DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions

Second Biannual, 2020 Coding Cycle for Non-Drug and Non-Biological Items and Services

This document presents a summary of each HCPCS code application and CMS' HCPCS coding decision for each application processed in CMS' Second Biannual 2020 non-drug and non-biological items and services HCPCS code application review cycle. Each individual summary includes: the application number; topic; summary of the applicant's request as written by the applicant with occasional minor, non-substantive editorial changes made by CMS; CMS' preliminary HCPCS coding recommendation; summary of primary speaker comments at the CMS' HCPCS public meeting; and CMS' final HCPCS coding decision. All new coding actions are effective April 1, 2021, unless otherwise indicated.

These Level II HCPCS coding decisions will also be included in the April 2021 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS

December 21, 2020 Meeting Agenda Items

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.

CMS 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker commented that Bulkamid is a first of class non-homologous, non-particulate combination bulking agent, unique when compared with particulate bulking agents in that it is more durable (mentioning a five to seven year duration in European studies) and is used with a different delivery system that allows direct visualization of implantation. While the speaker claimed that a smaller volume of Bulkamid is needed when compared with use of particulate agents, we were also provided information that Bulkamid is packaged at twice the volume (2 ml) of the dose descriptor of the existing code for bulking agents (1 ml). The speaker reiterated the original request to create distinct codes for a 1 ml supply of "particulate combination" bulking agents and a 2 ml supply of "non-particulate homogenous" bulking agents.

CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at CMS' HCPCS Public Meeting in response to our published preliminary recommendation. CMS is revising its preliminary recommendation to defer this application to a subsequent coding cycle because the scope of the request and the evolving science necessitates that additional consideration be given before CMS reaches a final decision.

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.

CMS 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Oro Devices Inc. submitted a request for one new HCPCS code for "audio/visual, on-demand, multi-factor customizable gait cueing device" applicable to their product, NexStride™. HCPCS code availability would allow for more efficient access to, tracking of and payment for this device to help enable many patients with gait abnormalities overcome their walking and stride advancement challenges. The primary speaker commented that the NexStride product is exempt from FDA regulation; is useful for persons with freezing of gait (FOG) and others, with gait abnormalities due to stroke, ALS or MS; and that there are no existing Level II HCPCS codes for cueing devices that "help restore normal gait". The speaker also commented that the NexStride device is the only device that utilizes line placement plus timing (metronome) together, for a therapeutic effect. The product has a 1 year warranty, and can be attached to a standard walker, cane or pole. Clinical studies include a 40 patient feedback survey.

CMS FINAL HCPCS CODING DECISION

CMS finalized its preliminary HCPCS coding recommendation. We remain interested in this emerging technology and welcome ongoing dialogue about insurers' needs for a unique code to idenitify these devices on electronic medical claims.

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.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing socket insert 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," 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, describe 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker presented scientific evidence pertaining to claims of moisture reduction and therapeutic benefits of use of the Blatchford's Silcare Breathe Liner. Specifically, there were three individual case studies and a low powered peer reviewed comparative study of perforated versus non-perforated liners during which "smelliness" (as an indicator of bacterial growth), "skin issues," and "pain" was reported. We also heard a discussion about wound healing with the use of this liner.

CMS FINAL HCPCS CODING DECISION

Following the HCPCS public meeting, CMS re-reviewed this application together with all information provided. We see the scientific data presented as preliminary and emerging, and not definitive from a clinical evidence perspective at this time. However; we remain interested in moisture reduction technology for prosthetic liners. . CMS is deferring this application to a subsequent coding cycle and would be willing to to meet with the applicant to learn more about the nature of scientific evidence, product features and measurement standards that could be applied across products to demonstrate differential outcomes related to moisture retention resulting in reduction in skin excoriation and other adverse outcomes. In the meantime, consistent with our preliminary HCPCS coding recommendation, existing socket insert 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," 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, describe the socket insert that is the subject of this request.

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.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing socket insert 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", 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, describe 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker explained that micropores in the liners reduce sweat accumulation and temperature for active persons. We also received a comment that the Softskin Air Liners are 20-25% more expensive, and an additional code that would facilitate additional payment is desired.

CMS FINAL HCPCS CODING DECISION

Following the HCPCS public meeting CMS re-reviewed this application together with all information provided. We see the scientific data presented as preliminary and emerging, and not definitive from a clinical evidence perspective at this time. However; we remain interested in moisture reduction technology for prosthetic liners. CMS is deferring this application to a subsequent coding cycle and would be willing to to meet with the applicant to learn more about the nature of scientific evidence, product features and measurement standards that could be applied across products to demonstrate differential outcomes related to moisture retention resulting in reduction in skin excoriation and other adverse outcomes. In the meantime, consistent with our preliminary HCPCS coding recommendation, existing socket insert 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," 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, describe the socket insert that is the subject of this request.

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)

CMS 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

See also application #20.158. The Primary Speaker commented that Alpha SmartTemp liners use “phase change” materials that absorb thermal energy (e.g., as opposed to perforated material, as used in other liners), claiming that the temperature reduction is a result of absorption of thermal energy, allowing heat to escape, as opposed to perforations or other permeable materials. The speaker described clinical evidence including a low powered “n,” randomized crossover, double-blind trial where sweat was weighed following a single, 25-minute exercise session with each of two (unspecified) liners, which resulted in a 25% or greater reduction in sweat and a reduction in skin temperature.

CMS FINAL HCPCS CODING DECISION

See also application # 20.158. Following the HCPCS public meeting CMS re-reviewed this application together with all information provided. We see the scientific data presented as preliminary and emerging, and not definitive from a clinical evidence perspective at this time. However; we remain interested in moisture reduction technology for prosthetic liners. CMS is deferring this application to a subsequent coding cycle and would be willing to to meet with the applicant to learn more about the nature of scientific evidence, product features and measurement standards that could be applied across products to demonstrate differential outcomes related to

moisture retention resulting in reduction in skin excoriation and other adverse outcomes. In the meantime, consistent with our 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.

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)

CMS 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

See also application # 20.157. The Primary Speaker commented that Alpha SmartTemp liners use “phase change” materials that absorb thermal energy (e.g., as opposed to perforated material, as used in other liners), claiming that the temperature reduction is a result of absorption of thermal energy alljowing heat to escape, as opposed to perforations or other permeable materials. The speaker described clinical evidence including a low powered “n,” randomized crossover, double-blind trial where sweat was weighed following a single, 25-minutes exercise session with each of two (unspecified) liners, which resulted in a 25% or greater reduction in sweat and a reduction in skin temperature.

CMS FINAL HCPCS CODING DECISION

See also application # 20.157. Following the HCPCS public meeting CMS re-reviewed this application together with all information provided. We see the scientific data presented as preliminary and emerging, and not definitive from a clinical evidence perspective at this time. However; we remain interested in moisture reduction technology for prosthetic liners. CMS is deferring this application to a subsequent coding cycle and would be willing to to meet with the applicant to learn more about the nature of scientific evidence, product features and measurement standards that could be applied across products to demonstrate differential outcomes related to

moisture retention resulting in reduction in skin excoriation and other adverse outcomes. In the meantime, consistent with our 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.

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.

