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

### **Second Biannual, 2021 HCPCS Coding Cycle**

This document presents a summary of each HCPCS code application and CMS' coding decision for each application processed in CMS' Second Biannual 2021 Non-Drug and Non-Biological Items and Services HCPCS code application review cycle. Each individual summary includes the request number; topic; a summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS; CMS' preliminary HCPCS coding recommendation; a summary of the primary speaker's comments at the HCPCS public meeting; and CMS' final HCPCS coding decision. All new coding actions will be effective April 1, 2022, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the April 2022 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at:  
<https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

For inquiries regarding coverage, please contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at  
<https://www.cms.gov/Medicare/Coverage/DeterminationProcess> and  
<https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center>

## **December 1, 2021 Meeting Agenda Items**

### **eXciteOSA Control Unit - HCP210826HY98M**

#### **Topic**

Request to establish a new HCPCS Level II code to identify eXciteOSA Control Unit, and to describe EXXXX + A9279 “Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified”

Applicant’s suggested language: EXXXX “Tongue neuromuscular stimulation control unit for Obstructive Sleep Apnea (OSA), adjustable stimulation, each”

#### **Applicant’s Summary**

Signifier Medical Technologies, LLC (SMT) submitted a request to establish a new HCPCS Level II code to identify eXciteOSA durable control unit. The eXciteOSA device is a tongue neuromuscular stimulation device to treat mild obstructive sleep apnea (AHI 5-15) when prescribed to patients 18 years or older for in-home use. eXciteOSA starter kit consists of a control unit, disposable one-size fits all flexible silicone mouthpiece, and USB-C charger. An adherence coach Smartphone Application with patient specific intensity adjustment may be downloaded from the Apple or Android App Store. eXciteOSA functions by delivering neuromuscular electrical stimulation therapy to the tongue. The therapy is delivered during a wakeful state (typically daytime) to build tongue and upper airway muscle endurance, maintain tongue position during sleep, reduce obstructive sleep apnea events, and potentially mitigate OSA disease progression. A patient operates the device by inserting the mouthpiece into the Control unit, connecting the device to a patient-controlled App, and placing the mouthpiece on the tongue. An existing code is applicable to the integrated Bluetooth communication device for remote patient monitoring: A9279. No HCPCS codes currently exist to describe a tongue neuromuscular stimulation device for OSA. All existing neuromuscular stimulation devices are specific to other treatments and diagnoses. Existing HCPCS used to describe OSA therapies do not apply as they do not describe the eXciteOSA functions or form.

#### **Preliminary CMS HCPCS Coding Recommendation**

Establish new HCPCS Level II code KXXXX, “Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application.”

#### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker agreed with CMS’ HCPCS preliminary recommendation to establish a new HCPCS Level II code. The speaker suggested the device meets a Medicare's definition for durable medical equipment, and therefore supports CMS’ preliminary HCPCS coding recommendation and welcomes the opportunity to collaborate on any coding articles guidance or policies that are forthcoming.

## **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code K1028, "Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application"

We note that we are not taking a position on whether this device meets Medicare's definition of durable medical equipment, but intend to address the benefit category in a future meeting, as announced on our website (<https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center>).

Effective: 4/1/2022

## **eXciteOSA Mouthpiece - HCP2108265Y526**

### **Topic**

Request for a new HCPCS Level II code to identify the eXciteOSA disposable mouthpiece.

Applicant's suggested language: AXXXX, "Tongue neuromuscular stimulation mouthpiece for OSA, with 4 electrodes, each."

### **Applicant's Summary**

Signifier Medical Technologies, LLC (SMT) submitted a request to establish a new Level II code to identify eXciteOSA disposable mouthpiece. The eXciteOSA device is a tongue neuromuscular stimulation device to treat mild obstructive sleep apnea (AHI 5-15) when prescribed to patients 18 years or older for in-home use. eXciteOSA starter kit consists of a control unit, disposable one-size fits all flexible silicone mouthpiece, and USB-C charger. An adherence coach Smartphone Application with patient specific intensity adjustment may be downloaded from the Apple or Android App Store. eXciteOSA functions by delivering neuromuscular electrical stimulation therapy to the tongue. The therapy is delivered during a wakeful state (typically daytime) to build tongue and upper airway muscle endurance, maintain tongue position during sleep, reduce obstructive sleep apnea events, and potentially mitigate OSA disease progression. A patient operates the device by inserting the mouthpiece into the control unit, connecting the device to a patient-controlled App, and placing the mouthpiece on the tongue. A user starts therapy through the app which activates the 4 electrodes in the mouthpiece. No HCPCS codes currently exist to describe a tongue neuromuscular stimulation device for OSA. All existing neuromuscular stimulation devices are specific to other treatments and diagnoses. Existing HCPCSs used to describe OSA therapies do not apply as they do not describe the eXciteOSA functions or form.

### **Preliminary CMS HCPCS Coding Recommendation**

Establish new HCPCS Level II code KXXXX, "Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply."

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker agreed with CMS' HCPCS preliminary recommendation to establish a new HCPCS Level II code. The speaker suggested the device meets Medicare's definition for durable medical equipment, and therefore supports CMS' preliminary HCPCS coding recommendation and welcomes the opportunity to collaborate on any coding articles guidance or policies that are forthcoming.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code K1029, “Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply”

We note that we are not taking a position on whether this device meets Medicare’s definition of durable medical equipment, but intend to address the benefit category in a future meeting, as announced on our website (<https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center>).

Effective: 4/1/2022

## California Department of Healthcare Services - HCP2109021HAKD

### Topic

Request to establish three HCPCS Level II codes to identify skills training and development; financial management, self-directed, waiver; and supports brokerage, self-directed, waiver.

Applicant's suggested language: HXXXX, "Skills training and development, per diem"  
TXXXX "Financial management, self-directed, waiver; per diem" TXXXX "Supports  
brokerage, self-directed, waiver; per diem."

### Applicant's Summary

These codes support the enhanced benefits under the Medi-Cal managed care program known as "In Lieu of Services" which are medically appropriate and cost-effective alternatives to services that can be covered in the State Plan. These services are delivered by provider types or in settings that are not found in traditional State Plan services. Because of the unique provider types and settings, certain HCPCS codes that are available for use in this context include units (i.e. per 15 minutes) that are incompatible and with the capabilities of these provider types and are burdensome for the service environment.

### Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code HXXXX, "Skills training and development, per diem."

Establish new HCPCS Level II code TXXXX, "Financial management, self-directed, waiver; per diem."

Establish new HCPCS Level II code TXXXX, "Supports brokerage, self-directed, waiver; per diem."

### Summary of Primary Speaker Comments at the Public Meeting

No oral or written comments were provided by the applicant or anyone else in response to CMS' published preliminary HCPCS coding recommendation.

### CMS Final HCPCS Coding Decision

CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II codes: H2038, "Skills training and development, per diem"; T2050, "Financial management, self-directed, waiver; per diem"; and T2051, "Supports brokerage, self-directed, waiver; per diem"

Effective: 4/1/2022

## **Dayspring Lite - HCP210903LPG21**

### **Topic**

Request to revise existing HCPCS Level II code E0651.

Existing Code E0651: Pneumatic compressor, segmental home model without calibrated gradient pressure.

Applicant's suggested language: "Compressor, segmental home model without calibrated gradient pressure, or pneumatic and non-pneumatic compressor, segmental home model without calibrated gradient pressure."

### **Applicant's Summary**

Koya Medical, Inc. ("Koya") submitted a request for modification to HCPCS Level II code-E0651. The existing code descriptor restricts the method of compression to "pneumatic." Our request is to modify the E0651 descriptors to accommodate and recognize that compression can be pneumatic or non-pneumatic so that existing code sets accurately describe the items that perform the same clinical function and grouped at the broadest level, which is segmental compression without calibrated gradient pressure. The Dayspring Lite is a non-pneumatic compressor, segmental home model without calibrated gradient pressure and performs the same clinical functions as the pneumatic compressor, segmental home models without calibrated gradient pressure. Both pneumatic and non-pneumatic compressors with the various segmental appliances have identical clinical indications for use, intended patient populations, and perform the same clinical functions delivering the same ranges of therapeutic pressure ranges. In operation, both systems use a compressor and a segmental appliance and are similar in its function and clinical use. When a patient uses the Dayspring Lite compressor in conjunction with the various segmental appliances (full arm, half leg, full leg, etc.), the segmental appliance moves the excess fluid in a rhythmic, distal to proximal manner.

### **Preliminary CMS HCPCS Coding Recommendation**

Establish new HCPCS Level II code KXXXX, "Non-pneumatic compression controller without calibrated gradient pressure."

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker agreed with CMS' HCPCS preliminary recommendation to establish these three new HCPCS Level II codes for Koya Dayspring, as defined as non-pneumatic technology to treat lymphedema of the lower extremities. These three HCPCS Level II codes, if finalized would complement the two HCPCS codes established by CMS in 2021 for the Koya Dayspring controller, as well as the upper extremity garment, K1024 and K1025. Together, these five new HCPCS Level II codes will facilitate patient access to this new technology, which has shown from a clinical standpoint to improve adherence and patient outcomes. In conclusion, the primary speaker expressed a willingness to work with CMS, as well as the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) on coverage policy to ensure beneficiary access to this new technology.

## **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code K1031, "Non-pneumatic compression controller without calibrated gradient pressure"

Effective: 4/1/2022



## **Dayspring - HCP210903PMKF3**

### **Topic**

Request to revise existing HCPCS Level II code E0667, “Segmental pneumatic appliance for use with pneumatic compressor, full leg.”

Applicant’s suggested language: “Segmental appliance for use with compressor, full leg, or Segmental pneumatic and non-pneumatic appliance for use with pneumatic and non-pneumatic compressor, full leg.”

### **Applicant’s Summary**

Koya Medical, Inc. (“Koya”) requests a modification to HCPCS Level II code- E0667. The code description specifically limits the method of compression appliance to “pneumatic.” Our request is to modify the E0667 descriptors to accommodate and recognize that compression can be pneumatic or non-pneumatic so that existing code sets accurately describe the items that perform the same clinical function, which is segmental compression, are accurately described and grouped at the broadest level. The request is to remove the word “pneumatic,” or add the word “non-pneumatic.” The Dayspring segmental appliances perform the same clinical functions as the segmental pneumatic appliances and all Dayspring segmental appliances work with both calibrated gradient and non-calibrated gradient Dayspring compressors. Both segmental pneumatic and non-pneumatic appliances only work in conjunction with their respective compressors and have identical clinical indications for use, intended for the same patient populations, and perform the same clinical functions delivering the same ranges of therapeutic pressure ranges. In operation, both systems use a compressor and a segmental appliance and are similar in its function and clinical use.

### **Preliminary CMS HCPCS Coding Recommendation**

Establish new HCPCS Level II code KXXXX, “Non-pneumatic sequential compression garment, full leg.”

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker agreed with CMS’ HCPCS preliminary recommendation to establish these three new HCPCS Level II codes for Koya Dayspring, as defined as non-pneumatic technology to treat lymphedema of the lower extremities. These three HCPCS Level II codes, if finalized would complement the two HCPCS codes established by CMS in 2021 for the Koya Dayspring controller, as well as the upper extremity garment, K1024 and K1025. Together, these five new HCPCS Level II codes will facilitate patient access to this new technology, which has shown from a clinical standpoint to improve adherence and patient outcomes. In conclusion, the primary speaker expressed a willingness to work with CMS, as well as the DME MACs on coverage policy to ensure beneficiary access to this new technology.

## **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code K1032, "Non-pneumatic sequential compression garment, full leg"

Effective: 4/1/2022

## **Dayspring - HCP210903WBEG8**

### **Topic**

Request to revise existing HCPCS Level II code E0669, “Segmental pneumatic appliance for use with pneumatic compressor, half leg.”

Applicant’s suggested language: “Segmental appliance for use with compressor, half leg, or Segmental pneumatic and non-pneumatic appliance for use with pneumatic and non-pneumatic compressor, half leg.”

### **Applicant’s Summary**

Koya Medical, Inc. (“Koya”) requests a modification to HCPCS Level II code- E0669. The code description specifically limits the method of compression appliance to “pneumatic.” Our request is to modify the E0669 descriptors to accommodate and recognize that compression can be pneumatic or non-pneumatic so that existing code sets accurately describe the items that perform the same clinical function, which is segmental compression, are accurately described and grouped at the broadest level. Our request is to remove the word “pneumatic,” or add the word “non-pneumatic.” The Dayspring segmental appliances perform the same clinical functions as the segmental pneumatic appliances and all Dayspring segmental appliances work with both calibrated gradient and non-calibrated gradient Dayspring compressors. Both segmental pneumatic and non-pneumatic appliances only work in conjunction with their respective compressors and have identical clinical indications for use, intended for the same patient populations, and perform the same clinical functions delivering the same ranges of therapeutic pressure ranges. In operation, both systems use a compressor and a segmental appliance and are similar in its function and clinical use.

### **Preliminary CMS HCPCS Coding Recommendation**

Establish new HCPCS Level II code KXXXX, “Non-pneumatic sequential compression garment, half leg.”

