
For L7520, Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision that existing codes describe the iLimb products. According to the speaker, there is a coding precedent set to add "add-on" codes to the base codes of lower limb products. Therefore, add-on codes should be created to describe the i-Limb products. The speaker also claimed that a precedent exists to establish codes for features that offer significant therapeutic distinction, operate differently and perform different functions in terminal devices. The speaker requested that the descriptor of existing code L6881 be expanded to acknowledge the many added functional features of ProDigits™, i-Limb™ and i-Limb™Pulse. The speaker claimed that the positionable, rotatable thumb provides a significant therapeutic distinction when combined with the multi-articulation of digits 2 through 5. The speaker requested a new code to recognize the functional enhancements that a positional-rotatable thumb brings to individuals with upper limb amputation. According to the speaker, powered multi-articulating individually motorized digit technology operates differently and provides a very different function for partial hand prosthetic users, when compared with the use of currently coded products that are non-powered. Therefore, the speaker requested a new code to recognize the functional enhancements multi-articulating, motorized digit technology brings to individuals with upper limb amputation.

HCPCS Public Meeting Agenda Item #2
June 7, 2011

Attachment# 11.116

Topic/Issue:

Request to establish a code for a manual prosthetic cable control and locking system for an upper extremity prosthesis, Trade Name: Sure-Lok. Applicant's suggested language: "Addition to upper limb prosthetic, manual lock for cable-controlled system".

Background/Discussion:

According to the requester, the Sure-Lok is a manually-controlled locking cable control system developed for use in upper limb prostheses. It includes a unidirectional cable locking and control technology incorporating a manually actuated, self-energizing cam mechanism. The Sure-Lok mounts to the surface of an existing or new prostheses. It enhances the usefulness of cable operated prosthetic and orthotic devices by giving the user greater control over their upper limb prosthetic terminal device. It is particularly well-suited for use with voluntary opening and closing devices. The Sure-Lok is intended for use in general activities of daily living, and assists in carrying or holding objects for prolonged periods of time. In contrast to standard and heavy duty cables that only control opening and closing of a specific terminal device, the Sure-Lok not only provides cable control, but also allows the user to lock the device in an infinite number of positions. The Sure-Lok also costs more than basic cable and harness materials. According to the requester, based on testimonials, use of the Sure-Lok confers a significant therapeutic distinction when compared with the use of other locking control systems, in that use of the Sure-Lok 1) decreases energy expenditure of users; 2) improves control of terminal devices; 3) represents an improvement on existing cable-operated prosthetic technology; and 4) increases pinch force with voluntary-closing terminal devices. Of all the current HCPCS codes available for upper limb prosthetic componentry, none are applicable for a locking cable control system. Codes that describe part of the design of a locking control system include: L6655 "UPPER EXTREMITY ADDITION, STANDARD CONTROL CABLE, EXTRA"; L6660 UPPER EXTREMITY ADDITION, HEAVY DUTY CONTROL CABLE"; L6675 "UPPER EXTREMITY ADDITION, HARNESS, (E.G. FIGURE OF EIGHT TYPE), SINGLE CABLE DESIGN"; and L6676 "UPPER EXTREMITY ADDITION, HARNESS, (E.G. FIGURE OF EIGHT TYPE), DUAL CABLE DESIGN". However, these codes are not applicable to the Sure-Lok due to the differences in cost, function, and therapeutic benefit.

CMS HCPCS Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the Private Insurance sector to establish a code to separately identify the manual locking feature. This is a component included in the harness code L6675 "UPPER EXTREMITY ADDITION, HARNESS, (E.G. FIGURE OF EIGHT TYPE), SINGLE CABLE DESIGN." As such, code

L9900 "ORTHOTIC AND PROSTHETIC SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS "L" CODE" is available for assignment by all payers if they deem appropriate.

