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

Centers for Medicare & Medicaid Services' (CMS') First Biannual 2022 Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda

Zoom Meeting, for remote participation
Thursday, December 1, 2022 9:00 am – 5:00 pm, eastern time (ET)

8:45 am, ET:
• Zoom meeting login:
https://cms.zoomgov.com/webinar/register/WN_v9r9lfW_QZimHUNq__AXrg
• Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

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

Provided for each agenda item is a written overview of the applicant's request, CMS' preliminary coding recommendation, as well as CMS' preliminary benefit category and payment determination, if applicable. 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 any registered 5-minute speakers. Speaker 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, benefit category, and payment decisions will be published on CMS' HCPCS website at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCSLevelII-Coding-Decisions-Narrative-Summary around January 2023 and will be effective April 1, 2023, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Thursday, December 1, 2022. 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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Preliminary decisions for the HCPCS Virtual Public Meeting on December 1, 2022.

Agenda Item # 1
Personalized PseudoPatient™ PV - HCP220613WR6GD

Topic/Issue

Request to establish a new HCPCS Level II code to identify Personalized PseudoPatient™ PV.

Applicant's suggested language: XXXXX, "Personalized, single-use 3D printed patient phantom intended for personalized pre-treatment verification for external beam radiotherapy of the brain constructed from the patient's planning CT data"

Applicant's Summary

RT Safe, Inc. submitted a request to establish a new HCPCS Level II code to identify the Personalized PseudoPatient™ PV. Personalized PseudoPatient™ PV was 510(k) approved on July 10, 2018 by the Food and Drug Administration. Personalized PseudoPatient™ PV is an exact anatomical replica of the anatomy of a patient's head based on their pretreatment CT-scan. The device is used to obtain direct measurements of radiation dose for anatomic regions of high interest, designated by the end user, for quality assurance of patient specific brain treatments prior to and/or interfractionally to delivery by external beam radiotherapy. The device consists of 3D printed boney structure and external contours using bone equivalent material. The phantom is filled with water that serves as a tissue equivalent material and is loaded with an ion chamber (or any kind of insert for point dosimetry) insert and/or film dosimetry inserts at designated locations based on the treatment plan to enable pretreatment dose measurements at the most dosimetrically demanding areas and clinical cases. The ion chamber inserts are specifically designed for the detector type indicated by the end user and constructed of Poly (methyl methacrylate). The film insert is equipped with a real water insert to accommodate a dosimetry film which is filled with water by the end-user. The Personalized PseudoPatient™ PV enables absolute point dose radiation measurements, and absolute 2D film dosimetry. According to the applicant, numerous studies have documented the benefits associated with the use of the Personalized PseudoPatient™ PV on a pretreatment basis to target localization accuracy, end-to-end evaluation of all treatment processes, and treatment plan verification prior to cranial radiotherapy and stereotactic radiosurgery. According to applicant, there are currently no existing HCPCS Level II codes that accurately describe the Personalized PseudoPatient™ PV and its use. While the current HCPCS code A4650, "Implantable radiation dosimeter, each", describes a radiation dosimeter, the code is limited to implantable dosimeters and does not describe the use of dosimetry in conjunction with the patient phantom on a pretreatment basis for quality assurance and treatment plan verification.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the Personalized PseudoPatient™ PV would generally be used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used.

Agenda Item # 2
Bioventus® Neuromodulation System, External Pulse Transmitter - HCP220630UD3PG

Topic/Issue

Request to establish a new HCPCS Level II code to identify Bioventus® StimRouter Neuromodulation System's External Pulse Transmitter.

Applicant's suggested language: LXXXX, "Electric field energy transmitter (external) for use with implantable neurostimulator pulse generator or receiver, replacement only"

Applicant's Summary

Bioventus® submitted a request to establish a new HCPCS Level II code to identify Bioventus® StimRouter (SR) Neuromodulation System's External Pulse Transmitter (EPT). Bioventus® SR Neuromodulation System received the Food and Drug Administration's (FDA's) 510(k) clearance on February 20, 2015. SR Neuromodulation System is indicated for pain management in adults who have severe intractable pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). SR is not intended to treat pain in the craniofacial region. The SR EPT device, Patient Programmer (PP) device and the disposable Surface Electrode Patches (SEPs) are each separate accessory components to be used in conjunction with one another and an implanted lead for proper use of the SR Neuromodulation System by patients in their home. Replacement device(s) may be required due to product wear and tear, while disposable products (e.g., surface electrode patches) are required for continued use. Each SR EPT has a 2-year expected lifetime, so replacement may be necessary after the 1-year warranty against manufacturing defects. The EPT is the energy-generating device component of the SR Neuromodulation System and includes a system charger set with a plug-in AC/DC adapter and is powered by an integral IEC and UL approved rechargeable battery with a protection circuit. The EPT mechanically attaches to the adhesive SR SEP that is placed on the skin over the receiver end of the implanted lead. The patient uses the SR PP to wirelessly activate and control the EPT allowing for the adjustment of treatment parameters within the pre-programmed settings. Once the EPT is turned on, connected to the SEP and PP is activated, the EPT generates an electric field (EF) of energy that is captured by the implanted receiver which is connected to a lead, stimulating the target nerve, induces paresthesia and reduces pain. According to the applicant, a new code request is being submitted because HCPCS Level II code L8683 describes an external radiofrequency (RF) transmitter. SR technology uses EF energy rather than RF; therefore, use of the existing code is not appropriate for the SR EPT device, when replacement is necessary. According to the applicant, in the February 2022 meeting of the AMA CPT Editorial Panel, an application was approved to modify existing codes (64590) and create new Category I codes (64XX2) to be more reflective of the contemporary Neuromodulation Systems for Pain not using RF or inductive coupling.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code L8683, "Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver" describes Bioventus® Neuromodulation System External Pulse Transmitter. According to StimRouter® Neuromodulation System Clinician's Guide, 602-00631-001 Rev. G, "[t]his equipment generates, uses and can radiate radio frequency energy."

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code L8683 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code L8683 apply for this product, if covered. The current average fee schedule amount for L8683 is $5,569.76.

The average fee schedule amount is the average of the 2022 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 2
Bioventus® Neuromodulation System, Patient Programmer - HCP220630ABNCV

Topic/Issue

Request to establish a new HCPCS Level II code to identify Bioventus® StimRouter Neuromodulation System's Patient Programmer.

Applicant's suggested language: LXXXX, "Patient programmer (external) for use with implantable programmable neurostimulator pulse generator or receiver, replacement only"

Applicant's Summary

Bioventus® submitted a request to establish a new HCPCS Level II code to identify Bioventus® StimRouter (SR) Neuromodulation System's Patient Programmer (PP). Bioventus® SR Neuromodulation System received the Food and Drug Administration's (FDA's) 510(k) clearance on February 20, 2015. SR Neuromodulation System is indicated for pain management in adults who have severe intractable pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). SR is not intended to treat pain in the craniofacial region. The SR PP device, the External Pulse Transmitter (EPT) device and the disposable Surface Electrode Patches (SEPs) are each separate accessory component to be used in conjunction with one another and an implanted lead for proper use of the SR Neuromodulation System by patients in their home. Replacement device(s) may be required due to product wear and tear, while disposable products (e.g., surface electrode patches) are required for continued use. Each SR PP has a 2-year expected lifetime, so replacement may be necessary after the 1-year warranty against manufacturing defects. The PP is the wireless control unit of the SR Neuromodulation System and includes a plug-in AC/DC adapter, a neck strap, a wrist strap, and belt pouch. It is rechargeable and portable, using a commercially available rechargeable AAA NiMH battery. Patients use the PP to wirelessly (RF) control the SR EPT and places a disposable SR SEP on the skin. Patients then use the PP to select a treatment session pre-programmed by their physician, turn stimulation on or off, and increase or decrease intensity. The PP also logs all patient use and sessions, allowing the physician to track patient compliance. According to the applicant, a new code request is being submitted because HCPCS L8681 describes a patient programmer used with an implantable programmable neurostimulator pulse generator. SR technology uses an implantable receiver rather than a pulse generator; therefore, use of the existing code is not appropriate for the SR PP device, when replacement is necessary. According to the applicant, in the February 2022 meeting of the AMA CPT Editorial Panel, an application was approved to modify existing codes (64590) and create new Category I codes (64XX2) to be more reflective of the contemporary Neuromodulation Systems for Pain not using RF or inductive coupling.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code L8681, "Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only" describes Bioventus® Neuromodulation System Patient Programmer.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code L8681 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code L8681 apply for this product, if covered. The current average fee schedule amount for L8681 is $1,199.74.

The average fee schedule amount is the average of the 2022 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 2
Bioventus® Neuromodulation System, Surface Electrode Patch - HCP220630DY5Y8

Topic/Issue

Request to establish a new HCPCS Level II code to identify Bioventus® StimRouter Neuromodulation System's Surface Electrode Patch.

