



**Zoom Meeting, for remote participation**  
**Thursday, July 8, 2021 9:00 am – 5:00 pm, eastern daylight time (edt)**

8:45 am, edt:

- Zoom meeting login:  
[https://cms.zoomgov.com/webinar/register/WN\\_ukTCxcctSReHO2RJaD5O6w](https://cms.zoomgov.com/webinar/register/WN_ukTCxcctSReHO2RJaD5O6w)
- Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

9:00 am, edt:

- Welcome
- Background and purpose of meeting
- Meeting format and ground rules

For each agenda item, a written overview of the request and CMS' preliminary coding recommendation or other review status is provided. 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 other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for stakeholders 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 decisions will be published on CMS HCPCS web site at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelII-Coding-Decisions-Narrative-Summary> around the end of July 2021, and will be effective October 1, 2021, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Thursday, July 8, 2021. 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.

**July 8, 2021**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 1**

**Request # 21.036**

Request to establish a new HCPCS Level II code to identify Pressure Offloading System

**Agenda Item # 2**

**Request # 21.047**

Request to discontinue current HCPCS Level II code L5610 "Addition to lower extremity, endoskeletal system, above knee, hydracandence system."

**Agenda Item # 3**

**Request # 21.067**

Request to establish a new HCPCS Level II code to identify an innovative external penile rigidity device that works with and not against the natural physiology of an erection.

**Agenda Item # 4**

**Request # 21.068**

Request to revise HCPCS Level II code L3000 "Foot insert, removable, molded to patient model, UCB type, Berkeley shell, each."

Applicant's suggested language: L3000 "Prescription custom fabricated foot insert, each, removable, molded to patient model, with minimum of a 10mm heel cup, typically dispensed as pair."

**Request # 21.069**

Request to revise L3020 "Foot insert, molded to patient model, longitudinal/metatarsal support, each."

Applicant's suggested language: L3020 "Prescription custom fabricated foot insert, molded to patient model, longitudinal/metatarsal support, each, typically dispensed as a pair."

### **Agenda Item # 5**

#### **Request # 20.150**

Request to create a coding distinction between particulate and non-particulate bulking agents by (1) revising existing code L8606 which currently reads "Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies" to instead read "Injectable bulking agent, synthetic implant, particulate combination agent, urinary tract, 1 ml syringe, includes shipping and necessary supplies"; and (2) establishing a new Level II HCPCS Code to identify non-particulate injectable bulking agents.

Applicant's suggested language for the proposed new code: L86XX "Injectable bulking agent, synthetic implant, non-particulate homogenous agent, urinary tract, 2 ml, includes shipping and necessary supplies"

### **Agenda Item # 6**

#### **Request # 20.153**

Request to establish a new Level II HCPCS code to identify the additional therapeutic function and benefit of Blatchford's Silcare Breathe Liner.

### **Agenda Item # 7**

#### **Request # 20.154**

Request to establish a new HCPCS Level II code to identify the additional therapeutic function and benefit Uniprox's Softskin Air Liners.

Applicant's suggested language: LXXXX "Addition to lower extremity, moisture prevention/mitigation feature (for use with L5679, L5673, L5681 & L5683)"

### **Agenda Item # 8**

#### **Request # 20.156**

Request to establish two new Level II HCPCS codes to identify the ALLUX MPK knee.

Applicant's suggested language:

LXXXX “Addition, endoskeletal knee-shin system, 4-bar, fluid swing and stance phase control.”

LXXXX “Addition, microprocessor control feature, automatic stance-phase lock, automatic stance-phase lock.”

### **Agenda Item # 9**

#### **Request # 20.157**

Request to establish a new Level II HCPCS code to identify the additional therapeutic function and benefit of WillowWood’s Alpha SmartTemp Gel Liner

Applicant's suggested language: LXXXX “Addition to lower extremity socket insert, moisture prevention feature (for use with L5679, L5673, L5681 & L5683).”

#### **Request # 20.158**

Request to establish a new HCPCS Level II code to identify the additional therapeutic function and benefit of WillowWood’s Alpha SmartTemp Liner.

Applicant's suggested language: LXXXX “Addition to lower extremity socket insert, moisture prevention feature (for use with L5679, L5673, L5681 & L5683).”

### **Agenda Item # 10**

#### **Request # 21.029**

Request to establish a new HCPCS Level II code to identify Gap-flex system, Trade Name: Gap-Flex System.

Applicant's suggested language: EXXXX “Gravity Assisted Passive Flexion and Extension for Use on Knee.”

### **Agenda Item # 11**

#### **Request # 21.030**

Request to establish a new HCPCS Level II code to identify a low-magnitude, resonant mechanical stimulator (LMRMS)

Applicant's suggested language: E077X "low-magnitude, resonant mechanical stimulator (LMRMS)"

**Agenda Item # 12**

**Request # 21.034**

Request to establish a new HCPCS Level II code to identify Slow Wave DS8

No suggested language.

**Agenda Item # 13**

**Request # 21.051**

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

Applicant's suggested language: "Head-worn customizable bi-optic electronic central vision prosthetic with unoccluded peripheral fields."

