



Centers for Medicare & Medicaid Services' (CMS') Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations

Second Biannual (B2), 2022 HCPCS Coding Cycle

This document presents a summary of each HCPCS code application and CMS' coding decision for each application processed in CMS' Second Biannual 2022 Non-Drug and Non-Biological Items and Services HCPCS code application review cycle. Each individual summary includes the Medicare Electronic Application Request Information System™ (MEARIS™) identification number; topic; a summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS; CMS' preliminary HCPCS coding recommendation; a summary of public feedback from or following the HCPCS public meeting; CMS' final HCPCS coding decision, as well as CMS' preliminary and final benefit category and payment determination, if applicable.

In accordance with the procedures at 42 CFR §414.240 and §414.114, final Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) benefit category and payment determinations are listed below, if applicable. These procedures follow HCPCS determinations and payment determinations for new DME under Medicare Part B following public consultation held through public meetings in accordance with section 531(b) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub L. 106-554). CMS started using these public meetings and procedures for HCPCS Level II code requests for items and services other than DME in 2005. The procedures for making Medicare benefit category and payment determinations for new DMEPOS items and services using the BIPA 531(b) public meeting process were promulgated through regulations. The final rule (86 FR 73902) is available at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposfeesched>.

Whether or not an item or service falls under a Medicare benefit category, such as the Medicare Part B benefit category for DME, is a necessary step in determining whether an item may be covered under the Medicare program and, if applicable, what statutory and regulatory payment rules apply to the items and services. If the item is excluded from coverage by the Social Security Act or does not fall within the scope of a defined benefit category, the item cannot be covered under Medicare Part B. When the item is not excluded from coverage by statute and is found to fall within a benefit category, CMS needs to determine what payment rules apply to the item if other statutory criteria for coverage of the item are met. DMEPOS payment categories with corresponding HCPCS pricing indicator codes are included in the Appendix.

All new coding actions will be effective April 1, 2023, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the April 2023 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

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

Table of Contents

Final decisions for items discussed at the HCPCS Virtual Public Meeting on November 29, 2022 to December 1, 2022.

1. Cue Health Monitoring System and Accessories - HCP220705DDRJK.....	5
Cue COVID-19 Test Cartridge Pack - HCP2207052C281	8
2. Koya Dayspring® - HCP2207039VEAR	11
3. PainShield® Supplies - HCP220616GR6A0.....	15
4. Steri-Lift Kit - HCP220406X5KJQ	17
5. Doula Birth Worker - HCP220323830N1, HCP220323U8HVV, HCP220323DP0KP	18
6. Feelix Stethoscope - HCP220701D69QJ.....	20
7. Cochlear™ Osia® 2 System - HCP220705GRQ19	22
Cochlear™ Osia® 2 Sound Processor - HCP22070522MTY	25
8. SWIK™ - HCP2205316LKRL.....	28
9. NEURO SWING, Cup Disc Spring Force Unit - HCP220705GH052.....	30
NEURO SWING, System Ankle Joint - HCP220705UQPHF	33
10. ULTepap™ - HCP220628D8N92	36
11. Canvas Dx - HCP220705YK09X	39
12. OxyBand™ Wound Dressing Matrix - HCP22070507T93.....	41
13. CloudCath Peritoneal Dialysis Drain Set Monitoring System - HCP220701PTF4P	44
14. Theranova 400/500 - HCP2207048YCGW	45
15. SunWrap™ System Dialysis Access Guard - HCP220131BGMBQ	47
16. AMMA - HCP220704AAQ4D.....	49
AMMA - HCP220704P7W3Y.....	51
17. FOOTBAR® Walker - HCP220704VX6MB.....	53
18. geko™ T-3 and geko™ W-3 - HCP22063010MT6	56
19. D-Ostomy - HCP220704QETH9	59
20. Dr. Arthritis, Patella Tendon Knee Strap - HCP220331103NX.....	61
Dr. Arthritis, Shoulder Support Brace - HCP220331DKCD6.....	63
Dr. Arthritis, Elbow Support Strap - HCP220331KEXCD	65
Dr. Arthritis, Wrist Brace - HCP220420WCDD8	67
Dr. Arthritis, Thumb Support Brace - HCP220331EFF4D	69
Dr. Arthritis, Open Finger Compression Gloves - HCP2203319P57X.....	71
Dr. Arthritis, Elbow Compression Sleeve - HCP2204214YW7G.....	73
Dr. Arthritis, Wrist Brace - HCP220321YBBBBP	75
Dr. Arthritis, Foot Compression Sleeve - HCP220421KT8W1	77
21. HEMIGARD® ASRD - HCP220628EJE62.....	79

22. Keragel® 20gm Tube - HCP2207049R6X6.....	81
KeragelT® 20gm Tube - HCP2207053M4YQ.....	84
23. Crus Med - HCP220705RM6W4.....	87
Pedilay® Med- HCP22070547EEV	90
24. MariGen® Shield- HCP220630YGVWG	93
25. AC5® Advanced Wound System - HCP220629RD4XM.....	95
26. NeoMatriX® Wound Matrix - HCP220627LXLYC.....	97
27. OWYN™ - HCP220629C4ABF.....	99
28. Injectable Immunotherapies - HCP220705DHHCU	101
29. Shoulder Pacemaker™ - HCP220705H21VT	103
30. Personalized PseudoPatient™ PV - HCP220613WR6GD.....	105
31. Bioventus® Neuromodulation System, External Pulse Transmitter - HCP220630UD3PG	107
Bioventus® Neuromodulation System, Patient Programmer - HCP220630ABNCV	110
Bioventus® Neuromodulation System, Surface Electrode Patch - HCP220630DY5Y8	112
32. SPEAC® System - HCP220705KM2RJ	115
33. RelieVRx - HCP220701K2H96.....	118
34. JAS Elbow EZ Turnbuckle Orthosis - HCP220705MC6YY	121
35. Intermittent Urinary Catheters - HCP220701G0DRV.....	123
Intermittent Urinary Catheters - HCP220701Q1RK8.....	127
Intermittent Urinary Catheters - HCP220701EYPYU.....	131
36. Custom Drainable Pouches, Complexity Level 1 - HCP220705EJ92E	134
Custom Drainable Pouches, Complexity Level 2 - HCP220705RU05H	137
Custom Drainable Pouches, Complexity Level 3 - HCP220705KHCVK.....	140
37. Exersides™ Refrains™ System - HCP211227F8TPL.....	143
38. SpeechVive – 20.077	146
39. Cala Trio™ Supplies – 20.086.....	148
40. Lunoa System (NightBalance) – 19.118.....	151
41. PureWick™ Urine Collection System – 20.078	154
42. Ur24T, External Urinary Catheter - HCP220630FWK6R.....	158
43. Vesiflo inFlow™ System - IHC2210134UQQL	162
Appendix A: DMEPOS Payment Categories	168

Cue Health Monitoring System and Accessories - HCP220705DDRJK

Topic/Issue

Request to establish a new HCPCS Level II code to identify Cue Cartridge Reader and accessories (also called the Cue Reader, and commercially known as the Cue Health Monitoring System.)

Applicant's suggested language: EXXXX, "Molecular diagnostic test reader, for self-administered and self-collected samples, FDA approved, authorized, or cleared"

Applicant's Summary

Cue Health submitted a request to establish a new HCPCS Level II code to identify the Cue Cartridge Reader and accessories. The Cue Reader received Emergency Use Authorization by the Food and Drug Administration (FDA) for COVID-19 testing. However, patients will be able to use the Cue Reader with other test cartridges, for example influenza or respiratory syncytial virus (RSV), when those test cartridges receive marketing authorization from the FDA. The Cue Reader is an in vitro diagnostic medical device that activates the Nucleic Acid Amplification Test (NAAT) process with test-specific Cue Cartridges and interfaces with the Cue Health Mobile Application installed on a mobile smart device. This coding request is for the Cue Reader and its packaged accessories, which include the Cue Power Adapter, the Cue Charging Cable, and additional power sources manufactured specifically for this device. The Cue COVID-19 Test is an at-home molecular NAAT and is not equivalent to the at-home antigen tests commonly available on the market. The Cue Reader is a required device that can be used multiple times for analyzing specimens collected with the single-use Cue COVID-19 Test Cartridges. To complete a Cue COVID-19 Test, the Cue COVID-19 Test Cartridge is inserted into the Cue Reader. Next, a Cue Sample Wand is used to collect a direct nasal swab specimen. Then, the wand is inserted into the Cue COVID-19 Test Cartridge (which was already inserted into the Cue Reader in the previous step). When the wand is inserted into the Cue COVID-19 Test Cartridge, the NAAT begins automatically and provides a test result in 20 minutes. Test results are available in the Cue Health Mobile Application that can be accessed by patients and healthcare professionals (HCP). Based upon the test results, the HCP can determine the most appropriate treatment pathway based on the patient's conditions and symptoms.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code KXXXX, "Molecular diagnostic test reader, nonprescription self-administered and self-collected use, fda approved, authorized or cleared"

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category

Please note that the Cue Cartridge Reader and accessories are not considered by Medicare to be durable medical equipment (DME). DME is defined in section 1861(n) of the Social Security Act and in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202. It is further described in Medicare program instructions at chapter 15, section 110.1 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) and chapter 1, part 4, section

280.1 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03). DME is defined as equipment furnished by a supplier or a home health agency, that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally, is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. With respect to the first and second conditions, given that DME is a benefit for rental of equipment for use in the home, the equipment must be able to withstand repeated use by successive patients. While the manufacturer has indicated that the Cue Cartridge Reader and accessories have an expected life of at least 3 years, it also indicates that they are not intended for use by successive patients.

In addition, with respect to the third condition the item must be useful to a person for the treatment of an illness or injury, and be expected to make a meaningful contribution to the treatment of the individual's illness or injury. The Cue Cartridge Reader and accessories are used to diagnose whether an individual is infected with the COVID-19 virus, not to treat an individual with COVID-19. CMS considers diagnostic equipment such as the Cue Cartridge Reader and accessories to be an extension of or incident to a clinical service, and not DME. For example, prothrombin time home testing systems (HCPCS Code G0249) are diagnostic and not considered DME.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering that no comments were received, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code K1035, "Molecular diagnostic test reader, nonprescription self-administered and self-collected use, fda approved, authorized or cleared" to describe the Cue Cartridge Reader.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing Indicator = 00

Cue COVID-19 Test Cartridge Pack - HCP2207052C281

Topic/Issue

Request to establish a new HCPCS Level II code to identify Cue Cartridge for its COVID-19 at-home test to be used with the Cue Reader.

Applicant's suggested language: AXXXX, "Specimen sample cartridge, sterile, each, for use with COVID-19 molecular diagnostic test reader"

Applicant's Summary

Cue Health submitted a request to establish a new HCPCS Level II code to identify Cue Cartridge for its COVID-19 at-home test to be used with the Cue Reader. As a component of the Cue Health Monitoring System, the COVID-19 Test Cartridge is used with the Cue Reader, an in-vitro diagnostic medical device. The Cue Cartridge and the Cue Reader work with the proprietary Cue Health Mobile Application, which is accessed on a mobile smart device. This HCPCS request is for the Cue Cartridge with the Cue Sample Wand, used for collection of the sample to be analyzed for the presence of COVID-19 using Nucleic Acid Amplification Test (NAAT) technology. For the current Emergency Use Authorization indication of COVID-19 testing, a direct nasal swab specimen is collected from an individual using the Cue Sample Wand and then is inserted into the Cue COVID-19 Test Cartridge and run on the Cue Cartridge Reader. When the cartridge is inserted into the Cue Reader, the NAAT automatically begins and provides a positive or negative result within 20 minutes, and is transmitted to the Cue Health Mobile Application, to which the patient and the patient's healthcare professional (HCP) both have access. The HCP then determines the most appropriate treatment pathway for the patient's condition and symptoms.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1034, "Provision of covid-19 test, nonprescription self-administered and self-collected use, fda approved, authorized or cleared, one test count" describes Cue Cartridge.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category

Please note that the Cue Cartridge is not considered by Medicare to be durable medical equipment (DME). DME is defined in section 1861(n) of the Social Security Act and in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202. It is further described in Medicare program instructions at chapter 15, section 110.1 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) and chapter 1, part 4, section 280.1 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03). DME is defined as equipment furnished by a supplier or a home health agency, that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally, is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. With respect to the first and second conditions, given that DME is a benefit for rental of equipment for use in the home, the equipment must be able to withstand repeated use by successive patients. The Cue Cartridge is a single use product and is not intended for use by successive patients.

In addition, with respect to the third condition the item must be useful to a person for the treatment of an illness or injury, and be expected to make a meaningful contribution to the treatment of the individual's illness or injury. The Cue Cartridge is used to diagnose whether an individual is infected with the COVID-19 virus, not to treat an individual with COVID-19. CMS considers diagnostic equipment such as the Cue Cartridge to be an extension of or incident to a clinical service, and not DME. For example, prothrombin time home testing systems (HCPCS Code G0249) are diagnostic and not considered DME.

Summary of Public Feedback

Cue Health, Inc., the manufacturer of this product, disagreed with CMS' published preliminary recommendation and requested that a new HCPCS Level II code would be assigned to Cue Cartridge. The speaker requested code language stating, "Specimen sample cartridge, sterile, each, for use with COVID-19 molecular diagnostic test reader; amplified probe technique with automatic results interpretation." The speaker stated that the existing HCPCS Level II code K1034 does not differentiate between the different types of tests, and fails to recognize the fundamental clinical and technical differences of Cue Cartridge. The speaker commented that the Cue Cartridge tests results are definitive unlike other antigen tests. The speaker mentioned that the CPT® code set distinguishes between the nucleic acid tests and the antigen tests, and stated CMS should reflect the same distinction.

CMS Final HCPCS Coding Decision

CMS understands the evolving field of molecular diagnostic tests and antigen tests for COVID-19 tests, in particular. We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code K1034, "Provision of covid-19 test, nonprescription self-administered and self-collected use, fda approved, authorized or cleared, one test count" to describe the Cue Cartridge.

K1034 was established to facilitate claims processing for the Medicare Over-the-Counter COVID-19 Test Demonstration. The Department of Health and Human Services has communicated its intent for the federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service Act, to expire at the end of the day on May 11, 2023. Following the end of the PHE, Medicare will no longer pay for HCPCS code K1034. Non-Medicare payers still may continue to use and possibly pay post-PHE for at-home COVID-19 tests under HCPCS code K1034. CMS is not aware of other insurers potentially paying differently from K1034 for this type of at-home COVID-19 test.

If the Cue Cartridge is used by a registered clinical laboratory, existing HCPCS Level I (CPT®) codes can be utilized for claims submission.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing Indicator = 00

Koya Dayspring® - HCP2207039VEAR

Topic/Issue

Request to establish a new HCPCS Level II code to identify Koya Dayspring® trunk garment.

Applicant's suggested language: EXXXX, "Non-pneumatic sequential compression garment, trunk"

Applicant's Summary

Koya Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify Koya Dayspring® trunk garment. As a reference, E0656, "Segmental pneumatic appliance for use with pneumatic compressor, trunk" currently exists. This code description specifically limits the method of compression appliance to "pneumatic." The applicant stated that the Dayspring® non-pneumatic garments, including the trunk, perform the same clinical functions as the segmental pneumatic appliances and all Dayspring® garments work with both calibrated gradient and non-calibrated gradient Dayspring® controllers. Both segmental pneumatic and non-pneumatic appliances only work in conjunction with their respective compressors and have identical clinical indications for use, intended for the same patient populations, and perform the same clinical functions delivering the same ranges of therapeutic pressure ranges. In operation, both systems use a controller and a segmental appliance or garment and are similar in its function and clinical use.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code EXXXX, "Non-pneumatic sequential compression garment, trunk"

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and in Medicare regulations at title 42 Code of Federal Regulations (CFR) section 414.202, and means equipment, furnished by a supplier or a home health agency that meets the five conditions listed in the below table. All five of these conditions must be met in order for equipment to be classified as DME.

The final benefit category determinations for HCPCS applications numbers 21.032 Koya Dayspring® System and HCP210903LPG21 Koya Dayspring® Lite System established that these sequential compression devices meet the definition of DME found in 42 CFR §414.202.

Also, the Koya sequential compression devices' garment accessories were reviewed for HCPCS application numbers 21.070 (full arm), HCP210903PMKF3 (full leg) and HCP210903WBEG8 (half leg). The final determinations established that the garment accessories met the requirement of Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03) which indicates 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.

Similar to the garment accessories discussed above, as shown in the below table, the Koya Dayspring® non-pneumatic trunk garment meets all five DME classification conditions, and therefore is DME.

Condition Met?	Conditions that Must be Met for Equipment to be Classified as DME
Yes	1. Can withstand repeated use.
Yes	2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
Yes	3. Is primarily and customarily used to serve a medical purpose.
Yes	4. Generally, is not useful to an individual in the absence of an illness or injury.
Yes	5. Is appropriate for use in the home.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238, 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 new HCPCS code EXXXX for this particular garment is to establish the fee schedule amounts using the existing fee schedule amounts for comparable items described by HCPCS code E0656 (“segmental pneumatic appliance for use with pneumatic compressor, trunk”).

The Koya Dayspring® System consists of a segmental calibrated gradient compression device that provides compression comparable to existing pneumatic pump (K1025) and garments (e.g., E0656) through segments that contract and relax flexible frames in a segmental appliance without the use of air. The clinical conditions and indications for use for the Koya Dayspring® System’s garment trunk accessory is the same as those under the code for related pneumatic pump garment accessories (e.g., E0656). We believe that a non-pneumatic system such as the Koya Dayspring® System as a whole (controller and garment accessory) is comparable to existing pneumatic systems as a whole (pump and garment accessory).

	E0656	Koya Dayspring® non-pneumatic sequential compression garment, trunk
Physical Components	-Segmented garment with tubing to allow filling of pneumatic air. -Air bladders in select number of chambers. -Tubing to connect pump to appliance (used for air flow).	-Fabric shell composed of polyester and spandex. -Multiple compressive segments made of durable plastic nylon frames interlaced with Nickel-Titanium (Ni-Ti) shape-memory alloy.

Mechanical Components	-Pressure ranges from 0 – 100 mmHg. -Air flows through tubing, inflating bladders until they are exerting the desired pressure range for treatment.	-Controller activates segments to exert desired programmed calibrated pressure gradient sequentially in distal to proximal direction.
Electrical Components	-None. All electrical components are in pump.	-Receiver to expand/contract segments to attain desired pressure.
Function and Intended Use	-To move excess fluid in a rhythmic, distal to proximal manner and return it to the bloodstream. -Uses air to inflate and deflate a segmental appliance. -Generates pressure through compression of air. -Intended to treat many conditions such as: Lymphedema, Primary lymphedema, Post mastectomy edema, Edema following trauma and sports injury, Post immobilization edema, Venous insufficiency, and Reducing wound healing time.	-To move excess fluid in a rhythmic, distal to proximal Manner and return it to the bloodstream. -Uses segmental sections that expand/contract to exert intended pressure onto applied body area. -Intended to treat many conditions such as: Lymphedema, Primary lymphedema, Post mastectomy edema, Edema following trauma and sports injury, Post immobilization edema, Venous insufficiency, and Reducing wound healing time.
Additional Aspects and Features	None	None

Payment for the equipment described by HCPCS code EXXXX would be made on a capped rental basis in accordance with 42 CFR 414.229. It would be established using the fee schedule amounts for HCPCS code E0656, with the 2022 rental fee schedule amount for months 1 through 3 equaling \$70.70, and the rental fee schedule amount for months 4 through 13 equaling approximately \$53.02 for all areas except Puerto Rico. For Puerto Rico, the 2022 rental fee schedule amount for months 1 through 3 would be equal to \$84.83, and the rental fee schedule amount for months 4 through 13 would equal approximately \$63.62.

Pricing Indicator = 36

Summary of Public Feedback

Koya Medical, Inc., the manufacturer of this product, agreed with CMS’ published preliminary recommendations.

CMS Final HCPCS Coding Recommendation

We appreciate the comments provided in response to CMS’ published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code E0677, “Non-pneumatic sequential compression garment, trunk” to describe the Koya Dayspring® non-pneumatic sequential compression trunk garment.

Final Medicare Benefit Category Determination

Durable Medical Equipment

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code E0677 will be established using the fee schedule amounts for HCPCS code E0656. The 2023 rental fee schedule amount for months 1 through 3 is \$76.85, and the rental fee schedule amount for months 4 through 13 is \$57.64 except Puerto Rico. For Puerto Rico, the 2023 rental fee schedule amount for months 1 through 3 is \$92.21, and the rental fee schedule amount for months 4 through 13 is \$69.16.

Payment will be made on a capped rental basis for any covered claims.

Pricing Indicator = 36

PainShield® Supplies - HCP220616GR6A0

Topic/Issue

Request to establish a new HCPCS Level II code to identify PainShield® disposable supply kit.

Applicant's suggested language: XXXXX, “Disposable supply kit (1 transducer, 30 adhesive bandages) for use with the PainShieldMD, HCPCS K1004”

Applicant’s Summary

Nanovibronix submitted a request to establish a new HCPCS Level II code to identify the disposable supply kit for use with the PainShield® (HCPCS K1004). Each supply kit includes an ultrasound actuator (lasts 30 days) and 30 adhesive bandages. The PainShield® provides pain management using low frequency, ultrasonic diathermy. The ultrasound actuator included with the PainShield® durable handheld, battery-operated device is effective for 30 days, after which it must be replaced to maintain effective therapeutic action. The PainShield® is intended to apply ultrasonic energy, warming the tissues for the purpose of pain control, muscle spasms, and joint contractures. The mechanism of action is a warming of the skin for a period of 6.5 hours and as needed, as prescribed.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a disposable supply kit (1 transducer and 30 adhesive bandages) for use with the PainShield®. This follows our prior decision (published September 26, 2022) that the PainShield® device does not have a durable medical equipment, prosthetics, orthotics, and supplies Medicare benefit category. With regard to Medicare, we do not have a benefit category for PainShield®, a low-frequency ultrasonic diathermy treatment device for home use, as it does not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering that no comments were received, CMS is finalizing its preliminary recommendation. CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a disposable supply kit (1 transducer and 30 adhesive bandages) for use with the PainShield®. This follows our prior decision (published September 26, 2022) that the PainShield® device does not have a durable medical equipment, prosthetics, orthotics, and supplies Medicare benefit category. With regard to Medicare, we do not have a benefit category for PainShield®, a low-frequency ultrasonic

diathermy treatment device for home use, as it does not meet the definition of durable medical equipment.

Steri-Lift Kit - HCP220406X5KJQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Steri-Lift Kit.

The applicant did not submit any suggested language.

Applicant's Summary

L.A.D. Medical Innovations, LLC submitted a request to establish a new HCPCS Level II code to identify Steri-Lift Kit. Steri-Lift Kit is to be used as a drape to cover the floor or overhead lifts in sterile settings and to allow the lift to be used during surgery as a safe patient handling and movement tool. It is applied pre-op by the surgical team nurse and removed by the post-op personnel. Steri-Lift Kit is sterile and packaged individually for one-time use only. Steri-Lift Kit is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the Steri-Lift Kit 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. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

Summary of Public Feedback

L.A.D. Medical Innovations, the manufacturer of this product, disagreed with CMS' HCPCS preliminary recommendation that the Steri-Lift Kit would generally be used in a procedure reported with a CPT® code. Steri-Lift Kit is a universal draping and support system designed for floor based and overhead lifting mechanisms. Steri-Lift Kit is only used in a hospital setting. According to the speaker, the Steri-Lift Kit enhances staff and patient safety and allows for a sterile environment. Steri-Lift Kit can support the weight of the patient for either floor based, overhead, or mobile overhead lifts. According to the speaker, the Steri-Lift Kit is comprised of one sterile drape and one sterile sling.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. We continue to believe the Steri-Lift Kit is not suitable for inclusion in the HCPCS Level II code set because it is used during a procedure and certain items are considered bundled into the facility payment. We have not identified a specific need for this device to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

Doula Birth Worker - HCP220323830N1, HCP220323U8HVV, HCP220323DP0KP

Topic/Issue

Request to establish three new HCPCS Level II codes to identify doula birth worker prenatal visits, attendance at labor and delivery, and postpartum visits.

