Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions

First Biannual, 2020 Coding Cycle for Durable Medical Equipment (DME) and Accessories; Orthotics, Prosthetics (O & P), and Supplies

This HCPCS Code Application Summary document presents, in request number sequence, a summary of each HCPCS code application and CMS' HCPCS coding decision for each application processed in CMS' First Biannual 2020 Durable Medical Equipment (DME) and Accessories; Orthotics, Prosthetics (O & P), and Supplies 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; CMS' HCPCS coding decision; and the effective date of any coding action.

We also solicited public consultation on Medicare use of HCPCS codes for insulin infusion pumps that can also receive and display continuous glucose measurements.

These HCPCS coding decisions will also be included in the October 2020 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS

TOPIC

Medicare payment for insulin infusion pumps that can also receive and display continuous glucose measurements

BACKGROUND FOR THE PUBLIC MEETING

As part of the annual 2020 HCPCS update cycle last year, a request (application #19.128) was submitted on behalf of Tandem Diabetes, Inc. to establish a new Level II HCPCS code to identify Tandem t-slim X2 insulin pump. The applicant requested the following code:

EXXXX External ambulatory insulin infusion pump and therapeutic CGM receiver

According to the applicant, the t-slim X2 insulin pump is intended for 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 receive and utilize continuous glucose measurements from the Dexcom G5 and G6 Mobile Continuous Glucose Monitor (CGM) sensors and transmitters.

In response to this request, the following codes were added to the HCPCS effective January 1, 2020:

E0787 External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing

A4226 Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week

Prior to this change, the only code available for billing for insulin infusion pumps covered under Medicare was code E0784 (External ambulatory infusion pump, insulin). In addition, code K0554 (Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system) was available for billing for equipment used to receive and display continuous glucose measurements. Codes E0784 and K0554 describe separate items of equipment, whereas code E0787 describes one piece of equipment that performs the functions of equipment described by codes E0784 and K0554.

Insulin infusion pumps are paid on a capped rental basis under Medicare. Monthly rental payments are made for the equipment for up to 13 months of continuous use. Following month 13, the supplier of the pump must transfer title to the pump to the beneficiary. Therapeutic Continuous Glucose Monitors (CGMs) receivers are paid on a purchase or rental basis, with total payments capped at the purchase price of the equipment. These payment rules are mandated by the exclusive payment rule for DME at section 1834(a) of the Social Security Act.

Under the Local Coverage Determination for External Infusion Pumps (L33794), Medicare only covers insulin pumps that can also receive and display continuous glucose measurements (pumps described by code E0787) if the beneficiary meets the medical necessity criteria for both an insulin pump and a Continuous Glucose Monitor (CGM).

In order to allow access to this innovative technology for all Medicare beneficiaries, CMS is seeking public consultation to more fully consider how we can address the likely conflicting payment provisions and adhere to the payment limits in the statute. In addition, we need to consider what happens in cases where the patient wants to utilize this newer technology pump but already owns a CGM receiver and/or insulin pump paid for by Medicare or has been renting an insulin infusion pump without an integrated CGM receiver for less than 13 months of continuous use.

As we engage in this public consultation, we believe the best course of action may be to make code E0787 invalid for Medicare use and have suppliers bill for the rental of the equipment described by code E0787 using the separate codes E0784 with the RR (rental) modifier and K0554 with the RR modifier. This would allow for the correct application of the payment rules for insulin pumps and CGM receivers while allowing beneficiaries to receive and use this new technology. Code E0787 would still be valid for use by other payers. In addition, code A4226 would still be valid for use in billing for the supplies used with the pumps described by code E0787, which would not be billed for using a combination of codes E0784RR and K0554RR. We are soliciting public consultation on this option as well as any other ideas for coding and payment of this equipment.

FINAL

The following two insulin infusion codes that were added to the HCPCS file effective January 1, 2020:

E0787 External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing

A4226 Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week

Since becoming effective CMS has become aware of complexities associated with these two codes in terms of processing claims and payment. CMS sought public input on the status of these two codes as part of the June 2, 2020 HCPCS public meeting. After careful review of the comments submitted and the issues surrounding use and payment for these codes, CMS has decided to make these two codes invalid for Medicare submission.

Information related to implementation of these coding actions will be provided in the near future by the Durable Medical Equipment (DME) MACs. This guidance will include claims processing instructions for calendar year 2020 claims. CMS intends to continue to engage with the innovator community and stakeholders on this evolving and important product area and future coding.

REQUEST# 20.063

TOPIC

Request to include the product ENU Pro3+ in existing Level II HCPCS code category B4153

APPLICANT'S SUMMARY

Trovita Health Science submitted a request on behalf of Ajinomoto Cambrooke, Inc. (ACI) to include its product ENU Pro3+ Powdered Energy Source for oral or enteral, a new formula for enteral feeding, in existing Level II HCPCS code category B4153. According to the applicant, existing Level II HCPCS code B4153 adequately describes ENU Pro3+: B4153 – enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fat, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit. ENU Pro3+ Powdered Energy Source for Oral or Enteral Use is a flavorless, soluble powder providing complete enteral nutrition: including an advanced protein blend, with L-leucine, carbohydrates, and fat. ENU Pro3+ is fortified with 28 vitamins and minerals. 17% of the advanced protein blend is the free amino acid L-leucine. Leucine provides significant benefits to Medicare beneficiaries, whether ambulatory or non-ambulatory. Because ENU Pro3+ contains protein [plus L-leucine], carbohydrate, and fat, and 28 micronutrients, it is complete nutrition. Added L-leucine may help stabilize or prevent muscle wasting, cachexia, or sarcopenia in enterally fed patients. English et al. concluded, "…Leucine supplementation may partially protect muscle health during relatively brief periods of physical inactivity." ENU Pro3+ functions as a medical food for oral or enteral use, for the purpose of daily dietary intake of complete nutrition, plus added L-leucine to promote muscle synthesis and prevent muscle wasting, cachexia or sarcopenia. ENU Pro3+ is packaged in a single 350g can, containing blended powder and a measuring scoop.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing Level II HCPCS code B4153 "Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit" adequately describes ENU Pro3+.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments offered.

FINAL DECISION

CMS finalized its preliminary recommendation. Existing Level II HCPCS code B4153 "Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit" adequately describes ENU Pro3+.

REQUEST# 20.064

TOPIC

Request to establish a new Level II HCPCS code to identify Suturegard ISR (Intraoperative Skin Relaxation).

APPLICANT'S SUMMARY

Suturegard Medical, Inc. submitted a request to establish a new Level II HCPCS code to identify the SUTUREGARD ISR (Intraoperative Skin Relaxation) Device.

According to applicant, this device is a Class 1 sterile single use device that allows surgeons to quickly and safely stretch skin and simply close wounds that normally cannot be closed. Patients with these open wounds must undergo prolonged wound care as they heal naturally or additional surgery for wound closure by skin flap or graft. These secondary procedures are often done in an ambulatory surgery center or hospital setting and often require general anesthesia. Intraoperative skin relaxation with SUTUREGARD ISR allows many more wounds to be closed in an office setting under local anesthesia, and as such impart value and savings to the patient, physician and the health system. Current codes do not describe the procedure of intraoperative skin relaxation, nor a device that allows one to do so. CPT code 11960 describes insertion of a subcutaneous balloon which is sequentially filled over several weeks to stretch the overlying soft tissues. That stretched expanded soft tissue can be used to accommodate a breast implant or be advanced to cover a scarred area with supple unscarred skin. ISR stretches only skin, and takes just 30-60 minutes. It is done to reduce closure tension, lowering risk of wound dehiscence, site infection and wide scar, while allowing many more wounds to be closed in a simple linear fashion. Further, IRS eliminates the need for undermining, reducing risk of hematoma, skin necrosis and dehiscence. The applicant is requesting a new code to cover the SUTUREGARD ISR device cost; and to cover the ISR procedure. The applicant comments that current HCPCS code A4649 "Surgical Supply, Miscellaneous"; doesn't account for patient value brought by the SUTUREGARD ISR device.

