

**Centers for Medicare & Medicaid Services (CMS) Agenda for Healthcare  
Common Procedure Coding System (HCPCS) Public Meeting for Code  
Applications for Non- Drug and Non-Biological Items and Services Submitted to  
CMS' 2<sup>nd</sup> 2020 Biannual HCPCS Coding Cycle**

**Zoom Meeting, for remote participation**

**Monday, December 21, 2020 9:00 am – 5:00 pm**

8:45 a.m.:

- Zoom Meeting Login
- <https://cms.zoomgov.com/j/1610701817?pwd=R3hYaWtPaGVVREh2YVNMSkFQMThEQT09>
- Or join by phone: Dial US: +1 669 254 5252 or +1 646 828 7666
- Webinar ID: 161 070 1817
- Password: 083822

9:00 a.m.:

- Welcome
- Background and purpose of meeting
- Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS' 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 meetings provide an opportunity for the public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. CMS' final coding decisions will be published on CMS HCPCS web site at:

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelIII-Coding-Decisions-Narrative-Summary> on or about January 2021, and will be effective April 1, 2021, unless otherwise specified.

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

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 1**

**Application # 20.150**

Request to create a coding distinction between particulate and non-particulate bulking agents by revising existing Level II HCPCS code L8606, which currently reads “Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies” to specify a particulate agent; and establishing a separate new code to specifically identify non-particulate agents.

**Agenda Item # 2**

**Application # 20.152**

Request to establish a new Level II HCPCS code to identify the NexStride device.

**Agenda Item # 3**

**Application # 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 # 4**

**Application # 20.154**

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

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 5**

**Application # 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.

**Application # 20.158**

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

**Agenda Item # 6**

**Application # 20.155**

Request to establish a single new Level II HCPCS code to identify VACOCast Diabetic and all its components.

**Agenda Item # 7**

**Application # 20.156**

Request to establish two new Level II HCPCS codes: one to identify the ALLUX MPK knee, and a second to identify a microprocessor control feature, automatic stance-phase lock.

**Agenda Item # 8**

**Application # 20.159**

Request to establish a new Level II HCPCS code to identify the UNFO-S.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 9**

**Application # 20.160**

Request to revise Level II HCPCS Code language for L3010 "Foot, insert, removable, molded to patient model, longitudinal arch support, each" to add text describing the product as "prescription custom fabricated" and also "typically dispensed as a pair"

**Agenda Item # 10**

**Application # 20.165**

Request to create a coding distinction between disposable and reusable irrigation sleeves by revising existing code A4397 which currently reads "Irrigation supply; sleeve, each" to specify that this code is for reusable sleeves; and establishing a new code to specifically identify disposable sleeves.

**Agenda Item # 11**

**Application # 20.166**

Request to establish a new Level II HCPCS code to identify the Deterra Drug Deactivation System, a deactivation and disposal pouch for unused drugs.

**Agenda Item # 12**

**Application # 20.167**

Request to establish a new Level II HCPCS code to identify the LEVL device that measures breath acetone.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 13**

**Application # 20.168**

Request to establish a new Level II HCPCS code to identify a single-use sterile cover for use by healthcare professionals in a sterile, clinical setting to cover the tablet used to operate ControlRad equipment.

**Agenda Item # 14**

**Application # 20.171**

Request to modify the language of existing Level II HCPCS catheter and catheter kit HCPCS codes A4311, A4312, A4314, A4315, A4348, A4340, A4344, A4351, A4353 to include the phrase "Lotus no balloon catheter".

**Agenda Item # 15**

**Application # 20.172**

Request to establish a new Level II HCPCS code to identify the MiniACE device.

**Agenda Item # 16**

**Application # 20.164**

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

**Agenda Item # 17**

**Application # 20.110**

Request to establish a new Level II HCPCS code to identify the lymphatic tracer Magtrace.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 1**

**Application # 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 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

**APPLICANT’S SUMMARY**

PRS Consulting, LLC, submitted a request for 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 device specifically designed 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**

Existing code L8606, “Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies”, adequately describes bulkamid. The language of the code does not preclude coding non-particulate bulking agents. Based on the information provided, CMS is unable to identify a significant therapeutic distinction between particulate and non-particulate bulking agents.