CMS 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker commented that the VACOcast is primarily indicated for immobilization and it is also used for offloading. Clinical evidence includes four individual case studies, and the primary speaker claimed that complete wound healing in 6 weeks was a demonstrated outcome. We also heard testimony that the language of existing codes specified in our preliminary coding recommendation do not describe the VACOcast, which is a “hybrid” of more than one other device.

CMS FINAL HCPCS CODING DECISION

Following the HCPCS public meeting, CMS re-reviewed this application together with all information provided. The clinical evidence described consists largly of non-case study information and articulation of claims that are not well documented or available. This information is insufficient to support the establishment of a unique code to distinguish the VACOcast from products categorized under existing codes.

CMS is finalizing its preliminary coding recommendation that 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. The individual case studies presented by the applicant is not the strength of evidence CMS would look for to 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.

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.

CMS 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".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker agreed with CMS' recommendation to establish a new code, but requested that the phrase "above knee disarticulation" be omitted from the code language, so as not to limit use of this code for persons with above the knee disarticulation, and also for consistency with other, similar codes. The speaker also reiterated the request included in the HCPCS code application for another new code "Addition, microprocessor control feature, automatic stance-phase lock", that is not specifically addressed in our preliminary HCPCS code recommendation.

CMS FINAL HCPCS CODING DECISION

Following the HCPCS public meeting, CMS re-reviewed this application together with all information provided. CMS finalized its decision to establish a new Level II HCPCS code and is also making revisions to the proposed code language consistent with the applicant's suggestion to omit the phrase "above knee disarticulation" from the code text proposed in our preliminary coding recommendation. In addition, we are replacing the word "hydraulic" in our proposed code text with the word fluid. CMS will establish new code K1014 "Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control".

In addition to K1014, 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 the following typographical correction: Revise the short descriptor for existing code L5613 which currently reads "Ak 4 bar lin*g* w/hydro swig' to instead read "Ak 4 bar lin*k* hyd swing".

CMS is deferring, to a subsequent HCPCS coding cycle, only the component of this application that seeks a second new code: "Addition, microprocessor control feature, automatic stance-phase lock." We will continue our review of the microprocessor control feature of the device and engage the applicant in that regard.

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).

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No primary speaker presented at the public meeting.

CMS FINAL HCPCS CODING DECISION

CMS finalized its decision to establish a new code with a change in the code text from our preliminary recommendation, which was necessary in order to make a distinction between the new code and the language of existing code L3160.

Establish new Level II HCPCS code K1015 "Foot, adductus positioning device, adjustable"

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.

CMS 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker explained that an ICD-10 code was not established to identify laterality, and that a HCPCS code is being sought to overcome the lack of an ICD-10 code. We heard testimony that it would be rare for a person receiving a foot insert to not also receive a complementary device for the contralateral (unaffected) limb. And we also heard that there is a need to maintain the ability to continue to code inserts as "each" to facilitate billing in instances where only one is dispensed, such as when one is repaired or replaced or for persons who have had an amputation or otherwise do not need a complementary device.

CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting particularly in response to our request for additional information regarding laterality issues. CMS is finalizing its preliminary recommendation that 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. Retaining the "each" unit designation is consistent with testimony provided at our public meeting that there is a need to retain the ability to accurately report when a single unit is dispensed. Also, CMS is aware of claims history of single units, including for 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, specifically, suppliers could bill for two units when appropriate.

This decision to not revise the existing code, and our decision rationale similarly applies to the language of the other existing Level II HCPCS codes mentioned in this application, including code L3000 "Foot, insert, removable, molded to patient model, 'ucb' type, berkeley shell, each"

and code L3020 “Foot, insert, removable, molded to patient model, longitudinal/ metatarsal support, each.”

Inquiries regarding coverage for complimentary devices for the unaffected limb should be submitted directly to the insurer in whose jurisdiction a claim will be filed.

Application # 20.165

TOPIC

1) Request to establish a new Level II HCPCS code to identify a 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 hours 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

CMS 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker disagreed with CMS' preliminary recommendation and reiterated the original request to create a coding distinction between single-use disposable and multi-use or reusable colostomy irrigation sleeves by creating a new code for disposable sleeves and revising the text of existing code A4397 to specify "reusable" sleeves. The speaker claimed that current coding creates a barrier to access to disposable sleeves. The manufacturer noted that the company approached the MACs in March 2020 and were referred to CMS regarding coding. The speaker commented that certain persons cannot use disposable sleeves, such as persons whose stool is thick and pasty for whom disposable sleeves may not easily stay fixed; persons whose daily ostomy products are not compatable with disposable sleeves; persons whose faceplate would not provide a secure fit with other sleeves and would leak; and persons with (unspecified) lifestyle differences. We also heard testimony that certain persons have difficulty using reusable sleeves. For example, persons with challenging abdominal contours have difficulty using reusable sleeves, which tend to be more rigid and less flexible, and persons with lifestyle differences, and for example, for persons in a shared living situation, use and disposal of a single-use disposable sleeve may afford more privacy than use of a reusable sleeve, which would need be be rinsed and hung to dry.

CMS FINAL HCPCS CODING DECISION

CMS is examining the potential clinical distinction between single-use and multi-use (reusable) colostomy irrigation sleeves, and found the public comments informative. We are deferring this application to a subsequent coding cycle to provide an opportunity for further consideration of clinical distinction and to how to best implement a coding change, should one be made, for these products. In the meantime, additional information and supporting studies pertaining specifically to the clinical benefits and clinical distinctions that users might experience related to the use of single-use disposable vs. reusable (which are also disposable) colostomy irrigation sleeves, in response to the request made in our preliminary recommendation, would be helpful, as well as additional information in regard to how other insurers might be able to adopt such a coding change.

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.

CMS 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker offered more general, policy-related comments, such as citing the White House Opioid Abuse Report Support Act of 2018, Section 3032; California, New Jersey and Florida have safe disposal stewardship laws pertaining to home disposal of unused drugs; Cigna has an advanced opioid management directive that calls for dispensing the Deterra product with each prescription; the Mayo Clinic in Arizona and Twin Cities, Minnesota, co-dispenses drugs with a disposal system for use at home.

CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at CMS' HCPCS Public Meeting in reaction to our published preliminary recommendation, particularly general information in response to our request for input related to insurer policy that would describe a payer's need for a code. CMS considered all input and adopted its preliminary coding recommendation. CMS still does not have clear information that any insurance sector has a claims processing need for a new Level II HCPCS code to identify the product that is subject of this application, on an electronic medical claim. We note that this decision is similar to the approach for products that handle other disposable medical devices, like sharps.

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.

CMS 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).

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker disagreed with CMS' preliminary HCPCS coding recommendation, stating that "it is a clinical laboratory test" that does not have to be performed by a practitioner. It could be performed in a lab and can be used in the ER and in obesity clinics. Similar codes in the CPT code set, such as CPT code 82010 are "old" and have "low reimbursement".

CMS FINAL HCPCS CODING DECISION

CMS considered all of the information presented at the public meeting, as well as the information submitted with the HCPCS application. We note that LEVL has not been coded as a clinical laboratory test by the AMA. We further reiterate our view that existing CPT code 82010 (Ketone body(s) (eg, acetone, acetoacetic acid, beta-hydroxybutyrate); quantitative) adequately describes the acetone measurement test. We encourage the applicant to consider reaching out to the AMA with any concerns regarding whether LEVL should be coded as a clinical laboratory test.