PRELIMINARY HCPCS CODING RECOMMENDATION

It is our understanding that the item that is the subject of this application is factored into the practice expense 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 applicant disagreed on the basis that Suturegard ISR provides a significant therapeutic distinction as a method of surgical wound closure.

FINAL DECISION

We appreciate the comments provided at CMS' HCPCS Public Meeting in reaction to our published preliminary recommendation. It is our understanding that to the extent the Suturegard ISR is used during a procedure, it is considered to be part of the Medicare payment to the practitioner or to the facility payment, depending on setting of use. For additional details and coding guidance, CMS refers the applicant to the American Medical Association (AMA).

REQUEST# 20.065

TOPIC

Request to establish a new Level II HCPCS code for BioFlo AutoValve

APPLICANT'S SUMMARY

Request submitted on behalf of BioFlo, LLC to establish a new Level II HCPCS code to identify the BioFlo AutoValve.

According to applicant, the documentation attached to the application shows that the product is manufactured by Insert Molding Solutions, Inc., and distributed by BioFlo, LLC. The application was submitted by The Wells Health Group on behalf of the distributor (BioFlo, LLC), not on behalf of the manufacturer (Insert Molding Solutions, Inc.). The BioFlo AutoValve is a single patient use device designed to function as an integral part of the urinary collection and retention system that replaces bladder function in the case of permanent urinary incontinence including the functionality to provide a mechanism to control the flow of urine as in a normal functioning bladder. There are no existing codes today that adequately describe the BioFlo AutoValve. The BioFlo AutoValve is not and should not be confused with an anti-reflux valve or flutter valve. The AutoValve is intended to be inserted between an indwelling catheter or suprapubic catheter and the urinary drainage bag to mechanically regulate the flow of urine. The AutoValve closed urinary management system replicates a critical function of the bladder that maintains a closed urinary tract pathway to prevent microbial colonization. Currently there are no urinary collection and retention systems available that are capable of providing a completely closed urinary tract pathway to prevent microbial colonization. The applicant notes that microbial colonization is a leading cause of urinary tract infections. Existing urinary collection and retention systems standards of care are not structurally designed to maintain a completely closed system and not mechanically designed to provide a mechanism to control the flow of urine as in a normal functioning bladder. As a result, patients suffering with permanent urinary incontinence are susceptible to common risk factors from Catheter Associated Urinary Tract Infections (CAUTI). The BioFlo patented two-housing system with flow control magnets, allows for a measured flow of urine to be released when the amount of urine in the catheter reaches about 20 cubic centimeters of volume. The two ceramic magnets separate inside the BioFlo® AutoValve allowing urine to flow through the Quick Disconnect into the collection bag. When the Quick Disconnect is engaged and separated from the Auto Valve housing the drain end seal, plunger overmold and plunger engage, stopping the floating magnet from separating from the fixed magnet. The innovative Auto Valve mechanism ensures a closed urinary system even during disconnection to empty the bag. This critical mechanism also prevents the potential backflow of urine from a dependent loop "standing column of urine" and a pathway for microbial colonization. BioFlo, LLC is submitting this application to request a new unique HCPCS code for the BioFlo AutoValve.

PRELIMINARY HCPCS CODING RECOMMENDATION

Anti-reflux capability is included in existing Level II HCPCS code A4357 "Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each"; and existing code A9900 "Miscellaneous DME supply, accessory, and/or service component of another HCPCS code" describe the BioFlo AutoValve and are available for assignment by insurers, if they deem appropriate. We do not have information that any insurance sector has a claims processing need to uniquely or separately identify the BioFlo AutoValve “auto-release" release feature.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary code recommendation and claimed that use of the BioFlo AutoValve, when added to a standard-of-care two-part system confers a significant therapeutic distinction in that it aids in prevention of microbial colonization back into the bladder; that it maintains a closed system even when the drainage bag is disconnected and subsequently reconnected; that its use prevents Catheter Associated Urinary Tract Infections (CAUTI); and as such, a unique code is warranted.

FINAL DECISION

Following the HCPCS public meeting CMS re-reviewed this application with all new information provided and revised its preliminary coding recommendation. The FDA has advised CMS that the BioFlo AutoValve may not fall under the FDA class II exemption specified by the applicant. We recommend that the manufacturer have further consultation with FDA regarding the appropriate market approval pathway, and we will be available to meet with the applicant and the manufacturer following those discussions with the FDA. CMS is also willing to discuss with the applicant whether to consider a subsequent application following those discussions with the FDA or otherwise.

REQUEST# 20.066

TOPIC

Request to establish a new Level II HCPCS code for Alfred SmartBag.

Applicant's suggested language: "Alfred SmartBag, each".

APPLICANT'S SUMMARY

11 Health and Technologies, Inc. submitted a request to establish a new Level II HCPCS code to identify Alfred SmartBag. According to the applicant, the Alfred SmartBag is a drainable ostomy pouch with integrated sensors/transmitter/battery. It serves as an ostomy pouch for stoma opening post-surgery. This product's unique components include an integrated thermistor and capacitive sensor sheet, a Bluetooth Low Energy microprocessor and transceiver, and a battery. The thermistors read the thermal signature of the stoma output/effluent and work in unison with the capacitive sensors, which detect the change in impedance as a function of the flow of effluent into and out of the pouch, and the accelerometer sensor detects bag positioning. The integrated sensor system continuously monitors and transmit vital information, such as dehydration, leaks, or blockage to the patient and medical professionals so preventive and reactive activities can occur prior to the patient's condition becoming acute.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4426 "Ostomy pouch, drainable; for use on barrier with locking flange (2-piece system), each" adequately describes the ostomy pouch component of the ostomy smart pouch and existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the monitoring component of the ostomy smart pouch. Codes A4426 and A9279 are available for assignment by insurers if they deem appropriate and consistent with current practice.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that the SmartCare system provides individualized assistance to ostomy patients, reduces complications, including dehydration and stoma site inflammation; reduces delays for adjuvant treatments; reduces unscheduled outpatient visits, ER visits and hospital readmissions from complications. The speaker also commented that existing codes are inadequate to describe the Alfred SmartBag as they do not consider the sophisticated data collection, interpretation and transmission and monitoring functions, and do not address data for algorithmic interpretation.

FINAL DECISION

We appreciate the comments provided at CMS' HCPCS Public Meeting in reaction to our published preliminary recommendation. CMS re-considered all input and adopted its preliminary

coding recommendation. It is our determination that the existing code A4426 "Ostomy pouch, drainable; for use on barrier with locking flange (2-piece system), each" adequately describes the ostomy pouch component of the ostomy smart pouch and existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the monitoring component of the ostomy smart pouch. Codes A4426 and A9279 are available for assignment by insurers if they deem appropriate and consistent with current practice. CMS refers the applicant to the American Medical Association (AMA) for CPT coding guidance for the practitioner service component involved in interpreting data and making treatment decisions.

REQUEST# 20.067

TOPIC

Request to establish a new Level II HCPCS code to identify the Nella VuSleeve.

Applicant's suggested language: "Vaginal Speculum retraction sleeve, disposable each".

APPLICANT'S SUMMARY

Ceek Women's Health submitted a request to establish a new Level II HCPCS code to identify Nella VuSleeve.

According to the applicant, the Nella VuSleeve is a single-use Vaginal Tissue Retraction sheath for use with a vaginal speculum that is used by physicians to enhance cellular collection while screening for cervical cancer. The VuSleeve improves visibility and accessibility of the cervix, improving cervical cancer screening by facilitating retraction of encroaching vaginal sidewall tissue. This function is of particular importance in multiparous, obese, and/or women with vaginal laxity, because it enables physicians and qualified healthcare professionals to obtain a full, unobstructed view of and access to the cervix, improving quality of preventive and diagnostic care for women. According to the applicant, they "reapplying for a unique HCPCS code because there are no current HCPCS or CPT codes which adequately describe the Nella VuSleeve." In addition, the applicant stated that "The VuSleeve, however, is an expense to the physician billing for the supply, as Medicare does not consider that a speculum and associated supplies such as the VuSleeve are of a type that the physician would usually furnish in the course of performing their services."

