



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

First Biannual (B1), 2023 HCPCS Coding Cycle

This document presents a summary of each HCPCS code application and CMS' coding decision for each application processed in CMS' First Biannual 2023 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/DMEPOS-Fee-Schedule>.

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 October 1, 2023, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the October 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>.

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Traditional Healing Services - HCP22082337YAR

Topic/Issue

Request to establish a new HCPCS Level II code to identify traditional healing services.

Applicant's suggested language: XXXXX, "Traditional healing services"

Summary of Applicant's Submission

Blue Cross Blue Shield of Minnesota, doing business as Blue Plus (serving the Medicaid and Dual eligible populations in Minnesota), submitted a request to establish a new HCPCS Level II code to identify traditional healing services. According to the applicant, this new code will be used in Minnesota for Tribal Members to receive and bill the health plan for traditional healing services. According to the applicant, this code will be used initially for programs including Medicaid and dual-eligible members. Types of services that would be included in this code would include but not be limited to smudging, storytelling/healing circles, or sweat lodges and would expand to other traditional healing services in the future. According to the applicant, there are no codes already in place that fit this description.

CMS Preliminary HCPCS Coding Recommendation

CMS welcomes public comments from Tribal members, State Medicaid agencies, payers, and other interested parties regarding the two considerations described below:

1. Should traditional healing services be included in the HCPCS Level II code set for electronic claims processing requirements according to the current transaction standards of the Health Insurance Portability and Accountability Act (HIPAA)?

In 2000, the HCPCS Level II codes were established by CMS regulations to implement the HIPAA requirement for a standardized coding system to describe and identify health care, equipment, and supplies that are not identified by the HCPCS Level I, Current Procedural Terminology (CPT®) codes in electronic transactions. Most claims are submitted electronically using HCPCS codes to insurers using various bill types, such as an 837P bill type. This means that a traditional healing service, when covered and paid, would most likely be electronically submitted to a payer, such as Blue Cross Blue Shield of Minnesota, using a standardized claim form.

CMS also welcomes comments discussing whether it may be more appropriate for traditional healing services to not be described by a HCPCS code, but rather for services to continue to engage with each payer directly in an approach that is more tailored for all involved.

2. How general should the suggested language be for a HCPCS Level II code?

Traditional healing services are recognized by the Indian Healthcare Improvement Act, but there is no statutory definition for traditional healing services. If CMS was to create a HCPCS Level II code, CMS welcomes comments about the code descriptor language. Is the suggested code description of "Traditional healing services" too broad? Should CMS consider developing tiers of codes? For instance, CMS might

designate one code as “Traditional healing services, tier 1” and another code as “Traditional healing services, tier 2”. Payers could then indicate with billing instructions which code is appropriate for a particular traditional healing service that is covered and payable by the payer.

Summary of Public Feedback

The comment during the public meeting and from the Tribal Technical Advisory Group (TTAG) consultation, which was held on June 14th, 2023, resulted in varied responses to our questions in the preliminary recommendation. In general, all commenters emphasized the need to consider the diverse healing practices amongst the 574 federally-recognized tribes and many more state-recognized tribes. Many commenters agreed that one broad code describing “traditional healing services” is sufficient, while other commenters suggested the need to more closely consider multiple codes for these services. Some commenters also stated that no code is needed at all.

CMS Final HCPCS Coding Decision

Based on the information provided in the application and after consideration of the comments we received, CMS believes additional time is needed to allow for further review and discussion around coding traditional healing services. As a result, CMS is deferring this application to a subsequent coding cycle. We will be gathering additional information at a forthcoming tribal meeting and intend to issue a final determination following that discussion.

Coordinated Specialty Care - HCP2212301T8X3

Topic/Issue

Request to establish a new HCPCS Level II code to identify Coordinated Specialty Care.

Applicant's suggested language: XXXXX, “Coordinated specialty care is an evidence based service delivered by a multidisciplinary team to individuals experiencing a first episode of psychosis”

Summary of Applicant’s Submission

The National Association of State Mental Health Programs submitted a request to establish a new HCPCS Level II code to identify Coordinated Specialty Care for early or first episode of psychosis (hereafter referred to as CSC). CSC is delivered by a multi-disciplinary team to individuals in the earliest phase of a psychotic illness with the goal of avoiding long-term disability and other costs associated with severe mental health conditions. CSC has been available internationally for several years and in the US for more than 14 years. Following completion of the National Institute of Mental Health-sponsored multi-site Recovery After an Initial Schizophrenia Episode trial, Congress earmarked new funding in the mental health block grant (MHBG) to be provided to the states to stimulate the development of this evidence-based model of care nationally. According to the applicant, while Medicaid funds and some commercial insurers have been billed for individual components of CSC, key components of CSC, such as outreach and engagement, are not captured by existing codes. According to the applicant, providers of CSC have utilized braided funding approaches that involve some combination of the MHBG funds, Medicaid funds, some commercial insurance funds, other state and local funding, as well as philanthropic and other grant dollars to support CSC treatment. This approach is variable by state and region. In addition, much of this braided funding is from discretionary sources and therefore subject to yearly appropriations. According to the applicant, lack of a recognized code specifically developed for CSC has impeded CSC programs’ ability to bill insurers for the full service and to expand the coverage of this treatment to other individuals in need. According to the applicant, use of discretionary funds threatens the sustainability of the programs as well as limits the accessibility of CSC treatment since these funds are inadequate to meet the population need. According to the applicant, it has been estimated that 52 percent of costs associated with adequate implementation of CSC is not covered by existing codes/billing mechanisms. According to the applicant, without adequate, stable reimbursement, the sustainability – and the associated personal, societal, and financial costs – will continue to be at significant risk. According to the applicant, given the importance of CSC for staving off the lifelong disability that often accompanies psychotic illnesses, appropriate codes and sustainable insurance payments are critically needed.

CMS Preliminary HCPCS Coding Recommendation

We are open to establishing a new code but would like feedback on whether there is overlap with existing HCPCS Level I, Current Procedural Terminology (CPT®) codes and HCPCS Level II codes. We welcome information from the applicant and other insurers, especially individual state Medicaid agencies, to describe how they would approach a unique HCPCS Level II code to identify CSC.

For instance, we are currently aware of many HCPCS Level I CPT® codes and HCPCS Level II codes that describe collaborative psychological and behavioral health care services for medical and administrative activity matching such as evaluation, peer specialty services, individual/family/group therapy, and principal care management. Some example codes include, but are not limited to, CPT® codes 90832, 90834, 90837, 90853, 90846, 99212-99215, 99424-99427, 99484, 99492-99494, and HCPCS Level II codes G0323, G2214, H0036, H0038, H2023, H2024, T1016, T1024, T2022, and T2023. We believe these and other existing codes can be utilized to describe certain coordinated specialty care in different ways. While the applicant suggests that establishing one unique code to recognize coordinated specialty care may be easier for industry tracking purposes, we have observed that when multiple parties are involved in providing aspects of care - particularly when the care includes clinical professionals who customarily bill for services using CPT® codes like 90832 or evaluation and management service codes - that bundled codes can be complex to administer for the multiple parties involved.

More specifically, would payers continue to use some or all of these codes and also a code to identify CSC? If so, should a code for CSC be less universal or “bundled” in its description? If the applicant’s suggested description is adopted, would the expectation be that payers describe when to use the code for CSC and when other CPT® codes may be used concurrently for the same patient during a first episode of psychosis?

We welcome comments from all interested parties, including state Medicaid agencies and other payers, regarding the request for one bundled code to identify CSC or suggested code language descriptor(s) that would be most useful.

Summary of Public Feedback

The National Association of State Mental Health Programs, the applicant, responded to CMS’ published preliminary HCPCS coding recommendation by providing answers to the questions that CMS presented. The commenters generally stated that a unique HCPCS Level II code to identify team-based CSC would help to ensure increased access for individuals with early psychosis and create a streamlined billing experience for insurers and administrators. Many commenters stated that a team-based code would be better utilized by multidisciplinary clinics to identify the entire coordinated service consistent with each payer’s billing guidance. The comments suggested that establishing a new code would also enable public and private insurers to more readily identify CSC in their claims data, facilitate research across the various payers to identify the use of CSC in larger databases, and measure the long-term outcomes and effectiveness of this team-based service.

The commenters explained that some public insurers use various combinations of existing codes, such as 90832, H0036, H0038, H0047, T1024, T2022, and T2023, to partially identify services within the CSC model. Many comments stated that while existing codes could be billed for a portion of the provided services such as psychotherapy and medication management, most of these codes are also being used by insurers for other services. According to the comments, the existing codes also do not capture other non-clinical services offered by the CSC team such as education and employment support for the patients. According to the speakers, some public insurers currently use a single code to identify the entire CSC team, while other insurers may also use modifiers or “shadow claims” to further identify services provided by certain practitioners.

Some commenters suggested two HCPCS codes to describe both the monthly and individual encounters. According to the speakers, a monthly case rate is commonly used, but the need for services may vary over time; so, a separate code for an individual encounter rate is helpful when a patient does not meet the minimum requirements to bill a monthly rate. The speakers explained that some insurers may prefer to use only one code for each encounter and may describe each encounter with specific time increments; but the speakers also suggested that existing modifiers would be sufficient for the time increments. The speakers reiterated that two codes for the monthly and individual encounters will allow greater flexibility in the application of various insurance billing policies as well as transparency for the integrity of claims data.

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 received, CMS is finalizing the decision to:

Establish the following two new HCPCS Level II codes:

1. H2040, "Coordinated specialty care, team-based, for first episode psychosis, per month"
2. H2041, "Coordinated specialty care, team-based, for first episode psychosis, per encounter"

Mobility+ - HCP2212220WF9Y

Topic/Issue

Request to establish a new HCPCS Level II code to identify Mobility+.

Applicant's suggested language: XXXXX, "Enteral feeding supply kit; disposable pump fed, per day, includes elastomeric pump, filling set, giving set"

Summary of Applicant's Submission

Rockfield Medical Devices submitted a request to establish a new HCPCS Level II code to identify Mobility+. Mobility+ received the Food and Drug Administration (FDA's) 510(k) clearance on October 27, 2022. Mobility+ is a portable, lightweight, non-electronic, disposable enteral feeding system intended to deliver commercially available liquid nutrition formula to a patient using a standard feeding tube (or extension tube) with an ENFit connector. Mobility+ can be used in a clinical or home care setting, in patients aged two and older. Mobility+ has an internal elastomeric pouch, filled by the user with formula, that consistently deflates once feeding begins. The deflation of the elastomeric pouch generates a constant, low-pressure force that pushes the formula from the pouch through the supplied tubing set ("Giving Set") to an already implanted feeding tube. The System is self-contained, portable and does not require an external pump, nor a power source, nor an IV pole/clamp which are common among other enteral feeding systems. Mobility+ is designed to provide the patient and caregiver improved mobility, discretion, and ease of use. The Mobility+ Feeding pouch, an elastomeric pump, operates silently, in comparison to the noise generated by many of the current pumps on the market. According to the applicant, existing pump noises can be disruptive not only during the day but also during sleeping hours for patients that are night feeding. According to the applicant, Mobility+ offers the simplicity of a gravity-fed system without the requirements of being sedentary and tethered to an IV pole while feeding. Mobility+ brings mobility and discretion to all patient populations whether gravity/bolus fed or infusion pump fed. According to the applicant, existing codes only cover discrete componentry of the current modalities.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code BXXXX, "Enteral feeding supply kit; disposable pump fed, per day, includes disposable pump and all additional supplies necessary for daily disposable pump feeding"

Preliminary Medicare Benefit Category Determination

Prosthetic Device

The Mobility+ enteral feeding system permits disposable portable enteral nutrition with a reduced force mechanism. Medicare covers enteral nutritional therapy administered through feeding tubes under the prosthetic device benefit (Social Security Act § 1861(s)(8)), with the feeding tube being the prosthetic device. If the coverage requirements for the enteral nutrition are met, medically necessary nutrients, administration supplies and equipment are covered.

