Centers for Medicare & Medicaid Services (CMS)
Level II Healthcare Common Procedure Coding System (HCPCS)
Application Summary 2015-2016 Coding Cycle for Items Discussed at
Thursday, May 21, 2015 for Supplies and Other

Thursday, May 21, 2015

Introduction and Overview

Approximately 60 people attended. The agenda included 17 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 the 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 Supplies and "Other"
Thursday, May 21, 2015, 10:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

9:15 a.m. Arrival and sign-in

10:00 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# 15.006
Request to establish a unique Level II HCPCS Level II code to identify a monitoring and biofeedback gait training system, Trade Name: My iSmartStep™ System. Applicant's suggested language: E80XX-Gait trainer, monitoring and biofeedback software and pressure sensing insole system, for gait training therapy and muscle re-education of weight-bearing skills, includes all accessories and components.

AGENDA ITEM #2
Attachment# 15.068
Request to establish a unique Level II HCPCS code to identify Gait Lift Assistance Device (GLAD), Trade Name: Grip-n-Assist™ Belt.

AGENDA ITEM #3
Attachment# 15.005
Request to establish a unique Level II HCPCS code to identify a non-invasive, portable, table-top arm rehabilitation device, Trade Name: Tailwind™. Applicant's suggested language: E18xx-Dynamic, upper extremity paralysis, bilateral arm rehabilitation, repetitive movement device with auditory cues and range of motion adjustments, includes all accessories and components.

AGENDA ITEM #4
Attachment# 15.095
Third request to establish two unique Level II HCPCS codes to identify the following BalanceWear® Balance - Based Proprioceptive Neuromuscular Strategic Weighting Balance Correction Devices: BW300 Full Torso Device and BW500 device. Applicant's suggested language for the BW500: Balance-Based Proprioceptive Neuromuscular Strategic Weighting BalanceWear with LSO. Applicant did not suggest code language for the BW300 Full Torso Device.

AGENDA ITEM #5
Attachment# 15.103
Repeat request to establish a unique Level II HCPCS code to identify Mechanical Advantage Xtremety Mobilization (MAXM).

AGENDA ITEM #6
Attachment# 15.107
Request to establish a unique level II HCPCS code to identify a powered, computer-controlled, Pressure Modulated Knee Rehabilitation Machine (PMKR), Trade Name: X10 Pressure Modulated Knee Rehabilitation Machine.

AGENDA ITEM #7
Attachment# 15.075 A & B
Two separate, related requests to establish a total of 3 Level II HCPCS codes to identify components of a urethral insert with pump for bladder drainage, Trade Name: inFlow™ temporary intraurethral valve-pump system: one to identify a sterile single-use urethral insert packaged with a disposable introducer; one to identify a hand-held remote control "Activator"; and one to identify 3-volt lithium batteries used with patient-owned Activator, (2 batteries required). The requester also asks that the inFlow™ device be considered a prosthetic. Applicant's suggested language: 15.075 A: LXXX1: Female urinary prosthesis, temporary, with delivery system. 15.075 B: LXXX2: Activator for female urinary prosthesis; and L736X: Three volt lithium battery for patient-owned Activator for female urinary prosthesis.

AGENDA ITEM #8
Attachment# 15.102
Request to establish a unique HCPCS Level II code to identify Blom-Singer Adjustable Bi - flanged Fistula prosthesis. Applicant's suggested language: Fistula prosthesis, bi-flanged, each.

AGENDA ITEM #9
Attachment# 15.099
Request to establish a unique Level II HCPCS code to identify a Rotation Medical Rotator Cuff Bio-Inductive Implant system. Applicant's suggested language: QXXXX - Rotation Medical Bio-inductive Implant.

No Primary Speaker

AGENDA ITEM #10
Attachment# 15.100
Request to establish a unique HCPCS Level II code to identify a customizable pliable mouthpiece which incorporates pressure sensors which connects to a tablet/notebook computer for use as a biofeedback device during lingual strengthening therapy, Trade Name: SwallowSTRONG. Applicant's suggested language: A9XXX - Oral pressure sensor mouthpiece, biofeedback device.

Primary Speaker: Jacqueline Hind of Swallow Solutions

AGENDA ITEM #11
Attachment #s: 15.076, 15.077, 15.078, 15.079, 15.080, 15.081, 15.082 and 15.083
Eight separate requests, each to establish a Level II HCPCS code to identify one of 8 blood products processed using Rejuvesol® Red Blood Cell Processing Solution for extracorporeal rejuvenation of Red Blood Cells.
Applicant's suggested language:

15.076	P90X1 Red Blood Cells, Rejuvenated, Washed, Each Unit
15.077	P90X2 Red Blood Cells, Irradiated, Rejuvenated, Washed, Each Unit
15.078	P90X3 Red Blood Cells, Rejuvenated Deglycerolized, Each Unit
15.079	P90X4 Red Blood Cells, Leukocytes Reduced, Irradiated
15.080	P90X5 Whole Blood or Red Blood Cells, Leukocytes Reduced, CMV-Negative, Rejuvenated, Washed, Each Unit
15.081	P90X6 Whole Blood or Red Blood Cells, Leukocytes Reduced, Rejuvenated, Deglycerolized, Each Unit
15.082	P90X7 Red Blood Cells, Rejuvenated, Deglycerolized, Leukocytes Reduced, Irradiated, Each Unit
15.083	P90X8 Red Blood Cells, Leukocytes Reduced, CMV-Negative, Irradiated, Rejuvenated, Washed, Each Unit

Primary Speaker: Alan Gray of Biomet Biologics

AGENDA ITEM #12
Attachment# 15.084
Request to establish a unique Level II HCPCS code to identify a fresh frozen plasma (FFP) product processed using INTERCEPT® Blood System for Plasma, sourced from 2 to 3 donors, Amotosalen/UVA Light-Treated, Frozen within 24 hours of collection. Applicant's suggested

language: Fresh Frozen Plasma, Sourced from 2-3 Donor Pool, Amotosalen/UVA Light-Treated, Frozen Within 24 Hours of Collection, Each Unit.

Attachment# 15.085
Request to establish a unique Level II HCPCS code to identify a fresh frozen plasma (FFP) product processed using INTERCEPT® Blood System for Plasma, sourced from a single donor, Amotosalen/UVA Light-Treated, Frozen within 8 hours of collection. Applicant's suggested language: Fresh Frozen Plasma (Single Donor), Amotosalen/UVA Light-Treated, Frozen Within 8 Hours of Collection, Each Unit.

Attachment# 15.086
Request to establish a unique Level II HCPCS code to identify a platelet product collected by apheresis and processed using the INTERCEPT® Blood System for Platelets. Applicant's suggested language: Platelets, Pheresis, Amotosalen/UVA Light-Treated, Each Unit.

Primary Speaker: Dr. Theresa Boyd of Blood Bank of Delmarva

AGENDA ITEM #13
Attachment# 15.073
Request to make a coding distinction between non-coated and hydrophilic coated intermittent urinary catheters, by revising 3 existing HCPCS codes A4351, A4352 and A4353 to omit references to coating; and establishing 3 new Level II HCPCS codes to specifically identify hydrophilic coated intermittent catheters. Trade Name: Speedicath.