We are interested in better understanding particulate vs. non-particulate bulking agents, and we invite input regarding whether there are differences in patient population that can benefit from a particulate vs. non-particulate bulking agents, and any specific clinical benefits related to the use of particulate vs. non-particulate bulking agents. Clinical studies provided by the applicant do not support the claim of a significant therapeutic distinction between particulate and non-particulate formulations. The applicant’s claim of differences in reliability and durability are also not documented and not scientifically linked to a difference in clinical benefit. We invite additional input that would inform the applicant’s claims.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 2**

**Application # 20.152**

**TOPIC**

Request to establish a new Level II HCPCS code to identify the NexStride device.

The applicant did not suggest any specific language.

**APPLICANT'S SUMMARY**

De Oro Devices Inc. submitted a request for one new HCPCS code for “audio/visual, on-demand, multi-factor customizable gait cueing device.” The Trade/Brand Name of the product is NexStride. The device functions to provide clinically beneficial auditory and visual cueing along with on-demand, customizable gait cueing for use with a cane, walker and/or walking pole. This cueing is beneficial to many patients with gait abnormalities including those with freezing of gait (FOG) induced by Parkinson’s Disease or stroke. No codes exist for cueing devices but CMS has reviewed the clinical value of cueing in 2019 and 2020.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS has information that the manufacturer plans to initiate a trial using the NexStride device. CMS is interested in this emerging technology that has not been reviewed or cleared for marketing by the FDA, as of this date, and the result of this pending trial, and welcomes the applicant to submit an application in a subsequent coding cycle. CMS looks forward to better understanding the clinical evidence supporting the applicant's claim that the use of the NexStride device results in reduction of freezing of gait and increased mobility.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 3**

**Application # 20.153**

**TOPIC**

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

The applicant did not suggest any specific language.

**APPLICANT'S SUMMARY**

Blatchford, Inc. submitted a request for one new Level II HCPCS 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**

Existing socket insert code 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," code L5673 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism ," code 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)," together with 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)," depending on product characteristics, describes the socket insert that is the subject of this request.

CMS would like to better understand the scientific evidence and measurement standards applied to different products that confirm differential outcomes related to moisture retention resulting in reduction in skin excoriation and other adverse outcomes. At this time, the clinical information provided with this application does not support the claim of significant therapeutic distinction that would warrant a new Level II HCPCS code when the subject liner is used in comparison to other liners that share a code category.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 4**

**Application # 20.154**

**TOPIC**

Request to establish a new Level II HCPCS 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 submitted a request for one new Level II HCPCS add-on 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**

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

depending on product characteristics, describes the socket insert that is the subject of this request.

CMS would like to better understand the scientific evidence and measurement standards applied to different products that confirm differential outcomes related to moisture retention resulting in reduction in skin excoriation and other adverse outcomes. At this time, the clinical information provided with this application does not support the claim of significant therapeutic distinction that would warrant a new Level II HCPCS code when the subject liner is used in comparison to other liners that share a code category.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 5**

**Application # 20.157**

**TOPIC**

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)

**APPLICANT'S SUMMARY**

WillowWood Global submitted a request for 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**

Existing socket insert code 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", code L5673 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism ", code 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)", together with 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)", depending on product characteristics, describes the socket insert that is the subject of this request.

CMS would like to better understand the scientific evidence and measurement standards applied to different products that confirm differential outcomes related to moisture retention resulting in reduction in skin excoriation and other adverse outcomes. At this time, the clinical information provided with this application does not support the claim of significant therapeutic distinction that would warrant a new Level II HCPCS code when the subject liner is used in comparison to other liners that share a code category.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 5**

**Application # 20.158**

**TOPIC**

Request to establish a new Level II HCPCS 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 submitted a request for 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 as 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 proposed 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**

Existing socket insert code 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", code L5673 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism ", code 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)", together with 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)", depending on product characteristics, describes the socket insert that is the subject of this request.