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker agreed with CMS’ HCPCS preliminary recommendation to establish these three new HCPCS Level II codes for Koya Dayspring, as defined as non-pneumatic technology to treat lymphedema of the lower extremities. These three HCPCS Level II codes, if finalized, would complement the two HCPCS codes established by CMS in 2021 for the Koya Dayspring controller, as well as the upper extremity garment, K1024 and K1025. Together, these five new HCPCS Level II codes will facilitate patient access to this new technology, which has shown from a clinical standpoint to improve adherence and patient outcomes. In conclusion, the primary speaker expressed a willingness to work with CMS, as well as the DME MACs on coverage policy to ensure beneficiary access to this new technology.

## **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code K1033, "Non-pneumatic sequential compression garment, half leg"

Effective: 4/1/2022

## **Optimizer Patient Charger - HCP21090362W2D**

### **Topic**

Request to revise existing HCPCS Level II code L8689 “External recharging system for battery (internal) for use with implantable neurostimulator, replacement only.”

Applicant’s suggested language: “External recharging system for battery (internal) for use with implantable medical device, replacement only.”

### **Applicant’s Summary**

Impulse Dynamics, Inc, submitted a request to modify existing HCPCS code L8689. The Optimizer® Smart System delivers Cardiac Contractility Modulation (CCM) therapy, which obtained Food and Drug Administration (FDA) approval in March of 2019 and has been the subject of 90+ peer-reviewed publications. CCM is periodic, high-energy, non-excitatory electrical stimulation of the cardiac muscle with the intent to increase exercise tolerance, functional capacity and quality of life for a subset of heart failure patients with very limited therapeutic options. It reverses the biology of a failing heart. A CCM system consists of a hermetically-sealed implantable pulse generator (IPG) and external battery charging device. Implantation of the system includes placement of two transvenous pacemaker leads into the right ventricular septum and connection of those leads to the IPG. The IPG is then inserted into a subcutaneous pocket, typically located in the right pectoral region. The energy required to deliver CCM therapy exceeds the capacity of any available non-rechargeable battery, necessitating use of a rechargeable battery and external charging unit. Patients receive periodic CCM therapy daily, as programmed by their prescribing physicians, and recharge their device approximately weekly. A typical charging session lasts approximately 45 minutes, during which the device conducts a series of self-checks to confirm appropriate function. Without an external recharging device, a patient’s battery will drain and render a CCM device inoperable after approximately three weeks. In instances where patient loses or damages a patient charger, providers need a means to replace it. While a code exists to describe a CCM system that includes an IPG and an external charger, currently no HCPCS code describes the replacement of the external charging device.

### **Preliminary CMS HCPCS Coding Recommendation**

CMS recognizes that this product is new to the market and the charger may need to be replaced in the event of unanticipated damage or loss that would not be covered in the current 5-year warranty. How have private payers addressed this scenario? How would someone get a charger replaced – from the company directly, a supplier, or a clinician? Is any calibration needed, and if so by whom, when a new charger is used?

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker noted that no replacement chargers have been needed to date. There are approximately 1200 patients in the United States with the device, and they receive a charger on placement. The charger has a 5-year warranty whereas the expected longevity for Cardiac Contractility Modulation device is 15 years. The speaker commented that the battery that charges a rechargeable neurostimulator and CCM device are very similar from the practical, technical and engineering points of view. The speaker also proposed to CMS to revise the

existing HCPCS Level II code L8689, which currently reads, “External recharging system for battery (internal) for use with implantable neurostimulator, replacement only”, to instead read, “External recharging system for battery (internal) for use with implantable medical device, replacement only.”

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS’ published preliminary recommendation. CMS has re-reviewed this application, together with the information provided, and we agree there is no existing code that describes this product. Therefore, CMS has decided to:

Establish new HCPCS Level II code K1030 “External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only”

Effective: 4/1/2022

As a result, CMS will not be revising existing code L8689, as suggested.

## **Portable Neuromodulation Stimulator Controller - HCP210921MV8C5**

### **Topic**

Request to establish a new HCPCS Level II code to identify the Portable Neuromodulation Stimulator (PoNS™) Controller.

Applicant's suggested language: EXXXX "Nonimplantable Translingual Neurostimulation Controller."

### **Applicant's Summary**

Helius Medical, Inc (Helius) submitted a request for the Portable Neuromodulation Stimulator (PoNS™) Controller. PoNS™ device is a translingual, neurostimulation device that is indicated for use as a short-term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and older and is available by prescription only. The PoNS™ device has two primary components - the Controller (which is the subject of this HCPCS application) and the Mouthpiece (which is the subject of a separate HCPCS application). The Controller is a programmable, electronic, durable medical device that, when connected to the Mouthpiece, generates electrical pulses for stimulation of the nerves in the tongue to provide treatment of motor deficits. The Controller includes the primary user interface and electronics for controlling the electro tactile waveform. It sends commands to the Mouthpiece and receives status messages from the Mouthpiece. The PoNS™ device, including the Controller, is intended to be used in the home in conjunction with a supervised therapeutic exercise program. The PoNS™ device is prescribed by a healthcare provider. The supervised therapeutic exercise program includes training on use of the PoNS™ device, establishment of an at-home therapeutic exercise program to be performed while using the PoNS™ device (e.g., balance training, gait training, movement control exercises, breathing awareness training), and weekly appointments with a qualified healthcare provider. There are no existing HCPCS codes that describe the function of a non-implantable translingual neurostimulation controller. Existing electrical stimulator codes describe neuromuscular or transcutaneous stimulators. There are no specific HCPCS codes that describe translingual neurostimulation.

### **Preliminary CMS HCPCS Coding Recommendation**

CMS is seeking additional detailed information to further inform our decision making. Please provide responses to the following questions:

1. In what setting and by whom are the PoNS™ controller and the mouthpiece prescribed and dispensed/supplied? Are they dispensed/supplied separately? Is the device only available with a prescription and what types of practitioners would typically prescribe the device?
2. Is the device used in a clinical setting with the practitioner present?
3. When the practitioner evaluates the outcome of use of the PoNS™ device, is this an extension of clinician service? How are all the clinician services related to the use of PoNS™ expected to be reported and paid?
4. What is the nature of the supervision required for patient home use? Is in-person visual supervision required and if so by whom?

5. How is home use recorded/reported to the practitioner?
6. Please provide an additional detailed description of how trigeminal and facial nerve stimulation affects the brainstem and cerebellum and how that impacts gait and breathing.
7. What types of coverage and payment policies have private insurers adopted in terms of separate or bundled payment with the professional service for the PoNS™ controller and the mouthpiece?

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker responded that the PoNS™ device primarily is used in the home by the patient. The clinical benefit of the PoNS™ device is specifically derived from its home use and provider supervision (which is not in-person visual supervision). The PoNS™ device (including the Controller and Mouthpiece) is prescribed by the patient's treating physician, typically a primary care physician or neurologist. The physician also prescribes physical therapy for the purpose of training the patient on home use of the PoNS™ device.

There is a two-week evaluation and training period, during which patients bring the device to the physical therapist's (PT's) office as they learn to use the device, download the data and ensure proper functioning of the device. The PT typically includes notes about the patient's use of the device and outcomes associated with use of the device in the medical record, which can be shared with the prescribing physician. The Controller and Mouthpiece are dispensed by a durable medical equipment (DME) supplier directly to the patient.

Any clinician services provided to support home use of the PoNS™ device are reported using existing procedure codes that do not include supply of the PoNS™ device, such as: 97116 (Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing); 97750 (Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes); or 98960 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient), amongst others. Because the devices may be supplied to a patient separately depending on the prescribed course of treatment by a physician, separate HCPCS codes are necessary to facilitate claim submission by DME suppliers and payment by payers. The PoNS™ Controller and Mouthpiece are not primarily used as part of a provider service, are not dispensed by providers, nor do associated services performed by providers (mainly PTs) include payment for the PoNS™ Controller or Mouthpiece.

For all of these reasons, the primary speaker believes CMS should create new HCPCS codes EXXXX, Non-implantable Translingual Neurostimulation System and AXXX, Non-implantable Translingual Neurostimulation Mouthpiece for this breakthrough-designated device.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS would like to further understand the PoNS™ device indication for use as illustrated by the FDA, to be used as adjunct to a supervised therapeutic exercise program. As many payers do not have reimbursement policies for exercise programs, CMS encourage the applicant to share any



information they may have regarding how other payers are treating the PoNS™ device as adjunct to the supervised therapeutic exercise program. Also, CMS would like to know if other payers would consider the use of the PoNS™ device as an “incident to” supply.

## **Portable Neuromodulation Stimulator Mouthpiece - HCP210913TB3M7**

### **Topic**

Request to establish HCPCS Level II code to identify the Portable Neuromodulation Stimulator (PoNS™) Mouthpiece.

Applicant's suggested language: AXXXX "Non-implantable Translingual Neurostimulation Mouthpiece."

### **Applicant's Summary**

Helius Medical, Inc submitted a request for the Portable Neuromodulation Stimulator (PoNS™) Mouthpiece. The PoNS™ device is a translingual, neurostimulation device that is indicated for use as a short-term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and older and is available by prescription only. The PoNS™ device has two primary components—the Mouthpiece (which is the subject of this HCPCS application) and the Controller (which is the subject of a separate HCPCS application). The Mouthpiece contains an array of 143 gold-plated electrodes through which electrotactile stimulation is applied to the dorsal surface of the patient's tongue. The Mouthpiece connects to the Controller and receives status messages and instructions from the Controller. The stimulation is distributed by software and electronics within the Mouthpiece. The Mouthpiece is designed for single-patient use and has a 14-week useful life. The PoNS™ device, including the Mouthpiece, is intended to be used in the home in conjunction with a supervised therapeutic exercise program (e.g., balance training, gait training, movement control exercises, breathing awareness training) and is prescribed by a healthcare provider. There are no existing HCPCS codes that describe the function of a non-implantable translingual neurostimulation mouthpiece. Existing electrical stimulator supply codes describe transcutaneous or neuromuscular electrodes that have significantly different electronics and mechanisms of action.

### **Preliminary CMS HCPCS Coding Recommendation**

CMS is seeking additional detailed information to further inform our decision making. Please provide responses to the following questions:

1. In what setting and by whom are the PoNS™ device controller and the mouthpiece prescribed and dispensed/supplied? Are they dispensed/supplied separately? Is the device only available with a prescription and what types of practitioners would typically prescribe the device?
2. Is the device used in a clinical setting with the practitioner present?
3. When the practitioner evaluates the outcome of use of the PoNS™ device, is this an extension of clinician service? How are all the clinician services related to the use of PoNS™ device expected to be reported and paid?
4. What is the nature of the supervision required for patient home use? Is in-person visual supervision required and if so by whom?
5. How is home use recorded/reported to the practitioner?

6. Please provide an additional detailed description of how trigeminal and facial nerve stimulation affects the brainstem and cerebellum and how that impacts gait and breathing.
7. What types of coverage and payment policies have private insurers adopted in terms of separate or bundled payment with the professional service for the PoNS™ device controller and the mouthpiece?

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker responded that the PoNS™ device primarily is used in the home by the patient. The clinical benefit of the PoNS™ device is specifically derived from its home use and provider supervision (which is not in-person visual supervision). The PoNS™ device (including the Controller and Mouthpiece) is prescribed by the patient's treating physician, typically a primary care physician or neurologist. The physician also prescribes physical therapy for the purpose of training the patient on home use of the PoNS™ device.

A required evaluation and training period of two weeks occurs with the patients bringing the device to the physical therapist's (PT's) office as they learn to use the device, to download the data and ensure proper functioning of the device. The PT typically includes notes about the patient's use of the device and outcomes associated with use of the device in the medical record, which can be shared with the prescribing physician. The Controller and Mouthpiece are dispensed by a durable medical equipment (DME) supplier directly to the patient.

Any clinician services provided to support home use of the PoNS™ device are reported using existing procedure codes that do not include supply of the PoNS™ device, such as: 97116 (Therapeutic procedure, one or more areas, each fifteen minutes; gait training (includes stair climbing); 97750 (Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each fifteen minutes); or 98960 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each thirty minutes; individual patient), amongst others.

For all of these reasons, the primary speaker believes CMS should create new HCPCS codes EXXXX, Non-implantable Translingual Neurostimulation System and AXXX, Non-implantable Translingual Neurostimulation Mouthpiece for this breakthrough-designated device.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS would like to further understand the PoNS™ device indication for use as illustrated by the FDA, to be used as adjunct to a supervised therapeutic exercise program. As many payers do not have reimbursement policies for exercise programs, CMS encourages the applicant to share any information they may have regarding how other payers are treating the PoNS™ device as adjunct to the supervised therapeutic exercise program. Also, CMS would like to know if other payers would consider the use of the PoNS™ device as an "incident to" supply.

## **iLevel, Safe Seat Elevation - HCP210913PDDCR**

### **Topic**

Request to establish two new HCPCS Level II codes to identify wheelchair accessory, power seating system.

Applicant's suggested language:

EXXX1, "Wheelchair accessory, Power seating system, elevation only, group 3 Standard, patient weight capacity up to and including 300 pounds."

EXXX2, "Wheelchair accessory, Power seating system, elevation only, group 3 heavy duty, patient weight capacity 301 – 450 pounds."

Request to revise HCPCS Level II code E2300, "Wheelchair accessory, power, power seat elevation system, any type."

Recommended Language for revision E2300, "Wheelchair accessory, power seat elevation system."