**Agenda Item # 14**

**Request # 21.055**

Request to establish a new HCPCS Level II code that accurately reflects the active use and non-continuous motion and strengthening mechanisms of the X10, and the treatment duration.

**Agenda Item # 15**

**Request # 20.164**

Request to establish a new HCPCS Level II code to identify the Chait Access Adapter with Connecting Tube.

Applicant's suggested language: AXXXX "Cecostomy irrigation supply; tubing with adapter."

### **Agenda Item # 16**

#### **Request # 21.056**

Request to establish two new HCPCS Level II codes, the first for an EPAP device, which includes a nasal pillow body and two cartridge valves (similar to a CPAP mask A code) and a code for a pair of cartridge valve replacements (similar to a CPAP mask replacement A code). Applicant further request to add "EPAP" to the CPAP Headgear code (A7035) and to the CPAP Replacement Nasal Mask Cushion code (A7033).

### **Agenda Item # 17**

#### **Request # 21.065**

Request to establish a new HCPCS Level II code to identify the provision and remote interpretation of data collected via a purchased or leased Food and Drug Administration (FDA)-registered at-home uroflow medical device.

No suggested language.

### **Agenda Item # 18**

#### **Request # 21.066**

Request to establish two new HCPCS Level II codes to identify:

1. Felix Device Wireless stethoscope with recording device and LED indicators.
2. FelixPro Wireless stethoscope with recording device with headset attachment for physician use only.

### **Agenda Item # 19**

#### **Request # 21.050**

Request to modify HCPCS Level II code B9998, to include a patented undershirt for children who are fed enterally.

No suggested language.

**Agenda Item # 20**

**Request # 21.059**

Request is to establish a new HCPCS Level II code for a prescription and over-the-counter drug deactivation and disposal pouch. Brand Name: Deterra Drug Deactivation System.

No suggested language.

**Agenda Item # 21**

**Request # 21.042 – 21.046**

Request to establish a new HCPCS Level II code to identify Whole Health Partners within the Veterans Health Administration (VHA).

Applicant's suggested language: QXXXX "Department of veterans affairs whole health partner services."

## **Agenda Item # 1**

### **Request # 21.036**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify Pressure Offloading System.

#### **APPLICANT'S SUMMARY**

Advanced Brace submitted a request to establish a new HCPCS Level II code for the Pressure Offloading System as each one is made custom to the Patient Model. The technology within the device suspends the Patient's foot in a way that the wound being addressed is offloaded which allows for optimum healing. The diagnoses that qualify a patient for the Pressure Offloading System AFO (P.O.S. AFO) are going to be as follows: Charcot Foot, Ankle Instability, Various Wounds, Absence of toe(s), Partial foot Amputation, etc. The current codes being used are: L1904 Ankle Gauntlet Custom Fabricated, L3030 Custom Insert, L2820 Soft Interface, L2275 Varus / Valgus Correction, L2330 Lacer Molded to Patient Model. The P.O.S. AFO is a custom product that is designed specifically for each patient's needs. Due to the custom process, Advanced Brace is able to fabricate this unique device--regardless of wound location, size, or shape of foot. This device is designed for anyone who has one or more of the previously listed conditions, and has developed an ulcer on the plantar surface, anterior, or even top of foot. The P.O.S. AFO is fabricated with a custom 3/8th inch tri-lam diabetic industry standard material insole, with an additional 1/8th neoprene to prevent drainage from wound. This custom insert is modified to apply pressure directly posterior, medial, or lateral to the wound site--which is key in the offloading, which allows the wound to heal. Our device achieves an additional 1/2 inch pressure reduction by utilizing the actual sole of the P.O.S AFO. This can be accomplished due to its fabrication process. Finally, a non-slip rubber sole is added to enhance the patient's safety. This device is lightweight, breathable, washable, and overall effective. Our P.O.S. AFO redistributes pressure over the entire plantar surface of the foot where the foot will tolerate, in order to offload existing pressure off of the wound site. It can serve any patient with a stubborn foot wound that won't heal correctly. Regardless of any underlying condition, due to the constant pressure of day to day activities. By reducing pressure, the wound should heal, without causing any other issues along the way. Due to the custom nature of the device, each P.O.S AFO is different as it is molded and created around the patient model and the Patient's needs. The current codes that are available make it very challenging in billing and reimbursement as Insurance Providers don't understand that our product contains: L1904 Ankle Gauntlet Custom Fabricated, L3030 Custom Insert, L2820 Soft Interface, L2275 Varus / Valgus Correction, L2330 Lacer Molded to Patient Model. It would be best to have an umbrella code that covered all of these specifically for the P.O.S AFO.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing code A9283 "Foot Pressure off loading/ supportive device, any type each," describes this product. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim

would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.

## **Agenda Item # 2**

### **Request # 21.047**

#### **TOPIC**

Request to discontinue current HCPCS Level II code L5610 “Addition to lower extremity, endoskeletal system, above knee, hydracadence system”

#### **APPLICANT’S SUMMARY**

This code was originally created for the Hydracadence hydraulic knee and ankle system. This consisted of a steel frame that was ordered in a specific length for the intended user. It was not modular for height adjustments. The hydraulic system of the Hydracadence consisted of a dual chambered mechanism that provided independent function/resistance of both the knee and the ankle, but also allowed for these joints to move synergistically with each other in swing phase. It includes a dedicated foot that is similar in function to a SACH (Solid Ankle Cushion Heel) foot. Heel height adjustability is included.