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.

CMS 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker commented that the ControlRad Sterile Cover is not included in the practice expense and is not in CMS practice expense files. The speaker also commented that sterile covers are not used in all procedures; the procedure is sometimes, but not always done with imaging; and CPT code 37184 does not include the labor. The speaker cited the "as low as reasonably achievable" (ALARA) safety principle to avoid radiation exposure and an (unspecified) statement that "CMS says hospitals must implement ALARA". The speaker asked CMS to reverse its preliminary decision and create a new, unique Level II HCPCS code to describe the ControlRad Sterile Cover. When asked at the public meeting whether the company has approached the AMA RUC, the speaker replied that because the ControlRad SterileCover is not always used in procedures, the applicants preferred approach is to report and separately pay for the cover only when it is used.

CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at CMS' HCPCS Public Meeting in reaction to CMS' preliminary recommendation. CMS considered all input and is adopting its preliminary recommendation. The ControlRad Sterile Cover is not suitable for coding in Level II HCPCS. When the ControlRad Sterile Cover is used, it is used as part of a procedure that would be described by a CPT code. As such, we believe that it is similar to the type of item that would be considered a supply, and would be included as an item of practice expense if it met the threshold set by the AMA RUC. Our understanding is that the AMA RUC considers supplies that are typically included whenever a particular service is furnished. Accordingly, the applicant's next step would be to approach the AMA for guidance regarding CPT coding and demonstration that the ControlRad Sterile Cover has become a "typical supply". At that point, the AMA may initiate communication with CMS regarding inclusion of this item as a supply in an appropriate CPT code(s).

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.

CMS 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS finalized its preliminary 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.

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-fimetioning gastrointestinal tract.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker agreed with CMS preliminary recommendation to establish a new Level II HCPCS code to identify the AMT MiniACE® device.

CMS FINAL HCPCS CODING DECISION

CMS finalized its preliminary decision to establish new Level II HCPCS code K1013 "Enema tube, any type, replacement only, each."

Effective Date: 04/01/2021

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.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

CMS FINAL HCPCS CODING DECISION

At the time CMS formulated its preliminary HCPCS coding recommendation, there were two separate applications submitted for our review, the subject products of which we thought were best described by the same code. However, upon further review, we now believe the products are not the same, and CMS requires additional time for further consideration of this application. As such, we are not finalizing our preliminary recommendation and instead, we are deferring this application to the subsequent coding cycle for continued review and engagement with the

applicant. In the meantime, requests for coding guidance should be submitted directly to the insurer(s) in whose jurisdiction(s) claim(s) would be filed, such as the jurisdictional Medicare contractor, the Medicaid Agency in the state in which the claim is filed, or the individual private insurance entity.

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.

CMS 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary recommendation. Magtrace is not suitable for coding in Level II HCPCS. 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.

Application # 20.070

TOPIC

Request to establish a new Level II HCPCS code to identify Monarch external Trigeminal Nerve Stimulation (eTNS) System.

APPLICANT'S SUMMARY

NeuroSigma Inc, submitted a request to establish a new Level II HCPCS code to identify Monarch external Trigeminal Nerve Stimulation (eTNS) System. The applicant requested the addition of a new code to the HCPCS code set for a non-implantable Trigeminal Nerve Stimulation device for the treatment for pediatric attention deficit hyperactivity disorder (ADHD). This code will be used for the Monarch external Trigeminal Nerve Stimulation (eTNS) System. It is indicated for the treatment of pediatric ADHD as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications. The device is by prescription only and intended to be used in the home under the caregiver supervision during periods of sleep. This system acts by providing therapeutic electrical stimulation of the V1 branch of the Trigeminal Nerve in the forehead. Neuroimaging and EEG studies have demonstrated that use of the device increases metabolic activity in regions of the brain associated with executive function, attention and mood. To administer therapy with the Monarch, patients place a custom disposable electric patch in the center of their forehead just above the eyebrows. The patch is connected to a hand held Pulse generator that creates and transmits a proprietary electrical signal to the patch. Patients initiate the therapy immediately prior to sleep and stop the treatment upon wakening in the morning. According to the applicant, there are no existing codes to describe devices used for this indication, as this is the only medical device to receive an FDA indication for treating pediatric ADHD.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code KXXXX "Transcutaneous electrical nerve stimulator for electrical stimulation of the Trigeminal nerve".

CMS is also considering an alternative, new Level II HCPCS code KXXXX: "Transcutaneous electrical nerve stimulator for electrical stimulation through electrodes placed on the forehead."

CMS has been considering this issue based on comments and input from the previous public meeting. CMS notes that FDA identifies this device as a "transcutaneous electrical nerve stimulator".

CMS continues to consider the most appropriate manner to describe the distinctions of these products, recognizing that clinical indications may change over time. We are seeking input from stakeholders, the general public, and insurers regarding what product distinctions would warrant a separate code. For example, should CMS specify the codes based on its application to the body rather than a nerve, considering the complexity of the nervous system(s)?

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker supported CMS' first preliminary coding phrasing option, to establish new Level II HCPCS code KXXXX "Transcutaneous electrical nerve stimulator for electrical stimulation of the Trigeminal Nerve" as it adequately and appropriately identifies the nerve, and asked that CMS consider deleting the first instance of the word "electrical" in the proposed code, to make the description more concise. The speaker disagreed with CMS' proposed alternative code language on the basis that the language would limit reporting to products used on the forehead, which would not include stimulation of Vagus nerves V2 (cheeks) and V3 (jaw), and which would exclude future embodiments of the technology.

CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided throughout this coding cycle pertaining to HCPCS coding for electical stimulation devices, and the comments offered at CMS' HCPCS Public Meeting, specifically in reaction to CMS' published preliminary coding recommendation. CMS reconsidered this application, together with all input provided. CMS plans to monitor closely as new products and treatments for different nerves come to the market and may need to further refine this emerging area of the code set. Based on product offerings at this time, CMS has finalized its first preliminary coding phrasing option to establish new Level II HCPCS code K1016 "Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve", retaining both instances of the word "electrical" within the code text, as that is more closely associated with language in the FDA market authorization.

Effective Date: 04/01/2021

Application # 20.071

TOPIC

Request to establish a new Level II HCPCS code to identify Monarch NS-2 Electric Patch Pouch.

APPLICANT'S SUMMARY

NeuroSigma Inc., submitted a request to establish a new Level II HCPCS code to identify Monarch NS-2 Electric Patch Pouch. The applicant requested to establish a new Level II HCPCS code for disposable electric patches for a non-implantable Trigeminal Nerve Stimulation device for the treatment for pediatric ADHD. According to the applicant, this code will be used for a pouch of seven refill disposable electric patches for the Monarch external Trigeminal Nerve Stimulation device. The device is indicated for treatment of pediatric ADHD as a monotherapy in patients ages 7 through 12 years who are currently not taking any ADHD medications. The device is available by prescription only and is used in home under the supervision of a caregiver during periods of sleep. The Monarch system acts by providing therapeutic electrical stimulation of the V1 branch of the Trigeminal Nerve in the forehead. Neuroimaging and EEG studies have demonstrated use of the device increases metabolic activity in regions of the brain associated with executive function, attention and mood. To administer therapy with the Monarch, patients place a custom disposable electric patch in the center of their forehead just above the eyebrow. The patch is connected to a hand held Monarch Pulse Generator that creates and transmits proprietary electrical signal to the patch. Patients initiate therapy immediately prior to sleep and stop the treatment upon wakening in the morning. According to the applicant, the existing codes do not describe devices used for this indication, as this is the only medical device to receive an FDA indication for treating pediatric ADHD.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4595 "Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes)" describes the refill disposable electric patches that are the subject of this application.