Applicant's suggested language: XXXXX, "Electrical stimulator supplies, per month, (e.g., pns), conductive adhesive surface patch"

Applicant's Summary

Bioventus® submitted a request to establish a new HCPCS Level II code to identify Bioventus® StimRouter (SR) Neuromodulation System's Surface Electrode Patch (SEP). Bioventus® SR Neuromodulation System received the Food and Drug Administration's (FDA's) 510(k) clearance on February 20, 2015. SR Neuromodulation System is indicated for pain management in adults who have severe intractable pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). SR is not intended to treat pain in the craniofacial region. The SR SEPs, the External Pulse Transmitter (EPT) device and the Patient Programmer (PP) device are each separate accessory component to be used in conjunction with one another and an implanted lead for proper use of the SR Neuromodulator System by patients in their home. Replacement device(s) may be required due to product wear and tear, while disposable products (e.g., surface electrode patches) are required for continued use. Each adhesive SR SEP has a 12-month shelf life and are shipped in packages of 8 individually packaged SEPs. Each patch may be re-used for a period of 2-4 days, so that 2 packages of 8 (each) will last a patient no less than 32 days, when used as intended. The SR SEP functionality is two-fold: via 2 custom snap connectors the SEP provides a mechanical attachment to secure and maintain alignment of the SR EPT device to the skin of the patient and over top of the implanted receiver, and the hydrogel electrode component of the SEP (electrically connected to the EPT via the custom snaps) transcutaneously transmits an electrical field (EF) of energy from the EPT to the receiver end of the implanted lead, stimulating the target peripheral nerve to induce paresthesia resulting in the reduction of pain via a stimulation program selected from the PP device. According to the applicant, a new code request is being submitted because neither HCPCS A4595 nor A5126 alone describe SR SEP technology which serves two unique functions (mechanical and electrical); therefore, a single new code would be more appropriate, when additional disposable SEPs are necessary. According to the applicant, in the February 2022 meeting of the AMA CPT Editorial Panel, an application was approved to modify existing codes (64590) and create new Category I codes (64XX2) to be more reflective of the contemporary Neuromodulation Systems for Pain not using RF or inductive coupling.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code LXXXX, "Electrical stimulator supplies (external) for use with implantable neurostimulator, per month" to describe Bioventus® StimRouter Neuromodulation System's Surface Electrode Patch. The coding recommendation for the Bioventus® StimRouter Neuromodulation System falls into the prosthetic benefit for Medicare. In turn, the supplies necessary for the device should also fall in the same benefit category.

Preliminary Medicare Benefit Category Determination

Prosthetic Device

The application supports a preliminary benefit category determination that LXXXX would fall under the Medicare benefit for prosthetic devices, per NCD 160.7 for Electrical Nerve Stimulators.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. The preliminary payment determination for code LXXXX, for this particular type of supply, is that this item should be priced using the existing fee schedule amounts for comparable items described by HCPCS code A4595.

The average fee schedule amount for LXXXX would be $20.31.

The average fee schedule amount is the average of the 2022 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 3
SPEAC® System - HCP220705KM2RJ

Topic/Issue

Request to establish a new HCPCS Level II code to identify SPEAC® System.

Applicant's suggested language: XXXXX, "Surface electromyography-based ambulatory system for detection of generalized tonic-clonic seizures"

Applicant's Summary

Novela Neurotechnologies, Inc. submitted a request to establish a new HCPCS Level II code to identify the SPEAC® System. The SPEAC® System is a wireless, non-invasive, physiological, surface electromyography (sEMG) recording, monitoring, and alerting system to be used as an adjunct to seizure monitoring during periods of rest. It is prescribed by a physician for use in seizure monitoring of adults in the home or healthcare facilities during periods of rest. The SPEAC® System is the first FDA-cleared portable seizure monitoring and alerting technology using sEMG. The SPEAC® System received the Food and Drug Administration's (FDA's) de novo clearance on February 16, 2017. The product initially received de novo designation in February 2017, with subsequent 510(k) clearances in 2019 and 2021, where the predicate devices were based on previous versions of the SPEAC® System. The system continuously records and stores sEMG data at 1,000 (and audio around detected events) for post-hoc review by physicians (or other trained healthcare professionals) for the characterization of generalized tonic-clonic (GTC) seizure events. The sEMG data together with other contextual data gives healthcare professionals another diagnostic tool to characterize upper-extremity motor activity (UEMA) ipsilateral to the device from other activity. According to the applicant, there are currently no HCPCS Level II codes which describe a portable, sEMG system for the detection of GTC seizures.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E0746, "Electromyography (emg), biofeedback device" describes SPEAC® System.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0746 apply to this item.

The application explains the SPEAC® System is a wireless, non-invasive, physiological, surface electromyography (sEMG) recording, monitoring, and alerting system to be used as an adjunct to seizure monitoring during periods of rest. At the end of a monitoring period, the physician will receive a summary report to help with clinical decisions. The Medicare Benefit Policy Manual, Chapter 15, Section 80.2 (Pub. 100-2) "Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests" and Local Coverage Determination number 34594 "Nerve Conduction Studies and Electromyography" guide that the items used for electromyography are associated with the professional services. Items used in the patient's home that provide monitoring and measurements for the physician / practitioner to

evaluate the patient's condition and course of treatment do not fall under the Medicare benefit for DME used in the home.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0746 apply to this product. Items or services described by HCPCS code E0746 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 4
RelieVRx - HCP220701K2H96

Topic/Issue

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

Applicant's suggested language: XXXXX, "Virtual reality behavioral therapy system for pain relief, including equipment and pre-programmed behavioral therapy content, FDA-cleared, per course of treatment"

Applicant's Summary

AppliedVR, Inc. submitted a request to establish a new HCPCS Level II code to identify RelieVRx. RelieVRx was granted FDA breakthrough status for the first de novo FDA-authorized immersive virtual reality (VR) medical device for home use that is indicated for the treatment of chronic low back pain on March 3, 2021. RelieVRx is a Class II medical device, available only by prescription, that consists of a modified proprietary Pico G2 4G VR headset, which is not available for retail sale, as well as a patented Breathing Amplifier™ to allow integration of bio-enabled immersive experiences, and preloaded software. The device is locked such that it can only be used for treatment of the specified clinical indication. The device delivers a clinically based multimodal pain self-management program incorporating evidence-based principles of Cognitive Behavioral Therapy (CBT) and other neuroscience-based behavioral health methods to reduce pain intensity and pain interference with daily activities, sleep, mood and stress for patients diagnosed with moderate to severe chronic low back pain. The device engages all four major regions of the brain to address maladaptive neuroplastic changes associated with chronic pain and has been demonstrated in published peer-reviewed literature to produce statistically and clinically significant reductions in pain intensity and pain interference. RelieVRx therapy is administered daily as a 3-16 minute module (averaging 7 minutes per day) over the course of 56 days. The de novo FDA authorization encompasses the integrated hardware and software, as the headset is required to deliver the 3-dimensional 360° multimodal pain self-management curriculum and is tested to meet American National Standards Institute (ANSI) medical device standards. According to the applicant, clinical trial evidence demonstrates that the durable VR hardware is required to deliver significantly greater reductions in pain intensity and pain interference compared to software-only or application-only methods. RelieVRx is self-administered, unsupervised in the patient's home while the patient is in a seated position. The therapy is not delivered as part of a clinician service. The device is returned upon completion of the 56-day course of treatment and is available for reuse. The device has an expected useful life of 3 years or greater, is suitable for repeated use, and does not include non-medical software or allow non-medical use. According to the applicant, there are no existing HCPCS Level II codes available for immersive VR for pain or other therapeutic indications used in the home.

CMS Preliminary HCPCS Coding Recommendation

In an effort to better understand the request to use a virtual reality device to treat chronic back pain, CMS is interested in additional information or more explanation of how the immersive nature of this device creates an outcome for the patient that would not have the same effect were the software to instead be used on a non-virtual reality device such as a computer, tablet, or phone.

CMS has no preliminary recommendation with regard to this product as we continue to consider its clinical distinction relative to other products. In the meantime, classification, coverage, and payment for RelieVRx will be made on an individual claim-by-claim basis by the MACs.

Agenda Item # 5
JAS Elbow EZ Turnbuckle Orthosis - HCP220705MC6YY

Topic/Issue

Request to revise existing HCPCS Level II code L3761 to include JAS Elbow Turnbuckle Orthosis.

Applicant's suggested language: L3761, “Elbow orthosis (eo), with adjustable position locking joint(s), prefabricated, off-the-shelf, including stretching devices used to treat contractures and increase range of motion”

Applicant’s Summary

Joint Active Systems, Inc. submitted a request to revise an existing HCPCS Level II code to include JAS Elbow Turnbuckle Orthosis. According to the applicant, the requested language change to L3761 is based on the Medicare Contractor for Pricing, Data Analysis and Coding of HCPCS Level II DMEPOS Codes (PDAC) determination that "stretching devices used to treat contractures and increase range of motion" are required by CMS to be classified as durable medical equipment (DME). The applicant believes this is a misapplication of CMS rules and policy for DME benefit category determinations and coding assignments that can be corrected with clarification to the respective HCPCS "L" codes affected by this PDAC Policy. The JAS Elbow EZ Turnbuckle Orthosis is a single-patient bi-directional use, prefabricated orthosis that has a range of sizes to fit patients based on measurements of the upper extremity. The EZ Elbow is used for the treatment of elbow joint stiffness, most commonly prescribed for post-traumatic contracture, elbow fracture (e.g., radial head, olecranon, and distal humerus), elbow dislocation, and tendon/ligament repairs. The wearing schedule, which includes duration and frequency of use, is determined by the prescribing physician or supervising practitioner. The applicant believes the current language of L3761 fits the JAS Elbow EZ product. According to the applicant, PDAC has directed the applicant to this application process based on the PDAC's indication that stretching devices are classified by CMS as DME. The applicant noted that PDAC stated, "if a device's primary clinical function is to increase/enhance joint motion, it does not meet CMS's definition of a brace. According to the applicant, CMS created the E18XX code series to describe devices that stretch the anatomical joint." The applicant believes these positions are contrary to CMS published guidance. First, CMS's definition of a brace "includes rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.” CMS Pub. 100-02, Ch. 15, S 130. There is no limitation for the "clinical function" which is ultimately determined by the provider. A brace that can be adjusted and locked into multiple fixed positions via turnbuckle is still a brace (i.e. rigid and supporting of elbow while in use, enhancing motion by virtue of different rigid and supporting positions). The applicant further stated that CMS created the E18XX series to describe DME devices (not just any orthosis that stretches the anatomical joint). DME is a benefit category with specific regulatory requirements, including durability (42 CFR 414.202(a)). The JAS EZ Elbow is a single-patient use orthosis not designed for repeated use from multiple patients and could not withstand a life expectancy of more than 3 years for such circumstances. There is not a therapy protocol (i.e. stretching device) limitation in the DME regulation. If a product does not meet the DME definition of durable, it cannot be assigned an "E18XX" regardless of its therapeutic protocol. The applicant has submitted this application to clarify CMS policy by revising L3761 to confirm its appropriate

use for "stretching devices" that meet other elements of that code's description as the JAZ EZ Prefab Elbow does.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to revise existing HCPCS Level II code L3761. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a revision to HCPCS level II code L3761.