### **Applicant's Summary**

Quantum Rehab, a division of Pride Mobility Products Corp. is requesting two new HCPCS codes that represent advanced technology and innovative power seat elevation systems, such as iLevel®, designed for use on Group 3 and higher power wheelchair bases. Recommended Language for NEW HCPCS Codes: EXXX1 – Wheelchair accessory, Power seating system, elevation only, group 3 Standard, patient weight capacity up to and including 300 pounds, EXXX2 – Wheelchair accessory, Power seating system, elevation only, group 3 heavy duty, patient weight capacity 301 – 450 pounds and Recommended Language for Revision of Current HCPCS Code: E2300 – Wheelchair accessory, power seat elevation system, any type. While E2300, with six inches of elevation may be useful on a Group 2 standard power wheelchair designed for continuous use needs; defined as greater than two hours per day, is inadequate in defining the advanced performance characteristics of elevated motion seating used on Group 3 and above Complex Rehab Technology (CRT) power wheelchairs. These types of power wheelchairs are designed for active users with significant disabilities and all-day mobility needs. The differences between the E2300 accessory used on a standard power wheelchair and the new accessory codes intended for use on CRT power wheelchairs are clinically relevant. As such, products that meet the requirements of the new codes differ significantly from the existing E2300 HCPCS code in the following manner: 1. Elevate a minimum of ten inches, 2. Minimum top end speed of three mph in an elevated position, 3. Elevate and descend while moving. These enhanced characteristics are designed to promote the performance of or participation in mobility related activities of daily living (MRADLs) by persons with permanent mobility related disabilities. To safely achieve this, the design intent of CRT seat elevation systems necessitates the static and dynamic stability performance characteristics required on Group 3 and higher power wheelchair bases.

## **Preliminary CMS HCPCS Coding Recommendation**

CMS is unsure what the purpose of the maximum speed is relative to the code descriptors suggested by the applicant related to patient weight. CMS is also interested in learning more about the technical differences between equipment for individuals in different weight categories. Why are the weight-based categories defined at those particular values? We also welcome input on how this product is distinct from other products described by HCPCS code E2300 and why E2300 is insufficient. We encourage broad dialogue on these points from all interested stakeholders that might be impacted by this application.

## **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker stated that when Quantum Rehab submitted the code application, they anticipated publication of the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Final Rule prior to receipt of a preliminary code recommendation by CMS, and in advance of the public meeting to address these four areas. While they believe the code application and supporting materials addressed the questions of the preliminary CMS HCPCS Coding Recommendation, it is unclear what other benchmarks CMS will want, need or be required to utilize in the evaluation of a request for new HCPCS codes that differentiate complex rehab power seat elevation systems (EXXX1 and EXXX2) from a standard seat elevation system (E2300).

The primary speaker believed deferring actions on these code requests could allow the applicant to proceed with a clear framework for evaluation and resubmission of the application, as set forth by the DMEPOS Final Rule. It may also obviate the need for CMS to revisit a coding decision in the future, once the National Coverage Determination (NCD) and DMEPOS Final Rule are issued, saving CMS valuable time and effort.

## **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS has re-reviewed this application together with the information provided. In light of the fact that the DMEPOS Final Rule (<https://www.federalregister.gov/documents/2021/12/28/2021-27763/medicare-program-durable-medical-equipment-prosthetics-orthotics-and-supplies-dmepos-policy-issues>) was issued on December 28, 2021, and that the primary speaker recommended that CMS defer action on these coding requests, CMS considers this request to be withdrawn. The applicant is welcome to submit a new HCPCS Level II coding application in a subsequent coding cycle, informed by the DMEPOS Final Rule and any other variables that the applicant considers. CMS acknowledges that we continue to be working on a request for reconsideration of NCD 280.3.

## **HealthBeacon HB2 Sharps Bin - HCP210902L0Q5G**

### **Topic**

Request to establish a new modifier code to identify HealthBeacon HB2 Sharps Bin.

Applicant's suggested language: XXXXX, "Digitally connected sharps disposal containers"

### **Applicant's Summary**

HealthBeacon Limited (HealthBeacon) submitted a request for digitally connected sharps disposal containers. The current U3 modifier code for 'sharps disposal containers' does not specifically include digitally connected sharps containers, which more accurately describes the HB2 Sharps Bin. HealthBeacon sharps bins, including the HB2 and Flexi Sharps Bins are digitally connected sharps containers for use by a single patient on injectable medication in the home. Both are equivalent in function and purpose with differences only in appearance and connectivity. For the purposes of this application, the HB2 Sharps Bin will be detailed. The HB2 Sharps Bin is composed of an outer, HealthBeacon sharps container, with a replaceable, custom-made bin within as a reciprocal for sharps waste, accessible via a side door. The HealthBeacon unit is digitally connected; a trap door with inbuilt camera on the upper surface records each time a patient deposits an injection into it, creating a digital record of every medication disposal event. The HB2 Sharps Bin must be plugged into a power source and an LED screen displays patients' adherence scores, calculated from the number of drops made compared to patients' treatment schedules, programmed into the unit. As a reminder, a blue light alerts patient when their next dose is due. Online Healthcare Practitioner (HCP) dashboards allow physicians to track and monitor patient medication adherence in real-time from data obtained via the HealthBeacon bin. Patients are supported by HealthBeacon customer care for missed doses, schedule changes and any technical issues. Existing codes for sharps containers describe only standard sharps bins with no reference to digitally connected containers. Standard sharps bins do not have injection monitoring, tracking and reminder functions as detailed above and hence their codes do not accurately reflect the function and value of the HealthBeacon Sharps Bin.

### **Preliminary CMS HCPCS Coding Recommendation**

CMS does not have clear information that any insurance sector has a claims processing need for a new HCPCS Level II code to identify a non-prescription HealthBeacon HB2 sharps bin. State Medicaid agencies may continue to use the U3 modifier at their discretion. Existing HCPCS Level II code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" is available for insurers if they deem appropriate for the digital monitoring feature of the HealthBeacon HB2 sharps bin.

For inquiries regarding coverage, please contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at:

<https://www.cms.gov/Medicare/Coverage/DeterminationProcess> and  
<https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center>.

## **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker for HealthBeacon presented newly published evidence demonstrating the positive effects of the HealthBeacon system. Due to the additional benefits of the system, HealthBeacon is seeking a new, unique HCPCS Level II code or new unique HCPCS Level II modifier to better reflect its features and ability to improve medication compliance for patients compared to standard sharps bins. HealthBeacon feels that the currently available codes do not adequately reflect the HealthBeacon system and hence specific coding is both requested and needed. With more specific coding, the HealthBeacon HB2 Sharps Bin can be more consistently coded for and widely available for Medicare patients to gain the potential clinical benefits of the system. With increased compliance to therapy achieved through the unique features of the HealthBeacon HB2 Sharps Bin, improved patient outcomes can be achieved and further, poor medication adherence related costs reduced.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to our preliminary recommendation. CMS has re-reviewed this application together with the information provided. CMS appreciates the positive effects and the additional benefits of the HealthBeacon system; however, CMS still does not have clear information that any insurance sector has a claims processing need for a new HCPCS Level II code to identify a non-prescription HealthBeacon HB2 sharps bin. Therefore, CMS is finalizing its preliminary recommendation.

State Medicaid agencies may continue to use the U3 modifier at their discretion. Existing HCPCS Level II code A9279 “Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified” is also available for insurers, if they deem appropriate, for the digital monitoring feature of the HealthBeacon HB2 sharps bin.

For inquiries regarding coverage, please contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS’ national coverage determination process, refer to information published at:

<https://www.cms.gov/Medicare/Coverage/DeterminationProcess>  
and, <https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center>

## SmartClip - HCP210902KK9Q5

### Topic

Request to establish a new HCPCS Level II code to identify SmartClip soft tissue marker.

Applicant's suggested language: XXXXX, "Placement of Soft Tissue Marker; (electromagnetic activated) single or multiple used for anatomical surgical guidance."

### Applicant's Summary

Elucent Medical, Inc. submitted a request to establish a unique HCPCS code for the SmartClip soft tissue marker. Currently, when physicians' biopsy a suspicious breast lesion, they leave behind a small metal clip to mark the location. If the patient needs breast-conserving surgery (lumpectomy), this clip alone does not guide the physician back to the biopsy site. Instead, on the day of surgery, a radiologist will insert a hook wire through the skin down to the biopsy clip. This hook wire protrudes from the skin and provides a visible road map to the lesion. The SmartClip eliminates the need for a hook wire on the day of surgery, thereby streamlining surgical procedure and accuracy in addition to reducing patient pain, stress, and potential infection exposure. The SmartClip received FDA 510(k) clearance K180640 in June 2018 for use in soft tissue. The SmartClip is 1.4mm x 8mm and consists of a ferrite core, and ACSC computer chip that when activated utilizing electromagnetic waves delivered by the EnVisio Navigation System provides the precise coordinates of the SmartClip location in three dimensions (Stereotactic). Physicians utilize the SmartClip in most anatomical locations where they would have previously used standard fiducial markers to localize a tumor. The additional benefit of continuous real-time position tracking throughout treatment and stereotactic three-dimension measurements from the tip of the electrocautery tool, ensures accurate location when the tissue or organ is moved or displaced.

### Preliminary CMS HCPCS Coding Recommendation

This product may not be suitable for inclusion in HCPCS Level II code set because it is used in a procedure reported using a HCPCS Level I (CPT) code. It is our understanding that the SmartClip would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physicians' service? If so, what CPT code(s) describe the service(s)?

If the applicant is interested in Medicare hospital outpatient pass-through designation, please refer to CMS' pass-through application procedures as detailed on:

[https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough\\_payment](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment).

### Summary of Primary Speaker Comments at the Public Meeting

No oral or written comments were provided by the applicant in response to CMS' published preliminary HCPCS coding recommendation.



## **CMS Final HCPCS Coding Decision**

CMS is finalizing its preliminary recommendation. We continue to believe the SmartClip is not suitable for inclusion in the HCPCS Level II code set because it is used in a procedure reported using a HCPCS Level I (CPT) code. It is our understanding that the SmartClip would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable.

If the applicant is interested in Medicare hospital outpatient pass-through designation, please refer to CMS' pass-through application procedures as detailed at:

[https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough\\_payment](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment).

## **Navigation Device - HCP2109022QRXT**

### **Topic**

Request to establish a new HCPCS Level II code to identify the Navigation Device.

Applicant's suggested language: KXXXX, "Navigation Device, single-use (disposable) for real-time stereotactic three-dimensional navigation in the excision of pre-defined soft tissue specimen."

### **Applicant's Summary**

Elucent Medical submitted the application to request a unique HCPCS code for the NAV-PENCIL or NAV-SLIM (Navigators), a real time single use wireless navigation device that enables minimally invasive removal of physician pre-defined tissue specimen (specimen = tumor plus margin) without disruption of the known cancerous tissue. The sterile single-use Navigator affixes to an electrocautery tool (aka Bovie device) for real time stereotactic three-dimensional navigation to the specified margin, reducing the risk of tumor microenvironment (TME) caused by tissue disruption during surgery. Studies showing correlation between post-surgery infection (SSI) and breast cancer recurrence demonstrate the clinical impact SSI's have on recurrence rates, leading to incremental costs per patient. The national average of surgical site infection rate reported is 12%-15%, coupled with re-excision rate of 30%. According to the American Cancer Society, 281,550 new cases of invasive breast cancer will be diagnosed in 2021. The Navigators, FDA 510(k) cleared (March 2019) were introduced to the oncologic surgery market in March 2019, with the first clinical case performed in May 2019. At the time of this application submission, the Navigators have been utilized in over 1,000 patient cases. Literature for single-use electrosurgical energy devices demonstrates efficiency and reduction of complications, including reducing surgical site infections in soft tissue excision

### **Preliminary CMS HCPCS Coding Recommendation**

This product may not be suitable for inclusion in HCPCS Level II code set because it is used in a procedure reported using a HCPCS Level I (CPT) code. It is our understanding that the Navigation Device would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physicians' service? If so, what CPT code(s) describe the service(s)?

### **Summary of Primary Speaker Comments at the Public Meeting**

No oral or written comments were provided by the applicant in response to CMS' published preliminary HCPCS coding recommendation.

### **CMS Final HCPCS Coding Decision**

CMS is finalizing its preliminary recommendation. We continue to believe the Navigation Device is not suitable for inclusion in the HCPCS Level II code set because it is used in a procedure reported using a HCPCS Level I (CPT) code. It is our understanding that the Navigation Device would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable.

## **ActiGraft - HCP2109019H6KW**

### **Topic**

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

Applicant's suggested language: XXXX I -ActiGraft, each, including all components.

### **Applicant's Summary**

RedDress Ltd submitted a request to establish a new HCPCS Level II code for ActiGraft. ActiGraft is an FDA 510(k)-cleared peripheral blood processing device that enables health care providers to create an autologous whole blood treatment for chronic wounds in real time at the site of care. It is topically applied by a healthcare professional to treat debrided and/or surgically prepared wounds, including exuding cutaneous wounds, such as venous leg ulcers, pressure ulcers, and diabetic foot ulcers. It is then absorbed into the wound over a period of time depending on the size and type of wound. It is packaged as a single system that includes (1) Blood withdrawal (phlebotomy) system (2) coagulation initiation and accelerator system (3) secondary single use sterile wound covering. A new unique HCPCS code is necessary, so that the providers can properly report ActiGraft on claims.