PRELIMINARY HCPCS CODING RECOMMENDATION

It is our understanding that the item that is the subject of this application is factored into the practice expense 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 applicant's representative presented information related to a conversation with the AMA, specifically, that the AMA referred the applicant back to CMS.

FINAL DECISION

We appreciate the comments provided at CMS' HCPCS Public Meeting in reaction to our published preliminary recommendation. The VuSleeve is not suitable for coding in Level II HCPCS. For additional information and coding guidance, CMS refers the applicant to the American Medical Association (AMA).

REQUEST# 20.068

TOPIC

Request to establish a new Level II HCPCS code to identify Nu Bandage.

APPLICANT'S SUMMARY

New bandage Technology LLC., submitted a request to identify Nu Bandage.

According to the applicant, the Nu Bandage is a multipurpose, and multifunctional, non-woven one-piece plastic mold-injected tubular securement and compression device, that is made in America with FDA approved thermoplastic elastomer materials (TPE) no latex (Please refer to polymers properties database). The applicant stated that the Nu Bandage is specifically formulated to be microbial-resistant and is re-usable on the same patient. One of the many functionalities of Nu Bandage is that it has memory and can expand up to four times and retract to its original size and shape and can conform and articulate to fit most any body part. It grips and supports the fascia of the skin and performs like external tendons and muscles, and secures wound care dressings and other medical devices in place without the use of tapes or adhesives, supporting soft tissue for wound care, orthopedic pre-op and post-op surgery, and compression for vascular issues like lymphedema and reducing inflammation using compression. Nu Bandage is non-woven and has no seams, eliminating pressure points that causes unnecessary trauma and blood flow disruption, and offers 360 degrees of kinesio function for muscle and joint support, mobility, and recovery. Nu Bandage is new technology and we are requesting to establish a new HCPCS reimbursement code that describe our product accurately. Nu Bandage is the only microbial-resistant securement, and compression device that is reusable on the same patient, and free of any woven seams that interrupt blood flow, for better patient comfort and better patient outcomes.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing Level II HCPCS code A6457 "Tubular dressing with or without elastic, any width, per linear yard" adequately describes the Nu bandage.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Comments were provided that a new code is warranted because the Nu Bandage is a one-piece injection molded product that is the only non-woven tubular device on the market; that it offers microbial resistance; that the fee associated with existing code A6457 is cost prohibitive to manufacture the Nu Bandage; and that existing code A6545 "Gradient compression wrap, non-elastic, below knee, 30-50 mm hg, each" more closely reflects the Nu Bandage.

FINAL DECISION

Following the HCPCS public meeting CMS re-reviewed this application with all new information provided and adopted its preliminary coding recommendation. Existing Level II

HCPCS code A6457 "Tubular dressing with or without elastic, any width, per linear yard" adequately describes the Nu Bandage. With regard to the suggestion at the public meeting that the Nu Bandage is more accurately coded by existing code A6545 "Gradient compression wrap, non-elastic, below knee, 30-50 mm hg, each", products categorized in A6545 are expected to be cleared by the FDA under a different regulatory clearance than 880.5075, as associated with the Nu Bandage in the application.

REQUEST# 20.069

TOPIC

Request to establish a new Level II HCPCS code to identify the Athelas One Rapid Neutrophil Test

APPLICANT'S SUMMARY

Athelas Inc. submitted a request to establish a new Level II HCPCS code to Athelas One Rapid Neutrophil Test.

According to the applicant, the Athelas One Rapid Neutrophil Test is a recently FDA cleared Neutropenia testing system that uses artificial intelligence, deep neural networks and microfluidics to generate a WBC and Neutrophil count from a single drop of blood (3.5 microliters) instantly. The system is the 1st only available, capable of measuring Neutropenia instantly in the point of care from a single finger stick. This is made possible by the Athelas One's novel machine learning and rapid consumable microfluidic technology. A new code is requested to reimburse for the use of an Athelas One test strip and the automated cloud based computer vision analysis of the sample to generate the result. Through usage of the rapid Athelas One Neutrophil Test incidence of Neutropenia can be flagged in point of care of to healthcare providers hours earlier or even days earlier than standard of care; preventing hospitalization, progression of an infection and related severe complications attributable to Febrile Neutropenia. Per the applicant, existing codes for differential cell counters only cover lab based analysis conducted in batches on large venous tubes of blood and therefore do not cover costs associated with the rapid microfluidic test strip that enables the test to be conducted within minutes in near patient settings. Costs of operating the device in PoC by a HCP along with connection to the cloud based infrastructure for algorithmic analysis are not covered by existing codes.

PRELIMINARY HCPCS CODING RECOMMENDATION

On February 24, 2020, CMS referred this applicant to the American Medical Association (AMA) for Level I CPT coding guidance, and provided a contact for clinical lab guidance. We also made a referral to CMS' Clinical Lab Fee Schedule staff for guidance regarding notification of new, FDA approved lab tests.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

None offered.

FINAL DECISION

This lab test is not suitable for coding in Level II HCPCS. On February 24, 2020, CMS referred this applicant to the American Medical Association (AMA) for Level I CPT coding guidance, and provided a contact for clinical lab guidance. We also made a referral to CMS' Clinical Lab Fee Schedule staff for guidance regarding notification of new, FDA approved lab tests.

REQUEST# 20.070

TOPIC

Request to establish a new Level II HCPCS to identify the 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, a non-implantable trigeminal nerve stimulation device for the treatment for pediatric attention deficit hyperactivity disorder (ADHD). According to the applicant, the Monarch external Trigeminal Nerve Stimulation (eTNS) System 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 awakening 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.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code E0720 "Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation" adequately describes the nerve stimulating device.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary coding recommendation and commented that a unique code is warranted for the Monarch external Trigeminal Nerve Stimulation system on the following bases: (1) differences in design, function and anatomic target; (2) difference in mechanism of action, namely, it stimulates the trigeminal nerve, which is part of the central nervous system, as opposed to a peripheral nerve, which the applicant equates with localized stimulation as described in code E0720; (3) according to the speaker, indication of the Monarch system to treat ADHD (as opposed to pain treatment, as previously associated with transcutaneous electrical nerve stimulation devices) equates to a significant therapeutic distinction (because it is a distinct therapy); (4) CMS preliminary recommendation is inconsistent with coding precedent for other electrical stimulation devices relative to specifying use indications; and (5) as payers have adopted unfavorable coverage policies for code E0720 absence of a unique code could inhibit patient access. The speaker reiterated the request for a

unique code that would specify within the code text: the nerve to be stimulated (trigeminal), the diagnosis being treated (ADHD), and the subpopulation (pediatric).

FINAL DECISION

This application is deferred for additional consideration in the next coding Bi-annual cycle. As nerve stimulation technology is evolving, CMS welcomes a broader conversation by this manufacturer and others to identify potential distinctions in nerve stimulation technology, both between TENS devices and for nerve stimulation technology generally, to consider coding trajectory and appropriate granularity in coding. We are interested in innovator views on key distinguishing factors between the devices that provide transcutaneous electrical nerve stimulation, and how to best categorize such products for the purpose of reporting to insurers that recognizes innovative technology consistent with the HCPCS decision making process and the maintenance of a practical code set for the use of insurers.

REQUEST# 20.071

TOPIC

Request to establish a new Level II HCPCS code to identify replacement Monarch NS-2 Electric Patches for use with the Monarch eTNS system.

APPLICANT'S SUMMARY

NeuroSigma Inc., submitted a request to establish a new Level II HCPCS code to identify the Monarch NS-2 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 awakening 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.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4595 "Electrical stimulator supplies, two lead, per month, (e.g., TENS, NMES)" adequately describes the Monarch NS-2 electric patch pouch.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The speaker requested a product-specific supply code to correspond with the requested product-specific device code, that would also specify within the code text the population, specific diagnosis being treated, the exact nerve being targeted, and also naming the specific device within the supply code.