CMS is also considering an alternative, new Level II HCPCS code KXXXX: "Electrical nerve stimulator supplies per lead, per month (e.g., for electrical transcutaneous nerve stimulation, nmes)"; and discontinuing the following existing code, as it would be redundant:

Discontinue existing code A4595 "Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes)."

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker disagreed with both of CMS' preliminary coding options as being "too generic for the product and population", and recommended alternative language for a new code to describe the Monarch NS-2 Electric Patch Pouch: "electrical nerve stimulator refill patches, per month, for transcutaneous trigeminal nerve stimulation", that reflects the specific nerve target of the patch, in order to avoid confusion with products that are contraindicated for use on the forehead. The speaker discussed unique design features of the subject patches include bilateral stimulation of the 4 nerves of V1, by design; incorporation of specific adhesives and gels that would last for an overnight treatment without irritating the skin; and significant clinical testing of the subject patches.

CMS FINAL HCPCS CODING DECISION

CMS reconsidered this application, together with all input provided. CMS plans to monitor closely as new products and treatments for different nerves come to the market and experience of payers in implementing this part of the code set. However, based on product offerings at this time, CMS has established new Level II HCPCS code K1017: "Monthly supplies for use of device coded at K1016".

Effective Date: 04/01/2021

Application # 20.086

TOPIC

Request to establish a new Level II HCPCS code to identify the Cala Trio nerve stimulating device.

Applicant's suggested language: "Wrist-worn peripheral nerve stimulating device providing transcutaneous afferent patterned stimulation (including charging station)"

APPLICANT'S SUMMARY

Cala Health, Inc. submitted a request to establish a new Level II HCPCS code to identify the Cala Trio nerve stimulating device. The Cala Trio device is provided with two components: rechargeable stimulator that generates electrical impulses during times of active therapy together with a base station to recharge the stimulator; and wrist-worn connector that securely attaches the stimulator to the patient's wrist and assures that electrical impulses are properly targeted to each individual patient's nerves. Cala Trio is prescribed by a physician for use by patients in their home. It is the only peripherally worn device that is FDA- cleared to treat essential tremors, a chronic and progressive movement disorder. Cala Trio is a non-invasive, wrist-worn stimulator that delivers electrical stimulation to the nerves in the wrist to stimulate the Central Tremor Network via the peripheral nervous system. On-board sensors are used to measure the patient's tremor frequency during an initial calibration to individualize the stimulation delivered by the device.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code KXXXX "External Upper Limb Tremor Stimulator of the peripheral nerves of the wrist".

CMS is also considering an alternative, new Level II HCPCS code KXXXX: "wrist-worn nerve stimulating device."

CMS has been considering this issue based on comments and input from the previous public meeting. CMS notes that FDA identifies this device as an "external upper limb tremor stimulator". CMS continues to consider the most appropriate manner to describe the distinctions of these products, recognizing that clinical indications may change over time. We are seeking input from stakeholders, the general public, and insurers regarding what product distinctions would warrant a separate code. For example, should CMS specify the codes based on its application to the body rather than a nerve, considering the complexity of the nervous system(s)?

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary speaker commented that the Cala Trio nerve stimulator is accurately described by CMS first recommended coding option, KXXXX – External upper limb tremor stimulator of the peripheral nerves of the wrist, and asked that CMS finalize this coding action and language.

CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided throughout this coding cycle pertaining to HCPCS coding for electical stimulation devices, and the comments offered at CMS' HCPCS Public Meeting, specifically in reaction to CMS' published preliminary coding recommendation. CMS reconsidered this application, together with all input provided. CMS plans to monitor closely as new products and treatments for different nerves come to the market and may need to further refine this emerging area of the code set. Based on product offerings at this time, CMS has finalized its first preliminary coding phrasing option to establish new Level II HCPCS code K1018 " "External Upper Limb Tremor Stimulator of the peripheral nerves of the wrist".

Effective Date: 04/01/2021

Application # 20.087

TOPIC

Request to establish a new Level II HCPCS code to identify a supply that is associated with the Cala Trio device.

Applicant's suggested language: "Wrist-worn connectors for use with transcutaneous afferent patterned stimulation device"

APPLICANT'S SUMMARY

Cala Health, Inc. submitted a request to establish a new Level II HCPCS code to identify Cala Trio Wrist-Worn Connector. The stimulator/charging station (different application) and the wrist-worn connector are supplied initially, but replacement component of the wrist-worn connector can be provided as needed by the patient. The wrist-worn connector is only associated with the Cala Trio device. Cala Trio device is a non-invasive, wrist-worn stimulation that delivers electrical stimulation to the nerves in the wrist to stimulate the central tremor network via the peripheral nervous system. The wrist-worn connector is good for 90 days.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4595 "Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes)" describes the refill disposable electric patches that are the subject of this application.

CMS is also considering an alternative, new Level II HCPCS code KXXXX: "Electrical nerve stimulator supplies per lead, per month (e.g., for electrical transcutaneous nerve stimulation, nmes)"; and discontinuing the following existing code, as it would be redundant:

Discontinue existing code A4595 "Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes)."

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker commented that the Cala Trio wrist interface is not accurately described by the existing HCPCS code A4595, because it is intended for TENS products and does not describe the Cala Trio wrist interface. The speaker commented that the Cala Trio wrist interface satisfies CMS criteria for issuance of unique Level II HCPCS codes based on differential useful lifetime of the product and 510(k) authorization for special multiuse electrodes; a rigid interface; specific anatomical placement accommodated by availability of three sizes; and specialized componentry such as dry carbon nanotube electrodes; and as such, issuance of a new code would be consistent with HCPCS precedent.

The speaker requested that CMS establish a new, unique HCPCS code that aligns descriptor of the wrist interface with the preliminary coding recommendation for the nerve stimulator: KXXXX – Wrist interface for external upper limb tremor stimulator of the peripheral nerves of the wrist.

CMS FINAL HCPCS CODING DECISION

CMS reconsidered this application, together with all input provided. CMS plans to monitor closely as new products and treatments for different nerves come to the market and experience of payers in implementing this part of the code set. Based on product offerings at this time, CMS has established new Level II HCPCS code K1019 "Monthly supplies for use of device coded at K1018".

Effective Date: 04/01/2021

Application # 20.173

TOPIC

Request is to establish a new Level II HCPCS code to identify a non-invasive vagus nerve stimulator that provides therapy to prevent and acutely treat cluster headaches in adult patients, trade name: GammaCore Sapphire D.