Agenda Item # 6
Intermittent Urinary Catheters - HCP220701G0DRV

Topic/Issue

Request to discontinue existing HCPCS Level II code A4351 "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each" and establish seven new HCPCS Level II codes to identify straight tip intermittent urinary catheters.

Applicant's suggested language:

1. AXXXX, "Intermittent urinary catheter; straight tip, without coating, each"

2. AXXXX, "Intermittent urinary catheter; straight tip, with pre-lubricated gel coating, without protective elements, each"

3. AXXXX "Intermittent urinary catheter; straight tip, with pre-lubricated gel coating, with protective elements (e.g., gripper, partial sleeve, full length sleeve, etc.), each"

4. AXXXX, "Intermittent urinary catheter; straight tip, with manually activated hydrophilic coating, without protective elements, each"

5. AXXXX, "Intermittent urinary catheter; straight tip, with manually activated hydrophilic coating, with protective elements (e.g., gripper, partial sleeve, full length sleeve, etc.), each"

6. AXXXX, "Intermittent urinary catheter; straight tip, with pre-activated hydrophilic coating, without protective elements, each"

7. AXXXX, "Intermittent urinary catheter; straight tip, with pre-activated hydrophilic coating, with protective elements (e.g., gripper, partial sleeve, full length sleeve, etc.), each"

Applicant's Summary

The American Association for Homecare and its incontinence care manufacturer members, Coloplast, Hollister, and Wellspect submitted a request to discontinue existing HCPCS Level II code A4351, "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each" and establish seven new HCPCS Level II codes to further distinguish the functionalities of straight tip intermittent urinary catheters. According to the applicant, the current HCPCS code covers such a broad range of intermittent urinary catheters that CMS and its contractors often do not know specifically what they are paying for, which leads to vulnerabilities in the administration of the Medicare program. Additionally, the wide variation in functionality between products currently classified under HCPCS code A4351 creates a lack of transparency, which may result in patients receiving the least expensive intermittent urinary catheter described by the HCPCS code being used. However, this catheter may not meet the patient's clinical needs to consistently perform successful self-catheterization. Lastly, because HCPCS code A4351 does not accurately reflect the different features and functionalities of various intermittent urinary catheters, payors other than the Medicare program have been forced to implement a

variety of coding "workarounds" in order to better identify and separately reimburse for catheters with different features. This conflicts with the federal requirement and purpose of the uniform code set that CMS has been charged with overseeing for the benefit of all payors, not just the Medicare program. According to the applicant, the 7 recommended HCPCS codes for straight tip urinary catheters identify differences in catheters that are not coated; require a coating to be separately provided and manually applied; pre-coated catheters that need to be manually activated; ready-to-use catheters that include hydrophilic technology that reduce the risk of urethral trauma; and catheters that have protective elements, which helps aid with insertion into the urethra.

CMS Preliminary HCPCS Coding Recommendation

In an effort to better understand the request to create more granular codes for intermittent catheters that would specify clinical distinctions and physical components of intermittent urinary catheters, CMS is interested in input from non-Medicare insurers as to the business need for more granular coding of intermittent catheters, as well as input from the applicant and other interested parties pertaining to the following claims made in the application:

The applicant states that "coding distinctions between catheter differences, including surface material (e.g. hydrophilic technology) and features that aid with clean insertion of the catheter are necessary to ensure patients receive a catheter that fits their individual needs."

1. Please provide specific examples of program integrity issues to support your claim that patients did not receive proper care as a result of the existing codes A4351, A4352, and A4353.

2. To the extent the applicant claims a therapeutic distinction between products that are included in the same code, please specify and provide supporting clinical evidence of such claim.

3. What "workarounds" have other payers outside of Medicare implemented to better identify and separately pay for catheters? Is there any publicly available insurer policy that can be provided to demonstrate these "workarounds"?

The applicant states that "the Centers for Medicare and Medicaid Services (CMS) and its contractors often do not know specifically what they are paying for, which leads to vulnerabilities in the administration of the Medicare program."

4. Please provide specific examples of the vulnerabilities to the Medicare program as mentioned in the application and how they relate to existing codes. Unless the "vulnerabilities" are the same as "program integrity issues" (as in #1 above), in which case, this entry is redundant and could be omitted.

5. Palmetto GBA, Medicare's contractor for pricing, data analysis and coding of HCPCS Level II DMEPOS codes, maintains a product classification list (PCL) (https://www4.palmettogba.com/pdac_dmecs/initProductClassificationResults.do) for items that could be billed under a code for Medicare. Yet the applicant has claimed that this list does not accurately identify the product(s) that Medicare might pay for under the existing intermittent urinary catheter codes A4351, A4352, and A4353.

Please provide specific examples of product(s) that are not accurately identified in these existing codes and in the PCL.

6. We do not understand how is there a “lack in transparency”, as stated in the incoming applications, when the products are listed specifically on the PCL. Please elaborate.

Please be advised that, in accordance with regulations at 42 CFR § 414.236, Medicare fee schedule amounts for new HCPCS codes for items and services that have a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing. Mapping fee schedule amounts can occur based on different kinds of coding changes. This includes when there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.

Agenda Item # 6
Intermittent Urinary Catheters - HCP220701Q1RK8

Topic/Issue

Request to discontinue existing HCPCS Level II code A4352 "Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each" and establish seven new HCPCS Level II codes to identify coude (curved) tip intermittent urinary catheters.

Applicant's suggested language:

1. AXXXX, "Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), without coating, each"

2. AXXXX, "Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-lubricated gel coating, without protective elements, each"

3. AXXXX, "Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-lubricated gel coating, with protective elements (e.g. gripper, partial sleeve, full length sleeve, etc.), each"

4. AXXXX, "Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with manually activated hydrophilic coating, without protective elements, each"

5. AXXXX, "Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with manually activated hydrophilic coating, with protective elements (e.g. gripper, partial sleeve, full length sleeve, etc.), each"

6. AXXXX, "Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-activated hydrophilic coating, without protective elements, each"

7. AXXXX, "Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-activated hydrophilic coating, with protective elements (e.g. gripper, partial sleeve, full length sleeve, etc.), each"

Applicant's Summary

The American Association for Homecare and its incontinence care manufacturer members, Coloplast, Hollister, and Wellspect submitted a request to discontinue existing HCPCS Level II code A4352, "Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each" and establish seven new HCPCS Level II codes to identify curved tip intermittent urinary catheters. According to the applicant, the current HCPCS code covers such a broad range of intermittent urinary catheters that CMS and its contractors often do not know specifically what they are paying for, which leads to vulnerabilities in the administration of the Medicare program. Additionally, the wide variation in functionality between products currently classified under HCPCS code A4352 creates a lack of transparency, which may result in patients receiving the least expensive intermittent urinary catheter described by the HCPCS code being used. However, this catheter may not meet the patient's clinical needs to consistently perform successful self-

catheterization. Lastly, because HCPCS codes A4352 does not accurately reflect the different features and functionalities of various intermittent urinary catheters, other payors have been forced to implement a variety of coding workarounds in order to better identify and separately reimburse for catheters with different features. According to the applicant, the seven recommended HCPCS codes for curved tip urinary catheters identify differences in catheters that are not coated; require a coating to be separately provided and manually applied; pre-coated catheters that need to be manually activated; ready-to-use catheters that include hydrophilic technology that reduce the risk of urethral trauma; and catheters that have protective elements, which help aid with insertion into the urethra.

CMS Preliminary HCPCS Coding Recommendation

In an effort to better understand the request to create more granular codes for intermittent catheters that would specify clinical distinctions and physical components of intermittent urinary catheters, CMS is interested in input from non-Medicare insurers as to the business need for more granular coding of intermittent catheters, as well as input from the applicant and other interested parties pertaining to the following claims made in the application:

The applicant states that "coding distinctions between catheter differences, including surface material (e.g. hydrophilic technology) and features that aid with clean insertion of the catheter are necessary to ensure patients receive a catheter that fits their individual needs."

1. Please provide specific examples of program integrity issues to support your claim that patients did not receive proper care as a result of the existing codes A4351, A4352, and A4353.

2. To the extent the applicant claims a therapeutic distinction between products that are included in the same code, please specify and provide supporting clinical evidence of such claim.

3. What "workarounds" have other payers outside of Medicare implemented to better identify and separately pay for catheters? Is there any publicly available insurer policy that can be provided to demonstrate these "workarounds"?

The applicant states that "the Centers for Medicare and Medicaid Services (CMS) and its contractors often do not know specifically what they are paying for, which leads to vulnerabilities in the administration of the Medicare program."

4. Please provide specific examples of the vulnerabilities to the Medicare program as mentioned in the application and how they relate to existing codes. Unless the "vulnerabilities" are the same as "program integrity issues" (as in #1 above), in which case, this entry is redundant and could be omitted.

5. Palmetto GBA, Medicare's contractor for pricing, data analysis and coding of HCPCS Level II DMEPOS codes, maintains a product classification list (PCL) (https://www4.palmettogba.com/pdac_dmecs/initProductClassificationResults.do) for items that could be billed under a code for Medicare. Yet the applicant has claimed that this list does not accurately identify the product(s) that Medicare might pay for under the existing intermittent urinary catheter codes A4351, A4352, and A4353.

Please provide specific examples of product(s) that are not accurately identified in these existing codes and in the PCL.

6. We do not understand how is there a “lack in transparency”, as stated in the incoming applications, when the products are listed specifically on the PCL. Please elaborate.

Please be advised that, in accordance with regulations at 42 CFR § 414.236, Medicare fee schedule amounts for new HCPCS codes for items and services that have a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing. Mapping fee schedule amounts can occur based on different kinds of coding changes. This includes when there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.