Applicant's suggested language:

Revise A4351 - Intermittent urinary catheter; straight tip, ~~with or~~ without coating (Teflon, silicone, silicone elastometer, ~~or hydrophilic,~~ etc), each.

Revise A4352 - Intermittent urinary catheter; coude tip, ~~with or~~ without coating (Teflon, silicone, silicone elastometer, ~~or hydrophilic,~~ etc), each.

Revise A4353 - Intermittent urinary catheter (<u>conventional uncoated</u>) with insertion supplies

Establish AXXX1 Hydrophilic coated intermittent urinary catheter, straight tip, each

Establish AXXX2 Hydrophilic coated intermittent urinary catheter, coude tip, each

Establish AXXX3 Hydrophilic coated intermittent urinary catheter, with insertion supplies, each

Primary Speaker: Martin Nottmeier of Coloplast Corporation

AGENDA ITEM #14
Attachment# 15.069
Request to establish a unique Level II HCPCS code to identify an electronic sensor for monitoring pressure within ostomy/stoma pouches, Trade Name: Ostom-i™. Applicants

suggested language: AXXXX OSTOM-i Alert Sensor for electronically monitoring pressure within ostomy/stoma bags, one unit per 3 months.

No Primary Speaker

AGENDA ITEM #15
Attachment# 15.090
Request to establish three unique Level II HCPCS codes, one each to identify 3 size categories of silver-containing composite absorptive multi-layer dressings *with* adhesive border, Trade Names: BCT Silver Bandage and KoCarbon Ag Silver Bandage.
Applicant's suggested language:

A62X1 - Composite absorptive multiple layer dressing with highly absorptive layer *with* adhesive border, less than 16 square inches, each dressing.

A62X2 - Composite absorptive multiple layer dressing with highly absorptive layer *with* adhesive border, more than 16 square inches but less than or equal to 48 square inches, each dressing.

A62X3 - Composite absorptive multiple layer dressing with highly absorptive layer *with* adhesive border, more than 48 square inches, each dressing.

Attachment# 15.091
Request to establish three unique Level II HCPCS codes, one each to identify 3 size categories of silver-containing composite absorptive multi-layer dressings *without* adhesive border, Trade Names: BCT Antimicrobial Dressing and KoCarbon Ag Antimicrobial Dressing.
Applicant's suggested language:

A62X1 - Composite absorptive multiple layer dressing with highly absorptive layer *without* adhesive border, less than 16 square inches, each dressing.

A62X2 - Composite absorptive multiple layer dressing with highly absorptive layer *without* adhesive border, more than 16 square inches but less than or equal to 48 square inches, each dressing.

A62X3 - Composite absorptive multiple layer dressing with highly absorptive layer *without* adhesive border, more than 48 square inches, each dressing.

No Primary Speaker

AGENDA ITEM #16
Attachment# 15.072
Request to establish a unique Level II HCPCS code to identify MuGard® Mucoadhesive.
Applicant's suggested language: AXXXX - Mucoadhesive oral wound rinse.

Primary Speaker: Dr. Marc Posner of Northwestern Lake Forest Hospital

AGENDA ITEM #17
Attachment# 15.092
Request to establish a unique Level II HCPCS code to identify Cadexomer Iodine Gel, trade name: IODOSORB. Applicant's suggested language: AXXXX Cadexomer Iodine Wound Filler, gel/paste, per fluid ounce.

Primary Speaker: Dr. Arthur Stone of MedNexus, Inc.

HCPCS Public Meeting Agenda Item #1

May 21, 2015

Attachment# 15.006

Topic/Issue:

Request to establish a unique Level II HCPCS Level II code to identify a monitoring and biofeedback gait training system, Trade Name: My iSmartStep™ System.

Applicant's suggested language: E80XX-Gait trainer, monitoring and biofeedback software and pressure sensing insole system, for gait training therapy and muscle re-education of weight-bearing skills, includes all accessories and components.

Background/Discussion:

Andante Medical Devices submitted a request to establish a HCPCS code to identify the My iSmartStep System™, a monitoring and biofeedback gait training system, and to categorize the system as Durable Medical Equipment. According to the requester, this system is intended for use in the restoration of the functional abilities as a result of orthopedic or neurological trauma, in any situation in which a therapist and/or patient would benefit from objectively assessing the amount of weight being applied to the lower limb. My iSmartStep consists of three components, including (1) a flexible insole that is placed in the patient's shoe and acts as a pressure-sensing element; (2) the control unit, connected to PC software; and (3) PC software that acts as a patient medical record and patient assessment tool. The device assists in accurately assessing patients who are undergoing weight-bearing restrictions and gait therapy training. It senses the amount of weight applied to the plantar surface of the foot during rehabilitation, and can also be used in the home setting. My iSmartStep alerts the user and/or therapist with an alarm when the weight applied to the plantar surface exceeds the preselected value.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private insurance sector to establish a code to identify this device, which is included in the biofeedback procedure.

Medicare Payment:

Included in procedure.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker indicated that no existing permanent HCPCS code appropriately defines the My iSmartStep. The speaker stated, currently available HCPCS codes for DME gait training technologies are limited to non-

biofeedback, pediatric gait trainers, individualized for each patient and do not include reference to software system support or monitoring capabilities. According to the speaker in the clinic setting, CPT code 90901 (biofeedback training by any modality) is used by the provider to report his/her time in training the patient with the biofeedback device. This code does not report the utilization or the purchase/rental of a specific device. The speaker reiterated the original request for a unique code.

Final Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private insurance sector to establish a code to identify this device, which is included in the service provided.

HCPCS Public Meeting Agenda Item #2

May 21, 2015

Attachment# 15.068

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Gait Lift Assistance Device (GLAD), Trade Name: Grip-n-Assist™ Belt.

Background/Discussion:

Left Coast Sports Innovation submitted a request to establish a HCPCS code to identify Grip-n-Assist™ Gait Lift Assistance Devices (GLAD) mobility belts. These devices are made of latex-free material that include from 2 to 6 (depending on design) vertical handles for use by care-givers; a lift cable and D-ring support for use with lifting machines; adjustable buckles and Velcro. Grip-n-Assist belts are available in a variety of designs and sizes based on the wearer's Body Mass Index and level of independence with transfer: Grip-n-Assist Lite; Professional; Professional Petite; Professional Plus; Professional Lift; and Military. According to the requester, the GLAD device is a paradigm changing device to advance better outcomes and rehabilitation helping children and adults to walk and improve gait, transfers and overall mobility. The GLAD is worn by the patient around their waist and, as necessary for lifting and transfer, with attachments around the thighs and or over the shoulders.

The requester claims a significant therapeutic distinction in terms of "greater safety, better feelings, security, comfort, rehabilitation, therapeutic value and quality of life" when the Grip-n-Assist devices is used, when compared with the use of other mobility belts, due to the Grip-n-Assist devices' unique, special construction, design and materials.

The requester comments that existing codes do not describe a device that performs nearly or qualitatively or effectively, as the GLAD device, or that provides the desired and imperative therapeutic and clinical outcomes.

Preliminary Decision:

Existing code E0700 "Safety equipment, device or accessory, any type" 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=00

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

CMS upheld its decision that the existing code E0700 “Safety equipment, device or accessory, any type” adequately describes the product that is the subject of this request.