APPLICANT'S SUMMARY

Electrocore, Inc. submitted a request to establish a new Level II HCPCS code to identify the GammaCore Sapphire D device, a non-invasive vagus nerve stimulator that externally stimulates the cervical branch of the vagus nerve to reduce the number of cluster headaches when used preventively and decrease the severity of cluster attacks when used acutely. Existing code categories are inadequate to describe the product. This is primarily due to miscellaneous coding requiring manual intervention for every claim submission. This delays patient care, does not allow for consistent and standardized reimbursement and leads to additional administrative and logistical support and expense.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new code KXXXX "Non-invasive vagus nerve stimulator"

CMS is also considering an alternative, new Level II HCPCS code KXXXX: "neck worn nerve stimulating device."

Existing code A4595 "Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes)" describes the refill disposable electric patches that are the subject of this application.

CMS is also considering an alternative, new Level II HCPCS code KXXXX: "Electrical nerve stimulator supplies per lead, per month (e.g., for electrical transcutaneous nerve stimulation, nmes)"; and discontinuing the following existing code, as it would be redundant:

Discontinue existing code A4595 "Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes)."

CMS continues to consider the most appropriate manner to describe the distinctions of these products, recognizing that clinical indications may change over time. We are seeking input from stakeholders, the general public, and insurers regarding what product distinctions would warrant a separate code. For example, should CMS specify the codes based on its application to the body rather than a nerve, considering the complexity of the nervous system(s)?

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Electrocore supports CMS preliminary HCPCS coding recommendation to establish a new code to describe gammaCore SapphireTM D (non-invasive Vagus Nerve Stimulator) to prevent and acutely treat cluster headaches in adult patients: KXXXX "Non-invasive vagus nerve stimulator"

CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided throughout this coding cycle pertaining to HCPCS coding for electical stimulation devices, and the comments offered at CMS' HCPCS Public Meeting, specifically in reaction to CMS' published preliminary coding recommendation. CMS reconsidered this application, together with all input provided. CMS plans to monitor closely as new products and treatments for different nerves come to the market and may need to further refine this emerging area of the code set. Based on product offerings at this time, CMS has finalized its first preliminary coding phrasing option to establish new Level II HCPCS code K1020 "Non-invasive vagus nerve stimulator" to identify the nerve stimulation device that is the subject of this application.

Effective Date: 04/01/2021

It is our understanding that there is no separate accessory for use with the Non-invasive vagus nerve stimulator, with the exception of replacement supplies of conductive gel. Existing code A4558 "Conductive gel or paste, for use with electrical device (e.g., tens, nmes), per oz" adequately describes the conductive gel used with the device that is the subject of this application and is available for assignment by insurers if they deem appropriate to report replacement supply of conductive gel.

InFlow® device by Vesiflo, Inc.

TOPIC

CMS requests additional input pertaining to our establishment of three new Level II HCPCS codes to identify replacement components of the inFlow device manufactured by Vesiflo, Inc. These codes were implemented Oct. 1, 2020.

SUMMARY

CMS is seeking additional input pertaining to the establishment of three new Level II HCPCS codes effective October 1, 2020, to identify replacement components of the inFlow device manufactured by Vesiflo, Inc., specifically, the replacement urethral drainage device with valve; replacement hand-held activation device; and replacement charger and base station for the activation device.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Three new Level II HCPCS codes implemented Oct. 1, 2020:

K1010 (Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each)

K1011 (Activation device for intraurethral drainage device with valve, replacement only, each)

K1012 (Charger and base station for intraurethral activation device, replacement only)

It is CMS' understanding that the initial issuance of the device includes fitting and placement by the provider and issuance of all components. Thus, all components provided on initial issue would be included in the practice expense amount paid to a professional, submitted using the appropriate CPT code, and would not be separately billable. As a result, CMS established these three new codes, effective October 1, for the replacement components. CMS seeks comment on this approach.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker commented that the replacement Vesiflo device may be inserted by a caregiver or other individual under the patient's direction, and in some instances, a patient inserts the device at home. The Primary Speaker requested that the phrase "patient inserted, replacement only" be omitted from the language of code K1010; and also that the phrase "replacement only" be omitted from code K1011. Regarding the Medicare payment methodology, the Primary Speaker suggested that it may be beneficial and appropriate to provide payment under the DME Capped Rental Program, given that some patients discontinue use of the

Vesiflo device early, often in the first month of use, and revert back to intermittent catheterization.

In addition to comments offered at CMS' HCPCS Public meeting, the Primary Speaker also separately submitted written comments to CMS stating that the "codes are not needed at this time."

CMS FINAL HCPCS CODING DECISION

Note of correction: The text of existing code K1010 as included under "CMS PRELIMINARY HCPCS CODING RECOMMENDATION" (as originally published in the Public Meeting Agenda) contained an error. The accurate code text as published in CMS official code set reads: "Indwelling intraurethral drainage device with valve, *patient inserted*, replacement only, each".

Given the nature of the comments received pertaining to existing codes K1010, K1011 and K1012, in particular, that the "codes are not needed at this time", CMS agrees with the views of the Primary Speaker to discontinue these codes, as a need for them is not supported at this time. If insurer needs change in the future, as experience is gained with this technology, CMS would review a code application in a subsequent coding cycle. In the meantime, requests for coding guidance should be submitted to the insurer in whose jurisdiction the claim would be filed, and claims may be adjudicated on an individual basis.

Effective Date: 04/01/2021

CMS will be available to facilitate a follow up discussion, if desired, to discuss the pricing methodology undertaken by the DME MACs for Medicare payment. The Medicare payment methodology is not part of the consideration of this process.

Application # 20.111

TOPIC

Request to establish a new Level II HCPCS code to identify NovoSorb SynPath

Applicant's suggested language: QXXXX: NovoSorb SynPath Dermal Matrix

APPLICANT'S SUMMARY

PolyNovo North America, LLC requests to establish a new Level II HCPCS code to identify NovoSorb SynPath.

NovoSorb SynPath is a sterile, acellular, synthetic dermal matrix made from the proprietary NovoSorb technology. The porous network of non-toxic, biodegradable synthetic polymers act as a template to support the proliferation of vital cells involved in cellular repair. As the matrix integrates into the wound bed, it supports the creation of a neodermal structure. The fenestrated matrix allows excess exudate from the wound to pass through to a secondary absorbent dressing to prevent maceration. The matrix is covered by a sealing membrane that reduces water vapor loss, helps maintain a moist wound environment, and acts as a barrier to prevent external contamination of the wound. The membrane remains intact with the dermal matrix until the clinician determines when to remove it based on the wound progression, the need for surgical closure or grafting, or application of another dermal template. It is indicated for management of partial and full thickness wounds, chronic ulcers (pressure, venous, diabetic), surgical wounds, and traumatic wounds. The device provides a dermal template to support the development of a neodermis for wound healing. Dosing does not apply to the device. After preparing the wound site, the clinician applies the textured side of the matrix directly into the wound surface flush against the wound bed. The device can be further fenestrated with a scalpel to facilitate drainage. The clinician secures the matrix using their choice of fixation. The product is presented in a sterile, inner transparent pouch encased by an outer aluminized pouch. The product is available in a range of sizes from 2cm x 2cm square to 20cm X 40cm square.