CMS would like to better understand the scientific evidence and measurement standards applied to different products that confirm differential outcomes related to moisture retention resulting in reduction in skin excoriation and other adverse outcomes. At this time, the clinical information provided with this application does not support the claim of significant therapeutic distinction that would warrant a new Level II HCPCS code when the subject liner is used in comparison to other liners that share a code category.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 6**

**Application # 20.155**

**TOPIC**

Request to establish a new Level II HCPCS code to identify VACOCast Diabetic and all its components.

Applicant's suggested language: L4632-Lower Extremity Ankle Foot Orthotic Rigid Boot, with Vacuum Inner Boot, Replaceable Inner Liner (2), Rocker Sole, Custom Fitted "Instant Total Contact Cast"

**APPLICANT'S SUMMARY**

Park DPM Consulting, LLC, on behalf of OPED Medical Inc., submitted a request for a single new Level II HCPCS code to describe VACOCast Diabetic and all its components as they are all inherently applied together by a qualified health care practitioner trained in the use of custom fitted orthotics.

The product shall be named VACOCast Diabetic. This device combines the properties of a total contact cast (29445) and custom fabricated CROW Boot (L4631). The product provides both below the knee immobilization and off-loading, in a way that allows for continued adjustment by a qualified health care practitioner in order to respond to both continued anatomical and physiological changes.

According to the applicant, an existing Level I HCPCS Current Procedural Terminology (CPT) code provides a code for a custom total contact cast which requires continuous replacement with repeated reimbursement. HCPCS Level II code L4631 provides for a custom Crow Boot at far greater expense without the ability to continuous and repeated easy adjustments in order to facilitate continuous use. No other HCPCS codes provide for all the essential properties inherent to the VACOCast Diabetic.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing Level II HCPCS code L4361 "Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated, off-the-shelf " describes the VACOCast Diabetic and is available for assignment by insurers if used as a walking boot to support weak/deformed body member.

Existing Level II HCPCS code A9283 "Foot pressure off loading/supportive device, any type, each" also describes the VACOCast Diabetic and is available for assignment by insurers when

used as described by the applicant for offloading forefoot and midfoot ulcers for persons with diabetes. Clinical evidence provided by the applicant does not support the applicant's claim of significant therapeutic distinction between the VACOcast Diabetic and products coded at L4360 and L4361. For coding guidance contact the insurer in whose jurisdiction a claim will be filed.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 7**

**Application # 20.156**

**TOPIC**

Request to establish 2 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.

**APPLICANT'S SUMMARY**

Proteor USA submitted a request 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 are no adequate L codes 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**

Establish new Level II HCPCS code KXXXX "Addition to lower extremity, endoskeletal system, above knee disarticulation, 4 bar linkage, with hydraulic swing and stance phase control"

In addition to KXXXX, suppliers may also report the following codes if appropriate:

- L5856 "Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type"
- Plus L5845 "Addition, endoskeletal, knee-shin system, stance flexion feature, adjustable"
- Plus L5848 "Addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability".

We will also make a typographical correction: Revise the short descriptor for existing code L5613 which currently reads "Ak 4 bar ling w/hydro swig' to instead read "Ak 4 bar link hyd swing"

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 8**

**Application # 20.159**

**TOPIC**

Request to establish a new Level II HCPCS code to identify UNFO-S.

Applicant's suggested language: "Pediatric metatarsus adductus/varus brace, rigid, with anti-adductus shape and adjustable strap."

**APPLICANT'S SUMMARY**

Magic Orthopedics Ltd on behalf of UNFO Med Ltd, submitted a request for a new Level II HCPCS code to identify an orthopedic device.

A branded version of this product already exists in the form of the UNFO-S, which is an orthopedic device worn below the ankle that offers improved outcomes for metatarsus adductus / varus over traditional serial casting. The device functions by stabilizing the heel in the heel cage and the rest of the foot in the brace while applying corrective pressures to the midfoot, thereby realigning the malformed pediatric foot. This is an alternative to serial casting.