Preliminary Medicare Payment Determination

No determination. More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. The payment determination for this item will be addressed at a subsequent HCPCS public meeting.

Summary of Public Feedback

Rockfield Medical Devices, the manufacturer of this product, agreed with CMS' published preliminary recommendation. According to the speaker, Mobility+ is an elastomeric feeding device that relies on pouch pressure created by the filling process and variations in lengths of giving sets to regulate the infusion rate as opposed to gravity bags or electronically controlled infusion pumps both of which require gravity or a power source. Gravity feeding options include either small or large bore bags with roller clamps that enable a slower gravity feeding infusion, does not allow for a specified rate, and will differ depending on the type of formula infused. According to the speaker, Mobility+ uses an elastomeric technology, that infuses formula independent of bag height, absent of a roller clamp, does not use a pole for hanging, and allows better user mobility while infusing.

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 received, CMS is revising the coding language from the preliminary recommendation and finalizing the decision to:

Establish a new HCPCS Level II code B4148, "Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape" to describe Mobility+.

During our analysis, we discovered that "disposable pump fed" did not accurately describe Mobility+. Comments provided during and in response to the public meeting confirmed that Mobility+ uses elastomeric technology to infuse formula and would be best described as "elastomeric control fed".

Final Medicare Benefit Category Determination

Prosthetic Device

The information supports finalizing our preliminary benefit category determination that the Mobility+ enteral feeding system permits disposable portable enteral nutrition with an elastomeric control fed mechanism. Medicare covers enteral nutritional therapy administered through feeding tubes under the prosthetic device benefit (Social Security Act § 1861(s)(8)), with the feeding tube being the prosthetic device. If the coverage requirements for the enteral nutrition are met, medically necessary nutrients, administration supplies and equipment are covered.

Final Medicare Payment Determination

No determination. CMS did not previously issue a preliminary payment determination for Mobility+ in this cycle. A preliminary payment determination is stated below, and interested

parties will have an opportunity to provide comment to CMS during the second biannual 2023 HCPCS coding cycle later this year. For claims payment on an interim basis, payment for the Mobility+ enteral feeding system will be made at the discretion of the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240.

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. As a result, the preliminary pricing methodology for new HCPCS code B4148 is to use the existing fee schedule amounts for comparable items described by HCPCS code B4035 (“Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape”), with an additional amount added to account for the elastomeric technology that allows for infusion of the nutrients without the aid of separate equipment (infusion pump or IV pole).

CMS has compared two HCPCS codes to Mobility+: B4036 (“Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape”) and B4035, as shown in the below comparability table. Mobility+, B4035, and B4036 are all comparable with respect to physical components, function and intended use, and with respect to numerous additional attributes and features. We have concluded that Mobility+ is more comparable to B4035 than B4036 due to greater portability and the continuous feeding functionality.

	Mobility+	B4035	B4036
Physical Components	Feeding pouch, filling set, giving set, EnFit connector, extension set, and additional supplies (gauze, tape, dressings, etc.) The feeding pouch can hold up to 500ml of feed	Feeding pouch, filling set, giving set, EnFit connector, extension set, and additional supplies (gauze, tape, dressings, etc.) The catheter tip or oral syringe can hold up to 1200 ml of feed	Feeding pouch, filling set, giving set, EnFit connector, extension set, and additional supplies (gauze, tape, dressings, etc.) The catheter tip or oral syringe can hold up to 600 ml of feed
Mechanical Components	Feeding pouch is made using elastomeric material which creates a force to administer the nutrition. Multiple extension sets (tubing) of different lengths are provided to allow for different rates of infusion.	Poly vinyl chloride (PVC) pouch (uses separate pump to control rate of infusion)	Poly vinyl chloride (PVC) pouch (uses gravitational force to administer nutrition without controlling rate of infusion)
Electrical Components	NA	NA	NA

Function and Intended Use	Function: Provide nutritional content to patients unable to eat or drink in a controlled and sterile fashion Intended Use: To treat tube fed patients with swallowing difficulties such as Gastrointestinal dysfunction	Function: Provide nutritional content to patients unable to eat or drink in a controlled and sterile fashion Intended Use: To treat tube fed patients with swallowing difficulties such as Gastrointestinal dysfunction	Function: Provide nutritional content to patients unable to eat or drink in a controlled and sterile fashion Intended Use: To treat tube fed patients with swallowing difficulties such as Gastrointestinal dysfunction
Additional Aspects and Features	Does not require separate equipment. Very Portable Continuous feeding Disposable feeding set No power source/ electricity	Requires separate equipment (pump to control rate of infusion) Less portable (some pumps can be carried in backpacks) Can be continuous, dose, or bulbous feeding Disposable feeding set Battery power source	Requires separate equipment (IV pole) Least portable (IV pole with wheels) Non-continuous feeding Disposable feeding set No power source/ electricity

As indicated above, the preliminary payment determination is to use the pricing for code B4035 and an additional amount to account for the ability of the Mobility+ supplies to administer the nutrients without the aid of either an infusion pump or IV pole. We believe the added cost of the elastomeric technology can be accounted for by the daily payment rate for a durable infusion pump, HCPCS code B9002 (“Enteral nutrition infusion pump, any type”), which is computed by dividing the purchase fee schedule amount for a new infusion pump by the number of days in the five-year life of the pump (1,826). We believe the type of infusion provided by the Mobility+ modality is more comparable to the type of infusion provided by the infusion pump modality rather than gravity drip modality.

Payment for the daily supplies described by HCPCS code B4148 would be established using the daily fee schedule amounts for HCPCS code B4035 plus the daily fee schedule payment for a new infusion pump (HCPCS code B9002NU). HCPCS modifier NU is a pricing modifier used to describe “new equipment.” The average 2023 non-rural fee schedule amount for code B4148 would be approximately \$8.72 and the average 2023 rural fee schedule amount for code B4148 would be approximately \$11.21.

Pricing Indicator = 39

Hummingbird® Tympanostomy Tube System (HTTS) - HCP230103Y22E6

Topic/Issue

Request to establish a new HCPCS Level II code to identify Hummingbird® Tympanostomy Tube System (HTTS).

Applicant's suggested language: SXXXX, "Disposable, single-handle, tympanostomy ventilation tube insertion device for patients <18 years old"

Summary of Applicant's Submission

Preceptis Medical submitted a request to establish a new HCPCS Level II code to identify HTTS. The HTTS was initially cleared by the Food and Drug Administration (FDA) on June 5, 2020 through a 510(k) pathway for use in patients that are 6 months to 24 months in age. The HTTS received a second 510(k) clearance on July 27, 2022 for use in pediatric patients that are 6 months and older in age. According to the applicant, this HCPCS Level II code would describe this device used to place tympanostomy tube(s) in pediatric patients in the physician office setting. According to the applicant, this is an innovative surgical technology that combines the separate functions of creating a myringotomy (incision in the eardrum), and positioning and placing a ventilation tube across the tympanic membrane. The HTTS is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient and is indicated to be used in office settings for pediatric patients 6 months and older. Using the HTTS, the surgeon manually advances the sharpened sheath to create a myringotomy and simultaneously positions the ventilation tube within the myringotomy, always under direct visualization. The user then manually retracts the sharpened sheath away from the myringotomy using the manual actuator located on the handle. The retraction of the sheath releases the tube within the myringotomy. This device allows the tympanostomy service to be furnished to pediatric patients without general anesthesia and the service can therefore be performed in the physician office setting. According to the applicant, existing procedure codes do not identify the setting of the service or the age of the patient and do not allow payers to identify services performed using this technology. Per the applicant, private payers such as Blue Cross Blue Shield of Minnesota have published policies using a non-specific modifier (i.e., "-CG") with the American Medical Association (AMA) Current Procedural Terminology (CPT®) Level I code 69433 for the tympanostomy procedure performed under local or topical anesthesia, to identify services using tube delivery systems approved by the FDA. According to the applicant, other payers, such as Medica and Preferred One, have directed providers to append the modifier - 22 to identify the use of the HTTS. According to the applicant, a specific, new unique S code would fulfill a program operating need and allow private payers, including Medicaid managed care plans, to consistently identify services that use the technology and pay appropriately for those services. Per the applicant, the S code would also allow physicians to report the use of the technology when used for pediatric patients for whom it is deemed suitable to perform the tympanostomy in the office setting, and to facilitate processing of healthcare claims in a consistent and timely manner.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the HTTS 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. We welcome further information from the applicant and other insurers to further explain why the existing HCPCS Level I Current Procedural Terminology (CPT®) code 69433, “Tympanostomy (requiring insertion of ventilation tube), local or topical anesthesia” is not an adequate code for HTTS as well as whether any parties have approached the AMA about code revisions.

Summary of Public Feedback

Preceptis Medical, the manufacturer of this product, disagreed with CMS’ HCPCS preliminary recommendation that the HTTS would generally be used in a procedure reported with a CPT® code. The speakers requested to obtain a unique HCPCS Level II S code to enable ear, nose, and throat doctors (ENTs) to adopt the technology and offer this service to children. One of the speakers commented that an in-office ear tube procedure for children has been viewed as a clinical need by the ENT community for decades. Ear tubes are routinely placed in-office in adults, but according to the speaker, has been too difficult to do in-office ear tube procedures for children because surgeons needed the patients to remain completely still and the existing tools were not designed to be used with a child and with any movement. According to the speakers, HTTS has changed this by enabling the ENT to perform the same in-office tympanostomy procedure with the same outcome but on an awake child. The ENT still needs to use an operating microscope, needs to remove ear wax for visualization, anesthetize the tympanic membrane (TM) with a topical anesthetic like phenol, and place the same type of ear tube in the TM. Another speaker added that, however, to do the procedure successfully with children, there are additional, meaningful procedural steps, such as swaddling the patient, holding the patient’s head still, coaching the parent on behavioral techniques to help the child through the procedure, and importantly, the need for this one-pass device to complete the procedure. According to the speakers, CMS should mimic existing add-on S codes, such as, S2900, “Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure”, S2351, “Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophylectomy; lumbar, each additional interspace (list separately in addition to code for primary procedure”, and S0310, “Hospitalist services (list separately in addition to code for appropriate evaluation and management service”. According to the speakers, a new “in addition to code” could be utilized in conjunction with the existing CPT® code to better help capture any additional costs for HTTS.

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.

The HTTS 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 understand other payers have been utilizing modifiers to better help capture the use of HTTS. However, 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.