During normal ambulation, as the knee flexes in swing phase, the ankle actively dorsiflexes to assist in clearing the toes. The ankle provides the user the ability to adjust heel height to accommodate different shoes. The ankle also provides approximately 20 degrees of plantar flexion to accommodate slope descent.

The reason for the request of the retirement or change of L5610 is multifaceted. The Hydracadence has long been discontinued and is no longer available for purchase anywhere in the world. The average utilization of L5610 has been less than 5 units annually for the last several years. Proteor was the only company to create a knee of similar function (Hydracadence 2), but it has also been discontinued due to low sales caused by low reimbursement rates.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS is considering discontinuing existing HCPCS Level II code L5610 “Addition to lower extremity, endoskeletal system, above knee, hydracadence system” as very few claims are being processed for L5610. We are actively seeking input from all stakeholders regarding any impact of discontinuing this code and the necessary amount of lead-time before effectuating the discontinuation.

### **Agenda Item # 3**

#### **Request # 21.067**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify an innovative external penile rigidity device that works with and not against the natural physiology of an erection.

#### **APPLICANT'S SUMMARY**

Eddie is a unique and innovative FDA Class II registered medical device for erectile dysfunction that was uniquely designed to work in conjunction with the natural physiology of an erection. Eddie does not require a Doctor's visit or a prescription and it has none of the side effects of ED medications (e.g. Viagra, Cialis, Levitra). Eddie provides comparable success to that of an implant without the need for an invasive surgery.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

This request to establish a new HCPCS Level II code to separately identify the Eddie has not been approved. Erectile dysfunction devices, such as the Eddie, are considered over-the-counter devices and are not typically paid by insurance. For instance, these types of devices are statutorily excluded from Medicare.

## **Agenda Item # 4**

### **Request # 21.068**

#### **TOPIC**

Request to revise HCPCS Level II code L3000 "Foot insert, removable, molded to patient model, UCB type, Berkeley shell, each."

Applicant suggested language: L3000 "Prescription custom fabricated foot insert, each, removable, molded to patient model, with minimum of a 10mm heel cup, typically dispensed as pair."

#### **APPLICANT'S SUMMARY**

L3000 coding language has not been updated since the inception of the original HCPCS coding set, prior to modern-day materials and manufacturing techniques currently used in custom foot orthotic production. The reference to "UCB"-Berkeley shell is confusing and antiquated. The introduction of ICD10 and the laterality that accompanies certain codes has created confusion with certain non-Medicare payers. Often, non-Medicare payers provide reimbursement only for the device intended for the symptomatic extremity, which creates an iatrogenically induced limb length discrepancy. The current use of the word, "each" in the descriptor does not sufficiently address this problem. This application does not seek to influence Medicare's current orthopedic footwear policies.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing code L3000 "Foot, insert, removable, molded to patient model, 'ucb' type, berkeley shell, each" describes the product of this application.

CMS does not believe there is a need to revise the code to add "prescription custom fabricated" as the current language, "molded to patient model," indicates the device is custom made and can only fit the patient for which the mold was taken. These devices are by prescription only. Additionally, the billing unit "each" identifies the relevant body part and enables accurate billing when one unit is dispensed, whereas reporting as a pair, and particularly, inclusion of the terms "each" and "pair" together in the same code text, could result in confusion and inaccurate billing. Retaining the "each" unit designation is consistent with testimony provided at a past public meeting that there is a need to retain the ability to accurately report when a single unit is dispensed. For instance, CMS is aware of L3000 claims for a single unit (e.g., patients with an amputation of one foot or lower limb). Retaining the "each" unit designation also enables accurate reporting of two devices when dispensed as a pair, allowing suppliers to bill for two units when appropriate.

## **Agenda Item # 4**

### **Request # 21.069**

#### **TOPIC**

Request to revise L3020 "Foot insert, molded to patient model, longitudinal/metatarsal support, each."

Applicant suggested language: L3020 "Prescription custom fabricated foot insert, molded to patient model, longitudinal/metatarsal support, each, typically dispensed as a pair."

#### **APPLICANT'S SUMMARY**

The American Podiatric Medical Association is requesting a coding language change for HCPCS L3020. The current coding language mainly dates back to when the HCPCS code set was developed in the 1970's and has not been updated since 1993, both prior to the advent of modern-day materials and manufacturing techniques. With the introduction of ICD10, additional burdens are faced by providers and patients in obtaining reimbursement for custom fabricated foot orthotics, mainly due to laterality issues associated with ICD10 and payers not understanding the medical necessity of dispensing these as a pair, despite the code description including the word "each". This application is being submitted solely for coding language modernization only, not in an attempt to change or influence Medicare reimbursement policy. No brand name products are provided in this application because we are not seeking a separate therapeutic distinction for any specific product.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing code L3020 "Foot, insert, removable, molded to patient model, longitudinal/ metatarsal support, each" describes this product.