Medicare Payment:

The payment rules associated with the existing code L9900 apply to this product if covered. Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item, however; the applicant submitted a written comment asking for clarification as to how to demonstrate a national program operating need and claiming that the use of “miscellaneous” code L9900 is “ineffective”.

HCPCS Public Meeting Agenda Item #3
June 7, 2011

Attachment# 11.114

Topic/Issue:

Request for a new HCPCS "addition" code to identify a lower extremity silicone liner that incorporates biaxial electromagnetic shielding fabric. Trade Name: Medipro® RELAX Liner with Umbrellan® (the Medipro® RELAX Liner). Requester's Suggested Language: "Addition to lower extremity, below knee/above knee, with or without locking mechanism, prefabricated socket insert, silicone gel with biaxial electromagnetic shielding to reduce phantom limb pain."

Background/Discussion:

Umbrellan® is a knitted fabric with biaxial electrical conductivity. The function of the fabric is to dissipate electrostatic charge or to distribute it over the knitted fabric. Although the precise mechanism of action has not yet been established, the requester claims that incorporation of Umbrellan® into the protective outer covering of a liner provides electromagnetic shielding to the residuum, which has been shown to reduce phantom leg pain (PLP), and even provide ongoing reduction in reported PLP symptoms when the prosthesis has been removed. According to the requester, there is no existing code to describe a product with these features because there is no existing alternative product to address this painful condition. The prevalence of PLP among amputees (50% - 90%) demonstrates a national program operating need to code this product in order to enable insurers to develop and implement coverage policies for prosthetic limb users who have significant PLP.

CMS HCPCS Preliminary Decision:

Existing code L5673 "ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED FROM EXISTING MOLD OR PREFABRICATED, SOCKET INSERT, SILICONE GEL, ELASTOMERIC OR EQUAL, FOR USE WITH LOCKING MECHANISM" or L5679 "ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED FROM EXISTING MOLD OR PREFABRICATED, SOCKET INSERT, SILICONE GEL, ELASTOMERIC OR EQUAL, NOT FOR USE WITH LOCKING MECHANISM", depending on whether the product is with or without lock, adequately describes this product . The elecromagnetic feature is not separately billable.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For L5673, Pricing = 38
For L5679, Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker claimed that the preliminary HCPCS coding decision denied the request for the establishment of a separate HCPCS code but offers no reason for this decision and does not reference the criteria CMS uses to assess code applications. According to the speaker, Medipro RELAX Liner is primarily used to reduce or eliminate phantom limb pain (PLP) in amputees while providing the benefits of prosthetic liners. The speaker claimed that there is no existing HCPCS code that covers a device that is designed to reduce or eliminate PLP. The speaker requested that the CMS HCPCS Workgroup reconsider the preliminary decision in light of the Medipro RELAX Liner's satisfaction of the requirements for creation of a separate code under the HCPCS coding system: 1) The RELAX Liner meaningfully addresses a major complication of amputation through application of an evidence-based, device-oriented approach with no equivalent product and, therefore, meets a national program operating need. 2) The RELAX liner performs a significantly different function than items currently categorized in the HCPCS code set through the use of Umbrellan® to dissipate electrostatic charge. 3) The RELAX Liner's use of Umbrellan® creates a significant therapeutic distinction compared to existing code treatments or products.

HCPCS Public Meeting Agenda Item #4
June 7, 2011

Attachment# 11.055

Topic/Issue:

Request to reinstate code L5989 "ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL SYSTEM, PYLON WITH INTEGRATED ELECTRONIC FORCE SENSORS" with a verbiage change to delete the word “pylon” and insert the word “pyramid,” to describe the Smart Pyramid™.

