DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, Maryland 21244-1850

Centers for Medicare & Medicaid Services' (CMS') First Biannual 2022 Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda

Zoom Meeting, for remote participation
Thursday, June 9, 2022, 9:00 am – 5:00 pm, eastern daylight time (e.d.t.)

8:45 am, e.d.t.:
• Zoom meeting login:
https://cms.zoomgov.com/meeting/register/vJIsd-mgpz4jEvObPtTKB0-BGiFBQ80CuHQ
• Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

9:00 am, e.d.t.:
• Welcome
• Background and purpose of meeting
• Meeting format and ground rules

Provided for each agenda item is a written overview of the applicant's request, CMS' preliminary coding recommendation, as well as CMS' preliminary benefit category and payment determination, if applicable. Preliminary recommendations are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and any registered 5-minute speakers. Speaker presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for stakeholders and interested parties to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meeting. CMS' final coding, benefit category, and payment decisions will be published on CMS' HCPCS website at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelII-Coding-Decisions-Narrative-Summary around September 2022 and will be effective October 1, 2022, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Thursday, June 9, 2022. 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.

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Agenda Item # 1

Automated Lateral Turning System - HCP211220VECUE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Automated Lateral Turning System.

Applicant's suggested language: XXXXX, "Automated lateral turning system: positioned beneath patient's mattress"

Applicant's Summary

Frontier Therapeutics submitted a request to establish a new HCPCS Level II code to identify Toto automated lateral turning system. Toto is an automated lateral turning system consisting of a digital control unit and platform which is fitted beneath the patient's mattress. Toto effectively is designed to reposition the patient to an angle of approximately 30 degrees at regular intervals and thus reduce the risk of pressure damage to at risk patients. It works by tilting the patient from side to side using discreet inflatable air cells; evenly, smoothly, and consistently even while they are sleeping. Toto is suitable for the following patient types: Weighing up to 250kg (551 lbs.), who are unable to change their position without assistance, identified as requiring regular repositioning and are non-compliant with manual turning. Toto supports the National Pressure Ulcer Advisory Panel guideline recommendations and is also designed to help reduce the risk of personal injury to patient and caregiver. The platform is controlled by a touch-control unit, which allows the platform to work automatically, turning the patient at regular intervals that can be set for the individual patient. Toto platform is positioned beneath the patient's mattress.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code EXXXX, "Powered pressure reducing underlay/pad, alternating, with pump, includes heavy duty"

Preliminary Benefit Category Determination

Durable Medical Equipment

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

The information provided for the Toto System supports the preliminary benefit category determination for durable medical equipment.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. The preliminary payment determination for code EXXXX, for this particular device, is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS code E0181.

The Toto device can provide pressure relief to patients similar to devices under E0181. Toto uses inflatable air cells that inflate and deflate at set alternating intervals that are controlled by a control unit and pump similar to devices under E0181.

	E0181	Toto
Physical Components	Goes on top of a mattress Air cells or chambers	Goes underneath a mattress Air cells or chambers
Mechanical and Electrical Components	Air pump or blower	Air pump or blower
Function and Intended Use	Provide pressure relief to patients by sequential alternating inflation and deflation of air cells on top of a mattress Air pressure can produce patient lift	Provide pressure relief to patients by sequential alternating inflation and deflation of air cells underneath a mattress Air pressure can produce patient lift
Additional Aspects and Features	Could assist with adjustments of positioning a patient	Assists with adjustments of positioning a patient

The average 2022 fee schedule amount for EXXXX would be $22.78. Payment for the equipment would be made on a capped rental basis if covered.

Pricing = 36

Agenda Item # 2

Doula Birth Worker - HCP211001WRVXM

Topic/Issue

Request to establish a new HCPCS Level II code to identify Doula birth worker.

Applicant's suggested language: XXXXX, "Doula birth worker attendance at labor and delivery"

Applicant's Summary

Maryland Department of Health submitted a request to establish a new HCPCS Level II code to identify doula birth worker attendance at labor and delivery. This code would cover birth worker attendance and services during birth, whether vaginal or caesarian, live or stillbirth. Services provided during labor and delivery may include emotional support as well as physical comfort measures to the individual and their partner while giving birth that are not clinical interventions. This service can only be conducted while a qualifying attending provider (e.g., Obstetrician-Gynecologist, Family Medicine Practitioner, or Certified Nurse Midwife) is also in attendance during the birthing process. Many states are now reimbursing doula birth workers through Medicaid for physical, emotional and psychosocial support throughout the perinatal period. However, codes used in other states for attendance at labor and delivery, such as CPT codes 59400 and 59409 are obstetric codes meant to be used by clinical provider types while CPT codes 99199 and 99499 are unlisted codes meant to capture other medical services or evaluation by physicians. Upon further analysis of HCPCS codes, Maryland was unable to find a suitable code that adequately captures the function of this service without making substantial coding edits to accommodate this new provider type and will be using a home-grown HCPCS code in the interim while requesting a new code be created as more states seek to reimburse this service.

Preliminary CMS HCPCS Coding Recommendation

Establish the following two new HCPCS Level II codes:

1. TXXXX, "Services performed by a doula birth worker, per 15 minutes"
2. TXXXX, "Services performed by a doula birth worker, per diem"

From prior experience, Medicaid agencies have indicated interest in options to make payment using per diem and time-based codes. Individual state Medicaid agencies have the flexibility to further define doula birth worker services by assigning one or more state defined HCPCS modifiers in the U1 through U9 series.