CMS does not believe there is a need to revise the code to add "prescription custom fabricated" as the current language, "molded to patient model," indicates the device is custom made and can only fit the patient for which the mold was taken. These devices are by prescription only. Additionally, the billing unit "each" identifies the relevant body part and enables accurate billing when one unit is dispensed, whereas reporting as a pair, and particularly, inclusion of the terms "each" and "pair" together in the same code text, could result in confusion and inaccurate billing. Retaining the "each" unit designation is consistent with testimony provided at a past public meeting that there is a need to retain the ability to accurately report when a single unit is dispensed. For instance, CMS is aware of L3020 claims for a single unit (e.g., patients with an amputation of one foot or lower limb). Retaining the "each" unit designation also enables accurate reporting of two devices when dispensed as a pair, allowing suppliers to bill for two units when appropriate.

## **Agenda Item # 5**

### **Request # 20.150**

#### **TOPIC**

Request to create a coding distinction between particulate and non-particulate bulking agents by (1) revising existing code L8606 which currently reads “Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies” to instead read “Injectable bulking agent, synthetic implant, particulate combination agent, urinary tract, 1 ml syringe, includes shipping and necessary supplies” and (2) establishing a new HCPCS Level II Code to identify non-particulate injectable bulking agents.

Applicant's suggested language: L86XX “Injectable bulking agent, synthetic implant, non-particulate homogenous agent, urinary tract, 2 ml, includes shipping and necessary supplies.”

#### **APPLICANT’S SUMMARY**

PRS Consulting, LLC, is requesting a HCPCS Level II code revision as well as addition of a new code to identify Bulkamid.

Bulkamid is a new polyacrylamide hydrogel bulking agent for stress urinary incontinence (SUI), consisting of cross-linked polyacrylamide (2.5% w/w) and water (97.5% w/w), supplied in sterile pre-filled syringes. Bulkamid is indicated for treatment of SUI or stress predominant mixed incontinence due to intrinsic sphincter deficiency (ISD) in adult women. Bulking is an established procedure in women with SUI. Bulkamid does not contain microparticles and its effect is achieved through the volume of hydrogel injected, which integrates with host tissue to provide durable outcomes. Bulkamid is injected in the urethra under cystoscopic guidance using a specifically designed device for exact placement. It is packaged and shipped as a 2ml kit, containing 2x 1ml syringes, disposable rotatable sheath and 2 injection needles. L8606 is used to report currently approved urethral bulking agents (Macroplastique, Coaptite, Durasphere), all containing microparticles in a carrier gel. Bulking for this class of bulking agent is clinically achieved through the body's reaction to the microparticles once the carrier gel has dissipated. Bulkamid represents a different class and requires a unique code as it is: A hydrogel containing no microparticles; Used in lower volumes than the particulate combination agents; significantly distinct therapeutic, as it is nondegradable and remains unchanged, allowing durability and; Packaged as a delivery system kit, allowing for more accurate injection.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS will defer this request to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

## **Agenda Item # 6**

### **Request # 20.153**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify the additional therapeutic function and benefit of Blatchford's Silcare Breathe Liner.

#### **APPLICANT'S SUMMARY**

Blatchford, Inc. requests one new HCPCS Level II code to describe the additional therapeutic function and benefit of Blatchford's Silcare Breathe Liner.

These liners utilize added technology to prevent/mitigate perspiration of the residual limb and facilitate the removal of this perspiration from the skin surface, reducing risk of tissue injury, enhancing suspension through creation of a natural vacuum in every step taken, and significantly differentiating them from all other prosthetic liners. These liner products are suitable for amputees who participate in a variety of activities and whose prosthesis suspension is compromised due to perspiration/moisture, causing loss of control, unwanted movement of the residual limb in the socket and associated risk of falls, causing tissue health issues and potential additional health costs.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS will defer this request to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

## **Agenda Item # 7**

### **Request # 20.154**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify the additional therapeutic function and benefit Uniprox's Softskin Air Liners.

Applicant's suggested language: LXXXX "Addition to lower extremity, moisture prevention/mitigation feature (for use with L5679, L5673, L5681 & L5683)"

#### **APPLICANT'S SUMMARY**

Uniprox GmbH & Co. KG requests one new HCPCS Level II code to describe the additional therapeutic function and benefit Uniprox's Softskin Air Liners.

These liners utilize added technology to prevent/mitigate perspiration of the residual limb, reducing risk of tissue injury and significantly differentiating them from all other prosthetic liners. These liner products are suitable for amputees who participate in a variety of activities and whose prosthesis suspension is compromised due to perspiration/moisture, causing loss of control, unwanted movement of the residual limb in the socket and associated risk of falls, causing tissue health issues and potential additional health costs.

Existing codes describe elastomeric socket inserts in various configurations. No existing codes address residual limb moisture/perspiration management and the improved clinical outcomes provided. The new code is for use in conjunction with the base liner codes.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS will defer this request to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

## **Agenda Item # 8**

### **Request # 20.156**

#### **TOPIC**

Request to establish two new Level II HCPCS codes to identify the ALLUX MPK knee.

Applicant's suggested language:

LXXXX “Addition, endoskeletal knee-shin system, 4-bar, fluid swing and stance phase control.”

LXXXX “Addition, microprocessor control feature, automatic stance-phase lock, automatic stance-phase lock.”