NeuroNode® - HCP221230PJ0M6

Topic/Issue

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

Applicant's suggested language: EXXXX, "Accessory for speech generating device, sEMG sensor"

Summary of Applicant's Submission

Control Bionics Limited submitted a request to establish a new HCPCS Level II code to identify NeuroNode®. NeuroNode® is a class II device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). According to the applicant, the NeuroNode® sensor is a critical access solution to utilize an augmentative and alternative communication (AAC) device intended to provide noninvasive, electromyographic (EMG) mediated computer access, communication, robotic, and environmental control capability for users with impaired speech and/or motor function. NeuroNode® uses the body's EMG signals or 3D spatial movements to give the user precise control of their AAC device. Individuals can access their technology, including but not limited to, an AAC device, computer, phone or tablet with the device. NeuroNode® can interpret coherent volitional commands. These minute bioelectric signals can be detected even if the muscle's ability to contract is diminished by as much as 95%. The user sends an initiating signal from their motor cortex to the fibers of the target muscle. If any action potential is generated along those muscle fibers, or a vector shift occurs in the electrical field, NeuroNode® can compute sufficient data to generate a coherent, unambiguous command to the target speech generating device (SGD). For example, a person squeezing their hand can generate up to 800 μ V; NeuroNode® can generate a coherent command to an SGD in response to an EMG voltage of 0.5 μ V. According to the applicant, this provides a statistically significant advantage to a person with a disability. Per the applicant, it functionally enhances the results of the speech generating system for people with conditions like progressive amyotrophic lateral sclerosis, spinal cord injury, spinal muscular atrophy, cerebral palsy, and certain traumatic brain injury. According to the applicant, the existing HCPCS code E2599 is a miscellaneous code that does not describe the technology adequately. According to the applicant, E2599 is used to describe a variety of technologies such as joysticks, buttons, and keyguards. According to the applicant, these technologies are different from the NeuroNode® in terms of sophistication of the technology, functionality, and cost. The other control devices require tactile or physical input from the user, such as the ability to press a button or grasp and maneuver a joystick. NeuroNode® detects EMG to allow the user to control the SGD through any type of intentional, detectable movement. NeuroNode® also allows the user to control their device using a range of motion or 3D spatial awareness. NeuroNode® can be placed on almost any muscle that the user can control. Additionally, alternative input devices like the NeuroNode® are needed when a patient cannot use, or the prescriber does not recommend, standard input devices. According to the applicant, the addition of a unique code will allow patients with a variety of limited motor function and communication abilities access to vital Assistive Technology. According to the applicant, the new code will allow health care providers to accurately report, and payers to accurately capture product-specific information to adjudicate claims more efficiently.

CMS Preliminary HCPCS Coding Recommendation

This application is being deferred for additional consideration in a subsequent biannual coding cycle. We will continue to examine coding for this item as well as other accessory items for speech generating devices that currently fall under existing HCPCS Level II code E2599, “Accessory for speech generating device, not otherwise classified.” The applicant addresses that NeuroNode® uses an electromyographic sensor to assist with control for an SGD. The applicant addresses that alternative input devices, like NeuroNode®, are assistive technology when a patient cannot use, or the prescriber does not recommend, standard input devices such as joysticks, buttons, and keyguards which are also billable under existing code E2599. Ocular and head tracking SGD accessories are also input devices billable under existing code E2599. We are interested in coding consideration for the range of input devices used with SGDs.

While we continue to review this request, existing code E2599, “Accessory for speech generating device, not otherwise classified” continues to be available for billing the NeuroNode® accessory for SGDs.

Summary of Public Feedback

Control Bionics, the sole provider of the NeuroNode®, agreed with CMS’ published preliminary recommendation. The speaker described the need for a unique code because the current E2599 code is not specific to the NeuroNode®, or any other accessory for SGDs.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS’ published preliminary recommendation to defer this application for additional consideration in a subsequent biannual coding cycle. We are examining coding for this item, as well as other accessory items for speech generating devices, that currently fall under existing HCPCS Level II code E2599, “Accessory for speech generating device, not otherwise classified.” While we continue to review this request, existing code E2599, “Accessory for speech generating device, not otherwise classified” continues to be available for billing the NeuroNode® accessory for SGDs.

RADPAD® Radiation Protection Shield - HCP2301020T0J9

Topic/Issue

Request to establish a new HCPCS Level II code to identify RADPAD® radiation protection shield.

Applicant's suggested language: AXXXX, "Sterile, disposable, non-lead, two-metal shields to aid in the prevention of radiation-induced diseases"

Summary of Applicant's Submission

Worldwide Innovations & Technologies, Inc. submitted a request to establish a new HCPCS Level II code to identify RADPAD® radiation protection shields. RADPAD® radiation protection shield is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). RADPAD® radiation protection shields are single use, sterile (individually packaged), disposable shields designed to aid in the prevention of radiation-induced diseases for patients and medical personnel. Per the applicant, these unique two-metal shields are made of bismuth and antimony and contain no lead, latex, or PVC/vinyl, rendering them an eco-friendly product. Their purpose is to block and absorb scatter radiation that emanates from the patient during X-ray-guided medical procedures. During a procedure, the sterile shield is affixed on top of the surgical drape which covers the patient, thus placing it between the physician and the primary beam. This creates an area of protection (sometimes called a "shade zone") in which the physician and medical staff stand to conduct the procedure. This shield blocks and absorbs radiation in the "shade zone" thus reducing the patient's and medical staff's exposure to scatter radiation, thereby aiding in the prevention of radiation-induced diseases. According to the applicant, this product can be categorized as a 'supply' product that can be used for a wide array of fluoroscopically guided procedures. According to the applicant, no existing code adequately describes this class of product or is sufficiently related to scatter radiation exposure mitigation. According to the applicant, a new code to cover radiation shielding is merited due to the high volume of fluoroscopically guided procedures and the availability of codes for other necessary supplies for these surgeries.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that RADPAD® radiation protection shield 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 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.

Summary of Public Feedback

Worldwide Innovations & Technologies, Inc, the manufacturer of this product, disagreed with CMS' preliminary recommendation that RADPAD® radiation protection shield would generally be used in a procedure and certain items are considered bundled into the facility payment. The speaker stated that hospitals avoid or limit use of radiation protection because they lack coding to bill and derive reimbursement. The speaker also stated that cost concerns

are often cited, despite radiation protection representing less than one percent of the procedure costs. The speaker stated that they approached the American Medical Association (AMA) and also sought guidance from hospital administrators regarding whether radiation shields could fit under an existing surgical miscellaneous supply code, A4649, but found this could not be accommodated. Commenters stated that the use of X-ray radiation can be harmful to patients, doctors and all healthcare workers, when proper precautions are not used. Commenters also stated that 80% of high dose procedures are performed without adequate radiation shielding and that this is in contradiction to the Centers for Disease Control and Prevention's (CDC's) As Low As Reasonably Achievable (ALARA) principle, that directs that residual risk is reduced as far as reasonably practicable when it comes to radiation regulation and management of safety-critical and safety-involved systems. Commenters stated that two-metal radiation protection is a recognized solution by 8 of the top 10, and 17 of the top 20 U.S. hospitals; however, of the approximately 40% of American hospitals that do use radiation protection shields, most use them on less than 25% of their fluoroscopy-guided procedures because of the absence of adequate codes that describe them for billing purposes.

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 RADPAD® radiation protection shield is not suitable for inclusion in the HCPCS Level II code set because it is used during an inpatient procedure where certain items are considered bundled into the facility payment. For instance, Medicare would typically reflect the costs of the item in the payment for the procedure, if it is used, and as such it would not be separately payable.

DarkDrape - HCP221225MH4HQ

Topic/Issue

Request to establish two new HCPCS Level II codes to identify DarkDrape.

Applicant's suggested language: XXXXX, "DarkDrape contrast agent for point of care fluorescence imaging, one patient use"

Summary of Applicant's Submission

Institute for Quality Resource Management submitted a request to establish a new HCPCS Level II code to identify DarkDrape (DD). DD Received the Food and Drug Administration's (FDA's) 510(k) clearance on July 21, 2021. According to the applicant, DD is a medically necessary contrast agent. It is used as a medical supply with the portable Point of Care (POC) fluorescence imaging (FL) device MolecuLight® i:X and DX devices. MolecuLight® (ML) is a real-time handheld non-contrast FL device to detect in wounds bacteria at loads $\geq 10^4$ CFU/g (colony-forming units per gram). According to the applicant, clinical evidence from randomized control trails has proven ML FL leads to improved wound treatment bringing wounds to closure and avoiding amputations. DD is needed for ML FL of bacteria to reliably identify bacterial presence, location, and load leading to cost-effective patient outcomes. At the POC the DD is necessary to remove the lighting "noise", creating darkness necessary for accurate and clinically relevant fluorescence signals. According to the applicant, DD is used in approximately 50% of the procedures. DD used in FL is designed to be portable; used outside of traditional patient care settings; where wound assessment is need. DD is needed in the physician office, hospital outpatient, skilled nursing facility, home health services, and assisted living centers. Bacteria at loads $> 10^4$ CFU/g reduce wound healing, and often progress to infection with exudates and necrotic tissue-too late to control this wound. According to the applicant, a consensus document defines the use of the DD to create the appropriate absence of light to achieve darkness for appropriate FL (Oropallo 2021). Use of DD in FL to accurately identify bacteria pathogens stalling wound healing or advancing to an amputation requires a code and payment to enable appropriate ML FL in settings where these patients need medical care. According to the applicant coding and payment are required.

CMS Preliminary HCPCS Coding Decision

DarkDrape is not suitable for coding in the HCPCS Level II code set because it is used in inpatient and outpatient settings as an adjunctive item during procedure reported using a HCPCS Level I (CPT®) code or other code for the setting. For inpatient and outpatient settings, DarkDrape would typically be bundled into the payment for the procedure or home visit.

Summary of Public Feedback

The Institute for Quality Resource Management disagreed with CMS' HCPCS preliminary recommendation that DD would generally be used in a procedure and reported with a CPT® code. The speakers believe DD is a variable cost that is a reasonable and necessary medical accessory to create the correct darkness for accurate fluorescence imaging of bacteria location and load. According to the speaker, a desired level of darkness is not universally attainable for all places of service. While windowless exam rooms or operating rooms may effortlessly

achieve this requirement, real-world scenarios often present challenges. According to the speakers, a surgical drape or just any sheet cannot be used to achieve the same results as using the DD. The comments elaborated that any darkening drape must consider the properties important for fluorescence imaging and avoid inducing any imaging artifacts. The drape material and its attachment to the device must be completely impenetrable to light and allow for no gaps. Comments further explained that light contamination would create a red hue, which is a false positive on the image. Even the slightest penetration of light through the drape material itself will eliminate all image contrast and ability to interpret signals.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary decision. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary decision. DarkDrape is not suitable for coding in the HCPCS Level II code set because it is used in inpatient and outpatient settings as adjunctive item during procedure reported using a HCPCS Level I (CPT®) code or other code for the setting. For inpatient and outpatient settings, DarkDrape would typically be bundled into the payment for the procedure or home visit.

Heartfelt-3 Device - HCP221230F0NJ0

Topic/Issue

Request to establish a new HCPCS Level II code to identify Heartfelt-3 Device.

Applicant's suggested language: XXXXX, "Foot and lower leg volume tracking device"

Summary of Applicant's Submission

Heartfelt Technologies submitted a request to establish a new HCPCS Level II code to identify Heartfelt-3 Device. Heartfelt-3 Device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Heartfelt-3 Device is a 3D scanner that automatically detects and scans the patient's feet/legs, providing a quantitative measurement of foot/lower leg volume. Heartfelt-3 Device is used to track volume changes in a patient's foot/lower leg. Changes in fluid status, such as peripheral edema, result in changes in foot/lower leg volume, which is frequently seen in conditions such as heart failure. The Heartfelt-3 Device consists of a controller and camera which is connected to the internet. According to the applicant, there are no HCPCS Level II codes that describe a device like the Heartfelt-3 Device.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" describes Heartfelt-3 Device.