A review of the current HCPCS code set revealed no current appropriate code as this device is not an ankle-foot, knee-ankle-foot, or hip-knee-ankle-foot orthosis. It is also not an arch support, nor is it molded to patient model or patient foot. It is also not an addition to a lower extremity orthosis. Finally, there is no bar involved as described by L3140 and L3150 and this is not in the style of a shoe (L3160) or heel stabilizer (L3170).

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish a new Level II HCPCS code KXXXX "Foot, adjustable shoe-styled positioning device".

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 9**

**Application # 20.160**

**TOPIC**

Request to revise existing Level II HCPCS Code L3010 which currently reads: "Foot, insert, removable, molded to patient model, longitudinal arch support, each"; to instead read: "Prescription custom fabricated foot insert, removable, molded to patient model, longitudinal arch support, each, typically dispensed as a pair"

**APPLICANT'S SUMMARY**

The American Podiatric Medical Association submitted a request for a coding language change for HCPCS L3010.

The current coding language mainly dates back to when the HCPCS code set was developed in the 1970s and has not been updated since 1993, both prior to the advent of modern-day materials and manufacturing techniques. With the introduction of ICD-10, additional burdens are faced by providers and patients in obtaining reimbursement for custom fabricated foot orthotics, mainly due to laterality issues associated with ICD-10 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.

Current language L3010 - Foot, insert, removable, molded to patient model, longitudinal arch support, each.

Requested Language: L3010 - Prescription custom fabricated foot insert, removable, molded to patient model, longitudinal arch support, each, typically dispensed as a pair.

Explanation: This type of device is fabricated from a three-dimensional model of the patient's own foot (e.g. cast, foam impression, or virtual true 3-D digital image). This type of orthotic is an accommodative/functional device, with a heel cup of less than 10 mm and is intended to control the forefoot through a longitudinal arch support. It may also have an intrinsic or extrinsic post designed to control foot motion. This device is made of a sufficiently rigid material to reduce pathological forces. HCPCS L3010 includes additions such as postings, padded top covers, soft tissue supplements, balance padding and lesion or structure accommodations. Other additions may be required. Unless otherwise noted, this device is normally dispensed as a pair.

## **PRELIMINARY HCPCS CODING RECOMMENDATION**

The current language of existing Level II HCPCS code L3010 describes the product that is subject of this application. CMS notes that issuance by prescription does not change the description of the device itself. The billing unit of “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. Suppliers could bill for two units when appropriate and CMS is aware of claims history of single units, including for patients with an amputation of one foot or lower limb.

However, CMS is interested in better understanding the applicant’s statement about laterality issues and its clinical significance, relative to ICD-10.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 10**

**Application # 20.165**

**TOPIC**

1) Request to establish a new Level II HCPCS code to identify an disposable irrigation sleeve.

Applicant's suggested language: A4XXX- Irrigation supply; sleeve, disposable, each

2) Request to modify HCPCS code A4397 Irrigation supply; sleeve, each to read Irrigation supply; sleeve, reusable, each.

**APPLICANT'S SUMMARY**

Coloplast submitted a request for a new Level II HCPCS code to identify Disposable Irrigation Sleeves. Coloplast Disposable Irrigation Sleeves serve a clinical purpose for a specific patient population compared to reusable sleeve described by A4397. Therefore, we ask for a new HCPCS code to differentiate the disposable ostomy irrigation sleeve from the reusable ostomy irrigation sleeve.

**Method of Irrigation:**

Irrigation is a way to manage effluent from a surgically created sigmoid or colostomy stoma. The accessories include a cone, a water bag, a sleeve. Reusable sleeves are either attached to a belt to secure the sleeve or a locking barrier that will adhere to the peristomal skin surrounding the stoma. Disposable sleeves have adhesive that adheres directly to the patient's skin. Once the adhesive is used on the skin, it is not meant to be reused, similar to a disposable band-aid. Irrigation is generally accomplished by instillation of lukewarm tap water through the stoma, which stimulates peristalsis and contractions of the colon leading to the evacuation of stool. Once the water is installed, the cone is removed, the user waits for the contents of the colon to be expelled from the stoma to the sleeve and into the toilet. The irrigation process can take from 30 minutes to 1 hour depending on the person and their specific bowel regimen. According to the applicant, In addition to the difference in frequency of usage, the unique clinical rationale supports the need for a new HCPCS code for disposable irrigation sleeves.