### **Preliminary CMS HCPCS Coding Recommendation**

This product may not be suitable for inclusion in HCPCS Level II code set because it used in a procedure reported using a HCPCS Level I (CPT) code. It is our understanding that ActiGraft would typically be bundled into the payment for the procedure if it is used, and as such, would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physicians' service? If so, what CPT code(s) describe the service(s)?

### **Summary of Primary Speaker Comments at the Public Meeting**

No oral or written comments were provided by the applicant in response to CMS' published preliminary HCPCS coding recommendation.

### **CMS Final HCPCS Coding Decision**

CMS is finalizing its preliminary recommendation. We continue to believe that ActiGraft is not suitable for inclusion in HCPCS Level II code set because it used in a procedure reported using a HCPCS Level I (CPT) code. It is our understanding that ActiGraft would typically be bundled into the payment for the procedure if it is used, and as such, would not be separately payable.

## **Strados Remote Electronic Stethoscope Platform - HCP210913Y0PAV**

### **Topic**

Request to establish a new HCPCS Level II codes to identify RESP kit for home use.

Applicant's suggested language: EXXX - RESP Kit, for remote capture of patient lung sounds.

### **Applicant's Summary**

In order to allow for automation of claims processing, and specific payer and provider contract administration, Strados Labs, Inc. requests the creation of a HCPCS level II code for the acquisition of the RESP kit for home use according to the following description: EXXXX - RESP Kit, for remote capture of patient lung sounds. The Strados Remote Electronic Stethoscope Platform (RESP™) provides lung sound data used for home monitoring and remote management of respiratory disease patients. The RESP™ kit includes the following components: Two (2) Strados Wearable Device (SWD), Strados Charging Station (SCS), Strados Mobile Application (SMA), Strados Patient Adhesives (SPA), Strados Cloud Platform (SCP) that provides access to patient lung sounds. The RESP™ Kit is necessary for recording and transmitting the lung sound measurements from the patient's home to the secure database for clinician review. The SWD is placed on the patient's torso and adhered with an adhesive patch. The SWD is controlled by the SMA and recordings on the SWD are retrieved by the SMA via Bluetooth connection and sent to the SCP for physician review. The SWD sits on the chest wall and passively records the patient's lung sounds and chest wall movement. The SMA on a smartphone allows playback of lung sounds from the wearable device in order for clinicians to listen to the patient's lung sounds. The SCP also allows for lung sound storage and playback through a secure web portal. It also allows for recording without a clinician present. The SPA Adhesive is reported using A4452. However, there are no other home respiratory monitoring systems for remote patient management and as such, no dedicated codes exist to describe this product Strados Remote Electronic Stethoscope Platform.

### **Preliminary CMS HCPCS Coding Recommendation**

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

## **Summary of Primary Speaker Comments at the Public Meeting**

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## **CMS Final HCPCS Coding Decision**

CMS is finalizing its preliminary recommendation. We continue to believe this product is not suitable for inclusion in the HCPCS Level II code set because the subject of this application could be used in furnishing remote monitoring HCPCS Level I (CPT) codes 99453 "Remote monitoring of physiologic parameters, initial set up and patient education on use of equipment," 99454 "Remote monitoring of physiologic parameters, supply with daily recordings or programmed alert transmission, each thirty days," and 99457 "Remote physiologic monitoring treatment management services, twenty minutes or more of clinical staff/physician/other qualified healthcare professional time in calendar month requiring interactive communication with the patient/caregiver during the month".

## Sirius MRI Source Device - HCP210914F42N2

### Topic

Request to establish a new HCPCS Level II codes to identify Sirius.

Applicant's suggested language: Axxxx, "Magnetic Resonance Imaging (MRI) source device for localization, each."

### Applicant's Summary

C4 Imaging LLC requests that CMS establish a new, unique HCPCS code Axxxx, "Magnetic Resonance Imaging (MRI) source device for localization, each." The FDA-cleared Sirius® MRI localization device is incorporated as part of FDA-approved radioactive source strands that are implanted for the treatment of cancer. This MRI device is approved for use with FDA approved sources, which include iodine 125, palladium 103 and cesium 131. The device contains a positive-signal MRI solution that can be easily identified when imaged with MRI following a source implant. By embedding the MRI device in the source strand, it allows precise localization of the radioactive source on the same image that shows detailed MRI based anatomy. Consequently, a radioactive source strand that incorporates the Sirius device facilitates precise MRI based anatomical localization of implanted sources with a single procedure and offers more accurate post-implant dosimetry than computed tomography (CT) imaging alone. It also eliminates the need to fuse CT and MR images, which to date, has been the only option for physicians wishing to use MR for anatomical imaging and CT for source localization; an approach which requires two procedures and presents a clinically significant challenge in ensuring the CT and MR images are accurately aligned. Existing HCPCS codes for stranded radioactive sources (C2638/C2640/C2642) do not include the incorporation of a localization device and there are no MRI localization device codes that can be reported that describe this device. There are no HCPCS device codes that support the use of MRI imaging for identifying source location after thus requiring the development of an appropriate HCPCS code for providers to report this medical device.

### Preliminary CMS HCPCS Coding Recommendation

This product may not be suitable for inclusion in HCPCS Level II code set because it is used in a procedure reported using a HCPCS Level I (CPT) code. It is our understanding that the Sirius MRI Source Device would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physicians' service? If so, what CPT code(s) describe the service(s)?

### Summary of Primary Speaker Comments at the Public Meeting

The primary speaker commented on CMS' preliminary recommendation that the Sirius MRI Source Device is already reported with a HCPCS Level I Current Procedural Terminology (CPT) code; however, the primary speaker believes, in today's coding system, there are no CPT codes that allow providers to report source localization devices as part of the implant procedure. In addition, the number of devices used in a brachytherapy procedure (as is the case with sources) vary based upon each unique patient prescription. These patient

prescription sources are always reported separately, either with a device specific HCPCS code, or with a general source code (Q3001). There is no device specific code for the source localization devices. CMS also commented that this device would typically be bundled into the payment for the procedure. Packaging or bundling are not criteria for HCPCS codes. In addition, hospitals, physicians, Medicare, and private payers use HCPCS codes, not just for payment, but also for tracking purposes. These HCPCS codes may or may not be paid separately, but again, this is not part of the HCPCS application criteria. An MRI source localization device facilitates anatomical localization after radioactive sources have been implanted based upon a unique patient prescription, and as such, this device meets the criteria for a unique HCPCS code.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS is finalizing its preliminary recommendation. We continue to believe this product is not suitable for inclusion in the HCPCS Level II code set because it is used in a procedure reported using a HCPCS Level I (CPT) code. Sirius is a device that is implanted into the patient and embedded into each brachytherapy source strand. It is our understanding that the Sirius MRI Source Device would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable.

## **Orion - HCP210826989LH**

### **Topic**

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

Applicant's suggested language: AXXXX, "Magnetic Resonance Imaging (MRI) positioning device for High Dose Rate (HDR) brachytherapy localization, each."

### **Applicant's Summary**

C4 Imaging LLC submitted a request for a unique HCPCS Level II code to describe the FDA-cleared Orion device. Orion is used for magnetic resonance image (MRI) localization of HDR brachytherapy applicator and interstitial needle positions prior to radioactive source placement. It is an accessory to HDR brachytherapy remote controlled radionuclide applicator systems and is intended to be used to identify treatment lumens in FDA approved MR compatible HDR applicators and needles once they have been placed in the treatment site. The device is placed in an HDR applicator or needle lumen and imaged with MRI and then removed prior to treatment delivery. The device contains a positive-signal MRI solution that can be easily localized when imaged with MR once placed in an HDR applicator or interstitial needle. Consequently, the device facilitates precise MRI based anatomical localization of the position of the HDR radioactive source that is subsequently placed in the applicator and/or needle. This offers more accurate positional guidance than can be achieved with computed tomography (CT) imaging of the applicators or needles alone. It also eliminates the need to fuse CT and MR images, which to date has been the only option for physicians wishing to use MR for anatomical imaging and CT for source position identification; an approach which requires two procedures and presents a clinically significant challenge in ensuring the CT and MR images are accurately aligned. With the exception of miscellaneous codes, there are no existing HCPCS codes that describe this product. A specific permanent HCPCS code for the Orion as a positioning device for HDR brachytherapy localization would facilitate accurate reporting of the product and streamline reimbursement for providers and payers.

### **Preliminary CMS HCPCS Coding Recommendation**

This product may not be suitable for inclusion in the HCPCS Level II code set because it is used in a procedure reported using a HCPCS Level I (CPT) code. It is our understanding that the Orion device would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physicians' service? If so, what CPT code(s) describe the service(s)?

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker commented on CMS' preliminary recommendation that the Orion device is already reported with a HCPCS Level I Current Procedural Terminology (CPT) code; however, the primary speaker believes, in today's coding system, there are no CPT codes that allow providers to report positioning localization devices as part of the implant procedure. In addition, the number of devices used in an HDR brachytherapy procedure vary



based upon each unique patient prescription. These patient prescription positional or positive signal MRI position devices are always reported separately, with only general miscellaneous codes, as there is no device specific HCPCS Level II code for a single-patient use MRI HDR positioning localization device that is not specific to a single anatomical site. CMS also commented that this device would typically be bundled into the payment for the procedure. Packaging or bundling are not criteria for HCPCS codes. In addition, hospitals, physicians, Medicare, and private payers use HCPCS codes, not just for payment, but also for tracking purposes. These HCPCS codes may or may not be paid separately, but again, this is not part of the HCPCS application criteria. An MRI positioning localization device facilitates anatomical localization after radioactive sources have been implanted based upon a unique patient prescription, and as such, this device meets the criteria for a unique HCPCS code.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS is finalizing its preliminary recommendation. We continue to believe that this product is not suitable for inclusion in the HCPCS Level II code set because it is used in a procedure reported using a HCPCS Level I (CPT) code. Orion is comprised of a flexible, sealed polymer tube, containing an MRI visible solution and is used as a positive-contrast MRI HDR applicator and needle positional location device. It is placed in the open lumen of HDR applicators and needles once they have been inserted or implanted into the patient prior to the introduction of the HDR brachytherapy radioactive source. It is our understanding that the Orion device would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable.

## **Precice System External Remote Controller - HCP210908E0KFN**

### **Topic**

Request to establish a new HCPCS Level II code to identify Precice System External Remote Controller.

Applicant's suggested language: EXXXX, "Intramedullary Limb Lengthening or Compression External Remote Controller."

### **Applicant's Summary**

NuVasive Specialized Orthopedics, Inc. (NSO) submitted a request for a new HCPCS Level II code to identify the Precice System External Remote Controller (ERC). The ERC is a programmable, durable medical device that is electrically powered and contains rare earth magnets that, when placed in a specific spot on the patient's body directly above the Precice System implant, rotates the magnets in the implant to distract (e.g., lengthen) or retract (e.g., shorten) the implant to carry out the limb lengthening or compression protocol for the patient. The ERC is used for patients with limb length discrepancy (LLD) and other conditions requiring lengthening or compression. The ERC is indicated for limb-lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions or bone transport of long bones. Following the implantation surgery, the patient is required to undergo a latency period of 3 to 10 days to allow the surgical site and bone to heal and to ensure that there is no infection. At the end of the latency period, an ERC is supplied to the patient. The ERC is intended to be used in the home by the patient for approximately 5 minutes per day, seven days per week for approximately 6 months (ranging from 3 months to 12 months). The ERC is programmed to contain the patient's limb lengthening or compression protocol. At the end of the patient's treatment, the ERC is returned to the supplier and re-processed for use by another patient. There are no existing HCPCS codes that describe the function of an intramedullary limb lengthening or compression external remote controller designed for patients suffering with LLD and other conditions requiring bone lengthening or compression.

### **Preliminary CMS HCPCS Coding Recommendation**

We understand that the controller is integral to the procedure. Thus, this product may not be suitable for inclusion in the HCPCS Level II code set because it is used in a procedure reported using a HCPCS Level I (CPT) code. It is our understanding that the Precice System External Remote Controller would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physicians' service? If so, what CPT code(s) describe the service(s)?

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker expressed that the ERC is not integral to any procedure, the ERC is used to effectuate the lengthening or retraction of the implant, which occurs well after the surgical procedure. The first step in treatment with the Precice System is surgical implantation of the Precice System implantable rod. The implantable rod is sold by NSO to hospitals and included on hospital cost reports and included in Medicare payment rates to hospitals. The

ERC that is provided to the patient is not sold to hospitals because it cannot be furnished by the hospital to the patient. The second step in treatment is the latency period: a 3-to-10-day period after the patient is discharged following the implantation procedure. The latency period is necessary to allow the bone to heal and ensure there is no infection. The ERC must not be supplied to the patient during the latency period for critical safety reasons. If the patient is prematurely supplied with the ERC and uses it, the patient can be harmed.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS is finalizing its preliminary recommendation. Based on our understanding that the ERC is integral to the procedure, we continue to believe this product is not suitable for inclusion in the HCPCS Level II code set because it is essential to the success of the outcomes of the procedure reported using a HCPCS Level I (CPT) code and that without the ERC, the procedure would not occur. It is our understanding that the Precice System External Remote Controller would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable.