Background/Discussion:

According to the requester, the Smart Pyramid™ is a prosthesis-coupling pyramid with integrated sensors that analyzes prosthetic-socket forces and recommends changes to prosthetic components to reduce injurious socket loading. The Smart Pyramid™ is intended for single-patient use for the useful lifetime of the prosthesis. As part of the prosthesis, Smart Pyramid™ is used any time when clinical indicators reveal skin, joint, or balance problems. Its embedded, electronic force sensors detect the forces that the socket exerts on the wearer's residual limb during ambulation. Smart Pyramid™ also measures axial weight-bearing through the prosthesis, sagittal and coronal-plane torques, stance and swing time, and cadence. It is placed just below the socket and it measures the ground-reaction forces that translate into socket pressures as the amputee walks. The data is stored and alterations are made by the prosthetist based on review of the stored data. This process is repeated until the system detects optimal socket forces. Benefits of the Smart Pyramid's functionality include reduction of skin ulcerations, excessive joint forces, and socket replacement. These features distinguish Smart Pyramid™ from non-instrumented pyramids, which are simply structural components described by existing HCPCS codes L5910 and L5920. The requester is asking CMS to reinstate code L5989 (discontinued 12/31/04) to identify the Smart Pyramid™. According to the requester, the original code application which was submitted for code L5989 had indicated there were future expectations for this element to be available in additional prosthetic devices or as a stand-alone item.

CMS HCPCS Preliminary Decision:

Existing code A9279 "MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED "is available for assignment by insurers if they deem appropriate, to identify the data gathering or diagnostic component of the Smart Pyramid. The alignment component of this device is included in existing code L5910 "ADDITION, ENDOSKELETAL SYSTEM, BELOW KNEE, ALIGNABLE SYSTEM" or L5920 "ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE OR HIP DISARTICULATION, ALIGNABLE SYSTEM", depending upon level of disarticulation.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For A9279, Pricing = 00
For L5910 & L5920, Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that codes L5910 and L5920 do not describe the Smart Pyramid because this device's "function" is far beyond what is envisioned in existing codes L5910 and L5920. According to the speaker, products identified by codes L5910 and L5920 (e.g. the compass reader) are furnished one per clinic (and used in the clinic), whereas the Smart Pyramid remains attached to each individual prosthesis (although still used in the clinic by the prosthetist to determine alignment). In addition, the products described by codes L5910 and L5920 do not include any type of electronic sensing for quantitative adjustment of the prosthesis to reduce trauma and enable treatment protocols for skin breakdown and chronic pain "due to pathological mal-alignment" to the amputated limb. The speaker reiterated the original request that CMS reinstate code L5989 or create a new code to identify a dynamic alignable system with digital force sensors.

HCPCS Public Meeting Agenda Item #5
June 7, 2011

Attachment# 11.015

Topic/Issue:

Request to establish a code for a knee extension assist (KEA), Trade Name: Townsend Design Knee Joint Extension Assist.

Background/Discussion:

According to the requester, the knee extension assist (KEA) is a mechanical device that provides a knee extension force when applied to knee joints on a Townsend Design KO or KAFO. It replaces or enhances the weak or absent knee extensors that are needed for a stable, symmetrical gait. The KEA is indicated for individuals with partial or complete paralysis of one or both of their lower extremities who wear a knee orthosis or KAFO to stabilize their leg during ambulation. According to the requester, there is no base code or add-on code that describes an extension assist knee joint.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a separate code to identify the knee extension flexion assist feature was not identified by Medicare, Medicaid or the Private Insurance Sector. The knee extension assist feature is included in existing codes L2005 "KNEE ANKLE FOOT ORTHOSIS, ANY MATERIAL, SINGLE OR DOUBLE UPRIGHT, STANCE CONTROL, AUTOMATIC LOCK AND SWING PHASE RELEASE, MECHANICAL ACTIVATION, INCLUDES ANKLE JOINT, ANY TYPE, CUSTOM FABRICATED"; L1843 "KNEE ORTHOSIS, SINGLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT"; L1844 KNEE ORTHOSIS, SINGLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, CUSTOM FABRICATED, INCLUDES FITTING AND ADJUSTMENT"; L1845 KNEE ORTHOSIS, DOUBLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT"; and L1846 KNEE ORTHOSIS, DOUBLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, CUSTOM FABRICATED, INCLUDES FITTING AND ADJUSTMENT".