Heartfelt-3 Device is a foot/lower leg monitor that collects and measures various parameters, similar to other devices in existing HCPCS Level II code A9279.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The Heartfelt-3 Device is used to monitor or track volume changes in a patient's foot/lower leg. 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. For example, the SPEAC® System, which is not DME, is a recording and monitoring system in which the physician receives a summary report to help with clinical decisions.

The current Medicare policy and prior established benefit category determination of no DMEPOS benefit category for code A4279 apply to this item.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

Heartfelt Technologies, the manufacturer of this product, disagreed with CMS' HCPCS preliminary recommendations. The Heartfelt-3 Device is a passive device used for tracking non-adherent heart failure patients. This device functions by having a 3D scanner that passively scans the environment that it is located in, typically the patient's bedroom. It recognizes when the patient is present, recognizes and captures images of their feet, and then sends this 3D scan to the computer server. The device sends the data to the monitoring physician. The physician then reviews this data and makes a clinical decision and recommendation. According to the speaker, most of the remote patient monitoring companies in the U.S. that are currently billing HCPCS Level I, Current Procedural Terminology (CPT®) code 99454 report that between thirty to fifty percent of their patients fail to meet the current Medicare threshold for billing that code of 16 days of data out of 30 days. The speaker mentioned that they are working on producing a new version of the Heartfelt-3 Device with a feature that alerts the patient directly, not the patient's physician, when medication(s) is/are needed. According to the speaker, this new product is not FDA-approved, and it is still in clinical trials.

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 A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" to describe the Heartfelt-3 Device.

The current, marketed, Heartfelt-3 Device is a foot/lower leg monitor that collects and measures various parameters, similar to other devices in existing HCPCS Level II code A9279.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

As stated in the preliminary determination, the Heartfelt-3 Device is used to monitor or track volume changes in a patient's foot/lower leg. 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. For example, the SPEAC® System, which is not DME, is a recording and monitoring system in which the physician receives a summary report to help with clinical decisions.

In the public meeting the applicant mentioned that they are producing a version of the Heartfelt-3 Device which alerts the patient when medication is needed. As stated in the meeting, this product is not FDA-approved and is still in trial and thus cannot be considered as part of this application. A new application would need to be submitted after the device has received FDA approval for further CMS consideration.

The current Medicare policy and prior established benefit category determination of no DMEPOS benefit category for code A4279 apply to this item.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

CEFALY Dual and CEFALY Dual Enhanced - HCP221024C2L63

Topic/Issue

Request to revise existing HCPCS Level II code E0720, “Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation”.

Applicant's suggested language: E0720, “External transcutaneous supraorbital nerve stimulator, stimulates the supraorbital and supratrochlear nerve branches of the trigeminal nerve”

Summary of Applicant’s Submission

CEFALY Technologies submitted a request to revise an existing HCPCS Level II code E0720, “Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation” to instead read “External transcutaneous supraorbital nerve stimulator, stimulates the supraorbital and supratrochlear nerve branches of the trigeminal nerve.” CEFALY received the Food and Drug Administration’s (FDA’s) De Novo clearance on December 13, 2012. External Trigeminal Nerve Stimulator (e-TNS), CEFALY Dual, is a non-invasive, reusable medical device that stimulates supraorbital and supratrochlear branches of the ophthalmic division of the trigeminal nerve using a pre-specified electrical algorithm. E-TNS CEFALY is a class II medical device for the preventative and acute treatment of migraine headaches in adults age 18 or older. When activated, the e-TNS device sends specific, pre-specified electrical signals according to the user's desired treatment modality (i.e., prevention of migraine or acute treatment of migraine attacks) according to a stimulation algorithm designed to optimize therapeutic benefit. Per the applicant, the efficacy and safety of migraine preventative and acute treatment were established in randomized, sham-controlled clinical trials. According to the applicant, since the FDA clearance, new information and research has become available which indicates that the existing code E0720, is insufficient to adequately account for the item or service of e-TNS CEFALY for the following three reasons: 1) The mechanism of e-TNS therapy is distinct from conventional Transcutaneous Electrical Nerve Stimulation (TENS) units as e-TNS CEFALY utilizes both long and short-term central (brain and brainstem) anti-nociceptive modulation. This is evidenced by several studies demonstrating functional changes in the brain and brainstem following short term and long-term supraorbital and supratrochlear stimulation with the CEFALY device. According to the applicant, further support that the mechanism of action is different from conventional TENS devices includes the clinical evidence that trigeminal nerve stimulation has benefits in reducing drug-resistant focal seizures and improving symptoms of Attention Deficit/Hyperactivity Disorder (ADHD) as NeuroSigma found in a similar e-TNS device. Per the applicant, conventional TENS devices do not have evidence for centrally acting benefits for neurological and psychiatric disorders such as epilepsy and ADHD. 2) The technology significantly differs from conventional TENS units as it delivers microcurrents to small branches to the small and nociceptive supraorbital nerves as opposed to larger mechanical nerve fibers in traditional TENS devices. Per the applicant, this is critical as the microcurrent technology of the CEFALY device cannot safely be replaced with traditional TENS due to excess stimulation damaging the smaller nociceptive nerves. 3) The target supraorbital and supratrochlear nerves are branches of a cranial nerve which has its origin in the mid-brain as opposed to conventional TENS units which are designed to stimulate the peripheral nerve. According to the applicant, the HCPCS Level II code for External Trigeminal nerve stimulation with CEFALY should exist as a separate code from

conventional TENS units (E0720) due to differences in the mechanism of action, substantial differences in the stimulation targets and, therefore, substantial differences in the technology and delivery to modulate the stimulation targets safely. According to the applicant, as of January 11, 2023, CEFALY Dual is no longer marketed in the United States. CEFALY Dual is replaced with CEFALY Dual Enhanced and CEFALY Dual Connected. Both the CEFALY Dual Enhanced and CEFALY Dual Connected are available over the counter and by prescription.

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 E0720, “Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation” to instead read “External transcutaneous supraorbital nerve stimulator, stimulates the supraorbital and supratrochlear nerve branches of the trigeminal nerve.” As stated in the application, the technology of CEFALY has not changed since HCPCS Level II code E0720 was assigned to CEFALY; as such, the existing code E0720, “Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation” appropriately describes the CEFALY devices. 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 E0720.

Summary of Public Feedback

CEFALY Technologies, the manufacturer of this product, disagreed with CMS’ published preliminary HCPCS coding recommendation. The speaker requested that CEFALY obtain a unique HCPCS code and updated fee schedule amount. According to the speaker, fundamentally, CEFALY Dual Enhanced and CEFLAY Dual Connected are "transcutaneous electrical nerve stimulation (TENS) devices, two lead with localized stimulation," and based on this broad description, they understand why CEFALY is assigned E0720. However, CEFALY Dual Enhanced and CEFALY Dual Connected are non-wired, targeted TENS devices that stimulate only the trigeminal nerve's supraorbital and supratrochlear branches. According to the speaker, the targeted microcurrent technology mechanism is similar to the Neurosigma’s Monarch Device, assigned HCPCS Level II code K1016 on April 1, 2021. The speaker commented that conventional TENS devices under E0720 do not have an FDA indication for acute and preventative treatment of migraine and lack the unique microcurrent stimulation parameter and safeguards. According to the speaker, the technology of the CEFALY device has changed significantly since the 2018 CMS HCPCS Level II application for CEFALY Acute. The 2018 application was for a CEFALY device that only treated active migraine attacks. The current application for CEFALY Dual Enhanced and Connected has therapeutic distinction and clinical utility in providing acute and preventative therapeutic modalities within one device. Furthermore, the CEFALY DUAL Connected has the added functionality of tracking the patient's device usage and migraine response, with clinical utility in the patient-provider partnership in managing migraine headaches. According to the speaker, the current HCPCS code assignment has served as a barrier to allowing patients and providers access to the therapy and results in claim denials. Under the current DMEPOS fee schedule, the purchase and reimbursement is capped at \$150, significantly below the purchase cost. The speaker requested a reassigned pricing indicator for CEFALY to 46, carrier price item, to help facilitate reasonable reimbursement or billing for the device, especially with cost efficacy analysis. According to the speaker, the FDA has awarded clearance for direct to customer or over the counter sales options.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary HCPCS coding 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 K1016, "Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve" to describe CEFALY Dual Enhanced and CEFLAY Dual Connected.

We believe code K1016 more accurately describes the CEFALY Dual Enhanced and CEFLAY Dual Connected devices than existing HCPCS Level II code E0720, "Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation", because it describes devices specifically used to stimulate the trigeminal nerve.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination for code K1016 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code K1016 apply to this product, if covered. The current average 2023 fee schedule amount for K1016 is \$46.59.

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 = 36

eXciteOSA® with Remote - HCP2301030EGV4

Topic/Issue

Request to establish HCPCS Level II code to identify eXciteOSA® durable control unit with a hardware remote.

Applicant's suggested language: XXXXX, "Power source, control electronics unit, and hardware remote for oral device for neuromuscular electrical stimulation of the tongue muscle for obstructive sleep apnea treatment"

Summary of Applicant's Submission

Signifier Medical Technologies submitted a request to establish a new HCPCS Level II code to identify eXciteOSA® durable control unit with a hardware remote. eXciteOSA® without remote control, eXciteOSA® with remote control received the Food and Drug Administration's (FDA's) De Novo clearance on February 5, 2021. The eXciteOSA® device is a tongue neuromuscular stimulation device to treat mild obstructive sleep apnea (OSA) using Apnea-Hypopnea Index (<15) when prescribed to patients 18 years or older for in-home use. The eXciteOSA® starter kit with remote consists of a control unit ("S-device"), remote control, disposable one-size fits all flexible silicone mouthpiece, and USB-C charger. The therapy is delivered during a wakeful state (typically daytime) to build tongue and upper airway muscle endurance, maintain tongue position during sleep, reduce obstructive sleep apnea events, and potentially mitigate OSA disease progression. A patient operates the device by inserting the mouthpiece into the control unit, connecting the device to a patient controlled remote, and placing the mouthpiece on the tongue. According to the applicant, existing HCPCS Level II code used to describe OSA therapies do not apply as they do not describe the eXciteOSA® functions or form when use with a dedicated hardware remote. Per the applicant, the descriptor for HCPCS Level II code K1028 does not include a dedicated hardware remote.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code EXXXX, "Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote."

CMS decided to remove the indication from the descriptor, in the event that a new indication becomes available for this product or other similar product developed by the same or different manufacturer. As such, we recommend revising the descriptor for HCPCS code K1028, "Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application" to instead read, "Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application."

CMS is starting to establish permanent codes for supplies and other products that received a temporary HCPCS code ("K" code) that became effective January 1, 2020 through 2022. Please reference the temporary code migration agenda item number 10 on June 1, 2023 (Day 3) for proposed changes to HCPCS code K1028.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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. It is important to note that this application for the eXciteOSA® device differs from the previously submitted application from 2021 in that the revised device does not use software and a smartphone to function. The eXciteOSA®'s software and smartphone version of this device did not meet the definition of DME because the smartphone, which delivers the medically necessary function of providing treatment, is useful to an individual in the absence of an illness or injury. Per the 2011 final rule, CMS-1577-F (76 FR 70291), a multi-component device consisting of durable and non-durable components is considered nondurable if the component that performs the medically necessary function of the device is non-durable, even if other components that are part of the device are durable. In this request, the applicant has distinguished this version of the eXciteOSA® device to meet the definition of DME by modifying the device to include a durable control unit and a hardware remote instead of the software and smartphone components. The eXciteOSA® durable control unit with hardware remote now meets the definition of DME because the durable components perform the medically necessary function of driving the neuromuscular electrical stimulation, including generating, starting, ending and adjusting the intensity of the stimulation that is delivered to the tongue.