Agenda Item # 3

PermeaDerm B - HCP210922AG6K1

Topic/Issue

Request to establish a new HCPCS Level II code to identify PermeaDerm B.

Applicant's suggested language: QXXXX, "PermeaDerm B, per sq cm"

Applicant's Summary

Stedical Scientific submitted a request to establish a new HCPCS Level II code to identifyPermeaDerm B, as there is currently no HCPCS code that describes this product. PermeaDerm B is an FDA 510(k) cleared biosynthetic wound covering. PermeaDerm B is intended for use as a wound covering and to provide a moist wound healing environment on cleanly prepared wounds after hemostasis has been established. PermeaDerm B is indicated for partial thickness burn wounds, donor sites and coverage of meshed autograft. PermeaDerm B is comprised of an adherent and transparent monofilament nylon knitted fabric that is bonded to a thin, slitted, silicone membrane. PermeaDerm B contains physical slits that are configured to create pores (similar to human skin) when the product is stretched. The nylon side is coated with a mixture of USP Pharmaceutical Grade hypoallergenic porcine gelatin and a pure fraction of Aloe Vera. PermeaDerm B contains 2,280 parallel slits per square foot. PermeaDerm B is supplied in 5 x 10, 10 x 15 or 15 x 30-inch sheets. Key characteristics of PermeaDerm B include transparency, porosity, strength, stretchability and stability, all qualities which are essential for healing. PermeaDerm B is applied to a prepared wound and covered with any clinician chosen secondary absorbent outer dressing.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Permeaderm b, per square centimeter"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 3

PermeaDerm Glove - HCP210922ABGQC

Topic/Issue

Request to establish a new HCPCS Level II code to identify the PermeaDerm Glove.

Applicant's suggested language: QXXXX, "PermeaDerm Glove, each"

Applicant's Summary

Stedical Scientific submitted a request to establish a new HCPCS Level II code to identify the PermeaDerm Glove, as there is currently no HCPCS code that describes this product. The PermeaDerm Glove is intended for use as a wound covering and to provide a moist wound healing environment on cleanly prepared wounds after hemostasis has been established. The PermeaDerm Glove is indicated for debrided partial thickness hand burns. The PermeaDerm Glove is an FDA 510(k) cleared biosynthetic wound covering that is comprised of an adherent and transparent monofilament nylon knitted fabric that is bonded to a thin, slitted, silicone membrane. The PermeaDerm Glove has physical slits that are configured to create pores (similar to human skin) when the product is stretched. The nylon side of this wound covering is coated with a mixture of USP Pharmaceutical Grade hypoallergenic porcine gelatin and a pure fraction of aloe vera. The PermeaDerm Glove is available in sizes extra small to extra-large. Key characteristics of the PermeaDerm Glove include transparency, porosity, strength, stretchability and stability, all qualities which are essential for healing. The PermeaDerm Glove is applied to a prepared wound and covered with any clinician chosen secondary absorbent outer dressing.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Permeaderm glove, each"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 3

PermeaDerm C - HCP210922MBCG1

Topic/Issue

Request to establish a new HCPCS Level II code to identify PermeaDerm C.

Applicant's suggested language: QXXXX, "PermeaDerm C, per sq cm"

Applicant's Summary

Stedical Scientific submitted a request to establish a new HCPCS Level II code to identify PermeaDerm C, as there is currently no HCPCS code that describes this product. PermeaDerm C is intended for use as a wound covering and to provide a moist wound healing environment on cleanly prepared wounds after hemostasis has been established. PermeaDerm C is indicated for partial thickness wounds, pressure sores, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Mohs, post-laser surgery, podiatric, wound dehiscence, trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. PermeaDerm C is an FDA 510(k) cleared biosynthetic wound covering that is comprised of an adherent and transparent monofilament nylon knitted fabric that is bonded to a thin, slitted, silicone membrane. PermeaDerm C contains physical slits that are configured to create pores (similar to human skin) when the product is stretched. The nylon side is coated with a mixture of USP Pharmaceutical Grade hypoallergenic porcine gelatin and a pure fraction of Aloe Vera. PermeaDerm C has 4,464 slits per square foot, which are parallel and perpendicular in orientation. PermeaDerm C is supplied in 5 x 5-inch sheets. Key characteristics of PermeaDerm C include transparency, porosity, strength, stretchability and stability, all qualities which are essential for healing. PermeaDerm C is applied to a prepared wound and covered with any clinician chosen secondary absorbent outer dressing.

Preliminary HCPCS Coding Recommendation

Upon review of the information submitted with this application, the applicant submitted a 510(k) clearance from the FDA without PermeaDerm C listed. CMS has determined that all device listings should include all of the current proprietary names that are used to market the devices in the United States. As a result, CMS is denying the request to establish a new HCPCS Level II code to identify PermeaDerm C. The applicant is encouraged to review the FDA's requirements for device distributions in the United States. The applicant is welcome to submit a new HCPCS Level II coding application in a subsequent coding cycle.

Agenda Item # 4

PHOENIX Wound Matrix - HCP211231RA6TG

Topic/Issue

Request to establish a new HCPCS Level II code to identify PHOENIX Wound Matrix.