**Clinical rationale for disposable irrigation sleeves:**

1. Difficult pouching situations requiring better fit of disposable irrigation sleeve
  - a. Challenging abdominal contours
  - b. Concerns with leakage / infection
2. Type of pouching system individual uses when not irrigating is not compatible with reusable sleeve

3. Thick and pasty stool consistency is a clinical reason to use a disposable irrigation sleeve
4. Inability to care for reusable sleeves or lifestyle preference

### **PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing Level II HCPCS code A4397 "irrigation supply; sleeve, each" adequately describes the subject of this application.

We are interested in the differences between a disposable vs. a reusable sleeve, and we invite input regarding whether there are differences in the patient population that can benefit from a disposable sleeve vs. a reusable sleeve, and in particular, specific clinical benefits and distinctions related to the use of the disposable vs. reusable sleeves.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 11**

**Application # 20.166**

**TOPIC**

Request to establish a new Level II HCPCS code to identify a prescription and over-the-counter drug deactivation and disposal pouch.

The applicant did not suggest any specific language.

**APPLICANT'S SUMMARY**

Verde Environmental Technologies, Inc submitted a request for a new Level II HCPCS code to identify The Deterra Drug Deactivation System.

The Deterra Drug Deactivation System is a safe, activated carbon-based medication disposal pouch intended for in-home use. It is demonstrated to render unavailable and properly dispose of unused, unwanted, or expired medications with the simple addition of tap water. 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 nonretrievable 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.

There are currently no codes that can be used for safe and effective disposal of unused, unwanted, or expired medications and prevention of diversion.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS was unable to identify a need on the part of any insurer for reporting this drug deactivation pouch on a medical claim. We invite input, particularly related to insurer policy, that would describe a payer's need for a code on an electronic claim.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 12**

**Application # 20.167**

**TOPIC**

Request to establish a new Level II HCPCS code for measuring breath acetone for the treatment of obesity through use of the LEVL device in a clinical environment.

The applicant did not suggest any specific language.

**APPLICANT'S SUMMARY**

LEVL submitted a request to establish a new HCPCS Level II code for measuring breath acetone for the treatment of obesity through use of the LEVL device in a clinical environment.

LEVL is an FDA registered Class I medical device that was specifically developed for the medical weight loss and bariatric market. The LEVL device can be used with any prescribed weight loss plan to show quantitative, predictive data as the body transitions from utilizing carbohydrates and sugars as its primary fuel source to burning fat. Frequent measurements using the LEVL device indicate the impact of changes in nutrition and supports program adherence which can reduce the long-term consequences of obesity and the potential of type 2 diabetes and cardiovascular disease.

Ketone body testing was originally developed to diagnose ketoacidosis which is represented by high levels of ketone bodies in blood and urine. While the weight loss market has adopted blood and urine ketone testing to confirm elevated fat metabolism, those testing methods were developed to measure higher levels of ketone bodies that are often only present when a patient is on a ketogenic diet or on an extended fast. The LEVL device was developed specifically for the clinical weight loss market with the sensitivity to measure very low levels of acetone as the body transitions to elevated fat metabolism.

As per the applicant, the existing CPT code 82010 does not adequately describe the LEVL device because that description covers all ketone bodies; acetone (breath), acetoacetic (urine) acid and beta-hydroxybutyrate (blood) for the prevention of ketoacidosis and do not have the sensitivity for the treatment of obesity. There are no other medical devices, listed or registered with the FDA, that can measure the low levels of acetone and that can be calibrated with known concentrations of acetone to confirm accuracy.

## **PRELIMINARY HCPCS CODING RECOMMENDATION**

It is our understanding that the measurement is administered by a practitioner at the point of care, and the LEVL device would be factored into the practice expense relative values under the Physician Fee Schedule if used during the procedure. For additional details and for coding guidance, CMS refers the applicant to the American Medical Association (AMA).

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 13**

**Application # 20.168**

**TOPIC**

Request to establish a new Level II HCPCS code to identify ControlRad Sterile Cover.