Applicant's suggested language:

1. XXXXX, “Doula birth worker prenatal visit”
2. XXXXX, “Doula birth worker attendance at labor and delivery”
3. XXXXX, “Doula birth worker postpartum visit”

Applicant’s Summary

Maryland Department of Health submitted a request to establish three new HCPCS Level II codes to identify doula birth worker prenatal visits, attendance at labor and delivery, and postpartum visits. According to the applicant, one of the new requested codes would cover doula birth worker prenatal visits, usually occurring at the birth parent's home, but could also include accompaniment to medical appointments. In these visits, doula birth workers and birth parents would discuss topics such as: anatomy and physiology of labor, birth, maternal postpartum, neonatal transition, and breastfeeding; labor coping strategies, comfort measures and non-pharmacological techniques for pain management; the reasons for, procedures of, and risks and benefits of common medical interventions, medications, and Cesarean birth; the role of the doula with members of the birth team; communication skills, including active listening, cross-cultural communication, and interprofessional communication; self-advocacy and empowerment techniques; perinatal mental health; family adjustment and dynamics; evidence-informed educational and informational strategies; and community resource referrals. According to the applicant, another new requested code would cover birth worker attendance and services during birth, vaginal or caesarian, live or stillbirth. Services provided during labor and delivery may include emotional support as well as physical comfort measures to the individual and their partner while giving birth that are not clinical interventions. This service can only be conducted while a qualifying attending provider (e.g., Obstetrician-Gynecologist, Family Medicine Practitioner, or Certified Nurse Midwife) is also in attendance during the birthing process. According to the applicant, a third new requested code would cover doula birth worker postpartum visits, usually occurring at the birthing parent's home, but could also include accompaniment to medical appointments. In these visits, doula birth workers and birth parents would discuss topics such as: anatomy and physiology of labor, birth, maternal postpartum, neonatal transition, and breastfeeding; labor coping strategies, comfort measures and non-pharmacological techniques for pain management; the reasons for, procedures of, and risks and benefits of common medical interventions, medications, and Cesarean birth; the role of the doula with members of the birth team; communication skills, including active listening, cross-cultural communication, and interprofessional communication; self-advocacy and empowerment techniques; perinatal mental health; family adjustment and dynamics; evidence-informed educational and informational strategies; and community resource referrals.

According to the applicant, many states are now reimbursing doula birth workers through Medicaid for physical, emotional and psychosocial support throughout the perinatal period. Upon further analysis of HCPCS codes, the applicant was unable to find a suitable code that adequately captures the function of this service without making substantial coding edits to accommodate this new provider type and will be using a home-grown HCPCS code in the interim while requesting a new code be created as more states seek to reimburse this service.

CMS Preliminary HCPCS Coding Recommendation

CMS recently established codes that can be used in a multi-purpose manner for services performed by a doula birth worker. Existing HCPCS Level II codes describe the doula birth worker prenatal visits, attendance at labor and delivery, and postpartum visits:

T1032, “Services performed by a doula birth worker, per 15 minutes”

T1033, “Services performed by a doula birth worker, per diem”

Individual state Medicaid agencies have the flexibility to further define doula birth worker services by assigning one or more state defined HCPCS modifiers in the U1 through U9 series. These modifiers offer each state’s Medicaid program the opportunity to define the level of care (e.g., prenatal visits, active labor and delivery, postpartum visits).

Summary of Public Feedback

Maryland Department of Health commented that they agreed with our preliminary determination.

CMS Final HCPCS Coding Decision

Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. Existing HCPCS Level II codes describe the doula birth worker prenatal visits, attendance at labor and delivery, and postpartum visits:

T1032, “Services performed by a doula birth worker, per 15 minutes”

T1033, “Services performed by a doula birth worker, per diem”

Individual state Medicaid agencies have the flexibility to further define doula birth worker services by assigning one or more state defined HCPCS modifiers in the U1 through U9 series. These modifiers offer each state’s Medicaid program the opportunity to define the level of care (e.g., prenatal visits, active labor and delivery, postpartum visits).

Feelix Stethoscope - HCP220701D69QJ

Topic/Issue

Request to establish a new HCPCS Level II code to identify digital stethoscope that collects high-fidelity recordings in any environment and transmit data wirelessly.

Applicant's suggested language: XXXXX, "Smart wireless digital platform with recording device and LED indicators"

Applicant's Summary

Sonavi Labs submitted a request to establish a new HCPCS Level II code to identify Feelix Device. Feelix Stethoscope received the Food and Drug Administration's (FDA's) 510(k) clearance on September 14, 2020. Feelix Stethoscope is a digital stethoscope that collects high-fidelity recordings in any environment and transmit data wirelessly. Feelix collects recordings of patient body sounds including cough and allows clinicians to review, store and share recordings via a HIPAA-compliant cloud. Feelix hardware is designed to run diagnostic and prognostic algorithms for specific respiratory diseases such as chronic obstructive pulmonary disease (COPD), pneumonia, asthma and cystic fibrosis. These algorithms will be separate Software as a Medical Device (SAMD) devices and will be downloaded to the hardware by prescription. According to the applicant, no code exists to define devices used to telemeter, analyze and diagnose body sound recordings. According to the applicant, a new code should be created to incorporate the use of recording devices for the management and treatment of respiratory patients remotely. Feelix is a prescription only device. The Feelix Stethoscope is intended for the detection, amplification and recording of sounds from the heart, lungs, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with selective frequency ranges. It can be used on any person undergoing a physical examination.

CMS Preliminary HCPCS Coding Recommendation

This is a repeat application, previously submitted in B1 2021, application 21.066. It is our understanding that the Feelix Stethoscope could be used in furnishing remote monitoring HCPCS Level I (CPT®) codes 99453, "Remote monitoring of physiologic parameters, initial set up and patient education on use of equipment," 99454, "Remote monitoring of physiologic parameters, supply with daily recordings or programmed alert transmission, each 30 days," and 99457, "Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in calendar month requiring interactive communication with the patient/caregiver during the month." CMS continues to believe that HCPCS Level I (CPT®) is the appropriate code set for the Feelix Device.

Summary of Public Feedback

Sonavi Labs, the manufacturer of this product, disagreed with CMS' published preliminary recommendation and requested that a new HCPCS Level II code would be established to identify Feelix Stethoscope. According to the speaker, only CPT® code 99454, "Remote monitoring of physiologic parameters, supply with daily recordings or programmed alert transmission, each 30 days," provides reimbursement for any monitoring devices used by a patient in a month, with exceptions for devices such as continuous glucose monitors (CGM).

The speaker commented that CPT® code 99454 does not provide an adequate payment for the Felix Stethoscope. The speaker further stated that CGMs are separately covered for patients with diabetes, so patients with COPD and asthma should be treated similarly. The speaker commented that current costs of manufacturing significantly supersede the reimbursement provided under CPT® code 99454, which is \$55.72. The Felix Stethoscope has a list price of \$499 and has a battery life expectancy of up to four years. According to the speaker, a unique HCPCS Level II code will support a separate payment for Felix Stethoscope, and that without a unique code, patients will not have access to this product.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. It is our understanding Felix Stethoscope could be used in furnishing remote monitoring HCPCS Level I (CPT®) codes 99453, "Remote monitoring of physiologic parameters, initial set up and patient education on use of equipment," 99454, "Remote monitoring of physiologic parameters, supply with daily recordings or programmed alert transmission, each 30 days," and 99457, "Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in calendar month requiring interactive communication with the patient/caregiver during the month." Based on this understanding, and in the absence of information regarding a claims processing need on the part of a payer to establish a separate HCPCS Level II code for this product, we are denying the request to establish a separate HCPCS Level II code.

Cochlear™ Osia® 2 System - HCP220705GRQ19

Topic/Issue

Request to establish a new HCPCS Level II code to identify Cochlear™ Osia® 2 System.

Applicant's suggested language: LXXXX, “Active, auditory osseointegrated device, including implanted transducer/actuator with digital link to external sound processor”

Applicant’s Summary

Cochlear Americas submitted a request to establish a new HCPCS Level II code to identify the Osia® 2 System. The Cochlear™ Osia® 2 System is an active, auditory osseointegrated implant with transcutaneous attachment to external system components. The Osia® 2 System is intended for patients 12 years-of-age or older who have conductive or mixed hearing loss, or single-sided deafness and still can benefit from sound amplification. The Osia® 2 System is a prosthetic that replaces the functioning of the middle ear. The Osia® 2 System is surgically implanted during an outpatient procedure. According to applicant, unlike the passive osseointegrated devices recognized by the current HCPCS Level II code set in which sound is converted to mechanical vibrations in the external sound processor/actuator then transmitted to the internal components, the Osia® 2 System converts the sound to mechanical vibrations after it has reached the internal components. The active, piezoelectric design of the OSI200 Implant, which is one component of the Osia® 2 System, thereby allows for an efficient delivery of the sound from the external environment to the cochlea (inner ear). The Osia® 2 System mechanically vibrates the skull bone, and subsequently the cochlea, acting as a prosthetic to replace the functioning of the middle ear. What is unique about the Osia® 2 System is that it uses a magnetic coupling to transfer the sound received by the external processor to the implanted component via a digital link (e.g., transcutaneous pathway) where it is then transformed into mechanical vibrations by the (active) OSI200 implant, transferred directly to the BI300 Implant, and then to the cochlea via the skull bone. The Osia® 2 System improves upon passive percutaneous systems by eliminating issues associated with the skin penetrating abutment, and solves for the sound diminution issues of passive transcutaneous systems due to the active design of the implant and generation of vibrations under the scalp. According to the applicant, when HCPCS Level II code L8690, “Auditory osseointegrated device, includes all internal and external components” was created, the technology to fully implant the transducer/actuator and thereby transform sound into mechanical vibrations directly at the bone implant did not exist. This technology transforms the functioning of the external sound processor and internal components of active auditory osseointegrated implants because the mechanism of action is entirely different from the passive systems of the past. According to applicant, for these reasons, and as acknowledged by CMS in the 2022 Hospital Outpatient Prospective Payment System (OPPS) final rule (86 Fed. Reg. 63,458, 63,591 and 63,605 (Nov. 16, 2021)), existing HCPCS Level II code L8690 does not describe active osseointegrated systems, like the Osia® 2 System, and a new HCPCS Level II code should be created to specifically describe them. The Cochlear™ Osia® 2 Sound Processor received the Food and Drug Administration’s (FDA’s) 510(k) clearance on November 15, 2019.

CMS Preliminary HCPCS Coding Recommendation

The Calendar Year 2022 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (86 FR 63458) determination was that the Cochlear™ Osia® 2 Sound Processor does not

meet the substantial clinical improvement criterion. Though the mechanism of action with comparable devices may differ, the vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear) is the same. CMS did not find any new evidence in the HCPCS Level II application to establish a significant therapeutic distinction. CMS, as an agency, continues to believe that our decision in the 2022 OPFS Final Rule remains accurate. As such, existing HCPCS Level II code L8690, "Auditory osseointegrated device, includes all internal and external components" describes the Cochlear™ Osia® 2 System.

Preliminary Medicare Benefit Category Determination

The Osia® 2 System meets the criteria to be considered a prosthetic device as it is an osseointegrated implant in the skull bone that provides mechanical energy to the cochlea via a mechanical transducer per §411.15(d)(2)(i). As such, it is not subject to the hearing aid exclusion at §411.15(d)(1).

The current Medicare policy and prior established benefit category determination for code L8690 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code L8690 apply to this product, if covered. The current average fee schedule amount for L8690 is \$5,004.81.

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

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to use existing HCPCS Level II code L8690, "Auditory osseointegrated device, includes all internal and external components" to describe the Cochlear™ Osia® 2 System and HCPCS Level II code L8691, "Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each" to describe the Cochlear™ Osia® 2 Sound Processor. The Osia® 2 System applies a vibration directly to the bone of the skull which in turn causes the production of sound, the system provides a significant therapeutic distinction because it both reduces skin-related complications associated with passive/percutaneous devices and improves audiological outcomes as compared to passive/transcutaneous systems, and it eliminates the issues with feedback. The speaker stated when the original HCPCS L8690 code was created in 2007, the technology to fully implant the transducer and actuator did not exist. Another speaker stated that the Osia® 2 System has better longevity due to its design, provides higher frequency resolution, requires decreased post-operative care and provides improved cosmetic benefits, and for these reasons this technology deserves a new HCPCS Level II code. Commenters stated that the internally implanted piezoelectric actuator met the criteria of new technology and the mechanism of action was also active, not passive like devices of the past. Commenters also stated that that CMS conflated two standards for new technology and HCPCS code creation and therefore the preliminary recommendation was inaccurate.

CMS received a written comment that agreed with the HCPCS preliminary recommendation for the Osia® 2 System and Processor in accordance with the Calendar Year 2022 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (86 FR 63458) determination was that the Cochlear™ Osia® 2 Sound Processor does not meet the substantial clinical improvement criterion.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code L8690, "Auditory osseointegrated device, includes all internal and external components" to describe the Cochlear™ Osia® 2 System.

We note that neither the application nor the comments provided during or in response to the public meeting provided any compelling new evidence pointing to a significant therapeutic distinction that would support establishing a new HCPCS Level II code as opposed to using the previously established codes.

Final Medicare Benefit Category Determination

Prosthetic

The current Medicare policy and prior established benefit category determination for code L8690 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code L8690 apply to this product, if covered. The current average fee schedule amount for L8690 is \$5,440.23.

The average fee schedule amount is the average of the 2023 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

Cochlear™ Osia® 2 Sound Processor - HCP22070522MTY

Topic/Issue

Request to establish a new HCPCS Level II code to identify to Cochlear™ Osia® 2 Sound Processor.

Applicant's suggested language: LXXXX, “Active, auditory osseointegrated device, external sound processor with digital link to implanted transducer/actuator; replacement only, each”

Applicant’s Summary

Cochlear Americas submitted a request to establish a new HCPCS Level II code to identify replacements for the Osia® 2 External Sound Processor. The Osia® 2 System is an active, auditory osseointegrated implant with transcutaneous attachment to external system components that are surgically placed in the temporal bone posterior to the pinna. The Osia® 2 Sound Processor is worn off-the-ear and picks up sound from the environment. After processing sound, the Osia® 2 Sound Processor sends the information to the OSI200 Implant via a transcutaneous inductive link (also referred to as a radiofrequency link). The Osia® 2 Sound Processor houses the microphones that pick-up sound, the battery that powers the microphones as well as the implanted components of the Osia® 2 System, and the magnet that transcutaneously links the external sound processor to the internal transducer/actuator. The Osia® 2 Sound Processor does not contain the actuator/transducer, which is implanted as part of the active Osia® System. The Osia® 2 System is intended for patients 12 years-of-age or older who have conductive or mixed hearing loss, or single-sided deafness and still can benefit from sound amplification. The Osia® 2 Sound Processor is a prosthetic supply. It has a warranty period of two years after which time it may need to be replaced. According to the applicant, unlike the passive osseointegrated devices recognized by the current HCPCS Level II code set in which sound is converted to mechanical vibrations in the external sound processor/actuator then transmitted to the internal components, the Osia® 2 System converts the sound to mechanical vibrations after it has reached the internal components. This innovative technology has made it possible for there to be a single external component of the auditory osseointegrated implant (AOI) system, the sound processor. Passive AOIs all have external sound processors, which include a processing unit and a transducer/actuator. Those external sound processors may contain both the processing unit and transducer/actuator within a single unit or may consist of both pieces separated but connected via a physical wire. Because the Osia® 2 System’s transducer/actuator is implanted, the technology in the Osia® 2 Sound Processor itself also is different from passive sound processors because the device must incorporate a digital link to communicate the sounds transcutaneously to the internal components. According to applicant, CMS acknowledged in the 2022 Hospital Outpatient Prospective Payment System (OPPS) final rule that existing HCPCS code L8690 (Auditory osseointegrated device, includes all internal and external components) does not describe the Osia® 2 System. For the same reason, HCPCS Level II code L8691, “Auditory osseointegrated device, external sound processor; excludes transducer/actuator; replacement only, each” does not describe the Osia® 2 Sound Processor. The Cochlear™ Osia® 2 Sound Processor received the Food and Drug Administration’s (FDA’s) 510(k) clearance on November 15, 2019.

CMS Preliminary HCPCS Coding Recommendation

The Calendar Year 2022 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (86 FR 63458) determination was that the Cochlear™ Osia® 2 Sound Processor does not meet the substantial clinical improvement criterion. Though the mechanism of action with comparable devices may differ, the vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear) is the same. CMS did not find any new evidence in the HCPCS Level II application to establish a significant therapeutic distinction. CMS, as an agency, continues to believe that our decision in the 2022 OPPS Final Rule remains accurate. As such, existing HCPCS Level II code L8691, "Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each" describes the Cochlear™ Osia® 2 Sound Processor.

Preliminary Medicare Benefit Category Determination

The sound processor is an external component of the implanted Osia® 2 System. The Osia® 2 system meets the criteria to be considered a prosthetic device as it is an osseointegrated implant in the skull bone that provides mechanical energy to the cochlea via a mechanical transducer per §411.15(d)(2)(i). As such, it is not subject to the hearing aid exclusion at §411.15(d)(1).

The current Medicare policy and prior established benefit category determination for code L8691 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code L8691 apply to this product, if covered. The current average fee schedule amount for L8691 is \$1,811.79.

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 = 38

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to use existing HCPCS Level II code L8690, "Auditory osseointegrated device, includes all internal and external components" to describe the Cochlear™ Osia® 2 System and HCPCS Level II code L8691, "Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each" to describe the Cochlear™ Osia® 2 Sound Processor. The Osia® 2 System applies a vibration directly to the bone of the skull which in turn causes the production of sound, they system provides a significant therapeutic distinction because it both reduces skin-related complications associated with passive/percutaneous devices and improves audiological outcomes as compared to passive/transcutaneous systems, and it eliminates the issues with feedback. The speaker stated when the original HCPCS L8690 code was created in 2007, the technology to fully implant the transducer and actuator did not exist. Another speaker stated that the Osia® 2 System has better longevity due to its design, provides higher frequency resolution, requires decreased post-operative care and

provides improved cosmetic benefits, and for these reasons this technology deserves a new HCPCS Level II code. Commenters stated that the internally implanted piezoelectric actuator met the criteria of new technology and the mechanism of action was also active, not passive like devices of the past. Commenters also stated that CMS conflated two standards for new technology and HCPCS code creation and therefore the preliminary recommendation was inaccurate.

CMS received a written comment that agreed with the HCPCS preliminary recommendation for the Osia® 2 System and Processor in accordance with the Calendar Year 2022 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (86 FR 63458) determination was that the Cochlear™ Osia® 2 Sound Processor does not meet the substantial clinical improvement criterion.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code L8691, "Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each" to describe the Cochlear™ Osia® 2 Sound Processor.

We note that neither the application nor the comments provided during or in response to the public meeting provided any compelling new evidence pointing to a significant therapeutic distinction that would support establishing a new HCPCS Level II code as opposed to using the previously established codes.

Final Medicare Benefit Category Determination

Prosthetic

The current Medicare policy and prior established benefit category determination for code L8691 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code L8691 apply to this product, if covered. The current average fee schedule amount for L8691 is \$1,969.42.

The average fee schedule amount is the average of the 2023 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

SWIK™ - HCP2205316LKRL

Topic/Issue

Request to establish a new HCPCS Level II code to identify SWIK™.

The applicant did not submit any suggested language.

Applicant's Summary

Saliva Systems submitted a request to establish a new HCPCS Level II code to identify the SWIK™ Oral Suction System. SWIK™ is a class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. SWIK™ is a single-use, disposable device to manage secretions in the oral cavity. The device includes a mouthpiece attached to tubing with a custom molded connector. The tubing then connects to a negative pressure pump with a universal connector. SWIK™ is installed in the mouth and remains in place, for up to 12 hours at a time, while connected to negative pressure. The device does not require intervention during use; only installation and removal of the device. According to the applicant, the current assigned code, A4628, describes a device that requires human intervention to operate and is used intermittently rather than continuously.

CMS Preliminary HCPCS Coding Recommendation

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

1. How does the SWIK™ Oral Suction System compare to some of the other products in this space or those that currently fall under A4628, "Oropharyngeal suction catheter, each" (such as, materials, componentry, etc.)?
2. Who is the patient population utilizing the SWIK™ Oral Suction System?
3. In what clinical setting would a patient use this for 12 hours?
4. Are there any data that show the SWIK™ Oral Suction System is preferable to other oral secretion devices, provides better health outcomes, offers statistically significant improvements in care, etc.?

Summary of Public Feedback

Saliva Systems, the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, there is no predicate device to measure the value of SWIK™, as it is the only continuous and handsfree oral secretion management device on the market. SWIK™ was previously assigned HCPCS codes A4628, "Oropharyngeal suction catheter, each" and A7002, "Tubing, used with suction pump, each". According to the speaker, the current coding descriptions assigned implies that the device can be used in the pharyngeal area, which is not true for the SWIK™ device. The SWIK™ device is installed in the vestibule between the lower lip and teeth and wraps around to the back molars without extending past them. Also, it does not cross the biting surface of the patient, which allows a

patient to speak while in use. When suction is applied, the device remains in place for 8-10 hours without intervention, and continuously manages oral secretions that are located from the soft pallet forward. SWIK™ should never extend back to the pharyngeal area, like the currently assigned codes indicate. Using the device in this manner would constitute misuse of the product, which may result in an unintended adverse event for the patient. According to the speaker, the suction catheter Yankauer, also covered by these codes, is intermittent, manual, made from hard material, and not intended for extended use. Saliva Systems specifically requested the assignment of a unique HCPCS Level II code that represents the SWIK™ device.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. During our analysis, we have become aware that there are existing devices that are being billed under HCPCS code A4628 that are, or could be, used in other areas than just the pharyngeal region of the oral cavity. We also agree that A4628 does not describe the anatomy in the way that the product is used, though the intended uses are similar. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the decision to:

Revise existing HCPCS code A4628, "Oropharyngeal suction catheter, each" to read "Oral and/or oropharyngeal suction catheter, each". HCPCS code A4628, as revised, together with existing HCPCS Level II code A7002, "Tubing, used with suction pump, each" describe SWIK™ Oral Suction System.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for codes A4628 and A7002 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing codes A4628 and A7002 apply to this product, if covered. The current average fee schedule amount for A4628 is \$4.94. The current average fee schedule amount for A7002 is \$4.78

The average fee schedule amount is the average of the 2023 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 = 32

NEURO SWING, Cup Disc Spring Force Unit - HCP220705GH052

Topic/Issue

Request to establish a new HCPCS Level II code to identify a cup disc spring force unit.

Applicant's suggested language: XXXXX, "Addition to lower extremity, exchangeable, pre-compressed cup disc spring force unit with integrated range of motion control feature"

Applicant's Summary

FIOR & GENTZ submitted a request to establish a new HCPCS Level II code to identify a pre-compressed cup disc spring force unit in an ankle foot orthosis (AFO). The NEURO SWING is a class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. According to the applicant, this innovative device not only allows adjustable range of motion in an AFO, but provides more therapeutic benefit than either a coil or helical spring due to a pre-compressed cup disc spring force unit's ability to generate a higher magnitude force capacity than ever previously available in an orthotic joint. The pre-compressed cup disc spring force units are incorporated into the NEURO SWING ankle joint system so that not only can adequate resistance forces be applied, but also an assistive force can be generated that is sufficient to assist the leg with a magnitude of force necessary to return the leg to a proper starting position during gait. The applicant believes the NEURO SWING pre-compressed cup disc spring force unit is therapeutically distinct due to the capability to assist the leg and control the heel strike and return to a proper starting position in the fourth rocker of gait cycle. According to the applicant, other joint devices from competitors do not use pre-compressed springs (helical/coil or cup disc). This feature allows even severely impacted limbs to be moved back into the correct starting position in normal gait cycle.

CMS Preliminary HCPCS Coding Recommendation

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

1. Can you explain the difference from the NEURO SWING pre-compressed cup disc spring force unit within the ankle joint system current application and previous HCPCS Level II application 16.016?
2. What are the principal elements and functions of L2220 versus NEURO SWING pre-compressed cup disc spring force unit?
3. What is the therapeutic distinction of the NEURO SWING pre-compressed cup disc spring force unit compared to existing joints? Specifically, those described by L2220.
4. How does the NEURO SWING pre-compressed cup disc spring force unit anterior and posterior adjustment channel differ from L2220's anterior and posterior channels?

5. Do you think the NEURO SWING pre-compressed cup disc spring force unit's spring mechanism is a completely new product over the springs and pins included in the L2220 product notwithstanding the reported range of spring dynamics?