Applicant's suggested language: XXXXX, "Resorbable synthetic graft per square cm"

Applicant's Summary

Nanofiber Solutions, LLC submitted a request to establish a new HCPCS Level II code to identify PHOENIX Wound Matrix, which is a sterile, 3D electrospun synthetic polymer matrix. Comprised of two non-woven bioresorbable synthetic polymers, polyglycolic acid (PGA) and polylactide-co-caprolactone (PLCL), PHOENIX Wound Matrix is designed to provide scaffold support for cellular migration, adherence, and proliferation for tissue regeneration and repair of acute and chronic wounds and burns. PHOENIX Wound Matrix is indicated for the management of partial to full thickness acute and chronic wounds, and burns including; pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. PHOENIX Wound Matrix ranges in size from a 16mm disc to a 20 x 10cm sheet, providing flexibility in product selection to minimize the risk of product waste. After thorough debridement, PHOENIX Wound Matrix is used as a synthetic graft/skin substitute, placed within the confines of the wound environment to support wound healing. PHOENIX Wound Matrix acts as a protective barrier and persists within the wound environment until it completely degrades via hydrolysis, within 7-14 days. It is not meant to be removed. PHOENIX Wound Matrix should be reapplied every 7-14 days, or as clinically necessary, following the appropriate preparation and application steps along with best-practice standard of care for wound management. PHOENIX Wound Matrix is intended to be used as clinically necessary for wound healing and can be used from the wound onset through to wound closure. PHOENIX Wound Matrix is packaged as a sterile, single-use product, within an inner protective pouch, packaged in a shelf box. 1 matrix per pouch/box.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Phoenix wound matrix, per square centimeter"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 5

Omeza® Collagen Matrix - HCP210930GLM48

Topic/Issue

Request to establish a new HCPCS Level II code to identify Omeza® Collagen Matrix.

Applicant's suggested language: QXXXX, "Omeza® Collagen Matrix per 1.6g"

Applicant's Summary

Omeza LLC submitted a request to establish a new HCPCS Level II code to identify Omeza® Collagen Matrix. Name/Description: Omeza® Collagen Matrix is an anhydrous acellular matrix comprised of hydrolyzed fish collagen infused with cod liver oil and other plant-derived oils and waxes. Function: Omeza® Collagen Matrix's primary intended clinical purpose is to support the critical phases of wound healing by delivering diverse collagen types in an anhydrous carrier that creates a conforming physical collagen microstructure at the wound site for cellular migration and wound revascularization. It softens and spreads at body temperature, creating a three-dimensional microstructural framework that conforms with surface tissues within the wound bed. Over time, the patient's cells replace the acellular matrix with a native extracellular matrix, and the hydrolyzed fish collagen microstructure biodegrades. The cod liver oil and other oils and waxes within the Omeza® Collagen Matrix enhance the final product's conformability to the irregularities of the wound site. Why Existing HCPCS Codes do not adequately describe it: Currently the HCPCS coding system for cellular and/or tissue-based products for skin wounds (skin substitutes) is product and brand specific. For dates of service on or after January 1, 2009, product specific Q codes replaced non- product specific J codes. Therefore, no existing HCPCS Level II codes currently describe Omeza® Collagen Matrix. Indications for Use: Omeza® Collagen Matrix is used to treat chronic non-healing wounds such as venous, diabetic and pressure injury/ulcers, as well as surgical sites and trauma wounds to help in the healing process. It is intended for homologous use only. Action: Omeza® Collagen Matrix's primary intended clinical purpose is to support the critical phases of wound healing by delivering diverse collagen types in an anhydrous carrier that creates a conforming physical collagen microstructure at the wound site for cellular migration and wound revascularization. It softens and spreads at body temperature, creating a three-dimensional microstructural framework that conforms with surface tissues within the wound bed. Over time, the patient's cells replace the acellular matrix with a native extracellular matrix, and the hydrolyzed fish collagen microstructure biodegrades. The cod liver oil and other oils and waxes within the Omeza® Collagen Matrix enhance the final product's conformability to the irregularities of the wound site. Dosage/Route of Administration: Omeza® Collagen Matrix is supplied in a sterile, single use 1.6g vial. It is dispensed from the vial and applied directly or via suitable applicator to the wound bed by a physician, podiatrist, nurse practitioner, surgeon. Packaging: Omeza® Collagen Matrix is supplied in a sterile, single use 1.6g vial. It should be stored at room temperature (77°F/ 25°C) and should kept away from sunlight.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Omeza collagen matrix, per 100 mg"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust, and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form.

Agenda Item # 6

OrthoNovis Connect - HCP220204GQMWK

Topic/Issue

Request to revise existing HCPCS Level II code Q4161 "Bio-connekt wound matrix, per square centimeter" to include OrthoNovis Connect product in the code descriptor.

Applicant's Summary

MLM Biologics, Inc. submitted a request to revise an existing HCPCS Level II code Q4161, "Bio-connekt wound matrix, per square centimeter." Medicare and a few private payers cover bio-ConneKt®, therefore MLM Biologics, Inc. is requesting that existing HCPCS Level II code Q4161 is revised to include the OrthoNovis Connect product, in order to be eligible for claims submission and reimbursement. The private label OrthoNovis Connect and its five different sizes of product offerings will be manufactured exactly the same as bio-ConneKt® Wound Matrix with the same existing FDA 510(k) cleared indications. Nothing will change except for the name on the private label, and MLM Biologics, Inc. will continue to market existing bio-ConneKt® Wound Matrix product to healthcare professionals. All raw material, chemical processing, and manufacturing of OrthoNovis Connect is exactly the same as bio-ConneKt® Wound Matrix. Bio-ConneKt® Wound Matrix is an FDA 510(k) cleared product. As a bioengineered skin substitute, the FDA 510(k) cleared bio-ConneKt® Wound Matrix is clinically indicated for the local management of moderately to heavily exuding wounds, including: partial and full thickness wounds, draining wounds, tunneling wounds, pressure sores/ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds and surgical wounds. It is an all-biologic, xenograft collagen-based scaffold that is supplied sterile and subject to proprietary processing to withstand challenges of wound micro-environment. bio-ConneKt® Wound Matrix is fully absorbed into the wound bed where it is vascularized by healing tissue. The product is covered by secondary wound dressings to help keep the wound site clean and protected from infections. Clinical testing indicates no need for product removal of bio-ConneKt® Wound Matrix and one-time application for most conditions.