Applicant's suggested language: AXXXX- Equipment cover, disposable, for use with radiation reduction system for interventional x-ray or fluoroscopy

**APPLICANT'S SUMMARY**

ControlRad submitted a request for a modification of the HCPCS code set for ControlRad Sterile Cover.

The name and description of the product is ControlRad Sterile Cover, a terminally sterilized device that covers the ControlRad Trace Tablet so that tablet can operate the ControlRad Trace system in a sterile environment to prevent contamination during various procedures. The cover is an intrinsic component of the ControlRad Trace system, as it is the component of the system that health care providers purchase each time they use the system to achieve the radiation reduction – a reduction of 50 percent to 89 percent (depending upon the specific imaging parameters). That reduction is achieved without negatively impacting workflow or image quality within the region of interest.

The product is used for patients undergoing a broad range of procedures – cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures involving interventional x-ray or fluoroscopy. The function of the ControlRad Trace system is of particular importance for patients and healthcare workers because it reduces unnecessary exposure to harmful radiation, which has been linked to significantly increased risk of cancer in patients surgically treated for scoliosis 25 years post-operatively, increased risk of brain cancer, cataracts, and stroke for medical staff performing frequent interventional procedures, and significant increase in early signs of subclinical atherosclerosis. The use of the ControlRad Sterile Cover is necessary for this radiation reduction to occur.

There are no existing specific HCPCS codes that accurately describe the product.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

The ControlRad sterile cover, when used, is included in the practice expense and not separately billable. As such, CMS is not issuing a code to describe this product.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 14**

**Application # 20.171**

**TOPIC**

Request to modify existing Level II HCPCS codes A4311, A4312, A4314, A4315, A4348, A4340, A4344, A4351, A4353 to adequately describe a novel indwelling catheter designed without a balloon configuration or the need for additional accessories for placement and removal.

Applicant's recommended language: to include "Lotus No Balloon Catheter"

**APPLICANT'S SUMMARY**

Hakki Medical Technologies, Inc. submitted a request for the modification of the following current HCPCS code descriptions to adequately describe a novel indwelling catheter designed without a balloon configuration or the need for additional accessories for placement and removal: A4311, A4312, A4314, A4315, A4348, A4340, A4344, A4351, A4353.

The Lotus No Balloon Catheter is a sterile, single patient use, no balloon catheter made from medical grade silicone elastomer or natural rubber latex. The Lotus No Balloon Catheter renders a straight catheter upon insertion; to retain the device, a self-contained activating bellows are pulled open to render the flower-like lumen. To remove the device, the bellows are pushed closed to collapse the winged lumen, returning the Lotus No Balloon Catheter to a straight catheter. This device is cleared for use for continuous drainage of fluid, including continuous bladder irrigation and intermittent catheterization. Drainage is generally accomplished by inserting the catheter through the urethra, supra pubically into the bladder or through a nephrostomy tract. The Lotus No Balloon Catheter is to be used in patients 5 years of age or older.

The existing codes refer to an indwelling catheter as a Foley catheter, two-way a balloon-type catheter. The Lotus No Balloon Catheter does not require a balloon for retention. The Lotus No Balloon Catheter's retaining design is similar to the Malecot catheter; however, the Malecot catheter is considered a 'specialty type' while the Lotus No Balloon Catheter has broader applications such as bladder drainage through the urethra and use as intermittent catheterization.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

The existing code A4340 "Indwelling catheter; specialty type, (e.g., coude, mushroom, wing, etc.), each" describes the Lotus catheter and is available for assignment by insurers to identify use of the Lotus catheter as the indwelling catheter if they deem appropriate. Existing code A4351 "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone,

silicone elastomer, or hydrophilic, etc.), each" or A4353 "Intermittent urinary catheter, with insertion supplies" describes the catheter that is the subject of this application when the Lotus anchoring mechanism is not deployed and it is used for intermittent catheterization.

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 15**

**Application # 20.172**

**TOPIC**

Request to establish a new Level II HCPCS code with the language: AXXXX  
"Cecostomy/Appendicostomy tube, low-profile, silicone, any type, each."