#### **APPLICANT’S SUMMARY**

Proteor USA requests to establish two new HCPCS L codes to identify the ALLUX MPK knee.

This request is regarding the ALLUX microprocessor controlled knee. It is the only microprocessor-controlled knee, utilizing a 4-bar geometry with hydraulic control of both stance and swing phases of gait. One of its many features is an advanced microprocessor controlled standing function, called the Safety Lock. The ALLUX is intended for use by amputees that are missing their leg through knee joint or higher (KD through HD). It uses a 4-bar knee geometry, paired with a microprocessor controlled hydraulic unit providing varying levels of resistance depending on the phases of gait (stance or swing phase). This combination enhances ROM (Range Of Motion) and toe clearance, offering a high level of versatility to the user using up to five different modes. There is an enhanced functionality through the use of an automatic stance-phase lock (called the Safety Lock). This feature will automatically lock knee flexion when the user maintains a load on a flexed, stationary knee. Upon knee extension, the lock is released, and the knee returns to normal function.

Currently, there is no adequate L code(s) to describe any 4-bar knee with hydraulic control of both stance and swing phases of gait. Also, the microprocessor code (L5856) does not describe or incorporate the automatic stance lock feature. That functionality was not included in the predicate product (C-Leg) and is an enhanced safety function providing additional stability to the user while standing on slopes, uneven terrain, and/or crouched positions, like picking objects off the ground or a low shelf.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS will defer this request to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

## **Agenda Item # 9**

### **Request # 20.157**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify the additional therapeutic function and benefit of WillowWood's Alpha SmartTemp Gel Liner

Applicant's suggested language: LXXXX "Addition to lower extremity socket insert, moisture prevention feature (for use with L5679, L5673, L5681 & L5683)"

#### **APPLICANT'S SUMMARY**

WillowWood Global requests one new code to describe the additional therapeutic function and benefit of WillowWood's Alpha SmartTemp Gel Liner.

These liners utilize unique technology to prevent perspiration of the residual limb, reducing risk of tissue injury and significantly differentiating them from all other prosthetic liners. These liner products are suitable for amputees who participate in a variety of activities and whose prosthesis suspension is compromised due to perspiration/moisture, causing loss of control, unwanted movement of the residual limb in the socket and associated risk of falls, causing tissue health issues and potential additional health costs.

Existing codes, listed below, describe elastomeric socket inserts in various configurations. No existing codes address residual limb moisture/perspiration reduction and the improved clinical outcomes provided. The new code is for use in conjunction with the base liner codes.

Existing/Associated codes:

L5679 – Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism

L5673 - Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism

L5681 – Addition to lower extremity, below knee/above knee, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)

L5683 - Addition to lower extremity, below knee/above knee, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)

## **PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS will defer this request to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

## **Agenda Item # 9**

### **Request # 20.158**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify the additional therapeutic function and benefit of WillowWood's Alpha SmartTemp Liner.

Applicant's suggested language: LXXXX "Addition to lower extremity socket insert, moisture prevention feature (for use with L5679, L5673, L5681 & L5683)"

#### **APPLICANT'S SUMMARY**

WillowWood Global requests one new code to describe the additional therapeutic function and benefit of WillowWood's Alpha SmartTemp Liner.

These liners utilize unique technology to prevent perspiration of the residual limb, reducing risk of tissue injury and significantly differentiating them from all other prosthetic liners. These liner products are suitable for amputees who participate in a variety of activities and whose prosthesis suspension is compromised due to perspiration/moisture, causing loss of control, unwanted movement of the residual limb in the socket and associated risk of falls, causing tissue health issues and potential additional health costs.

Existing codes, listed below, describe elastomeric socket inserts in various configurations. No existing codes address residual limb moisture/perspiration reduction and the improved clinical outcomes provided. The new code is for use in conjunction with the base liner codes.

Existing/Associated codes:

L5679 – Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism

L5673 - Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism

L5681 – Addition to lower extremity, below knee/above knee, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)

L5683 - Addition to lower extremity, below knee/above knee, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)

## **PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS will defer this request to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

## **Agenda Item # 10**

### **Request # 21.029**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify Gap-flex system, Trade Name: Gap-Flex System.

Applicant's suggested language: EXXXX "Gravity Assisted Passive Flexion and Extension for Use on Knee."

#### **APPLICANT'S SUMMARY**

Xeras Medical Technologic Inc. d.b.a. Gap Flex Inc. submitted a request to establish a new HCPCS Level II code to identify Gap-flex. According to applicant, Gap-flex is a new Durable Medical Equipment (DME) Device. Our device comes in two different sizes, "Regular" and "Tall". We are requesting a code for each size or a combined code for both; whichever is more applicable.

The Gap-flex system is sturdy, simple setup, lightweight, compact, and easily stored. The product consists of an aluminum T-bar frame with removable therapeutic foam layers and a separate, integrated foam extension block. The system includes a mobile app to track progress and compliance. Gap-flex is designed to accelerate range-of-motion recovery and rehabilitation. Utilizing the simple platform of gravity, patients using our device notice a faster, more comfortable, highly compliant and less painful method of recovery. Gap-flex provides patients with contactless (particularly important now with COVID-19 associated risks) knee recovery more quickly, more efficiently, and less costly than any other method available.