HCPCS Public Meeting Agenda Item #3

May 21, 2015

Attachment# 15.005

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a non-invasive, portable, table-top arm rehabilitation device, Trade Name: Tailwind™.

Applicant's suggested language: E18xx- Dynamic, upper extremity paralysis, bilateral arm rehabilitation, repetitive movement device with auditory cues and range of motion adjustments, includes all accessories and components.

Background/Discussion:

Encore Path, Inc. submitted a request to establish a HCPCS code to identify the Tailwind Bilateral Arm Trainer with Rhythmic Auditory Cueing (BATRAC), and to categorize the device as Durable Medical Equipment. According to the requester, the device is a non-invasive portable arm rehabilitation device intended for use in the restoration of arm movement and function by persons with paretic arm(s), (e.g., as a results of stroke or brain injury). The device consists of two handles that move along independent, resistance free-free tracks. The user moves the handles along each track in response to auditory cues. The combination of the repetitive arm movement with auditory cues causes motor cortex activation, helping the brain to improve arm mobility and function. The Tailwind is distinct from other static and dynamic flexion/extension devices due to its incorporation of auditory cuing via a metronome into the rehabilitation program. The Tailwind does not measure arm force or range of motion, nor does it rely on computer software or an LCD screen as part of the rehabilitation regimen. The Tailwind improves upper extremity function, as opposed to a single joint or anatomical body part.

The requester comments that no existing HCPCS code adequately describes the Tailwind.

Preliminary Decision:

Existing code A9300 "Exercise Equipment" 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=00

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated existing code A9300 does not accurately or appropriate describe Tailwind. Tailwind in not intended to improve upper extremity function through arm strengthening only through brain re-training and is not used in the absence of hemiparesis. According to the speaker the use of Tailwind has been proven to actually increase hemispheric activation during paretic arm movement through neuro-functional couplings. The speaker reiterated the original request for an "E" code.

Final Decision:

Existing code A9300 "Exercise Equipment" adequately describes the product that is the subject of this request.

HCPCS Public Meeting Agenda Item #4

May 21, 2015

Attachment# 15.095

Topic/Issue:

Third request to establish two unique Level II HCPCS codes to identify the following BalanceWear® Balance - Based Proprioceptive Neuromuscular Strategic Weighting Balance Correction Devices: BW300 Full Torso Device and BW500 device

Applicant's suggested language for the BW500: Balance-Based Proprioceptive Neuromuscular Strategic Weighting BalanceWear with LSO.

Applicant did not suggest code language for the BW300 Full Torso Device.

Background/Discussion:

Motion Therapeutics submitted a request to establish 2 new HCPCS codes; one each to identify 2 models of BalanceWear® balance-based proprioceptive neuromuscular strategic weighting balance correction devices: the BW300 full torso device; and the BW500. According to the requester, the BW300 is an "orthotic/prosthetic" worn on the torso that provides the patient balance control that they lack prior to wearing the device. It contains strategically placed small weights to improve postural control and balance of a patient with compromised balance due to many neurologic causes. The BW500 is the same as the BW300, except the BW500 also includes a custom vest, lumbo sacral orthotic (LSO) and weights. Both devices stabilize the torso in both standing and sitting control and dynamic conditions providing immediate improvement in balance and mobility. The BW500 lumbo sacral orthotic provides improvement beyond what the BW300 offers in about 60% of patients who have need of additional trunk support. Fall prevention is the most important design objective of BalanceWear.

According to the requester, existing codes do not identify apparatuses to balance a patient.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a HCPCS code to identify weighted balance correction devices.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There were written comments provided for the CMS' HCPCS Public Meeting in reaction to our preliminary decision. The applicant disagreed with CMS preliminary decision, stating that the BW300 is an orthotic/prosthetic worn on the torso that provides the patient balance control that they lack prior to wearing the device. It contains strategically placed small weights to improve postural control and balance of a patient with compromised balance due to many neurologic causes. The BW500 is the same as the BW300 except the BW500 also includes a custom vest, lumbo sacral orthotic (LSO).

Final Decision:

This request to establish a Level II HCPCS codes to identify Weighted Balance Correction device has not been approved, because these devices are not primarily medical in nature.

HCPCS Public Meeting Agenda Item #5

May 21, 2015

Attachment# 15.103

Topic/Issue:

Repeat request to establish a unique Level II HCPCS code to identify Mechanical Advantage Xtremity Mobilization (MAXM).

Background/Discussion:

Mechanical Advantage, Ltd. submitted a request to establish a new HCPCS code to identify the MAXM device and to "change its status" from existing code A9300 'Exercise Equipment". According to the requester, the MAXM device is a static progressive knee stretching device which employs a pulley system to assists knee patients with the leverage and force needed to maintain and control a long slow progressive orthopedic stretch. MAXM is indicated for all patients subject to knee range of motion difficulties and is used in hospitals and nursing facilities immediately post-operative and outpatient PT clinics for the long term. The requester maintains that the device provides the patient with assistance, *not* resistance, as with other exercise equipment; and that it is "impossible to exercise" with the MAXM device.

The requester comments that existing codes are adequate to describe the MAXM device.

Preliminary Decision:

Existing code A9300, Exercise Equipment, adequately describes the product that is subject to this request.

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 applicant disagreed with CMS' preliminary decision stating that MAXM™ design and function is the complete opposite function of exercise equipment. The function of MAXM is to provide assistance. The applicant described MAXM as a miniature pulley system that creates leverage and power to maintain and hold the stretch in a reiterated a request for a code.

Final Decision:

Existing code E1811 "Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories", adequately describes the product that is subject of this request.

HCPCS Public Meeting Agenda Item #6

May 21, 2015

Attachment# 15.107

Topic/Issue:

Request to establish a unique level II HCPCS code to identify a powered, computer-controlled, Pressure Modulated Knee Rehabilitation Machine (PMKR), Trade Name: X10 Pressure Modulated Knee Rehabilitation Machine.

Background/Discussion:

Halley Orthopedics submitted a request to establish a HCPCS code to identify Pressure Modulated Knee Rehabilitation (PKMR), computer-controlled, powered exercise equipment manufactured by the Scientemp Corporation. According to the requester, these machines are used by patients recovering from knee injury or surgery (e.g., total knee arthroplasty) as well as individuals looking to maintain or build lower extremity strength. The machine consists of an anchored, adjustable chair attached to exercise equipment which is also attached to a cabinet with a computer and LED screen. To use the machine, the patient sits in the machine's chair and places his/her foot in the ankle grips. The patient uses the LED touch screen to select a program, and treatment begins. Patients independently operate the machine several times a day for 3 to 5 weeks. The machine collects and transmits real-time data from the point of care, enabling feedback to patients and remote monitoring of results by the patient's medical team.

The requester comments that existing code E0935 "Continuous passive motion exercise device for use on knee only" describes machines that only offer passive Range of Motion (ROM). PKMR machines, in contrast, incorporate biofeedback, active and passive ROM, proprioceptive neuromuscular re-education, dynamic and static stretching, as well as isotonic isometric and eccentric strengthening. The requester claims superior results when using the X10, as compared with the use of CPM machines, in terms of greater and faster gains in ROM, more rapid muscle activation, prevention of muscle atrophy, faster return to normal life, less variability in recovery and lower rehab cost. As such, code E0935 does not adequately describe the attributes and potential advantages of PMKR machines, and a new code is warranted.