We believe that the payment for the surgical procedure should encompass the rod; therefore, payment for the ERC is considered to be bundled into the payment for the surgical procedure.

## **Oxinium - HCP210826MCQFN**

### **Topic**

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

Applicant's suggested language: CXXXX "Oxidized Zirconium on Polyethylene Joint device (implantable)."

### **Applicant's Summary**

Smith+Nephew requested the following new code to track use of oxidized zirconium implants for total joint replacements: CXXXX "Oxidized Zirconium on Polyethylene Joint device (implantable)." Oxidized zirconium is used in multiple implanted devices and is a clinically proven technology with vast potential to reduce mortality, improve care, and reduce Medicare spending. Oxidized zirconium implants are used in hip and knee total joint arthroplasty (TJA) procedures. Existing codes do not allow for outpatient tracking and analysis of quality differences between implants using oxidized zirconium versus other materials. In the inpatient context (and internationally), CMS has established codes already that allow for tracking of these quality differences. An analogous HCPCS code is needed to facilitate tracking and analysis in outpatient settings.

### **Preliminary CMS HCPCS Coding Recommendation**

This application for a HCPCS Level II code to describe oxidized zirconium implants for total joint replacements is not approved. The purpose of the HCPCS Level II code set, in part, is to provide a standardized way to convey information that is required for claims processing purposes. We welcome information from the applicant or other stakeholders that would demonstrate that there is a claims processing need for this code.

In general, CMS establishes C codes to designate products that have been approved for drug or device pass-through in the Medicare Hospital Outpatient Prospective Payment System.

### **Summary of Primary Speaker Comments at the Public Meeting**

A new HCPCS code is needed to monitor utilization of oxidized zirconium devices in hospital outpatient departments and allow for enhanced tracking of outcomes for this type of device given difference in resource use and the potential of significant therapeutic distinction between oxidized zirconium devices and other types of joint implant devices. The current joint implant HCPCS code (C1776) does not differentiate device types.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the CMS HCPCS Level II Public Meeting, in response to CMS' published preliminary recommendation. CMS is finalizing its preliminary recommendation, to not approve this application for a HCPCS Level II code to describe oxidized zirconium implants for total joint replacements. The purpose of the HCPCS Level II code set, in part, is to provide a standardized way to convey information that is required for accurate payment of claims, not necessarily to differentiate among similar devices.

## **Tablo Hemodialysis System - HCP210826JU18N**

### **Topic**

Request to establish a new HCPCS Level II code to identify Tablo Hemodialysis System, effective January 1, 2022. We are requesting feedback on the language in the code descriptor.

### **Applicant's Summary**

Tablo Hemodialysis System (Tablo System), has been specifically designed for patient-driven self-care using an iterative human factors process. The Tablo System is also used in various inpatient and outpatient settings. Real world experience with patients and human factors studies have demonstrated that patients can accurately learn and manage the Tablo System after a brief training period. A recent prospective, multicenter, open-label, crossover trial comparing in-center and in-home hemodialysis using the Tablo System supports the clinical efficacy, safety, and ease of use of the system.

Although we anticipate that the Tablo System will be used in a variety of settings including hospital inpatient or hospital outpatient, among others HCPCS Level II code application is a requirement to qualify for the End-stage Renal Disease (ESRD) Prospective Payment System (PPS) Transitional Add-on Payment for New and Innovative Equipment and Supplies (TPNIES). Until CMS created the TPNIES for the ESRD PPS there was no existing opportunity or incentive for providers to adopt innovative technology to improve dialysis care. The TPNIES provides this incentive and requires a HCPCS code application in order for End Stage Renal Disease (ESRD) facilities to receive reimbursement for a TPNIES approved technology. The Tablo System has submitted both TPNIES and HCPCS code applications. CMS approved the TPNIES application in the CY 2022 ESRD Prospective Payment System final rule.

The Tablo System is comprised of:

- **Tablo Console:** A compact console with integrated water purification, on-demand dialysate production and a simple-to-use touchscreen interface.
- **Tablo Cartridge:** A proprietary, disposable single-use pre-strung cartridge that easily clicks into place, minimizing steps, touch points and connections.
- **Tablo Connectivity and Data Ecosystem:** Designed to bring data to dialysis, Tablo is built to live in a connected setting with cloud-based system monitoring, patient analytics and clinical recordkeeping.

The Tablo System is used to treat patients with permanent or acute kidney failure also known as ESRD and Acute Kidney Injury (AKI). Patients with kidney failure are no longer able to adequately remove toxins from their blood stream or manage their own fluid balance. As a result, in the absence of sufficient kidney function, these patients require dialysis to perform these processes in order to sustain life. Without dialysis, kidney failure is terminal. The Tablo System is FDA approved and is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. The Tablo System is also indicated for use in the home. The Tablo System is durable and can withstand repeated use. It has a useful life of seven years. The Tablo Cartridge is separately purchased and is a single-use disposable cartridge that can be used for up to 24 hours.

## **CMS HCPCS Coding Recommendation**

We established a new HCPCS Level II code E1629, “Tablo hemodialysis system, for the billable dialysis service”, effective January 1, 2022, and are seeking feedback on the code descriptor.

## **Summary of Primary Speaker Comments at the Public Meeting**

No oral or written comments were provided by the primary speaker or applicant in response to CMS’ published preliminary HCPCS coding recommendation.

## **CMS Final HCPCS Coding Decision**

CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code E1629, “Tablo hemodialysis system, for the billable dialysis service”

Effective: 1/1/2022 through 12/31/2023

This code is effective from January 1, 2022 through December 31, 2023. This coding action is based on the CY 2022 ESRD Final Rule (<https://www.federalregister.gov/documents/2021/11/08/2021-23907/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis>) in regard to the review of the TPNIES application for the Tablo System.

## December 2, 2021 Meeting Agenda Items

### Supra SDRM - HCP210913KT8N0

#### Topic

Request to establish a new HCPCS Level II code to identify the Supra SDRM.

Applicant's suggested language: Q4XXX "Supra SDRM, per sq. cm."

#### Applicant's Summary

PolyMedics Innovations Inc. (PMI) requested a new HCPCS Level II code for Supra SDRM: Q4XXX "Supra SDRM, per sq. cm." Supra SDRM is a resorbable synthetic skin substitute used to treat epidermal and dermal wounds, including those caused by burns, pressure ulcers, and venous ulcers, among other wounds. Supra SDRM is composed of a tripolymer of polylactide, trimethylene carbonate, E-caprolactone and polyvinyl alcohol. It is highly permeable to oxygen and water vapor, providing a favorable environment for wound healing. Supra SDRM is fully malleable at room temperature and becomes more pliable at body temperature and can be conformed three dimensionally to multiple anatomical orientations. Supra SDRM is available in eight sheet membrane sizes: 1 x 1 cm, 18 mm disk, 2 x 2 cm, 5.1 x 5.1 cm, 9 x 9 cm, 9 x 12 cm, 18 x 9 cm, and 18 x 18 cm. While HCPCS code C1849 (Skin substitute, synthetic, resorbable, per square centimeter) may be used to report Supra SDRM when used in the hospital outpatient department, there is no existing HCPCS Q code that describes Supra SDRM when used in the physician office setting. Therefore, a new unique Q code is needed to help facilitate claims processing for providers that wish to treat patients in the physician office setting.

#### Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Supra sdrm, per square centimeter"

#### Summary of Primary Speaker Comments at the Public Meeting

The applicant supported CMS' preliminary decision to establish two new HCPCS Level II codes for both Supra SDRM and Suprathel as follows: AXXXX, "Supra sdrm, per square centimeter" and AXXXX, "Suprathel, per square centimeter." The applicant stated that they recognize and commend CMS' multi-year effort to establish proper coding and payment mechanisms for synthetic skin substitutes. They believe that establishing new HCPCS A-codes for both Supra SDRM and Suprathel, among other synthetic skin substitute products, will broaden availability and timely access to these products for Medicare beneficiaries.

#### CMS Final HCPCS Coding Decision

We appreciate the written comments provided at the HCPCS Level II Public Meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code A2011, "Supra sdrm, per square centimeter"

Effective: 4/1/2022

## **Suprathel - HCP210914Q5TVE**

### **Topic**

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

Applicant's suggested language: Q4XXX "Suprathel, per sq. cm."

### **Applicant's Summary**

PolyMedics Innovations Inc. requested a new Level II Healthcare Common Procedure Coding System (HCPCS) code for Suprathel: Q4XXX "Suprathel, per sq. cm." Suprathel is a resorbable synthetic skin substitute used to treat epidermal and dermal wounds, including those caused by burns, pressure ulcers, and venous ulcers, among other wounds. Suprathel is composed of a tripolymer of polylactide, trimethylene carbonate, and E-caprolactone. It is highly permeable to oxygen and water vapor, providing a favorable environment for wound healing. Suprathel is fully malleable at room temperature, becomes more pliable at body temperature and can be conformed three dimensionally to multiple anatomical orientations. Suprathel is available in four sheet membrane sizes: 5 x 5 cm; 9 x 10 cm; 18 x 10 cm; and 18 x 23 cm. While HCPCS code C1849 (Skin substitute, synthetic, resorbable, per square centimeter) may be used to report Suprathel when used in the hospital outpatient department, there is no existing HCPCS Q code that describes Suprathel when used in the physician office setting. Therefore, a new unique Q code is needed to help facilitate claims processing for providers that wish to treat patients in the physician office setting.

### **Preliminary CMS HCPCS Coding Recommendation**

Establish new HCPCS Level II code AXXXX, "Suprathel, per square centimeter"

### **Summary of Primary Speaker Comments at the Public Meeting**

The applicant supported CMS' preliminary decision to establish two new HCPCS Level II codes for both Supra SDRM and Suprathel as follows: AXXXX, "Supra sdrm, per square centimeter" and AXXXX, "Suprathel, per square centimeter." The applicant stated that they recognize and commend CMS' multi-year effort to establish proper coding and payment mechanisms for synthetic skin substitutes. They believe that establishing new HCPCS A-codes for both Supra SDRM and Suprathel, among other synthetic skin substitute products, will broaden availability and timely access to these products for Medicare beneficiaries.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the HCPCS Level II Public Meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code A2012, "Suprathel, per square centimeter"

Effective: 4/1/2022



## **InnovaMatrix FS - HCP2109145U5NH**

### **Topic**

Request to establish a new HCPCS Level II code to identify the InnovaMatrix FS.

Applicant's suggested language: Q4XXX "InnovaMatrix FS, per sq. cm."

### **Applicant's Summary**

Triad Life Sciences, Inc. requested a unique Q code under the Level II HCPCS code set for InnovaMatrix FS. InnovaMatrix FS is a sterile, single use, medical device consisting of extracellular matrix derived from porcine placental material used for safe and effective wound treatment. InnovaMatrix FS is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans and is produced in fenestrated sheets in a variety of sizes. This biodegradable wound matrix provides a protective cover to the wound. There are no current specific HCPCS codes that define a fenestrated skin substitute composed of an extracellular matrix derived from porcine placental material. InnovaMatrix FS is the first Food and Drug Administration cleared fenestrated medical device sourced from pig placenta. Therefore, the applicant requested a new HCPCS code category code: Q4XXX InnovaMatrix FS, per sq. cm to facilitate proper billing and coding to all payers in the full range of site of care settings. InnovaMatrix FS is intended for use in the management of wounds, including: partial- and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor site/grfts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds, (abrasions, lacerations, second-degree burns and skin tears), and draining wounds. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product will fully resorb and does not have to be removed. InnovaMatrix FS is supplied terminally sterile, in a single use package, and in a variety of sizes of fenestrated sheets.

### **Preliminary CMS HCPCS Coding Recommendation**

Establish new HCPCS Level II code AXXXX, "Innovamatrix fs, per square centimeter"

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker agreed with the decision to create a unique HCPCS Level II code for InnovaMatrix FS, and they agreed with the descriptor language in the preliminary recommendation. However, the speaker stated, while placing the newly created HCPCS code in the "A" series of codes is acceptable, it is preferable to place the new code in the "Q" series of codes, as they had requested. InnovaMatrix FS is a sheet skin substitute product that received 510(k) clearance as a medical device by the Food and Drug Administration (FDA) and should receive a "Q" code, just as 24 other 510(k) cleared sheet skin substitute products have received unique codes in the Q41XX or Q42XX series. The preliminary decision fails to explain why InnovaMatrix FS would be treated differently from these other similarly situated products. In addition, creating an "A" code instead of a "Q" code for InnovaMatrix FS will unnecessarily create confusion for coders and an unlevel playing field for the product compared to other similar sheet skin substitute products. As such, CMS should create a

unique HCPCS code in the Q42XX series using the descriptor language contained in the preliminary decision; if not, then the preliminary decision for an “A” code is acceptable.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the HCPCS Level II Public Meeting in response to our published preliminary recommendation. After further consideration, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code A2013, “Innovamatrix fs, per square centimeter”

Effective: 4/1/2022

## **Delete S codes - HCP210813XRPKE**

### **Topic**

Request to delete three existing HCPCS Level II codes S2066, S2067, and S2068.