Summary of Public Feedback

FIOR & GENTZ, the manufacturer of this product, believes a new code is warranted for the NEURO SWING. According to the speaker, the NEURO SWING is capable of resisting forces and providing support when necessary to a greater degree than the more typical model of products that currently fall under existing L2220 code. The NEURO SWING allows for a more normal gait cycle and improved static balance. The speaker commented that the NEURO SWING holds up against repeated days of use, which provides the necessary resistance to a lack of musculature while allowing for a range of motion to walk, therefore greater physical activity, which in turn opens the door for greater health outcomes. The NEURO SWING Cup Disc Spring Force Unit has been designed to allow the system to apply adjustable levels of resistance sufficiently large enough to impact the movement of the limb in stance phase. Thus, by mimicking the normal action of the dorsi-flexor muscles, and the plantar-flexor muscles, the system allows normalization of stance kinematics. According to the speaker, most of the devices currently coded under L2220 utilize either a pin or a low-tension spring, however, the NEURO SWING Cup Disc Spring Force Unit consists of a convex disc supported at the outer periphery by one force and an opposing force on the center of the disc.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing the decision to assign:

Existing HCPCS Level II code L2220, "Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint" to describe the NEURO SWING System.

We reviewed the features of the NEURO SWING System, such as the alignable shank, independent chambers, and allowable range of motion and resistance. In addition, we were not able to distinguish a difference in the patient population between devices currently coded under existing code L2220 and the NEURO SWING System. There are other comparable products currently billed, or recommended to bill, L2220 that utilize independent chambers for dorsiflexion and plantar motion control. The NEURO SWING System Spring Disc Cup and NEURO SWING System Ankle Joint are an integral part to the device as a whole (the NEURO SWING System). For Medicare, the NEURO SWING System should bill existing L2220 code per joint.

Final Medicare Benefit Category Determination

Leg brace (Orthotic)

The information submitted by the applicant was reviewed extensively and supports the benefit category determination of the NEURO SWING System Spring Disc Cup (Application #HCP220705GH052) is integral to the NEURO SWING Ankle Foot Orthosis (AFO) which is a type of leg or lower extremity brace (Orthotic). The Medicare benefit for Leg brace (Orthotic) requires the item to be used to support a weak or deformed lower extremity. Also,

the NEURO SWING System Ankle Joint (Application #HCP220705UQPHF) is integral to Neuro Swing Ankle Foot Orthosis (AFO).

The application and comments support the NEURO SWING System Spring Disc Cup (Application #HCP220705GH052) and the NEURO SWING System Ankle Joint (Application #HCP220705UQPHF) falls under current Medicare policy and prior established Leg brace (Orthotic) benefit category determination for code L2220, “Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint”.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code L2220 apply to this product, if covered. Code L2220 adequately describes the Neuro Swing System Spring Disc Cup (Application #HCP220705GH052). NEURO SWING System Ankle Joint (Application #HCP220705UQPHF) and NEURO SWING System Spring Disc Cup (Application #HCP220705GH052) are considered one product and must be billed under one code L2220.

The current average 2023 fee schedule amount for L2220 is \$96.70 except for Alaska and Hawaii. For Alaska, the 2023 fee schedule amount is \$171.87. For Hawaii, the 2023 fee schedule amount is \$183.76. Fee schedules are updated annually.

Payment will be made on a lump sum purchase basis for any covered claims.

Pricing Indicator = 38

NEURO SWING, System Ankle Joint - HCP220705UQPHF

Topic/Issue

Request to establish a new HCPCS Level II code to identify a system ankle joint.

Applicant's suggested language: XXXXX, "Addition to lower extremity, custom dynamic ankle joint, independently adjustable shank angle (sagittal) alignable system, independently adjustable range of motion, independently and simultaneously adjustable control of resistance and assistance forces of plantar/dorsiflexion"

Applicant's Summary

FIOR & GENTZ submitted a request to establish a new HCPCS Level II code to identify a system ankle joint. According to the applicant, the NEURO SWING system ankle joint is an entirely new class of ankle joints that differ from the existing code L2220 (Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint). The applicant stated, the reason for developing this new class of ankle joints is because of the additional capabilities not previously available in Ankle Foot Orthosis (AFO)/Knee Ankle Foot Orthosis (KAFO). This class of joint is independently adjustable in shank angle alignment and in the dorsi/plantar assist/resist control. The adjustment of one parameter will not affect the adjustment of the other. According to the applicant, this is in contrast to the dual action L2220 joints which affect the other parameter when the orthotist makes a single separate adjustment. These joints interconnect with a spring system that offers an independent repeatedly adjustable range of motion control. This class of joint can simultaneously control both the dorsiflexion and plantarflexion. With an ankle joint that qualifies under L2220, the practitioner must choose between adjusting either dorsi- or plantarflexion, whereas with this new class, adjustments in dorsi- or plantarflexion can be selected independently. According to the applicant, this improved ankle joint is an advancement to the current level of care because it does not block the physiological movement of the joint as occurs with traditional L2220 ankle joints. This class of joint can be adjusted after the device has been fully fabricated whereas a traditional L2220 AFO can only be adjusted in the sagittal plane after finalization and adjustments in this way cause immediate loss of mobility. The applicant asserts, that this new class of joint offers a therapeutic distinction in that its infinite adjustability allows for the accommodation of progress or decline of each individual patient during their specific rehabilitation process.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code L2220, "Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint" describes the NEURO SWING System Ankle Joint.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code L2220 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code L2220 apply to this product, if covered. The current average fee schedule amount for L2220 is \$91.78.

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

Summary of Public Feedback

FIOR & GENTZ, the manufacturer of this product, disagreed with CMS' published preliminary determination. According to the speaker, the NEURO SWING is capable of resisting forces and providing support when necessary to a greater degree than the more typical model of products that currently fall under existing L2220 code. The speaker commented that traditional double action ankle joints affect the range of movement at the ankle when the pins or springs in the chambers' position is changed. For example, if a pin is placed in the posterior compartment of a traditional double action ankle joint and adjusted downwardly to stop the shank from moving posteriorly at mid-stance, in order to control hyperextension of the knee, it also blocks plantar-flexion of the ankle. According to the speaker, the NEURO SWING system ankle joint allows the clinician to adjust the resistance in the anterior or posterior channel of the ankle joint, without affecting the range of movement of the joint, and avoids any impact on the kinematics of stance. The speaker commented that this function is similar to prosthetic addition code L5910, "Addition, endoskeletal system, below knee, alignable system." The speaker commented that a traditional L2220 device is for controlling range of motion, and the NEURO SWING is for stability, range of motion, and the dynamic properties it offers to patients.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation assign:

Existing HCPCS Level II code L2220, "Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint" to describe the NEURO SWING System.

We reviewed the features of the NEURO SWING System, such as the alignable shank, independent chambers, and allowable range of motion and resistance. In addition, we were not able to distinguish a difference in the patient population between devices currently coded under existing code L2220 and the NEURO SWING System. There are other comparable products currently billed, or recommended to bill, L2220 that utilize independent chambers for dorsiflexion and plantar motion control. The NEURO SWING System Spring Disc Cup and NEURO SWING System Ankle Joint are an integral part to the device as a whole (the NEURO SWING System). For Medicare, the NEURO SWING System should bill existing L2220 code per joint.

Final Medicare Benefit Category Determination

Leg brace (Orthotic)

The information submitted by the applicant was reviewed extensively and supports the benefit category determination of the NEURO SWING System Ankle Joint (Application #HCP220705UQPHF) is integral to the NEURO SWING Ankle Foot Orthosis (AFO) which is a type of leg or lower extremity brace (Orthotic). The Medicare benefit for Leg brace (Orthotic) requires the item to be used to support a weak or deformed lower extremity.

The application and comments support the NEURO SWING System Spring Disc Cup (Application #HCP220705GH052) and the NEURO SWING System Ankle Joint (Application #HCP220705UQPHF) falls under current Medicare policy and prior established Leg brace (Orthotic) benefit category determination for code L2220, "Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint".

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code L2220 apply to this product, if covered. Code L2220 adequately describes the NEURO SWING System Ankle Joint (Application #HCP220705UQPHF). NEURO SWING System Ankle Joint (Application #HCP220705UQPHF) and NEURO SWING System Spring Disc Cup (Application #HCP220705GH052) are considered one product and must be billed under one code L2220.

The current average 2023 fee schedule amount for L2220 is \$96.70 except for Alaska and Hawaii. For Alaska, the 2023 fee schedule amount is \$171.87. For Hawaii, the 2023 fee schedule amount is \$183.76. Fee schedules are updated annually.

Payment will be made on a lump sum purchase basis for any covered claims.

Pricing Indicator = 38

ULTepap™ - HCP220628D8N92

Topic/Issue

Request to establish a new HCPCS Level II code to identify ULTepap™.

Applicant's suggested language: XXXXX, "EPAP device, reusable, capable of use with multiple size nasal pillows"

Applicant's Summary

BRYGGS Medical, LLC submitted a request to establish a new HCPCS Level II code to identify ULTepap™ System. It is a single-patient, reusable Expiratory Positive Airway Pressure (EPAP) device for the treatment of mild to moderate obstructive sleep apnea marketed as ULTepap™. The ULTepap™ System received the Food and Drug Administration's (FDA's) 510(k) clearance on January 24, 2020. The device is comprised of a pair of bi-resistance cartridges which are designed and warranted for a 3-year expected service life. The ULTepap™ System includes a headgear and appropriate size nasal pillow for the patient. These accessory items are similar in design and performance to currently available products. As such, the applicant requests the following existing codes to be assigned for billing replacement accessories when needed: A7033, "Pillow for use on nasal cannula type interface, replacement only, pair" and A7035, "Headgear used with positive airway pressure device."

CMS Preliminary HCPCS Coding Recommendation

This application for the ULTepap™ System is a subsequent application to application number 21.056. Information in this application adequately demonstrates that changes have been made to extend the lifetime of the ULTepap™ device. As such, CMS will establish a new HCPCS Level II code AXXXX, "Expiratory positive airway pressure intranasal resistance valve" to describe the ULTepap™ System. Existing code A9270, "Non-covered item or service" is available for billing replacement accessories to the Medicare program such as nasal pillows and headgear.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment furnished by a supplier or a home health agency that meets the five conditions listed in the below table. All five of these conditions must be met in order for equipment to be classified as DME. As explained in the below table, the ULTepap™ expiratory positive airway pressure intranasal resistance valve does not meet all five conditions, and therefore would not fall under a DMEPOS benefit category.

In addition, the pillow and headgear are accessories for the ULTepap™ expiratory positive airway pressure intranasal resistance valve. The ULTepap™ expiratory positive airway pressure intranasal resistance valve does not fall under the DME benefit category and thus the pillow and headgear accessories also do not fall under the DME benefit category. For coding

guidance for other payors, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed.

Condition Met?	Conditions that Must be Met for Equipment to be Classified as DME
No	1. Can withstand repeated use. DME is a benefit for rental of equipment for use in the home and therefore DME items must be able to withstand repeated use by successive patients in accordance with Medicare regulations and as indicated in Medicare program instructions at chapter 15, section 110.1 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) and chapter 1, part 4, section 280.1 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03). The ULTepap™ expiratory positive airway pressure intranasal resistance valve is intended for single patient use and therefore cannot withstand repeated use.
Yes	2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
Yes	3. Is primarily and customarily used to serve a medical purpose.
Yes	4. Generally, is not useful to an individual in the absence of an illness or injury.
Yes	5. Is appropriate for use in the home.

Preliminary Medicare Payment Determination

No Medicare Payment. Pricing Indicator = 00

Summary of Public Feedback

Bryggs Medical, LLC, the manufacturer of the device, appreciated that CMS recognized the uniqueness of ULTepap™ to the extent it would require its own HCPCS Level II code, yet disagree with the preliminary benefit category determination, and the type of HCPCS Level II codes proposed for the device and supplies. The speaker disagreed with the preliminary benefit category determination that the ULTepap™ could not withstand repeated use. The speaker cited the Medicare Benefit Policy Manual, chapter 15 stating, “the type of item that could normally be rented” is merely an example of a type of item that is considered durable not a regulatory requirement for durable medical equipment. The speaker stated that they had tested the ULTepap™ and it can withstand repeated use. In addition, the speaker suggested that CMS makes the new code to be an E code using the same code description proposed in the preliminary determination versus an A code. According to the speaker, existing PAP coverage and payment categories should include EPAP devices, and respectfully request the ULTepap™ System be included in the PAP Local Coverage Determinations (LCDs). The speaker also requested the use of accessory codes A7033, “Pillow for use on nasal cannula type interface, replacement only, pair” and A7035, “Headgear used with positive airway pressure device.” Also, the speaker suggested a revision to the accessories long descriptor code language that denotes positive airway pressure because these supplies can be used on a variety of devices.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to:

Establish a new HCPCS Level II code A7049, "Expiratory positive airway pressure intranasal resistance valve" to describe the ULTepap™ System. Also, existing code A9270, "Non-covered item or service" is available for billing replacement accessories to the Medicare program, such as nasal pillows and headgear.

Existing HCPCS Level II codes A7033, "Pillow for use on nasal cannula type interface, replacement only, pair" and A7035, "Headgear used with positive airway pressure device" are available for assignment by insurers if they deem appropriate.

As related to the new request for the revision of other existing codes, CMS would require a new HCPCS Level II application in an upcoming cycle.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Medicare regulations at 42 CFR 414.202 set forth the conditions the item must meet in order to qualify for the DME benefit including the condition that the item can withstand repeated use which means the item must be able to be rented and used by successive patients. The regulation is in accordance with Section 1861(s)(6) of the Social Security Act which sets forth the DME benefit including rental of durable medical equipment although purchase of DME items is allowed in limited situations such as section 1834(a)(4) of the Social Security Act for custom DME. Therefore, we do not agree with the comments that Medicare states "the type of item that could normally be rented" is merely an example of a type of item that is considered durable but not a requirement for durable medical equipment. Our review does not find the ULTepap™ meets the condition for repeated use.

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing Indicator = 00

Canvas Dx - HCP220705YK09X

Topic/Issue

Request to establish a new HCPCS Level II code to identify Canvas Dx.

Applicant's suggested language: AXXXX, "Prescription digital diagnostic device for neurodevelopmental/behavioral disorders, FDA authorized, per diagnostic assessment"

Applicant's Summary

Cognoa, Inc. submitted a request to establish a new HCPCS Level II code to identify Canvas Dx. Canvas Dx received the Food and Drug Administration's (FDA's) De Novo classification on June 2, 2021. Canvas Dx is a prescription-only digital diagnostic product that aids healthcare professionals in diagnosing or ruling out Autism Spectrum Disorder (ASD) in children aged 18 months through 72 months. According to the applicant, existing HCPCS Level II code A9291 does not adequately describe Canvas Dx because Canvas Dx is a prescription-only diagnostic. The applicant believes a unique HCPCS Level II code to describe Canvas Dx is necessary because most payors have pushed Canvas Dx to be adjudicated under the medical benefit given that any observed healthcare cost offsets for ASD resulting from earlier diagnosis of ASD are typically observed under the medical benefit. Digital diagnostic devices have a different and unique use and cost profile that warrants different coding from therapeutics. Whereas therapeutics are typically prescribed for the ongoing or episodic treatment of chronic conditions, diagnostic digital devices like Canvas Dx are ordered at a singular point in time to aid a health care provider in assessing the presence or absence of a condition. For both private and public payors, the ability to accurately monitor the cost of, and evaluate holistically, each of the two distinct categories of emerging digital solutions will be of critical importance as the digital health field expands exponentially in the coming years. Assessing the cost of a "one and done" digital diagnostic device compared to ongoing spend for digital therapeutics would be extremely challenging under a single digital therapeutic umbrella code. Cognoa, Inc.'s Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of Autism Spectrum Disorder for patients aged 18 months through 72 months who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare provider. This device is not intended as a stand-alone diagnostic, but as an adjunct to the diagnostic process.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the Canvas Dx 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. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

Summary of Public Feedback

Cognoa, Inc., the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, the emphasis should be highlighting the similarities between Cognoa Inc.'s request at issue here, and CMS's decision on a similar

request in the December 2021 HCPCS Public Meeting establishing HCPCS Level II code A9291. There, CMS ultimately recognized that a prescription digital therapeutic is dispensed to a patient directly by a specialty pharmacy, and that specialty pharmacies do not use CPT® codes to bill payers for technologies covered under the patient's medical benefit. Likewise, Canvas Dx is dispensed directly to a patient by a specialty pharmacy for use in the home. According to the speaker, the lack of a HCPCS code to describe a prescription digital diagnostic limits payers' ability to cover and process claims for Canvas Dx. The speaker emphasized that Canvas Dx is unlike other diagnostic tools that has been considered previously under CPT® codes. For instance, an artificial intelligence (AI) technology that diagnoses diabetic retinopathy and is described by CPT® code 92229 is used in the office. In contrast, Canvas Dx is self-administered by the caregiver/patient in their home wholly separate from a clinical encounter, and the physician does not incur a cost for use of the technology that they would separately bill for under a CPT® code. According to the speaker, the use case of Canvas Dx is clearly distinguishable from other diagnostic tools described by CPT® codes, which explains why payers are exploring separately paying for Canvas Dx under the medical benefit, and thus the need to provide a unique HCPCS code for Canvas Dx to allow non-Medicare payers the flexibility to determine appropriate coverage and payment for these novel and innovative technologies. Another speaker commented that, to date, they have been unable to submit and process medical claims for Canvas Dx. The speaker claimed that payers include Anthem, United Healthcare, Centene, Molina, Magellan, CVS, Express Scripts, and many others. According to the speaker, these payers have indicated that they cannot cover claims for Canvas Dx using HCPCS codes A9999 or E1399. The speaker commented that the availability of an appropriate HCPCS Level II code that describes FDA-cleared digital diagnostic and therapeutic devices will advance the development of appropriate medical policies and reimbursement.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. We continue to believe the Canvas Dx is not suitable for inclusion in the HCPCS Level II code set because it is used in or for a procedure and certain items are considered bundled into the facility payment. Even though the device is used in the home, it is a diagnostic tool used in conjunction with other diagnostic processes. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer would pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure/professional service, if it is used, and as such it would not be separately payable.

OxyBand™ Wound Dressing Matrix - HCP22070507T93

Topic/Issue

Request to establish a new HCPCS Level II code to identify Oxyband™ Wound Dressing Matrix.

The applicant did not submit any suggested language.

Applicant's Summary

Oxyband™ submitted a request to establish a new HCPCS Level II code to identify Oxyband™ Wound Dressing Matrix. Oxyband™ received the Food and Drug Administration's (FDA's) 510(k) clearance on March 24, 2005. Oxyband™ is a multi-layer wound dressing matrix that provides a moist oxygen rich environment to protect, maintain, and facilitate the wound healing process including supporting cellular repair and regeneration. Its advanced matrix technology provides transdermal delivery of 100% oxygen to both acute wounds and chronic ulcers and delivers oxygen continuously via sustained release over an extended period of time directly from the proprietary reservoir as long as the Oxyband™ Wound Dressing Matrix cover remains intact and secure around the perimeter frame. OxyBand™ Wound Dressing Matrix is designed to provide a framed structure with a cover and border to keep out contaminants that compromise healing and cause infection. The number of days between Oxyband™ Wound Dressing Matrix changes depends upon the size and metabolic characteristics of the wound, and can be applied as either a primary, or secondary therapeutic utilized with skin grafts or other advanced technologies and dressings (alginate, foam, collagen, hydro fiber, hydrocolloid, etc.) Provided in a pouch as a single use sterile device, Oxyband™ Wound Dressing Matrix is FDA cleared to cover and protect wounds and catheter sites or used as a secondary dressing for other wounds such as gauze, alginates, hydrogels, debridement facilitators, or a protective cover over at-risk skin. The Oxyband™ Wound Dressing Matrix is indicated for: clean closed surgical incisions, skin graft donor sites, Stage 1 and II pressure ulcers, pressure sores, superficial wounds such as abrasions, skin tears, and blisters, lacerations, first- and second-degree burns, chafed skin, skin continuously exposed to moisture, secondary dressing over gauzes, alginates and hydrogels.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A6204, "Composite dressing, sterile, pad size more than 16 sq. in. but less than or equal to 48 sq. in., with any size adhesive border, each dressing" describes Oxyband™ Wound Dressing Matrix.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A6204 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A6204 apply to this product, if covered. The current average fee schedule amount for A6204 is \$7.68.

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 = 35

Summary of Public Feedback

OxyBand Technologies, Inc., the manufacturer of this product, disagreed with CMS' published preliminary recommendation that existing HCPCS Level II code A6204 describes Oxyband™ Wound Dressing Matrix. According to the commenter, OxyBand™ has been used by providers successfully to heal difficult, non-healing wounds; however, without a reimbursement code that adequately pays for the device, the company cannot manufacture and sell OxyBand™. Oxyband™ Wound Dressing Matrix requires more layers than a traditional composite dressing including a specialized oxygen delivery fibrous layer. Therefore, while some of the components seem similar to a composite dressing such as a barrier film, the barrier film in OxyBand™ is intended to keep oxygen in the proprietary fibrous matrix reservoir to directionally provide the oxygen to the wound and to protect the wound. In contrast, composite dressings are designed with a barrier layer only to protect the wound from outside contamination. According to the comments, this design of matrixed materials and the complex manufacturing and packaging was developed over many years and the company cannot even manufacture an OxyBand™ for the reimbursement stated in the CMS recommendation for a composite dressing. There have been published studies conducted by independent clinicians related to OxyBand™ that demonstrate healing of non-healing, chronic wounds, and regeneration of tissue. The commenter stated that in 2021 CMS determined a new category wound matrix (Equine, Placental, Synthetic) and several unclassified devices were provided with codes. Therefore, the commenters request that OxyBand™ should be classified and reimbursed as a wound matrix (Equine, Placental, Synthetic).

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A6204, "Composite dressing, sterile, pad size more than 16 sq. in. but less than or equal to 48 sq. in., with any size adhesive border, each dressing" to describe Oxyband™ Wound Dressing Matrix.

The new codes that CMS previously created related to Equine, Placental, and Synthetic, as mentioned by the applicant, are skin substitute related products. Oxyband™ is a wound dressing matrix and not a skin substitute.

According to the FDA 510(k) notification letter, OxyBand™ Wound Dressings is substantially equivalent to Tegaderm Transparent dressing, of which is currently coded under A6204. However, based on the HCPCS Level II application, "the proprietary reservoir and multiple layer matrix design are unique in that they provide both a matrix for wound repair cellular regeneration and the only transdermal oxygenated matrix wound device that has been

shown to accelerate healing, reduce pain and reduce infection.” Also, the primary speaker stated that the studies submitted within the application demonstrate OxyBand's™ capability to heal non-healing, chronic wounds, and regeneration of tissue and has shown to heal failed and infected hip replacements in patients with multiple comorbidities. This information related to healing of non-healing wounds, provided to CMS, differs from the FDA 510(k) indications.

Based on the information provided by the applicant, CMS believes that the next appropriate step for the applicant would be to approach the FDA to discuss the information presented to CMS in the HCPCS Level II application and during the public meeting, including unique characteristics (e.g., healing of non-healing wounds) and studies that in applicant’s view show OxyBand’s™ superiority, and to inquire on the most appropriate classification of OxyBand™ Wound Dressing.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A6204 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A6204 apply to this product, if covered. The current average fee schedule amount for A6204 is \$8.34.

The average fee schedule amount is the average of the 2023 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 = 35

CloudCath Peritoneal Dialysis Drain Set Monitoring System - HCP220701PTF4P

Topic/Issue

Request to establish a new HCPCS Level II code to identify CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System).

Applicant's suggested language: XXXXX, "Peritoneal dialysate effluent turbidity monitoring system, including sensor, drain set, computer algorithm/software and user interface that processes, communicates and transmits the information, and all required supplies"

Applicant's Summary

Hull Associates LLC submitted a request to establish a new HCPCS Level II code to identify CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System). The CloudCath System received the Food and Drug Administration's (FDA's) 510(k) clearance on February 9, 2022. The CloudCath System is a complete peritoneal dialysate effluent turbidity monitoring system, inclusive of all required supplies and equipment. The CloudCath System is a tabletop passive drainage system used as an attachment during a peritoneal dialysis treatment and indicated for use by patients with acute and chronic end-stage renal disease (ESRD) undergoing peritoneal dialysis. The system contains an optical sensor that measures turbidity, reported as a turbidity score, of patient's peritoneal dialysate effluent as a supplement to visual examination of cloudiness in the dialysate drain line. According to the applicant, there is no existing HCPCS Level II code describing a peritoneal dialysate effluent turbidity monitoring system.