Extension Assist is included in base code L2005 if the knee joint is used as a KAFO. Extension Assist is included in code L1843, L1844, L1845 or L1846 (whichever is appropriate) if the joint is used as a KO. Billing separate codes for the KEA as an addition would therefore be redundant. Existing code L9900 "ORTHOTIC OR PROSTHETIC SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS "L" CODE" is available for assignment by insurers to separately identify the KEA if they deem appropriate.

Medicare Payment:

The payment rules associated with the existing L9900 code apply to this product if covered. Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #6
June 7, 2011

Attachment# 11.117

Topic/Issue:

Request to establish an "addition" code for an electronically activated knee joint used in custom-made KAFOs, Trade Name: E-MAG Active Knee Joint. Applicant's suggested language: "Addition to lower extremity stance control orthosis, electronic activation, stance phase only."

Background/Discussion:

According to the requester, the E-MAG Active Knee Joint is an electronically activated knee joint with a secure stance phase and free swing phase that is controlled independent of the ankle or sole of the foot. It consists of the E-MAG active knee joint, battery, electronic control unit with sensors, and constituent fabrication supplies. The electronically activated E-MAG Active Knee Joint unlocks KAFOs during the appropriate time in the patient's gait pattern. Sensors housed in the control unit measure the position of the leg as a patient walks. When the leg is in position to come off the ground for swing, a signal is sent to the electromagnet in the knee joint to unlock, enabling the knee to bend and swing, allowing foot clearance. This enables the patient to walk with a more physiological gait and lessens the need for compensatory movements. According to the requester, the E-MAG Active Knee Joint is a separate orthotic component, and electronic activation should be separately described by a new "addition" code, to be used in conjunction with a custom stance control orthosis base code. There is no existing code to describe an electronically activated orthotic knee joint. Existing code L2005 is a base code that describes a stance control mechanism with automatic, mechanical locking and unlocking, however items included in code L2005 are not electronically activated.

CMS HCPCS Preliminary Decision:

The E-MAG Active Knee Joint is included in code L2005 "KNEE ANKLE FOOT ORTHOSIS ANY MATERIAL SINGLE OR DOUBLE UPRIGHT, STANCE CONTROL, AUTOMATIC LOCK AND SWING PHASE, RELEASE, MECHANICAL ACTIVATION, INCLUDES ANKLE JOINT, ANY TYPE, CUSTOM FABRICATED." Electromagnetic activation is inherently included in L2005.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision to assign existing code L2005 to the E-MAG Active Knee Joint. The speaker stated that code L2005 describes mechanical activation whereas the E-MAG has electronic activation. According to the speaker, E-MAG has a therapeutic distinction over similar products because it improves balance and safety; improves compliance, and has effective PT outcomes. In addition, the speaker commented that there are populations that cannot use mechanical activation (e.g., post ankle fusion, polio, post CVA or other patients who do not have ankle motion). The speaker reiterated the original request to establish a code for the E-MAG.

HCPCS Public Meeting Agenda Item #7
June 7, 2011

Attachment# 11.115

Topic/Issue:

Request to establish a code for a prefabricated ankle foot orthosis, Trade Name: Noodle AFO. Applicant's suggested language: AFO, dynamic braided composite strut, total carbon fiber or equal material, prefabricated, includes fitting and adjustment.