Preliminary CMS HCPCS Coding Recommendation

CMS could not identify information in the application confirming that the bio-ConneKt® Wound Matrix and OrthoNovis are identical products. The bio-ConneKt® Wound Matrix has received 510(k) clearance from the FDA, which was included as part of its HCPCS Level II application. CMS would expect OrthoNovis to receive similar clearance from the FDA. As a result, we are unable to revise existing HCPCS Level II code Q4161 "Bio-connekt wound matrix, per square centimeter" to include OrthoNovis in the code descriptor.

Agenda Item # 7

Vapro Intermittent Catheter - HCP2112177QWUE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Vapro Intermittent Catheter.

Applicant's suggested language: XXXXX, "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), fully enclosed, without collection bag, each"

Applicant's Summary

Hollister Incorporated submitted a request to establish a new HCPCS Level II code for Intermittent Urinary Catheters that are fully enclosed. Urinary tract infections (UTI) are a complication of catheterization that can lead to serious health issues, including hospitalization and even death. Common causes of catheter associated UTIs include urinary catheter contamination, such as touch transfer from contaminated surfaces prior to insertion of the catheter into the urethra (e.g., the user's hands) and/or transfer from a contaminated meatus during insertions. Fully enclosed products are differentiated in that they protect users from both of these types of catheter contamination. First, the presence of a full sleeve protects from accidental touch or bacterial contamination while catheterizing, which is especially critical for patients with limited dexterity, who may not have full control over the catheter while inserting. Catheters with sleeve protection are different from products with other protective features that do not protect the catheter from the environment, such as products with a gripper. Second, catheters with an introducer tip enable the catheter to 'bypass' the distal end of the urethra which is a heavy bacterial zone. This bypass reduces the bacterial transfer to the urethra, thus improving patient outcomes by lowering the risk of UTIs. VaPro Straight and VaPro Pocket Intermittent Catheters are hydrophilic-coated catheters that are fully enclosed with both an introducer tip and protective sleeve but do not include an integrated collection bag. They offer full protection from touch contamination and bypass the bacterial zone of the distal urethra like other A4353 products but do not include the collection chamber, which is not always needed. Existing HCPCS codes identify catheters with insertion supplies (A4353) and without insertion supplies (A4351 and A4352). The DME MACs have determined that "no-touch" catheter systems are described by A4353 but only systems that include a collection tray or bag can be reported under this code. There is no code to describe fully enclosed, protective catheter systems that do include all necessary insertion supplies but which do not include a collection tray or bag. We request a new code to represent the significant difference in level of protection and therapeutic benefit offered by intermittent catheters without a collection bag, but are enclosed the full length of the catheter (from tip to funnel).

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code A4353, "Intermittent urinary catheter, with insertion supplies" describes the Vapro intermittent urinary catheter, fully enclosed and without collection bag. The applicant referred to the following sentence in the Policy Article (A52487), "Systems that do not have a collection chamber or otherwise are not functionally equivalent in performing a sterile-technique catheter insertion must be coded as an intermittent catheter,

A4351 or A4352, depending upon the catheter configuration." However, Policy Article A52487 for Ostomy Supplies does not refer to existing HCPCS Level II code A4353, meaning the reference to a collection chamber does not apply.

Policy Article A52521 for Urological Supplies states, "an intermittent urinary catheter with insertion supplies (A4353) is a kit, which includes a catheter and all supplies necessary for a single, sterile insertion (see below). Code A4353 may be used if any of the following 1, 2 or 3 is supplied:

1. A single sterile package containing both an intermittent urinary catheter and all necessary insertion/collection supplies; or
2. A sterile intermittent urinary catheter plus a separately-packaged sterile kit containing all necessary insertion/collection supplies; or
3. A sterile "no-touch" type of catheter system."

"The product described in #3 is a single-catheter system that is functionally equivalent to a complete sterile insertion kit (A4353) containing a catheter and the additional components as described in the previous paragraph. In order to be coded as A4353, a "no-touch" type of catheter system must be a sterile, all-inclusive, self-contained system capable of accomplishing intermittent catheterization with sterile technique without the use of additional supplies such as gloves, lubricant, collection chamber, etc. Additional individual components must not be separately billed. Separate billing of additional supply items is considered as unbundling." The Vapro Intermittent Urinary Catheter would be comparable to a sterile "no-touch" type of catheter system. These "no-touch" systems must be sterile and self-contained, similar to the Vapro Intermittent Urinary Catheter, allowing for insertion with minimal risk of contamination.

Additionally, CMS has conducted a clinical review, which indicates no differences in the incidence of asymptomatic bacteriuria or catheter-associated urinary tract infection have been found between sterile versus clean technique for intermittent catheterization, coated versus uncoated catheters, or single use versus multi-use catheters. If proper application technique is used, other intermittent catheters described by HCPCS Level II code A4353 offer the same clinical benefit.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for A4353 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4353 apply to this product if covered.

