DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, Maryland 21244-1850

Centers for Medicare & Medicaid Services (CMS) Agenda for Healthcare Common Procedure Coding System (HCPCS) Public Meeting for Code Applications for Non-Drug and Non-Biological Items and Services Submitted to CMS' 2nd 2021 Biannual HCPCS Coding Cycle

Zoom Meeting, for remote participation
Wednesday, December 1, 2021 9:00 am – 5:00 pm, eastern standard time (est)

8:45 am, est:
• Zoom meeting login:
https://cms.zoomgov.com/meeting/register/vJItf-mtpjsrGmPUe9EFh3kSrpwZX1tVtVE.
• Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

9:00 am, est:
• Welcome
• Background and purpose of meeting
• Meeting format and ground rules

For each agenda item, a written overview of the request and CMS' preliminary coding recommendation or other review status is provided. Preliminary recommendations are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for stakeholders and interested parties to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meeting. CMS' final coding decisions will be published on CMS' HCPCS website at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelII-Coding-Decisions-Narrative-Summary around the beginning of January 2022 and will be effective April 1, 2022, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Wednesday, December 1, 2021. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government

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December 1, 2021

CMS HCPCS Virtual Public Meeting

Agenda Item # 1

eXciteOSA Control Unit - HCP210826HY98M

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 OSA, adjustable stimulation, each."

eXciteOSA Mouthpiece - HCP2108265Y526

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

Agenda Item # 2

California Department of Healthcare Services - HCP2109021HAKD

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."

Agenda Item # 3

Dayspring Lite - HCP210903LPG21

Request to revise existing HCPCS Level II 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."

Dayspring - HCP210903PMKF3

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."

Dayspring - HCP210903WBEG8

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."

Agenda Item # 4

Optimizer® Patient Charger - HCP21090362W2D

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."

Agenda Item # 5

Portable Neuromodulation Stimulator Controller - HCP210921MV8C5

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."

Portable Neuromodulation Stimulator Mouthpiece - HCP210913TB3M7

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."

Agenda Item # 6

iLevel, Safe Seat Elevation - HCP210913PDDCR

PLEASE REVIEW THE FULL WRITEUP FOR THE AGENDA ITEM ON SUBSEQUENT PAGES OF THIS DOCUMENT

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."

Applicant's suggested language:

: E2300, "Wheelchair accessory, power seat elevation system."

Agenda Item # 7

HealthBeacon HB2 Sharps Bin - HCP210902L0Q5G

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

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

Agenda Item # 8

SmartClip - HCP210902KK9Q5

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."

Navigation Device - HCP2109022QRXT

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."

Agenda Item # 9

ActiGraft - HCP2109019H6KW

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

Applicant's suggested language: XXXXX, "ActiGraft, each, including all components."

Agenda Item # 10

Strados Remote Electronic Stethoscope Platform - HCP210913Y0PAV

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

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

Agenda Item # 11

Sirius MRI Source Device - HCP210914F42N2

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."

Orion - HCP210826989LH

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."

Agenda Item # 12

Precice System External Remote Controller - HCP210908E0KFN

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."

Agenda Item # 13

Oxinium - HCP210826MCQFN

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

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

Agenda Item # 14

Tablo - HCP210826JU18N

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.

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Agenda Item # 1

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 OSA, adjustable stimulation, each"

Applicant's Summary

Signifier Medical Technologies, LLC (SMT) submitted a request for the 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 App 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."

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Agenda Item # 1

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 for the 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 App 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 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, "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."

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Agenda Item # 2

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."

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Agenda Item # 3

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, which is segmental compression without calibrated gradient pressure, are accurately described and grouped at the broadest level. 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."

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Agenda Items # 3

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."

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Agenda Item # 3

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."

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Agenda Item # 4

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 therapy, which obtained 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 3 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?

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Agenda Item # 5

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 electrotactile 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?

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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?

PLEASE REVIEW THE FULL WRITEUP FOR THE AGENDA ITEM ON SUBSEQUENT PAGES OF THIS DOCUMENT

Agenda Item # 5

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. There are electronics and software within the Mouthpiece that distribute the stimulation. The Mouthpiece is intended 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. The PoNS device is prescribed by a healthcare provider. The supervised therapeutic exercise program includes 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 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 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?

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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?

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Agenda Item #6

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 6 inches of elevation may be useful on a Group 2 standard power wheelchair designed for continuous use (> 2 hours/day) needs it is inadequate in defining the advanced performance characteristics of elevated motion seating used on Group 3 and above Complex Rehab Technology (CRT) power wheelchairs 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 complex rehabilitation technology (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 10 inches 2. Minimum top end speed of 3 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.

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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 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.

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Agenda Item # 7

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 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.

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Agenda Item # 8

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.

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Agenda Item # 8

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)?

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Agenda Item # 9

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)?

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Agenda Item # 10

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).

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Agenda Item # 11

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 request 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 magnetic resonance imaging (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)?

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Agenda Item # 11

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

The FDA-cleared Orion device, from C4 Imaging LLC, 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)?

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Agenda Item # 12

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)?

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Agenda Item # 13

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.

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Agenda Item # 14

Tablo Hemodialysis System - HCP210826JU18N

Topic

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.

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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.