FINAL DECISION

This application is deferred for additional consideration in the next coding bi-annual cycle. As nerve stimulation technology is evolving, CMS welcomes a broader conversation by this manufacturer and others to identify potential distinctions in nerve stimulation technology, both between TENS devices and for nerve stimulation technology generally, to consider coding trajectory and appropriate granularity in coding. We are interested in innovator views on key

distinguishing factors between the devices that provide transcutaneous electrical nerve stimulation, and how to best categorize such products for the purpose of reporting to insurers that recognizes innovative technology consistent with the HCPCS decision making process and the maintenance of a practical code set for the use of insurers.

REQUEST# 20.072

TOPIC

Request to establish two new Level II HCPCS codes to identify ORBERA Intragastric Balloon:

Applicant's suggested language:

1) “Endoscopic placement and filling of intragastric balloon device with saline”

2) “Endoscopic deflation and removal of intragastic balloon device by release of saline and removal of the device”

APPLICANT’S SUMMARY

Request submitted on behalf of Apollo Endosurgery to establish two new Level II HCPCS codes to identify placement and removal of ORBERA Intragastric Balloon. According to the applicant, the Orbera is a fluid filled, intragastric balloon designed to assist weight loss by partially filling the stomach. The filled balloon is designed to occupy space and move freely within the stomach. The Orebera Balloon System is indicated for weight reduction for adults with obesity with a Body Mass Index (BMI) of >30 and <40 kg/m2 who have previously failed more conservative weight reduction alternatives. Orbera is to be used in conjunction with a long-term diet and behavior modification program designed to increase the possibility of significant weight loss and maintenance of that weight loss. The maximum placement period is 6 month. The expandable design of Orbera permits a fill volume range of 400 cc (minimum) to a maximum of 700 cc.

PRELIMINARY HCPCS CODING RECOMMENDATION

Not suitable for coding in Level II HCPCS due to setting of use as this procedure is not performed in a physician’s office or a patient’s home. For use in Hospital Outpatient settings and Freestanding Ambulatory Surgical settings, please refer to CMS’ Pass-Through Application procedures as detailed on:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

None offered.

FINAL DECISION

Having received no public input on this application, CMS adopted its preliminary recommendation. The endoscopic intra-gastric balloon placement and removal procedures that are the subject of this application are not suitable for coding in Level II HCPCS due to setting of use, as these procedures are not performed in a physician’s office or in a patient’s home.

For use in Hospital Outpatient settings and Freestanding Ambulatory Surgical settings, please refer to CMS' Pass-Through Application procedures as detailed on:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.

REQUEST# 20.073

TOPIC

Request to establish a new Level II HCPCS code to identify the four-wheeled, therapeutic pediatric ride on mobility device called the Pumper Car.

APPLICANT'S SUMMARY

Columbia-Inland Corporation submitted a request to establish a new Level II HCPCS code to identify the pumper car. The pumper car is a four wheeled, therapeutic pediatric ride-on mobility device. It is made of durable, child-safe materials. The unique feature of the pumper car is the pumping action, which results in simultaneous activation of the rider's muscle groups in the upper and lower body. Children propel the vehicle by pushing their feet and legs forward as they pull their arms back using the handles on the steering column. They push their arms forward while bringing their feet and leg back and continue this push-pull motion. Pumper car is used for therapy for children with Autism, downs syndrome and cerebral palsy. It helps the children with balance, motor skills and muscle strengthening. The children enjoy riding the pumper car and therefore increase engagement in a therapy session. The pumper car is available in three models for children ages two to eighteen years depending on height and weight.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A9300 "Exercise Equipment", adequately describes the pumper car; is consistent with FDA classification; and is available for assignment by insurers if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

None offered.

FINAL DECISION

Having received no comment at our HCPCS public meeting, CMS adopted its preliminary recommendation. Existing code A9300 "Exercise Equipment", adequately describes the pumper car; is consistent with FDA classification; and is available for assignment by insurers if they deem appropriate.

REQUEST# 20.074

TOPIC

Request to establish a new Level II HCPCS code to identify ACUVUE OASYS Contact Lenses with Transitions photochromic additive.

Applicant's suggested language: “Contact Lens, hydrophilic, spherical, with photochromic additive, per lens”.

APPLICANT’S SUMMARY

Johnson and Johnson Vision Care, Inc. submitted a request to establish a new Level II HCPCS code to identify ACUVUE OASYS Contact Lenses with Transitions. ACUVUE OASYS Contact Lenses with Transitions are the first contact lenses with light-adaptive technology cleared in the United States. These contact lenses are soft (hydrophilic) available as spherical lenses. The lenses are made of silicone hydrogel material (senofilcon A) containing an internal wetting agent and UV absorbing monomers. A combination of the benzotriazole UV absorbing monomer and the naphthopyran monomer (photochromic additive) is used to block UV radiation. The contact lenses are for daily wear, optical correction of refractive ametropia (myopia and hyperopia), in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism. It is also for attenuation of bright light to help protect against transmission of harmful UV radiation to the cornea and the eye. ACUVUE OASYS Contact Lenses with Transitions quickly adjusts from clear to dark and back in response to changing light conditions while reducing exposure to bight light indoors and out.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish a new Level II HCPCS code VXXXX "Contact lens, hydrophilic, spherical, photochromic additive, per lens”

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS preliminary HCPCS code decision.

FINAL DECISION

Establish new Level II HCPCS code V2524 "Contact lens, hydrophilic, spherical, photochromic additive, per lens”

Effective: 10/1/2020

REQUEST# 20.075

TOPIC

Request to establish a new Level II HCPCS code to identify habilitation, prevocational, waiver services.

Applicant's suggested language: “Habilitation, prevocational, waiver, 15 minutes”

APPLICANT’S SUMMARY

Minnesota State department of health services submitted a request to establish a new Level II HCPCS code to identify Habilitation, prevocational, waiver service at 15-minute increments. According to applicant, prevocational service is to prepare people with disabilities for jobs with competitive pay. It is to help people achieve greater independence in their community. Prevocational services teach general work skills and concepts such as attendance, attention span, effective workplace communication, effective social skills and conduct, following directions, motor skills, personal self-care and appearance, problem solving, public transportation, safety and task completion. A legislation passed in Minnesota changed the service time from one hour to 15-minute increments. Current HCPCS codes available are per diem and per hour codes.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code TXXXX "Habilitation, prevocational, waiver; per 15 minutes"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

None offered.

FINAL DECISION

Establish new Level II HCPCS code T2047 "Habilitation, prevocational, waiver; per 15 minutes”

Effective: 10/1/2020

REQUEST# 20.076

TOPIC

Request to establish a new Level II HCPCS code to identify X10's Interactive pressure modulated device for leg strengthening and active plus passive range of motion (ROM) Knee only.