CMS Preliminary HCPCS Coding Recommendation

After consideration of all the public comments received for the Calendar Year 2023 ESRD Prospective Payment System Proposed Rule (87 FR 38505), CMS has determined that the evidence and public comments submitted are not sufficient to demonstrate that the CloudCath System meets all eligibility criteria to qualify for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). As a result, the CloudCath System will not be paid for under TPNIES per § 413.236(d). Therefore, we are denying this applicant's request to establish a new HCPCS Level II code for the CloudCath System.

Summary of Public Feedback

We received written comment from the applicant in agreement with CMS' published preliminary determination.

CMS Final HCPCS Coding Decision

We appreciate the comment provided in response to CMS' published preliminary recommendation. After consideration of the Calendar Year 2023 ESRD Prospective Payment System Final Rule (87 FR 67136) determination that CloudCath System will not be paid for using the TPNIES per § 413.236(d) and the comment we received, CMS is finalizing its preliminary recommendation. As a result, CMS is denying this applicant's request to establish a new HCPCS Level II code for the CloudCath System.

Theranova 400/500 - HCP2207048YCGW

Topic/Issue

Request to establish a new HCPCS Level II code to identify Theranova 400/500.

Applicant's suggested language: AXXXX, "Dialyzer (artificial kidneys), Theranova, for expanded hemodialysis, each"

Applicant's Summary

Baxter Healthcare submitted a request to establish a new HCPCS Level II code to identify Theranova 400/500 (Theranova). The applicant believes, in the absence of a new code, end-stage renal disease (ESRD) hemodialysis providers will use HCPCS Level II code A4690, "Dialyzer (artificial kidneys), all types, all sizes, for hemodialysis, each." According to the applicant, this code does not adequately describe Theranova. Theranova is an innovative dialyzer intended to treat renal failure by Expanded Hemodialysis (HDx). It features a unique 3-layer membrane structure that offers a higher permeability than regular high-flux dialyzers, with improved removal of large middle molecules while selectively maintaining essential proteins such as albumin. Theranova has the potential to transform in-center hemodialysis by allowing patients, including Medicare beneficiaries, with renal failure to benefit from HDx, the process of blood purification that includes the clearance of small and large middle molecular uremic toxins with existing hemodialysis infrastructure without the need for external infusion of replacement fluid. According to the applicant, a new code is needed to differentiate Theranova from other dialyzers. Baxter Healthcare has submitted a Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) application for Theranova as well. A product-specific HCPCS Level II code is a requirement for the TPNIES program. The Food and Drug Administration (FDA) authorized Theranova under the de novo pathway on August 28, 2020.

CMS Preliminary HCPCS Coding Recommendation

After consideration of all the public comments received for Calendar Year 2023 ESRD Prospective Payment System Proposed Rule (87 FR 38505), CMS has determined that the evidence and public comments submitted are not sufficient to demonstrate that Theranova meets all eligibility criteria to qualify for the TPNIES. As a result, Theranova will not be paid for under TPNIES per § 413.236(d). Therefore, we are denying this applicant's request to establish a new HCPCS Level II code for Theranova.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

After consideration of the Calendar Year 2023 ESRD Prospective Payment System Final Rule (87 FR 67136) determination that Theranova will not be paid for using the TPNIES per § 413.236(d) and considering that no comments were received, CMS is finalizing its

preliminary recommendation. As a result, CMS is denying this applicant's request to establish a new HCPCS Level II code for the Theranova.

SunWrap™ System Dialysis Access Guard - HCP220131BGMBQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify SunWrap™ System Dialysis Access Guard.

Applicant's suggested language: XXXXX, “Reusable Compression wrap for post-dialysis bleeding control consisting of Patient enabled velcro-secured application, custom compression control with transparent inflatable bolster window to enable visualization of dialysis needle sites”

Applicant’s Summary

Sun Scientific submitted a request to establish a new HCPCS Level II code to identify SunWrap™ System Dialysis Access Guard. The SunWrap™ System is a single-patient reusable compression wrap with a transparent window that incorporates compression directly over the wound sites while simultaneously allowing visibility of potential bleeding following hemodialysis via arm access (fistula or graft). The SunWrap™ System Dialysis Access Guard is class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. The SunWrap™ System is secured by Velcro which accommodates variability of arm circumference. It also incorporates patient controlled adjustable static compression across the transparent window, providing consistent pressure to needle sites post-dialysis, while offering visibility of the wound sites through the transparent static compression window, allowing real time visualization and ability to manage any bleeding. This design enables more consistent and autonomous application of wrap and compression to reduce the need for additional personnel and manual compression immediately following hemodialysis. According to applicant, existing codes do not adequately describe the product and specific service because they are supply codes designed to cover the cost of disposable single patient use supplies that are used and disposed of per hemodialysis event. The SunWrap™ System is a reusable compression wrap that is warrantied for 6 months of normal use, and as a result, is not a typical supply covered under current coding.

CMS Preliminary HCPCS Coding Recommendation

After consideration of all the public comments received for the Calendar Year 2023 ESRD Prospective Payment System Proposed Rule (87 FR 38505), CMS has determined that the evidence and public comments submitted are not sufficient to demonstrate that the SunWrap™ System meets all eligibility criteria to qualify for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). As a result, the SunWrap™ System will not be paid for under TPNIES per § 413.236(d). Therefore, we are denying this applicant’s request to establish a new HCPCS Level II code.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

After consideration of the Calendar Year 2023 ESRD Prospective Payment System Final Rule (87 FR 67136) determination that SunWrap™ System will not be paid for using the TPNIES per § 413.236(d) and considering that no comments were received, CMS is finalizing its preliminary recommendation. As a result, CMS is denying this applicant's request to establish a new HCPCS Level II code for the SunWrap™ System.

AMMA - HCP220704AAQ4D

Topic/Issue

Request to establish a new HCPCS Level II code to identify AMMA Portable Scalp Cooling System.

Applicant's suggested language: XXXXX, "Portable scalp coolant generator for therapeutic temperature and duration to reduce chemotherapy-induced alopecia synchronized with single-patient use responding head worn cooling cap for uniform consistent scalp cooling therapy"

Applicant's Summary

Cooler Heads submitted a request to establish a new HCPCS Level II code to identify Portable Scalp Cooling System (PSCS). The PSCS is a wearable device having two device components. The portable coolant generating system cooling unit is synchronized with the one patient use Cooling Cap custom fitted to the patient's scalp to maintain 64.4°F cooling. The PSCS is used by adult patients 21 years of age and older, undergoing chemotherapy treatment (CT) for solid tumor cancer who want to avoid chemotherapy-induced hair loss, or alopecia (CIA). PSCS received the Food and Drug Administration's (FDA's) 510(k) clearance on October 21, 2021. The FDA's indication for use states, "PSCS is used to reduce the likelihood of CIA in adult cancer patients with solid tumors and is compliant with 21 CFR 878.4360." Scalp cooling prevents CIA in 53-66.3% of patients. According to the applicant, the novel materials of the Cooling Cap allow it to be custom molded to adequately cover each patient's unique scalp contours. The materials and wrap method are unique to AMMA and necessary to deliver uniformly dispersed cooling to prevent patchy hair loss. Once the Cooling Wrap has been well molded to the patient's scalp, the Compression Cap is securely fitted to the patient's head, constituting the AMMA head cooling device or the Cooling Cap. The temperature sensors in the Portable Cooling Unit are synchronized to monitor and adjust cooling to maintain a consistent controlled delivery of therapeutic cooling for the duration of the prescribed therapy. The PSCS is intended to lower the scalp temperature to an average of 64.4°F (18°C), reducing blood flow to the hair follicles which may protect them from the effect of chemotherapy drugs, preserve existing hair, and safeguard new growth. The circulation of the refrigerated coolant through the cap extracts heat from the patient's scalp. The PSCS is a prescription only device and therefore can only be used if prescribed by a healthcare provider. Treatment with the PSCS is administered by the user, their caregiver, or assisted by a nurse in a healthcare treatment center, for use in a home setting, and during transit to home from the treatment center. The AMMA PSCS is taken by the patient to the CT infusion center where clinical staff may assist the patient with final set up, supplies for the coolant generator. AMMA is started 30 minutes before CT infusion, used during the infusion, and continued for 2 hours thereafter in the patient's residence, work, or at another location outside of the infusion center. The Portable Cooling Unit monitors and maintains the therapeutic temperature of 64.4°F for the duration of the device's use. The PSCS is delivered to the patient by either the infusion center at the start of the patients CT, or the PSCS may be delivered to the patient's house. The PSCS and its accessories are packaged in a custom constructed transport case.

CMS Preliminary HCPCS Coding Recommendation

The AMMA Portable Scalp Cooling System is not suitable for coding in HCPCS Level II because this product, if covered, would be expected to be included within the payment for the professional service.

Summary of Public Feedback

The applicant commented that they are taking our published preliminary determination into consideration. The applicant stated after analysis of the utilization of AMMA and payer recognition of reimbursement for the place of service intended for AMMA, they will return to the HCPCS review team to present further evidence of AMMA portable home use and need for a unique HCPCS code to allow patients to complete their chemotherapy outside of the healthcare setting.

CMS Final HCPCS Coding Decision

Based on the information provided in the application and after consideration of the comment we received that further evidence will be submitted, CMS understands that the manufacturer may return with additional information and thus CMS will take additional time to consider Cooler Heads' request to establish a new HCPCS Level II code to identify AMMA Portable Scalp Cooling System. As a result, CMS is deferring this application to a subsequent coding cycle.

AMMA - HCP220704P7W3Y

Topic/Issue

Request to establish a new HCPCS Level II code to identify AMMA, Cooling Cap.

Applicant's suggested language: XXXXX, "Single-patient use head worn cooling cap receiving unit, for the Cooling Unit to deliver portable uniform consistent scalp cooling therapy"

Applicant's Summary

Cooler Heads submitted a request to establish a new HCPCS Level II code to identify Cooling Cap used with the Portable Scalp Cooling System (PSCS). The Cooling Cap is for the single-patient use and worn on the head. According to the applicant, the durable portable coolant generating system, Cooling Unit, is synchronized with the single-patient use Cooling Cap custom fitted to the patient's scalp to maintain 64.4°F. AMMA is used by adult patients 21 years of age and older, undergoing chemotherapy treatment (CT) for solid tumor cancer who want to avoid chemotherapy-induced hair loss, or alopecia (CIA). PSCS received the Food and Drug Administration's (FDA's) 510(k) clearance on October 21, 2021. The FDA's indication for use states PSCS is used to reduce the likelihood of CIA in adult cancer patients with solid tumors and is compliant with 21 CFR 878.4360. Scalp cooling prevents CIA in 53-66.3% of patients. According to the applicant, the Cooling Cap's novel materials allow it to be custom molded to adequately cover each patient's unique scalp contours. According to the applicant, the materials and wrap method used to construct this AMMA device are unique to AMMA and necessary to deliver uniformly dispersed cooling to prevent patchy hair loss. Once the Cooling Wrap has been well molded to the patient's scalp, the Compression Cap is securely fitted to the patient's head, constituting the AMMA head cooling device or the Cooling Cap. The temperature sensors in the portable Cooling Unit are synchronized to monitor and adjust cooling to maintain a consistent controlled delivery of therapeutic cooling for the duration of the prescribed therapy. The PSCS is intended to lower the scalp temperature to an average of 64.4°F (18°C), reducing blood flow to the hair follicles which may protect them from the effect of chemotherapy drugs, preserve existing hair, and safeguard new growth. The circulation of the refrigerated coolant through the cap extracts heat from the patient's scalp. The PSCS is by prescription only and therefore can only be used if prescribed by a healthcare provider. Placement of the Cooling Cap, necessary for use with the PSCS, is done by the user, their caregiver, or assisted by a nurse in a healthcare treatment center, for later use in a home setting, and during transit to home from the treatment center. The AMMA Cooling Cap is taken by the patient to the CT infusion center where clinical staff may assist the patient with the final set up and supplies for the coolant generator. AMMA is started 30 minutes before CT infusion, used during the infusion, and continued for 2 hours thereafter at the patient's residence, work, or at another location outside of the infusion center. The Portable Cooling Unit monitors temperature to maintain scalp cooling at 64.4° F for the duration of the PSCS device use. The PSCS is delivered to the patient by either the infusion center at the start of the patients CT, or more often the PSCS is delivered to the patient's house. The Cooling Cap and accessories are packaged in a custom constructed transport case.

CMS Preliminary HCPCS Coding Recommendation

The AMMA Cooling Cap is not suitable for coding in HCPCS Level II because this product, if covered, would be expected to be included within the payment for the professional service.

Summary of Public Feedback

The applicant commented that they are taking our published preliminary determination into consideration. The applicant stated after analysis of the utilization of AMMA and payer recognition of reimbursement for the place of service intended for AMMA, they will return to the HCPCS review team to present further evidence of AMMA portable home use and need for a unique HCPCS code to allow patients to complete their chemotherapy outside of the healthcare setting.

CMS Final HCPCS Coding Decision

Based on the information provided in the application and after consideration of the comment we received that further evidence will be submitted, CMS understands that the manufacturer may return with additional information and thus CMS will take additional time to consider Cooler Heads' request to establish a new HCPCS Level II code to identify AMMA Portable Scalp Cooling System. As a result, CMS is deferring this application to a subsequent coding cycle.

FOOTBAR® Walker - HCP220704VX6MB

Topic/Issue

Request to establish a new HCPCS Level II code to identify FOOTBAR® Walker.

Applicant's suggested language: XXXXX, "Sit-to-stand transfer walker, folding, adjustable or fixed height, with or without wheels"

Applicant's Summary

GANM, LLC submitted a request to establish a new HCPCS Level II code to identify FOOTBAR® Walker. The FOOTBAR® Walker is class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. This patented walker features a pull bar designed to improve, retrain or regain sit-to-stand (STS) transfer function often lost due to: temporary injury, surgery (hip/knee replacement), chronic medical conditions or disease progression that may be physical or neurological in nature. The FOOTBAR® Walker functions as an assistive device when sit-to-stand movement (an important and proven medically necessary basic skill) is impaired preventing mobility and/or activities of daily living. According to the applicant, there are no current codes that adequately describe the FOOTBAR® Walker and its therapeutic function. Walkers as a whole describe ambulation mobility function only (if a person cannot stand, they cannot use a walker). A walker by definition cannot meet this functional need that enables a person to safely move from a seated position to a standing position. Lifts are used for individuals who are not able to perform sit to stand for themselves or ambulate and are authorized if a patient meets the specific criteria. According to the applicant, if a lift is approved, per CMS Local Coverage Determination (LCD), other MAE such as canes, walkers, wheelchairs, crutches, etc. are no longer approved in conjunction with an approved lift. The applicant stated that the HCPCS codes for lifts also do not accurately describe the STS function and are limited in their description to very specific conditions. The applicant asserted, a lift is approved by CMS if the patient is "bed confined" or requires "supine positioning for transfers" When a lift is approved for a patient, it removes CMS coverage for any other mobility assist equipment (MAE) such as canes, walkers, wheelchairs, etc. due to a patient's defined medical condition and in most cases inability to ambulate. Patients of the FOOTBAR® Walker are mobile and able to ambulate. The applicant has applied for inclusion of current HCPCS codes on the original accessory design. After a recent appeal, the applicant was awarded under DCN# 22136003000010 codes E0143+A9900 and A9999 on June 16, 2022. According to the applicant, these are miscellaneous accessory codes that apply to the original model. Accessories were added and permanently affixed to an existing walker of another manufacturer. According to the applicant, these do not accurately align with the new 1-unit model and its fully integrated design all manufactured in line at the factory. Over the past 4 years, the applicant claims to have proven the original model's concept, function and market acceptance through both public and medical professional approval.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E0143, "Walker, folding, wheeled, adjustable or fixed height" describes the FOOTBAR®. Wheeled walkers are typically furnished with brakes since they have wheels. The types of brakes included with the walker is not specified in the code

descriptor and therefore folding wheeled walkers with any type of brakes are described by code E0143.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment

The current Medicare policy and prior established benefit category determination for code E0143 applies to the design of the FOOTBAR® Walker.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0143 apply to the FOOTBAR® Walker, if covered. The current average fee schedule amount for E0143 is \$78.69.

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 = 32

Summary of Public Feedback

GANM, LLC, the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, the FOOTBAR® Walker offers features and benefits unlike a standard walker and requires a new HCPCS code in either a new transfer category or with a differentiated walker title, such as sit-to-stand. The FOOTBAR® Walker is not for all patients that require a walker to ambulate, the pull bar and foot bar are designed to assist to transfer. Thus, the speaker stated that utilizing the E0143 code is not sufficient due to billing and cost purposes. According to the speaker, the FOOTBAR® Walker is not a walker with a braking system as there is no pressure applied to the wheels when the foot bar is engaged, instead the foot bar's function is as a counter-balancing stabilizer. When deployed, along with the necessary applied force from the caregiver, the patient can safely pull themselves up to standing. According to the speaker, without its own code, DME suppliers refuse to carry the FOOTBAR® Walker due to coverage limitations of one walker every five years. The speaker commented that the manufacturing and storage costs are much higher than the current average fee schedule for this code, and it puts the manufacturer and CMS at risk for liability. Another speaker stated that the FOOTBAR® Walker is best suited for patients that cannot accomplish a normal sit-to-stand on their own and yet are able to take steps with a walker once they are up. Commenters requested that CMS assign a new HCPCS code to align with the cost of the FOOTBAR® Walker to permit the patient to remain at home with the assistance of a caregiver and reduce the physical and financial burden on the healthcare system and its caregivers.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after

consideration of the comments we received, CMS is revising its preliminary recommendation. Instead CMS will assign:

Existing HCPCS Level II code E0143, "Walker, folding, wheeled, adjustable or fixed height" to describe the FOOTBAR® Walker.

The foot bar on the FOOTBAR® Walker is a counter-balancing stabilizer and not a brake. A caregiver is necessary for the foot bar to be engaged. Technically, a caregiver can hold down the top of a walker to counter-balance the stabilization, similar to the function of the FOOTBAR® Walker. If a patient does not have the necessary muscle strength to pull themselves up, other measures still would have to be used by the caregiver to help the patient stand, similar to those walkers within E0143. The foot bar is a feature of the FOOTBAR® Walker. During ambulation, the FOOTBAR® Walker functions the same way as other walkers within E0143.

Final Medicare Benefit Category Determination

Durable Medical Equipment

The current Medicare policy and prior established benefit category determination for code E0143 applies to the design of the FOOTBAR® Walker.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code E0143 apply to the FOOTBAR® Walker, if covered. The current average fee schedule amount for E0143 is \$85.67.

The average fee schedule amount is the average of the 2023 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 = 32

geko™ T-3 and geko™ W-3 - HCP22063010MT6

Topic/Issue

Request to establish a new HCPCS Level II code to identify geko™ T-3 and geko™ W-3.

Applicant's suggested language: XXXXX, "Low frequency (1 Hz) wearable neuromuscular electro-stimulation (NMES) device to increase local blood circulation, reduce, edema, and prevent venous thrombosis"

Applicant's Summary

Firstkind Ltd. submitted a request to establish a new HCPCS Level II code to identify geko™ T-3 and geko™ W-3. The geko™ devices with OnPulse™ technology are a low-frequency (1 Hz) neuromuscular electro-stimulation (NMES) devices that stimulate the common peroneal nerve activating the calf and foot muscle pumps, resulting in isometric muscle contraction and increased blood flow. The geko™ device stimulates the motor neurons within the nerve bundle that carry signals to the muscle fibers to cause contraction. Stimulating the common peroneal nerve activates the tibialis, peroneus longus and lateral gastrocnemius muscles. Together, their simultaneous contraction compresses the venous system, efficiently evacuating blood in the deep veins of the calf at a rate equal to 60% of walking. The device is worn just below the knee on one or both legs and is available in two versions; geko™ T-3 and geko™ W-3, which can deliver NMES for up to 24 hours per day. The lightweight battery-operated device has integrated electronics composed of a constant pulse generator with embedded software and a lithium-ion battery enclosed in a molded plastic casing, and embedded electrodes that deliver stimulation via an adhesive surface. The devices deliver multiple stimulation levels that increase the electrical charge, muscle contractions are achieved. The settings address the variation in responsiveness of patients to stimulation due to individual specifics. Two buttons control the on/off function and intensity levels of the device output. According to the applicant, there are no HCPCS codes to describe a wearable NMES device that delivers low-frequency stimulation to increase blood circulation, reduce edema, prevent venous thrombosis, or increase microcirculation in the lower limb for the patient's use at home. Indications include increasing local blood circulation, reduction of edema, prevention of venous thrombosis, and increasing microcirculatory blood flow in lower limb with venous insufficiency and/or ischemia to support wound or tissue healing. The devices can deliver an effective stimulation for up to 24 hours per day, depending on the device selected and the indication for use. After use, the device is removed, discarded and a new device is applied and activated as required. The device is applied to the skin and positioned over the peroneal nerve just below the knee. An indicator line on the device is aligned to the fibula head, for optimal electrode placement. The devices are packaged in sealed, easily opened, pouches. The geko™ W-3 devices are supplied as 7 single units in a cardboard wallet along with instructions for use. The geko™ T-3 devices are supplied in pairs of devices as either 3, 4, or 5 pairs in a cardboard wallet or 25 pairs in a carton. Again, the instructions for use are provided with all the devices. geko™ T-3 and geko™ W-3 received the Food and Drug Administration's (FDA's) 510(k) clearance on May 23, 2018.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a single-patient use, disposable NMES device. CMS would

like to further understand the geko™ T-3 and geko™ W-3 device indication for use by the FDA to be used as immediate post-surgical stimulation. With regard to Medicare, we do not have a benefit category for single-patient use or disposable devices, as they do not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code. Also, CMS would like to know if other payers would consider the use of the geko™ T-3 and geko™ W-3 device as an “incident to” supply.

Summary of Public Feedback

Firstkind Ltd., the manufacturer of this product, disagreed with CMS’ published preliminary recommendation that there is no operational need for a new HCPCS Level II code. According to the speaker, claims for geko™ T-3 and geko™ W-3 have been processed through durable medical equipment (DME) distributors RestoreMotion and Athletic Recovery and Performance for at home supplies and claims have been paid by United Healthcare, BlueCross/BlueShield-CA, CIGNA and CA State Compensation Insurance Fund (SCIF) and the State Fund Insurance for workers compensation claims processed to the state of California through third party administrators One Call, Orchid Medical, Accurate Medical, and MTI America. These billers have used HCPCS codes E1399, “Durable medical equipment, miscellaneous” and/or E0676, “Intermittent limb compression device (includes all accessories), not otherwise specified.” According to the speaker, E0676 was utilized since the geko™ T-3 and geko™ W-3 device does internally compress the veins of the calf through contraction of the calf muscles after nerve stimulation. According to the speaker, these codes do not accurately describe the disposable NMES supplies and cause delays in review time and increased rejection rates. The geko™ T-3 is applied post orthopedic surgery of the lower extremity or abdominal surgery. The geko™ W-3 is approved for both post-surgical and non-surgical patients at risk for venous thromboembolism. However, both the geko™ T-3 and geko™ W-3 device(s) are applied the day of surgery and the patients are trained on how to use the device at home. Upon discharge, treatment at home continues for up to 28 days for deep vein thrombosis treatment and 10 days for post-op surgical edema. According to the speaker, these devices are not provided by the hospital. At-home supplies to continue NMES treatment are ordered by the physician and provided to the patient’s home. According to the speaker, there is no mechanism to include the devices as an ‘incident to’ supply as most of the product is supplied outside of the hospital setting.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS’ published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the decision to:

Establish new HCPCS Level II code A4560, “Neuromuscular electrical stimulator (nmes), disposable, replacement only” to describe geko™ T-3 and geko™ W-3 devices.