### **Applicant's Summary**

The Blue Cross and Blue Shield Association submitted a request to discontinue three S codes related to breast reconstruction: S2066 Breast reconstruction with gluteal artery perforator (GAP) flap; including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral; S2067 Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral; and S2068 Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral S codes are temporary national codes established by private payers. They are not recognized by Medicare or other federal payers and are not assigned a fee schedule. These codes were established in 2006 (S2068) and in 2007 (S2066 and S2067) to describe a new method of breast reconstruction that had not reached the sufficient literature and utilization threshold to apply for Current Procedural Terminology (CPT) Category I Code status. Since that time, the procedures represented by these three codes have grown in acceptance, and in 2021, CPT code 19364 was modified to report these procedures. As of January 1, 2021, the descriptor for CPT code 19364 now reads "Breast reconstruction; with free flap (e.g., fTRAM, DIEP, SIEA, GAP flap). As there is now an established Category I CPT code that represents these services, the S codes are no longer needed, and the Blue Cross and Blue Shield Association requests their discontinuation. This surgical procedure does not involve any drugs or biologicals.

### **Preliminary CMS HCPCS Coding Recommendation**

We appreciate that methods of breast reconstruction have advanced to the point where the procedures described by HCPCS codes S2066, S2067, and S2068 are now described by CPT code 19364; however, we note that discontinuing the S codes may affect multiple manufacturers and payers. We seek a broad range of input on any implications of discontinuing S2066, S2067, and S2068, including whether we should consider a later effective date for discontinuing the codes for claims processing or other purposes.

### **Summary of Primary Speaker Comments at the Public Meeting**

No oral or written comments were provided by a primary speaker or the applicant in response to CMS' published preliminary HCPCS coding recommendation. However, CMS did receive written comments from the American Society of Plastic Surgeons (ASPS) concerning this application. The ASPS believes it would be problematic to discontinue these S codes as it may affect multiple manufacturers, surgeons, and payers. While some insurers had previously or are now deciding to use only CPT code 19364, individual payers are not precluded from continuing to allow the use of the S codes in their contracts. Of note, the S codes are still currently listed in numerous policies as applicable codes in breast reconstruction, demonstrating present day utility.

## **CMS Final HCPCS Coding Decision**

Based on our review of the feedback we received at the HCPCS Level II Public Meeting, CMS has decided to delay discontinuing the following S codes related to breast reconstruction: S2066 Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral; S2067 Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral; and S2068 Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral. HCPCS codes S2066, S2067, and S2068 will be discontinued on December 31, 2024. We believe this delay will allow time for any entities that currently list these codes in their written policies or contracts to make any necessary updates.

## **reSET - HCP21090135K6E**

### **Topic**

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

Applicant's suggested language: QXXXX "12-week, outpatient prescription digital cognitive behavioral therapy for substance use disorder as an adjunct to contingency management."

### **Applicant's Summary**

Pear Therapeutics' reSET is intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients 18 years of age and older who are currently enrolled in outpatient treatment under the supervision of a clinician. reSET is indicated as a twelve-week (90-day) prescription-only treatment for patients with substance use disorder (SUD) who are not currently on opioid replacement therapy, who do not abuse alcohol solely or who do not abuse opioids as their primary substance of abuse. It is intended to increase abstinence from a patient's substances of abuse during treatment and increase retention in the outpatient treatment program. Delivers therapy based on the community reinforcement approach, an intensive form of validated neurobehavioral therapy for SUD, along with contingency management and fluency training to enhance learning. reSET is currently comprised of sixty-two interactive modules: thirty-two core modules and thirty supplemental modules. reSET was cleared as the first in class of a rapidly emerging field of prescription digital therapeutics (PDTs), a new therapeutic class that leverages regulated and clinically validated prescription software, as determined by the Food and Drug Administration (FDA), to treat human disease. There are currently no HCPCS codes that describe PDTs. The lack of a unique HCPCS code for PDTs has contributed to patient access concerns because government/commercial payers lack the necessary coding infrastructure to appropriately cover and pay for PDTs. As coverage and payment for PDTs among government/commercial payers continue to evolve, a unique Q code for reSET will facilitate claims billing/processing across diverse payer claims processing and billing systems, thereby improving patient access.

### **Preliminary CMS HCPCS Coding Recommendation**

We understand that this product is intended to be used in conjunction with face-to-face treatment delivered by the clinician. HCPCS Level I (CPT) coding is the typical approach for physicians' services. Please let us know about any previous engagement that you may have had thus far with the AMA about potential HCPCS Level I (CPT) coding. Please also inform us if you have any more information that describes the role of the practitioner relative to this device, and if a HCPCS Level I (CPT) code covers this device.

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker stated that recent CPT code changes did not create billing pathway for the product. A recent American Medical Association (AMA) meeting clarified physician work with digital Cognitive Behavioral Therapy (CBT) programs. This resulted in the inclusion of CBT into the existing Remote Therapeutic Monitoring (RTM) codes. The CBT RTM Supply code is for FDA cleared devices prescribed by a physician, when the physician has a) incurred a cost, b) taken ownership/title of that device, and c) billed for that device.

The provider does not a) pay for, b) take ownership/title over, or c) dispense Pear's prescription digital therapeutics. The provider writes a prescription which is sent to a specialty pharmacy. The specialty pharmacy is the sole entity who verifies the prescription, submits a claim to an insurer, and dispenses the product to the patient. HCPCS codes are needed to enable medical coding for commercial and Medicaid payers who want to cover Prescription Digital Therapeutics (PDTs). PDTs are prescribed by healthcare providers, sent to a specialty pharmacy, and dispensed to a patient – delivering therapeutic content directly during times when their physician may not be available. Physicians do not pay for or take ownership over the product. The patient engages with the PDT in their own home. Pear's PDTs are prescribed in conjunction with outpatient treatment.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the HCPCS Level II Public Meeting in response to our published preliminary recommendation. After further consideration, CMS' final coding decision is to:

Establish new HCPCS Level II code A9291, "Prescription digital behavioral therapy, fda cleared, per course of treatment"

CMS believes that establishing a code at this time may facilitate options for non-Medicare payers to provide access to this therapy in the home setting. CMS continues to be open to hearing from manufacturers and payers about their experience in implementing this code relative to the three products from Pear Therapeutics and other manufacturers.

Effective: 4/1/2022

## reSET-O - HCP210902RNB7C

### Topic

Request to establish a new HCPCS Level II code to identify reSET-O.

Applicant's suggested language: QXXXX "12-week, outpatient prescription digital cognitive behavioral therapy for opioid use disorder as an adjunct to transmucosal buprenorphine and contingency management."

### Applicant's Summary

Pear Therapeutics' reSET-O is a 12-week interval prescription digital therapeutic for opioid use disorder (OUD). reSET-O is modeled on the Community Reinforcement Approach (CRA) and delivers CRA therapy as a series of interactive therapy lessons. Each therapy lesson is comprised of a cognitive behavioral therapy component and skill building exercises. Therapy lesson content is delivered primarily via text or audio, and may include videos, animations and graphics. reSET-O is intended as an adjunct to standard of care for patients with OUD and is limited to persons with a valid prescription from their licensed provider. reSET-O reinforces the importance of using buprenorphine for treatment of OUD. reSET-O was cleared as the second in class of a rapidly emerging field of "prescription digital therapeutics" (PDTs), a new therapeutic class that leverages regulated and clinically validated prescription software, as determined by the Food and Drug Administration, to treat human disease. There are currently no HCPCS codes that describe prescription digital therapeutics (PDTs). The lack of a unique HCPCS code for PDTs, including for reSET-O, contributes to patient access concerns because government/commercial payers lack the necessary coding infrastructure to appropriately cover and pay for PDTs, thereby negatively impacting patient access to these products. As coverage and payment for PDTs among government/commercial payers continue to evolve, a unique Q code for reSET-O will facilitate claims billing/processing across diverse payer claims processing and billing systems, thereby improving patient access.

### Preliminary CMS HCPCS Coding Recommendation

We understand that this product is intended to be used in conjunction with face-to-face treatment delivered by the clinician. HCPCS Level I (CPT) coding is the typical approach for physician services. Please let us know about any previous engagement that you may have had thus far with the AMA about potential HCPCS Level I (CPT) coding. Please also inform us if you have any more information that describes the role of the practitioner relative to this device, and if a HCPCS Level I (CPT) code covers this device.

### Summary of Primary Speaker Comments at the Public Meeting

The primary speaker stated that recent CPT code changes did not create a billing pathway for this product. A recent AMA meeting clarified physician work with digital Cognitive Behavioral Therapy (CBT) programs. This resulted in the inclusion of CBT into the existing Remote Therapeutic Monitoring (RTM) codes. The CBT RTM Supply code is for FDA cleared devices prescribed by a physician, when the physician has a) incurred a cost, b) taken ownership/title of that device, and c) billed for that device. The provider does not a) pay for, b) take ownership/title over, or c) dispense Pear's prescription digital therapeutics. The

provider writes a prescription, which is sent to a specialty pharmacy. The specialty pharmacy is the sole entity who verifies the prescription, submits a claim to an insurer, and dispenses the product to the patient. HCPCS codes are needed to enable medical coding for commercial and Medicaid payers who want to cover Prescription Digital Therapeutics (PDTs). PDTs are prescribed by healthcare providers, sent to a specialty pharmacy, and dispensed to a patient – delivering therapeutic content directly during times when their physician may not be available. Physicians do not pay for or take ownership over the product. The patient engages with the PDT in their own home. Pear’s PDTs are prescribed in conjunction with outpatient treatment.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the HCPCS Level II Public Meeting in response to our published preliminary recommendation. After further consideration, CMS’ final coding decision is to:

Establish new HCPCS Level II code A9291, “Prescription digital behavioral therapy, fda cleared, per course of treatment”

CMS believes that establishing a code at this time may facilitate options for non-Medicare payers to provide access to this therapy in the home setting. CMS continues to be open to hearing from manufacturers and payers about their experience in implementing this code relative to the three products from Pear Therapeutics and other manufacturers.

Effective: 4/1/2022



## Somryst - HCP2109034KYG9

### Topic

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

Applicant's suggested language: QXXXX "9-week, outpatient prescription digital cognitive therapy for chronic insomnia."

### Applicant's Summary

Pear Therapeutics' Somryst is a 9-week prescription-only digital therapeutic intended to provide a neurobehavioral intervention (Cognitive Behavioral Therapy for Insomnia - CBT-I) in patients 22 years of age and older with chronic insomnia. CBT-I is a neurobehavioral treatment, which focuses on addressing the maladaptive behaviors, routines, and dysfunctional thoughts that perpetuate sleep problems, regardless of the original source of the sleep problem. Somryst is comprised of 6 interactive modules, which consist of text, video, animation and graphics. Somryst belongs to a new therapeutic class that leverages regulated and clinically validated prescription software, as determined by the Food and Drug Administration through its "Software as Medical Device" (SaMD) framework, to treat human disease. There are currently no HCPCS codes that describe any prescription digital therapeutics (PDTs). The lack of a unique HCPCS code for PDTs, including Somryst, contributes to patient access concerns because government/commercial payers lack the necessary coding infrastructure to appropriately cover and pay for PDTs, thereby negatively impacting patient access to these products. As coverage and payment for PDTs among government/commercial payers continue to evolve, a unique Q code for Somryst will facilitate claims billing/processing across diverse payer claims processing and billing systems, thereby improving patient access.

### Preliminary CMS HCPCS Coding Recommendation

We understand that this product is intended to be used in conjunction with face-to-face treatment delivered by the clinician. HCPCS Level I (CPT) coding is the typical approach for physician services. Please let us know about any previous engagement that you may have had thus far with the AMA about potential HCPCS Level I (CPT) coding. Please also inform us if you have any more information that describes the role of the practitioner relative to this device, and if a HCPCS Level I (CPT) code covers this device.

### Summary of Primary Speaker Comments at the Public Meeting

The primary speaker stated that recent CPT code changes did not create billing pathway for product mentioned. A recent AMA meeting clarified physician work with digital Cognitive Behavioral Therapy (CBT) programs. This resulted in the inclusion of CBT into the existing Remote Therapeutic Monitoring (RTM) codes. The CBT RTM Supply code is for FDA cleared devices prescribed by a physician, when the physician has a) incurred a cost, b) taken ownership/title of that device, and c) billed for that device. The provider does not a) pay for, b) take ownership/title over, or c) dispense Pear's prescription digital therapeutics. The provider writes a prescription which is sent to a specialty pharmacy. The specialty pharmacy is the sole entity who verifies the prescription, submits a claim to an insurer, and dispenses the product to the patient. HCPCS codes are needed to enable medical coding for commercial

and Medicaid payers who want to cover Prescription Digital Therapeutics (PDTs). PDTs are prescribed by healthcare providers, sent to a specialty pharmacy, and dispensed to a patient – delivering therapeutic content directly during times when their physician may not be available. Physicians do not pay for or take ownership over the product. The patient engages with the PDT in their own home. Pear’s PDTs are prescribed in conjunction with outpatient treatment.