Agenda Item # 6
Intermittent Urinary Catheters - HCP220701EYPYU

Topic/Issue

Request to discontinue existing HCPCS Level II code A4353," Intermittent urinary catheter, with insertion supplies" and establish five new HCPCS Level II codes to identify intermittent urinary catheter, with insertion supplies."

Applicant's suggested language:

1. AXXXX, "Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter without coating, each"

2. AXXXX, "Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter with pre-lubricated gel coating, each"

3. AXXXX, "Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter with manually activated hydrophilic coating, each"

4. AXXXX, "Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter with pre-activated hydrophilic coating, each"

5. AXXXX, "Sterile no-touch catheter system, each"

Applicant's Summary

The American Association for Homecare and its incontinence care manufacturer members, Coloplast, Hollister, and Wellspect submitted a request to discontinue existing HCPCS Level II code A4353, "Intermittent urinary catheter, with insertion supplies" and establish five new HCPCS Level II codes to identify intermittent urinary catheter, with insertion supplies." According to the applicant, the current HCPCS code covers such a broad range of intermittent urinary catheters that CMS and its contractors often do not know specifically what they are paying for, which leads to vulnerabilities in the administration of the Medicare program. Additionally, the wide variation in functionality between products currently classified under HCPCS code A4353 creates a lack of transparency, which may result in patients receiving the least expensive intermittent urinary catheter described by the HCPCS code being used. However, this catheter may not meet the patient's clinical needs to consistently perform successful catheterization. Lastly, because HCPCS codes A4353 does not accurately reflect the different features and functionalities of various intermittent urinary catheters, payors other than the Medicare program have been forced to implement a variety of coding "workarounds" in order to better identify and separately reimburse for catheters with different features. This conflicts with the federal requirement and purpose of the uniform code set that CMS has been charged with overseeing for the benefit of all payors, not just the Medicare program. According to the applicant, the five recommended HCPCS codes for intermittent urinary catheters with insertion supplies identify differences in catheters that are not coated; require a coating to be separately provided and manually applied; pre-coated catheters that need to be manually activated; ready-to-use catheters that include hydrophilic technology that reduce the risk of urethral trauma; and catheters that have fully enclosed, no touch catheter systems to prevent touch contamination during insertion into the urethra.

CMS Preliminary HCPCS Coding Recommendation

In an effort to better understand the request to create more granular codes for intermittent catheters that would specify clinical distinctions and physical components of intermittent urinary catheters, CMS is interested in input from non-Medicare insurers as to the business need for more granular coding of intermittent catheters, as well as input from the applicant and other interested parties pertaining to the following claims made in the application:

The applicant states that "coding distinctions between catheter differences, including surface material (e.g. hydrophilic technology) and features that aid with clean insertion of the catheter are necessary to ensure patients receive a catheter that fits their individual needs."

1. Please provide specific examples of program integrity issues to support your claim that patients did not receive proper care as a result of the existing codes A4351, A4352, and A4353.

2. To the extent the applicant claims a therapeutic distinction between products that are included in the same code, please specify and provide supporting clinical evidence of such claim.

3. What "workarounds" have other payers outside of Medicare implemented to better identify and separately pay for catheters? Is there any publicly available insurer policy that can be provided to demonstrate these "workarounds"?

The applicant states that "the Centers for Medicare and Medicaid Services (CMS) and its contractors often do not know specifically what they are paying for, which leads to vulnerabilities in the administration of the Medicare program."

4. Please provide specific examples of the vulnerabilities to the Medicare program as mentioned in the application and how they relate to existing codes. Unless the "vulnerabilities" are the same as "program integrity issues" (as in #1 above), in which case, this entry is redundant and could be omitted.

5. Palmetto GBA, Medicare's contractor for pricing, data analysis and coding of HCPCS Level II DMEPOS codes, maintains a product classification list (PCL) (https://www4.palmettogba.com/pdac_dmecs/initProductClassificationResults.do) for items that could be billed under a code for Medicare. Yet the applicant has claimed that this list does not accurately identify the product(s) that Medicare might pay for under the existing intermittent urinary catheter codes A4351, A4352, and A4353. Please provide specific examples of product(s) that are not accurately identified in these existing codes and in the PCL.

6. We do not understand how is there a "lack in transparency", as stated in the incoming applications, when the products are listed specifically on the PCL. Please elaborate.

Please be advised that, in accordance with regulations at 42 CFR § 414.236, Medicare fee schedule amounts for new HCPCS codes for items and services that have a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing. Mapping fee schedule amounts can occur based on different kinds of coding changes. This includes when there is a single code that describes

two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.

Agenda Item # 7
Custom Drainable Pouches, Complexity Level 1 - HCP220705EJ92E

Topic/Issue

Request to establish a new HCPCS Level II code to identify custom ostomy drainable pouches.

Applicant's Suggested Language: XXXXX, "Custom ostomy drainable pouches, complexity level 1"

Applicant's Summary

Nu-Hope Laboratories, Inc. submitted a request to establish a new HCPCS Level II code to identify custom ostomy drainable pouches, complexity level 1. Custom ostomy drainable pouches are exempt from the premarket notification procedures. Trained personnel with expertise design the custom pouches which are shaped, formed, assembled and custom (hand) fabricated to fit a specific patient. Focused measurements, photographs and alginate mold impressions are used to support custom design. Integrated into the pouch system are plastic discs, (support shields) which give support to the peristomal area. Support shields are available in degrees of support, firm, flexible and ultra-flexible. Support shields can be cut to desired sizes and shapes. They can be flat or formed to a variety of depths of convexities. Each shape is made to match the specific contours of the individual patient. Convex points are fabricated to offer focused support for peristomal skin creases, dimples, or divots. The most common configuration of points is eye shape (2 points), or tear drop shape (one point). Customized dies or stone casts are used to form the convexity for the peristomal area. This results in an individualized secure support and seal where needed. Pouch leakage that requires an increased frequency of pouch changes occurring as often as every one to two days or multiple times in a 24-hour period is an indication for a custom pouch. Off the shelf prefabricated convex systems may not supply the needed depth of convexity in one area and too much convexity in another area. Without the proper configuration, the off the shelf convex pouch may lift and leak and/or give too much pressure causing a pressure injury to one area of the peristomal skin. The same pouch can also give inadequate seal to the peristomal skin, contributing to unreliable seal, leakage, and skin breakdown. This contributes to an inability to perform normal activities of daily living, psychological stress, physical, economic, and social implications, including unplanned visits to the clinic or hospital. Custom features may include degree of support, custom shape convexities, closed cell foam pad, and/or custom stoma opening(s). The standard size pouch comes in 24 or 30 ounces. According to applicant, there is no current HCPCS code to describe this style custom pouch system.

CMS Preliminary HCPCS Coding Recommendation

There is insufficient information in the application to determine that the custom ostomy drainable pouches are custom fabricated. As such, CMS believes the existing HCPCS Level II code A4390, "Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each" describes the custom ostomy drainable pouches.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4390 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4390 apply to this product, if covered. The current average fee schedule amount for A4390 is $11.79.

The average fee schedule amount is the average of the 2022 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 37

Agenda Item # 7
Custom Drainable Pouches, Complexity Level 2 - HCP220705RU05H

Topic/Issue

Request to establish a new HCPCS Level II code to identify custom ostomy drainable pouches.

Applicant's Suggested Language: XXXXX, "Custom ostomy drainable pouches, complexity level 2"

Applicant's Summary

Nu-Hope Laboratories, Inc. submitted a request to establish a new HCPCS Level II code to identify custom ostomy drainable pouches, complexity level 2. Custom ostomy drainable pouches are exempt from the premarket notification procedures. Trained personnel with expertise design the custom pouches which are shaped, formed assembled and custom (hand) fabricated to fit a specific patient. Focused measurements, photographs and alginate mold impressions are used to support custom design. Integrated into the pouch system are plastic discs, (support shields) which give support to the peristomal area. Support shields are available in degrees of support: firm, flexible and ultra-flexible. Support shields can be cut to desired sizes and shapes. They can be flat or formed to a variety of depths of convexities. Each is made to match the specific contours of the individual patient. Convex points are fabricated to offer focused support for peristomal skin creases, dimples, or divots. The most common configuration of points is eye shape (2 points), or tear drop shape (one point). Customized dies or stone casts are used to form the convexity for the peristomal area. This results in an individualized secure support and seal where needed. Pre-attached hydrocolloid barriers increase longevity of pouch wear and supports skin healing by absorbing moisture from stoma mucosa and weeping skin related to peristomal irritant contact dermatitis (L24D0, L24B1, L24B3). It simplifies the process in individuals with limited dexterity, poor vision and diminished mental capabilities. Pouch leakage requiring an increased frequency of pouch changes as often as every one to two days or multiple times in a 24-hour period is an indication for a custom pouch. Prefabricated convex pouches may not supply needed depth of convexity in one area and too much convexity in another. Without proper configuration, prefabricated pouches may lift, leak, and/or give too much pressure causing a pressure injury to the peristomal skin. The same pouch can give inadequate seal to the peristomal skin, contributing to unreliable seal, leakage, and skin breakdown. This contributes to an inability to perform normal activities of daily living, psychological stress, physical, economic, and social implications, including unplanned visits to the clinic or hospital. Custom features may include degree of support, shape convexities, closed cell foam pad, and/or stoma opening(s), handmade oversize or oval shape. According to applicant, there is no current HCPCS code to describe this style custom pouch system.

CMS Preliminary HCPCS Coding Recommendation

There is insufficient information in the application to determine that the custom ostomy drainable pouches are custom fabricated. As such, CMS believes the existing HCPCS Level II code A4390, "Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each" describes the custom ostomy drainable pouches.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4390 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4390 apply to this product, if covered. The current average fee schedule amount for A4390 is $11.79.

The average fee schedule amount is the average of the 2022 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 37

Agenda Item # 7
Custom Drainable Pouches, Complexity Level 3 - HCP220705KHCVK

Topic/Issue

Request to establish a new HCPCS Level II code to identify custom ostomy drainable pouches.