Background/Discussion:

According to the requester, the Noodle AFO is a prefabricated ankle foot orthosis. It has a flexible/dynamic composite strut made from a tubular braid of composite fibers that is impregnated with an oven-cured epoxy resin. This strut connects the calf portion of the brace to the foot portion of the brace. Unlike other carbon composite devices, the Noodle strut absorbs and releases energy as the user goes through their gait cycle, creating a very fluid motion. The flexibility of the strut allows the patient to have a more natural and less restrictive gait than other non articulating orthotic devices. The mechanical effect of the Noodle AFO is similar to an articulated AFO with a dorsiflexion/plantar flexion assist/resist joint. However, there are three key differences: 1) the Noodle is smaller in size; 2) it has progressive resistance with no endpoint; and 3) it is prefabricated and without articulation. The Noodle is available as medial or lateral strut placement to address the user's anatomical structure or deformity. According to the requester, code L1951 does not describe this product because it is hemi-spiral. Code L1930 does not describe this product because it does not address the dynamic energy return that advanced carbon fiber composites offer to patients. Code L1932 provides the closest description of the Noodle AFO, however; this code specifically describes a brace with a rigid anterior section.

CMS HCPCS Preliminary Decision:

Existing code L1930 "ANKLE FOOT ORTHOSIS, PLASTIC OR OTHER MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT" was created for other materials including carbon fiber, and therefore, this code adequately describes the Noodle AFO.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that the quality of resins and fibers along with changes in techniques, have evolved over the years and

today's composites are far more advanced and also far more expensive than they once were. According to the speaker, carbon's ability to absorb and release energy, and flex repetitively over millions of cycles and years of service is unlike any other material known to man. The speaker claimed that the posterior cuff Noodle AFO uses advanced, braided carbon fiber and offers not only the performance of the carbon composite, but it does it in a more palatable format compared to the rigid anterior design. The speaker predicted that assignment of code L1930 would destroy the technology and remove the product from the U.S. market because the associated reimbursement rate is too far removed from the costs associated with carbon composite production and application. The speaker requested the creation of a new code that addresses the posterior equivalent to existing code L1932 or the modification of L1932 to allow for an anterior or posterior shell placement.

HCPCS Public Meeting Agenda Item #8
June 7, 2011

Attachment# 11.108

Topic/Issue:

Request to establish a new addition code to add to existing base codes for all prosthetic feet. Applicant's suggested language: "Dynamically accommodates additional load carriage exceeding 20% of user's body weight".

Background/Discussion:

According to the requester, the Thrive™ prosthetic foot accommodates increased loads when the user is lifting or carrying heavy objects. It is clinically indicated for individuals who frequently are lifting or carrying heavy objects including, but not limited to automotive mechanics, carpenters, child care providers, construction workers, delivery workers, factory workers, farmers, firefighters, maintenance workers, plumbers, police officers, military personnel, and/or warehouse workers. Thrive™ has two keels, a primary lower keel and a secondary upper keel. The primary lower keel provides function for the amputee's activities of daily living. The secondary upper keel is engaged in addition to the primary lower keel when the amputee lifts or carries a heavy object. Thrive™ also has a carbon fiber heel lever and urethane heel bumper. It is available in various sizes (22-30 cm), in nine stiffness categories, and is available for amputees weighing up to 365 pounds. The Thrive ™ dynamically adjusts to the amputee's activity with his/her input and is provided as a definitive component with the amputee's prosthesis. A prosthetic foot that dynamically accommodates increased loading will provide the user with increased function for activities of daily living. It may also reduce the need for a secondary prothetic foot. According to the requester, existing codes do not describe the function of a prosthetic foot which dynamically accommodates additional load carriage.

CMS HCPCS Preliminary Decision:

Existing code L5981 "ALL LOWER EXTREMITY PROSTHESIS, FLEX-WALK SYSTEM OR EQUAL" adequately describes this dual keel technology without add-on codes. Deflection of the keel does not equate to vertical shock compression, therefore existing code L5987 "ALL LOWER EXTREMITY PROSTHESIS, SHANK FOOT SYSTEM WITH VERTICAL LOADING PYLON" for vertical shock reduction does not apply.