Applicant's suggested language: “Interactive pressure modulated DEVICE FOR leg strengthening and active plus ROM KNEE ONLY”

APPLICANT’S SUMMARY

Halley Orthopedics submitted a request to establish a new Level II HCPCS code to identify X10 Knee Rehabilitation machine. According to the applicant, the X10 therapy system consist of X10 machine is robotic, integrated with computer, touch screen, and a specific therapy protocol. The therapy is managed between patient and the licensed X10 personal physical therapy coach. Patient’s progress is monitored by the coach in-person or via telemedicine daily and adjust therapy as needed. Weekly patient progress report is sent to the surgeon for therapy recommendations. The X10 therapy system is for range of motion and strengthening exercises after knee replacement surgery. According to applicant, the X10 therapy rapidly improves strength and range of motion utilizing clinical approach that is pain-free. The X10 uses precise controlled pressure to bend and straighten the leg. As a result, the X10 slows down and creeps when it senses the pressure is approaching the patient’s preset limit, it will then stop and reverse and reverse when the limit is reached. Patient’s pain is maintained below threshold and it builds patients’ confidence and therefore are able to engage in more therapy sessions up to 21 per week, compared with standard physical therapy, which is 3 per week. The X10 system gently and effectively pumps the fluid into the lymph and excretes out. The X10 therapy system is primarily for knee arthroplasty (single or bilateral), patients with other knee surgeries, and knee injury. It is effective for all patients, including those who typically do not respond to traditional therapy. Designed to use multiple times a day and several weeks at a time. The X10 can easily be cleaned between therapy treatment plans. The roller pads and the thigh straps are replaced following each rental period.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code E0935 "Continuous passive motion exercise device for use on knee only" adequately describes the X10 device; and existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the monitoring feature. These codes are available for assignment by insurers if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker for Harnessed Motion, LLC (mfr.) disagreed, stating that the X10 is “light years beyond standard CPM” in that its use: provides biofeedback; reduces recovery time; reduces opioid use; allows providers to be resident for every session; and also provides Active ROM.

FINAL DECISION

The X10 device has CPM and also non-CPM features. The CPM features of the X10 are adequately described by existing code E0935 "Continuous passive motion exercise device for use on knee only". Existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the monitoring features of the device. We understand that a particular insurer may, on a claim-by-claim review basis, prefer to assign a different code when it is paying for a broader range of services and equipment usage, including for the practitioner service component involved in interpreting data and making treatment decisions.

REQUEST # 20.077

TOPIC

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

Applicant's suggested language: “Speech volume modulation device”

BACKGROUND

SpeechVive, Inc. submitted a request to establish a new Level II HCPCS code to identify the SpeechVive device which, according to the applicant, is a wearable technology comprised of an ear-worn device, charging station and charging cord. SpeechVive is regulated by 21 CFR 874.5840 and is recognized by FDA under Product Code KTH: Class I 510(k) exempt device. SpeechVive treats Parkinson’s patients diagnosed with the medical condition that is identified by ICD 10 Code – R47.1: Dysarthria and Anarthria. SpeechVive utilizes an in-ear device that plays noise (multi-talker babble) only when the patient speaks. The noise elicits the Lombard Effect, automatically increasing the patient’s vocal intensity, slowing their speech rate, and/or increasing the clarity of their speech. The function and impact of the product on vocal intensity has been demonstrated in randomized clinical trial with delayed treatment groups and multiple baselines that are included as attachments to the application. The SpeechVice device is an innovative new technology and as such there is no current HCPCS code that fits the product’s description and function. This lack of an existing HCPCS code has been validated in e-mail discussions with the Pricing, Data and Analysis Committee (PDAC) and through the submission and payment of the unlisted HCPCS code. To date, the Veterans Administration (VA), Durable Medical Equipment Medicare Administrative Contractors (DME MAC) and Commercial Insurers have questioned the lack of a SpeechVive specific code, have not been able to offer alternative HCPCS codes, and have agreed that, in absence of a code, the miscellaneous code should be used.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish a new Level II HCPCS code KXXXX "Speech volume modulation system, any type, including all components and accessories"

Effective: 10/01/2020

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

None offered.

FINAL DECISION

CMS adopted its preliminary Level II HCPCS coding recommendation to establish new Level II HCPCS code K1009 "Speech volume modulation system, any type, including all components and accessories". Effective: 10/01/2020

REQUEST # 20.078

TOPIC

Request to establish a new Level II HCPCS code to identify the PureWick Urine Collection System.

Applicant's suggested language: “Urine Collection pump, home model, portable or stationary, battery powered or electric”

BACKGROUND

BD submitted a request to establish a new Level II HCPCS code to identify the PureWick Urine Collection System. The PureWick System is an alternative to an indwelling catheter for female adult patients suffering from permanent urinary incontinence. It is indicated for non-invasive urine output management in females and is contraindicated in patients with urinary retention. It funnels the urine and removes it to the Collection Canister once it passes through the patient tubing. Suction enables efficient removal of urine from the Female External Catheter (FEC). According to the applicant in 2018, the PDAC responded to a coding verification request for various items of the PureWick System. The applicant believes that HCPCS codes exist for other components of the PureWick System: Collection Canister; A5102; Patient Tubing; A4331; PureWick FEC; A4328.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code KXXXX "Suction pump, home model, portable or stationary, electric, any type for use with external urine management system"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS preliminary recommendation.

FINAL DECISION

CMS adopted its preliminary Level II HCPCS coding recommendation. Establish new Level II HCPCS code K1006 "Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system".

Effective: 10/01/2020

REQUEST # 20.079

TOPIC

Request to establish a new Level II HCPCS code to identify "HipTrac".

Applicant's suggested language: “Hip (femoral-acetabular) joint traction equipment (e.g. HipTrac)”

BACKGROUND

MedRock, Inc. submitted a request to establish a new Level II HCPCS code to identify the "HipTrac" device. Specifically, MedRock, Inc. is requesting the creation of one new HCPCS code for HipTrac, a Hip (femoral-acetabular) joint traction medical device used in the treatment of pain and joint capsule restriction commonly associated with hip osteoarthritis. According to the applicant, the HipTrac replicates the manual therapy technique in clinics by physical therapists, physicians and chiropractors, it is independent – used by the patient at home between visits and after discharge from the clinic to decrease pain while increasing mobility and exercise – tolerance of the patient. The applicant stated that PDAC and HCPCS do not just place products by the title description alone, but rather evaluates the primary and customary medical use, therapeutic distinctions, mechanical engineering and capable predicates. Existing HCPCS code E0880 was established 26 years ago and provides the example Bucks Traction as a device that would be under this code. Bucks use 15 lbs. of force HipTrac uses 90 – 180lbs. of force. FDA Class 1 First Marketed June 2013, primary setting patient home.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing Level II HCPCS code E0880 "Traction stand, free standing, extremity traction, (e.g., buck's)” adequately describes the HipTrac.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that the manufacturer twice requested different coding from the PDAC and the request was denied each time. The speaker commented that existing code EO880 “definitely describes HipTrac, the problem is reimbursement. It pays $150, but costs $250 - $300 to mfr., and price is $895 - $995”. A new code is needed to create access. The speaker also commented that clinical indications and outcomes are different than for the HipTrac. Asked if the word “Bucks” were to be removed from the existing code, would the remaining words describe HipTrac”, the speaker replied affirmatively.

FINAL DECISION

CMS re-reviewed this application with all information provided at CMS' June 2, 2020 HCPCS public meeting, and modified its decision. Now that we are aware of at least two products described by existing code E0880, the inclusion of the example “buck’s” is no longer appropriate and may cause confusion in the marketplace. To clarify that use of the example “(e.g., buck’s)”

was never intended to indicate exclusivity to buck’s traction, CMS revised Level II HCPCS code category E0880 which currently reads: "Traction stand, free standing, extremity traction, (e.g., buck's)” to eliminate the parenthetical “(e.g., buck’s)”, and to instead read: "Traction stand, free standing, extremity traction". Revised code E0880 adequately describes the HipTrac.

REQUEST # 20.080

TOPIC

Request to establish a new Level II HCPCS code to identify the MolecuLight i:X. See also Request number 20.092 for the MolecuLight DarkDrape supply associated with the use of the MolecuLight i:X device).

Applicant's suggested language: “MolecuLight i:X real-time hand-held non-contrast fluorescent imaging device; tissue; bacterial presence, location and load”.

BACKGROUND

Request submitted on behalf of MolecuLight, Inc. to establish a new Level II HCPCPS code to identify the MolecuLight i:X™ Fluorescence Imaging Device, to describe the unique device enabling a medically necessary procedure.