There is no current HCPCS code to describe an acellular, biodegradable synthetic polymer-based template (dermal matrix) with a sealing membrane for cellular repair of wounds.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

This request is being deferred to the subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision. Comment is particularly welcome on how different insurers would typically make a payment for this type of device.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker described Novosorb Synpath as "polyurethane foam with sealing membrane and adhesive layer" and exclusively discussed its use in surgery, particularly, reconstructive surgery and application over tendon and bone for extensive and deep wounds. Regarding Novosorb Synpath being a synthetic product, the speaker commented that it does "not elicit an immune response"; is associated with less infection risk than biological products; and there are "clinical studies showing that synthtic products are a safe alternative to biologcical products". The Primary Speaker made several comments describing Novosorb Synpath as a "skin substitute". The Primary Speaker made a non-specific comment about an AHRQ study relative to "what a skin substitute is and how it differes from a dressing".

We heard additional comments from other interested parites that Novosorb is developiong a portfolio of polyester urethane products that "behave similarly to biologics in terms of wound healing"; Synpath is used in post-mastectomy breast reconstruction; and the descriptor of "skin substitutes" in CMS' Physician Fee Schedule for the physician office setting specifies that synthetics and biologics are considered skin substiutes for payment in the Mediare system. We also received a comment in agreement with CMS preliminary recommendation to defer this application to a subsequent coding cycle in order to have the opportunity to consider further.

CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at CMS' HCPCS Public Meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation to defer this application to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Application # 20.120

TOPIC

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

Applicant's suggested language: Q42XX Restrata per square centimeter.

APPLICANT'S SUMMARY

Acera Surgical, Inc. requests a unique Level II HCPCS Q code to describe Restrata Wound Matrix, a fully-synthetic, nanofiber wound matrix.

Restrata functions as a matrix for treating wounds and is engineered utilizing nano-scale materials to provide a resorbable scaffolding to initiate cell migration, revascularization, and soft tissue formation and reinforcement in the prepared wound bed. CMS classifies Restrata as a skin substitute: "We have determined that the product may be treated as a skin substitute for Medicare payment purposes." Restrata is currently described by the code C1849 "Skin substitute, synthetic, resorbable, per square centimeter." This code can be used by hospitals to report use of Restrata but is not recognized by Medicare in other sites of service, including sites which are paid under the Medicare Physician Fee Schedule, such as physician offices and ambulatory wound care clinics. Restrata will commonly be administered in those sites of service and a product-specific Q code, comparable to the codes available for other skin substitute products, is necessary to report the product. The HCPCS codes previously assigned by CMS in response to Acera's 2018 HCPCS application, A6460 and A6461, do not appropriately describe the product, which functions like other skin substitutes and is implanted by a physician into the wound bed, and completely resorbed into the wound. Additional product applications follow as clinically necessary and prescribed by the provider. Restrata is indicated for use in management of wounds, including partial and full thickness wounds, pressure sores, venous, diabetic and chronic vascular ulcers, wounds with tunneling or undermining, surgical (e.g. donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma and draining wounds. The fibrous structure of Restrata is highly porous. It has a structure similar to native extracellular matrix of the skin and has a defined rate of resorption, which provides a scaffold for cellular infiltration and vascularization before completely degrading via hydrolysis in the wound bed. Restrata permits the migration of cells and formation of soft tissue in the wound bed and does not contain any human or animal materials or tissues. The dosage includes size selection appropriate to the prepared wound bed and is reapplied every 7 days or as necessary. The product is cut to the desired shape of the wound bed and hydrated before being anchored securely using the physician's preferred fixation method based on wound type/location. Restrata is supplied in a single use double peel package in a variety of sizes.

Applicant also requested that CMS delete HCPCS codes A6460 and A6461 as they serve no purpose and may create confusion.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

This request is being deferred to the subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision. Comment is particularly welcome on how different insurers would typically make a payment for this type of device.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker provided comments that "in the 2021 OPPS Final Rule, CMS expanded the skin substitute benefit to include synthetics"; Restrata is currently described by code C1849 (For HOPPS use); and Restrata manufacturer, Acera Surgical, Inc., is requesting a "specific code", in the "Q" section of the code "for payment consistent with other skin substutes in the physician's office setting". A prior application to CMS to code Restrata resulted in the establishment of codes A6460 "Synthetic resorbable wound dressing, sterile, pad size 16 sq. in. or less, without adhesive border, each dressing" and A6461 "Synthetic resorbable wound dressing, sterile, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing" . The Primary Speaker stated that "the current codes do not allow for payment in all sites of service". Code C1849, for example, may not be reported for Medicare payment for a service performed in a physician's office.

The Primary Speaker described Restrata as "electrospun matrices of polymer fibers whose architecture resembles that of native tissues", and commented that the product, which has 510(k) market authorization as wound dressing, is used "to aid in wound healing". The speaker claimed that Restrata's "intended use is the same as other skin substitutes" and commented that other 510(k) skin substitutes have been given Q codes by CMS. The speaker also suggested discontinuance of existing synthetic wound dressing codes A6460 and A6461 because: "A" codes are not suited to Restrata because it "is not DMEPOS"; "these codes do not allow for payment in all sites of service".

We heard additional comments that "CMS should create Q codes for Restrata and any other synthetics"; and "CMS now defines synthetics as skin substitutes and we need to now revisit all A6460 and A6461 and make them all Q codes or invite application so make them all Q codes".

CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at CMS' HCPCS Public Meeting in response to our published preliminary recommendation. This request is being deferred to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Application # 20.142

TOPIC

Request to establish a new Level II HCPCS code to identify Selenious Acid Injection.

Applicants suggested language: B42XX: Selenious Acid Injection, trace element, parenteral nutrition, admixture

APPLICANT'S SUMMARY

American Regent Inc. submitted a request to establish a new Level II HCPCS code to separately identify Selenious Acid Injection. Currently, there is no code specifically, separately identify Selenious Acid Injection as an admixture in parenteral nutrition (PN) solutions. A new HCPCS code is required to specify the use of Selenious Acid Injection as an admixture in PN solutions, as current coding specifying "home mix" is not appropriate for Selenious Acid Injection. The FDA approved the NDA for Selenious Acid Injection on April 30, 2019 for adult and pediatric patients as a source of selenium for PN when oral or enteral nutrition is not possible, insufficient, or contraindicated. Selenious Acid Injection is supplied as a pharmacy bulk package for admixing use only. It is not for direct intravenous infusion. Prior to administration, Selenious Acid Injection must be transferred to a separate PN container, prepared and used as an admixture in PN solutions. Selenious Acid Injection should be added to the parenteral nutrition solution only in a suitable work area such as a laminar flow hood (or an equivalent clear air compounding area). The key factor in the preparation is careful aseptic technique to avoid inadvertent touch contamination during mixing of solutions and addition of other nutrients. The dosage of Selenious Acid Injection is individualized based on the patient's clinical condition, nutritional requirements, and the contribution of oral or enteral selenium intake. Selenious Acid Injection is a clear, colorless solution packaged as 600 mcg/10 mL (60 mcg/mL) of selenium in a 10 mL pharmacy bulk package vial.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing HCPCS codes B4189 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 grams of protein - premix", B4193 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 52 to 73 grams of protein - premix", B4197 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, 74 to 100 grams of protein - premix", B4199 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, over 100 grams of protein - premix", B5000 "Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal-aminosyn-rf,

nephramine, renamine-premix", B5100 "Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic, hepatamine-premix", or B5200 "Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, stress-branch chain amino acids-freamine-hbc-premix" depending on content, adequately describe the complete formula, including the trace element that is the subject of this application.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no speaker or comments for this item.