### **CMS Final HCPCS Coding Decision**

We appreciate the comments provided at the HCPCS Level II Public Meeting in response to our published preliminary recommendation. After further consideration, CMS’ final coding decision is to:

Establish new HCPCS Level II code A9291, “Prescription digital behavioral therapy, fda cleared, per course of treatment”

CMS believes that establishing a code at this time may facilitate options for non-Medicare payers to provide access to this therapy in the home setting. CMS continues to be open to hearing from manufacturers and payers about their experience in implementing this code relative to the three products from Pear Therapeutics and other manufacturers.

Effective: 4/1/2022

## **MiSight 1 day- HCP210904KY8NE**

### **Topic**

Request to establish a new HCPCS Level II code to identify the MiSight 1 day contact lens.

Applicant's suggested language: VXXXX "Contact lens, hydrophilic, dual-focus, myopia control."

### **Applicant's Summary**

CooperVision, Inc. submitted a request for a new V-code for the MiSight 1-day (omafilcon A) soft contact lens. MiSight 1-day is an FDA-approved device indicated for the correction of myopic ametropia and for slowing the progression of myopia in children, who at the initiation of treatment, are 8-12 years of age and have a refraction of -0.75 D to -4.00 D (spherical equivalent) with less than or equal to 0.75 diopters of astigmatism. MiSight 1 day is an FDA Class III device with PMA approval, and is the only soft contact lens approved by the FDA to slow the progression of myopia in children. When approved, MiSight 1-day was assigned a unique product classification code, QIT, as it is a novel lens which provides a therapeutic mode of action in addition to a refractive mode of action. Because other contact lenses' mode of action only serves to refract light to correct ametropia, current V-codes for contact lenses (e.g. V2520: contact lens, hydrophilic, spherical, per lens; V2522: contact lens, hydrophilic, bifocal, per lens; V2599: contact lens/es, other type) do not address the novel, therapeutic nature of the MiSight 1-day lens. Additionally, current V-codes do not address the optical design through which the therapeutic action is achieved (the MiSight 1-day lens employs a dual-focus design which has a central zone containing distance vision and concentric peripheral zones to provide peripheral myopic defocus). The proposed code will provide the appropriate differentiation for the MiSight 1-day lens by specifying the design (dual-focus) and the therapeutic nature (myopia control) of the lens.

### **Preliminary CMS HCPCS Coding Recommendation**

Upon review of the information submitted with this application, we are considering whether existing code V2522 "Contact lens, hydrophilic, bifocal, per lens" describes the MiSight 1-day contact lens. We are also considering whether creating a new code to describe MiSight would be warranted. Accordingly, we are interested in gaining a better understanding of how the MiSight lens is distinguishable from other products on the market. Specifically, whether and exactly how the difference in design from other bifocal lenses confers a different function and/or a significant therapeutic distinction when compared with the use of other products on the market, separate FDA authorization notwithstanding. Clinical studies that demonstrate such comparison and distinction would be welcome. We are also interested in learning about emerging technologies in this area of practice. We invite comments from payers regarding whether they perceive a benefit to code distinctions for similar products based on specific indications for use, and how such coding might improve efficiency, accuracy or other programmatic need; how/whether it might add administrative complexity; and what might be preferable, on balance.

## **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker stated that MiSight “dual focus” design employs a different design strategy than traditional lenses for presbyopia. Standard practice in eye care today is not to do anything about the increasing severity of myopia which is associated with an elongation of the eyeballs but is to simply correct myopia by applying myopia contact lens which solves the issue of blurred vision but it does not address the issue of the underlying pathological eye growth. Over the last few decades, there has been significant research conducted to try to alter the trajectory in both the prevalence and severity of myopia pathological eye growth. Data presented from animal-based research showed that medical practice could manipulate the elongation of the eye and animal model with different types of defocused presented in front of the eye. Thus, one could shrink or reverse the myopia by employing a positive defocus in front of the retina and if hyper optic defocus is placed in front of the retina, the eyeball would grow excessively. Thus, one can employ what we could call competing defocus where this myopic defocus is combined with a corrective lens, and still see the same positive effect the myopic defocus signal to slow growth dominates even with it is not the primary signal in mean in the optical lens.

This led CooperVision to develop the MiSight, dual focus lens. Dual focus design has multiple rings of correction zone and treatment zone. The correction zone is where the light refraction is like a traditional contact lens. It corrects the myopia so one can enjoy clear vision, just like they would in an ordinary single vision contact lens. The treatment zone provides an appropriate signal to slow down the pathologic eye growth. The idea of having these novel multiple rings is to make sure that the balance between the areas, giving clear vision to correct the myopia, and the defocus signal to slow down a pathologic eye growth, is approximately proportional. That proportion remains constant whether the child is looking at a distance object or looking at a near object, and in both those situations the child is using the correction zones, not the treatment zones, which is important to differentiate from a traditional bifocal lens used to correct presbyopia.

MiSight study is the only intervention showing sustained effect over six years. Myopia control effect is dependent on duration, age of population, ethnicity, and comparison between studies is challenging. MiSight received a first FDA approval for slowing myopia progression. Companies are seeking FDA indications for spectacle and contact lens designs to slow progression of myopia. According to the speaker, a new code should reflect this paradigm shift.

### **CMS Final HCPCS Coding Decision**

Following the HCPCS Level II Public Meeting, CMS re-reviewed this application along with the comments that were provided during the public meeting. The technology utilized in the MiSight contact lens is substantially different from existing contact lenses that are described by HCPCS Level II code V2522. After further consideration, CMS’ final coding decision is to:

Establish new HCPCS Level II code V2525 “Contact lens, hydrophilic, dual focus, per lens”

Effective: 4/1/2022

## **Willow Wearable Breast Pump - HCP210914A4XQA**

### **Topic**

Request to establish a HCPCS Level II code modifier to add to existing code E0603 “Breast pump, electric (ac and/or dc), any type”

Applicant’s suggested language: E0603 XX “Breast pump, electric, with continuous latch technology.”

### **Applicant’s Summary**

Willow Innovations, Inc. is submitted a request to establish one HCPCS code modifier to add to existing code E0603 (breast pump, electric) that specifies the continuous latch technology feature of the pump. Recommended language: E0603 XX Breast pump, electric, with continuous latch technology B) Product Name and Description: The Willow Wearable Breast Pump featuring continuous latch technology is an all-in-one breast pump and collection system worn entirely inside a bra. It is intended for lactating women to express and collect breast milk into a disposable collection storage bag or reusable container. The pump is intended for multiple uses with the individual user and may be operated as a single or double pumping system. Product Function: The Willow Wearable Breast Pump is a battery-powered rechargeable electromechanical device. Willow provides an untethered, hands-free, mobile pumping option where the entire pump and milk collection system is contained in one wearable device. The continuous latch technology feature is novel and functions to maintain latch that very closely mimics the natural suckling action of a breastfeeding baby, in contrast to other pumps which alternate between suction and release. Continuous latch provides the pumping mother the ability to be entirely mobile during her pumping sessions. The technology promotes spill-proof mobility for the mother during pumping; leak disruption and milk loss is minimized with continuous latch. Reason: There are currently no HCPCS code modifiers that describe the continuous latch feature of a wearable breast pump. Mobility for the mother while pumping is not a feature identified by HCPCS E0603, as traditional pumps leverage gravity to allow milk to drain into a bottle or container, requiring the mother to lean forward while pumping and maintain a fixed position often connected to tubes and cords. This HCPCS code modifier is necessary for claim submission, processing and adjudication, offering differentiation from traditional (suction and release, tether based) pumps.

### **Preliminary CMS HCPCS Coding Recommendation**

CMS is interested in hearing from the applicant and other stakeholders regarding the difference between the Willow Breast Pump and existing products in the market. Also, we are looking to understand the clinical benefits and distinctions between breast pumps, including any data, if available, to support the applicant’s claims of technological advancement. Does the applicant have information about a patient population that utilizes the Willow Breast Pump in comparison to other pumps on the market? In the meantime, existing code E0603 "Breast pump, electric (ac and/or dc), any type" describes the Willow Breast Pump and is available for assignment by insurers if they deem appropriate.

## **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker stated that Continuous Latch Technology functions to maintain suction that closely mimics a baby's breastfeeding. The technology provides the pumping mother the ability to be entirely mobile during her pumping sessions, allowing for 360 degrees of motion when pumping into self-sealing bags and 190 degrees when using reusable containers.

In addition to the discretion offered by wearable breast pumps, the continuous latch technology provides the pumping mother the ability to be entirely mobile during her pumping sessions.

In a lab performed mobility spill test, continuous latch technology allowed for a range of motion of 360 degrees of motion when pumping into self-sealing bags and 190 degrees when using reusable containers compared with lower mobility of traditional breast pumps and other wearable pumps currently on the market.

Mobility for the mother while pumping is not a feature identified by HCPCS code E0603, as traditional pumps leverage gravity to allow milk to drain into a bottle or container, requiring the mother to lean forward while pumping and maintain a fixed position often connected to tubes and cords. This HCPCS code modifier is necessary for claim submission, processing and adjudication, offering differentiation from traditional (suction and release, tether based) pumps.

## **CMS Final HCPCS Coding Decision**

CMS notes that the Health Resources and Services Administration (HRSA) recently updated Women Preventive Services Initiative (WPSI) guidelines to be effective 2023. The new guidelines are below:

“Women Preventive Services Initiative (WPSI) recommends comprehensive lactation support services (including consultation; counseling; education by clinicians and peer support services; and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to optimize the successful initiation and maintenance of breastfeeding.

Breastfeeding equipment and supplies include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be a priority to optimize breastfeeding and should not be predicated on prior failure of a manual pump. Breastfeeding equipment may also include equipment and supplies as clinically indicated to support dyads with breastfeeding difficulties and those who need additional services.”

We believe that manufacturers and payers may need to assess these guidelines and submit a subsequent HCPCS coding request to CMS in regard to whether the existing code E0603 is suitable for current payment approaches, and if not, what additional differentiation in HCPCS codes would be helpful for payers. As we anticipate hearing further from manufacturers and payers in regard to the HRSA guidelines, we are not modifying HCPCS code E0603 "Breast pump, electric (ac and/or dc), any type" or developing a new code that more specifically describes the Willow Breast Pump, at this time. We will continue examining the impact of these updated guidelines and will consider whether we need to implement any changes to coding for breast pump products in the future.

## **IntelliHab System - HCP210914Q1AXK**

### **Topic**

Request to establish a new HCPCS Level II codes to identify IntelliHab system.

Applicant's suggested language: "Neuromuscular electrical stimulation system for treatment of pain, with conductive garment, integrated goniometer and supplies."

### **Applicant's Summary**

CyMedica requested to create a new HCPCS Level II code for the IntelliHab system, a next generation neuromuscular electrical stimulation (NMES) system with an interconnected "smart" conductive garment indicated for treatment of pain associated with knee osteoarthritis. The IntelliHab system was recently cleared by the FDA for the treatment of knee osteoarthritis pain. The IntelliHab system is the first and only NMES system cleared by the FDA for treatment of knee osteoarthritis pain. It is a non-invasive, non-pharmacological prescription treatment for knee osteoarthritis pain for use by patients in their homes. The IntelliHab system is comprised of a novel, power regulated, patented, closed loop feedback NMES therapy with a wireless application for control of electrical stimulation therapy and an interconnected, conductive garment with integrated goniometers to measure range of motion (ROM). The patented waveform technology and interconnected garment deliver a unique therapeutic dose that has been clinically demonstrated and cleared by the FDA for the treatment of osteoarthritis pain. The current codes for NMES and conductive garments do not adequately describe the new interconnected system and advancements in NMES technology that have been shown to provide the clinically therapeutic dose needed to achieve treatment of osteoarthritis pain. Additionally, there is a programmatic need for a distinct code to differentiate the novel therapy of osteoarthritis pain treatment using an advanced NMES system from the crowded field of traditional NMES devices that have neither demonstrated effectiveness in the treatment of osteoarthritis pain nor have been cleared for this therapeutic use by the FDA.

### **Preliminary CMS HCPCS Coding Recommendation**

CMS does not see a clear distinction between the IntelliHab system and the predicate product CyMedica-e-vive system; CY 1000. FDA 510(k) premarket notification determined the device is substantially equivalent to the predicate product. The indication of use for neuromuscular electrical stimulation (NMES) system with interconnected "smart" conductive garment, to treat knee pain from osteoarthritis by increasing quadricep strength. We are unclear how this product is distinct from the e-vive system, which is used for muscle atrophy. CMS believes that it may be appropriate to use existing codes E0745 "Neuromuscular Stimulation Device, electronic shock unit" and E0731 "Form fitting conductive garment."

### **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker requested that CMS reconsider its preliminary recommendation on the IntelliHab system and add a new HCPCS code for the first and only neuromuscular electrical stimulation (NMES) system that is FDA-cleared to treat knee osteoarthritis (OA) pain. Designed for use by patients in their homes, the IntelliHab system is a non-invasive, non-pharmacological prescription treatment for knee OA pain, improving the OA treatment for

many Medicare patients and offering an alternative therapy option to opioids. The IntelliHab System is distinct from the predicate device, CyMedica's e-vive NMES system, and all other currently FDA cleared NMES devices in that IntelliHab has been cleared by the FDA for this new medical benefit for the treatment of knee OA pain. IntelliHab's FDA clearance was based on a 510(k) submission using the e-vive device as the predicate device for comparison of technological similarities but included new data from a randomized controlled trial for the treatment of knee OA pain demonstrating the clinical efficacy for its new clinical use. We therefore strongly recommend that CMS reconsider its preliminary decision and add a new code for the IntelliHab system. Specifically, CyMedica requests a new E code (EXXXX) for Neuromuscular electrical stimulation system for treatment of pain, with conductive garment, integrated goniometer, and supplies (or a K code similarly defined). Alternatively, CyMedica requests a modifier for the current code E0745 with the descriptor, E0745 XX - Neuromuscular Stimulator, Electronic Shock Unit for Treatment of Pain. Either of these HCPCS coding changes would distinguish IntelliHab's novel therapeutic benefit both for Medicare beneficiaries and for the Medicare program.