Preliminary Decision:

Existing code A9300 "Exercise Equipment" describes the device that is the subject of this request.

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 our preliminary decision, stating that the X10 Pressure Modulated Knee Rehabilitation machine is a medical device prescribed by orthopedic surgeons to rehabilitate the knee joint following surgery. The machine requires physician oversight and serves a medical purpose; it provides real-time data at the point of care and empowers patients with superior results at lower cost. The speaker reiterated that this device requires a new code for powered, computer controlled, Pressure Modulated Knee Rehabilitation Machine (PMKR), in order to make this technology and its benefits available to Medicare beneficiaries.

Final Decision:

Existing code E0935 "Continuous passive motion exercise device for use on knee only", adequately describes the device that is the subject of this request.

HCPCS Public Meeting Agenda Item #7

May 21, 2015

Attachment# 15.075 A & B

Topic/Issue:

Two separate, related requests to establish a total of 3 Level II HCPCS codes to identify components of a urethral insert with pump for bladder drainage, Trade Name: inFlow™ temporary intraurethral valve-pump system: one to identify a sterile single-use urethral insert packaged with a disposable introducer; one to identify a hand-held remote control "Activator"; and one to identify 3-volt lithium batteries used with patient-owned Activator, (2 batteries required). The requester also asks that the inFlow™ device be considered a prosthetic.

Applicant's suggested language:

15.075 A: LXXX1: Female urinary prosthesis, temporary, with delivery system.

15.075 B: LXXX2: Activator for female urinary prosthesis; and

L736X: Three volt lithium battery for patient-owned Activator for female urinary prosthesis.

Background/Discussion:

On behalf of Vesiflo, Inc., two separate, related requests were submitted to establish a total of 3 HCPCS codes to identify components of the inFlow™ a urethral insert with pump for bladder drainage, described by the FDA as a "catheter-like device" with internal pump mechanism that is placed in the urethra. Under patient control, the internal pump draws urine out of the bladder when voiding is desired, and blocks urine flow when continence is desired. The device is intended for use by women who cannot empty their bladder due to impaired detrusor contractility (IDC). The device is a 3 – 7 cm non-collapsible plastic tube that anchors at the bladder neck. It is initially sized and inserted by a physician. Afterwards, it is removed and replaced every 29 days, typically by a care-giver or spouse. The device resides "almost entirely in the urethra so that only the user knows it is there." When the user sits on a toilet, she uses the remote control to magnetically activate a miniature internal pump that drains the bladder. According to the requester, as a prosthetic device, it is designed to compensate for a specific anatomic deficiency. The inflow device's internal pump compensates for the inability of women with IDC to generate bladder pressure by providing forceful, virtually complete evacuation of urine on demand.

The requester comments that codes describing urinary catheters do not describe the device, as it is not a catheter. Code A4336 for incontinence supply urethral insert is also inadequate because the inserts are used to keep urine, whereas the inFlow is intended to drain urine. Also, existing battery codes for prosthetic use do not reflect the size and type used with the inFlow Activator.

Preliminary Decision:

Reported sales volume is insufficient to support a 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(s).

Medicare Payment:

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS preliminary decision stating that a new code is needed regardless of insufficient commercial sales, on the basis that the device is unique and serves a strong need on the part of a poorly served patient population.

Final Decision:

Reported sales volume for the system that is the subject of this request is insufficient to support a 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(s).

HCPCS Public Meeting Agenda Item #8

May 21, 2015

Attachment# 15.102

Topic/Issue:

Request to establish a unique HCPCS Level II code to identify Blom-Singer Adjustable Bi-flanged Fistula prosthesis.

Applicant's suggested language: Fistula prosthesis, bi-flanged, each.

Background/Discussion:

Helix Medical, LLC submitted a request to establish a new code to identify the Blom-Singer® "Adjustable Bi-Flanged Fistula Prosthesis" indicated for the management of hypopharyngeal fistula as a means to reduce leakage of saliva and food/drink or esophageal contents into soft tissue, or external to the body. The device comprises of two silicone flanges and an elastomeric, radio-opaque beaded stem with a locking loop designed to prevent flange movement. It is inserted and removed by a physician. Once inserted, the semi-rigid flanges seal against the peri-fistula tissue distally in the hypopharynx and against the peri-fistula skin epidermis proximally. This short-term (not more than 29 days) single-use device helps to maintain a dry fistula tract and reduces leakage of saliva, food and liquids. The device is supplied in three sizes: 22mm, 38mm and 50mm.

The requester comments that no existing HCPCS codes describe a flange-type prosthetic device specifically designed and indicated for use to manage hypopharyngeal or esophageal fistulae.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a code to identify the product that is the subject of this request, which is included in the procedure, and as such, separate reporting could be considered duplicative and inappropriate.

Medicare Payment:

If payment were made for this item, we believe it may be included in some other Medicare service or procedure.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

CMS upheld its decision not to establish a code. This request to establish a Level II HCPCS code to separately identify the Blom-Singer Adjustable Bi-Flanged Fistula prosthesis has not been approved, because this product is an integral part of the procedure. Payment for the procedure includes payment for the fistula prosthesis, if used.

HCPCS Public Meeting Agenda Item #9

May 21, 2015

Attachment# 15.099

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a Rotation Medical Rotator Cuff Bio-Inductive Implant system.

Applicant's suggested language: QXXXX - Rotation Medical Bio-inductive Implant.

Background/Discussion:

On behalf of Rotation Medical, Inc. a request was submitted to establish a HCPCS code to identify the Rotation Medical Rotator Cuff Bio-inductive implant, a bovine Achilles tendon-derived surgical mesh "tendon protector" collagen tendon sheet. It is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The Rotation Medical Rotator cuff system includes the bio-inductive implant and a disposable instrument system. According to the requester, the physical and chemical properties of the bio-inductive implant are specifically designed to allow fibroblasts and blood vessels to infiltrate the porous bio-inductive implant. As a result, new tendinous tissue is produced, which remodels with the bio-inductive implant.

The requester claims a significant therapeutic distinction when the Rotation Medical Bio-Inductive implant is used, when compared with "other tendon wraps" which do not induce the formation of new tendinous tissue.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a Level II HCPCS code to identify the device that is the subject of this request, which is included in the surgical procedure.

Medicare Payment:

Included in procedure.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

CMS upheld its decision not to establish a code. This request to establish a Level II HCPCS code to separately identify Rotation Medical Rotator Cuff Bio-Inductive Implant has not been approved because this product is an integral part of a surgical procedure and payments for that service includes payment for Rotation Medical Rotator Cuff Bio-Inductive Implant if it is used.

HCPCS Public Meeting Agenda Item #10

May 21, 2015

Attachment# 15.100

Topic/Issue:

Request to establish a unique HCPCS Level II code to identify a customizable pliable mouthpiece which incorporates pressure sensors which connects to a tablet/notebook computer for use as a biofeedback device during lingual strengthening therapy, Trade Name: SwallowSTRONG.