Comments provided during and in response to the public meeting confirmed that only the initial supply is applied and/or provided to the patient during the day of surgery and the rest of the devices are supplied post-discharge. CMS agreed with the applicant that there were no existing codes to adequately describe the replacement of the geko™ T-3 and geko™ W-3 devices. As such, the newly established code, A4560, reflects the replacement of the geko™

T-3 and geko™ W-3 device(s) which are provided post-surgery. CMS considers the initial supply of the geko™ T-3 and geko™ W-3 device(s) to be an extension of or incident to a clinical service or procedure. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. Since DME is a benefit for rental of equipment for use in the home, the equipment must be able to withstand repeated use by successive patients under the first condition. The geko™ T-3 and geko™ W-3 devices are single-patient use, disposable devices that do not meet the Medicare definition of DME.

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing Indicator = 00

D-Ostomy - HCP220704QETH9

Topic/Issue

Request to establish a new HCPCS Level II code to identify D-Ostomy.

Applicant's suggested language: XXXXX, "Ostomy skin barrier, with flange including substantially straight edge, each"

Applicant's Summary

Sanguine Technology, LLC submitted a request to establish a new HCPCS Level II code to identify D-Ostomy. D-Ostomy is class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. According to the applicant, the item is a novel ostomy barrier comprising a flange having a substantially straight edge. For example, the flange on the barrier may be D-shaped. The flange with a substantially straight edge permits ostomy barrier placement in close proximity to a wound, negative pressure wound device, or patient feature (such as skin rolls or folds) without overlap. Overlap of traditional ostomy barriers can cause unwanted leaks of stoma effluent, which can raise the risk of infection or further complications. When traditional ostomy barriers are used in close proximity with negative pressure wound devices, the increased pressure can draw stoma effluent with the vacuum pressure, potentially drawing such effluent through a wound. The D-Ostomy barrier is used similar to that of traditional ostomy barriers: the barrier is placed around a patient's stoma. Unlike traditional ostomy barriers, the straight edge of the D-Ostomy barrier is oriented in proximity to the body feature (wound, scar, skin roll or fold) or negative pressure wound device. Pouches with corresponding D-shaped flanges are attached to the barrier to collect effluent.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4361, "Ostomy faceplate, each" describes the D-Ostomy barrier.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4361 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4361 apply to this product, if covered. The current average fee schedule amount for A4361 is \$ 21.75.

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

Summary of Public Feedback

Sanguine Technology, LLC, the manufacturer of this product, disagreed with CMS' preliminary HCPCS coding recommendation to use existing HCPCS Level II code A4361, "Ostomy faceplate, each" to describe the D-Ostomy barrier. The speaker stated that the D-Ostomy Barrier and Pouch should receive a new HCPCS Level II code because the novel straight-edge flange provides significant benefits in certain scenarios and that new codes have been created for similar shape changes, such as convexity, in the past. According to the speaker, Policy Article A52487 states that a faceplate does not have an adhesive property, is solid, and is made of plastic, rubber or encased metal. The policy article also refers to barriers as being those items larger than 4x4 inches. The speaker commented that the original code granted is inaccurate because D-Ostomy has an adhesive property, is not a long-term durable item, is 4.5x4.5 inches and has a flexible flange for the attachment to a corresponding pouch without built in convexity. For these reasons, the speaker asked, if having to work within existing codes, for code HCPCS Level II code A4415, "Ostomy skin barrier, with flange (solid, flexible or accordion), without built-in convexity, larger than 4 x 4 inches, each" be used instead to describe D-Ostomy.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the decision to assign:

Existing HCPCS Level II code A4414, "Ostomy skin barrier, with flange (solid, flexible or accordion), without built-in convexity, 4 x 4 inches or smaller, each" to describe the D-Ostomy barrier.

The D-Ostomy adheres to the skin through the built-in adhesive property and the pouch is attached to the solid flange, making D-Ostomy a skin barrier and not only an ostomy faceplate. The flange, itself, is smaller than 4 x 4 inches.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4414 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4414 apply to this product, if covered. The current average fee schedule amount for A4414 is \$6.56.

The average fee schedule amount is the average of the 2023 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

Dr. Arthritis, Patella Tendon Knee Strap - HCP220331103NX

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable patella tendon knee strap.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable patella tendon knee strap. This reusable strap comes in one size and is used for the following conditions: sports related injuries and fatigue, patellar tendonitis (jumper's knee), patellofemoral pain syndrome (runner's knee), iliotibial band syndrome (ITBS), chondromalacia, patellar Tracking and Osgood–Schlatter disease. This device is an adjustable patella tendon knee strap, which provides support to the patella tendon insertion point and knee joint itself through compression. The patella tendon knee strap is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable patella tendon knee strap.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Patella Tendon Knee Strap is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Summary of Public Feedback

Dr. Arthritis, the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, the adjustable patella tendon knee strap conforms with section 130 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02).

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" to describe the adjustable patella tendon knee strap.

The adjustable patella tendon knee strap is similar to those compression and sleeve devices within A4467.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. During the Public Meeting, representatives from Gravitq Acquisitions Co., indicated that the Patella Tendon Knee Strap contains a high percentage of copper within the weave. However, we do not consider this to meet the definition of a rigid or semi-rigid device. Therefore, the final determination is that the Dr. Arthritis Patella Tendon Knee Strap is not a brace.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Dr. Arthritis, Shoulder Support Brace - HCP220331DKCD6

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable shoulder strap.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable shoulder strap. This reusable brace comes in one size and used the following conditions: chronic shoulder pain, dislocated, shoulder, rotator cuff injury, tendon inflammation (bursitis or tendinitis) or tendon tears, shoulder instability, frozen shoulder syndrome. This device is an adjustable shoulder brace that provides graduated compression and relative immobilization of the shoulder. The shoulder support brace is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable shoulder support brace.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Shoulder Support Brace is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Summary of Public Feedback

Dr. Arthritis, the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, the shoulder brace conforms with section 130 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02). Written comments further explained that they can confirm that this is a semi-rigid device by merit of rigid diagonal splinting of the shoulder, this provides restriction of movement in the abduction/adduction as

well as flexion/extension planes of shoulder movement. There is 88% nylon stiffness which specifically supports the acromioclavicular joint, over the deltoid and the posterior surface of the scapula. According to the comments, this would be particularly helpful in the following diseases and injuries: adhesive capsulitis, shoulder impingement syndrome anterior and posterior shoulder dislocation.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" to describe the adjustable shoulder support brace.

The adjustable shoulder support brace is similar to those compression and sleeve devices within A4467.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. During the Public Meeting, representatives from Gravitiq Acquisitions Co., indicated that the Shoulder Support Brace contains a high percentage of copper within the weave. However, we do not consider this to meet the definition of a rigid or semi-rigid device. Therefore, the final determination is that the Dr. Arthritis Shoulder Support Brace is not a brace.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Dr. Arthritis, Elbow Support Strap - HCP220331KEXCD

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable elbow strap.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable elbow strap. This reusable strap comes in one size and used the following conditions: lateral epicondylitis (tennis elbow,) medial epicondylitis (golfers' elbow) and musculoskeletal elbow conditions. This device is an adjustable elbow strap, which provides support to the elbow joint through compression. The elbow support strap is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable elbow support strap.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Elbow Support Strap is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Summary of Public Feedback

Dr. Arthritis, the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, the elbow brace conforms with section 130 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02). Written comments further explained that this is a semi-rigid device by merit of the materials used in construction. There is high percentage of copper within the weave and supports the common flexor (medial epicondyle) and extensor origin (lateral epicondyle), alongside the distal attachments of the

medial and lateral collateral ligaments. There is differential restriction of movement in the varus and valgus plane as well as pronation and supination of the forearm. The flexion and extension of the elbow joint is preserved. According to the comments, this would be particularly helpful in the following diseases and injuries: tennis elbow, golfers' elbow, elbow ligament strains, and epicondylitis.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" to describe the elbow support strap.

The elbow support strap is similar to those compression and sleeve devices within A4467.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. During the Public Meeting, representatives from Gravitiq Acquisitions Co., indicated that the Elbow Support Strap contains a high percentage of copper within the weave. However, we do not consider this to meet the definition of a rigid or semi-rigid device. Therefore, the final determination is that the Dr. Arthritis Elbow Support Strap is not a brace.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Dr. Arthritis, Wrist Brace - HCP220420WCDD8

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable wrist brace.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable carpal tunnel wrist brace. This reusable brace comes in one size and used the following conditions: carpal tunnel syndrome, sports-related injuries, and fatigue ligament/tendon support, wrist sprains/strains, wrist arthritis basal thumb arthritis and ganglion cysts. This device is a carpal tunnel wrist brace that provides graduated compression and relative immobilization of the wrist joint. The user would wear the device directly over the skin, over the lower arm covering the wrist joint. The user would secure the device in place using a hook and loop fastener. The wrist brace is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable wrist brace.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Wrist Brace is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Summary of Public Feedback

Dr. Arthritis, the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, the wrist brace conforms with section 130 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02). Written comments further explained that this is a semi-rigid device by merit of having a metal aluminum splint which

runs across the forearm and contains a 10-degree dorsal tint at the radiocarpal joint. Furthermore, this wrist brace contains a high percentage of copper weave within the fabric (35%). This metal splint eliminates the following movement: wrist flexion/extension, radial and ulnar deviation. According to the comments, the functional and symptomatic effects on Carpal Tunnel Syndrome were explored at six weeks using wrist with a metacarpophalangeal unit, and compared to baseline the splint significantly decreased pain and increased function, pinch strength, and grip strength.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and in the written comment, and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the decision to assign:

Existing HCPCS Level II code L3908, "Wrist hand orthosis, wrist extension control cock-up, non molded, prefabricated, off-the-shelf" to describe the adjustable wrist brace.

CMS understands that an adjustable carpal tunnel wrist brace is a semi-rigid device that is similar to those devices within L3908.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code L3908 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. During the Public Meeting, representatives from Gravitq Acquisitions Co., provided evidence that the Dr. Arthritis Carpal Tunnel Wrist Band includes a metal aluminum splint that runs across the forearm. Given that this is a rigid component that is used to restrict or eliminate wrist motion for individuals with carpal tunnel syndrome, the final benefit category determination is that this item is a brace.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code L3908 apply to this product, if covered. The current average fee schedule amount for L3908 is \$72.90.

The average fee schedule amount is the average of the 2023 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

Dr. Arthritis, Thumb Support Brace - HCP220331EFF4D

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable thumb brace.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable thumb brace. This reusable brace comes in one size and used the following conditions: basal thumb pain, thumb ligament issues, tendinitis/tendinopathy, trigger thumb (stenosing tenosynovitis), repetitive strain injury (RSI), De Quervain's Syndrome (De Quervain's tenosynovitis) and thumb sprains. This device is an adjustable thumb brace that provides graduated compression and relative immobilization of the wrist joint and 1st carpal metacarpal joint (thumb). The user would apply it directly over the skin, across the wrist joint and covering the thumb. The user would secure the device in place using a hook and loop fastener, tightening as appropriate to achieve the desired level of supportive compression. The thumb support brace is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable thumb brace.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Thumb Support Brace is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Summary of Public Feedback

Dr. Arthritis, the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, the thumb brace conforms with section 130 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02). Written comments further explained that this is a semi-rigid device by merit of having a metal aluminum splint which runs across the posterior aspect of the thumb, which fixes the thumb in the neutral anatomical position. The metal splint eliminates the following movements: thumb flexion/extension, abduction, and adduction. According to the comments, this would be particularly helpful in the following diseases and injuries: Osteoarthritis of the thumb, thumb tenosynovitis, thumb and wrist ligament strains, repetitive strain injury and trigger thumb.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and in the public comment, and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the decision to assign:

Existing HCPCS Level II code L3924, "Hand finger orthosis, without joints, may include soft interface, straps, prefabricated, off-the-shelf" to describe the adjustable thumb brace.

CMS understands that an adjustable thumb brace is a semi-rigid device that is similar to those devices within L3924.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code L3924 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. During the Public Meeting, representatives from Gravitiq Acquisitions Co., provided evidence that the Dr. Arthritis Thumb Support Brace includes a metal aluminum splint that runs across the posterior side of the thumb. Given that this is a rigid component that is used to restrict or eliminate thumb movement for individuals with various injuries or diseases in the thumb, the final benefit category determination is that this item is a brace.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code L3924 apply to this product, if covered. The current average fee schedule amount for L3924 is \$96.52.

The average fee schedule amount is the average of the 2023 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

Dr. Arthritis, Open Finger Compression Gloves - HCP2203319P57X

Topic/Issue

Request to establish a new HCPCS Level II code to identify pair of open finger gloves.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify pair of open finger gloves. The gloves are used with arthritis, carpal tunnel, and musculoskeletal hand conditions. This device is a pair of open finger compression gloves, which provides graduated compression of the wrist, hand and finger. It supports and stabilizes the small joints of the hand, through compression and partial immobilization. User wears the device over the skin; it can be easily removed/reused. The finger compression gloves are exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the pair of open finger compression gloves.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Open Finger Compression Gloves are not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Summary of Public Feedback

Dr. Arthritis, the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, the wrist open finger medical device conforms with section 130 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02). Written comments further explained that this is a semi-rigid device by merit of having a high percentage of copper fabric within the weave (88% Copper weave), this provides extra

stiffness to support the multiple small joints of the hands. According to the comments, this would be particularly helpful in the following diseases and injuries: osteoarthritis, rheumatoid arthritis, gout, thumb and wrist tendinopathies.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" to describe the open finger compression gloves.

The open finger compression glove is similar to those compression and sleeve devices within A4467.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. During the Public Meeting, representatives from Gravitq Acquisitions Co., indicated that the Open Finger Compression Gloves contain a high percentage of copper within the weave. However, we do not consider this to meet the definition of a rigid or semi-rigid device. Therefore, the final determination is that the Dr. Arthritis Open Finger Compression Gloves are not a brace.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Dr. Arthritis, Elbow Compression Sleeve - HCP2204214YW7G

Topic/Issue

Request to establish a new HCPCS Level II code to identify an elbow sleeve.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an elbow sleeve. This sleeve comes in one size and used the following conditions: sports related injuries and fatigue, elbow arthritis, tennis elbow, golfer's elbow, olecranon bursitis, cubital tunnel syndrome and any other musculoskeletal elbow injuries. This device is an elbow compression sleeve, which provides support to the elbow joint through stabilization, relative immobilization and compression. The user would wear it directly over the skin, the center of the elbow sleeve should be positioned across the elbow joint itself. The elbow sleeve is easy to remove and reapply. The elbow compression sleeve is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the elbow compression sleeve.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Elbow Compression Sleeve is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Summary of Public Feedback

Dr. Arthritis, the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, the elbow compression device conforms with section 130 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02). Written

comments further explained that this is a semi-rigid device by merit of having a high percentage of copper fabric within the weave (88% Copper weave), this provides extra stiffness to support the tendinous and ligamentous insertions into the olecranon and the epicondyles of the elbow. According to the comments, this would be particularly helpful in the following diseases and injuries: medial and lateral epicondylitis, olecranon bursitis and elbow strains.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" to describe the elbow compression sleeve.

The elbow compression sleeve is similar to those compression and sleeve devices within A4467.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. During the Public Meeting, representatives from Gravitq Acquisitions Co., indicated that the Elbow Compression Sleeve contains a high percentage of copper within the weave. However, we do not consider this to meet the definition of a rigid or semi-rigid device. Therefore, the final determination is that the Dr. Arthritis Elbow Compression Sleeve is not a brace.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Dr. Arthritis, Wrist Brace - HCP220321YBBBBP

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable wrist brace.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable wrist brace. This reusable brace comes in one size and used the following conditions: for use with arthritis, carpal tunnel, etc. This device is a wrist brace that provides graduated compression and relative immobilization of the wrist joint. It supports and stabilizes the wrist joint, and through compression and partial immobilization promotes recovery for common musculoskeletal injuries. User applies to wrist joint and secures using hook and loop fastener. The device is easy to remove and reapply. The wrist brace is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable wrist brace.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Wrist Brace is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Summary of Public Feedback

Dr. Arthritis, the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, the wrist brace conforms with section 130 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02). Written comments further explained that this is a semi-rigid device by merit of Y strap stabilization of the wrist. This occurs by wrapping the brace around the radiocarpal joints and then across the palm of the

hand and then between the thumb and index finger. Furthermore, this wrist brace contains a high percentage of copper weave within the fabric (35%). According to the comments, the Y strap brace eliminates the following movement: wrist flexion/extension, radial and ulnar deviation, and this would be particularly helpful in the following diseases and injuries, wrist tendinopathies, osteoarthritis, rheumatoid arthritis, carpal tunnel and wrist sprains.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" to describe the wrist brace.

The wrist brace is similar to those compression and sleeve devices within A4467.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. During the Public Meeting, representatives from Gravitiq Acquisitions Co., indicated that the Wrist Brace contains a high percentage of copper within the weave. However, we do not consider this to meet the definition of a rigid or semi-rigid device. Therefore, the final determination is that the Dr. Arthritis Wrist Brace is not a brace.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Dr. Arthritis, Foot Compression Sleeve - HCP220421KT8W1

Topic/Issue

Request to establish a new HCPCS Level II code to identify a foot compression sleeve.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify a foot compression sleeve. This sleeve provides support to the ankle and foot joint, through compression, relative immobilization and joint stabilization. This would promote the recovery during sport or strenuous exercise, sports related injuries and fatigue, ligament/tendon support, ankle sprains/strains, ankle arthritis, heel/arch support. The user would wear it directly over the skin and it would be positioned to cover the lower leg, ankle joint and midfoot. The foot compression sleeve is easy to remove and reapply. The foot compression sleeve is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the foot compression sleeve.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Foot Compression Sleeve is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

Summary of Public Feedback

Dr. Arthritis, the manufacturer of this product, disagreed with CMS' published preliminary recommendation. According to the speaker, the foot compression device conforms with section 130 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02). Written

comments further explained that this is a semi-rigid device by merit of having a high percentage of copper fabric within the weave (88% Copper weave), this provides extra stiffness to support the multiple small joints of the foot and ankle. According to the comments, this would be particularly helpful in the following diseases and injuries: relieve pain from past injuries, plantar fasciitis, chronic heel pain, swollen arthritic ankles and feet, or poor circulation.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" to describe foot compression device.

The foot compression device is similar to those compression and sleeve devices within A4467.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device 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. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. During the Public Meeting, representatives from Gravitiq Acquisitions Co., indicated that the Foot Compression Sleeve contains a high percentage of copper within the weave. However, we do not consider this to meet the definition of a rigid or semi-rigid device. Therefore, the final determination is that the Dr. Arthritis Foot Compression Sleeve is not a brace.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing Indicator = 00

HEMIGARD® ASRD - HCP220628EJE62

Topic/Issue

Request to establish a new HCPCS Level II code to identify HEMIGARD® ASRD (Adhesive Suture Retention Device).

Applicant's suggested language: XXXXX, "HEMIGARD, 12 pairs of adhesive suture retention devices per box"

Applicant's Summary

Suturegard submitted a request to establish a new HCPCS Level II code to identify HEMIGARD® ASRD. HEMIGARD® ASRD is a class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. HEMIGARD® ASRD is a sterile, single use device. The HEMIGARD® ASRD is a wound closure device comprised of two 60x15 mm sterile, single use, adhesive strips, placed on either side of a wound. It is used in combination with suture, which is passed through its' apertures before the suture enters and exits the skin. It is made of nonwoven polyester, transparent polyethylene film and a PETG (Polyethylene terephthalate glycol) plastic insert with two apertures for suture passage. It has peel away paper backing and has an acrylate based hypoallergenic skin adhesive for attachment.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the HEMIGARD® ASRD 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 would pay for the service in which this product is used.

Summary of Public Feedback

Suturegard Medical Inc., the manufacturer of the product, disagreed with CMS' published preliminary recommendation and requested that a new HCPCS Level II code be established to identify HEMIGARD® ASRD. The primary speaker stated that Suturegard Medical won the American Diabetes Association (ADA) 2022 Showcase Innovation Award and that the ADA heard their message about how the HEMIGARD® ASRD product has dramatically improved surgical outcomes for diabetic amputation patients. According to the primary speaker, many initial amputations do not heal on these patients who almost always have vascular disease and neuropathy, and often require more morbid above or below knee amputations with high risk of systemic complications including mortality. HEMIGARD® ASR reduced need for further amputation by 89% by preventing healing complications with the initial amputation. The study of 80 patients that the company conducted, is valid real-world evidence that resonated with the ADA judges.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. We continue to believe the HEMIGARD® ASRD is not suitable

for inclusion in the HCPCS Level II code set because it is used in a procedure and certain items are considered bundled into the facility payment. Neither the application nor the comments provided during or in response to the public meeting provided any compelling new evidence pointing to significant therapeutic distinction that would warrant a new HCPCS Level II code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer would pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

Keragel® 20gm Tube - HCP2207049R6X6

Topic/Issue

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

Applicant's suggested language: XXXXX, "KERATIN - Keragel 20gm sterile tube, each"

Applicant's Summary

Molecular Biologicals Inc. submitted a request to establish a new HCPCS Level II code to identify Keragel® 20gm tube. Keragel® received the Food and Drug Administration's (FDA's) 510(k) clearance on February 11, 2009. It is a patient self-administered gel in a tube consisting of bioactive keratin, Replicine™, as the clinically predominant and distinguishing ingredient. Keragel® is a topical gel product designed for acute/chronic partial and full thickness wounds with low to moderate exudate in conditions such as: venous leg ulcers, arterial ulcers, diabetic foot ulcers, skin graft donor sites, and first and second-degree burns. Keragel® can be self-applied topically to the wound bed surface. Keragel® is applied with dressing changes to the wound bed, commonly daily. The clinically predominant function of Keragel® is to deliver bioactive keratin to the wound bed to facilitate wound healing, as well as establish more durable skin structure. Exogenous Keratin has demonstrated activation and proliferation of keratinocytes by upregulating Keratin 6, 16, and 17 and activating fibroblasts, collagen IV and collagen VII. By activating keratinocytes, a scaffold is developed to allow for epithelial cell migration and granulation of the wound bed. Keragel® is beneficial in patients suffering from chronic, recalcitrant wounds such as diabetic foot ulcer, venous leg ulcer, pressure ulcers, wounds from dystrophic epidermolysis bullosa among others.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A6248, "Hydrogel dressing, wound filler, gel, per fluid ounce," describes Keragel®.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A6248 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A6248 apply to this product, if covered. The current average fee schedule amount for A6248 is \$19.99.

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 = 35

Summary of Public Feedback

Molecular Biologics, Inc., disagreed with CMS' published preliminary recommendation that existing HCPCS Level II code A6248 describes Keragel® and KeragelT®. According to the speaker, the bioactive ingredient, Replicine™, is in a hydrogel base, however, is not to serve as a wound filler or moisturizer. Keragel® and KeragelT®'s bioactive ingredient stimulates healing by activating keratinocytes in the wound that have stalled. The speaker stated that CMS' definition of hydrogel does not support this mechanism. The speaker mentioned that the FDA defines hydrogels as not containing products derived from animals. The Replicine™ ingredient is derived from sheep wool. The speaker said that their products offer a cost-effective in-home treatment option for unhealed, debilitating wounds.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A6248, "Hydrogel dressing, wound filler, gel, per fluid ounce," to describe Keragel®.

We continue to believe Keragel® is a hydrogel. We reviewed Molecular Biologics Inc.'s, website (<https://molecularbiologics.com/productinfo.php?prod=keragel>), where Keragel® is advertised as a "thick hydrogel rich in keratin protein." As stated in the application, Keragel® was cleared via the 510(k) pathway in 2009 with a predicate product from Biocore Medical Technologies Inc. Medifil Collatek Hydrogel. In contrast, the applicant has stated that the predicate product is solely and primarily used to maintain a moist healing environment at the wound site, and that the hydrogel category is not a sufficient representation of the full activities of keratin in wound healing. Contradictory to the speaker's comments related to wound filler or moisturizer, the 510(k) states "Keragel is a dressing that provides moisture to dry wound beds..." We were unable to locate in Keragel's® label the claim that the bioactive ingredient stimulates healing by activating keratinocytes in the wound that have stalled. We note that the 510(k) does state, "the primary mode of action of keratin containing dressings Keragel, Keraderm and Keaform is to absorb and interact with wound fluids to form a soft, hydrophilic keratin gel that facilitates a moist wound healing environment. The secondary mode of action is to provide cells in the wound with a friendly structural framework that allows cellular migration where no framework exists."

The applicant stated that FDA's definition of hydrogel has changed to now exclude those products containing animal derived products. However, according to the applicant, Keragel® contains animal derived ingredients. Based on the information provided by the applicant, CMS believes that the next appropriate step for the applicant would be to approach the FDA to discuss the information presented to CMS and to inquire on the most appropriate classification of Keragel® and terms that may be used for marketing and medical claims.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A6248 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A6248 apply to this product, if covered. The current average fee schedule amount for A6248 is \$21.73.