Pricing = 37

Agenda Item # 8

Repose Contur Overlay - HCP2112200N9K8

Topic/Issue

Request to establish a new HCPCS Level II code to identify Repose Contur Overlay.

Applicant's suggested language: XXXXX, "Reactive air pressure relief overlay for reclining chair, Length 69" Width 21""

Applicant's Summary

Frontier Therapeutics submitted a request to establish a new HCPCS Level II code to identify the Repose Contur Overlay. The Repose Contur Overlay is a pressure redistribution and reduction support surface that reduces peak and average pressures and consistently delivers low levels of pressure ulcer incidence. The Repose Contur Overlay is indicated for the prevention of pressure ulcers for patients at all levels of risk and treatment of all categories of pressure ulcer when used as part of a protocol of care. The Repose Contur Overlay is designed to provide full body pressure relief for a high risk patient when sitting in a chair.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0190, "Positioning cushion/pillow/wedge, any shape or size, includes all components and accessories" describes the Repose Contur Overlay.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0190 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0190 apply to this product. Items or services described by HCPCS code E0190 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 9

Electro Flo 6 Airway Clearance System - HCP220104QRKLN

Topic/Issue

Request to establish a new HCPCS Level II code to identify Electro Flo 6 Airway Clearance system.

Applicant's suggested language: XXXXX, "Chest wall compression impact vibrator"

Applicant's Summary

Med Systems Inc. submitted a request to establish a new HCPCS Level II code to identify Electro Flo 6 Airway Clearance System. The Pricing, Data Analysis and Coding (PDAC) contractor has coded the Electro Flo in E0480. This coding decision effectively denies patient access to the Electro Flo because the payment for E0480 does not cover the cost of the device. The proposed new HCPCS "E" code recognizes the Electro Flo's technological and therapeutic distinctions from other "powered percussor" airway clearance systems, and it would enable the PDAC to price it appropriately. The Electro Flo Airway Clearance System's operating principle is actual percussion because it employs a "hammer and anvil" striking mechanism: the hammer is the handheld body of the power head; the anvil is the surface of the power head that is held in contact with the chest. The force from the therapist's hand drives the hammer through a gap until it strikes the anvil and delivers its accumulated momentum in a robust mechanical impact to the chest. The frequency of the impulse train can be varied between about 4 and 20 Hz. An included self-administration strap enables the patient to position the device anywhere on the front or back of the chest without assistance. Because the Electro Flo provides true percussion (striking impact) to targeted areas of the chest wall, it is the only powered percussor that accomplishes all the airway clearance functions of manual percussion: Powerful impulse waves that radiate into the chest and generate mass airflow in the lungs with cephalad airflow bias and deliver high-frequency vibrations that loosen secretions. HCPCS Codes E0480, "Percussor, electric or pneumatic, home model" and E0483, "High frequency chest wall oscillation system, includes all accessories and supplies, each" are used for airway clearance devices. The terminology of the HCPCS code is vague and does not differentiate devices by their mechanism of action, clinical utility, device complexity, or cost. The PDAC has created a local coverage policy with a very restrictive definition E0483 that is independent of the HCPCS descriptions. However, no such policy defines E0480, which serves as a catch-all for any device that does not include a vest. The Electro Flo meets all the requirements for E0483 described in the policy, except that it achieves high-frequency chest wall compression without the need for a vest. Nevertheless, PDAC has placed the Electro Flo impact percussor with two acoustic vibrator devices in E0480. However, they are very different technologies with different therapeutic characteristics, complexity, and cost. Because of the vast difference in payments in E0480 and E0483, the PDAC coding decisions deny Medicare beneficiaries and the beneficiaries of other health plans access to this therapeutically distinct technology.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0480, "Percussor, electric or pneumatic, home model" describes the Electro Flo 6 Airway Clearance System. According to the applicant, "The

Electro Flo Airway Clearance System's operating principle is actual percussion because it employs a "hammer and anvil" striking mechanism: the hammer is the handheld body of the power head; the anvil is the surface of the power head that is held in contact with the chest." The Electro Flo allows for a single area of percussion that is controlled by the patient, similar to those devices in existing HCPCS Level II code E0480. Items that fall under HCPCS Level II code E0483 include percussors that provide oscillations and compression to the chest, back and torso simultaneously.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0480 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0480 apply to this product if covered.

Pricing = 36

Agenda Item # 10

VibraLung® Acoustical Percussor (VAP) - HCP22010483DKP

Topic/Issue

Request to establish a new HCPCS Level II code to identify the VibraLung® Acoustical Percussor (VAP).