Applicant's suggested language: A9XXX - Oral pressure sensor mouthpiece, biofeedback device.

Background/Discussion:

On behalf of Swallow Solutions, LLC, a request was submitted to establish a new HCPCS code to identify the SwallowSTRONG device, an oral pressure sensor mouthpiece, biofeedback device that measures the strength of the tongue muscle. The mouthpiece is a plastic molded device with four pressure sensors. It connects to an electronic interface on a tablet/notebook computer. The mouthpiece sensors measure pressure exerted by the patient from 4 distinct areas of contact between the tongue and palate. These pressure readings are electronically transmitted to the tablet/laptop where the patient and the therapist can immediately see the results and compare performance to therapeutic goals. This device is indicated for patients who have dysphagia or other swallowing dysfunction for which lingual strengthening may improve swallowing function and reduce the incidence of aspiration pneumonia.

The requester comments that existing code A9279 “monitoring feature/device, stand-alone or integrate, any type, includes all accessories, components and electronics, not otherwise classified” does not describe the SwallowSTRONG device, because the device provides immediate feedback to enhance the treatment of the patient and as such, is not a monitoring device.

Preliminary Decision:

Existing code A9279, Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified, 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=00

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that the SwallowSTRONG mouthpiece is clearly not a monitoring device, but is an active therapy delivery device. According to the speaker, the mouthpiece is used to direct strengthening therapy for an individual patient and is an active therapy device; it is used for short-duration measurement for knowledge of performance only and does not monitor the patient; devices currently categorized by the PDAC at code A9279 are stand-alone or integrated monitoring features designed for passive monitoring. The speaker stated that there are no existing HCPCS codes which describe the swallowSTRONG oral mouthpiece, and lack of a code results in denied access to this therapy.

Final Decision:

CMS upheld its decision not to establish a code. This request to establish a Level II HCPCS code to identify SwallowSTRONG device has not been approved because the device is included in the service provider payment. Payment for the service includes payment for a monitoring device, if used.

HCPCS Public Meeting Agenda Item #11

May 21, 2015

Attachment #s: 15.076, 15.077, 15.078, 15.079, 15.080, 15.081, 15.082 and 15.083

Topic/Issue:

Eight separate requests, each to establish a Level II HCPCS code to identify one of 8 blood products processed using Rejuvesol® Red Blood Cell Processing Solution for extracorporeal rejuvenation of Red Blood Cells.

Applicant's suggested language:

15.076	P90X1 Red Blood Cells, Rejuvenated, Washed, Each Unit
15.077	P90X2 Red Blood Cells, Irradiated, Rejuvenated, Washed, Each Unit
15.078	P90X3 Red Blood Cells, Rejuvenated Deglycerolized, Each Unit
15.079	P90X4 Red Blood Cells, Leukocytes Reduced, Irradiated
15.080	P90X5 Whole Blood or Red Blood Cells, Leukocytes Reduced, CMV-Negative, Rejuvenated, Washed, Each Unit
15.081	P90X6 Whole Blood or Red Blood Cells, Leukocytes Reduced, Rejuvenated, Deglycerolized, Each Unit
15.082	P90X7 Red Blood Cells, Rejuvenated, Deglycerolized, Leukocytes Reduced, Irradiated, Each Unit
15.083	P90X8 Red Blood Cells, Leukocytes Reduced, CMV-Negative, Irradiated, Rejuvenated, Washed, Each Unit

Background/Discussion:

On behalf of Citra Labs; Biomet Biologics, 8 separate requests were submitted, each to establish a unique HCPCS code to identify one of 8 blood products processed using Rejuvesol® Red Blood Cell Processing Solution for extracorporeal rejuvenation of Red Blood Cells. Rejuvesol® is a sterile, non-pyrogenic solution in Water for Injection. According to the requester, Rejuvesol is indicated as an in vitro processing solution for the rejuvenation of a unit of red blood cell concentrate (RBC) stored in AS-1 additive systems. Rejuvesol is supplied in 50 mL single-use vials containing sodium pyruvate 0.550 g, inosine 1.34 g, adenine 0.034 g, dibasic sodium phosphate (heptahydrate) 0.730 g, and monobasic sodium phosphate (monohydrate) 0.311 g, in Water for Injection, pH 6.7-7.4. Each injection is intended only for use in the extracorporeal rejuvenation of a unit of RBC and may be appropriate for the following uses: Rejuvenation of CPD or CPDA-1 RBC prior to immediate use or rejuvenation of CPD, CPDA-1, or CPD/AS-1 RBC prior to cryopreservation. It should never be directly administered to Humans.

The requester comments that existing HCPCS codes do not describe Rejuvesol Solution.

Preliminary Decision:

Existing Level II HCPCS codes adequately describe final blood and blood component products. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to distinguish these products based on processing materials or methods.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision, stating that Rejuvesol solution is the only commercially available red blood cell concentrate (RBC) rejuvenation product in the United States and existing HCPCS Level II codes do not adequately describe Rejuvesol solution or include rejuvenation as part of any RBC descriptor. Rejuvenation of stored blood means restoring these molecules to levels found in fresh blood or greater. The speaker reiterated the original request for eight new, unique codes.

Final Decision:

CMS upheld its decision not to establish new codes. Existing Level II HCPCS codes adequately describe final blood and blood component products. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to distinguish final blood and blood component products based on whether they have been rejuvenated.

HCPCS Public Meeting Agenda Item #12

May 21, 2015

Attachment# 15.084

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a fresh frozen plasma (FFP) product processed using INTERCEPT® Blood System for Plasma, sourced from 2 to 3 donors, Amotosalen/UVA Light-Treated, Frozen within 24 hours of collection.

Applicant's suggested language: Fresh Frozen Plasma, Sourced from 2-3 Donor Pool, Amotosalen/UVA Light-Treated, Frozen Within 24 Hours of Collection, Each Unit

Background/Discussion:

The Cerus Corporation submitted a request to establish a HCPCS code to identify a fresh frozen plasma (FFP) product processed using INTERCEPT® Blood System for Plasma, sourced from 2 to 3 donors, Amotosalen/UVA Light-Treated, Frozen within 24 hours of collection. This product is intended for treatment of clinically significant coagulation deficiencies due to blood loss or transfusion, warfarin reversal, TTP, selected congenital or acquired coagulation factor deficiencies, and rare specific plasma protein deficiencies. According to the requester, this product differs from other FFP products identified by existing HCPCS codes because no other licensed blood plasma component is subjected to amotosalen and UVA light exposure or any process to inactivate donor leukocytes and a broad range of viruses, Gram-positive and Gram-negative bacteria, spirochetes and parasites. In addition, this product is contraindicated in patients with a history of hypersensitivity reaction to amotosalen or other psoralens, and in neonatal patients treated with phototherapy devices that emit wavelengths <425 nm.

A starting volume of 585-560 mL of whole blood derived plasma is processed in a closed system that uses amotosalen in combination with UVA light exposure to inactivate a broad spectrum of viruses, Gram-positive and Gram-negative bacteria, spirochetes, parasites and leukocytes. The resulting pathogen-reduced plasma is frozen within 24 hours of collection of the oldest of the pooled units of donor blood. Each stored unit may contain up to 325 mL of plasma.