CMS FINAL HCPCS CODING DECISION

Having received no comment at our HCPCS public meeting, CMS finalized its preliminary recommendation. Existing HCPCS codes B4189 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 grams of protein - premix", B4193 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 52 to 73 grams of protein - premix", B4197 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, 74 to 100 grams of protein - premix", B4199 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, over 100 grams of protein - premix", B5000 "Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal-aminosyn-rf, nephramine, renamine-premix", B5100 "Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic, hepatamine-premix" or B5200 "Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, stress-branch chain amino acids-freamine-hbc-premix" depending on content, adequately describe the complete formula, including the trace element that is the subject of this application.

Application # 20.123

TOPIC

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

Applicant's suggested language: JXXXX Synthetic hydrogel cervical dilator; each hydrogel dilator

APPLICANT'S SUMMARY

Medicem Inc. submitted a request to establish a new Level II HCPCS code to identify Dilapan-S. According to the applicant, Dilapan-S is a mechanical, non-pharmacologic firm hygroscopic cervical dilator rod composed of Aquacryl, a synthetic patented hydrogel.

Placement is performed by OB/GYN-trained healthcare providers. Typically, 3-5 rods are inserted into the cervix. Post-insertion, Dilapan-S initiates a cascade of biophysical, mechanical, and physiological changes in the cervical tissue that continue until removal. Each rod absorbs fluid from the surrounding cervical tissue and expands to several times its original diameter, gradually dilating the cervical canal by exerting evenly distributed radial pressure. This mechanical stretch leads to the release of endogenous prostaglandins that initiate collagen degradation and cervical softening and ripening. Dilapan-S may remain in-situ for up to 24 hours. The majority of rod expansion occurs in 4-6 hours. Average cervical ripening time is 12-15 hours.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Dilapan-S is not suitable for coding in Level II HCPCS. It is our understanding that Dilapan-S would likely be included by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) as a supply in the existing CPT code(s). In making such determinations, the AMA considers evidence that use of Dilapan-S has become a typical supply provided (greater than 50% of the time) during the relevant procedure(s). We recommend that the applicant work with the AMA RUC to determine whether this item should be included as a supply for existing CPT codes.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker explained how Dilapan-S works, and disagreed with CMS preliminary HCPCS coding recommendation that Dilapan-S is not suitable for coding in HCPCS Level II and referring the applicant to the AMA RUC. The speaker reiterated the request for a HCPCS Level II code, stating that a code is needed "to allow for tracking of patient outcomes for a coverage initiative" and also for comparison of outcomes to that of other cervical ripening agents. The speaker also commented on a need for a code to facilitate accurate tracking,

reporting and payment for the number of rods (hydrogel osmotic cervical dilators) used in the procedure, as the number of rods (and therefore the treatment cost) used can vary between patients, as three to five rods may be typically inserted.The speaker commented that the American College of Obstetrics & Gynecology (ACOG) is in the process of updating induction of labor guidelines.

CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at CMS' HCPCS Public Meeting in reaction to our published preliminary recommendation. CMS is finalizing its preliminary recommendation. Dilapan-S is not suitable for coding in Level II HCPCS. It is our understanding that Dilapan-S would likely be included by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) as a supply in the existing CPT code(s). In making such determinations, the AMA considers evidence that use of Dilapan-S has become a typical supply provided (greater than 50% of the time) during the relevant procedure(s). We recommend that the applicant work with the AMA RUC to determine whether this item should be included as a supply for existing CPT codes. Hearing the speaker comment that ACOG is in the process of updating induction of labor guidelines, the applicant may wish to consider approaching ACOG regarding any potential interest in sponsoring a request to the AMA RUC.

Application # 20.161

TOPIC

Request to establish a new Level II HCPCS code to identify a low coefficient of friction (COF ≤ 0.35) skin interface device system. Trade Name: DermaTherapy. In addition, as indicated by the request for a code in the EXXXX section of the code, the applicant is also asking that the product be deemed Durable Medical Equipment.

Applicant's suggested language: EXXXX: Low Friction (COF ≤ 0.35) Skin Interface System.

APPLICANT'S SUMMARY

Precision Fabrics Group, Inc. submitted a request to establish a new HCPCS code to identify DermaTherapy.

DermaTherapy is a low COF skin protective interface system with four components: 1) mattress/overlay interface cover with elasticized edge and depth to accommodate a mattress plus an overlay, 2) pillow interface cover, 3) skin interface overlay, and 4) an absorbent interface underpad. All four components function to provide a low COF interface between the mattress surface and/or overlay and the patients' skin to protect against shear and friction forces on the skin and wick moisture away from skin. These are the major contributors to development of pressure injuries. In addition, the interface material has a durable antimicrobial finish to reduce bacterial growth. Currently no HCPCS codes describe an interface system with a low COF ≤0.35 for use with Pressure Reduction Support Surfaces Groups 1, 2 or 3 or hospital beds used in the home. The system is indicated to protect the skin from development of pressure ulcers for patients that are immobilized or have limited mobility due to disease, surgery, trauma or injury.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

CMS has not identified a need on the part of any insurance sector to establish a unique code to identify low coefficient of friction bed and pillow covers and pads, which are available without a prescription.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no speaker or comments for this item.

CMS FINAL HCPCS CODING DECISION

Having received no comment at our HCPCS public meeting, CMS finalized its preliminary HCPCS coding recommendation. CMS has not identified a need on the part of any insurance

sector to establish a unique code to identify low coefficient of friction bed and pillow covers and pads, which are available without a prescription.

Application # 20.162

TOPIC

Request to:

1) Modify Level II HCPCS code E0787 descriptor "External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing" to clarify that it excludes systems that only suspend insulin delivery based on continuous glucose sensing;

(2) Clarify that E0784 includes insulin pumps that suspend insulin delivery based on continuous glucose sensing along with other items classified to that code; and

(3) Discontinue Level II HCPCS code A4226.

APPLICANT'S SUMMARY

Tandem Diabetes Care, Inc., submitted a request to: 1) Modify Level II HCPCS code E0787 descriptor "External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing" to clarify that it excludes systems that only suspend insulin delivery based on continuous glucose sensing;

(2) Clarify that E0784 includes insulin pumps that suspend insulin delivery based on continuous glucose sensing along with other items classified to that code; and

(3) Discontinue the code A4226.

Tandem t:slim X2 insulin pumps are the only items classified to E0787. The t:slim X2 pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 pump can also be used as part of a system to receive and display continuous glucose measurements from the Dexcom G6 CGM. If granted, this request would reclassify the t:slim X2 with embedded Basal-IQ technology to E0784 and the t:slim X2 with embedded Control-IQ™ technology would remain classified to E0787. This request is the same as the request Tandem made at the June 2, 2020, HCPCS public meeting. Presently, Medicare beneficiaries lack access to updateable Tandem pumps under E0784 unless they also meet Medicare requirements for continuous glucose monitoring and qualify for an E0787. According the applicant, these recommendations would ensure that Medicare beneficiaries could use a Tandem pump even if they do not use a CGM, in the same way they were able to obtain a Tandem pump before CMS created code E0787. Elimination of the A4226 bundled supply code and use of the three existing codes that describe the same supplies: A4224 (infusion sets), A4225 (insulin reservoirs), and K0553 (CGM supplies) would accommodate Medicare beneficiaries who often do not begin insulin pump and CGM therapy simultaneously or who purchase supplies from more than one supplier.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

This application was submitted on June 29, 2020. Following this submission, CMS issued biannual determinations in July (https://www.cms.gov/files/document/2020-hcpcs-application-summary-bi-annual-1-2020-durable-medical-equipment-dme-and-accessories.pdf). CMS understands that the applicant is engaging with the Pricing, Data Analysis and Coding (PDAC) contractor, and we believe that is an appropriate avenue at this time.