Medicare Payment:

The payment rules associated with the existing L5981 code apply to this product if covered. Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker claimed that the engineered design of the Thrive prosthetic foot offers the unique ability to safely increase the user's load carriage up to 30% of their body weight and facilitates sound biomechanical gait. The Thrive has two keels, a primary lower keel and a secondary upper keel. According to the speaker, the secondary keel dynamically accommodates the increased loading to assure sound biomechanics and structural integrity of the prosthetic foot. The speaker reiterated the original request for a new addition code to describe the prosthetic foot component enhancement.

HCPCS Public Meeting Agenda Item #9
June 7, 2011

Attachment# 11.053

Topic/Issue:

Request to establish a HCPCS "addition" code for endoskeletal ankle foot systems to describe the Hydraulic (Fluid) dampening capabilities of the Echelon foot. Applicant's suggested language: "Addition, Endoskeletal Ankle Foot System, Polycentric or Single Axis Joint, Hydraulic, with or without Plantar or Dorsiflexion Control."

Background/Discussion:

According to the requester, the Echelon, designed for K3 level amputees, introduces new functionality which enables the foot to move to a new position under load without the wearer straining as the foot moves to conform to changing ground surface inclinations. This new function and benefit is called hydraulic fluid yielding stance phase control. Balanced hydraulic yielding means the foot can move through a range of motion in stance phase without pushing back or deflecting on the body. Standing and walking can take place with minimal compensation, and the individual is therefore able to safely and comfortably traverse varied terrain, slopes and stairs. According to the requester, existing codes L5981 and L5968 describe mechanical foot response designs that are elastic-based, and do not have the ability to adapt under load. The self alignment capability offered by the Echelon is therefore new, previously not described in coding, and medically necessary. Therefore a new code is warranted.

CMS HCPCS Preliminary Decision:

Existing code L5981 "ALL LOWER EXTREMITY PROSTHESIS, FLEX-WALK SYSTEM OR EQUAL" used together with code L5968 "ADDITION TO LOWER LIMB PROSTHESIS, MULTIAXIAL ANKLE WITH SWING PHASE ACTIVE DORSIFLEXION FEATURE" describes the Echelon and the functions and benefits attributed to it. The Echelon has inherent alignment as process of the hydraulic joint.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For L5981, Pricing = 38
For L5968, Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. According to the speaker, existing code L5968 includes hydraulic only during swing phase, not stance and therefore a new addition code is needed to separately identify hydraulic stance phase feature.

HCPCS Public Meeting Agenda Item #10
June 7, 2011

Attachment# 11.109

Topic/Issue:

Request to: 1) establish a new HCPCS code to describe a prosthetic foot/ankle system, trade name: The Motion Foot;
2) broaden the language of existing codes L5810, L5988 and L5999 to include the functions of this prosthesis, so that these codes may also be applied to the Motion Foot: Revise L5810 which currently reads: ADDITION, ENDOSKELETAL KNEE-SHIN, SINGLE AXIS, MANUAL LOCK to instead read: Addition, endoskeletal knee-shin *or ankle*, single axis, manual lock; Revise code L5988 which currently reads: ADDITION TO LOWER LIMB PROSTHESIS, VERTICAL SHOCK-REDUCING PYLON FEATURE to instead read: Addition to lower limb prosthesis, shock-reducing pylon *or ankle*; Revise L5990 which currently reads: ADDITION TO LOWER EXTREMITY PROSTHESIS, USER ADJUSTABLE HEEL HEIGHT to instead read: Addition to lower extremity prosthesis, user *automatic or* adjustable heel height *and plantarflexion/dorsiflexion hydraulic alignment*; and
3) also assign existing codes L5981 and L5968 to the Motion Foot; and
4) also permit use of code L5999 to describe other individual functions of the Motion Foot functions, such as dynamic and toe motion, multi-axial motion with active dorsiflexion, automatic heel height adjustment, shock absorption, and manual lock.