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 EXXXX, for this particular tongue neuromuscular electrical stimulator control unit and hardware remote, is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS code E0745.

A neuromuscular stimulator involves the transmission of an electrical impulse to selected muscle groups by way of electrodes. The eXciteOSA® control unit and hardware remote and devices under E0745 are external electrical stimulation devices that utilize electrodes for the delivery of electrical stimulation to affected muscle. Devices under E0745 have a range of electrical forms, treatment times and can include rechargeable power sources.

	eXciteOSA® control unit and remote	E0745
Physical Components	External Electrical Stimulator and Remote	External Electrical Stimulator
Mechanical Components	NA	NA
Electrical Components	Stimulator Stimulation delivered via electrodes Rechargeable Batteries	Stimulator Stimulation delivered via electrodes Can include Rechargeable Batteries
Function and Intended Use	Delivers NMES to genioglossus muscle For the reduction of obstructive sleep apnea	Delivers NMES to muscles Can be used to treat muscle atrophy
Additional Aspects and Features	Uses Bluetooth for the control unit	Can use Bluetooth

Based on this preliminary determination, the 2023 fee schedule amounts for EXXXXX would be based on the rental fee schedule amounts for E0745 of approximately \$112 on average. Payment for the equipment would be made on a capped rental basis, if covered.

Pricing Indicator = 36

Summary of Public Feedback

Signifier Medical Technologies, the manufacturer of this product, agreed with CMS' published preliminary recommendations.

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:

1. Establish a new HCPCS Level II code E0490, "Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote" to describe eXciteOSA® with a remote.
2. Revise HCPCS Level II code K1028, "Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone

application” to instead read, “Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application.” CMS decided to remove the indication from the descriptor, in the event that a new indication becomes available for this product or other similar product developed by the same or different manufacturer.

Final Medicare Benefit Category Determination

Durable Medical Equipment

During the benefit category determination process for multi-component devices, CMS has a longstanding policy of first determining which specific component provides the medically necessary function of rendering direct treatment. The eXciteOSA® kit’s components consist of a control unit (the S-device), a remote control, a disposable one-size fits all flexible silicone mouthpiece, and a USB-C charger. Of the components listed, the S-device is the component that directly and actively provides the neuromuscular electrical stimulation to treat mild OSA. eXciteOSA® meets the definition of DME because the S-device meets all of the conditions listed in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and thus is DME.

With respect to the original version of the eXciteOSA® device, we stated that the smartphone delivered the medically necessary function of providing treatment. Please note for clarification that it is the S-device that is performing the medically necessary function. However, this clarification does not change the determination that the original version of the eXciteOSA® device does not meet the definition of DME because it relies on a patient’s smartphone and eXciteOSA®’s app to function (e.g., turn on, turn off, and program settings). In this request the applicant has distinguished the newer version of the eXciteOSA® device from the original one by including a durable control unit and a durable hardware remote while excluding reliance on the use of a smartphone and an app to function.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code E0490 will be established using the fee schedule amounts for HCPCS code E0745. The 2023 rental fee schedule amount for E0490 for months 1 through 3 is approximately \$112 on average, and approximately \$84 on average for months 4 through 13. Payment for the equipment will be made on a capped rental basis for any covered claims.

Pricing Indicator = 36

eXciteOSA® Mouthpiece - HCP2301032FA3J

Topic/Issue

Request to establish HCPCS Level II code to identify eXciteOSA® mouthpiece.

Applicant's suggested language: XXXXX, "Oral mouthpiece accessory for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply"

Summary of Applicant's Submission

Signifier Medical Technologies submitted a request to establish a new HCPCS Level II code to identify eXciteOSA® mouthpiece accessory. eXciteOSA® without remote control, eXciteOSA® with remote control received the Food and Drug Administration's (FDA's) De Novo clearance on February 5, 2021. eXciteOSA® mouthpiece is used with the durable control unit and dedicated hardware remote. The eXciteOSA® device is a tongue neuromuscular stimulation device to treat mild obstructive sleep apnea (OSA) using Apnea-Hypopnea Index (<15) when prescribed to patients 18 years or older for in-home use. eXciteOSA® mouthpiece accessory consists of a one-size fits all flexible silicone mouthpiece with four electrodes. The therapy is delivered during a wakeful state (typically daytime) to build tongue and upper airway muscle endurance, maintain tongue position during sleep, reduce obstructive sleep apnea events, and potentially mitigate OSA disease progression. A patient operates the device by inserting the mouthpiece into the control unit, connecting the device to a patient controlled remote, and placing the mouthpiece on the tongue. According to the applicant, existing HCPCS Level II code used to describe OSA therapies do not apply as they do not describe the eXciteOSA® functions or form when use with a dedicated hardware remote. Per the applicant, the descriptor for HCPCS Level II code K1029 does not include a dedicated hardware remote.

CMS Preliminary HCPCS Coding Recommendation

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

CMS is starting to establish permanent codes for supplies and other products that received a temporary Healthcare Common Procedure Coding System (HCPCS) code ("K" code) that became effective January 1, 2020 through 2022. Please reference the temporary code migration agenda item number 10 on June 1, 2023 (Day 3) for proposed changes to K1029.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment

The eXciteOSA® mouthpiece serves as a DME accessory to the eXciteOSA® device that has been modified to meet the definition of DME. The mouthpiece is an integral part of the eXciteOSA®'s multi-component system that provides treatment for mild obstructive sleep apnea. Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03) indicates that payment may be made for supplies that are necessary for the effective use of durable medical

equipment. Because the eXciteOSA® mouthpiece is an accessory for a code that is DME (EXXXX), the mouthpiece falls under the DME benefit category.

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 supplies, the 12-month period of 1986/1987), 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.

Several internet websites in March 2023 place the retail price of the eXciteOSA® mouthpiece at \$150.¹ The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME. Payment for the mouthpiece would be made as a DME supply. The average 2023 purchase fee schedule amount for EXXXX would be approximately \$98.32.

Pricing Indicator = 34

Summary of Public Feedback

Signifier Medical Technologies, the manufacturer of this product, agreed with CMS' published preliminary recommendations. The speaker did recommend that CMS utilize a HCPCS Level II A Code prefix (AXXXX) for mouthpiece supply.

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 E0491, "Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply" to describe eXciteOSA® mouthpiece.

The eXciteOSA® mouthpiece serves as a Durable Medical Equipment accessory to the eXciteOSA® device, as such, assigned a HCPCS Level II alphanumeric E code. This should help better distinguish between the two eXciteOSA® devices and accessories.

Final Medicare Benefit Category Determination

¹ For example, <https://cpapsupplies.com/exciteosa-replacement-mouthpiece>;
<https://www.directhomemedical.com/excite-osa-replacement-mountpiece-16049.html>

Durable Medical Equipment

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code E0491 will be established using the March 2023 retail price of \$150 as discussed in the preliminary determination. Deflating the retail price and increasing by the update factors specified in section 1834(a)(14) results in an average 2023 purchase fee schedule amount for E0491 of approximately \$98.32.

Pricing Indicator = 34

FLUME Catheter - HCP221017U5BBH

Topic/Issue

Request to revise existing HCPCS Level II code A4344, "Indwelling catheter, foley type, two-way, all silicone, each" to identify FLUME catheter.

Applicant's suggested language: A4344, "Indwelling catheter, foley type, two-way, all silicone or polyurethane, each"

Summary of Applicant's Submission

The Flume Catheter Company Inc. submitted a request to revise existing HCPCS Level II code A4344, "Indwelling catheter, foley type, two-way, all silicone, each" to include Polyurethane to instead read; "Indwelling catheter, foley type, two-way, all silicone or polyurethane, each" The FLUME catheter received the Food and Drug Administration's (FDA's) 510(k) clearance on November 03, 2021. The FLUME catheter has similar configuration of a standard Foley type, two-way catheters overall. The FLUME catheter has an inflatable retention balloon, which is attached to the catheter shaft. The FLUME catheter has a dual lumen tube, the larger lumen is for draining urine from the urinary tract and the smaller lumen is to inflate and deflate the balloon with sterile water. The distal end has two opposite eye holes, which are used for drainage. The FLUME catheter and its predicate product (Teleflex Rusch all-silicone foley catheter) functions the same and it is distinguished by its balloon configuration. The balloon of the predicate is positioned at or near the distal tip of the catheter when inflated, however, the balloon of the FLUME catheter envelops the tip of the catheter. The manufacture selected biocompatible polyurethane-based polymers over silicone for the balloon configuration for FLUME catheter. Although latex and silicone catheters are more common, polyurethane is cleared for use in urinary drainage catheters as well. According to the applicant, catheters made of silicone and polyurethane go through the same construction process and differs from that of latex. As well as the manufacturing process for Silicone and polyurethane catheters are complex and expensive than latex.

CMS Preliminary HCPCS Coding Recommendation

Revise existing HCPCS Level II code A4344, "Indwelling catheter, foley type, two-way, all silicone, each" to instead read, "Indwelling catheter; foley type, two-way, all silicone or polyurethane, each"

Preliminary Medicare Benefit Category Determination

Urological Supplies

The current Medicare policy and prior established benefit category determination for code A4344 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4344 apply to this product, if covered. The current average 2023 fee schedule amount for A4344 is \$20.66.

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

Summary of Public Feedback

The Flume Catheter Company, the manufacturer of this product, agreed with CMS' preliminary decision to expand the existing HCPCS Level II code A4344 to include polyurethane. Polyurethane has been cleared by FDA for use in urinary catheters and other indwelling devices. According to the speaker, the FLUME catheter has been cleared by FDA as substantially equivalent to the Teleflex Rusch All-Silicone Catheter, which is coded under HCPCS Level II code A4344.

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 A4344, "Indwelling catheter, foley type, two-way, all silicone, each" to instead read, "Indwelling catheter; foley type, two-way, all silicone or polyurethane, each" to describe the FLUME catheter.

Final Medicare Benefit Category Determination

Urological Supplies

The current Medicare policy and prior established benefit category determination for code A4344 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4344 apply to this product, if covered. The current average 2023 fee schedule amount for A4344 is \$20.66.

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

Axor™ II - HCP221230H4TCT

Topic/Issue

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

Applicant's suggested language: LXXXX, "Addition to lower extremity prostheses, osseointegrated external prosthetic connector"

Summary of Applicant's Submission

Integrum, S.E. submitted a request to establish a new HCPCS Level II code to identify Axor™ II. Axor™ II was approved under a Premarket Approval (PMA) application by the Food and Drug Administration (FDA) on December 18, 2020. The Axor™ II is an osseointegrated external prosthetic connection device that provides a standard connection between the OPRA™ Implant System implantable components and other external prosthetic components, specifically the prosthetic knee and foot. The OPRA™ Implant System is indicated for patients who have transfemoral amputation due to trauma or cancer and who have or are anticipated to have rehabilitation problems with, or cannot use, a conventional socket prosthesis. The Axor™ II osseointegrated external prosthetic connection device is designed to protect the OPRA™ Implant System from damage caused by overloads. The Axor™ II connects the osseointegrated implant and skin penetrating abutment to a standard external prosthetic knee and foot. In the event of excessive twisting or bending of the prosthesis, the Axor™ II osseointegrated external prosthetic connection device releases the prosthesis to prevent damage to the bone anchored fixture. The Axor™ II osseointegrated external prosthetic connection device utilizes a standard 4-hole male/female mounting system. This allows the OPRA™ Implant System to be connected to commercially available prosthetic systems that utilize this standardized connection method. The Axor™ II osseointegrated external prosthetic connection device is recommended for use with commercially available non-microprocessor-controlled prosthetic knees and microprocessor-controlled prosthetic knees that do not include powered activation of flexion and extension of the prosthetic knee. The Axor™ II osseointegrated external prosthetic connection device is installed by a certified prosthetist. According to the applicant, the OPRA™ Implant System is the only FDA-approved osseointegrated prosthesis.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, "Addition to lower extremity prostheses, osseointegrated external prosthetic connector"

Preliminary Medicare Benefit Category Determination

Artificial Leg (Prosthetic)

The application supports a preliminary benefit category determination that the Axor™ II Osseointegrated External Prosthetic Connection Device is used in addition to a lower extremity prosthesis and would fall under the Medicare benefit for artificial legs (prosthetics).