The applicant comments that a unique code is warranted to facilitate accurate billing.

Preliminary Decision:

Existing Level II HCPCS codes adequately describe final blood and blood component products. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to distinguish these products based on processing materials or methods.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision stating that therapeutic blood component processing methods define how blood components are clinically differentiated. Existing HCPCS codes do not adequately describe these new plasma or platelet products. The products are manufactured using a chemical (amotosalen) in conjunction with UVA light treatment to inactivate a broad spectrum of enveloped and non-enveloped viruses, Gram-positive and Gram-negative bacteria, spirochetes and protozoa. According to the speaker, no existing national HCPCS Level II codes for plasma or apheresis platelet products include descriptors that adequately describe amotosalen/UVA light-treated products.

Final Decision:

The following modification has been made to the HCPCS Level II standard, national code set:

Establish P9070 Plasma, pooled multiple donor, pathogen reduced, frozen, each unit

HCPCS Public Meeting Agenda Item #12

May 21, 2015

Attachment# 15.085

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a fresh frozen plasma (FFP) product processed using INTERCEPT® Blood System for Plasma, sourced from a single donor, Amotosalen/UVA Light-Treated, Frozen within 8 hours of collection.

Applicant's suggested language: Fresh Frozen Plasma (Single Donor), Amotosalen/UVA Light-Treated, Frozen Within 8 Hours of Collection, Each Unit.

Background/Discussion:

The Cerus Corporation submitted a request to establish a HCPCS code to identify a fresh frozen plasma (FFP) product processed using INTERCEPT® Blood System for Plasma, sourced from a single donor, Amotosalen/UVA Light-Treated, Frozen within 8 hours of collection. This product is intended for treatment of clinically significant coagulation deficiencies due to blood loss or transfusion, warfarin reversal, TTP, selected congenital or acquired coagulation factor deficiencies, and rare specific plasma protein deficiencies. According to the requester, this product is human fresh frozen plasma product prepared from plasma collected by apheresis from a single healthy blood donor and manufactured using a the INTERCEPT® Blood System for Plasma pathogen reduction process to reduce the risk of transfusion-transmitted infection (TTI). According to the requester, this product differs from other FFP products identified by existing HCPCS codes because no other licensed blood plasma component is subjected to amotosalen and UVA light exposure or any process to inactivate donor leukocytes and a broad range of viruses, Gram-positive and Gram-negative bacteria, spirochetes and parasites. Also, this product is contraindicated in patients with a history of hypersensitivity reaction to amotosalen or other psoralens, and in neonatal patients treated with phototherapy devices that emit wavelengths <425 nm. A starting volume of 585-560 mL of apherisis plasma is processed in a closed system that uses amotosalen in combination with UVA light exposure to inactivate a broad spectrum of viruses, Gram-positive and Gram-negative bacteria, spirochetes, parasites and leukocytes. The resulting pathogen-reduced plasma is frozen within 8 hours of apheresis collection. Each stored unit may contain up to 325 mL of plasma.

The applicant comments that a unique code is warranted to facilitate accurate billing.

Preliminary Decision:

Existing Level II HCPCS codes adequately describe final blood and blood component products. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to distinguish these products based on processing materials or methods.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision, stating that therapeutic blood component processing methods define how blood components are clinically differentiated. Existing HCPCS codes do not adequately describe these new plasma or platelet products. The products are manufactured using a chemical (amotosalen) in conjunction with UVA light treatment to inactivate a broad spectrum of enveloped and non-enveloped viruses, Gram-positive and Gram-negative bacteria, spirochetes and protozoa. According to the speaker, no existing national HCPCS Level II codes for plasma or apheresis platelet products include descriptors that adequately describe amotosalen/UVA light-treated products.

Final Decision:

The following modification has been made to the HCPCS Level II standard, national code set:

Establish P9071 Plasma (single donor), pathogen reduced, frozen, each unit

HCPCS Public Meeting Agenda Item #12

May 21, 2015

Attachment# 15.086

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a platelet product collected by apheresis and processed using the INTERCEPT® Blood System for Platelets.

Applicant's suggested language: Platelets, Pheresis, Amotosalen/UVA Light-Treated, Each Unit.

Background/Discussion:

The Cerus Corporation submitted a request to establish a HCPCS code to identify a platelet product collected by apheresis from a single donor and processed using INTERCEPT® Blood System for Plasma; amotosalen and ultraviolet A (UVA) light to reduce the risk of transfusion-transmitted infection (TTI), including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease. This product is intended for treatment of patients with thrombocytopenia, dysfunctional platelet disorders (congenital, metabolic, or medication-induced), active platelet-relatedbleeding, and for prophylactic therapy of patients at serious risk of platelet-related bleeding.

According to the requester, this product differs from other apheresis platelet products identified by existing HCPCS codes because it is the only product that uses amotosalen and UVA light exposure during manufacturing to inactivate a broad spectrum of enveloped and non-enveloped viruses, Gram-positive and Gran-negative bacteria, spirochetes, parasites and leukocytes. Also, this product is contraindicated in patients with a history of hypersensitivity reaction to amotosalen or other psoralens, and in neonatal patients treated with phototherapy devices that emit wavelengths <425 nm. Donor platelets are processed in a closed system that uses amotosalen in combination with UVA light exposure to inactivate a broad spectrum of viruses, Gram-positive and Gram-negative bacteria, spirochetes, parasites and leukocytes. The resulting pathogen-reduced platelets are stored in units containing approximately 300 mL.

The applicant comments that a unique code is warranted to facilitate accurate billing.

Preliminary Decision:

Existing Level II HCPCS codes adequately describe final blood and blood component products. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to distinguish these products based on processing materials or methods.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision, stating that therapeutic blood component processing methods define how blood components are clinically differentiated. Existing HCPCS codes do not adequately describe these new plasma or platelet products. The products are manufactured using a chemical (amotosalen) in conjunction with UVA light treatment to inactivate a broad spectrum of enveloped and non-enveloped viruses, Gram-positive and Gram-negative bacteria, spirochetes and protozoa. According to the speaker, no existing national HCPCS Level II codes for plasma or apheresis platelet products include descriptors that adequately describe these there amotosalen/UVA light-treated products.

Final Decision:

The following modification has been made to the HCPCS Level II standard, national code set:

Establish P9072 Platelets, Pheresis, Pathogen Reduced, Each Unit

HCPCS Public Meeting Agenda Item #13

May 21, 2015

Attachment# 15.073

Topic/Issue:

Request to make a coding distinction between non-coated and hydrophilic coated intermittent urinary catheters, by revising 3 existing HCPCS codes A4351, A4352 and A4353 to omit references to coating; and establishing 3 new Level II HCPCS codes to specifically identify hydrophilic coated intermittent catheters. Trade Name: Speedicath.

Applicant's suggested language:

Revise A4351 - Intermittent urinary catheter; straight tip, ~~with or~~ without coating (Teflon, silicone, silicone elastomer, ~~or hydrophilic,~~ etc), each.

Revise A4352 - Intermittent urinary catheter; coude tip, ~~with or~~ without coating (Teflon, silicone, silicone elastomer, ~~or hydrophilic,~~ etc), each.