Applicant's suggested language: XXXXX, "Custom ostomy drainable pouches, complexity level 3"

Applicant's Summary

Nu-Hope Laboratories, Inc. submitted a request to establish a new HCPCS Level II code to identify custom ostomy drainable pouches, complexity level 3. Custom ostomy drainable pouches are exempt from the premarket notification procedures. Trained personnel with expertise design custom pouches which are shaped, formed assembled and hand fabricated using focused measurements, photographs and alginate mold impressions to fit a specific patient. Integrated into the pouch system are plastic discs, (support shields) give support to the peristomal area. Support shields come in degrees of support: firm, flexible and ultra-flexible. Support shields are cut to desired sizes and shapes, flat or formed to a variety of depths of convexities. Each is made to match the specific contours of the individual patient. Convex points are fabricated to offer focused support for peristomal skin creases, dimples, or divots. Customized dies or stone casts are used to form the convexity for the peristomal area resulting in an individualized secure support and seal. Pre-attached hydrocolloid barriers increase longevity of pouch wear and support skin healing by absorbing moisture from stoma mucosa or weeping skin related to peristomal irritant contact dermatitis (L24D0, L24B1, L24B3). It simplifies the process in individuals with limited dexterity, poor vision or diminished mental capabilities. Pouch leakage requiring frequent pouch changes as often as every one to two days or multiple times in a 24-hour period is an indication for a custom pouch. Prefabricated convex pouches may not supply needed depth of convexity in one area and too much convexity in another. Without proper configuration, prefabricated pouches may lift, leak, and/or give too much pressure causing a pressure injury to the peristomal skin and give inadequate seal to the peristomal skin, contributing to unreliable seal, leakage, and skin breakdown. This contributes to an inability to perform normal activities of daily living, psychological stress, physical, economic, and social implications, including unplanned visits to the clinic or hospital. Custom features may include degree of support, shape convexities, closed cell foam pad, and/or stoma opening(s), handmade oversize or various shapes. According to applicant, there is no current HCPCS code to describe this style custom pouch system.

CMS Preliminary HCPCS Coding Recommendation

There is insufficient information in the application to determine that the custom ostomy drainable pouches are custom fabricated. As such, CMS believes the existing HCPCS Level II code A4390, "Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each" describes the custom ostomy drainable pouches.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4390 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4390 apply to this product, if covered. The current average fee schedule amount for A4390 is $11.79.

The average fee schedule amount is the average of the 2022 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 37

Agenda Item # 8
Exersides™ Refraint™ System - HCP211227F8TPL

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Exersides™ Refraint™ System.

Applicant's suggested language: XXXXX, "Upper extremity mobility device with medical equipment safety integration"

Applicant's Summary

Healthy Design submitted a request to establish a new HCPCS Level II code to identify the Exersides™ Refraint™ System. The Exersides™ Refraint™ System is a class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. The Exersides™ Refraint™ System can be used both in the inpatient setting and at home as durable medical equipment. It is a mobility device for patients who are attached to and at risk for entanglement in vital tubes, lines and catheters such as ventilators, intravenous lines, or feeding tubes. According to the applicant, the novel device is intended for people/patients who would otherwise require restraint, be it physical or chemical, to prevent dislodgement of attached vital medical equipment which would then render them immobile. The innovative mobility device significantly differs from physical restraint devices in that it allows and encourages mobility, and in such a way that not only complies with CMS' regulations which require use of 'least restraint necessary' by offering multiple levels of restraint including the proprietary most minimized level within its system, but also entrains tubing and cords to move with the device as the person/patient moves to prevent entanglement during mobility and allows every joint to move while allowing people/patients the ability to move safely while attached to vital tubes, lines, and catheters. The current code which most closely resembles the novel device is a physical restraint code which describes apparatuses that preclude movement of one or more joints and do not entrain lines and cords in such a way as to improve mobilization or maintain safety and mobility for the person/patient attached to vital medical equipment. In short, restraint devices are used to reduce mobility in a (failed) attempt to keep patients safe in the short-term; the Exersides™ Refraint™ System is a never-before-seen mobilization device intended to increase mobility to keep patients safe and functional in the short and long-term.

CMS Preliminary HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary B1 2022 recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS did not make a final decision regarding HCPCS coding, Medicare benefit category, or Medicare payment at that time. Instead, we sought further information to better understand this device.

In an effort to better understand the clinical distinction and mechanistic parts in terms of how this product varies from other restraint devices, CMS has the following questions for the applicant:

1. How does the Exersides™ Refraint™ System compare to some of the other products in this space (such as, soft surgical arm support, wearable medical tubing and cabling containment harness, arm board device, patient positioning device, arm abduction splint, arm rest for IV injections, protective arm and leg restraint, etc.)?

2. Are there any data that show the Exersides™ Refraint™ System is preferable to other restraint devices, provides better health outcomes, offers statistically significant improvements in care, results in a reduction in time needing restraint, etc.?

CMS has received additional information from the applicant that we are still reviewing and will take that input into consideration prior to making a final coding determination.

Agenda Item # 9
SpeechVive – 20.077

Topic

Medicare payment determination for SpeechVive.

Applicant's Summary

According to information submitted by SpeechVive, Inc., the SpeechVive device utilizes an ear device that plays background noise (multi-talker babble) in the patient's ear only when the patient speaks. The noise elicits the Lombard Effect, automatically increasing the patient's vocal intensity, slowing their speech rate, and/or increasing the clarity of their speech. The SpeechVive device is worn behind the ear. When the patient stops speaking, the device turns off. The lifespan of the SpeechVive is estimated to be 5 years. The SpeechVive is powered by an internal, rechargeable, lithium-ion battery. The applicant states the device is used to help Parkinson's patients diagnosed with Dysarthria and Anarthria.

CMS Final HCPCS Coding Decision

HCPCS Level II code K1009, "Speech volume modulation system, any type, including all components and accessories" was established to describe the SpeechVive device, effective October 1, 2020.

Medicare Benefit Category Determination

CMS determined that the SpeechVive device is durable medical equipment and published that determination on September 26, 2022.

Preliminary Medicare Payment Determination

The fee schedule amounts for HCPCS code K1009 will be established using the 2022 price of $3,495, which results in capped rental payments of $2,207.19 on average over 13 months of continuous use. As the price used in calculating the fee schedule amounts is greater than $150, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229.

In accordance with regulations at 42 CFR 414.238(c), the current price of $3,495 is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to 2022 using the covered item update factors at section 1834(a)(14) of the Social Security Act. In accordance with 42 CFR §414.229, the capped rental fee schedule amount for months 1 through 3 is equal to 10 percent of the purchase price, or approximately $210.20, and the capped rental fee schedule amount for months 4 through 13 is equal to 7.5 percent of the purchase price, or approximately $157.65.

Agenda Item # 10
Cala Trio™ Supplies – 20.086

Topic

Request to revise existing HCPCS Level II code to K1019 and address Medicare payment determination for Cala Trio™ supplies.

Applicant's suggested language: K1019, "Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist"

Applicant's Summary

According to information submitted by Cala Health Inc., the Cala Trio™ is a non-invasive, wrist-worn stimulator that delivers electrical stimulation to the nerves in the wrist to stimulate the peripheral nervous system for the treatment of essential tremors. The Cala Trio™ device is provided with two components: rechargeable stimulator that generates electrical impulses during times of active therapy together with a base station to recharge the stimulator; and wrist-worn connector that securely attaches the stimulator to the patient's wrist and assures that electrical impulses are properly targeted to each individual patient's nerves. The Cala Trio™ uses circumferential stimulation with three access points to target the median and radial nerves at the wrist embedded in the band. The band is available in left or right handed to target the appropriate nerve locations. The wrist worn connector electrodes has a useful life of 90 days. The current is delivered to alternating electrode pairs in the band that target the nerves. The tremor frequency is measured by motion sensors (accelerometer and gyroscope) contained within the stimulator which gathers kinematic data. An on-board microcontroller alternates the current between the electrode pairs.

CMS Preliminary HCPCS Coding Decision

Revise existing HCPCS Level II code K1019, "Replacement supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist" to now read "Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist".

The word "replacement" in the descriptor for code K1019 was originally added when modifying the code for Cala Trio™ supplies from one for a monthly supply and allowance to one for "replacement" of the individual accessories, including the accessories that are initially furnished with the device. This should not be confused with the words "replacement only," which are generally used in a descriptor when the initial accessories/items are bundled into the payment for the base equipment or paid for under another benefit category/payment system. Regardless, there was some confusion over the use of the term "replacement" in relation to this device and thus we are moving it from the descriptor for code K1019.

Medicare Benefit Category Determination

CMS determined that Cala Trio™ supplies are durable medical equipment and published that determination on September 26, 2022.

Preliminary Medicare Payment Determination

The Cala Trio™ stimulator is powered with a lithium-ion rechargeable battery, which can be recharged with the base station. The recharging base station also falls under HCPCS code A4595. The electrical stimulator supplies described by HCPCS code A4595 include electrodes (any type), conductive paste or gel (if needed, depending on the type of electrode), tape or other adhesive (if needed, depending on the type of electrode), adhesive remover, skin preparation materials, batteries (9 volt or AA, single use or rechargeable), and a battery charger (if rechargeable batteries are used).

The special componentry and patterned stimulation is produced by the Cala Trio™ stimulation device and not by the wristband/electrode accessory, which are reusable electrodes and which may be comparable to electrodes coded and paid for using existing code A4595. HCPCS code A4595, "electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)", covers a wide range of electrodes and supplies. When it comes to electrodes, there are many options based on shape, size, and configuration to fit the need of the patient and therapeutic goal for electrical stimulation. The electrodes can vary from the size (e.g., 4 cm and 4" x 7"), the shape (e.g., round, oval, and butterfly), and the materials. The materials and properties of the electrodes that fall within A4595 can include metal plates, rubber, self-adhering, single use, multiple use, etc. When it comes to the Cala Trio's™ electrodes, there are three electrodes embedded in the band of the device that function as two pairs (positive and negative) that target the median and radial nerves. Current is delivered to alternating electrode pairs in the band. Since the stimulation alters between the electrode pair, only two of the three electrodes are active at a time. The Cala Trio™ uses dry, metal electrodes that last up to three months. The fixed, metal electrodes used in the Cala Trio™ wrist band seem to be comparable to other reusable or fixed electrodes coded using A4595.