According to the applicant, the MolecuLight i:X Fluorescence Imaging Device received FDA marketing clearance on December 04, 2019 as a 510(k) Class II device. The MolecuLight i:X™ Fluorescence Imaging Device is a real-time handheld non-contrast fluorescence imaging device that visualizes tissue to detect bacteria in wounds at loads >104 CFU/g (colony-forming units per gram), enabling improved wound treatment. Presence of bacteria is known to prevent wound healing. The i:X’s fluorescence image, when used in combination with clinical signs and symptoms (CSS), has demonstrated an increased likelihood that clinicians can identify wounds containing bacterial loads of >104 CFU/g and make treatment changes as compared to examination of CSS alone. This new, real-time imaging option is gaining significant acceptance among clinicians due to its novel ability to identify bacteria at clinically important levels: it is the only device to provide evidence of the presence, location and load of bacteria when clinicians are assessing the wound or tissue bed, changing treatment decisions, leading to improved outcomes for patients with acute or chronic wounds. Evidence demonstrates when used in clinic settings, the MolecuLight i:X leads to cost effective bacterial management, resulting in reduced healing times, less laboratory tests, and improved antibiotic stewardship. There is no code in the 2020 HCPCS code descriptions for the MolecuLight i:X device. For the first time, clinicians have a device that can identify in real-time bacterial location and load, improving the management of wounds. Clinicians are requesting one code to bill for the use of the device to identify the presence, location and load of bacteria (pricing indicator 34).

PRELIMINARY HCPCS CODING RECOMMENDATION

It is our understanding that the item that is the subject of this application is factored into the practice expense 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 commented that the MolecuLight i:X device performs a unique function and discussed the use and efficacy of the MolecuLight i:X device; and specifically, that use of the device provides point-of-care feedback (e.g., as opposed to or sooner than awaiting lab results of a culture); enables validation with certainty that a wound is "infection free"; identifies with certainty, bacterial presence and pathogenicity; impacts wound healing; and that the MolecuLight i:X device and the DarkDrape accessory "provide real-time information for treatment planning leading to healing" and are "separate from physician work".

FINAL DECISION

We appreciate the comments provided at CMS' HCPCS Public Meeting in reaction to our published preliminary recommendation. It is our understanding that to the extent the MolecuLight i:X is used in a procedure, it is considered to be part of the Medicare payment to the practitioner or the facility, depending on setting of use. For additional details and coding guidance, CMS refers the applicant to the American Medical Association (AMA).

REQUEST # 20.081

TOPIC

Request to establish a new Level II HCPCS code to identify Orpyx SI Sensory Insole system, (previously named “Surrosense”).

Applicant's Suggested language: "For diabetics only, multiple density insert, made by direct carving with cam technology from a rectified cad model created from a digitalized scan of the patient, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material, includes all components of plantar sensing system (pressure sensors, temperature sensors, motion sensor and wireless enabled electronics), custom fabricated, each."

BACKGROUND

Orpyx Medical Technologies Inc., submitted a request to establish a new Level II HCPCS code to identify Orpyx SI Sensory Insole system. Specifically, Orpyx Medical Technologies Inc. is requesting the creation of one new HCPCS code for Orpyx SI Sensory Insole system as described below: A5514, but also include sensor that monitor pressure temperature, and activity which can provide real-time audiovisual alerts. According to the applicant, the descriptor of the new HCPCS code would be: For diabetics only, multiple density insert, made by direct carving with cam technology from a rectified cad model created from a digitized scan of the patient Orpyx SI Sensory Insole system is prescribed by physicians and attempt to prevent plantar foot ulcerations in the most vulnerable patient population. Patient who are at higher risk to develop foot ulcers and other pedal pathology use this system

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A5514 "For diabetics only, multiple density insert, made by direct carving with cam technology from a rectified cad model created from a digitized scan of the patient, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each" adequately describes the insole; and existing code and A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the sensors and electronics. These codes are available for use by insurers if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary coding recommendation, and reiterated the request for a new code on the basis that: live feedback, pressure, and sensor monitoring are not captured in existing code A5514; that existing code A9279 does not precisely describe a product that is wireless enabled, with mobile downloads, AC adaptor, and charging cables; and that use of two codes to describe one device could result in administrative error, administrative burden, and does not foster innovation.

FINAL DECISION

Following the HCPCS public meeting CMS re-reviewed this application with all the new information provided and adopted its preliminary coding recommendation. Existing code A5514 "For diabetics only, multiple density insert, made by direct carving with cam technology from a rectified cad model created from a digitized scan of the patient, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each" adequately describes the insole; and existing code and A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the sensors and electronics.

At this time, these existing two codes offer insurers the capability to adequately process claims.

The FDA has advised CMS that the Orpyx SI Sensory Insole system may not fall under the FDA class II exemption specified by the applicant. We recommend that the manufacturer have further consultation with FDA regarding the appropriate market approval pathway.

REQUEST # 20.082

TOPIC

Request to revise existing Level II HCPCS code A4467 “Belt, strap, sleeve, garment, or covering, any type” to include the company’s name change from Med Zip UP to Medcross Products LLC.

BACKGROUND

Medcross Products, LLC. Submitted a request to revise existing Level II HCPCS code A4467 “Belt, strap, sleeve, garment, or covering, any type”. According to applicant, A4467 is for Med Zip Up Inc. and request to change the name to Medcross Products LLC. The company has changed its name. Name change may be corrected in the CMS system and listed in code system during the next update. Medcross Products, LLC states their uniforms and other clothing protect patients from getting infections at home and in the hospital or nursing homes. Medcross jacket design is the only jacket on the market that is universal allowing access to a portal wherever it may be. Use of a double ended zipper for Hickman Catheter at the neck, simply unzip from the neck, the side of where the portal is located. To access the fistula, simply unzip at the sleeve cuff to allow access to the portal in the forearm while the antimicrobial spikes create a protective barrier from infectious disease during the administering of dialysis treatment. First marketed September 8, 2018 Class II medical device.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4467 "Belt, strap, sleeve, garment, or covering, any type" as established in 2017 to identify "med zip up" and other similar products adequately describes this product.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

None offered.

FINAL DECISION

Having received no comments via our public meeting procedures, CMS adopted its preliminary recommendation. Existing code A4467 "Belt, strap, sleeve, garment, or covering, any type" as established in 2017 to identify "med zip up" and other similar products adequately describes this product.

REQUEST # 20.083

TOPIC

Request to establish a new Level II HCPCS code to identify the Virtual Exercise Rehabilitation Assistant (VERA)

Applicant's suggested language: “Monitoring Feature/device, stand alone or integrated, to sport virtual physical rehabilitation, includes 3D markerless motion technology for clinician review of quality/completion of physical therapy exercises with patient progress via video records, synchronous telemedicine visits (tele-rehabilitation), report generation, and real-time patient performance feedback”.

BACKGROUND

Reflexion Health, Inc. submitted a request to establish a new Level II HCPCS code to identify Virtual Exercise Rehabilitation Assistant (VERA) device. According to the applicant, VERA is a software system used with Microsoft Kinect v2 intended to support the physical rehabilitation of adults in the clinic at home. The system includes rehabilitation exercises for the upper extremity, trunk and lower extremity with the audio-visual feedback & graphic movement representations for patients as well as remotely accessible patient performance video. Patient assessment, exercise guidance and approval by medical professional is required prior to use. Patients are provided an all-inclusive kit (monitor, cellular wireless access point, 3D motion sensing camera) to enable real accountability while a patient is doing their exercise. The device is FDA Class II, first marketed October 30, 2015

PRELIMINARY HCPCS CODING RECOMMENDATION

It is our understanding that the item that is the subject of this application is factored into the practice expense. 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

None offered.

FINAL DECISION

Following the HCPCS Public Meeting, CMS re-reviewed this application with all new information provided and adopted its preliminary coding recommendation as a final decision. For additional details and coding guidance, CMS refers the applicant to the American Medical Association (AMA).

REQUEST # 20.084

TOPIC

Request to revise the description of L2006 "Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated", to instead read “Knee-ankle-foot-orthosis, any material, single or double upright, swing and stance phase microprocessor hydraulic control, stumble recovery feature, adjustable stance flexion feature, adjustable stance extension dampening feature, includes all components (sensors, batteries, and charger), with or without ankle joint(s), custom fabricated".