In addition, CMS has subsequently issued a proposed rule on CGMs. We believe it is most appropriate to review the public comments that will be submitted on the proposed rule before taking further action in regard to the codes that are the subject of this application. CMS appreciates the stakeholder engagement as we continue to consider how to develop and refine HCPCS Level II coding for use by all payers and ensure access to medically necessary devices and supplies for Medicare beneficiaries with diabetes.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no speaker or comments for this item.

CMS FINAL HCPCS CODING DECISION

CMS recognizes that the immediate questions raised by the applicant were addressed with the Pricing, Data Analysis and Coding (PDAC) contractor, and we are not taking any further action at this time, consistent with CMS' preliminary coding recommendation.

In addition, CMS has subsequently issued a proposed rule on CGMs. We believe it is most appropriate to review the public comments that were submitted on the proposed rule before taking further action in regard to the codes that are the subject of this application. CMS appreciates the stakeholder engagement as we continue to consider how to develop and refine HCPCS Level II coding for use by all payers and ensure access to medically necessary devices and supplies for Medicare beneficiaries with diabetes.

Application # 20.170

TOPIC

Request to establish a new Level II HCPCS code to identify a subscription-based software application, Natural Cycles.

APPLICANT'S SUMMARY

Natural Cycles USA Corp submitted a request to establish a new Level II HCPCS code to identify Natural Cycles, a subscription-based software application.

Natural Cycles is a subscription-based software application (app) that runs on mobile phones and is used in conjunction with patient-specific data and a woman's basal temperature taken by a basal thermometer as a method of fertility control, including contraception. Natural Cycles is the first and only app cleared by the FDA as a medical device for birth control. The "brain" behind the app is the dynamic individualized Natural Cycles algorithm. It continuously analyzes patient-specific data to display individualized daily fertility status.

The clearance led the FDA to create a new regulatory category called "Software application for contraception", setting the framework and guidance for future developments in this area. Natural Cycles provided the FDA with evidence to demonstrate the effectiveness of the app for contraception. This included a detailed description of its proprietary algorithm and an analysis of real-world data from 15,570 women who used the app for contraception, for a total exposure time of 7,353 woman-years.

The Patient Protection and Affordable Care Act ("ACA") mandates that private health plans require coverage for all FDA-approved methods of contraception used by women, including female sterilization, along with related counseling and services. It also requires this coverage to be provided with no patient out-of-pocket costs.

As per the applicant, Natural Cycles is first-in-class, having been granted the De Novo classification, none of the existing HCPCS codes apply, which is why Natural Cycles is requesting a new code. In order to enable insurance plans to cover Natural Cycles at no cost for the patient, Natural Cycles requires a new HCPCS code for a stand-alone software application for contraception.

CMS PRELIMINARY HCPCS CODING RECOMMENDATION

CMS recognizes the evolving manner of digital health technologies, like Natural Cycles. CMS requests information in regard to how private insurers are currently processing claims and covering this non-prescription product.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker described the Natural Cycles technology and algorithm, and the use of this device compared to basal temperature. The speaker disagreed with our preliminary recommendation, claiming that the primary use of the Natural Cycles device is contraception; it instructs women when to use contraception; coverage for contraception is mandated by the Affordable Care Act; and as such, a code is warranted.

CMS FINAL HCPCS CODING DECISION

CMS is finalizing its preliminary recommendation. CMS recognizes the evolving manner of digital health technologies, like Natural Cycles. CMS requests information in regard to how private insurers are currently processing electronic claims and covering this non-prescription product.

Application # 20.163

TOPIC

Request to establish a new Level II HCPCS code to identify the S.T. Genesis Percutaneous Nerve Field Stimulatory (PNFS) system.

APPLICANT'S SUMMARY

Wells Health Group, on behalf of DyAnsys, Inc. submitted a request to establish a new Level II HCPCS code to identify S.T. Genesis Percutaneous Nerve Field Stimulatory (PNFS) system.

The function of the S.T. Genesis Percutaneous Nerve Field Stimulatory (PNFS) system is to support reduction of opioid withdrawal symptoms through application to branches of cranial nerves V, VII, IX, and X as well as the occipital nerves. There are no existing Level II HCPCS codes that adequately describe the form and function of a Percutaneous Nerve Stimulator for Opioid Withdrawal. The newly granted FDA Product Code: PZR was effective 2/5/2018, and critical to this HCPCS Application. The new FDA product code was granted to allow for better treatment options for people suffering with Opioid Use Disorders (OUD). However, the consequences of innovative technology and new FDA product categories is the inevitable need for HCPCS coding modifications. FDA Indications For Use: Percutaneous Nerve Field Stimulatory (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX, and X, and the occipital nerves identified by trans illumination. S.T. Genesis PNFS is designed to administer auricular neurostimulation treatment while offering the patient a high degree of comfort and mobility. Stimulation is performed by sending electrical pulses emitted through needles strategically positioned in the ear. Once the device is applied, the therapy begins and continues for a maximum of 120 hours. Each patient's treatment is determined by frequent measurement of Clinical Opiate Withdrawal Scale (COWS) feedback until the opiate cravings have subsided. There are currently level II HCPCS codes for Implantable neurostimulator, pulse generators e.g. L8679 – up till now, no codes for non-implantable stimulators.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS would like to know more about the setting of use for this product. For instance, what type(s) of professionals are necessary for the appropriate application of this single-use product to the patient? Also, why would a Level II HCPCS Code be more appropriate than a CPT code? We would also like to know more about the applicant's claims experience with this product. What types of coverage and payment policies have private insurers adopted in terms of separate or bundled payment with the professional service for this product? We also would find it helpful to understand how market availability for this product has evolved over time. At this time, it seems to CMS that it would be most appropriate for the applicant to approach the AMA CPT Editorial Panel, though we welcome information to further inform our thinking.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Primary Speaker described the Genesis as a device that manages opioid withdrawal through percutaneous neuromodulation. It is used to detox and also post-detox. The speaker stated that there has been only one approval to date, from BCBS of Georgia, but the device has not yet been used. The speaker disagreed with CMS' preliminary HCPCS code recommendation, stating that there is no existing HCPCS code for implantable neuromodulation, and (without further specificity) that one insurer (Anthem) has expressed interest in a code for reimbursement.

CMS FINAL HCPCS CODING DECISION

CMS notes that this product is designed to be applied to the body by or under the supervison of a medical professional. CMS notes that this is also described as a single-use device. This type of supervised service is most consistent with HCPCS Level I (CPT) coding. CMS is finalizing its preliminary recommendation that the applicant approach the AMA CPT Editorial Panel for coding guidance for this service, including the device.