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.

While Integrum, S.E. states in its application that the MSRP for Axor™ II is \$35,424, we note that this item has a history of pricing under code L5999. In 2020, the fee paid for this item under L5999 was \$5,255.18. Therefore, the fee schedule amount for code L5999 for Axor™ II will be mapped to the new code LXXXX in accordance with the continuity of pricing rules at 42 CFR 414.236, and will be updated to the 2023 fee schedule. The average 2023 fee schedule amount for LXXXX is \$6,015.22.

Payment would be on a lump sum purchase basis.

Pricing Indicator = 38

Summary of Public Feedback

Integrum, S.E., the manufacturer of this product, agreed with the preliminary decision to issue a HCPCS Level II code for Axor™ II, however, disagreed with the decision regarding the preliminary Medicare payment determination of the device. The speakers requested CMS reconsider its proposal to use fee schedule pricing history from 2020 to establish pricing for the AXOR™ II, which was preliminarily proposed at \$6,015.22. According to the speakers, this amount does not represent the cost of the AXOR™ II and will limit Medicare beneficiaries' access to osseointegrated prosthesis as a therapeutic option. Integrum, S.E. submitted written comments requesting that CMS use "verified" charges of \$35,424 from Medicare remittance notices for what appear to be two claims submitted for the device using code L5999, one for an individual with a double amputation. Integrum, S.E indicated at the public meeting that the fee schedule amount for the device should include payment for regular, periodic alignments/adjustments to the device.

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 L5991, "Addition to lower extremity prostheses, osseointegrated external prosthetic connector" to describe Axor™ II.

Final Medicare Benefit Category Determination

Artificial Leg (Prosthetic)

Final Medicare Payment Determination

We appreciate the comments provided in response to CMS' published preliminary payment determination. Based on the information provided during the public meeting, and after consideration of the comments we received, CMS is revising its preliminary determination. CMS had originally proposed establishing the fee schedule for Axor™ II using the 2020 interim local fee schedule amount of \$5,255.18 established by the DME MACs for Axor™ II under HCPCS code L5999. The interim local fee schedule amount had been established based on the weighted average price of two devices, i.e., Axor™ II and another device that is no longer on the market. Furthermore, the Axor™ II price sources used in establishing the local fee schedule amount consisted of both the 2020 amount paid by the Department of Veterans Affairs (VA) of \$11,826.78 and the Axor™ II MSRP of \$32,130.00. Since the other device is no longer on the market, we cannot adequately assess Axor™ II's comparability to it and thus we believe it appropriate to only consider Axor™ II prices in developing a fee schedule under new code L5991. Also, when developing national fee schedule amounts CMS selects and uses only one type of commercial pricing source (e.g., supplier price lists, non-Medicare payor data, etc.) when establishing a price to ensure consistency. Therefore, we will not use a continuity of pricing approach to establish the fee schedule for an Axor™ II. We have also determined that there are no items with existing fee schedule amounts that are comparable to Axor™ II. Therefore, we are using the gap-fill process to establish the fee schedule amounts for Axor™ II.

Under the gap-fill process, fee schedule amounts for the lump sum purchase of prosthetics are established using commercial pricing for the lump sum purchase of the item, which can include supplier price lists, payments made by Medicare Advantage plans, and non-Medicare payor data. For the Axor™ II, we have access to a VA payor data source, to the current supplier price of \$35,424 as reported by Integrum, S.E., and to several third-party payer EOBs provided to CMS that display billed amounts ranging from \$34,423.90 to \$46,945.08. As explained by the speakers at the public meeting, and in written comments provided post-meeting, the supplier price for Axor™ II includes the wholesale price of the device as well as prosthetist costs for the initial fitting and adjustment for the device, the twice-yearly visual inspection/cleaning services, and the annual servicing performed by the prosthetist. Initial fitting and adjustment services for prosthetic devices are included in Medicare payment for the lump sum purchase of the device. Payment for subsequent adjustments or repairs to the device are not included in the lump-sum payment for purchase of the device. Separate payments are made for follow up services. In accordance with section 120.D of chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-03), "Adjustment of prosthetic devices required by wear or by a change in the patient's condition is covered when ordered by a physician. General provisions relating to the repair and replacement of durable medical equipment in §110.2 for the repair and replacement of prosthetic devices are applicable" and claims should be submitted for those services separately, at the time of service.

Because the VA data is from 2020 and we believe VA use of Axor™ II may not be widespread at this time, we are using the Axor™ II supplier price to establish a fee schedule under code L5991, but are backing out the costs that Medicare does not pre-pay for using the information that Integrum, S.E. provided to CMS. As such, we have used the reported current wholesale price of Axor™ II (\$14,000) along with the reported estimated 5 hours needed for the prosthetist to initially fit and adjust the Axor™ II for the patient, to obtain a current price of \$16,279.15 for the Axor™ II. The hourly rate for the prosthetist was estimated as \$455.83, which is calculated based on the MSRP cost of \$35,424 less the wholesale price of \$14,000

and then divided by the reported 47 prosthetist hours (5 for initial fitting, 18 for 3 years of twice-yearly visual inspection/cleaning services, and 24 for 3 years of annual servicing). The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act. Payment for Axor™ II would be made as a prosthetic. The average 2023 purchase fee schedule amount for L5991 would be approximately \$10,969.24. Fee schedule amounts are updated annually.

Payment would be on a lump sum basis.

Pricing Indicator = 38

Self-Measured Blood Pressure (SMBP) Devices - IHC221222X2AHC

Topic/Issue

Request for benefit category determination for self-measured blood pressure (SMBP) devices.

Applicant's Summary

The American Heart Association (AHA) and American Medical Association (AMA) submitted a combined request for a Benefit Category Determination of the use of self-measured blood pressure (SMBP) devices. Use of SMBP devices is an evidence-based intervention to help patients with hypertension achieve and maintain blood pressure (BP) control. SMBP devices are used by patients in their homes to monitor their BP. Understanding where their BP is in relation to their target BP level enables patients to adjust their behavior to lower their BP. The information also helps patients understand when they need to communicate with their physician about adjusting medications. According to the applicant, SMBPs should be classified by CMS as durable medical equipment (DME). Hypertension is the number one chronic condition of Medicare beneficiaries. Monitoring BP at home using a SMBP device is a key component in managing hypertension. When SMBP devices are used to manage hypertension there is evidence to support improved medication adherence, reduction in BP and improved BP. SMBP devices calculate systolic (top) and diastolic (bottom) BP values and provide patients with a digital display of their BP readings. The devices include an adjustable cuff that wraps around the patient's upper arm. A variety of cuff sizes are available to ensure accuracy. There are two main types of SMBP devices: manual and automatic. Manual SMBP devices consist of a cuff, an inflation bulb and a gauge that is read by looking at a pointer on the dial. Manual BP monitors require the use of a stethoscope to listen to the blood pulsing through the artery. Due to the training and skill required to accurately measure BP with manual SMBP devices, they are not recommended for home use. Automatic BP monitors have upper arm cuffs that automatically inflate, deflate, and calculate a patient's BP. The SMBP device's screen displays a digital readout of the patient's BP. The devices are available for purchase directly from device manufacturers through retail stores such as CVS, Walgreens, Walmart, and Costco, as well as online marketplaces like Amazon. SMBP devices may be equipped with one or more types of connectivity functions to transfer or store BP readings. These functions include WiFi, Bluetooth, or cellular connectivity. The devices can also vary in terms of the number of BP readings that can be stored on the device, as well as software compatibility with patient or clinic-level management software to compile and analyze BP readings and trends.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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 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. It is our understanding that SMBPs, when generally used in the home, are used to monitor BP and to report results to the clinician to determine the course of treatment. 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. For example, the SPEAC® System, which is not DME, is a recording and monitoring system in which the physician receives a summary report to help with clinical decisions. Items that are DME are used by the patient in the home for therapeutic and self-management purposes. SMBPs are generally not used by the patient to self-manage hypertension, but rather require clinical intervention to manage their medical condition, which is the basis for our determination.

The applicants suggested that SMBPs are comparable to glucose monitoring devices because they both provide information for patients and their physicians to take actions based on the readings. We do not agree that they are comparable. Section 1861(n) of the Social Security Act specifically states that glucose monitors are DME. Glucose monitors are home monitoring devices in which the patient immediately self-manages their medical condition in the home based on the readings from the monitor. They do not need to rely on their physician to determine a course of action.

However, we recognize the benefits to improving care in the home. To the degree that there is well accepted medical practice in which SMBPs are used in the home in a way that is similar to the use of glucose monitors to affect treatment actions by the patient, and the FDA has approved this specific use/indication as safe and effective, CMS would be interested in receiving information about those circumstances to inform our final determination.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

The speakers disagreed with CMS' preliminary recommendation that SMBP devices lack a Medicare DMEPOS benefit category and stated that these devices meet all five of the conditions to be considered durable medical equipment (DME). With respect to the third DME condition that the item or service be primarily and customarily used to serve a medical purpose, the speakers disagreed that SMBPs are generally not used by patients to self-manage hypertension and stated that they are used to guide self-management for hypertension. Similar to the self-management of a person with diabetes, commenters indicated a treatment plan intended to be for several weeks or months is created by a clinician to assist the patient in managing as yet uncontrolled hypertension by the patient at home. Once hypertension is diagnosed and management is initiated, SMBP readings are used for patients to assess blood pressure control and to take action to manage blood pressure and improve adherence to treatment. Concerning the relationship to glucose monitors, the speakers indicated that people

with diabetes rely on a treatment plan created by a clinician in the same way as a person with hypertension. In both cases the patients use the readings and follow instruction in the treatment plan in response to the readings. They use the data from the devices and follow the treatment plan. The speaker indicated that SMBP measurements provide information to patients in real-time so they can see the blood pressure lowering effects of their treatment and take immediate action based on their treatment plan without relying on communication with their physician to determine course of action. Commenters stated that patient education from their care teams on how they can take action to self-manage hypertension based on daily SMBP measurements includes instructions for when and how to adjust non-pharmacological treatments for hypertension. If SMBP measurements are too low, patients can take immediate action by following their treatment plan to reduce the risk of harm. If SMBP measurements are too high, patients can follow their treatment plan to reduce BP, including reducing salt intake, refraining from using alcohol and tobacco, and modifying their medications if indicated. One commenter said SMBPs empower the patient to call their provider for medication advice/modification or request a sooner appointment visit if indicated. Another commenter stated that recent research has shown the potential for patients to use SMBP to self-manage their high blood pressure through self-titration of antihypertensive medications, without needing to visit a clinical care provider for a prescription change following a high reading. Other commenters indicated that patients monitoring their blood pressure may modify their medications based on prior guidance from their clinician. A patient may hold or reduce a dose of medication, or require an additional dose, if their blood pressure is outside the necessary range. One comment stated that medications cause acute changes in BP (for example, some cancer treatments can elevate BP lead to malignant hypertension), and there is no way to monitor for this without a home BP monitor. For individuals with very low BP, having a home BP monitor can be critical to taking steps to avoid a fall and hip fracture. Commenters also noted that blood pressure measurements taken at home vary greatly from those measured in the healthcare setting and that this variation may lead to undertreatment or overtreatment of blood pressure. When clinicians have access to SMBP readings, it provides information which facilitates appropriate education, treatment and self-management. Another commenter stated out of the office measurements of blood pressure have been shown to have better prognostic ability in overall outcome than traditional in-office measurements. These forms of measurement also have the benefit of capturing repeated instances and avoiding artificially elevated readings. Commenters also stated that research shows that medication adherence improves in patients who use SMBP.