Revise A4353 - Intermittent urinary catheter (conventional uncoated) with insertion supplies

Establish AXXX1 Hydrophilic coated intermittent urinary catheter, straight tip, each

Establish AXXX2 Hydrophilic coated intermittent urinary catheter, coude tip, each

Establish AXXX3 Hydrophilic coated intermittent urinary catheter, with insertion supplies, each

Background/Discussion:

Coloplast, Corporation submitted a request to make a coding distinction between non-coated and hydrophilic coated intermittent urinary catheters, by revising 3 existing HCPCS codes A4351, A4352 and A4353 to omit references to coating; and establishing 3 new Level II HCPCS codes to specifically identify hydrophilic coated intermittent catheters. Intermittent urinary catheters facilitate the emptying of the bladder for patients who are unable to do so voluntarily due to surgery, illness, disease, injury or birth defect. According to the requester, the advanced hydrophilic coating (consisting of polyvinylpyrrolidone, salt, and polyurethane, bound evenly to the entire catheter surface of polymer on hydrophilic-coated catheters) reacts with water to form a slippery and virtually friction-free “buffer” zone between the catheter surface and the patient’s urethra during catheter insertion *and withdrawal*. SpeediCath comes in a self-contained sterile package and is to be inserted into the urethra and bladder and withdrawn once the bladder has emptied. Non-coated catheters are used with lubricant. The requester claims that hydrophilic coated catheters differ in terms of material composition and operation (hydrophilic coating vs. lubricant gel), and this difference results in a 20% reduction in frequency of urinary tract infections (UTI) and fewer antibiotic treatment episodes in experienced users of intermittent

catheters, compared to the use of non-coated intermittent catheters. Specifically, the requester claims that use of hydrophilic coated catheters confers a reduced risk of bacterial contamination and reduced risk of urethral trauma which leading to urinary tract infections (UTIs).

According to the requester, existing codes do not account for the significantly therapeutic distinction between uncoated catheters and hydrophilic-coated catheters.

Preliminary Decision:

Existing code A4351, Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each; or A4352, Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each; (depending on whether the catheter has a straight or curved tip), adequately describe the products that are subject of this request.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.
Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision stating that unique codes are needed to enable tracking UTI performance related to catheter technology. In addition, retaining a broad code description covering both 1st and 2nd generation intermittent catheters in reality hinders access to safe catheters. The applicant also commented that there is a significant therapeutic distinction in clinical outcomes when hydrophilic catheters are used when compared with non-hydrophilic catheters, which warrants establishment of separate codes. The applicant also agreed to forward and updated Cochrane review.

Final Decision:

CMS upheld its decision that existing code A4351, Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each; or A4352, Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each; (depending on whether the catheter has a straight or curved tip), adequately describe the products that are subject of this request.

HCPCS Public Meeting Agenda Item #14

May 21, 2015

Attachment# 15.069

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify an electronic sensor for monitoring pressure within ostomy/stoma pouches, Trade Name: Ostom-i™.

Applicants suggested language: AXXXX OSTOM-i Alert Sensor for electronically monitoring pressure within ostomy/stoma bags, one unit per 3 months.

Background/Discussion:

An application was submitted of behalf of 11 Health & Technologies, Ltd. to establish a HCPCS code to identify the Ostom-i™ Alert Sensor which electronically monitors the fullness of an ostomy bag and sends information via Bluetooth to a free downloadable app that sends information to a mobile phone or tablet to warn healthcare personnel when a patient's bag is almost full, so they can decide when to empty it. The sensor captures data as to the volume and timing of output which can used to monitor and trend the patient's health condition. The applicant suggests within the application that the device can be used by the patient to determine when to change their bag. Patients can e-mail data to their healthcare provider and a web login can also be created for data storage and remote access. The sensor is a discrete device that clips on the outside of the patient's ostomy bag. It can be adjusted to fit different pouch sizes. The sensor lies across the pouch and measures for a change in resistance as the pouch fills. The strip is attached to a circuit board that contains a Bluetoooth low energy module. As the pouch changes shape, it causes a change in resistance and the flex sensor bends. The change in resistance is sent via Bluetooth to the mobile app. An accelerometer enables a recalculation of the resistance depending on the patient's position and how that impacts resistance on the pouch. According to the applicant, this device is indicated for all patients who wear ostomy/stoma bags. Each sensor lasts up to 3 months. According to the requester, the OSTOM-i Alert Sensor dramatically improves the functionality of the ostomy bag and is an integral part of disease management.

The requester comments that no existing code accurately describes this device/functionality.

Preliminary Decision:

Existing code A9280 "Alert or Alarm Device, Not Otherwise Classified" adequately describes monitoring devices with alarms and is available for assignment by insurers to identify the OSTOM-i Alert Sensor if they deem appropriate.

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:

There was no primary speaker for this item.

Final Decision:

CMS upheld its decision. Existing code A9280 "Alert or Alarm Device, Not Otherwise Classified" adequately describes monitoring devices with alarms and is available for assignment by insurers to identify the OSTOM-i Alert Sensor, if they deem appropriate.

HCPCS Public Meeting Agenda Item #15

May 21, 2015

Attachment# 15.090

Topic/Issue:

Request to establish three unique Level II HCPCS codes, one each to identify 3 size categories of silver-containing composite absorptive multi-layer dressings *with* adhesive border, Trade Names: BCT Silver Bandage and KoCarbon Ag Silver Bandage.

Applicant's suggested language:

A62X1 - Composite absorptive multiple layer dressing with highly absorptive layer *with* adhesive border, less than 16 square inches, each dressing.

A62X2 - Composite absorptive multiple layer dressing with highly absorptive layer *with* adhesive border, more than 16 square inches but less than or equal to 48 square inches, each dressing.

A62X3 - Composite absorptive multiple layer dressing with highly absorptive layer *with* adhesive border, more than 48 square inches, each dressing.

Background/Discussion:

Bio-medical Carbon Technology Co., Ltd. submitted a request to establish 3 HCPCS codes to identify silver containing composite dressings with adhesive border, categorized by size. According to the requester, BCT Silver Bandage is a sterile primary wound dressing that consists of polyethylene terephthalate non-woven, silver-coated, activated carbon fiber cloth and polyethylene film. The dressings contain 100 micrograms/square centimeter of silver and are available in 58 individual sizes. BCT bandages are intended for the management of partial and full thickness wounds, pressure ulcers, diabetic ulcers, surgical wounds, first and second degree burns; and to provide an antimicrobial barrier. The bandage is applied topically and is in direct contact with the wound. According to the requester, this bandage absorbs wound fluid; the activated carbon fiber traps microbes in the dressing and the silver ions kill microbes. The requester comments that no existing HCPCS codes describe the BCT Silver Bandage, and codes are necessary to facilitate Medicare payment.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish code(s) to identify application of dressings that are predominantly silver. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed.

Medicare Payment:

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

CMS revised its decision as follows: Existing code A4649, "Surgical supply; miscellaneous" is the most appropriate code and is available for assignment by insurers if they deem appropriate to identify the products that are the subject of this request.