**APPLICANT'S SUMMARY**

Applied Medical Technology, Inc. (AMT) submitted a request for a new Level II HCPCS Code for MiniACE.

The AMT MiniACE is a low profile, percutaneous antegrade continence enema (ACE) device. The MiniACE is inserted into the cecum through either a cecostomy or a Malone/appendicostomy procedure. The MiniACE is held in place by an internal silicone balloon and an external silicone bolster. The low profile external bolster contains an irrigation port and a balloon inflation port; these features allow the user to administer an enema and inflate/deflate the balloon, respectively. Users are able to replace the MiniACE at the hospital, in a clinic, or at home using the same replacement method as a low profile gastrostomy tube, which are currently granted a Level II HCPCS Code (B4088). The MiniACE is used to facilitate ante grade enemas (*via* cecostomy or Malone/appendicostomy) in patients who have non-functioning colons and have not responded to conservative treatments (i.e., high-fiber diets, laxatives, rectal enemas, etc.).

Current HCPCS Level II codes do not accurately describe the function or form factor of the MiniACE. Code A4337 (Incontinence supply, rectal insert, any type, each) inaccurately describes the type of enema and the insertion method. The MiniACE is not inserted into the rectum and it does not facilitate a rectal enema. Codes A4458 (Enema bag with tubing, reusable) and A4459 (Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type) are also inaccurate. The MiniACE is not a bag or a pump; it is a conduit for administering an ante grade enema into a nonfunctioning colon. This is analogous to how a low profile gastrostomy/jejunostomy tube (B4088) is a conduit for administering nutrition to a non-functioning gastrointestinal tract.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish a new Level II HCPCS code KXXXX "Enema tube, any type, replacement only, each"

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 16**

**Application # 20.164**

**TOPIC**

Request to establish a new Level II HCPCS 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**

Establish a new Level II HCPCS code KXXXX "Enema tube, any type, replacement only, each"

**December 21, 2020**

**CMS HCPCS Virtual Public Meeting**

**Agenda Item # 17**

**Application # 20.110**

**TOPIC**

Request to establish a new Level II HCPCS code to identify Magtrace lymphatic tracer

Applicant's suggested language: Q99XX: injection, liquid magnetic marker, 2 ml vial

**APPLICANT'S SUMMARY**

Endomag submitted a request for a new Level II HCPCS code for their Magtrace lymphatic tracer.

The Magtrace lymphatic tracer is a unique nonradioactive liquid magnetic marker specifically designed for sentinel lymph node biopsy. It is used to map the lymphatic drainage to the axilla in patients with breast cancer. The Magtrace lymphatic tracer is a solution of iron nanoparticles coated with a carboxydextran shell. These magnetic particles are injected into the patient's breast tissue and absorbed into the lymph nodes. The surgeon uses the Sentimag probe to detect the magnetic particles located within the sentinel lymph node. The identified node(s) is removed and tested for the presence of cancer cells. The use of a liquid magnetic marker avoids injection of radioactive materials or blue dye which can cause severe allergic reaction in some patients. The Magtrace lymphatic tracer is provided in a 2 ml single use vial and administered in the physician office weeks/days/hours prior to surgery via subcutaneous injection into the interstitial breast tissue.

Current coding is limited to: 1) HCPCS Q9968 which is specific to blue dye and not applicable in the physician office setting; 2) CPT 38792 which is specific to injection of radioactive tracer (Tc99) which precludes the use of a nonradioactive liquid magnetic marker; 3) CPT code 38900 is an add-on code used intraoperatively and therefore is not applicable to the physician office setting. These codes do not appropriately describe a nonradioactive liquid magnetic tracer injected in the physician office.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Magtrace is not suitable for coding in Level II HCPCS. CMS reached out to the American Medical Association (AMA). The AMA suggested that CMS refer the applicant to AMA for coding guidance. The application refers to a highly analogous CPT code 38792, "Injection procedure; radioactive tracer for identification of sentinel node." CMS recommends that the applicant approach the AMA CPT Editorial Panel to discuss a possibility of a code similar to 38792, but specific to injection of a non-radioactive tracer.