Centers for Medicare & Medicaid Services (CMS)
Agenda for Healthcare Common Procedure Coding System (HCPCS) Public Meeting for code applications for Durable Medical Equipment (DME) and Accessories; Orthotics and Prosthetics (O & P); Supplies and Other Non-Drug and Non-Biological items and services submitted to CMS' first 2020 biannual HCPCS coding cycle

WebEx Meeting, for remote participation only

Monday, June 1, 2020
9:00 am – 5:00 pm

8:45 a.m. Webex Meeting Login

9:00 a.m. Welcome
Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS's preliminary coding recommendation is provided. Preliminary recommendations are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Final coding decisions will be published on CMS HCPCS web site at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCS-Coding-Decisions **on or about July 1, 2020, and will be effective October 1, 2020, unless otherwise specified.**

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

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 1

Application # 20.063

Request to add the product ENU Pro3+ to existing code B4153. As per applicant the code B4153 describes ENU Pro3+.

Agenda Item # 2

Application # 20.064

Request to establish a new HCPCS Q and/or G codes to identify the SUTUREGARD ISR (Intraoperative Skin Relaxation) device.

Agenda Item # 3

Application # 20.065

Request to establish a new Level II HCPCS code to identify the BioFlo AutoValve.

Agenda Item # 4

Application # 20.066

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

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 5

Application # 20.067

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

Agenda Item # 6

Application # 20.068

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

Agenda Item # 7

Application # 20.069

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

Agenda Item # 8

Application # 20.070

Request to establish a new Level II HCPCS for Monarch External Trigeminal Nerve Stimulation (eTNS) System.

Application # 20.071

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

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 9

Application # 20.086

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

Application # 20.087

Request to establish a new Level II HCPCS code to identify a wrist-worn connector, supply for use with the Cala Trio device.

Agenda Item # 10

Application # 20.073

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

Agenda Item # 11

Application # 20.074

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

Agenda Item # 12

Application # 20.075

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

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 13

Application # 20.080

Request to establish a new Level II HCPCS codes to identify MolecuLight i:X

Application # 20.092

Request to establish a new Level II HCPCS code for MolecuLight i:X Dark Drape

Agenda Item # 14

Application # 20.084

Request to revise the description of existing code L2006, which currently 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", 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".

Agenda Item # 15

Application # 20.085

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

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 16

Application # 20.072

Request to establish two new Level II HCPCS codes, one each to identify ORBERA intra-gastric Balloon placement and removal procedures:

Agenda Item # 17

Application # 20.088

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

Agenda Item # 18

Application # 20.089

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

Agenda Item # 19

Application # 20.090

Request to establish three new Level II HCPCS code to identify Department of Veteran's Affairs Chaplain services.

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 1

Application # 20.063

TOPIC

Request to add the product ENU Pro3+ to existing code B4153. As per the applicant, code B4153 describes ENU Pro3+.

SUMMARY

Trovita Health Science, on behalf of Ajinomoto Cambrooke, Inc. (ACI) submitted a request for HCPCS code recognition of its product ENU® Pro3+ Powdered Energy Source for Oral or Enteral Use (Trademarked as ENU® Pro3+) as a new formula for enteral feeding.

According to the applicant, existing HCPCS II 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 = 1unit. ENU® Pro3+ Powdered Energy Source for Oral or Enteral Use (Trademarked as ENU® Pro3+) 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. ENU® Pro3+ is a medical food, not a drug or biologic; therefore, no mechanism of action is provided. ENU® Pro3+ is a medical food administered orally or through a feeding tube. 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.

While CMS believes that existing codes, as indicated above, describe the products that are the subjects of this request, as a general rule, CMS does not assign individual products to existing

codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 2

Application # 20.064

TOPIC

Request to establish new HCPCS Q and/or G codes to identify the SUTUREGARD ISR (Intraoperative Skin Relaxation) device and procedure.

The applicant did not suggest any specific language.