There is an existing E0935 code that is used for Continuous Passive Motion (CPM) machines. Upon submission to the PDAC review board it was agreed that the Gap-flex system met and exceeded the clinical criteria for the code; however, the E0935 code language did not adequately describe the mode of action of our device in that it doesn't allow for a non-powered device despite its superior clinical benefits. The PDAC Medical Director strongly recommended for us to apply for an exclusive code for our device. Our product is specifically more effective and efficient because it's non-powered. Keeping the knee stable in a defined angle and allowing gravity to stretch the ligaments and muscles daily is clinically proven (study attached) to heal more quickly and more effectively.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing code A9300 "Exercise equipment" describes the Gap-flex system, and is available for assignment by insurers if they deem appropriate. In addition, A9300 is consistent with the manufacturer's self-designation with the Food and Drug Administration as exercise equipment. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be

filed. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.

## **Agenda Item # 11**

### **Request # 21.030**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify a low-magnitude, resonant mechanical stimulator (LMRMS)

Applicant's suggested language: E077X "Low-magnitude, resonant mechanical stimulator (LMRMS)."

#### **APPLICANT'S SUMMARY**

Emerson Consultants submitted a request to establish a new HCPCS Level II code for low-magnitude, resonant mechanical stimulator (LMRMS).

The Juvent Micro-Impact Platform is a low-magnitude, resonant-high frequency mechanical stimulator platform that patients stand on to receive their treatment. The platform functions by sending calibrated (to each patient, each time) mechanical energy micro-impacts up through the body which mimic the impact from walking 2 to 5 miles. These impacts gently move the body and increase blood flow and lymphatic drainage which improves bone health and increases muscle health. The Juvent platform is DME and we believe should fall under the "stimulation device" section of the HCPCS codes. There are no other codes in this section that describe "low magnitude, resonant, high frequency, mechanical stimulation. The other codes in this section describe "electrical stimulation" or non-thermal pulsed high frequency radiowaves. In addition, none of these codes describe a platform type device that the patient stands on to receive treatment. There have been numerous published clinical studies showing the benefit of this technology and it is important to be able to track utilization for this unique device.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing code A9300 "Exercise Equipment" describes Juvent Micro-Impact Platform, and is available for assignment by insurers if they deem appropriate. In addition, A9300 is consistent with the manufacturer's self-designation with the Food and Drug Administration as exercise equipment. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.

## **Agenda Item # 12**

### **Request # 21.034**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify Slow Wave DS8

#### **APPLICANT'S SUMMARY**

Slow Wave, Inc. submitted a request to establish a new code for Slow Wave DS8, an intra-oral device intended to reduce or alleviate snoring and mild to moderate Obstructive Sleep Apnea while sleeping in adults. DS8 consists of two custom fitted trays used to reposition the mandible. The trays are designed to be worn on the upper and lower teeth where they act to increase the patient's pharyngeal space by reducing obstructions of the airway during sleep. The device is designed to be retained on the teeth with saliva and surface tension and functions without any screws or fastening mechanism. The patient-custom devices are 3D print manufactured and made from biocompatible material. The Slow Wave DS8, is a mandibular repositioning device that acts to increase the users' pharyngeal space and improves their ability to exchange air during sleep. The device consists of two separate trays worn on the maxilla and mandible, which allow the user to open and close their jaw when asleep, provide full lateral movement of the mandible, move the tongue naturally forward to enhance air exchange during sleep. The DS8 trays worn on the maxilla and mandible with integrally formed molar extensions forming forward-leaning left and right ramps configured so that when the apparatus is in a users' mouth, the ramps create a tendency for the lower tray, lower dentition and mandible to move in a normal downward position keeping users' airway open by maintaining an anterior Gap making more space for the tongue. DS8 does not utilize code E0486 requirements for fixed mechanical hinges at the sides, front or palate. Nor does it incorporate a mechanism to allow the mandible to be advanced in increments of 1 mm. Neither of these E0486 code requirements are needed with the Slow Wave DS8 design.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS requests the applicant to explain why they believe a HCPCS Level II code would be more appropriate than a CDT (dental) code and whether there has been any engagement with the ADA.

## **Agenda Item # 13**

### **Request # 21.051**

#### **TOPIC**

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

Applicant's suggested language: "Head-worn customizable bi-optic electronic central vision prosthetic with unoccluded peripheral fields."

#### **APPLICANT'S SUMMARY**

The eSight device is an electronic image processing vision prosthetic technology (Class 1) with un-occluded peripheral fields for people with central vision impairment.

The eSight device performs various image modifications in real time such that the information provided to the compromised retina is optimized to generate peak synaptic response. The device can manipulate the temporal/spectral/spatial aspects of retinal stimulation, something not achievable through classical optical magnification. Specific electronic image enhancement strategies depend on the eyes' vestigial retinal function, are unique to each user and must be adjusted according to the users' desired ADLs, ambient conditions (cloudy versus bright sun for example), etc. It is important to note that traditional optical magnification aids, whether handheld or spectacle mounted, cannot achieve similarly effective image enhancement. In fact, optical magnification devices actually reduce contrast through light attenuation, which can degrade functional visual performance.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

This request to establish a new HCPCS Level II code to separately identify the eSight has not been approved. We are actively seeking input from non-Medicare insurers regarding a need for a unique HCPCS Level II code to identify eSight.