Applicant's suggested language: XXXXX, "Intrapulmonary Acoustical Airway Clearance, electric pertaining to devices generating variable frequency sound (acoustical) waves directed to pulmonary airways via a mouthpiece to facilitate the mobilization of mucus secretions, debris, and physical obstructions, and to open and relax airways"

Applicant's Summary

VibraLung Inc. submitted a request to establish a new HCPCS Level II code to identify the VAP, which is an intrapulmonary (direct to airways) acoustical airway clearance device that generates, using a transducer, a wide range of frequencies. With a significantly different mechanism, the VAP facilitates the mobilization of mucus secretions, and debris, opens and relaxes airways. Existing code E0480 is inadequate for "Intrapulmonary Acoustical Airway Clearance" (IAAC) therapy devices. Other devices operate by mechanical thumping, which transmits vibration through a patient's chest wall. They have the same FDA classification 868.5665. Note the VAP is intrapulmonary, transmitting sound waves, or acoustical oscillatory vibrations directly into the respiratory system via a mouthpiece, and not the chest wall in any manner. A study conducted in 2017 had 20 patients who had discharge diagnosis of either COPD or pneumonia. They were followed for a 90-day period, and only one patient was readmitted for the same diagnosis. Two other studies found readmission rates of 2 to 4.5 (5) patients. For 1 to 4 patients, readmissions cost could be up to $52,800 for a one-night stay, compared to with the cost of the VAP of $2,800 - $4,480 - a huge cost savings to the healthcare system. Due to the low reimbursement of E0480, distributors of the VAP do not accept Medicare assignment, because it barely covers the manufacturing, shipping and handling costs. It does not cover commissions, DME or regulatory costs. The lack of adequate and reasonable reimbursement is discriminatory to those of lower income who are on Medicare/Medicaid, and who cannot afford to private pay for the VAP. Also, doctors are reluctant to prescribe the VAP because their patients cannot easily obtain it. Indications of use: COPD, chronic bronchitis, bronchiectasis, asthma, cystic fibrosis, pneumonia, atelectasis and neuromuscular respiratory disease. Action: Intrapulmonary delivery of sound waves to the respiratory system. Dosage: Generally, two to three treatments per day, starting with Low followed by 2 minutes of Random Noise, then Medium and High clearing larger to smaller airways. Treatments administered through mouthpiece, with patient sitting mostly upright, relaxing and breathing through the device.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0480, "Percussor, electric or pneumatic, home model" describes the Vibralung® Acoustical Percussor. The Vibralung® Acoustical Percussor is an electric percussor indicated for airway secreation clearance. According to the applicant, "per FDA 510(k) clearance, the Vibralung® Acoustical Percussor is intended for use in the hospital or home for patient with respiratory diseases and related conditions that involve:

increased mucus production, infection and inspissation of respiratory secretions, and defective mucociliary clearance." To use this device, the patient breathes into a mouthpiece attached to a transducer which is connected to the control unit. The control unit generates sounds waves and controls the treatmeant. The Vibralung® Acoustical Percussor is for a single area of percussion, similar to devices described by existing HCPCS Level II code E0480, which only allow a single area of percussion at any moment.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0480 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0480 apply to this product if covered.

Pricing = 36

Agenda Item # 11

EndeavorRx® - HCP220103YXJ32

Topic/Issue

Request to establish a new HCPCS Level II code to identify EndeavorRx®.

Applicant's suggested language: QXXXX, "Prescription digital therapeutic (PDT), for attention deficit hyperactivity disorder, pediatric ages 8-12, strengthens 3 elements of attentional control (interference processing, focus, multitasking) by stimulating specific neural systems in the brain, used as part of a therapeutic program"

Applicant's Summary

Akili Interactive submitted a request to establish a new HCPCS Level II code to identify the EndeavorRx® treatment, a prescription digital therapeutic authorized by the U.S. Food and Drug Administration (FDA) in June 2020 with an indication to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type attention deficit hyperactivity disorder (ADHD), who have a demonstrated attention issue. Patients who engage with EndeavorRx® demonstrate improvements in a digitally assessed measure, Test of Variables of Attention (TOVA®), of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity. EndeavorRx® should be considered for use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or an educational program, which further address symptoms of the disorder. After a physician prescribes EndeavorRx® to a patient, a specialty pharmacy submits a claim to the patient's health plan for the product and provides an authorization code to the patient. Once the patient downloads EndeavorRx® onto a compatible personal electronic device, they are able to use the prescription digital therapeutic on their own time in their own home. Physicians are not required to pay for or take ownership of the product. Currently, payers adjudicate claims for EndeavorRx® through plan pharmacy benefits, using EndeavorRx®'s unique device identifier (UDI) as a proxy for a national drug code (NDC) number. However, Akili has had conversations with multiple payers that have expressed interest in covering EndeavorRx® through a plan's medical benefit, which would require a HCPCS billing code. Because EndeavorRx® is used by a patient on their own time in their own home, making it most similar to a non-drug, non-biological item that is used outside of a physician's office, Akili Interactive believes that EndeavorRx® should qualify for a Level II HCPCS code. There are currently no Level II (HCPCS) codes that adequately describe the EndeavorRx® treatment.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code A9291, "Prescription digital behavioral therapy, fda cleared, per course of treatment" describes EndeavorRx®.

Preliminary Benefit Category Determination

No benefit category

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. Digital therapies or computer software are not devices, equipment, or supplies and therefore would not fall under a DMEPOS benefit category. Whether or not the item could fall under some other Medicare benefit category can be considered, but would not be addressed under the DMEPOS benefit category determination process.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Agenda Item # 12

Tongueometer™ - HCP2112027WV28

Topic/Issue

Request to establish a new HCPCS Level II code to identify Tongueometer™.