SUMMARY

SUTUREGARD Medical, Inc. has submitted an application requesting new HCPCS Q and/or G-codes for SUTUREGARD® ISR (Intraoperative Skin Relaxation) Device. According to the applicant, the SUTUREGARD ISR 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 one Q code to cover the SUTUREGARD® ISR device cost; and one G code to cover the ISR procedure. Current HCPCS code A4649 doesn't account for patient value brought by the SUTUREGARD® ISR device. Please consider negative pressure wound therapy (NPWT) as a predicate clinical entity similar to ISR, awarded both product and procedure codes.

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).

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 3

Application # 20.065

TOPIC

Request to establish a new Level II HCPCS code to identify the BioFlo AutoValve.

The applicant did not suggest any specific language.

SUMMARY

The Wells Health Group, on behalf of BioFlo, LLC, is submitted a second request for a new unique HCPCS code for the BioFlo® AutoValve. According to the 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.). 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 over mold and plunger engage, stopping the floating magnet from separating from the fixed magnet. The innovate 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 there is a claims processing need to uniquely or separately identify the BioFlo AutoValve auto-release release feature. The bench study provided with this application is insufficient to support the applicant’s claim of Significant Therapeutic Distinction when the BioFlo AutoValve is used, compared with standard of care, specifically, that the AutoValve provides a “closed” system and that its use prevents microbial colonization in the bladder.

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 4

Application # 20.066

TOPIC

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

Applicant's suggested language: “AXXXX, Alfred SmartBag, each”

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 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.

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 5

Application # 20.067

TOPIC

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

Applicant's suggested language: “AXXXX, Vaginal Speculum retraction sleeve, disposable each”

SUMMARY

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).

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 6

Application # 20.068

TOPIC

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

The applicant did not suggest any specific language.

SUMMARY

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). As applicant stated, Nu Bandage is specifically formulated to be microbial-resistant (please refer to CFU resting), 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.

While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For

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

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June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 7

Application # 20.069

TOPIC

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

The applicant did not suggest any specific language.

SUMMARY

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 first and only available that is 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 single new HCPCS code is requested to reimburse for the usage 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. According to the applicant, existing code for differential cell counters only cover lab based analysis conducted in batches on large venous tubes of blood and therefore do not cover the costs associated with the rapid microfluidic test strip that enables the test to be conducted with in minutes in near patient settings. As per applicant, the costs associated with operating the device in POC by a HCP along with the connection to the cloud based infrastructure for algorithmic analysis are not covered by existing codes.

PRELIMINARY HCPCS CODING RECOMMENDATION

On 2/24/2020, 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 CLFS of new, FDA approved lab tests.

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 8

Application # 20.070

TOPIC

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

The applicant did not suggest any specific language.

SUMMARY

The applicant requests the addition of a new code to the HCPCS code set for a non-implantable trigeminal nerve stimulation device. According to the applicant, this device is used 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.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code E0720, "Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation" adequately describes this device. CMS notes that the code is non-specific for indication.

While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For

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

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June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 8

Application # 20.071

TOPIC

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

The applicant did not suggest any specific language.

SUMMARY

The applicant requests to establish a new Level II HCPCS code for disposable electric patches for use with 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.

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.

While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For

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

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June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 9

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)"

SUMMARY

According to the applicant, 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.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing HCPCS code E0720 "Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation" adequately describes this device. CMS notes that the code is non-specific for indication.

While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 9

Application # 20.087

TOPIC

Request to establish a new Level II HCPCS code to identify wrist worn connectors, a supply for use with the Cala Trio device.

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

SUMMARY

Cala Health, Inc. submitted a request to establish a 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. 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.

While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735- 1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may

request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 10

Application # 20.073

TOPIC

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

The applicant did not suggest any specific language.

SUMMARY

Columbia-Inland Corporation submitted a request to establish Level II HCPCS code to identify the pumper car. According to the applicant, 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.

While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735- 1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists

individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 11

Application # 20.074

TOPIC

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

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

SUMMARY

Johnson and Johnson Vision Care, Inc. submitted a request for HCPCS Level II code to identify ACUVUE OASYS Contact Lenses with Transitions. According to the applicant, 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 bright light indoors and out.