Otherwise, for coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.

## **Agenda Item # 14**

### **Request # 21.055**

#### **TOPIC**

Request to establish a new HCPCS Level II code that accurately reflects the active use and non-continuous motion and strengthening mechanisms of the X10, and the treatment duration.

#### **APPLICANT'S SUMMARY**

The X10 Knee Recovery System is an intelligent pressure-modulated recovery device consisting of a computer-controlled actuator arm with an ultra-sensitive inclinometer and load sensing ability. The X10 is used in-home guided by telehealth therapists and increases range of motion and strength. The X10 is used for patients who are lacking range of motion, have leg muscle weakness or are lacking central nervous system control of leg muscles. The X10 is currently assigned code E0935 "Continuous passive motion exercise device for use on knee only." E0935 applies to a machine that passively forces the patient's leg to move between two preset angles for increasing range of motion.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing code E0935 "Continuous passive motion exercise device for use on knee only," and existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified," describe the system. CMS understands that a particular insurer may, on a claim-by-claim review basis, prefer to assign a different code when it is paying for a broader range of services and equipment.

CMS found no new information in this current resubmitted application, and encourages the applicant to point out what new information was included in this application when compared to their previous application submission (20.076).

## **Agenda Item # 15**

### **Request # 20.164**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify the Chait Access Adapter with Connecting Tube.

Applicant's suggested language: AXXXX "Cecostomy irrigation supply; tubing with adapter"

#### **APPLICANT'S SUMMARY**

Cook Medical submitted a request to establish a new HCPCS Level II code to identify the Chait Access Adapter with Connecting Tube.

The Chait Access Adapter with Connecting Tube is a single-patient, reusable connecting tube with a flared fitting on one end and a metal cannula joined to a plastic block at the other end. The Chait Access Adapter with Connecting Tube is a replaceable accessory intended to allow connection between the Chait Cecostomy Catheter and the delivery tubing of an irrigation/enema bag system. The flared fitting of the Chait Access Adapter is connected to the enema delivery system tubing, while the metal cannula of the adapter is inserted into the lumen of the catheter's trap door fitting as needed to flush fluids through. This adapter allows enema solution to flow through the catheter into the cecum. This product is only used by patients who have been implanted with the Chait Cecostomy Catheter.

As per the applicant, there is currently no existing HCPCS Level II code that accurately describes the Chait Access Adapter with Connecting tube or its specific use.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS will defer this request to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

## **Agenda Item # 16**

### **Request # 21.056**

#### **TOPIC**

Request to establish two new HCPCS Level II codes, the first for an EPAP device, which includes a nasal pillow body and two cartridge valves (similar to a CPAP mask A code) and a code for a pair of cartridge valve replacements (similar to a CPAP mask replacement A code). We further request to add "EPAP" to the CPAP Headgear code (A7035) and to the CPAP Replacement Nasal Mask Cushion code (A7033).

#### **APPLICANT'S SUMMARY**

The ULTepap is an Expiratory Positive Airway Pressure (EPAP) device FDA cleared for the treatment of mild to moderate Obstructive Sleep Apnea (OSA) for adults >66 lbs. EPAP has been clinically proven to be equally efficacious to Continuous Positive Airway Pressure (CPAP) since 1983. Instead of relying on a blower like CPAP, EPAP uses a valve system which allows the patient to inhale with negligible resistance, but exhale with enough resistance to help inflate the upper airway. The ULTepap is comprised of body with nasal pillows which interface with the nose, and a pair of cartridge valves. It is these cartridge valves which produce the resistance on exhalation that creates the therapeutic back pressure. The device is held in place by a standard CPAP mask headgear. The obvious advantage of EPAP vs CPAP is the lack of a tube, blower, humidifier and filters, which can lead to better adherence to therapy and reduced costs.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS understands that no third party payers pay for any EPAP devices at this time. Thus, this request to establish two new HCPCS Level II codes has not been approved. CMS welcomes input about whether our understanding of third party payers is incorrect.

## **Agenda Item # 17**

### **Request # 21.065**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify the provision and remote interpretation of data collected via a purchased or leased FDA-registered at-home uroflow medical device.

No suggested language.

#### **APPLICANT'S SUMMARY**

The Stream Dx device is a novel point of care uroflowmeter that, unlike current office based uroflow meters, allows patients suffering from LUTS, BPH, OAB and UI to have an accurate uroflow test in the comfort of their homes at times when they normally void. This significantly improves the quality of both volume and flow rate data, in turn improving treatment efficacy and outcomes. It also provides for an electronic voiding summary, which is otherwise not currently available to physicians. The data that is collected can either be wirelessly uploaded or recorded on the device and uploaded later. The uploaded data is used to generate volume and flow rate reports, Liverpool nomograms, an IPSS score and an electronic home voiding summary. The reports that are generated are formatted for inclusion in the patient's Electronic Health Record (EHR).

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

This type of product would typically be included in the practice expense for a procedure and not separately coded.