The average fee schedule amount is the average of the 2023 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 = 35

KerageIT® 20gm Tube - HCP2207053M4YQ

Topic/Issue

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

Applicant's suggested language: XXXXX, "Keratin - KerageIT 20gm sterile tube, each"

Applicant's Summary

Molecular Biologicals Inc. submitted a request to establish a new HCPCS Level II code to identify KerageIT®. KerageIT® received the Food and Drug Administration's (FDA's) 510(k) clearance on February 11, 2009. KerageIT® 20gm tube is a patient self-administered gel in a tube consisting of bioactive keratin, Replicine™, as the clinically predominant and distinguishing ingredient. KerageIT® is a topical gel product designed for acute/chronic partial and full thickness wounds with low to moderate exudate in conditions such as: venous leg ulcers, arterial ulcers, diabetic foot ulcers, skin graft donor sites, and first and second-degree burns. KerageIT® can be self-applied topically to the wound bed surface. KerageIT® is applied with dressing changes to the wound bed, commonly daily. The clinically predominant function of KerageIT® is to deliver bioactive keratin to the wound bed to facilitate wound healing, as well as establish more durable skin structure. Exogenous Keratin has demonstrated activation and proliferation of keratinocytes by upregulating Keratin 6, 16, and 17 and activating fibroblasts, collagen IV and collagen VII. By activating keratinocytes, a scaffold is developed to allow for epithelial cell migration and granulation of the wound bed. KerageIT® is beneficial in patients suffering from chronic, recalcitrant wounds such as diabetic foot ulcer, venous leg ulcer, pressure ulcers, wounds from dystrophic epidermolysis bullosa among others.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A6248, "Hydrogel dressing, wound filler, gel, per fluid ounce," describes KerageIT®.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A6248 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A6248 apply to this product, if covered. The current average fee schedule amount for A6248 is \$19.99.

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 = 35

Summary of Public Feedback

Molecular Biologics, Inc., disagreed with CMS' published preliminary recommendation that existing HCPCS Level II code A6248 describes Keragel® and KeragelT®. According to the speaker, the bioactive ingredient, Replicine™, is in a hydrogel base, however, is not to serve as a wound filler or moisturizer. Keragel® and KeragelT®'s bioactive ingredient stimulates healing by activating keratinocytes in the wound that have stalled. The speaker stated that CMS' definition of hydrogel does not support this mechanism. The speaker mentioned that the FDA defines hydrogels as not containing products derived from animals. The Replicine™ ingredient is derived from sheep wool. The speaker said that their products offer a cost-effective in-home treatment option for unhealed, debilitating wounds.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A6248, "Hydrogel dressing, wound filler, gel, per fluid ounce," to describe KeragelT®.

As stated in the application, KeragelT® was cleared via the 510(k) pathway in 2009 with a predicate product from Biocore Medical Technologies Inc. Medifil™ Collatek Hydrogel. The applicant has stated that the predicate product is solely and primarily used to maintain a moist healing environment at the wound site, and that the hydrogel category is not a sufficient representation of the full activities of keratin in wound healing. Contradictory to the speaker's comments related to wound filler or moisturizer, the 510(k) states "Keragel is a dressing that provides moisture to dry wound beds..." We were unable to locate in KeragelT's® label the claim that the bioactive ingredient stimulates healing by activating keratinocytes in the wound that have stalled. We note that the 510(k) does state, "the primary mode of action of keratin containing dressings Keragel, Keraderm and Keaform is to absorb and interact with wound fluids to form a soft, hydrophilic keratin gel that facilitates a moist wound healing environment. The secondary mode of action is to provide cells in the wound with a friendly structural framework that allows cellular migration where no framework exists."

The applicant stated that FDA's definition of hydrogel has changed to now exclude those products containing animal derived products. However, according to the applicant, KeragelT® does contain animal derived ingredients. Based on the information provided by the applicant, CMS believes that the next appropriate step for the applicant would be to approach the FDA to discuss the information presented to the CMS and to inquire on the most appropriate classification of KeragelT®.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A6248 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A6248 apply to this product, if covered. The current average fee schedule amount for A6248 is \$21.73.

The average fee schedule amount is the average of the 2023 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 = 35

Crus Med - HCP220705RM6W4

Topic/Issue

Request to establish a new HCPCS Level II code to identify Crus Med.

Applicant's suggested language: XXXXX, "Ready for use slip-on bandage, for the lower leg"

Applicant's Summary

Pedilay® Care Inc. submitted a request to establish a new HCPCS Level II code to identify Crus Med. Crus Med is class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. According to the applicant, Crus Med is a new and innovative secondary slip-on bandage, ready for use for the lower leg. This ready to use bandage for the lower leg, covers it from the ankle up to below the knee, provides protection of primary wound care dressing, by covering and fixating the dressing. It has an easy application and removal, by stretching over the foot to the ankle and by employing intuitive fastening tabs without employing scissors and tape. According to the applicant, Crus Med is significantly different from other secondary or tertiary bandaging systems and corresponding application methods used for the same treatments, e.g., venous leg ulcer, surgical wounds, burns etc. It is a ready for use slip-on bandage, with a fast, simple and secure application, that does not require wrapping or fixation. It is not properly described by width or by length, it is preformed to the shape of the body. According to the applicant, current codes are inadequate to reflect this unique characteristic and/or the cost of the product. This difference translates into functional superiority with regard to application (there is no need to wrap the bandage or to secure it, no judgment is required about how tightly to wrap or how to apply smoothly to the body), removal or replacement, and security (there is a diminished chance of the bandage being accidentally dislodged or loosened during use).

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4461, "Surgical dressing holder, non-reusable, each," describes Crus Med Bandage. We have no evidence or information that would enable us to determine that the Crus Med Bandage is functionally superior to other surgical dressing holders classified under A4461. We welcome the applicant to submit any clinical studies that demonstrate such comparison and distinction.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4461 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4461 apply to this product, if covered. The current average fee schedule amount for A4461 is \$4.06.

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 = 35

Summary of Public Feedback

Pedilay® Care, the manufacturer of the product, disagreed with CMS' published preliminary recommendation and requested that a new HCPCS Level II code would be established to identify Crus Med. According to the primary speaker, there is a functional superiority of this product compared to the other products listed in HCPCS Level II code A4461. Crus Med is a ready-for-use bandage, that requires minimum training, and does not require scissors or tape. The speaker further stated that because this product is designed based on the shape of body, it provides the right fixation of primary dressing to keep it in place and secure. The speaker commented that the proposed average fee schedule amount does not adequately address the custom design as well as the significant dimensional differences in comparison to other products under HCPCS Level II code A4461.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4461, "Surgical dressing holder, non-reusable, each," to describe Crus Med Bandage.

This ready to use slip-on bandage covers and protects a primary dressing. The patient or caregiver would still need to have the ability to first correctly apply a primary dressing by using appropriate judgment and proper techniques, which requires as much or more training and dexterity than the application of any subsequent holder type bandages such as Crus Med. As such, while there is variation among the types of secondary and tertiary holder bandages, the overall application of bandaging a surgical wound does not necessarily warrant these distinctions from a clinical care standpoint. In other words, the complexity or simplicity of the application of the secondary or tertiary bandage is irrelevant without the successful application of the primary dressing.

Though requested, we did not receive significant evidence to support the claim that Crus Med is functionally superior from other secondary or tertiary bandaging systems. In addition, there is no evidence in clinical superiority of outcomes while using Crus Med Bandage.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4461 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4461 apply to this product, if covered. The current average fee schedule amount for A4461 is \$4.41.

The average fee schedule amount is the average of the 2023 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 = 35

Pedilay® Med- HCP22070547EEV

Topic/Issue

Request to establish a new HCPCS Level II code to identify Pedilay® Med.

Applicant's suggested language: XXXXX, "Ready for use slip-on bandage, for foot & ankle"

Applicant's Summary

Pedilay® Care Inc. submitted a request to establish a new HCPCS Level II code to identify Pedilay® Med. Pedilay® Med is class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. According to the applicant, Pedilay® Med is a new and innovative secondary slip-on bandage, ready for use for the foot and ankle. This is ready to use foot bandage that encloses the foot up to the ankle, provides protection of primary wound care dressing, by covering and fixating the dressing. It has an easy application and removal, by stretching over the heel and by employing intuitive fastening tabs without employing scissors and tape. According to the applicant, Pedilay® Med is significantly different from other secondary or tertiary bandaging systems and corresponding application methods used for the same treatments, e.g., diabetic foot ulcer. It is a ready for use slip-on bandage, with a fast, simple and secure application, that does not require wrapping or fixation. Pedilay® Med is not properly described by width or by length, it is preformed to the shape of the body. According to the applicant, current codes are inadequate to reflect this unique characteristic and/or the cost of the product. This difference translates into functional superiority with regard to application (there is no need to wrap the bandage or to secure it, no judgment is required about how tightly to wrap or how to apply smoothly to the body), removal or replacement, and security (there is a diminished chance of the bandage being accidentally dislodged or loosened during use).

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4461, "Surgical dressing holder, non-reusable, each," describes Pedilay® Med Bandage. We have no evidence or information that would enable us to determine that the Crus Med Bandage is functionally superior to other surgical dressing holders classified under A4461. We welcome the applicant to submit any clinical studies that demonstrate such comparison and distinction.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4461 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4461 apply to this product, if covered. The current average fee schedule amount for A4461 is \$4.06.

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 = 35

Summary of Public Feedback

Pedilay® Care, the manufacturer of the product, disagreed with CMS' published preliminary recommendation and requested that a new HCPCS Level II code would be established to identify Pedilay® Med. According to the primary speaker, there is a functional superiority of this product compared to the other products listed in HCPCS Level II code A4461. Pedilay® Med is a ready-for-use bandage, that requires minimum training, and does not require scissors or tape. The speaker further stated that because this product is designed based on the shape of body, it provides the right fixation of primary dressing to keep it in place and secure. The speaker commented that the proposed average fee schedule amount does not adequately address the custom design as well as the significant dimensional differences in comparison to other products under HCPCS Level II code A4461.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4461, "Surgical dressing holder, non-reusable, each," to describe Pedilay® Med Bandage.

This ready to use slip-on bandage covers and protects a primary dressing. The patient or caregiver would still need to have the ability to first correctly apply a primary dressing by using appropriate judgment and proper techniques, which requires as much or more training and dexterity than the application of any subsequent holder type bandages such as Crus Med. As such, while there is variation among the types of secondary and tertiary holder bandages, the overall application of bandaging a surgical wound does not necessarily warrant these distinctions from a clinical care standpoint. In other words, the complexity or simplicity of the application of the secondary or tertiary bandage is irrelevant without the successful application of the primary dressing.

Though requested, we did not receive significant evidence to support the claim that Pedilay® Med is functionally superior or significantly different from other secondary or tertiary bandaging systems. In addition, there is no evidence in clinical superiority while using Pedilay® Med Bandage.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4461 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4461 apply to this product, if covered. The current average fee schedule amount for A4461 is \$4.41.

The average fee schedule amount is the average of the 2023 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 = 35

MariGen® Shield- HCP220630YGVWG

Topic/Issue

Request to establish a new HCPCS Level II code to identify MariGen Shield.

Applicant's suggested language: Q4XXX, "MariGen Shield, per sq cm"

Applicant's Summary

Kerecis® submitted a request to establish a new HCPCS Level II code to identify MariGen® Shield. MariGen® Shield received the Food and Drug Administration's (FDA's) 510(k) clearance on June 29, 2022. MariGen® Shield is a bilayer of processed resorbable acellular fish dermal matrix skin substitute adhered to a thin, transparent, porous, soft silicone layer. MariGen® Shield is composed of a fish dermal matrix layer which is approximately 1 mm in thickness and is porous. The silicone layer is a transparent polyurethane film single-coated with soft, medical grade silicone that is attached to the scaly side of the fish dermal matrix. The silicone layer is porous, soft and conformable to the wound surface. The silicone layer can be peeled off as the fish dermal matrix is resorbed. MariGen® Shield is indicated for the management of wounds such as partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds (abrasions, lacerations, partial-thickness burns, skin tears), surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), draining wounds. The product is individually packaged in various sizes and dosed equally to the wound size in centimeters. The fish skin layer is made from wild-caught Atlantic Cod that is minimally processed in order to preserve the natural proteins and structure of the fish skin. The silicone acts to protect the fish dermal matrix layer and is intended to ease the application of the device.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Kerecis omega3 marigen shield, per square centimeter"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Summary of Public Feedback

Kerecis®, the manufacturer of MariGen® Shield, agreed with CMS' published preliminary HCPCS Level II coding recommendation to establish a new HCPCS Level II code to identify the Kerecis® Omega3 MariGen® Shield.

CMS Final HCPCS Coding Decision

We appreciate the written comment provided in response to CMS' published preliminary recommendation. Based on the information provided in the application to establish a new HCPCS Level II code, and after consideration of the applicant's written comment, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code A2019, “Kerecis omega3 marigen shield, per square centimeter” to describe MariGen® Shield.

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

AC5® Advanced Wound System - HCP220629RD4XM

Topic/Issue

Request to establish a new HCPCS Level II code to identify AC5® Advanced Wound System.

Applicant's suggested language: XXXXX, "AC5 Advanced Wound System (AC5)"

Applicant's Summary

Arch Therapeutics, Inc. submitted a request to establish a new HCPCS Level II code to identify AC5® Advanced Wound System. AC5® Topical Gel received the Food and Drug Administration's (FDA's) 510(k) clearance on December 14, 2018. A subsequent 510(k) was issued on March 11, 2020 (to add an additional manufacturing process and manufacturer). AC5® is a self-assembling wound care matrix that provides clinicians with multi-modal support and utility across all phases of wound healing. AC5® is made up of biocompatible and resorbable peptides that self-assemble into a nanofiber network which resembles the construct of the extracellular matrix. This self-assembly is a rearrangement of peptide units into a series of higher ordered nanofibril and nanofiber structures, culminating in an entangled network that creates a physical barrier to mitigate contamination and help modulate inflammation. The extracellular matrix-mimicking scaffold provides an environment conducive to cellular migration and soft tissue regeneration within the wound bed. AC5® Advanced Wound System is supplied as a powder that is hydrated at the point of care to form a 3-dimensional wound conforming matrix that allows for full wound contact. AC5® is provided as a kit that includes: 1 x 3 mL syringe with Luer-Lok tip, 1 x vial of lyophilized peptide, 1 x vial of sterile water for injection, USP 2 x 18-gauge, 1.5 inch needles, 1 x 18-gauge 1.5 inch blunt fill needles, 2 x alcohol prep pad wipes. AC5® peptide is sterilized by gamma irradiation. All other components of AC5® are sterile and packaged into a kit in a controlled environment. Each kit is for single patient use only and may be used on wounds between 20-25 square centimeters.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Ac5 advanced wound system (ac5)"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Summary of Public Feedback

Arch Therapeutic, Inc., the manufacturer of AC5® Advanced Wound System, agreed with CMS' published preliminary HCPCS coding recommendation to establish a new HCPCS Level II code to identify the AC5® Advanced Wound System.

CMS Final HCPCS Coding Decision

We appreciate the written comment provided in response to CMS' published preliminary recommendation. Based on the information provided in the application to establish a new

HCPCS Level II code, and after consideration of the applicant's written comment, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code A2020, "Ac5 advanced wound system (ac5)" to describe AC5® Advanced Wound System.

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

NeoMatriX® Wound Matrix - HCP220627LXLYC

Topic/Issue

Request to establish a new HCPCS Level II code to identify NeoMatriX Wound Matrix.

Applicant's suggested language: AXXXX, "NeoMatriX, per square centimeter"

Applicant's Summary

NeXtGen Biologics submitted a request to establish a new HCPCS Level II code to identify NeoMatriX® Wound Matrix. NeoMatriX® Wound Matrix is a single-use, medical device composed of acellular axolotl dermal extracellular matrix intended to support wound healing for chronic and hard-to-heal wounds. NeoMatriX® Wound Matrix received the Food and Drug Administration's (FDA's) 510(k) clearance on October 7, 2021. The device is derived from farm raised hybrid amphibian variants sourced from a closed herd in a dedicated facility. NeoMatriX® Wound Matrix is intended for use in the management of wounds, including partial- and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor site/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds, (abrasions, lacerations, second-degree burns and skin tears), and draining wounds. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product will fully resorb and does not have to be removed. NeoMatriX® Wound Matrix is supplied terminally sterile, in a single-use package, and in a variety of sizes.

CMS Preliminary HCPCS Coding Recommendation

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

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Summary of Public Feedback

NeXtGen Biologics, the manufacturer of NeoMatriX® Wound Matrix, agreed with CMS' published preliminary HCPCS coding recommendation to establish a new HCPCS Level II code to identify the NeoMatriX® Wound Matrix.

CMS Final HCPCS Coding Decision

We appreciate the written comment provided in response to CMS' published preliminary recommendation. Based on the information provided in the application to establish a new HCPCS Level II code, and after consideration of the applicant's written comment, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code A2021, "Neomatrix, per square centimeter" to describe NeoMatriX® Wound Matrix.

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

OWYN™ - HCP220629C4ABF

Topic/Issue

Request to revise existing HCPCS Level II code B4150 “Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit” to identify OWYN™.

Applicant's suggested language: B4150, “Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit” together with modifier BO “administered orally and not by a feeding tube”

Applicant’s Summary

Only What You Need, Inc. submitted a request to revise existing HCPCS Level II code B4150, “Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit” to identify OWYN™. The OWYN™ Complete Nutrition Shake is a plant base nutritionally balanced oral formula with nutrient-dense calories and includes protein, carbohydrate, fat, vitamins and minerals. Each shake provides 300 calories, 20 grams of protein, 31 grams of carbohydrates, 3 grams of fiber, 10 grams of fat (9 grams of healthy fat), and 23 vitamins and minerals. These shakes are intended for the nutrition management of patients with inadequate nutrient intake, malnutrition, risk of malnutrition associated with cancer, gastrointestinal disease, surgical recovery, chronic and acute illness, and food allergies. It is to be consumed orally a few times per day. The device is exempt from the premarket notification procedures by the Food and Drug Administration.

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 B4150. Medicare covers enteral nutritional therapy administered through feeding tubes under the prosthetic device benefit, with the feeding tube being the prosthetic device. Medicare does not cover oral nutrition since this is not a prosthetic device and there are no other DMEPOS benefit categories for these items. In addition, we are not aware of other payers that would have a need for a code with the suggested language.

Summary of Public Feedback

Only What You Need, Inc., the manufacturer of this product, clarified the HCPCS Level II request is to assign OWYN™ to existing code B4150 and not revise the code. The speaker agreed that the code language of B4150 should not be changed. OWYN™ Complete Nutrition Shake is a plant based oral formula. According to the speaker, B4150, “Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit” together with modifier BO “administered orally and not by a feeding tube” describes OWYN. According to the speaker, OWYN™ Complete Nutrition Shake is similar to Boost, Ensure, and Orgain products.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the decision to assign:

Existing HCPCS Level II code B4150, "Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit" together with modifier BO "administered orally and not by a feeding tube" to describe the OWYN™ Complete Nutrition Shake.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Medicare covers enteral nutritional therapy administered through feeding tubes under the prosthetic device benefit, with the feeding tube being the prosthetic device. However, Medicare does not cover oral nutrition. Therefore, this item is not a prosthetic device and there are no other DMEPOS benefit categories for this item.

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing Indicator = 00

Injectable Immunotherapies - HCP220705DHHCU

Topic/Issue

Request to revise an existing HCPCS Level II code S9562, “Home injectable therapy, palivizumab, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem” to replace palivizumab with immunotherapies.

Applicant's suggested language: S9562, “Home injectable therapy, immunotherapy, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem”

Applicant’s Summary

National Home Infusion Association submitted a request to revise existing HCPCS Level II code S9562 to replace “palivizumab” with “immunotherapies”. The applicant commented the code should be revised so that it can be used for a growing number of Food and Drug Administration (FDA) approved injectable therapies. According to applicant, at the time the code was created, 20 years ago, palivizumab was the only injectable immunotherapy administered in the home. Since then the FDA has approved additional injectable immunotherapies that are commonly administered in the home. The applicant requested that the description for S9562 be changed to “home injectable therapy, immunotherapy, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem.” According to the applicant, this change would be consistent with the other home infusion therapy S-codes, which are based on therapy type, not a specific drug.

CMS Preliminary HCPCS Coding Recommendation

CMS has been notified by the applicant that the claims volume submitted by non-Medicare payers under the not otherwise classified (NOC) codes for home injectable immunotherapies indicates further coding distinction is appropriate. In light of the developing RSV pediatrics issue, we want to continue to allow for differential code. As such, CMS will establish new HCPCS Level II code SXXXX, “Home injectable therapy, immunotherapy, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem”.

Summary of Public Feedback

The primary speaker agreed with CMS’ published preliminary HCPCS Level II coding recommendation to establish a new HCPCS Level II code for injectable immunotherapies while maintaining a distinct S code for RSV. Additionally, the speaker suggested a revision to code S9542 to be changed from drug specific language to therapy specific.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS’ published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code S9563, “Home injectable therapy, immunotherapy, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem”.

CMS is aware of the higher number of RSV cases among the pediatrics population and concerns about the availability of administration coding for the potential next generation of RSV pediatric monoclonal antibody(s) (mAb) that is under development. As such, CMS is also finalizing a revision to S9562 to facilitate administration of a broader range of mAbs, where S9562 has been appropriate for particular payers:

Revise existing HCPCS Level II code S9562, “Home injectable therapy, palivizumab, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem” to now read “Home injectable therapy, palivizumab or other monoclonal antibody for rsv, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem.”

As related to the new request for the revision of other existing codes, CMS would require a new HCPCS Level II application in an upcoming cycle.

Shoulder Pacemaker™ - HCP220705H21VT

Topic/Issue

Request to establish a new HCPCS Level II code to identify Shoulder Pacemaker™.

Applicant's suggested language: EXXXX, "Motion Activated Neuromuscular Stimulator, Dynamic Transcutaneous Stimulation of Nerve and Muscle Groups, Any Joint, Entire System"

Applicant's Summary

Alyve Medical Inc. submitted a request to establish a new HCPCS Level II code to identify the Shoulder Pacemaker™ device. According to the applicant, Shoulder Pacemaker™ is a therapeutic Motion Activated Stimulation (MAS) device that employs advanced sensor technology, coupled with neuromuscular electrical stimulation to aid patients in recalibrating complex muscle movements in order to restore optimal joint motion and function. The system includes the operating console that is worn on a patient's arm by use of a band strapped around the upper arm, lead wires attached to the console with electrodes at the other end that are placed on the patient over areas targeted for treatment, and a tablet-based app that controls the device, guides the patient through the prescribed therapeutic treatment regimen, tracks patient progress over time and conveys the results of a patient's treatment to the health care professional (HCP) overseeing their treatment. According to the applicant, the Shoulder Pacemaker™ is the first device introduced to the market that employs MAS. Shoulder Pacemaker™ received the Food and Drug Administration's (FDA's) 510(k) clearance on August 24, 2021. According to applicant, the use, operation, mechanism of action and resulting therapeutic treatment are different from existing devices classified either as neuromuscular electrical stimulators (E0745) or functional electrical stimulators (E0770). The intelligent components of the device and companion app provide dynamic stimulation the timing and intensity of which is specific to each individual movement by the patient during each individual therapeutic exercise repetition completed in each treatment session. The device and app also provide tri-modal biofeedback (sensory, auditory and visual) to the patient during execution of each exercise movement as well as collect and report data on the patient's progress through assigned treatment programs to both the patient and the attending HCP. According to the applicant, there is no current code category that describes such a device. According to the Shoulder Pacemaker's™ User Manual, Home Version, the expected lifespan of the Shoulder Pacemaker™ device is two years.