Applicant's suggested language: EXXXX, "Tongue Strength measurement and rehabilitation system"

Applicant's Summary

E2 Scientific submitted a request to establish a new HCPCS Level II code to identify Tongueometer™. Description: Tongueometer™ hand-held device, Tongueometer™ bulb, user manual, powerbank and cable, Tongueometer™ application compatible with Android and iOS with four modules to assess and exercise tongue strength and endurance. Function: used to measure and increase tongue strength and endurance by patients under guidance of their healthcare professional. New code requested as currently there are no codes that adequately describe this device. There are no specific codes for the function of this device. Indications for use: dysphagia, dysarthria, slurring, speech impediment, drooling, oral motor fatigability, strength assessment and rehabilitation.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code A9300, "Exercise equipment" describes Tongueometer™.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for A9300 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A9300 apply to this product. Items or services described by HCPCS code A9300 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 13

NovoPulse® - HCP211224EK2TK

Topic/Issue

Request to establish a new HCPCS Level II code to identify NovoPulse®.

Applicant's suggested language: XXXXX, "Electric Field and Thermal Stimulation Combination Therapy"

Applicant's Summary

BioMagnetic Sciences submitted a request to establish a new HCPCS Level II code to identify NovoPulse®. Existing codes do not support this unique technology of combined electric field and thermal stimulation for pain management. Two recent discoveries created the foundation for this combination therapy: The effect of Electric Field Stimulation on reducing inflammation and long-term pain relief; and the effect of Thermal Stimulation on the regenerative process with short-term pain management. Upregulation of Adenosine A2aR anti-inflammatory pathway by providing local Electric Field Stimulation, which reduces inflammation, provides long-term pain relief via blocking of the Prostaglandin E2, and promotes the restoration of damaged tissues. In NovoPulse® MKX-1, a unique multicoil system is designed to generate appropriate amplitude Electric Field and deliver it to intervertebral discs, facet, and extremity joints with adequate duration, amplitude, orientation, and distribution. In addition to the Electric Field Stimulation, NovoPulse® provides Thermal Stimulation, which is synergistically combined with Electric Field Stimulation. The computer controlled Thermal Stimulation is delivered through heating pads which converts the stored magnetic field energy at the end of each pulse. Thermal Stimulation of the joint increases blood flow around the joint, promotes diffusion of nutrients in and the waste product out of the joint. The most important aspect of using thermal stimulation is the generation of "heat shock proteins" (HSPs). The biological function of HSPs is to preserve cell survival by maintaining the vital functions of proteins. Improved protein function leads to 4-7 fold increase in production of the extracellular cartilage matrix, that significantly accelerates its repair and contributes to long-term pain relief in the joint. Current research, indicates pain reduction and promotion of cartilage tissue regeneration in osteoarthritis. Chronic pain due to wear and tear or pre-existing late-effect injuries or illnesses is mitigated by Electric Field and Thermal Stimulation which reduces inflammation and pain and promotes healing of damaged tissues. The NovoPulse® system is delivered in a carrying case consisting of a wearable applicator, a microprocessor-based controller, a power supply, and a user manual. The device fits on the patient's body region involved and the patient can be in a comfortable position (i.e., sitting, lying, standing) while the therapy is applied to the region for 30 minutes. The system automatically shuts down at the end of the 30-minute session. During operation, the microprocessor-based controller monitors the performance and health status of the device and shuts down the device in the event of any abnormal conditions. Dosage of treatments per day is recommended by the provider based on the patient's condition and response to care.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0762, "Transcutaneous electrical joint stimulation device system, includes all accessories" describes NovoPulse®. The thermal stimulation is a

byproduct of the stored magnetic field energy created from the pulsed electromagnetic stimulation. After a pulse, the energy stored in the magnetic field of the coils is converted to heat. CMS does not believe the NovoPulse® provides a clinical benefit beyond the other products in E0762. We welcome the applicant to submit any clinical studies that demonstrate such comparison and distinction.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0762 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0762 apply to this product if covered.

Pricing = 36

Agenda Item # 14

Biobeat - HCP2111231GDB0

Topic/Issue

Request to establish a new HCPCS Level II code to identify Biobeat.

Applicant's suggested language: XXXXX, "Non invasive wearable monitor device for monitoring of vital signs that transmits collected data to any web platform"

Applicant's Summary

Living Well Innovations, Inc. submitted a request to establish a new HCPCS Level II code to identify the Biobeat monitoring solution, which is based on the photoplethysmography (PPG) sensor. Biobeat is designed to allow a clear reading of PPG signal wave, enabling measurement of a wide range of vitals. The Biobeat chest monitor and wrist-monitor each collect and measure 12 parameters from the patient, and the chest-monitor measures a one-lead ECG. The device transmits the measurement data to the Biobeat gateway or cellphone app. All data are uploaded to and stored on the Biobeat Cloud (health insurance portability and accountability act and general data protection regulation compliant). The healthcare provider can then access all data through the Biobeat web platform.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" describes Biobeat.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for A9279 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A9279 apply to this product. Items or services described by HCPCS code A9279 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 15

GoSpiro® - HCP2109208A81K

Topic/Issue

Request to revise existing HCPCS Level II code E0487 to identify GoSpiro®.