### **CMS Final HCPCS Coding Decision**

Following the HCPCS Level II Public Meeting, CMS re-reviewed this application. Taking the comments provided during the public meeting into consideration, CMS is finalizing its preliminary recommendation. CMS still believes there is not a clear distinction between the IntelliHab system and the predicate product CyMedica-e-vive system. The FDA 510(k) premarket notification determined the device is substantially equivalent to the predicate product. The primary distinction between the devices appears to be indication of use. CMS believes it is appropriate to use existing codes E0745 "Neuromuscular Stimulation Device, electronic shock unit" and E0731 "Form fitting conductive garment."



## CardioBra - HCP2109010E9X7

### Topic

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

Applicant's suggested language: XXXXX "Radiolucent external chest wall electrode positioner to accommodate breast tissue, with electrodes, single use (external electrode positioner)"

### Applicant's Summary

CardioBra LLC submitted a request for "radiolucent external chest wall electrode positioner to accommodate breast tissue, with electrodes, single use (external electrode positioner)" for the CardioBra. External electrode positioners (EEPs) address important disparities facing women. EEPs are designed to address significant barriers to exercise stress echocardiogram (ECG) testing for women by promoting accurate placement of ECG leads around breast tissue, protecting ECG lead positioning during exercise testing, and allowing rapid access to the chest wall that is necessary during image acquisition. EEPs also provide breast compression and elevation to help alleviate back, shoulder, and chest pain from exercising during diagnostic testing without breast support. If women are unable to exercise to peak capacity due to non-cardiac pain, the exercise stress echocardiogram results may be non-diagnostic. EEPs can be worn before, during, and after the exercise portion of stress testing, allowing for modesty and dignity that is essential for women with cultural, religious, and personal concerns to participate in medically necessary exercise stress testing. The primary target population is premenopausal women because this cohort has not experienced the improvements in cardiovascular mortality seen in other segments of the population. These women typically are not yet eligible by age for Medicare, and we recommend establishing a new, non-Medicare HCPCS code such as an S-code. The barriers facing women in exercise stress testing are long-standing, predictable, avoidable, and require the HCPCS Workgroup's immediate attention. There are no existing unique codes for any product to address these barriers, and securing a separate, unique code for EEPs is an important, necessary step for addressing the gender-based disparities in diagnostic exercise testing for cardiovascular disease. Instead of deferring to other code sets, the HCPCS Workgroup should move expediently to establish this new code to help remove gender-based disparities in exercise stress testing.

### Preliminary CMS HCPCS Coding Recommendation

This product may not be suitable for inclusion in HCPCS Level II code set because it is a supply used in a procedure reported using HCPCS Level I (CPT) code. It is our understanding that the CardioBra would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physicians' service? If so, what CPT code(s) describe the service(s)?

## **Summary of Primary Speaker Comments at the Public Meeting**

The primary speaker urged CMS to issue a HCPCS Level II code for the CardioBra and disagreed with the CMS's preliminary recommendation that an EEP may not be suitable for inclusion in the HCPCS Level II code set because it is a supply used in a procedure reported using HCPCS Level I (CPT) Code. The primary speaker confirmed that an EEP is needed in stress testing for women to produce meaningful diagnostic information upon which cardiologists can rely to make medical judgments to improve their female patients' health. The speaker stated that some patients refuse to undergo exercise stress testing because of modesty and cultural complaints. In addition, there are a lot of difficulties with Electrocardiogram (EKG) lead placement in women; breast motion can cause those EKG leads to come off. The speaker stated that failing to issue a HCPCS Level II code would exacerbate existing gender-based disparities in cardiac care.

The current codes are insufficient for describing the use of EEP and exercise stress testing. Cardio Bra is designed to be used in conjunction with procedures that are reported using HCPCS Level I (CPT) codes. The current CPT codes are flawed because they cannot account for the anatomical differences between men and women. Neither, the Medicare PFS, nor the hospital OPSS system can ensure reimbursement rates that will fairly and adequately compensate freestanding or hospital outpatient facilities for performing exercise stress echocardiograms because women only comprise about 50% of the population undergoing these studies.

### **CMS Final HCPCS Coding Decision**

Following the HCPCS Level II Public Meeting, CMS re-reviewed this application along with the comments submitted. Taking the comments provided during the public meeting into consideration, CMS is finalizing its preliminary recommendation that this product may not be suitable for inclusion in the HCPCS Level II code set because it is a supply used in a procedure reported using a HCPCS Level I (CPT) code. CMS continues to believe that the CardioBra would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable.

## **Bandgrip Micro-Anchor Skin Closure - HCP210908WYT1H**

### **Topic**

Request to establish a new HCPCS Level II code to identify the Bandgrip Micro-Anchor Skin Closure.

Applicant's suggested language: XXXXX "Micro-anchor adhesive strip, more than 2 sq. in. but less than or equal to 16 sq. in., with any size adhesive border, each dressing."

### **Applicant's Summary**

Bandgrip Inc, submitted a request for a new HCPCS Level II code to identify the Bandgrip Micro-Anchor Skin Closures. The Bandgrip Micro-Anchor Skin Closure is a safe, sterile, Polycarbonate, class I, non-significant risk device for skin closure. The micro-anchor skin closure device is designed for speed of application, simplicity and strength. The device utilizes a novel method which precisely approximates skin edges utilizing several small skin anchors on a clear bandage-type patch. The clear micro-anchors are 0.29 inches in height and do not puncture through the dermis. Available evidence points to Bandgrip as a safe, effective alternative to traditional skin closure techniques such as staples, sutures and skin glues. There are currently no codes that can be used for the effective use for a micro-anchor skin closure device.

### **Preliminary CMS HCPCS Coding Recommendation**

This product may not be suitable for inclusion in HCPCS Level II code set because it is a supply used in a procedure reported using HCPCS Level I (CPT) code. It is our understanding that the Bandgrip would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physicians' service? If so, what CPT code(s) describe the service(s)?

### **Summary of Primary Speaker Comments at the Public Meeting**

No oral or written comments were provided by the applicant in response to CMS' published preliminary HCPCS coding recommendation.

### **CMS Final HCPCS Coding Decision**

Following the HCPCS Level II Public Meeting, CMS is finalizing its preliminary recommendation. This product is not suitable for inclusion in the HCPCS Level II code set because it is a supply used in a procedure reported using a HCPCS Level I (CPT) code. It is our understanding that the Bandgrip would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable.

## **InVoCell - HCP210913Y2C5W**

### **Topic**

Request to establish a new HCPCS Level II codes to identify InVoCell

Applicant's suggested language: SXXXX "Intravaginal culture (IVC) system, single use"

### **Applicant's Summary**

InVoCell Intravaginal Culture System contains the InVoCell Culture Device and InVoCell LL Retention Device. The Culture Device is FDA indicated for use in preparing, holding, and transferring human gametes or embryos during In Vitro Fertilization/Intravaginal Culture (IVF/IVC) and Intra-cytoplasmic Sperm Injection Fertilization/Intravaginal Culture (ICSI/IVC). The Retention Device is used during the incubation period to aid in holding the Culture Device in the vagina. During IVC eggs and sperm are combined in the InVoCell culture device. Then the InVoCell is placed in the patients' vagina, allowing for fertilization and incubation to occur. InVoCell is a new product and there are no other IVC products in the market. The InVoCell Retention Device is a single use, device that includes holes to allow for natural drainage of vaginal fluids (see Figure 3). The retention device is placed into the vaginal cavity with the InVoCell Culture Device to ensure that the InVoCell Culture Device is retained in the vaginal cavity. The retention device comes in a single size: 70mm. The InVoCell Culture Device is a three-part assembly enclosed in two separate packages. The inner vessel holds culture medium, eggs and sperm, or ICSI fertilized embryos. In an InVoCell procedure, the inner vessel is placed into the outer rigid shell, which provides additional resistance to contamination. Following the loading of gametes or embryos, the InVoCell Culture Device is assembled and placed in the vaginal cavity to allow for embryo development.

### **Preliminary CMS HCPCS Coding Recommendation**

This product may not be suitable for inclusion in HCPCS Level II code set because it is used in a procedure reported using HCPCS Level I (CPT) code. It is our understanding that the InVoCell Culture Device and InVoCell Retention Device would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physician's service? If so, what CPT code(s) describe the service(s)?

### **Summary of Primary Speaker Comments at the Public Meeting**

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

### **CMS Final HCPCS Coding Decision**

Following the HCPCS Level II Public Meeting, CMS is finalizing its preliminary recommendation. This product is not suitable for inclusion in the HCPCS Level II code set because it is used in a procedure reported using a HCPCS Level I (CPT) code. It is our understanding that the InVoCell Culture Device and InVoCell Retention Device would typically be bundled into the payment for the procedure, if it is used, and as such would not be separately payable.

## Internal Request: Continuous Glucose Monitoring

### Summary

On December 28, 2021, CMS published a final rule in the *Federal Register* entitled “Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas” (86 FR 73860) that addressed the classification and payment of continuous glucose monitors (CGMs) under the Medicare Part B benefit for durable medical equipment (DME). This rule expanded the classification of DME to a larger group of CGMs regardless of whether the CGMs are non-adjunctive (can alert patients when glucose levels are approaching dangerous levels, including while they sleep and also replace blood glucose monitors) or adjunctive (can alert patients when glucose levels are approaching dangerous levels, including while they sleep but do not replace blood glucose monitors), as long as the CGMs satisfy the regulatory definition of DME.

Non-adjunctive CGM receivers, which are DME that display and monitor the continuous glucose readings and trends, replace a blood glucose monitor for use in making diabetes treatment decisions. Medicare claims for non-adjunctive CGM receivers are submitted using code K0554 in the Healthcare Common Procedure Coding System (HCPCS). Medicare claims for the monthly supplies for non-adjunctive CGMs are submitted using HCPCS code K0553.

There are currently no existing HCPCS codes that describe an adjunctive CGM or the monthly supplies and accessories for adjunctive CGMs. The codes currently used for adjunctive CGM supplies and accessories, HCPCS codes A9276 and A9277, individually identify CGM supplies and accessories and are not reflective of a monthly allowance. Effective April 1, 2022, the new E2102 (Adjunctive continuous glucose monitor or receiver) will be used to submit claims for an adjunctive receiver and the new A4238 (Supply allowance for adjunctive continuous glucose monitor (CGM, includes all supplies and accessories, 1 month supply = 1 unit of service) will be used to identify one month of adjunctive CGM supplies and accessories.

Additionally, in light of the December 28, 2021 DMEPOS final rule, CMS plans to propose additional CGM coding changes at an upcoming HCPCS Level II Public Meeting. These changes would include revising existing codes K0553 (Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service) and K0554 (Receiver (monitor), dedicated for use with therapeutic glucose continuous monitor system) to change the alphanumeric description from “K” to “A” and “E” codes and to revise the descriptors. The proposed revised codes for K0553 and K0554, respectively, would read:

A423X “Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service”

E210X “Non-adjunctive, non-implanted continuous glucose monitor or receiver”

In conjunction with the above changes, we would also propose conforming changes to the codes added to the HCPCS file on April 1, 2022, codes A423X “Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service” and E210X “Adjunctive continuous glucose monitor or receiver”, at an upcoming HCPCS meeting. The proposed revised codes would read:

A423X “Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service”

E210X “Adjunctive, non-implanted continuous glucose monitor or receiver”

### **CMS Final HCPCS Coding Decision**

1. In order to implement the final rule provisions related to adjunctive CGMs, CMS is establishing the following two new HCPCS Level II codes effective April 1, 2022:

A4238 “Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service”

E2102 “Adjunctive continuous glucose monitor or receiver”

2. CMS is also revising the following existing codes to make them invalid for Medicare use:

A9276 “Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply”

A9277 “Transmitter; external, for use with interstitial continuous glucose monitoring system”

A9278 “Receiver (monitor); external, for use with interstitial continuous glucose monitoring system”

We will be seeking feedback on the above coding actions at an upcoming HCPCS Level II Public Meeting, as well as discussing the Medicare fee-for-service methodology for national payment allowances for adjunctive CGMs, supplies, and accessories.

## **Internal Request: Unspecified Skin Substitute A Code**

### **Summary**

CMS continues to process the FDA cleared 510(k) wound care products in our biannual coding cycles. CMS has identified a claims processing need for an unspecified code to identify these products when a unique HCPCS Level II code does not exist. As such, CMS is establishing a new HCPCS Level II code to facilitate billing in the interim, as CMS processes HCPCS Level II applications.

### **CMS Final HCPCS Coding Decision**

Establish HCPCS Level II code A4100 "Skin substitute, fda cleared as a device, not otherwise specified"

Effective: 4/1/2022