CMS Preliminary HCPCS Coding Recommendation

CMS believes the mechanism of action of the Shoulder Pacemaker™ aligns with other neuromuscular electrical stimulation devices. However, the issue of whether the device has a lifetime of at least 3 years is still in question. The manufacturer initially stated in the application to CMS that the device has an expected lifetime of 3 years. However, the Shoulder Pacemaker's™ User Manual, Home Version, attached as supporting documentation by the applicant, states the expected lifespan of the Shoulder Pacemaker™ device is two years. There are many ways to demonstrate lifetime durability of an entire device to CMS. For example, the manufacturer can provide standardized test results from an independent testing laboratory demonstrating that the device itself can last for at least 3 years. If the lifetime of the Shoulder Pacemaker™ is less than 3 years, then existing code A9270, "Non-

covered item or service” is available for Medicare. If the manufacturer can demonstrate lifetime durability of 3 years or more, we would likely determine that the product is described by existing code E0745, “Neuromuscular stimulator, electronic shock unit.” CMS seeks further clarification from the manufacturer.

Summary of Public Feedback

The applicant commented that in review of CMS’ published preliminary recommendation, they are working on gathering data and evidence to address CMS’ questions.

CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering that no further evidence was received, CMS is denying the application to establish a new HCPCS Level II code to identify Shoulder Pacemaker™. CMS continues to believe the mechanism of action of the Shoulder Pacemaker™ aligns with other neuromuscular electrical stimulation devices. However, the issue of whether the device has a lifetime of at least three years is still in question. The manufacturer initially stated in the application to CMS that the device has an expected lifetime of three years. However, the Shoulder Pacemaker’s™ User Manual, Home Version, provided to CMS as supporting documentation by the applicant, states the expected lifespan of the Shoulder Pacemaker™ device is two years. There are many ways to demonstrate lifetime durability of an entire device to CMS. For example, the manufacturer can provide standardized test results from an independent testing laboratory demonstrating that the device itself can last for at least 3 years. The applicant is welcome to submit a new HCPCS Level II coding application for a new HCPCS Level II code in a subsequent coding cycle if and when new information becomes available. The applicant could also apply for a code verification request through PDAC (Medicare Contractor for Pricing, Data Analysis and Coding of HCPCS Level II DMEPOS Codes) if they would like to be classified, for Medicare payment purposes, under an existing HCPCS Level II code.

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

RTsafe, 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.

Summary of Public Feedback

RTsafe, Inc., the manufacturer of this product, disagrees with CMS' published preliminary recommendation. Personalized PseudoPatient™ PV is an exact 3D-printed 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. According to the speaker, 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.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. We continue to believe Personalized PseudoPatient™ PV is not suitable for inclusion in the HCPCS Level II code set because it is used for a procedure and certain items are considered bundled into the facility payment. We have not identified a specific need for this device to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

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 American Medical Association (AMA) CPT® Editorial Panel, an application was approved to modify existing code (64590) and create a new HCPCS Level I code (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

Summary of Public Feedback

Bioventus®, the manufacturer of this product, requested a revision to CMS' published preliminary determination. The speaker requested that CMS revise the existing code language descriptor for L8683 to eliminate the term "radiofrequency." According to the speaker, updating the code descriptor as recommended more appropriately addresses both older technology which uses radiofrequency and newer technology that uses electric energy, such as Bioventus® StimRouter Neuromodulation System's External Pulse Transmitter (EPT). The speaker commented that even though the Bioventus® Clinician's Guide speaks to radiofrequency, that is specific to the communication between the Patient Programmer and the EPT, which is unrelated to the EPT transmitting electrical energy through the surface electrodes to the receiver. The speaker agreed from a functionally perspective the EPT is similar to L8683 that it is an external piece that powers an internal lead.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code L8683, "Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver" to describe Bioventus® Neuromodulation System External Pulse Transmitter.

According to the FDA's 510(k) clearance on February 22, 2022 (K211965) for StimRouter Neuromodulation System, the EPT device delivers a pulse frequency ranging from 1 to 200 Hz through the surface electrodes. This frequency range would be considered on the low or very low end of the radiofrequency spectrum but nevertheless seems to be appropriately described by the term radiofrequency.

Final Medicare Benefit Category Determination

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

Final 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 \$6,054.33.

The average fee schedule amount is the average of the 2023 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

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 American Medical Association (AMA) CPT® Editorial Panel, an application was approved to modify existing codes (64590) and create a new HCPCS Level I code (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

Summary of Public Feedback

Bioventus®, the manufacturer of this product, agreed CMS' published preliminary recommendation for the StimRouter Neuromodulation System's Patient Programmer.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

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

Final Medicare Benefit Category Determination

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

Final 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 \$1,304.12.

The average fee schedule amount is the average of the 2023 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

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 American Medical Association (AMA) CPT® Editorial Panel, an application was approved to modify existing code (64590) and create a new HCPCS Level I code (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 National Coverage Determination (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

Summary of Public Feedback

Bioventus®, the manufacturer of this product, agreed with CMS' published preliminary coding determination; however, disagreed with the proposed payment determination. The speaker agreed with CMS that a new code should be granted for the StimRouter Surface Electrode Patch (SEP). However, the speaker disagreed that the price mapping to A4595 is adequate. According to the speaker, the SEP is much more complex than A4595 in maintaining positional adherence of External Pulse Transmitter while simultaneously delivering external conduction of electrical energy in a uniform and consistent manner to power a surgically implanted lead. The speaker further explained that the quantity of SEPs required by patients who typically wear the SEP 6 hours per day is up to a 16 per month supply, while TENS electrodes, described by A4595, may only require a supply of up to 8 per month. The speaker recommended that CMS follow 42 CFR 414.238(c) to establish a fee schedule amount for the newly established code. As a supplement, Bioventus® included SEP pricing information.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to:

Establish a new HCPCS Level II code L8678, “Electrical stimulator supplies (external) for use with implantable neurostimulator, per month” to describe Bioventus® StimRouter Neuromodulation System’s Surface Electrode Patch.

Final Medicare Benefit Category Determination

Prosthetic Device

We are finalizing our preliminary benefit category determination that L8678 would fall under the Medicare benefit for prosthetic devices, per National Coverage Determination (NCD) 160.7 for Electrical Nerve Stimulators.

Final 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 final payment determination for code L8678, 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 applicant asserted in their oral and written comments that A4595 is not comparable to their SEPs because the two have different utilization parameters. For instance, the applicant mentioned that the quantity of the Bioventus® SR Neuromodulation System’s SEPs required by patients who typically wear the SEP 6 hours per day is up to 16 per month supply, while TENS electrodes described by A4595 may only require a supply of up to only 8 per month. However, we are unsure what CMS policy the applicant is referring to with regards to this specific monthly supply amount for A4595. We also note that HCPCS code A4595 has the following description: “electrical stimulator supplies, 2 lead, per month, (e.g., TENS, NMES).” The “e.g.” in this HCPCS descriptor denotes that TENS and Neuromuscular Electrical Stimulators (NMES) are examples of items these supplies are used with, meaning that TENS and NMES are not the only items used with this code. The components of the patch with the adhesive base to attach to the skin and the leads to allow for the transmitter to be attached is comparable to items that can be found under A4595. The composition, material properties, application, and disposability are all equivalent to items under A4595.

The average fee schedule amount for L8678 would be \$22.10.

The average fee schedule amount is the average of the 2023 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

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 Indicator = 00

Summary of Public Feedback

Novela Neurotechnologies, Inc., the manufacturer of this product, disagreed with CMS' published preliminary determination. According to the speaker, existing HCPCS Level II code E0746 does not adequately describe the SPEAC® System, its indications, or its capabilities. The SPEAC® System is an sEMG-based ambulatory system that continuously monitors and analyzes sEMG data to detect generalized tonic-clonic seizures (both primary and focal onset with secondary generalization) at home. The SPEAC® system provides physicians with a record of the users' sEMG history during the use of the system, allowing for seizure characterization and as appropriate changes to treatment management by the physicians. According to the speaker, other technologies currently reported under this code are vastly different in their mechanism of action, their patient population, and the conditions that these other devices are seeking to treat. The speaker commented that there is broad evidence to support the SPEAC® System and this underlying technology.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

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

The SPEAC® System is a surface electromyography (sEMG) recording, monitoring, and alerting system to be used as an adjunct to seizure monitoring during periods of rest. The system continuously records and stores sEMG data (and audio around detected events) for post-hoc review by physicians (or other trained healthcare professionals) for the characterization of seizure events. Neither the application nor the comments provided during or in response to the public meeting provided any compelling new evidence pointing to significant therapeutic distinction that would warrant new coding as opposed to using the previously established codes. The SPEAC® System is similar to those electromyography biofeedback devices within E0746.

Final Medicare Benefit Category Determination

There is not a benefit category under Medicare Part B for an electromyography (emg) device used in the home and, as such, it does not have a DMEPOS benefit category and is not payable. In accordance with Section 1842(s)(1)(B)(2) of the Social Security Act, payment for an electromyogram device is subject to carrier discretion under Medicare Part B. Upon review and implementation in 2001, it was set forth that Medicare does not cover

electromyogram devices under Medicare Part B and fee schedules were not established (66 FR 45174, CMS 1010-F).

Final 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 Indicator = 00

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.

Summary of Public Feedback

AppliedVR, Inc., the manufacturer of this product, urges CMS to establish a new unique HCPCS Level II code for the RelieVRx and recognize the RelieVRx as an item of durable medical equipment (DME). The RelieVRx was granted a breakthrough device designation, as a single, integrated medical device that uses durable equipment and proprietary treatment modules to reduce pain in individuals suffering from chronic lower back pain. According to the speaker, the FDA distinguishes between devices like the RelieVRx, which is an example of “Software in a Medical Device,” and devices that consist solely of “Software as a Medical Device,” which include the prescription digital therapeutics described by the already existing code A9291. Digital software-only tools described by A9291 do not involve an item of DME. The RelieVRx is intended to be used during an 8-week treatment program in the patient’s home. The 8-week program is a sequential set of immersive experiences with a mix of different components used in Cognitive Behavioral Therapy (CBT). These modules include pain education, diaphragmatic breathing practices (utilizing the attached breathing apparatus), pain distraction, gaining interceptive awareness, and mindfulness escapes. According to the speaker, clinical trials show statistically greater improvements in pain outcomes from use of the RelieVRx, with immersive VR, as compared to non-immersive interventions. The speaker commented that research shows that immersive therapies using virtual reality activate five regions of the brain and engage multiple neural systems. Written comments supported the speakers claim that the RelieVRx achieves better pain outcomes through a unique combination of hardware and software that overwhelms the brain’s sensory systems while delivering cognitive behavioral therapy-based concepts, routines, and coping mechanisms.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS’ published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the decision to:

Establish a new HCPCS Level II code E1905, “Virtual reality cognitive behavioral therapy device (cbt), including pre-programmed therapy software” to describe RelieVRx.

Final Medicare Benefit Category Determination

Durable Medical Equipment

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and in Medicare regulations at title 42 Code of Federal Regulations (CFR) section 414.202, and means equipment, furnished by a supplier or a home health agency that meets the five conditions listed in the below table. All five of these requirements must be met in order for equipment to be classified as DME. As shown below, RelieVRx meets all conditions and thus can be classified as DME.

Criteria Met?	Criteria in Definition of DME at 42 CFR 414.202
Yes	1. Can withstand repeated use.
Yes	2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
Yes	3. Is primarily and customarily used to serve a medical purpose.
Yes	4. Generally, is not useful to an individual in the absence of an illness or injury.
Yes	5. Is appropriate for use in the home.

For the RelieVRx, the medical software and the device on which it is housed are so integral to each other that we consider them to be one whole device, not software and a separate device. We consider RelieVRx to be one whole device for a few reasons, including because the software is locked to the device. In addition, the software cannot be used on any personal devices and no other non-medical software can be added to the device. Also, the software relies on the VR/immersive features of the device to deliver the benefit to the patient, and the device in turn has features that drive the effectiveness of the software. Specifically, the breathing apparatus on the headset impacts the algorithms played by the software. There are no personal devices, like computers or laptops, that can: (1) achieve the same affect with this software; or (2) interact with both the patient and the software algorithms the way that the RelieVRx does. Further, we note that FDA identified a special control (88 FR 983, January 6, 2023) that “the patient-contacting components of the device must be demonstrated to be biocompatible,” indicating that hardware and software are necessary components of the product. Because we consider RelieVRx to be a device, and because it meets the requirements for a device to be DME (see above table), we are issuing a final benefit category determination of DME.

Final Medicare Payment Determination

No determination. The payment determination for this item will be addressed at a subsequent HCPCS public meeting. We encourage AppliedVR to provide CMS with pricing information such as retail pricing information and invoices from commercial payers, the Veteran’s Administration, and State Medicaid Agencies.

At this time, the DME fee schedule amounts for this item would be established by the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240. We establish fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history in accordance with regulations at 42 CFR § 414.238. In particular, for new HCPCS codes for items and services without a fee schedule pricing history we use the existing fee schedule amounts for comparable items when these items 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. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, then we establish the fee schedule using supplier or commercial price lists. If the purchase price used in calculating the fee schedule amounts is greater than \$150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the purchase price used in calculating the fee schedule amounts is \$150 or less, then payment would be made on a rental or purchase basis in accordance with our regulations at 42 CFR 414.220.

Pricing Indicator = 46

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.

Summary of Public Feedback

Joint Active Systems (JAS), the manufacturer of this product, disagreed with CMS' published preliminary coding determination. According to the speaker, the JAS EZ Prefab Elbow turnbuckle device is an elbow orthosis, including forearm and arm cuffs, with adjustable position lock. The joints provide adjustable flexion and extension that enables the practitioner to set limits on flexion and extension while still allowing free motion of the elbow within those set limits. According to the speaker, PDAC, Medicare contractor for pricing, data analysis and coding of HCPCS Level II non-drug and non-biological products codes, responded to JAS' request that Medicare classifies stretching devices used to treat contractures and increase range of motion as durable medical equipment (DME), but did not provide a source of policy related to that statement. The speaker would like for CMS to either include "stretching devices" in the description of L3761 or for CMS to keep the same description of L3761 but provide instructions to the PDAC related to the JAS EZ Prefab Elbow PDAC application based on product description and features. According to the speaker, CMS should provide a regulatory source for PDAC's coding justification that stretching devices are classified as DME. The speaker would also like to receive confirmation that L3761 is the appropriate HCPCS Level II code for the JAS EZ Prefab Elbow.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. We have not identified a program operating need for Medicare or other payers to revise existing HCPCS Level II code L3761 to include "stretching devices" in the descriptor.

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.

Summary of Public Feedback

The American Association of Homecare provided a primary speaker that stated the rationale for the application is to expand the current 3 HCPCS codes to 19 codes to describe the universe of intermittent catheters (1,371 PDAC verified products) would address the program operating need to better differentiate between catheter types, features, and functions. According to the speakers and written comments, better aligning catheter selection with the coding system would:

1. Ensure patients receive the appropriate catheter;
2. Eliminate the need for non-Medicare payors to use modifiers/miscellaneous codes;
3. Allow better comparisons from one device to another; and
4. Result in better outcomes data that can lead to better care.

One speaker attested that the lack of transparency referred to in the application resides in the claims processing for intermittent catheters and the fulfillment of the actual catheter prescribed for a particular patient. Another speaker spoke on the inequity between patients of different socioeconomic classes. The higher socioeconomic group being able to pay out-of-pocket for whatever intermittent catheter they preferred and thus were able to remain compliant with catheterization five to seven times per day. The lower socioeconomic group were given less expensive and not clinically appropriate catheters, ones not specified on their prescriptions, resulting in increased pain and decreased compliance and thus worse outcomes. The assertion was that with more specific HCPCS codes this would allow for better demonstration of comorbidities, quality of life measures, and decreasing morbidity and mortality as it relates to the type of device dispensed.

CMS Final HCPCS Coding Decision

We would like to understand further how distinction among intermittent urinary catheters is clinically supported. The public comments state issues about decreasing morbidity and mortality related to particular devices. We assume this means that features of certain straight tipped catheters are leading to clinical improvement. However, we remain unclear on the evidence base that supports these claims. CMS is continuing to review the evidence base but we would welcome clinical evidence or clinical guidelines that help show these distinctions in prescribing behavior.

We also take seriously the statements that were made in the public feedback in regard to the Medicare program. For instance, Medicare beneficiaries, regardless of socioeconomic status,

should be receiving the appropriate catheter that is prescribed to them. Medicare DMEPOS suppliers must fill the physician's order as written. So, if the physician prescribes a specific brand or type of catheter, the supplier is expected to furnish that type of catheter. The supplier may discuss the issue with the physician to see if an alternative brand/type would work and the physician can then change the order. But, if the physician has provided a written order and does not amend the order, then the supplier would be expected to furnish that product to submit a claim to Medicare. If the supplier is not consulting the prescribing physician for any necessary changes, we recommend contacting CMS' Center for Program Integrity (CPI) to raise the concern.

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.

Summary of Public Feedback

The American Association of Homecare provided a primary speaker that stated the rationale for the application is to expand the current 3 HCPCS codes to 19 codes to describe the universe of intermittent catheters (1,371 PDAC verified products) would address the program operating need to better differentiate between catheter types, features, and functions. According to the speakers and written comments, better aligning catheter selection with the coding system would:

1. Ensure patients receive the appropriate catheter;
2. Eliminate the need for non-Medicare payors to use modifiers/miscellaneous codes;
3. Allow better comparisons from one device to another; and
4. Result in better outcomes data that can lead to better care.

One speaker attested that the lack of transparency referred to in the application resides in the claims processing for intermittent catheters and the fulfillment of the actual catheter prescribed for a particular patient. Another speaker spoke on the inequity between patients of different socioeconomic classes. The higher socioeconomic group being able to pay out-of-pocket for whatever intermittent catheter they preferred and thus were able to remain compliant with catheterization five to seven times per day. The lower socioeconomic group were given less expensive and not clinically appropriate catheters, ones not specified on their prescriptions, resulting in increased pain and decreased compliance and thus worse outcomes. The assertion was that with more specific HCPCS codes this would allow for better demonstration of comorbidities, quality of life measures, and decreasing morbidity and mortality as it relates to the type of device dispensed.

CMS Final HCPCS Coding Decision

We would like to understand further how distinction among intermittent urinary catheters is clinically supported. The public comments state issues about decreasing morbidity and mortality related to particular devices. We assume this means that features of certain straight tipped catheters are leading to clinical improvement. However, we remain unclear on the evidence base that supports these claims. CMS is continuing to review the evidence base but we would welcome clinical evidence or clinical guidelines that help show these distinctions in prescribing behavior.

We also take seriously the statements that were made in the public feedback in regard to the Medicare program. For instance, Medicare beneficiaries, regardless of socioeconomic status,

should be receiving the appropriate catheter that is prescribed to them. Medicare DMEPOS suppliers must fill the physician's order as written. So, if the physician prescribes a specific brand or type of catheter, the supplier is expected to furnish that type of catheter. The supplier may discuss the issue with the physician to see if an alternative brand/type would work and the physician can then change the order. But, if the physician has provided a written order and does not amend the order, then the supplier would be expected to furnish that product to submit a claim to Medicare. If the supplier is not consulting the prescribing physician for any necessary changes, we recommend contacting CMS' Center for Program Integrity (CPI) to raise the concern.

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.

Summary of Public Feedback

The American Association of Homecare provided a primary speaker that stated the rationale for the application is to expand the current 3 HCPCS codes to 19 codes to describe the universe of intermittent catheters (1,371 PDAC verified products) would address the program operating need to better differentiate between catheter types, features, and functions. According to the speakers and written comments, better aligning catheter selection with the coding system would:

1. Ensure patients receive the appropriate catheter;
2. Eliminate the need for non-Medicare payors to use modifiers/miscellaneous codes;
3. Allow better comparisons from one device to another; and
4. Result in better outcomes data that can lead to better care.

One speaker attested that the lack of transparency referred to in the application resides in the claims processing for intermittent catheters and the fulfillment of the actual catheter prescribed for a particular patient. Another speaker spoke on the inequity between patients of different socioeconomic classes. The higher socioeconomic group being able to pay out-of-pocket for whatever intermittent catheter they preferred and thus were able to remain compliant with catheterization five to seven times per day. The lower socioeconomic group were given less expensive and not clinically appropriate catheters, ones not specified on their prescriptions, resulting in increased pain and decreased compliance and thus worse outcomes. The assertion was that with more specific HCPCS codes this would allow for better demonstration of comorbidities, quality of life measures, and decreasing morbidity and mortality as it relates to the type of device dispensed.

CMS Final HCPCS Coding Decision

We would like to understand further how distinction among intermittent urinary catheters is clinically supported. The public comments state issues about decreasing morbidity and mortality related to particular devices. We assume this means that features of certain straight tipped catheters are leading to clinical improvement. However, we remain unclear on the evidence base that supports these claims. CMS is continuing to review the evidence base but we would welcome clinical evidence or clinical guidelines that help show these distinctions in prescribing behavior.

We also take seriously the statements that were made in the public feedback in regard to the Medicare program. For instance, Medicare beneficiaries, regardless of socioeconomic status, should be receiving the appropriate catheter that is prescribed to them. Medicare DMEPOS suppliers must fill the physician's order as written. So, if the physician prescribes a specific brand or type of catheter, the supplier is expected to furnish that type of catheter. The supplier may discuss the issue with the physician to see if an alternative brand/type would work and the physician can then change the order. But, if the physician has provided a written order and does not amend the order, then the supplier would be expected to furnish that product to submit a claim to Medicare. If the supplier is not consulting the prescribing physician for any necessary changes, we recommend contacting CMS' Center for Program Integrity (CPI) to raise the concern.

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

Summary of Public Feedback

Nu-Hope Laboratories, Inc., the manufacturer of this product, disagreed with CMS' published HCPCS preliminary recommendation to use existing HCPCS Level II code A4390, "Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each." The speaker commented that HCPCS A4390 code is for an ideally-created stoma on a flat abdominal surface with no scar tissue, creases or irregular contours and thus had no need for a custom fabricated pouch. Of which, most patients who have a stoma do not fit into this ideal situation. The speaker discussed how the custom fabricated ostomy pouches are made to order for an individual patient and required an assessment for its need by a qualified clinician that could include a patient's complications, their high consumption rate of pouches per month, and the irregularities of their stoma and surrounding skin. The customization includes varied depths of convexity, shapes, and opening shapes to provide adequate seal and avoid adverse effects and the time and materials needed to make each type of customized pouch increases as the complexity increases. However, the speaker noted that some of the materials used for the complexity level I pouches are prefabricated. Another speaker stated that the pouches are created by skilled technicians, using a combination of precise measurements, photos, and the alginate molded castings that are done by ostomy nurses. Additional commenters stated that the custom pouches made by Nu-Hope Laboratories afforded their patients with difficult to fit stomas or skin issues the ability to return to normal life where other pouches failed. In addition, one commenter stated that the A4390 pouches are mass produced and prefabricated for a more common stoma sizes that are symmetrical. It was acknowledged that the manufacturer has over 1,000 different models of products on the Product Classification List under A4390 currently.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4390, "Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each" to describe custom ostomy drainable pouches, complexity level 1.

The applicant requested new codes for multiple ostomy pouch items by levels of manufacturing processes. We believe that some extent of what is termed by the applicant as custom fabricated is an assembly of pre-fabricated features that are currently captured under existing HCPCS Level II codes. CMS is interested in knowing what features of the ostomy pouch are not currently covered under existing codes. The application cites a study that indicates that “up to half of ostomies are “problematic,” presenting management problems including skin irritation.” However, there was no supporting clinical evidence of such claim or information of clinical improvement for custom ostomy pouches. CMS would like to see further distinction of who would or who would not need a custom ostomy pouch.

HCPCS Level II code A4421, “Ostomy supply; miscellaneous” is available for billing an ostomy pouch furnished due to unusual circumstances and would be reviewed for coverage and payment after claims edits to determine if individual consideration for payment is warranted.

Final Medicare Benefit Category Determination

CMS is reaffirming its preliminary benefit category determination that the current Medicare policy and prior established benefit category determination for code A4390 apply to this item.

Final 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 \$12.82.