BACKGROUND

Ottobock, is requesting HCPCS modification for (L2006) Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated". Specifically, Ottobock is requesting modification of HCPCS code for C-Brace as described below: L2006: Knee ankle foot orthosis, any material, single or double upright, swing and stance phase microprocessor hydraulic control, stumble recovery feature, adjustable stance flexion feature, adjustable stance extension dampening feature, includes all components (e.g., sensor, batteries, and charger), with or without ankle joint(s), custom fabricate. According to the applicant, the C-Brace is a microprocessor swing and stance phase control orthosis consisting of a fully microprocessor controlled hydraulic knee joint unit. The knee joint is non powered, passive hydraulic unit where one hundred percent of the propulsive energy comes from the patient. The microprocessor controlled knee joint is mounted on the lateral side of orthosis, and the orientation of the joint unit in the frontal plane is fixed with the medial following joint. Depending on the patient’s needs, two design variations of the lower leg component have been developed. Class I exempt from 510K First marketed March 27, 2012.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code L2006 to read: “Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor fluid control, any type, includes all components (e.g., sensors, batteries, charger), with or without ankle joint(s), custom fabricated”. This revision clarifies that code L2006 adequately describes the product that is the subject of this application.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

OttoBock disagreed with CMS proposed revision, and reiterated its 2020 request to revise L2006 to specify proprietary method of control (hydraulic fluid); and to enumerate within the code features of the product that are afforded by microprocessor control. Ottobock also reiterated the request to specify in code text that the product is an orthotic.

FINAL DECISION

CMS considered all input provided at the June 1, 2020 HCPCS public meeting with the incoming application and supplemental material provided by Ottobock. CMS' decision is to uphold original code language for L2006 as published in 2019, which reads: "Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated"; and adequately describes the C-Brace. The essential function of the C-Brace is using a microprocessor with sensors to affect swing and stance function. Stumble recovery is included in the swing functionality. The stance flexion capability is included in stance phase microprocessor control.

REQUEST # 20.085

TOPIC

Request to establish a new Level II HCPCS code to identify a “wearable, motorized, personal lower body prosthetic exoskeleton system with adjustable ankle joint”. Trade name: ReWalk Personal Prosthetic Exoskeleton System. Note: In accordance with its FDA clearance, this device must be used only with a trained, constant companion.

Applicant's suggested language: “Lower body prosthetic wearable motorized and computerized exoskeleton system with adjustable ankle joint; for home and community use”

BACKGROUND

ReWalk Robotics submitted a request to establish a new Level II HCPCS code to identify wearable, motorized, computerized, personal lower body prosthetic exoskeleton system with adjustable ankle joint (e.g., “ReWalk). According to the applicant, the “prosthetic wearable, motorized, computerized exoskeleton” is used by individuals with lower body paralysis due to spinal cord injury (SCI) to restore the function of motor movement controlled by the spinal cord. The prosthetic wearable computerized exoskeleton enables individuals with SCI to stand upright and walk again. SCI users can “independently” control walking initiation, speed, and direction through a combination of controller commands and shifts in their body weight. The prosthetic computerized exoskeleton is used by individuals at home and in the community. Users are able to return to activities of daily living and work. Importantly, prosthetic exoskeleton systems help alleviate the adverse health consequences associated with SCI and the secondary medical conditions due to chronic sedentary behavior by restoring functional ambulation both at home and in the community. According to applicant, there is no HCPCS code to describe a prosthetic wearable, motorized, computerized exoskeleton system with adjustable ankle joint. Miscellaneous codes, including L2999, have been used. However, miscellaneous codes do not accurately describe this unique personal prosthetic exoskeleton system. Miscellaneous codes also create administrative billing challenges and thus barriers to access for individuals needing the prosthetic computerized exoskeleton system.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code KXXXX "Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker offered comments in agreement with CMS published preliminary coding decision to establish a new code, and with CMS recommended code language.

FINAL DECISION

Establish a new Level II HCPCS code K1007 "Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors".

Effective: 10/01/2020

REQUEST # 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)"

BACKGROUND

Cala Health, Inc. submitted a request to establish a new Level II HCPCS code to identify the Cala Trio nerve stimulating device. According to the applicant, the Cala Trio device is provided with two components: a 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. The 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.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing HCPCS code E0720 "Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation" adequately describes the Cala Trio device.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation. The speaker stated that the Cala Trio is a prescription-only item of durable medical equipment that is FDA-cleared for the specific indication of relieving symptoms of essential tremor in the upper limbs. The Cala Trio is not accurately described by HCPCS codes E0720 and A4595, per CMS' preliminary coding recommendation. The Cala Trio satisfies CMS' published criteria for issuance of unique Level II HCPCS codes: it performs a significantly different function than technologies described by HCPCS codes E0720 and A4595 by treating symptoms of essential tremor, not pain, through stimulation that interrupts CNS tremor signals; it operates differently from devices described by HCPCS codes E0720 and A4595, delivering Transcutaneous Afferent Patterned Stimulation (TAPS) and using on-board motion sensors to deliver patient-calibrated therapy; and it results in significantly superior clinical outcomes for relief of essential tremor – in the short-term and long-term – compared to devices described by HCPCS codes E0720 and A4595.

FINAL DECISION

This application is deferred for additional consideration in the next coding BiAnnual cycle. As nerve stimulation technology is evolving, CMS welcomes a broader conversation by this manufacturer and others to identify potential distinctions in nerve stimulation technology, both between TENS devices and for nerve stimulation technology generally, to consider coding trajectory and appropriate granularity in coding. We are interested in innovator views on key distinguishing factors between the devices that provide transcutaneous electrical nerve stimulation, and how to best categorize such products for the purpose of reporting to insurers that recognizes innovative technology consistent with the HCPCS decision making process and the maintenance of a practical code set for the use of insurers.

REQUEST # 20.087

TOPIC

Request to establish a new Level II HCPCS code to identify a supply associated with the Cala Trio device. Applicant's suggested language: "Wrist-worn connectors for use with transcutaneous afferent patterned stimulation device"

BACKGROUND

Cala Health, Inc. submitted a request to establish a new Level II HCPCS code to identify Cala Trio Wrist-Worn Connector. According to the applicant, 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. The 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.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4595 "Electrical stimulator supplies, two lead, per month, (e.g., TENS, NMES)" adequately describes the wrist worn connectors for use with the Cala Trio device.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that supplies associated with use of the Cala Trio device (see application 20.086 (above)) are not accurately described by existing code A4595; the device, and hence the supplies, perform a significantly different function by treating symptoms of essential tremor, not pain; the supplies operate differently than supplies coded at A4595, in that they deliver differently patterned stimulation and also use motion sensors to deliver calibrated therapy. And in addition, use of the supplies confer a significantly superior clinical outcome for relief of essential tremor compared to use of products coded at A4595.

FINAL DECISION

This application is deferred for additional consideration in the next BiAnnual coding cycle. As nerve stimulation technology is evolving, CMS welcomes a broader conversation by this manufacturer and others to identify potential distinctions in nerve stimulation technology, both between TENS devices and for nerve stimulation technology generally, to consider coding trajectory and appropriate granularity in coding. We are interested in innovator views on key distinguishing factors between the devices that provide transcutaneous electrical nerve stimulation, and how to best categorize such products for the purpose of reporting to insurers that recognizes innovative technology consistent with the HCPCS decision making process and the maintenance of a practical code set for the use of insurers.

REQUEST# 20.088

TOPIC

Request to establish a new LEVEL II HCPCS code to identify a UAV/UAS unmanned aerial vehicle/unmanned aerial system, (drone).

BACKGROUND

Unmanned Systems Operations Group (USOG) submitted a request to establish a new Level II HCPCS code to identify a UAV/UAS (unmanned aerial vehicle/ unmanned aerial system).