The applicant has identified CPT codes 99453 "Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment" and 99454 "Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; each 30 days" as relevant, but indicated that those codes require at least 16 out of 30 days for remote data collection as a rationale for CMS to develop a separate code. HCPCS Level I (CPT) coding is the typical approach for coding for physician services. CMS believes the appropriate starting point for correct coding is for the applicant to approach the AMA for guidance.

## **Agenda Item # 18**

### **Request # 21.066**

#### **TOPIC**

Request to establish two new HCPCS Level II codes to identify:

- a. Felix Device Wireless stethoscope with recording device and LED indicators
- b. FelixPro Wireless stethoscope with recording device with headset attachment for physician use only.

#### **APPLICANT'S SUMMARY**

Felix Device is a digital stethoscope that collects high-fidelity recordings in any environment and transmit data wirelessly. Felix collects recordings of patient body sounds and allows clinicians to review and share recordings via a HIPAA-compliant cloud. FelixPro is a connected device used by professional clinicians to collect high-fidelity sounds with a headset feature and EInk screen for point of care use. FelixPro collects recordings of patient body sounds and allows clinicians to save and transmit those recordings into a HIPAA-compliant cloud.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

It is our understanding that the item that is the subject of this application could be used in furnishing remote monitoring HCPCS Level I (CPT) codes 99453 "Remote monitoring of physiologic parameters, initial set up and patient education on use of equipment," 99454 "Remote monitoring of physiologic parameters, supply with daily recordings or programmed alert transmission, each 30 days," and 99457 "Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in calendar month requiring interactive communication with the patient/caregiver during the month". HCPCS Level I (CPT) coding is the typical approach for physician services. At this time, we encourage you to engage with the AMA about potential HCPCS Level I (CPT) coding.

CMS encourages the applicant to follow up with additional information shall it become available as a result of communication with the AMA.

## **Agenda Item # 19**

### **Request # 21.050**

#### **TOPIC**

Request to modify HCPCS Level II code B9998, to include a patented undershirt for children who are fed enterally.

No suggested language.

#### **APPLICANT'S SUMMARY**

The *starberrykids* feeding tube onesie is used exclusively for the g/gj tube population. The child will remain comfortable while the caregiver administers medication and feeds the child. It also provides easy access to maintain the cleanliness of the g-tube site.

This bodysuit was created exclusively to keep the child comfortable while the caregiver has access to the g/gj tube. An undershirt is a basic essential need for a child. A child that is not toilet trained typically wears an undershirt that snaps on the bottom. The snap on the bottom undershirts are cumbersome for children who are fed enterally as the caregiver cannot easily access the feeding tube. In such a case many children with g-tubes do not wear undershirts. During winter these undershirts provide an extra layer of warmth. In the summer, many children wear just these g-tube onesies with shorts, for a complete outfit. At night, many children wear these onesies with pajama bottoms, as this is an ideal way for the caregiver to have access for feeding the child throughout the night, and to be able to easily administer the medication without waking the child by moving him around to get to the g-tube. The flap has four snaps so that it can be closed to keep the child from touching the port and extensions.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing code A4467 "Belt, strap, sleeve, garment, or covering, any type," describes this product. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.

## **Agenda Item # 20**

### **Request # 21.059**

#### **TOPIC**

Request is to establish a new HCPCS Level II code for a prescription and over-the-counter drug deactivation and disposal pouch. Brand Name: Deterra Drug Deactivation System.

No suggested language.

#### **APPLICANT'S SUMMARY**

Deterra's purpose is to reduce the risk of substance use disorder, and negative environmental impact through effective deactivation and disposal of unused, unwanted, or expired medications. Available evidence points to Deterra as scientifically proven to render prescription and over-the-counter medicine, including addictive opioids, unavailable for misuse, abuse, and diversion. Deterra helps prevent diversion, misuse, and abuse because the advanced activated carbon system renders active pharmaceutical ingredients inert and non-retrievable for all practical purposes. Its plant-based packaging and non-toxic ingredients prevent harmful chemicals from entering our landfills and water supplies when drugs are disposed.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

As stated previously, CMS still does not have clear information that any insurance sector has a claims processing need for a new HCPCS Level II code to identify a prescription and over-the-counter drug deactivation and disposal pouch. We note that this decision is similar to the approach CMS took for other products that store disposable medical devices, like sharps disposal containers.

## **Agenda Item # 21**

### **Request # 21.042 - 21.046**

#### **TOPIC**

Request to establish a new HCPCS Level II code to identify Whole Health Partners within the Veterans Health Administration (VHA).

Applicant's suggested language: QXXXX "Department of veterans affairs whole health partner services."

#### **APPLICANT'S SUMMARY**

Whole Health Partners and related services help veterans navigate the healthcare system to find resources to meet those goals. They provide a safe and trusted environment for patients to share their experiences. They provide an opportunity to reach veterans in their communities and improve access to health education and information. The services they provide represent a critical component of VHA's Whole Health Approach to care. In order to accurately investigate the ongoing delivery of these well-being approaches, there is a need for specificity in coding. This will allow for more large-scale, high-quality trials, as well as the ability to accurately capture costs for provision of these approaches, and the provider type.

#### **PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish HCPCS Level II code QXXXX "Department of veterans affairs whole health partner services."