The average fee schedule amount is the average of the 2023 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

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

Summary of Public Feedback

Nu-Hope Laboratories, Inc., the manufacturer of this product, disagreed with CMS' published HCPCS preliminary recommendation to use existing HCPCS Level II code A4390, "Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each." The speaker commented that HCPCS A4390 code is for an ideally-created stoma on a flat abdominal surface with no scar tissue, creases or irregular contours and thus had no need for a custom fabricated pouch. Of which, most patients who have a stoma do not fit into this ideal situation. The speaker discussed how the custom fabricated ostomy pouches are made to order for an individual patient and required an assessment for its need by a qualified clinician that could include a patient's complications, their high consumption rate of pouches per month, and the irregularities of their stoma and surrounding skin. The customization includes varied depths of convexity, shapes, and opening shapes to provide adequate seal and avoid adverse effects and the time and materials needed to make each type of customized pouch increases as the complexity increases. Another speaker stated that the pouches are created by skilled technicians, using a combination of precise measurements, photos, and the alginate molded castings that are done by ostomy nurses. Additional commenters stated that the custom pouches made by Nu-Hope Laboratories afforded their patients with difficult to fit stomas or skin issues the ability to return to normal life where other pouches failed. In addition, one commenter stated that the A4390 pouches are mass produced and prefabricated for a more common stoma sizes that are symmetrical. It was acknowledged that the manufacturer has over 1,000 different models of products on the Product Classification List under A4390 currently.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4390, "Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each" to describe custom ostomy drainable pouches, complexity level 2.

The applicant requested new codes for multiple ostomy pouch items by levels of manufacturing processes. We believe that some extent of what is termed by the applicant as custom fabricated is an assembly of pre-fabricated features that are currently captured under existing HCPCS Level II codes. CMS is interested in knowing what features of the ostomy pouch are not currently covered under existing codes. The application cites a study that indicates that “up to half of ostomies are “problematic,” presenting management problems including skin irritation.” However, there was no supporting clinical evidence of such claim or information of clinical improvement for custom ostomy pouches. CMS would like to see further distinction of who would or who would not need a custom ostomy pouch.

HCPCS Level II code A4421, “Ostomy supply; miscellaneous” is available for billing an ostomy pouch furnished due to unusual circumstances and will be reviewed for coverage and payment after claims edits to determine if individual consideration for payment is warranted.

Final Medicare Benefit Category Determination

CMS is reaffirming its preliminary benefit category determination that the current Medicare policy and prior established benefit category determination for code A4390 apply to this item.

Final 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 \$12.82.

The average fee schedule amount is the average of the 2023 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

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

Summary of Public Feedback

Nu-Hope Laboratories, Inc., the manufacturer of this product, disagreed with CMS' published HCPCS preliminary recommendation to use existing HCPCS Level II code A4390, "Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each." The speaker commented that HCPCS A4390 code is for an ideally-created stoma on a flat abdominal surface with no scar tissue, creases or irregular contours and thus had no need for a custom fabricated pouch. Of which, most patients who have a stoma do not fit into this ideal situation. The speaker discussed how the custom fabricated ostomy pouches are made to order for an individual patient and required an assessment for its need by a qualified clinician that could include a patient's complications, their high consumption rate of pouches per month, and the irregularities of their stoma and surrounding skin. The customization includes varied depths of convexity, shapes, and opening shapes to provide adequate seal and avoid adverse effects and the time and materials needed to make each type of customized pouch increases as the complexity increases. Another speaker stated that the pouches are created by skilled technicians, using a combination of precise measurements, photos, and the alginate molded castings that are done by ostomy nurses. Additional commenters stated that the custom pouches made by Nu-Hope Laboratories afforded their patients with difficult to fit stomas or skin issues the ability to return to normal life where other pouches failed. In addition, one commenter stated that the A4390 pouches are mass produced and prefabricated for a more common stoma sizes that are symmetrical. It was acknowledged that the manufacturer has over 1,000 different models of products on the Product Classification List under A4390 currently.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4390, "Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each" to describe custom ostomy drainable pouches, complexity level 3.

The applicant requested new codes for multiple ostomy pouch items by levels of manufacturing processes. We believe that some extent of what is termed by the applicant as custom fabricated is an assembly of pre-fabricated features that are currently captured under existing HCPCS Level II codes. CMS is interested in knowing what features of the ostomy pouch are not currently covered under existing codes. The application cites a study that indicates that “up to half of ostomies are “problematic,” presenting management problems including skin irritation.” However, there was no supporting clinical evidence of such claim or information of clinical improvement for custom ostomy pouches. CMS would like to see further distinction of who would or who would not need a custom ostomy pouch.

HCPCS Level II code A4421, “Ostomy supply; miscellaneous” is available for billing an ostomy pouch furnished due to unusual circumstances and will be reviewed for coverage and payment after claims edits to determine if individual consideration for payment is warranted.

Final Medicare Benefit Category Determination

CMS is reaffirming its preliminary benefit category determination that the current Medicare policy and prior established benefit category determination for code A4390 apply to this item.

Final 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 \$12.82.

The average fee schedule amount is the average of the 2023 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

Exersides™ Refrains™ System - HCP211227F8TPL

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Exersides™ Refrains™ 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™ Refrains™ System. The Exersides™ Refrains™ System is a class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. The Exersides™ Refrains™ 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™ Refrains™ 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™ Refrains™ 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™ Refrains™ 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.

Summary of Public Feedback

Healthy Design, the manufacturer of this product, disagreed with CMS' HCPCS preliminary recommendation from B1 2022 to use existing HCPCS Level II code E0710, "Restraints, any type (body, chest, wrist or ankle)" and A9300, "Exercise equipment" to describe the Exersides™ Refrains™ System. According to the speaker, the Exersides™ Refrains™ System is a patient protective activity product that minimizes the need for restraint and allows for upper limb activity for uncoordinated or cognitively impaired adults or children who require safety in order to engage in upper limb mobility. This device is not intended for patients who predominantly require restraint or exercise equipment. The Exersides™ Refrains™ System allows for total range of motion in the shoulder, wrist and fingers. The speaker mentioned this device is useful for those patients with feeding tubes or IVs to be able to move without entanglement. The speaker commented that soft surgical arm supports or arm board devices are intended for cognitively intact patients and unsupervised confused, dementia, or delirium patients will become partially dislodged; however, the Exersides™ Refrains™ System will allow for a patient to move without entanglement. When comparing patient positioning devices to the Exersides™ Refrains™ System, patient positioning devices are intended for immobilization and not intended for an unattended actively confused patient. The Exersides™ Refrains™ System has three points of containment for tubes and lines to allow for movement and securement. The speaker commented that the pilot study, which was conducted only in a clinical setting, showed less sedation, better agitation scores and more time moving and interacting. The phase one study showed there were no device-related safety concerns. The speaker mentioned that the satisfaction form showed that 75% agreed or strongly agreed that the Exersides™ Refrains™ System was preferable and more humane than soft wrist restraints.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the decision to:

Establish a new HCPCS Level II code E0711, "Upper extremity medical tubing/lines enclosure or covering device, restricts elbow range of motion" to describe the Exersides™ Refrains™ System.

Final Medicare Benefit Category Determination

No DMEPOS benefit category.

There is not a benefit category under Medicare Part B for safety equipment used in the home and, as such, the Exersides™ Refrains™ System does not have a DMEPOS benefit category.

Final Medicare Payment Determination

Pricing Indicator = 00

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.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary HCPCS Level II coding recommendation.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code K1009 will be established using the 2022 price of \$3,495, which results in 2023 capped rental payments of \$2399.04 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. As such, the capped rental fee schedule amount for months 1 through 3 is equal to 10 percent of the purchase price, or approximately \$228.48, and the capped rental fee schedule amount for months 4 through 13 is equal to 7.5 percent of the purchase price, or approximately \$171.36.

Pricing Indicator = 36

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.

Summary of Public Feedback

Cala Health Inc., the manufacturer of the supplies used with the Cala Trio™ system, disagreed with the preliminary payment determination, stating that the supplies are not comparable to A4595 in function/intended use or in physical, mechanical, or electrical components. A former consultant for Cala Health, Inc. supported the position that A4595 is not comparable to the supplies. The speakers stated that no current HCPCS code is comparable to the supplies and that CMS should instead use the gap-fill technique to establish pricing.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to:

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".

Final Medicare Payment Determination

Based on the information provided in the public meeting and our further analysis of the Cala Trio™ wrist band as compared to other products in HCPCS code A4595, we agree that Cala Trio™ is a unique product, with a unique combination of features that comprise their electrodes to treat a patient population that does not have access to any other FDA-approved product like it on the market at this time (although some similar products are currently under development). Therefore, the final determination for the fee schedule amounts for HCPCS code K1019 will be established using the current price of \$750. In accordance with regulations at 42 CFR 414.238(c), the current price of \$750 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 2023 using the covered item update factors at section 1834(a)(14) of the Social Security Act, resulting in a 2023 price of approximately \$491.63 for a 3-month supply.

Pricing Indicator = 34

Note: As stated during the public meeting, the preliminary payment determination mistakenly stated that the Cala Trio™ recharging base station falls under HCPCS code K1019. Payment for the recharging base station is already included in the payment for the Cala Trio™ system, K1018. The inclusion of the recharging base station in K1018 (and not in K1019) is clearly supported by the purchase orders and invoices we have previously received from the Veteran's Administration, in which the Cala Trio™ simulator and base station are a combined unit price and the Cala Trio™ band is listed as a separate unit price.

Lunoa System (NightBalance) – 19.118

Topic/Issue

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 Social Security 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 Indicator = 36

Summary of Public Feedback

The applicant disagreed with Medicare’s preliminary payment determination. While the applicant agreed that CMS should use the gap-fill process to calculate the fee schedule amount for code K1001, the applicant was concerned that the data CMS used to arrive at a preliminary payment determination of \$529.99 does not accurately reflect the commercial price of the NightBalance device. The applicant was concerned that the sampling method and sources – some of which the applicant says no longer sell the NightBalance or are selling what the applicant considers to be an obsolete version of the device – fail to provide accurate, objective, and reliable data for CMS to establish a national Medicare fee schedule amount for the NightBalance. The applicant provided copies of sample invoices from the Philips Respironics store website, which showed prices of \$849.99, to which the applicant asserted that the commercial price of the initial NightBalance kit is not simply a manufacturer suggested retail price (MSRP) – it is the actual commercial price at which Philips sold the NightBalance devices to consumers from 2020 through 2022. The applicant also noted that the term “supplier” is defined by Medicare regulation at § 400.202, and “means a physician or other practitioner, or an entity other than a provider, that furnishes health care services

¹ <https://www.sleepdirect.com/cpap-machines/philips-respironics-nightbalance-lunooa-positional-sleep-therapy-device-package>

² <https://www.thecpapshop.com/philips-nightbalance-lunooa>

³ <https://www.directhomemedical.com/nightbalance-lunooa-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-lunooa-positional-sleep-therapy-device-package>

under Medicare.” The applicant asserted that under this definition, online retail prices posted by entities that do not provide services or items “under Medicare” (i.e., entities that do not qualify as suppliers) would not qualify as supplier price lists and should not be used by CMS to establish commercial pricing. Therefore, the applicant believed the prices published on the websites cited by CMS do not qualify as supplier price lists, and they should be discarded from CMS’ payment determination for code K1001.

Final Medicare Payment Determination

We thank the applicant for their input on our preliminary payment determination. The preliminary payment determination is based on internet retail prices, which are retail prices that can be used for gap-filling, per our regulation at § 414.238. We said in our 2019 final rule that we and our contractors have used internet retail prices in the past in addition to catalog prices, as well as wholesale prices plus a retail price mark up, and on one occasion hospital invoices plus a 10 percent markup as a source for commercial pricing information (84 FR 60730). Thus, we have a history of using internet prices to price new DMEPOS items and services. The gap-filling regulation at § 414.238 did not propose to change how we have used internet prices and other retail prices in the past. As such, the way in which we determined the payment determination for this item is consistent with how we have used this gap-filling option in the past. We note that our gap-filling process is different than the inherent reasonableness process, which outlines a distinct data collection methodology at § 405.502(g)(4). We also can confirm that the commercial prices we collected for the NightBalance’s preliminary payment determination were active at the time of our data collection in September 2022.

We will be finalizing our preliminary payment determination based on the 2022 median price of \$529.99. The 2023 average capped rental fee schedule amount for K1001 would be approximately \$34.65 for months 1 through 3 and approximately \$25.99 for months 4 through 13, which would result in payment of approximately \$363.85 over these 13 months.

Additionally, although we requested in our preliminary payment determination for the applicant to send us pricing information from private payers and/or the Veterans Administration (VA), we did not receive such information from the applicant.

Pricing Indicator = 36

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 ($\$567.97 \div 60$).

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

Summary of Public Feedback

The applicant agreed with CMS’ preliminary payment determination for HCPCS code K1006, but disagreed with CMS’ preliminary payment determination for code AXXXX. For code AXXXX, the applicant stated that PureWick™ is not indicated for male or pediatric patients, and the indications for use are vastly different. Furthermore, the applicant stated that the supplies associated with HCPCS E0600 are not similar in terms of use case or frequency. The applicant said it is arbitrary to base supply payments on unspecified suction pump supplies from 1993 when precise Medicare crosswalks verified by the PDAC in 2020 are available, and that CGS and Noridian paid for PureWick™ re-ordered supplies under A4328 and A5102 in 2021. The applicant also said that supplies included in E0600 do not directly relate to the type/quantity of supplies used with K1006. The applicant also said that adoption of this payment would result in payment that is a fraction of the appropriate amount for these supplies and would endanger beneficiary access. The applicant requested that CMS base

payment for AXXXX on the following three HCPCS codes: A4328 for the catheters, A5102 for the canisters, and A9999 for the tubing, resulting in a price of around \$399.43.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the decision to:

Establish a new HCPCS Level II code A6590, "External urinary catheters; disposable, with wicking material, for use with suction pump, per month" for the monthly external catheter supplies used with the K1006 device. Existing HCPCS Level II codes A7001, "Canister, non-disposable, used with suction pump, each," and A7002, "Tubing, used with suction pump, each," describe the canister and tubing used with the K1006 device.

Final Medicare Benefit Category Determination

CMS determined that the PureWick™ Urine Collection System is durable medical equipment and published that determination on September 26, 2022. Chapter 15, section 110.3 of the Medicare Benefit Policy Manual (CMS Pub.100-02) states that payment may be made for supplies that are necessary for the effective use of durable medical equipment.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code K1006 will be established using the fee schedule amounts for code E0600, the code used for all portable home suction pumps in 1986 and 1987, in accordance with the continuity of pricing rules at 42 CFR 414.236. Consistent with the preliminary decision discussion, the capped rental fee schedule amounts for code E0600 will be mapped to code K1006. The average 2023 rental amount for K1006 will be approximately \$58.79 for months 1-3 and approximately \$44.09 for months 4-13.

Based on the input that the supplies included under E0600 are not representative of the current product, CMS is revising the methodology used to calculate the fee schedule for the PureWick™ supplies in the preliminary payment determination. The fee schedule amounts for the external catheter HCPCS code A6590, "External urinary catheters; disposable, with wicking material, for use with suction pump, per month" will be established using pricing for HCPCS code A4328 "Female external urinary collection device; pouch, each." Specifically, fees for A6590 will be established using the fees for code A4328 (on average approximately \$13.50 for 2023) multiplied by 30 units for a monthly supply. The average 2023 monthly amount for A6590 would be approximately \$405.00.

We agree with the applicant that the PureWick™ external catheters are comparable to code A4328. The PureWick™ external catheters and devices under A4328 are external, non-invasive, single-use urine collection devices that are used as a conduit to funnel urine away from the body. The types of materials and design can vary under A4328 and can include materials such as silicone, plastic, or conical shapes. Like the PureWick™ catheter, products under A4328 are designed for use in the periurethral area. Below is a comparability table illustrating the comparison of items under code A4328 and those in the PureWick™ system.

	A4328	PureWick™ External Catheter
Physical Components	External Urine Collection Device Catheter connects to urine drainage bag/bottle Can consist of non-latex material/tubing in pouch type/funnel shape. May use adhesive to attach.	External Urine Collection Device Catheter connects to collection canister Consists of non-latex material tubing and soft flexible wicking material (gauze).
Mechanical Components	NA	NA
Electrical Components	NA	NA
Function and Intended Use	Non-invasive means to manage female urinary incontinence Not used with suction pump	Non-invasive means to manage female urinary incontinence Supply/accessory used with & necessary for the effective use of a suction pump
Additional Aspects and Features	Single-use external catheters- May use 1 per day	Single-use 8-12 hours external catheter – May use 1 per day

The payment rules and pricing associated with the existing code A7001 apply to the canister, if covered. The current average 2023 fee schedule amount for A7001⁶ is \$41.84. The payment rules and pricing associated with existing code A7002 apply to the tubing used with a K1006 device, if covered. The current average 2023 fee schedule amount for A7002 is \$4.78.

K1006 - Pricing Indicator = 36; A6590 - Pricing Indicator = 34; A7001 & A7002 - Pricing Indicator = 32

⁶ Revised March 28, 2023 to revise the HCPCS Level II alpha numeric.

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

Summary of Public Feedback

Ur24Technology, Inc., the manufacturer of this device, disagreed with CMS' HCPCS preliminary recommendation to use existing HCPCS Level II code K1006, "Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system" to describe the suction or the aspiration pump and partially agreed to establishing a new HCPCS Level II code AXXXX, "Supplies and accessories for home urinary suction pump, per month". According to the speaker, existing HCPCS code E0600 is a better descriptor for the pump utilized with this product as it is primarily an aspirator pump and was modified and registered with the FDA for urine extraction. They also commented that the device retailed for approximately \$129 and they were hoping for at least an 80% of retail reimbursement rate.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the decision to:

Assign HCPCS Level II code K1006, "Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system" to describe the suction or the aspiration pump. Also, establish a new HCPCS Level II code A6591, "External urinary catheter; non-disposable, for use with suction pump, per month" for the monthly external catheter supplies for the Ur24T.

Existing HCPCS Level II codes A7001, "Canister, non-disposable, used with suction pump, each," and A7002, "Tubing, used with suction pump, each," describe the canister and tubing used with the K1006 device.

The applicant requested during the public meeting to be coded under E0600, "Respiratory suction pump, home model, portable or stationary, electric." However, Ur24T is not a respiratory pump, but a suction pump used for urine collection.

Final Medicare Benefit Category Determination

We did not receive feedback on our preliminary benefit category determination for the Ur24T during the public meeting, and we did not receive written comments. We will be finalizing our preliminary benefit category determination, which 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.

Final Medicare Payment Determination

We received feedback on our preliminary payment determination for the Ur24T during the public meeting. The applicant disagreed with CMS' preliminary payment determination and felt that their retail price should be used to develop the fee schedule amounts for the urinary suction pump supplies and accessories. The applicant also said their product needs a pump to pull the urine out, and that it is fine to use E0600 as part of its payment determination.

We thank the applicant for their input regarding payment for the urinary suction pump supplies and accessories. After consideration of the comments we received on Ur24T as well as on the PureWick™ application (20.078), we are revising our preliminary decision and will be establishing a monthly allowance of approximately \$84.58 for these types of catheters (A6591) based on current retail pricing for the products since we have not identified a comparable item for this Ur24T product. For example, the below chart compares the female Ur24T catheter against existing code A4328.

	A4328	Ur24T Female External Catheter
Physical Components	External Urine Collection Device Catheter connects to urine drainage bag/bottle Can consist of non-latex material/tubing in pouch type/funnel shape. May use adhesive to attach	External Urine Collection Device Catheter connects to collection canister Consists of non-latex, non-adhesive, soft rubber material in a tubular shape
Mechanical Components	N/A	N/A
Electrical Components	N/A	N/A
Function and Intended Use	Non-invasive means to manage female urinary incontinence Not used with a suction pump	Suction pump accessory used to void the bladder Supply/Accessory used with & necessary for the effective use of a suction pump
Additional Aspects and Features	Single-use external catheters- May use 1 per day	Reusable for 30 days- May use 1 per month

We have determined that the Ur24T female catheters are not comparable to A4328 due to product differences found when comparing physical componentry, function and intended use as well as additional features. On the last comparability feature, the chart above illustrates that the Ur24T catheters are reusable with an expected life of at least 30 days compared to the single use nature of products under A4328.

Based on this determination, the fee schedule amounts for HCPCS code A6591 will be established using the current internet retail price of \$129 for male and female Ur24T catheters.⁷ In accordance with regulations at 42 CFR 414.238(c), the current price of \$129 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 2023 using the covered item update factors at section 1834(a)(14) of the Social Security Act, resulting in a 2023 price of approximately \$84.58.

A monthly payment using the new, separate A6591 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; A6591 - Pricing Indicator = 34

⁷ <https://shop.demetech.us/collections/ur24>

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 (lumens) 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

Summary of Public Feedback

Vesiflo, the manufacturer of this product, disagreed with some of CMS’ published preliminary recommendation. The speaker agreed with the benefit category determination as a prosthetic device, however, disagree with the proposed new code language and payment determination. The inFlow™ System is a device that actively empties the bladder. The device is inserted into the urethra that contains a small magnet attached to two rotors that, when activated by a handheld device (the Activator) that contains a large magnet, spins to create a pump that empties the bladder at a normal flow rate. According to the speaker, clean intermittent catheterization (CIC) requires insertion of tubing 4 to 6 times per day (approximately 200 per month) and usually allows urine to be released while standing up over the toilet. However, the inFlow™ System is inserted once every 29 days and allows for the female to release urine while sitting on the toilet. According to the speaker, being CMS proposed a new A code instead of a L code, they recommend revising the proposed description to include the term “prosthetic.” Also, the speaker requested to clarify that the inFlow™ System has a valve-pump and not just a valve. According to the speaker, a valve cannot provide the turbulent evacuation of urine. The speaker commented that the Activator does not need to say patient inserted, as the Activator is not inserted. According to the speaker, CMS has stated there is no weight or prioritization on the comparability analysis, as such, they still would recommend that the inFlow™ System is comparable to the maximum allowable amount under A4351. According to the speaker, devices that fall under A4344 are less comparable to the inFlow™ System than those under A4351. However, the speaker agreed with CMS’ pricing methodology for the Activator.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS’ published preliminary recommendation. Based on the information provided in the application and after

consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the decision to:

Establish the following two new HCPCS Level II codes:

1. A4341, “Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each”
2. A4342, “Accessories for patient inserted indwelling intraurethral drainage device with valve, replacement only, each”

The assignment of an A code is consistent with the assignment of code numbers for other urological items. The HCPCS Level II code set is a national code set for all insurers. Other payers might not agree or have the same definitions as CMS related to durable medical equipment or prosthetic devices. As such, we are not adding the word prosthetic into the code descriptors. For Medicare, the patient inserted inFlow™ System will be defined in policy as a prosthetic device. The inFlow™ System contains a small magnet attached to two rotors that, when activated by the Activator that contains a large magnet, spins to create a pump that empties the bladder at a normal flow rate. The pump effect is created as a result of the rotors and magnets. The inFlow™ System does not physically contain an active pump. As such, CMS does not agree with adding valve-pump to the code language descriptors. Patient inserted implies patient or caregiver. The language limitation here is intended to describe patient or caregiver inserted instead of physician (professional) inserted.

Final Medicare Benefit Category Determination

Prosthetic Device

Final Medicare Payment Determination

For code A4342, “Accessories for indwelling intraurethral drainage device with valve, patient inserted, replacement only, each”, finalize preliminary determination based on the current price of \$1,250, resulting in a 2023 average fee schedule amount of approximately \$819.36.

For code A4341, “Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each”, we still contend that there are no comparable HCPCS codes and that gap filling is the more appropriate approach for pricing of this device. The final determination is to deflate the current price of \$495 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 2023 using the covered item update factors at section 1834(a)(14) of the Social Security Act. As a result, the 2023 average fee schedule amount would be approximately \$324.49.

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. In the case of HCPCS Code A4351, which public meeting speakers

indicated they believe is comparable to the inFlow™ device, we conclude it is not comparable to 3 of 4 applicable components, namely the physical and mechanical components, and additional features. Also, the manufacturer is requesting payment be calculated using the maximum allowable number of intermittent catheters per month (200); however, intermittent catheters are changed multiple times a day whereas the Vesiflo catheter is changed only once a month. We believe it is inappropriate to say the cost of this urological device is comparable to 200 catheters when only one will be used. The below table summarizes our conclusion based on the points discussed during the public meeting.

	A4351	inFlow™ Female Intraurethral Valve-Pump
Physical Components	Straight tip Material components can consist of latex, silicone, Teflon, or equivalent Urethral insert	Six flexible “fins” on distal end Insert housed in silicone Urethral insert Applicator to help with insertion (disposable introducer)
Mechanical Components	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	NA	NA
Function and Intended Use	Aid in treating permanent 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 Single use (up to 200 allowable per month)	Inserted once per month Single-use (lasts 29 days) Voiding is controlled by patient

The average fee schedule amount is the average of the 2023 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.

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

Pricing Indicator = 37

Appendix A: 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).