Background/Discussion:

According to the requester, The Motion Foot is a unique prosthetic ankle/foot product that provides unparalleled ankle range of motion - a near normal 50° range of plantar/dorsi flexion. This hydraulic unit has independent plantarflexion and dorsiflexion resistances to adjust for patient weight, activity level, and lifestyle. It is currently paired with a dynamic carbon fiber footplate and main spring element to optimize gait efficiencies for the K3 & K4 patient population. There is also a manual lock to lock the foot in the fully dorsiflexed position to prevent unwanted movement while driving in a car, climbing ladders, standing for long periods of time, or whenever the patient wishes to prevent ankle movement temporarily. Use of this system increases stability; broadens the range of slopes on which the wearer may walk easily; and decreases stress on the remnant limb. Appropriate candidates for the Motion Foot are those of a K2, K3 or K4 level of activity. The weight limit is 220 pounds and sizes are available from 22 cm to 30 cm. According to the requester, Motion Foot differs from similar products in 1) product design, 2) range of motion, 3) convenience and comfort while sitting or standing; and 4) ability to wear various heel heights. According to the requester, existing codes L5988 and L5990 are inadequate to describe this product because the Motion Foot uses hydraulics to control the plantarflexion moment at heel strike and adapts to varying grades of slope and shoe heel heights without any action from the user. There is no existing code to describe this manual ankle.

CMS HCPCS Preliminary Decision:

Existing code L5981 "ALL LOWER EXTREMITY PROSTHESIS, FLEX-WALK SYSTEM OR EQUAL" used together with code L5990 "ADDITION TO LOWER EXTREMITY PROSTHESIS, USER ADJUSTABLE HEEL HEIGHT" adequately describes the product that is the subject of this request. The requested revisions to existing codes L5810 and L5988 would change the original intent of these codes and therefore do not improve the code language. As such, the verbiage for these codes will not be revised.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For L5981, Pricing = 38
For L5990, Pricing = 38

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, fiscal intermediaries and A/B MACs(e.g., claims for DME implanted in an ambulatory surgical center are processed by local carriers). Claims for DME and ostomy, tracheostomy and urological supplies furnished by a home health agency are processed by Regional Home Health Intermediaries (RHHIs)and A/B MACs.

Fee Schedule Payments

Prior to January 1, 1989, payment for most DMEPOS items and services was made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment is still made on a reasonable charge basis for home dialysis supplies and equipment and for IOLs inserted in a physician's office. There is a monthly limit per beneficiary on payments for home dialysis supplies and equipment. Payment for most of the other DMEPOS items and services is based on the lower of the actual charge for the item or a fee schedule amount. The Part B deductible and 20 percent coinsurance both apply to the DMEPOS items and services described above.

The Social Security Act requires that the DMEPOS fee schedule amounts be established based on average reasonable charges made during a base period (e.g., July 1, 1986 thru June 30, 1987 for prosthetic devices, prosthetics and orthotics). The fee schedule amounts are increased by annual update factors. Because the reasonable charge data required by the law in establishing fee schedule amounts does not exist for new DMEPOS items, the fee schedule amounts for new DMEPOS items are "gap-filled"

using fees for comparable items, supplier price lists, manufacturer suggested retail prices, or wholesale prices plus a markup. The gap-filling methodology is used to estimate the average reasonable charge for the item from the base period.

DMEPOS Payment Categories/HCPCS Pricing Indicators

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

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

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

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

- **Pricing = 33 Oxygen and Oxygen Equipment**
  Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36^{th} monthly payment is made, after which payment for the ongoing delivery of contents continues for patient owned gaseous or liquid systems.

- **Pricing = 34 Supplies Necessary for the Effective Use of DME**

Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

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

- **Pricing = 36 Capped Rental Items**
  Payment is made on a monthly rental fee schedule basis. For items furnished on or after January 1, 2006, the beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items other than power wheelchairs for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. Effective for items furnished on or after January 1, 2011, the rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Effective for items furnished on or after January 1, 2011, only complex rehabilitative power wheelchairs can be purchased in the first month.

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

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

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

- **Pricing = 45 Customized DME**
  Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item.

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

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