According to the applicant the time required to process the delivery request is A) Expedited- within 1 hour; B) Urgent- within 24 hours and C) Routine- within 72 hours and can be monitored such as if the package requires temperature control, shock monitoring and/or any other special handling. The Workhorse UAS is the HorseFly system designed, developed and fully tested by Workhorse. It is a custom built, high efficiency hexacopter-based delivery UAS that conforms to the FAA guidelines for UAV operation in the US and can be fully integrated with delivery trucks. The function of the product is to offer another delivery mode option, especially to areas difficult to reach by ground transport. As per the applicant, existing codes do not adequately describe the product because it is new technology and is just being tested for use throughout the medical sector.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS did not identify a claims processing need on the part of any government or non-government insurance sector to establish a code to separately identify on a claim, transportation or delivery of medical supplies.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

None offered.

FINAL DECISION

CMS adopted its preliminary HCPCS coding recommendation. CMS did not identify a claims processing need on the part of any government or non-government insurance sector to establish a code to separately identify on a claim, transportation or delivery of medical supplies.

REQUEST # 20.089

TOPIC

Request to establish a new Level II HCPCS code to identify concentrated platelets in fibrin membrane graft without thrombin, Trade Name: Fibrinet.

BACKGROUND

Royal Biologics submitted a request to establish a Level II HCPCS code to identify Fibrinet. According to the applicant, the Fibrinet system provides intact, concentrated platelets in a platelet-rich fibrin membrane graft without thrombin to be applied for soft tissue and bone defects. The fibrinet system is intended to be used at point-of-care for the safe and rapid preparation of platelet-rich-plasma (PRP) membrane from a small sample of a patient’s own peripheral blood.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code G0460 "Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment" and CPT 0232T "Platelet rich plasma injections" adequately describe the Fibrinet system procedure and administration of dressing are available for assignment by insurers to describe preparation procedures and administration (respectively). Existing code P9020 "Platelet rich plasma, each unit" is also available for assignment by insurers if they deem appropriate to identify the platelets.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

None offered.

FINAL DECISION

Having received no comment at our HCPCS public meeting, CMS adopted its preliminary recommendation. As previously conveyed to the applicant, existing code G0460 "Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment" and CPT 0232T "Platelet rich plasma injections" adequately describe the Fibrinet system procedure and administration of dressing are available for assignment by insurers to describe preparation procedures and administration (respectively). Existing code P9020 "Platelet rich plasma, each unit" is also available for assignment by insurers if they deem appropriate to identify the platelets.

REQUEST # 20.090

TOPIC

Request to establish three new Level II HCPCS codes to identify the Chaplain spiritual care.

Applicant's suggested language: 1) Chaplain Pastoral/ Spiritual Assessment Services in a Healthcare Setting, each 15 minutes; 2) Chaplain Individual Services in a Healthcare Setting, each 15 minutes; 3) Chaplain Group Services in a Healthcare Settings, each 15 minutes.

BACKGROUND

United States Department of Veterans Affairs National VA Chaplaincy submitted a request to establish three new Level II HCPCS codes to identify the Chaplain spiritual care. The primary purpose of Chaplain spiritual care is to provide in-depth spiritual and pastoral care and counseling, which is highly integrated into the total care and treatment program. Chaplains provide a full range of spiritual and pastoral care and counseling that is characterized by in-depth assessment, evaluation and treatment of patients often with many different physical, social, mental and spiritual needs as part of an integrated and comprehensive bio-psycho-social-spiritual approach, assessing a patient's intrinsic and extrinsic spirituality, ascertaining spiritual preference and practices, exploring and determining patient's spiritual health, coping mechanisms, well-being, and developing goals of spiritual care unique to a patient's needs and family/care giver support. The chaplain also provides consultation, counseling and support to family members and staff. Professional chaplains are clinically trained to provide this type of spiritual care.

PRELIMINARY HCPCS CODING RECOMMENDATION

In that the Department of Veteran's Affairs is using its authority to specifically include Chaplain services in medical services:

1. Establish new Level II HCPCS code XXXXX "Assessment by Department of Veterans Affairs chaplain services "

2. Establish new Level II HCPCS code XXXXX "Counseling, individual, by Department of Veterans Affairs chaplain services"

3. Establish new Level II HCPCS code XXXXX "Counseling, group, by Department of Veterans Affairs chaplain services"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

CMS received comments in full support of its preliminary recommendation.

FINAL DECISION

In that the Department of Veterans Affairs is using its authority to specifically include clinically trained Chaplains in their provision of medical services to veterans:

1. Establish new Level II HCPCS code Q9001 "Assessment by Department of Veterans Affairs chaplain services "

2. Establish new Level II HCPCS code Q9002 "Counseling, individual, by Department of Veterans Affairs chaplain services"

3. Establish new Level II HCPCS code Q9003 "Counseling, group, by Department of Veterans Affairs chaplain services"

Effective: 10/01/2020

Note that this file was updated by CMS on July 24, 2020, to reflect correction to the codes previously published for Department of Veterans Affairs Chaplain services. The final, corrected code assignments are Q9001, Q9002 and Q9003, as included at the FINAL DECISION for item for item 20.090 (above). Codes Q9001, Q9002 and Q9003 replace previously published codes Q4251, Q4252 and Q4253, respectively.

REQUEST # 20.092

TOPIC

Request to establish a new Level II HCPCS code to identify MolecuLight i:X DarkDrape. See also Request number 20.080 for the MolecuLight i:X device associated with use of the DarkDrape supply).

Applicant's suggested language: “MolecuLight i:X DarkDrape one wound use only, each wound”

BACKGROUND

Request submitted on behalf of MolecuLight, Inc. to establish a new Level II HCPCPS code to identify MolecuLight i:X. DarkDrape supply item enabling a medically necessary procedure. According to the applicant, the MolecuLight DarkDrape® received marketing clearance on December 04, 2019 as a 510(k) Class II device. The MolecuLight DarkDrape® creates optimal imaging for physicians using the MolecuLight i:X when room lights cannot be turned off. The i:X’s fluorescence image, when used in combination with clinical signs and symptoms (CSS), has demonstrated an increased likelihood that clinicians can identify wounds containing bacterial loads of >104 CFU/g and make treatment changes as compared to examination of CSS alone. This new, real-time imaging option is gaining significant acceptance among clinicians due to its novel ability to identify bacteria at clinically important levels: it is the only device to provide evidence of the presence, location and load of bacteria when clinicians are assessing the wound or tissue bed, changing treatment decisions, leading to improved outcomes for patients with acute or chronic wounds. According to the applicant, evidence demonstrates when used in clinic settings, the MolecuLight i:X leads to cost effective bacterial management, resulting in reduced healing times, less laboratory tests, and improved antibiotic stewardship and when used with ambient light it is not dark for the fluorescence to image the bacteria hence the physician is unable to observe the presence of bacteria. As per the applicant, there is no code in the 2020 HCPCS code descriptions for the MolecuLight DarkDrape, or their function. For the first time, clinicians have a device that can identify in real-time bacterial location and load, improving the management of wounds. Clinicians are requesting one code for the use of the dark drape (pricing indicator 32).

PRELIMINARY HCPCS CODING RECOMMENDATION

It is our understanding that the item that is the subject of this application is factored into the practice expense 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 DarkDrape is a single-use, single wound, disposable accessory to the Moleculight i:X device (see application 20.080, above). The DarkDrape is placed over the wound to block light (e.g.,

when the room itself cannot be sufficiently darkened), which is essential for fluorescent imaging of the wound by the MolecuLight device.

FINAL DECISION

We appreciate the comments provided at CMS' HCPCS Public Meeting in reaction to our published preliminary recommendation. It is our understanding that to the extent the MolecuLight i:X DarkDrape is used in a procedure, it is considered to be part of the Medicare payment to the practitioner or the facility, depending on setting of use. For additional details and for coding guidance, CMS refers the applicant to the American Medical Association (AMA).