PRELIMINARY HCPCS CODING RECOMMENDATION

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

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 12

Application # 20.075

TOPIC

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

Applicant's suggested language: TXXXX, Habilitation, prevocational, waiver, 15 minutes.

SUMMARY

Minnesota State department of health services submitted a request to establish 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”

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 13

Application # 20.080

TOPIC

Request to establish a new Level II HCPCS code to identify MolecuLight i:X device.

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

SUMMARY

The Institute for Quality Resource Management/Vantage View, on behalf of MolecuLight, Inc., has submitted an application for a new HCPCS code for the MolecuLight i.X™ Fluorescence Imaging Device, to describe the unique device enabling a medically necessary procedure. The recommended HCPCS language is: AXXXX – MolecuLight i:X real-time hand-held non-contrast fluorescent imaging device; tissue; bacterial presence, location and load.

MolecuLight i.X™ Fluorescence Imaging Device received 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). The MolecuLight i.X™ Fluorescence Imaging Device and the MolecuLight DarkDrape® are not drug/biologics, therefore items E-I do not apply.

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).

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 13

Application # 20.092

TOPIC

Request to establish a new Level II HCPCS code to identify the MolecuLight i:X DarkDrape, a supply for use with the MolecuLight i:X device.

Applicant's suggested language: AXXX1 MolecuLight i:X DarkDrape one wound use only, each wound

SUMMARY

The Institute for Quality Resource Management/Vantage View, on behalf of MolecuLight, Inc., has submitted an application for a new HCPCPS code for the MolecuLight i:X DarkDrape supply item enabling a medically necessary procedure. The recommended HCPCPS language is: AXXX1 – MolecuLight i:X DarkDrape one wound use only; each wound. 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 code to identify the one code to bill for the one-wound use 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).

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 14

Application # 20.084

TOPIC

Request to revise the description of existing code L2006, which currently 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"; 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".

SUMMARY

Ottobock, is requesting HCPCS modification of existing code L2006, which currently 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"; 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 (e.g., sensor, batteries, and charger), with or without ankle joint(s), custom fabricated”. 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.

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”. It is our understanding that specification of “fluid” control provides a distinction between L2005 and L2006, and also that “fluid” control indicates the individual features (stumble recovery, adjustable stance flexion) as requested by the applicant for inclusion in the code text. The microprocessor language covers the stance and stumble recovery features requested by the

applicant for inclusion in the code text The revised language clarifies that code L2006 adequately describes the product and features that are the subject of the application.

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 15

Application # 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

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

SUMMARY

ReWalk Robotics submitted a request a new HCPCS Level II code to identify wearable, motorized, computerized, personal lower body prosthetic exoskeleton system with adjustable ankle joint (e.g., “ReWalk). 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".

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 16

Application # 20.072

TOPIC

Request to establish two new Level II HCPCS codes, one each to identify endoscopic placement and removal of an intra-gastric balloon. Applicant's suggested language:

1) "Endoscopic placement and filling of intra-gastric balloon device with saline"

2) "Endoscopic deflation and removal of intra-gastric balloon device by release of saline and removal of the device"

SUMMARY

According to the applicant, Orbera is a fluid filled, intra-gastric 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 Orbera 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 months. The expandable design of Orbera permits a fill volume range of 400 cc (minimum) to a maximum of 700 cc.

PRELIMINARY HCPCS CODING 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 detailed information regarding how to apply for codes 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

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 17

Application # 20.088

TOPIC

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

The applicant did not suggest any specific language.

SUMMARY

Unmanned Systems Operations Group (USOG) submitted a request to establish a new Level II HCPCS code for 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 confirm 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.

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 18

Application # 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

Applicant's suggested language: "Fibrinet System, concentrated platelets in fibrin membrane graft without thrombin, for soft tissue and bone grafting defects"

SUMMARY

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.

June 1, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 19

Application # 20.090

TOPIC

Request to establish three new Level II HCPCS code to identify the Department of Veterans Affairs Chaplain services.

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.

SUMMARY

The Department of Veterans Affairs has a unique statutory obligation to provide Chaplaincy 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 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 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"