Final Medicare Benefit Category Determination

CMS appreciates the information shared and evolving evidence base for these devices. CMS is actively deliberating on this topic but is not able to issue a decision at this time.

Myriad Matrix™ - HCP230103Q66RU

Topic/Issue

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

Applicant's suggested language: QXXXX, "Myriad Matrix, per square centimeter"

Summary of Applicant's Submission

Aroa Biosurgery Limited submitted a request to establish a new HCPCS Level II code to identify Myriad Matrix™. Myriad Matrix™ is an advanced extracellular matrix (ECM) scaffold derived from Ovine (sheep) forestomach tissue. This advanced ECM scaffold is a non-reconstituted collagen; thus, it retains the innate biological structure and function of the native ECM associated macromolecules, including elastin, fibronectin, glycosaminoglycans and laminin. Myriad Matrix™ is a bioengineered scaffold derived from Ovine (sheep) forestomach tissue. Myriad Matrix™ absorbs cells, blood, and blood components into the matrix to form a reservoir. Fibroblast, endothelial and immune cells infiltrate the entire matrix and build new tissue. Overtime, Myriad Matrix™ is then completely replaced by the patient's own tissue. According to the applicant, there is no unique HCPCS code assigned to Myriad Matrix™ that properly identifies its dual indications for use in both soft tissue reinforcement and wound care management. According to the applicant, currently, providers are limited to using Q4100, (skin substitute, not otherwise specified) resulting in delayed claims processing, and the inability to specifically report the product being used for treatment. Myriad Matrix™ is indicated for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery, or for management of the following wounds: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, draining wounds. Myriad Matrix™ contain the natural porous structure of AROA ECM™, engineered with interstitial perforations to enable cell infiltration to facilitate rapid healing. Myriad Matrix™ is available in a range of sizes, up to 400 sq cm. Myriad Matrix™ is "delivered" via cutaneous application, or soft tissue implantation, and is packaged as a terminally sterilized single use graft. According to the applicant, the Myriad device manufactured by Aroa Biosurgery Ltd. is cleared in for use in plastic and reconstructive surgery under 510(k) (K162461, decided upon on 12/20/2016) under the name Endoform Plastic and Reconstructive Matrix, and in dermal application under 510(k) (K171231, decided upon 6/14/2017) under the name Endoform Topical Matrix. Per the applicant, the aforementioned devices are identical, and have been branded as a single device under the name Myriad Matrix and labelled in accordance with both clearances.

CMS Preliminary HCPCS Coding Decision

CMS could not identify information in the application confirming that Endoform Plastic and Reconstructive Matrix and Endoform Topical Matrix are identical products to be branded as a single device called "Myriad Matrix™". The Endoform Plastic and Reconstructive Matrix and Endoform Topical Matrix have received separate 510(k) clearances from the Food and Drug Administration (FDA), which were included as part of the HCPCS Level II application. CMS would expect Myriad Matrix™ to receive similar clearance from the FDA. As a result, CMS is unable to establish a new HCPCS Level II code for Myriad Matrix™.

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 could not identify information in the application confirming that Endoform Plastic and Reconstructive Matrix and Endoform Topical Matrix are identical products to be branded as a single device called "Myriad Matrix™". The Endoform Plastic and Reconstructive Matrix and Endoform Topical Matrix have received separate 510(k) clearances from the FDA, which were included as part of the HCPCS Level II application. CMS would expect Myriad Matrix™ to receive similar clearance from the FDA. As a result, CMS is unable to establish a new HCPCS Level II code for Myriad Matrix™.

InnovaBurn® and InnovaMatrix® XL - HCP230103KC768

Topic/Issue

Request to establish a new HCPCS Level II code to identify InnovaBurn® and InnovaMatrix® XL.

Applicant's suggested language: AXXXX, “InnovaBurn or InnovaMatrix XL, per square centimeter”

Summary of Applicant’s Submission

Convatec Triad Life Sciences, LLC submitted a request to establish a new HCPCS Level II code to identify InnovaBurn® and InnovaMatrix® XL. InnovaBurn® received the Food and Drug Administration’s (FDA) 510(k) clearance on September 29, 2022. InnovaMatrix® XL received the FDA’s 510(k) clearance on October 21, 2020. According to the applicant, InnovaBurn® will also have the commercial name InnovaMatrix® XL. InnovaBurn® is a sterile, single-use, medical device consisting of extracellular matrix derived from porcine placental material used for safe and effective wound treatment. InnovaBurn® and InnovaMatrix® XL are composed of collagen, elastin, laminin, fibronectin, hyaluronic acid, and sulfated glycosaminoglycans and is produced in sheet form in a variety of sizes. This biodegradable wound matrix provides a protective cover to the wound. InnovaBurn® and InnovaMatrix® XL are 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, and skin tears), partial-thickness second degree burns, and draining wounds. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product fully resorbs and does not have to be removed. InnovaBurn® and InnovaMatrix® XL are supplied terminally sterile, in a single use package, and in a variety of sizes up to 400 square centimeters.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, “Innovaburn or innovamatrix xl, 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

ConvatecTriad Life Sciences, LLC, the manufacturer of these products, agreed with CMS’ published preliminary HCPCS coding recommendation.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary HCPCS coding 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 A2022, "Innovaburn or innovamatrix xl, per square centimeter" to describe InnoVaBurn® and InnoVaMatrix® XL.

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.

InnovaMatrix® PD - HCP230103W0Q0W

Topic/Issue

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

Applicant's suggested language: AXXXX, “InnovaMatrix PD, 1 mg”

Summary of Applicant’s Submission

Convatec Triad Life Sciences, LLC submitted a request to establish a new HCPCS Level II code to identify InnovaMatrix® PD. InnovaMatrix® PD received the Food and Drug Administration’s 510(k) clearance on September 28, 2022. InnovaMatrix® PD is a sterile, single use, medical device consisting of extracellular matrix derived from porcine placental material used for safe and effective wound treatment. InnovaMatrix® PD is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans and is produced in particulate form in a variety of sizes. This biodegradable wound matrix provides a protective cover to the wound. InnovaMatrix® PD 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, and skin tears), draining wounds, and partial-thickness second-degree burns. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product fully resorbs and does not have to be removed. InnovaMatrix® PD is supplied terminally sterile, in a single use package, and in a variety of sizes up to 500 mg.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, “Innovamatrix pd, 1 mg”

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

Convatec Triad Life Sciences, LLC, the manufacturer of this product, agreed with CMS’ published preliminary HCPCS coding recommendation.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS’ published preliminary HCPCS coding 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 A2023, “Innovamatrix pd, 1 mg” to describe InnovaMatrix® PD.

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.

Resolve Matrix™ - HCP22121960DPF

Topic/Issue

Request to establish a new HCPCS Level II code to identify Resolve Matrix™ acellular peritoneum.

Applicant's suggested language: XXXXX, "Resolve matrix acellular peritoneum matrix (resolve matrix), 1 sq. cm"

Summary of Applicant's Submission

Parametrics Medical submitted a request to establish a new HCPCS Level II code to identify Resolve Matrix™ acellular peritoneum matrix (Resolve Matrix™). Meso Wound Matrix™ (now Resolve Matrix™) received the Food and Drug Administration's (FDA's) 510(k) clearance on February 10, 2012. According to the applicant, Meso Wound Matrix™ is not and will not be sold under the brand name Meso Wound Matrix™. In early 2022, Parametrics Medical engaged with DSM Biomedical regarding commercializing of the product and has since launch the product under the brand name "Resolve Matrix™." Resolve Matrix™ is a thin, flexible, yet strong acellular biologic dermal substitute which acts to support the body's own regenerative tissue repair process during wound healing. According to the applicant, it is uniquely derived from porcine peritoneum membrane and processed using the optrix tissue cleansing methodology. Resolve Matrix™ is indicated for the management of topical wounds, including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds, trauma wounds, draining wounds, and tunneled or undermined wounds. Resolve Matrix™ has a nominal thickness of ± 0.3 mm and is supplied in multiple sizes. Parametrics Medical is a licensed distributor for Resolve Matrix™, which is manufactured by DSM Biomedical.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Resolve matrix, 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

Parametrics Medical, the applicant of this request, agreed with CMS' published preliminary HCPCS coding recommendation.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary HCPCS coding 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 A2024, “Resolve matrix, per square centimeter” to describe Resolve 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.

Miro3D Wound Matrix - HCP220926BGPQ3

Topic/Issue

Request to establish a new HCPCS Level II code to identify Miro3D wound matrix.

Applicant's suggested language: QXXXX, "Miro3D, per cubed centimeter"

Summary of Applicant's Submission

Reprise Biomedical, Inc. submitted a request to establish a new HCPCS Level II code to identify Miro3D wound matrix. Miro3D received the Food and Drug Administration's (FDA's) 510(k) clearance on August 18, 2022. Miro3D wound matrix is a single use, sterile, porcine-derived non-crosslinked acellular collagen matrix. Miro3D is a porous scaffold, which provides a protective environment for wound management. The device is made by drying perfusion decellularized porcine liver in ambient air, cutting the resulting sponge-like scaffold into four defined sizes. Package is dry in a Polyethylene terephthalate glycol plastic tray with a snap-on lid and sealed Tyvek® lid. The unique three-dimensional shape of Miro3D has potential benefits to apply to deep, tunneling, and irregular wound beds, which may otherwise require multiple layers of other products/treatments or surgical treatment with full-thickness skin grafts. According to the applicant, existing HCPCS Level II codes do not adequately describe Miro3D, especially since Miro3D is measured by cubic cm. Applicant also stated that currently, providers must utilize HCPCS Q4100, "Skin substitute, not otherwise specified", which results in delayed claims processing, additional documentation, and the inability for providers to specifically report which product is being used for treatment. Miro3D is offered in four sizes, all 2 cm in thickness which include: 2 cm x 2 cm x 2 cm, 3 cm x 3 cm x 2 cm, 5 cm x 5 cm x 2 cm, and 5 cm x 10 cm x 2 cm.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Miro3d, per square centimeter"

Reprise Medical's instruction for use indicates that Miro3D is hydrated and rehydrated in sterile saline or lactated Ringer's solution prior to use. The device is packaged dry, terminally sterilized in its packaging, and is rehydrated with sterile saline or lactated Ringer's solution prior to use. Miro3D wound matrix can be cut to fit a wound size prior to rehydration or application.