HCPCS Public Meeting Agenda Item #15

May 21, 2015

Attachment# 15.091

Topic/Issue:

Request to establish three unique Level II HCPCS codes, one each to identify 3 size categories of silver-containing composite absorptive multi-layer dressings *without* adhesive border, Trade Names: BCT Antimicrobial Dressing and KoCarbon Ag Antimicrobial Dressing.

Applicant's suggested language:

A62X1 - Composite absorptive multiple layer dressing with highly absorptive layer *without* adhesive border, less than 16 square inches, each dressing.

A62X2 - Composite absorptive multiple layer dressing with highly absorptive layer *without* adhesive border, more than 16 square inches but less than or equal to 48 square inches, each dressing.

A62X3 - Composite absorptive multiple layer dressing with highly absorptive layer *without* adhesive border, more than 48 square inches, each dressing.

Background/Discussion:

Bio-medical Carbon Technology Co., Ltd. submitted a request to establish 3 HCPCS codes to identify silver containing composite dressings (without adhesive border), categorized by size. According to the requester, BCT Antimicrobial Dressing and KoCarbon AG Antimicrobial Dressing is a sterile primary wound dressing that consists of polyethylene terephthalate non-woven, silver-coated, activated carbon fiber cloth and polyethylene film. The activated carbon fiber cloth absorbs bacterial toxins and offensive odors. The dressings consist of a textile substrate that is impregnated with 100 micrograms of silver per square centimeter and are available in several sizes. The dressings are indicated for the management of partial and full thickness wounds, pressure ulcers, diabetic ulcers, surgical wounds, first and second degree burns; and to provide an antimicrobial barrier.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish code(s) to identify application of dressings that are predominantly silver. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed.

Medicare Payment:

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

CMS revised its decision as follows: Existing code A4649, "Surgical supply; miscellaneous" is the most appropriate code for each of the three multiple layer dressing that are the subject of this request, and this code is available for assignment by insurers if they deem appropriate to identify the products that are the subject of this application.

HCPCS Public Meeting Agenda Item #16

May 21, 2015

Attachment# 15.072

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify MuGard® Mucoadhesive.

Applicant's suggested language: AXXXX - Mucoadhesive oral wound rinse.

Background/Discussion:

AMAG Pharmaceuticals, Inc submitted a request to establish a HCPCS code to identify MuGard™ Mucoadhesive Oral Wound Rinse, manufactured by PlasmaTech Biopharmaceuticals, Inc. (formerly Access Pharmaceuticals, Inc.) MuGard is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/cancer sores and traumatic ulcers, such as those caused by oral surgery of ill-fitting dentures or braces. According to the requester, MuGard is a viscous liquid formulated to adhere to the inner surface of the mouth and form a soothing, protective coating over the oral mucosa. The recommended dosage for MuGard is 5mL, 4-6 times a day. It is to be poured into the mouth and rinsed in the oral cavity for a minute or longer. If necessary, 10mL can be used to coat the entire oral cavity. MuGard is supplied in 8 oz. bottles. The requester claims a significant therapeutic distinction when MuGard is used, when compared with use of other, similar products, as follows:

- MuGard reduces the mouth and throat soreness associated with OM and decreases the incidence of ulcerative OM at the end of radiotherapy.
- The severity of OM and associated erythema were reduced with MuGard treatment
- MuGard lacks systemic effects and drug interactions

The requester comments that no existing HCPCS code identifies MuGard.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a HCPCS code to identify MuGard.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for these items.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision, stating that MuGard is the equivalent of a "liquid bandaid" and is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/cancer sores and traumatic ulcers, such as those caused by oral surgery of ill-fitting dentures or braces. The speaker stated that there is a national program operating need to establish a code to identify MuGard, as certain private insurers need to separately identify it. The speaker also commented regarding our published preliminary Medicare payment determination, stating that, because MuGard is a "device" and it is indicated for treatment of oral wounds, it ought to be included in a Medicare benefit category.

Final Decision:

CMS upheld its decision not to establish a code. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a unique HCPCS code to identify MuGard.

HCPCS Public Meeting Agenda Item #17

May 21, 2015

Attachment# 15.092

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Cadexomer Iodine Gel, trade name: IODOSORB.

Applicant's suggested language: AXXXX Cadexomer Iodine Wound Filler, gel/paste, per fluid ounce.

Background/Discussion:

On behalf of Smith & Nephew, Inc. a request was submitted to establish a HCPCS code to identify Cadexomer Iodine Gel wound filler gel/paste. According to the requester, this is a dual-action wound management product that: assists in reducing ulcer size; inhibits formation of and disrupts biofilms; removes inflammatory substances from wound surface; removes slough and debris; reduces pain and odor; provides sustained antimicrobial activity; reduces bacterial load; manages exudate in highly exuding wounds and creates a moist wound environment. Wound fluid and exudate are absorbed into the Cadexomer beads allowing iodine to be released slowly. The beads turn into a gel. Once the iodine is released and fully utilized, the wound filler changes color (from orange/brown to white) and it is time to change the dressing. Iodosorb is indicated for use in cleaning wet ulcers and wounds such as venous stasis ulcers, pressure ulcers, and infected traumatic and surgical wounds. It is supplied in a 10g tube and a 40g tube. Iodosorb is placed on gauze which is then positioned onto the wound. Iodosorb is included in code A6261. The requester claims a significant therapeutic distinction when Iodosorb is used, compared with the use of other topical antimicrobial agents and wound fillers in the same code, because it is the only gel/paste that contains Cadexomer iodine; and it is the only product that claims in its package insert that it inhibits/disrupts biofilm; removes slough; and removes inflammatory substances from the wound surface. These differences warrant a unique code.

Preliminary Decision:

Existing code A6261, Wound filler, gel/paste, per fluid ounce, not otherwise specified, adequately describes the product that is subject of this request.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision, stating that Cadexomer Iodine is indicated for use in cleaning wet ulcers and wounds such as venous ulcers, pressure ulcers, and infected traumatic and surgical wounds. IODOSORB comes in a 10g tube and a 40g tube and is placed on gauze. According to the speaker a significant therapeutic distinction is conferred when IODOSORB is used when compared with the use of other topical antimicrobial agents and wound fillers included in the same code category. It is the only gel/paste that contains Cadexomer Iodine. The speaker also indicated that IODOSORB it is the only product that inhibits/disrupts biofilm (in vitro); removes slough; and removes inflammatory substances (in vitro). The speaker communicated that these differences, in themselves, warrant a unique code.

Final Decision:

CMS revised its decision as follows: Existing code A6260, "Wound cleanser, any type, any size", adequately describes the product that is subject of this request.

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, has an expected life of at least 3 years 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;
- Surgical Dressings
- Therapeutic Shoes and Inserts

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 for most DMEPOS items and services is now 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 or supplier price lists. 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. Payment for E0935 is based on a daily rental fee schedule basis since coverage of this device is limited to 21 days.

- **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, were purchased 75 percent of the time or more from July 1986 through June 1987,or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or respiratory assist 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 36th monthly payment is made, after which payment for the ongoing delivery of contents continues for 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. 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. 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. Complex rehabilitative power wheelchairs can also 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 and judgment of a reasonable payment amount, which, at a minimum, includes a review of the costs of labor and material used in constructing the equipment.

- **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.