As stated in the 2022 HCPCS Application Summary for Biannual 1, 2022 Non-Drug and Non-Biological Items and Services, CMS is considered adopting a pricing methodology similar to that used for the Monarch external Trigeminal Nerve Stimulation (eTNS) System® supplies, which would be approximately $106 for a 3-month supply. In accordance with Medicare regulations at 42 CFR § 414.238(b) regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history the fee schedule amounts for HCPCS code K1019 would be established using the existing fee schedule amounts for comparable items (supplies for electrical stimulation devices) under code A4595. Electrical stimulation supplies coded under A4595 covers a wide range of sizes (e.g., 4 cm and 4" x 7"), shapes (e.g., round, oval, and butterfly), and materials to which the Cala Trio™ is comparable. Thus, the fee schedule amounts for HCPCS code K1019 would be established using the unadjusted fee schedule amounts for HCPCS code A4595, or approximately $106 on average.

A monthly payment would be made for any covered claims for all supplies necessary for one month.

Pricing Indicator = 34

Note: CMS has received input from Cala Health on the payment determination proposed in the 2022 HCPCS Application Summary for Biannual 1, 2022 Non-Drug and Non-Biological Items and Services and will take that input into consideration prior to making a final payment determination.

Agenda Item # 11
Lunoa System (NightBalance) – 19.118

Topic

Medicare payment determination for sleep position therapy device, the Lunoa System.

Applicant's Summary

According to information submitted by Respironics, Inc., the Lunoa System is a device that provides treatment for positional obstructive sleep apnea (POSA) with a non-supine apnea-hypopnea index less than 20. The components and accessories include a sensor, chest strap, docking station, power adapter, travel case, and portal. The battery-operated, rechargeable sensor contains a digital accelerometer that continually monitors a patient's sleep position and is worn around the chest. By emitting the vibro-tactile feedback during sleep, the sensor helps keep patients with POSA from sleeping in the supine position by vibration until the patient moves to a non-supine position. When placed in the docking station to charge, the sensor encrypts and transmits the data to the cloud. The portal allows users, such as the patient and the physician to view the data.

CMS Final HCPCS Coding Decision

HCPCS Level II code K1001, "Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type" was established to describe the Lunoa System, effective January 1, 2020.

Medicare Benefit Category Determination

CMS determined that NightBalance is durable medical equipment and published that determination on September 26, 2022.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. If the only available price information is from a period other than the fee schedule base period (for capped rental items, the last 6 months of 1986), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME.

We have found several internet retail prices in September 2022 for this item and the median of these prices is $529.99.[1,2,3,4,5] As this median price will be used in calculating the fee schedule and the amount is greater than $150, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. The average 2022 capped rental fee schedule amount for K1001 would be approximately $31.87 for months 1 through 3 and approximately $23.90 for months 4 through 13, which would result in payment of approximately $334.61 over these 13 months.

We received information from the applicant in October 2022 that the commercial price for the NightBalance device has remained at $849 since 2019. However, as shown above, we have found other prices on the market from several internet retail sites. We believe that $849 is the MSRP, as confirmed by one of these internet retail sites.[6] In our 2019 final rule that set regulations for establishing payment amounts for new DMEPOS items and services, we stated that CMS would not use the MSRP to set the fee schedule rates, and instead, will rely on fees for comparable items and verifiable supplier or commercial prices in an effort to best approximate reasonable charges from the fee schedule base period for the item (84 FR 60739).[7]

Although we used internet retail prices in our preliminary payment determination, per 42 CFR § 414.238(c), potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. As such, we invite the applicant to send us pricing information from private payers or the Veterans Administration (VA).

Pricing = 36

[1] https://www.sleepdirect.com/cpap-machines/philips-respironics-nightbalance-lunoa-positional-sleep-therapy-device-package

[2] https://www.thecpapshop.com/philips-nightbalance-lunoa
[3] https://www.directhomemedical.com/nightbalance-lunoa-positional-osa-therapy-device.html
[4] https://www.respshop.com/more-products/cpap-alternatives/philips-nightbalance-positional-sleep-therapy-device-p-1478.html
[5] https://www.cpapdirect.com/cpap-machines/philips-respironics-nightbalance-lunoa-positional-sleep-therapy-device-package

Agenda Item # 12
PureWick™ Urine Collection System – 20.078

Topic

Medicare payment determination for PureWick™ Urine Collection System.

Applicant's Summary

According to information submitted by Becton, Dickinson and Company (BD), the PureWick™ System is an alternative to an indwelling catheter for female adult patients suffering from permanent urinary incontinence. It is indicated for non-invasive urine output management in females and is contraindicated in patients with urinary retention. It funnels the urine and removes it to the collection canister once it passes through the patient tubing. Suction enables efficient removal of urine from the female external catheter with a minimum suction of 40 mmHg. The application stated, the PureWick™ Urine Collection System will be 100% used in a patient's home; however, with components of the PureWick™ System can be used in the nursing facility, inpatient or outpatient hospital, or surgical center. Also, BD PureWick™ System's website (https://www.purewickathome.com/) advertised the device is for home use. Review of the BD PureWick™ System's website (https://www.purewickathome.com/) in March 2021 found information stating "…useful life of the PureWick™ Urine Collection System is one (1) year." However, in April 2021, this statement was updated removing the quantitative number of years associated with the useful life of the PureWick™ System. In June 2021, BD submitted independent lab testing stating that the PureWick System has a useful life of a minimum of three years.

CMS HCPCS Coding Decision

HCPCS Level II code K1006, "Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system" was established to describe the PureWick™ System, effective October 1, 2020.

Medicare Benefit Category Determination

CMS determined that the PureWick™ Urine Collection System is durable medical equipment and published that determination on September 26, 2022.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.236(a), if a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

This item is a portable home suction pump and therefore has a history of pricing under code E0600, the code used for all portable home suction pumps in 1986 and 1987. The Medicare monthly allowed payment amounts in 1986 and 1987 included payment for rental of the suction pump and all necessary supplies and accessories for the pump. A capped rental payment methodology was implemented for code E0600 in 1994, with separate payments made for the supplies and accessories using other HCPCS codes. The capped rental fee

schedule amounts for code E0600 will be mapped to the new code K1006 in accordance with the continuity of pricing rules at 42 CFR 414.236 since code K1006 is a code for portable home suction pumps.

The average 2022 rental amount for K1006 would be approximately $54.09 for months 1-3 and approximately $40.57 for months 4-13, which results in average 2022 payments over 13 months equaling approximately $567.97. Based on this average payment, if the pump is only used by one beneficiary over the 5-year lifetime of the pump (60 month), the average cost per month of the pump, not counting repairs and non-routine maintenance and servicing, would be approximately $9.47 ($567.97 ÷ 60).

In addition to the pump, the PureWick™ Urine Collection System is comprised of other components that are necessary for the effective use of the suction pump including a collection canister, pump, and collector tubing and female external catheters. -These components are currently billed using miscellaneous code A9999. -Other manufacturers also produce accessories that are used in conjunction with a urine suction pump that are designed for male and pediatric use and have different replacement frequencies than the PureWick™ components. -As part of this HCPCS cycle, CMS is proposing the establishment of a new supply and accessory code in keeping with the pricing history that would be paid on a monthly basis and include payment for all supplies and accessories necessary for the effective use of the home suction pump. Fee schedule amounts for new code AXXXX, "Supplies and accessories for home urinary suction pump, per month" for the monthly supplies and accessories (e.g., canister, tubing, catheters, etc.) for the K1006 device will be established using the updated monthly fee schedule amounts for 1993, the last year the fee schedule amount for code E0600 included payment for accessories and supplies for a portable home suction pump, for code E0600 (on average approximately $89.68 for 2022), which included payment for home portable suction pumps and all supplies and accessories, with the monthly payment for the pump (on average approximately $9.47) backed out of the amounts. This calculation results in a net payment from the pricing history for all supplies and accessories for home suction pumps for 1986/1987. -The average 2022 monthly amount for AXXXX would be approximately $80.21 (e.g., $89.68-$9.47=$80.21). A monthly payment using the new, separate code will be made for all covered claims for supplies or accessories necessary for the effective use of the device described by code K1006.

K1006 - Pricing Indicator = 36; AXXXX - Pricing Indicator = 34

Agenda Item # 13
Ur24T, External Urinary Catheter - HCP220630FWK6R

Topic/Issue

Request to establish a new HCPCS Level II code to identify Ur24T.

The applicant did not submit any suggested language.

Applicant's Summary

Ur24Technology, Inc. submitted a request to establish a new HCPCS Level II code to identify Ur24T. Ur24T is a class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. The applicant stated they have developed an external urinary catheter and collection system for all humans. The male and female collection apparatus (UCA) actively empties the bladder, allowing the bladder to be voided without any discomfort. The UCA are named the following: M9, M15, M18, F18 IF8, IM5. The Ur24T Apparatus comprises a polymeric tube and collection container that is capable of drawing urine from the urethra of males and females through the tube and collection container. The device may be used with a standard aspirator pump. According to the applicant, existing codes do not adequately describe or product due to the fact it is revolutionary, not only can it replace the internal catheter, but it is also reusable. The patient does not have to be able to urinate to use our product nor does the patient have to wait for gravity.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1006, "Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system" describes the suction or the aspiration pump. However, for the supplies and accessories, CMS will establish a new HCPCS Level II code AXXXX, "Supplies and accessories for home urinary suction pump, per month".

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment

The preliminary determination is that Ur24T meets the definition of DME found in 42 CFR 414.202.

CMS established new HCPCS Level II code K1006 effective October 1, 2020, "Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system" and assigned the PureWick™ Urine Collection System to K1006. CMS also established the Medicare benefit category determination for the PureWick™ Urine Collection System as DME (https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelII-Coding-Decisions-Narrative-Summary).

Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03) indicates that payment may be made for replacement of essential accessories such as hoses, tubes, mouthpieces, etc., for necessary DME, only if the beneficiary owns or is purchasing the

equipment. The Ur24T is an accessory for a code that is DME (K1006) and therefore Ur24T falls under the DME benefit category.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.236(a), if a new HCPCS Level II code is established, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

As mentioned in the PureWick™ application (20.078), other manufacturers also produce accessories that are used in conjunction with a urine suction pump that are designed for male and pediatric use and have different replacement frequencies. Therefore, as part of this HCPCS cycle, CMS is proposing the establishment of a new supply and accessory code in keeping with the pricing history that would be paid on a monthly basis and include payment for all supplies and accessories necessary for the effective use of the home suction pump. Fee schedule amounts for new code AXXXX, "Supplies and accessories for home urinary suction pump, per month" for the monthly supplies and accessories (e.g., canisters, tubing, catheters, etc.) for the K1006 device will be established using the updated monthly fee schedule amounts for 1993 for code E0600 (on average approximately $89.68 for 2022), which included payment for home portable suction pumps and all supplies and accessories, with the monthly payment for the pump (on average approximately $9.47) backed out of the amounts. This calculation results in a net payment from the pricing history for all supplies and accessories for home suction pumps for 1986/1987. The average 2022 monthly amount for AXXXX would be approximately $80.21 (e.g., $89.68-$9.47=$80.21). A monthly payment using the new, separate code will be made for all covered claims for supplies or accessories necessary for the effective use of the device described by code K1006.

K1006 - Pricing Indicator = 36; AXXXX - Pricing Indicator = 34

Agenda Item # 14
Request: Vesiflo inFlow™ System - IHC2210134UQQL

Topic/Issue

Request to establish two new HCPCS Level II codes to identify Vesiflo InFlow™ System and accessories.

Applicant's suggested language:

1. LXXXX, "Temporary female voiding prosthesis (i.e., intraurethral valve-pump), home replacement only, each"

2. LXXXX, "Activation device for temporary female voiding prosthesis, replacement only, each"

Applicant's Summary

The Vesiflo inFlow™ System is a urethral insert with pump for bladder drainage. The inFlow™ System received the Food and Drug Administration's (FDA's) de novo clearance on October 25, 2013. The inFlow™ System is intended for women with permanent urinary retention and includes both an intraurethral valve-pump and an Activator kit. The inFlow™ System operates via an intraurethral valve-pump inserted into the urethra that contains magnets attached to two rotors that, when activated by a handheld remote-control Activator that also contains magnets, spin to create a turbine pump that empties the bladder at a normal flow rate when the patient chooses. Initial device insertion is performed by a physician in the office setting. The patient receives a replacement inFlow™ device every 29 days (or less), and device removal/reinsertion can be performed by the healthcare provider in the office setting or by the patient's caregiver at home. According to the manufacturer, the Activator is initially provided by the physician as part of the initial insertion procedure, but replacement Activators are supplied to the patient by a DMEPOS supplier. The handheld remote, when held close to the patient's pubic region and turned on, magnetically actuates the internal inFlow™ device mechanism to transfer urine out of the bladder. After voiding, the Activator automatically closes an internal magnetic valve to block urine flow. The Activator is supplied as a kit that includes the Activator, a medical grade recharger, and a storage station.

CMS Preliminary HCPCS Coding Recommendation

CMS has been in discussions with the manufacturer about clarifying the role of HCPCS Level II codes and CPT® codes that describe the device and associated physician service, when used in the physician office setting.

Establish the following two new HCPCS Level II codes:

1. AXXXX, "Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each"

2. AXXXX, "Accessories for indwelling intraurethral drainage device with valve, patient inserted, replacement only, each"

Preliminary Medicare Benefit Category Determination

Prosthetic Device

Note: As described by the manufacturer in correspondence with CMS, the initial inFlow™ System (including the intraurethral valve-pump and the activator kit accessories) is provided in the physician office and in some instances, replacement valve-pumps may also be provided in the physician office. In these situations, when the device and accessories are provided as part of a professional or physician service, CMS anticipates that the appropriate CPT® codes are to be used, unless instructed otherwise by a Medicare Administrative Contractor. HCPCS Level II codes would be used in the home setting when replacement product is delivered directly to the home to be replaced by the patient or caregiver.

In accordance with Medicare program instructions at chapter 15, section 120 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), prosthetic devices (other than dental) are devices which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. The inFlow™ System (including the intraurethral valve-pump and the activator kit accessories) replaces the function of a permanently inoperative bladder and is a prosthetic device.

Preliminary Medicare Payment Determination

Vesiflo, Inc., the manufacturer of the inFlow™ System, applied for HCPCS codes for the inFlow™ System during the 2016 HCPCS Coding cycle. At the time, CMS denied the requests consistent with the policy in place at the time related to insufficient sales volume to support establishment of codes. In the 2020 B1 HCPCS Coding Cycle, CMS established three codes for the inFlow™ System (codes K1010, K1011, and K1012) after review of an internal application, effective for dates of service beginning October 1, 2020. The DME MACs established fee schedules for their jurisdictions for these codes using the information provided in the 2016 application.

CMS has received input from Vesiflo, Inc. that the methodology used by the DME MACs may be in error, indicating the intraurethral valve-pump within the Vesiflo inFlow™ System is comparable to HCPCS Level II A4351, “Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each”, at a rate of the maximum device allowance for A4351 at 200 catheters per month. The manufacturer stated that the Vesiflo inFlow™ System is replacing the use of a catheter coded within A4351 and as such should be comparable. Regulations at 42 CFR 414.238 state that if no pricing history exists, CMS is to establish the fee schedule using the fee schedule for comparable items, if any exist. If no comparable items exist, CMS is to use supplier or commercial price lists to establish the fee schedule.

To assess whether comparability is the appropriate methodology, we reviewed the comparability of A4351, “Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each”, and the intraurethral valve-pump catheter. We also compared it to A4344, “Indwelling catheter, foley type, two-way, all silicone, each”, primarily because upon initial review, we determined A4351 to not be comparable and after reviewing additional HCPCS codes for catheters, we determined A4344 had similarities that warranted further comparability analysis.

CMS indicated in its Final Rule, CMS-1713-F published November 8, 2019, that a new product does not need to be comparable within each of the five categories (physical, mechanical, electrical, function and intended use, and additional attributes and features) used for comparison in order to be considered comparable. CMS has noted that just because a device replaces the indicated use of a different device does not mean the device would be found comparable (see above comparability chart below for the intraurethral valve-pump catheter). For example, a continuous positive airway pressure (CPAP) device is not comparable to all sleep apnea devices.

	A4351	**A4344**	**inFlow™ Female Intraurethral Valve-Pump**
Physical Components	Straight tip Material components can consist of latex, silicone, Teflon, or equivalent	Saline/water-filled balloon on distal end Material components is silicone Flexible tube Tube with separated channels (lumnes) with one to drain into a collection bag and the other connected to a balloon port	Six flexible “fins” on distal end Insert housed in silicone Applicator to help with insertion (disposable introducer)
Mechanical Components	Passive drainage	Passive drainage	Active drainage - requires use of a negative pressure closed system that helps to “pump” out urine Magnetic pressure-release valve Two plastic rotors
Electrical Components	No electrical components	No electrical components	No electrical components
Function and Intended Use	Aid in treating permanent urinary retention in men and women Assist with bladder drainage	Aid in treating permanent/chronic urinary retention in men and women Assist with bladder drainage	Aid in treating permanent urinary retention in women Assist with bladder drainage
Additional Aspects and Features	Multiple insertions into the bladder per day	Inserted once and stays in the bladder until replaced	Inserted once per month Voiding is controlled by patient Single-use (29 days)

It is our preliminary determination that the intraurethral valve-pump is not comparable to either A4351 or A4344, principally because the physical and mechanical componentry are not comparable due to the distinctive components related to the active drainage (i.e., the magnetic pressure-release valve and rotors), and determined that the original comparability assessment performed by the DME MACs when establishing the fee schedule for their jurisdictions was correct, i.e., there is no comparability. As such and in accordance with regulations at 42 CFR 414.238(c), for code AXXXX (“Indwelling intraurethral drainage

device with valve, patient inserted, replacement only, each") the current price of $495 is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to 2022 using the covered item update factors at section 1834(a)(14) of the Social Security Act. As a result, the average fee schedule amount would be approximately $298.49.

Also in accordance with regulations at 42 CFR 414.238(c), for code AXXXX ("Accessories for indwelling intraurethral drainage device with valve, patient inserted, replacement only, each") the current price of $1,250 is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to 2022 using the covered item update factors at section 1834(a)(14) of the Social Security Act. As a result, the average fee schedule amount would be approximately $753.78.

Payment of both items would be on a lump sum basis.

Pricing Indicator = 38

Agenda Item # 15
Request: Oxygen Coverage Criteria - HCP22053156QUR

Topic/Issue

Request to establish three new HCPCS Level II modifiers to identify an indication of the appropriate treatment regimen and presence of supporting documentation for the beneficiary receiving Oxygen treatment.

Applicant's suggested language:

1. N1, "Group 1 oxygen coverage criteria met"
2. N2, "Group 2 oxygen coverage criteria met"
3. N3, "Group 3 oxygen coverage criteria met"

Applicant's Summary

Section 1834(a)(1)(5)(E) of the Social Security Act requires that for certain beneficiaries using oxygen, no payment can be made after an initial 90-day coverage period unless the attending physician certifies that the patient has had certain tests repeated and there is a continuing need for oxygen treatment. The statute specifies an oxygen saturation threshold that corresponds to National Coverage Determinations (NCD) Groups 2 and 3. The revised change request (CR 12607) transmittal (11429)[6], dated May 23, 2022, instructs the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) to discontinue Certificate of Medical Necessity (CMN) for various Local Coverage Determinations (LCDs). The addition of three modifiers will allow suppliers to indicate the appropriate treatment regimen and presence of supporting documentation for each beneficiary without the burden of supplying all the information which had been required on the CMN. In most cases, the existing KX modifier allows suppliers to indicate the presence of qualifying medical documentation. However, the Oxygen LCD[7] has multiple treatment regimens and different documentation is needed for each. Establishing these modifiers would be beneficial to the MACs by enabling them to distinguish claims between the three NCD Groups, because NCD Groups 2 and 3 have statutory payment and recertification requirements that do not apply to NCD Group 1. These modifiers will support auditing and the ability to track different types of oxygen usage for the purpose of the LCDs/applicable NCD.