Applicant's suggested language: XXXXX, "Electronic Spirometer, FDA Product Code BZG cleared for patient self-testing at home. Includes measurement of FVC, SVC and bidirectional flow"

Applicant's Summary

Monitored Therapeutics Inc. submitted a request to revise existing HCPCS Level II code E0487 to identify GoSpiro®, a diagnostic spirometer for physician's offices, clinics, and home settings to conduct basic lung function and spirometry testing. HCPCS code E0487's current language is inadequate. This broad description allows for devices that do not measure lung function with diagnostic accuracy, causing intermediary payors to reject claims even for devices that do provide hospital laboratory quality and actionable data for healthcare providers. "Non- diagnostic" electronic spirometers that fall under HCPCS code E0487 might include Peak Flow Meters or Spirometers that only measure forced expiratory volume in the first second (FEV1) or expiratory flow only. We request that CMS modify HCPCS code E0487 to include the above language so that its intermediary payors will recognize that they would be paying for true diagnostic devices that provide patient disease management value for the prescribing physician. The intermediary payors already pay for use of these "diagnostic" devices under CPT codes 99453, 99454, 99457, and 99458 for the labor components of their use for taking lung function measurements. Changing the specification for devices qualifying under E0487 will increase the likelihood that reimbursement will be approved for the device used to take those measurements. The GoSpiro® has been used for several years to provide clinically relevant data to healthcare providers to help guide patient management. The COVID-19 pandemic produced a significant effect, transitioning patient monitoring measurements from hospitals to the home. Collecting more frequent measurements increases the data's statistical power, improving the reliability and usefulness of what is collected when measured by a diagnostic device.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0487, "Spirometer, electronic, includes all accessories" describes GoSpiro®. Diagnostic equipment used in the patient's home that provides measurements a physician may use to evaluate the patient's condition and course of treatment does not have a DMEPOS benefit category. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0487 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0487 apply to this product. Items or services described by HCPCS code E0487 are not covered under a Medicare Part B DMEPOS benefit.

Pricing = 00

Agenda Item # 16

Eddie® - HCP220511UNGLE[1]

Topic/Issue

Request to establish a new HCPCS Level II code to describe the Eddie® device.

Applicant's suggested language: XXXXX, "External penile rigidity device that mimics the natural physiology of an erection"

Applicant's Summary

Giddy submitted a request to establish a new HCPCS Level II code to identify Eddie®, a new external penile rigidity device. Eddie® is not covered by existing HCPCS codes as it does not utilize a vacuum, inflation, deflation, surgery, or implants, and instead utilizes a first-of-its-kind design that works with the natural physiology of an erection. Eddie® is a wearable, FDA Registered Class II medical device designed to maintain penile rigidity in men with erectile dysfunction (ED). It doesn't require a prescription, vacuum, surgery, or cause any of the side effects of ED pills. Function of the product: Eddie® is designed to be worn at the base of the penis to treat ED. When worn at the base of the penis with a tension band affixed around both ends of the device, Eddie® constricts the veins in the penis, while leaving the arteries and urethra unencumbered, to maintain an erection by optimizing the blood flow in and out of the penis. Reason why existing codes do not adequately describe the product: Below are the current HCPCS codes for ED-related treatments, and explanations why none of these codes are applicable to Eddie®. C1813 - Inflatable Penile Prosthesis; This is a permanent, surgically-implanted penile prosthesis that uses inflation/deflation. This code does not adequately describe Eddie® because Eddie® is a wearable, reusable, external device that doesn't involve surgery. Eddie® is easily added and removed by the user as needed, and uses constriction around the base of the penis, not inflation or deflation, to maintain an erection. C2622 - Non-inflatable Penile Prosthesis; This is another permanent, surgically-implanted prosthesis. The only difference from C1813 is that this is a semi-rigid rod that doesn't use inflation. This code does not adequately describe Eddie® because Eddie® is a wearable, reusable, external device that doesn't involve surgery. Eddie® is easily added and removed by the user as needed, and uses constriction around the base of the penis, not a semi-rigid rod, to maintain an erection. L7900 - Male vacuum erection system + L7902 Accessory Ring; This is a "male vacuum erection system" with a component tension ring. These vacuum erection devices require multiple components to manually pump or pull blood into the penis with a vacuum. This code does not adequately describe Eddie® because Eddie® uses constriction at the base of the penis, not a vacuum, to maintain an erection. Eddie® works with the natural physiology of an erection, optimizing blood flow by constricting the veins, not the arteries or urethra, while L7900 forces the blood into the penis with a manual pump. L7900 is approximately 100 times the size of Eddie®. The applicant stated that certain third party insurers, including TRICARE, Aetna, and Blue Cross Blue Shield provide coverage of treatments for ED.

[1] The applicant properly submitted their HCPCS Level II application in advance of the January 4, 2022 submission deadline for the B1 2022 coding cycle. CMS was unable to include this application as part of the Day 3 Public Meeting Agenda when it was originally posted on May 6, 2022. As a result, the Day 3 Public Meeting Agenda was updated on May 13, 2022 to include Agenda Item #16: Eddie® - HCP220511UNGLE.

Preliminary CMS HCPCS Coding Recommendation

This application is a resubmission of an application that CMS reviewed in the B1 2021 coding cycle. In the B1 2021 coding cycle, CMS denied the request to establish a new HCPCS Level II code to separately identify the Eddie® device because ED devices such as the Eddie® are considered over-the-counter devices and are not typically paid by insurance. In the current submission, the applicant stated that certain insurers provide coverage of treatments for ED; however, they did not provide specific documentation that any insurers provide coverage of the Eddie® device. We invite the applicant to provide documentation to demonstrate that insurers provide coverage of the Eddie® device, such as publicly-available written policies, written correspondence from other insurers that the lack of a unique HCPCS Level II code is the reason for claims denials, or documentation that insurers are allowing the Eddie® device to be billed using an existing HCPCS Level II code(s).

Appendix: DMEPOS Payment Categories

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

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
The allowed payment amount for covered items is based on local carrier pricing (e.g., local fee schedule amounts or reasonable charges or other carrier pricing method.