CMS Final HCPCS Coding Recommendation

Establish three new HCPCS Level II modifiers:

1. N1, "Group 1 oxygen coverage criteria met"
2. N2, "Group 2 oxygen coverage criteria met"
3. N3, "Group 3 oxygen coverage criteria met"

Effective 1/1/23[8]

[6] The revised Transmittal 11429 can be found at: https://www.cms.gov/files/document/r11429cp.pdf
[7] Oxygen LCD, L33797 can be found at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33797
[8] CMS is establishing these modifiers with an effective date of January 1, 2023. CMS will provide further information and instructions regarding the use of these modifiers, including a timeframe for implementation.

Agenda Item # 16
HCPCS Level II Codes for Various FDA Approvals under the 505(b)(2) or Biologics License Application Pathways and Products "Not Otherwise Classified" - HCP220517FAENJ

Topic/Issue

We are requesting public comment on the language in the code descriptors for the new HCPCS Level II codes that we established in CMS' Third Quarter 2022 Drug and Biological HCPCS code application review cycle, effective January 1, 2023, per our posting at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCSLevelII-Coding-Decisions-Narrative-Summary.

Applicant's Summary

CMS reviewed its approach for establishing HCPCS Level II codes to identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book[9], and are therefore considered single source products. Also, this effort will help reduce use of the not otherwise classified (NOC) codes.

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS codes as described at the following CMS link: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf, CMS has made several code changes, including manufacturer specific codes to identify products approved under separate 505(b)(2) NDA or BLA pathways. Since the products are approved under separate 505(b)(2) NDAs and are not rated as therapeutically equivalent by the FDA in the Orange Book, they are single source drugs based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. Because these are single source drugs, there was a programmatic need for each product to have a unique billing and payment code.

In cases where certain products met the statutory definition of a "multiple source drug" in section 1847A(c)(6) of the Act, CMS removed the brand name of the drug from any existing HCPCS code as needed (e.g. remove "velcade" from J9041) as it would accommodate any associated generic product(s), if approved and marketed, that are rated as therapeutically equivalent. Of note, Baxter Healthcare Inc. submitted a request to revise existing HCPCS Level II code J9041 to allow for use with recently approved therapeutic equivalents, which has been addressed as part of this review.

Due to the complexity and nuanced nature of the differences between each product, we encourage providers to rely on the Average Sales Price (ASP) HCPCS-NDC crosswalk[10] to identify the correct billing and payment code for each applicable product.

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[9] The FDA's Orange Book, officially entitled, *Approved Drug Products With Therapeutic Equivalence Evaluations*, identifies drug products approved on the basis of safety and effectiveness by the FDA, and is published at the following FDA link: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[10] The ASP crosswalks are maintained by CMS on a quarterly basis to support ASP-based Medicare Part B payments only. The quarterly ASP crosswalks are published at the following CMS link:

CMS HCPCS Coding Decision

We established or revised 40 HCPCS Level II codes to separately identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code and products NOC, effective January 1, 2023, and are seeking feedback on the code descriptors.

See Appendix A for a complete list of new and revised HCPCS Level II codes that we are establishing under this initiative.

https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files.

Appendix A: HCPCS Level II Codes for Products Approved by the FDA Under the 505(b)(2) NDA or BLA Pathways and Products "Not Otherwise Classified"

HCPCS Code	Action	Long Descriptor
C9046	Revise	Cocaine hydrochloride nasal solution (goprelto), 1 mg
C9143	Add	Cocaine hydrochloride nasal solution (numbrino), 1 mg
J0131	Revise	Injection, acetaminophen, not otherwise specified, 10 mg
J0134	Add	Injection, acetaminophen (fresenius kabi) not therapeutically equivalent to J0131, 10 mg
J0136	Add	Injection, acetaminophen (b braun) not therapeutically equivalent to J0131, 10 mg
J0173	Add	Injection, epinephrine (belcher) not therapeutically equivalent to J0171, 0.1 mg
J0283	Add	Injection, amiodarone hydrochloride (nexterone), 30 mg
J0610	Revise	Injection, calcium gluconate (fresenius kabi), per 10 ml
J0611	Add	Injection, calcium gluconate (wg critical care), per 10 ml
J0689	Add	Injection, cefazolin sodium (baxter), not therapeutically equivalent to J0690, 500 mg
J0701	Add	Injection, cefepime hydrochloride (baxter), not therapeutically equivalent to maxipime, 500 mg
J0703	Add	Injection, cefepime hydrochloride (b braun), not therapeutically equivalent to maxipime, 500 mg
J0877	Add	Injection, daptomycin (hospira), not therapeutically equivalent to J0878, 1 mg
J0891	Add	Injection, argatroban (accord), not therapeutically equivalent to J0883, 1 mg (for non-esrd use)
J0892	Add	Injection, argatroban (accord), not therapeutically equivalent to J0884, 1 mg (for esrd on dialysis)
J0893	Add	Injection, decitabine (sun pharma) not therapeutically equivalent to J0894, 1 mg
J0898	Add	Injection, argatroban (auromedics), not therapeutically equivalent to J0883, 1 mg (for non-esrd use)
J0899	Add	Injection, argatroban (auromedics), not therapeutically equivalent to J0884, 1 mg (for esrd on dialysis)
J1456	Add	Injection, fosaprepitant (teva), not therapeutically equivalent to J1453, 1 mg
J1574	Add	Injection, ganciclovir sodium (exela) not therapeutically equivalent to J1570, 500 mg
J1611	Add	Injection, glucagon hydrochloride (fresenius kabi), not therapeutically equivalent to J1610, per 1 mg
J1643	Add	Injection, heparin sodium (pfizer), not therapeutically equivalent to J1644, per 1000 units
J1954	Add	Injection, leuprolide acetate for depot suspension (lutrate), 7.5 mg
J2021	Add	Injection, linezolid (hospira) not therapeutically equivalent to J2020, 200 mg

J2184	Add	Injection, meropenem (b. braun) not therapeutically equivalent to J2185, 100 mg
J2247	Add	Injection, micafungin sodium (par pharm) not therapeutically equivalent to J2248, 1 mg
J2251	Add	Injection, midazolam hydrochloride (wg critical care) not therapeutically equivalent to J2250, per 1 mg
J2272	Add	Injection, morphine sulfate (fresenius kabi) not therapeutically equivalent to J2270, up to 10 mg
J2281	Add	Injection, moxifloxacin (fresenius kabi) not therapeutically equivalent to J2280, 100 mg
J2311	Add	Injection, naloxone hydrochloride (zimhi), 1 mg
J2401	Add	Injection, chloroprocaine hydrochloride, per 1 mg
J2402	Add	Injection, chloroprocaine hydrochloride (clorotekal), per 1 mg
J3244	Add	Injection, tigecycline (accord) not therapeutically equivalent to J3243, 1 mg
J3371	Add	Injection, vancomycin hcl (mylan) not therapeutically equivalent to J3370, 500 mg
J3372	Add	Injection, vancomycin hcl (xellia) not therapeutically equivalent to J3370, 500 mg
J9041	Revise	Injection, bortezomib, 0.1 mg
J9046	Add	Injection, bortezomib, (dr. reddy's), not therapeutically equivalent to J9041, 0.1 mg
J9048	Add	Injection, bortezomib (fresenius kabi), not therapeutically equivalent to J9041, 0.1 mg
J9049	Add	Injection, bortezomib (hospira), not therapeutically equivalent to J9041, 0.1 mg
J9314	Add	Injection, pemetrexed (teva), 10 mg
J9393	Add	Injection, fulvestrant (teva) not therapeutically equivalent to J9395, 25 mg
J9394	Add	Injection, fulvestrant (fresenius kabi) not therapeutically equivalent to J9395, 25 mg

Appendix B: DMEPOS Payment Categories

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicator codes in the HCPCS identify which major payment category a HCPCS code falls under. The pricing indicator codes applicable to DMEPOS.

Pricing = 00 Service Not Separately Priced

Items or services described by the HCPCS codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

Pricing = 31 Frequently Serviced Items

Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health. Payment for E0935 is based on a daily rental fee schedule basis since coverage of this device is limited to 21 days.

Pricing = 32 Inexpensive and Other Routinely Purchased Items

Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of $150 or less, were purchased 75 percent of the time or more from July 1986 through June 1987, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or respiratory assist device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

Pricing = 33 Oxygen and Oxygen Equipment

Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after which payment for the ongoing delivery of contents continues for gaseous or liquid systems.

Pricing = 34 Supplies Necessary for the Effective Use of DME

Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

Pricing = 35 Surgical Dressings

Payment is made on a purchase fee schedule basis for surgical dressings.

Pricing = 36 Capped Rental Items

Payment is made on a monthly rental fee schedule basis. The beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items, other than power wheelchairs, for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. The rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee

for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Complex rehabilitative power wheelchairs can also be purchased in the first month.

Pricing = 37 Ostomy, Tracheostomy and Urological Supplies
Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)
Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

Pricing = 39 Parenteral and Enteral Nutrition (PEN)
Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

Pricing = 45 Customized DME
Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item and judgment of a reasonable payment amount, which, at a minimum, includes a review of the costs of labor and material used in constructing the equipment.

Pricing = 46 Carrier Priced Item
The allowed payment amount for covered items is based on local carrier pricing (e.g., local fee schedule amounts or reasonable charges or other carrier pricing method.