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

Reprise Biomedical, Inc., the manufacturer of this product, agreed with the preliminary decision to issue a HCPCS Level II code for Miro3D, but disagreed with the preliminary decision on the metric definition of the product. The speakers requested CMS to reconsider its decision and change the metric definition to a cubic centimeter description. According to the speaker, this product is unlike anything that has been in the speaker's hands for clinical practice of wound management, and thus deserves another level of distinction. Miro3D is available in four different size configurations, each size configuration has a three-dimensional

block shape in its original package, with a uniform 2 cm thickness. After rehydrating with saline, each size configuration retains its three-dimensional block shape. The rehydration step allows the as-packaged “crisp block” to become slightly softened while maintaining its three-dimensional shape and allows the material to conform to the full wound wall, almost like putty. Miro3D does not have any expansion properties when hydrated. The speaker also said Miro3D was cleared by FDA with the measurement descriptor of cubic centimeter, as opposed to square centimeter.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS’ published preliminary HCPCS coding recommendation. We appreciate the clarification that the product as supplied for use is a three-dimensional block shape with a uniform 2 cm thickness and retains its three-dimensional block shape after rehydration. 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 A2025, “Miro3d, per cubic centimeter” to describe Miro3D.

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.

MuGard™ Oral Mucoadhesive Hydrogel, Single Use - HCP230104E2DY0

Topic/Issue

Request to establish a new HCPCS Level II code to identify Mugard™ Oral Mucoadhesive Liquid Hydrogel.

Applicant's suggested language: XXXXX, “Mugard Oral Mucoadhesive Liquid Hydrogel with or w/o drug/biologic, Single Use (10 mL, Non-Substitutable)”

Summary of Applicant’s Submission

Soleva Pharmaceuticals, LLC submitted a request to establish a new HCPCS Level II code to identify MuGard™ Oral Mucoadhesive Hydrogel. MuGard™ received the Food and Drug Administration’s (FDA’s) 510(k) clearance on December 11, 2006. MuGard™ is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. The mucoadhesive polymers in the hydrogel formulation adhere to the oral mucosa and form a protective coating. Dosage and route of administration is to swish 5 to 10 mL of oral liquid every 4 to 6 hours. It may be swallowed or expelled. For the management of oral mucositis/stomatitis, it is recommended that MuGard™ is used 4–6 times a day. For other ulcerative conditions of the oral cavity, MuGard™ should be used 4–6 times a day or as needed. MuGard™ Oral Mucoadhesive is available in a 10 mL single dose unit and a multiple use, 240 mL bottle with dosage cup.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, “Oral mucoadhesive, any type (liquid, gel, paste, etc.), per 1 ml”

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category.

Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations are covered under Section 1861(s)(5) of the Act. The Medicare definition for surgical dressings is located in section 100 of the Medicare Benefit Policy Manual (CMS 100-02).

Surgical dressings are limited to primary and secondary dressings required for the treatment of a wound. Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered.

The Surgical Dressing benefit limits coverage to wounds of the skin. Treatments used for injuries to the oral mucosa are not eligible for coverage under this benefit as oral mucosa is not skin. It is a different tissue type and thus is excluded from this benefit.

Although these products may serve a beneficial purpose in the treatment of oral mucosal injuries, there is no coverage available under the Surgical Dressings benefit for these items. This item would not fall under any other DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

Soleva Pharmaceuticals, LLC, the manufacturer of this product, disagreed with part of CMS' published preliminary HCPCS recommendation. The manufacturer did not comment on the preliminary coding language but disagreed with the lack of benefit category and coverage determination. According to the speaker, a lack of DMEPOS category for oral mucoadhesive device is not valid justification to deny coverage and patient access to an effective treatment. They further stated that this is the same justification for refusal for a DME "K" code in 2016, rather than creating a new benefit category for coverage CMS is regressing not innovating. The applicant also requested in their public meeting slides that CMS should either create a new benefit category for Oral Mucoadhesive devices, broaden the surgical dressings benefit category to include oral mucoadhesives, or create a new DMEPOS "oncology palliative care device" benefit category for 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 slide presentation we received, CMS is finalizing its preliminary recommendation to:

Establish a new HCPCS Level II code A9156, "Oral mucoadhesive, any type (liquid, gel, paste, etc.), per 1 ml" to describe MuGard™ Oral Mucoadhesive Hydrogel.

MuGard™ Oral Mucoadhesive Liquid Hydrogel received the FDA 510(k) device clearance as substantially equivalent to the predicate devices (OraMagicRx™ Oral Wound Rinse and Gelclair® Concentrated Oral Gel) in December 2006. Based on the FDA's clearance, MuGard™ Oral Mucoadhesive Liquid Hydrogel does not possess the FDA's drug approval, as such it would not be considered a "drug."

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Soleva Pharmaceuticals, LLC submitted slides for the MuGard™ Oral Mucoadhesive for the May 30, 2023, public meeting. In these slides, the applicant stated that the MuGard™ Oral Mucoadhesive is not a surgical dressing. We agree and reaffirm our preliminary benefit category determination that the MuGard™ Oral Mucoadhesive is not a surgical dressing, and that it does not fall under a DMEPOS benefit category.

The applicant also requested in their public meeting slides that CMS should either create a new benefit category for Oral Mucoadhesive devices, broaden the surgical dressings benefit

category to include oral mucoadhesives, or create a new DMEPOS “oncology palliative care device” benefit category for products. We will not be taking these actions and will be finalizing our preliminary benefit category determination. CMS makes benefit category determinations based on the scope of Medicare Part B benefits identified in section 1832 of the Social Security Act, as well as certain statutory and regulatory definitions for specific items and services. If an item is excluded from coverage by the Social Security Act or does not fall within the scope of a defined Medicare benefit category (in this case, the MuGard™ Oral Mucoadhesive does not fall under any DMEPOS benefit category), the item cannot be covered under Medicare.

As discussed in our preliminary benefit category determination, surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations are covered under Section 1861(s)(5) of the Act. The Medicare definition for surgical dressings is in section 100 of the Medicare Benefit Policy Manual (CMS 100-02). Surgical dressings are limited to primary and secondary dressings required for the treatment of a wound caused by, or treated by, a surgical procedure that has been performed by a physician or other health care professional to the extent permissible under State law. In addition, surgical dressings required after debridement of a wound are also covered, irrespective of the type of debridement, as long as the debridement was reasonable and necessary and was performed by a health care professional acting within the scope of his/her legal authority when performing this function. Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered. Items such as adhesive tape, roll gauze, bandages, and disposable compression material are examples of secondary dressings. The Surgical Dressing benefit limits coverage to wounds of the skin. Treatments used for injuries to the oral mucosa are not eligible for coverage under this benefit as oral mucosa is not skin. It is a different tissue type and thus is excluded from this benefit. Although these products may serve a beneficial purpose in the treatment of oral mucosal injuries, there is no coverage available under the Surgical Dressings benefit for these items.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

MuGard™ Oral Mucoadhesive Hydrogel, Multiple Use – HCP2301044RWA8

Topic/Issue

Request to establish a new HCPCS Level II code to identify MuGard™ Oral Mucoadhesive Liquid Hydrogel.

Applicant's suggested language: XXXXX, "Mugard Oral Mucoadhesive Liquid Hydrogel with or w/o drug/biologic, Multiple Use (240 mL, Non-Substitutable)"

Summary of Applicant's Submission

Soleva Pharmaceuticals, LLC submitted a request to establish a new HCPCS Level II code to identify MuGard™ Oral Mucoadhesive Hydrogel. MuGard™ received the Food and Drug Administration's (FDA's) 510(k) clearance on December 11, 2006. MuGard™ is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. The mucoadhesive polymers in the hydrogel formulation adhere to the oral mucosa and form a protective coating. Dosage and route of administration is to swish 5 to 10 mL of oral liquid every 4 to 6 hours, it may be swallowed or expelled. For the management of oral mucositis/stomatitis, it is recommended that MuGard™ is used 4–6 times a day. For other ulcerative conditions of the oral cavity, MuGard™ should be used 4–6 times a day or as needed. MuGard™ Oral Mucoadhesive is available in a 10 mL single dose unit and a multiple use, 240 mL bottle with dosage cup.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Oral mucoadhesive, any type (liquid, gel, paste, etc.), per 1 ml"

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category.

Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations are covered under Section 1861(s)(5) of the Social Security Act (the Act). The Medicare definition for surgical dressings is located in section 100 of the Medicare Benefit Policy Manual (CMS 100-02).

Surgical dressings are limited to primary and secondary dressings required for the treatment of a wound. Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered.

The Surgical Dressing benefit limits coverage to wounds of the skin. Treatments used for injuries to the oral mucosa are not eligible for coverage under this benefit as oral mucosa is not skin. It is a different tissue type and thus is excluded from this benefit.

Although these products may serve a beneficial purpose in the treatment of oral mucosal injuries, there is no coverage available under the Surgical Dressings benefit for these items. This item would not fall under any other DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

Soleva Pharmaceuticals, LLC, the manufacturer of this product, disagreed with part of CMS' published preliminary HCPCS recommendation. The manufacturer did not comment on the preliminary coding language but disagreed with the lack of benefit category and coverage determination. According to the speaker, a lack of DMEPOS category for oral mucoadhesive device is not valid justification to deny coverage and patient access to an effective treatment. They further stated that this is the same justification for refusal for a DME "K" code in 2016, rather than creating a new benefit category for coverage CMS is regressing not innovating. The applicant suggested CMS create a new DMEPOS product benefit category for oral mucoadhesive devices; provide a letter demanding for pharmacy benefit managers under Part D to include liquid oral mucoadhesive as part of oncology palliative care products; broaden the "surgical dressing" category to include oral mucoadhesive; consider a "drug" J code for MuGard™ Oral Mucoadhesive Hydrogel as an oncology palliative care product; and create a new DMEPOS "oncology palliative care device" category for 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 slide presentation we received, CMS is finalizing its preliminary recommendation to:

Establish a new HCPCS Level II code A9156, "Oral mucoadhesive, any type (liquid, gel, paste, etc.), per 1 ml" to describe MuGard™ Oral Mucoadhesive Hydrogel.

MuGard™ Oral Mucoadhesive Liquid Hydrogel received the FDA's 510(k) device clearance as substantially equivalent to the predicate devices (OraMagicRx™ Oral Wound Rinse and Gelclair® Concentrated Oral Gel) in December 2006. Based on the FDA's clearance, MuGard™ Oral Mucoadhesive Liquid Hydrogel does not possess the FDA's drug approval, as such it would not be considered a "drug."

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Soleva Pharmaceuticals, LLC submitted slides for the MuGard™ Oral Mucoadhesive for the May 30, 2023, public meeting. In these slides, the applicant stated that the MuGard™ Oral Mucoadhesive is not a surgical dressing. We agree and reaffirm our preliminary benefit category determination that the MuGard™ Oral Mucoadhesive is not a surgical dressing, and that it does not fall under a DMEPOS benefit category.

The applicant also requested in their public meeting slides that CMS should either create a new benefit category for Oral Mucoadhesive devices, broaden the surgical dressings benefit category to include oral mucoadhesives, or create a new DMEPOS “oncology palliative care device” benefit category for products. We will not be taking these actions and will be finalizing our preliminary benefit category determination. CMS makes benefit category determinations based on the scope of Medicare Part B benefits identified in section 1832 of the Social Security Act, as well as certain statutory and regulatory definitions for specific items and services. If an item is excluded from coverage by the Social Security Act or does not fall within the scope of a defined Medicare benefit category (in this case, the MuGard™ Oral Mucoadhesive does not fall under any DMEPOS benefit category), the item cannot be covered under Medicare.

As discussed in our preliminary benefit category determination, surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations are covered under Section 1861(s)(5) of the Act. The Medicare definition for surgical dressings is in section 100 of the Medicare Benefit Policy Manual (CMS 100-02). Surgical dressings are limited to primary and secondary dressings required for the treatment of a wound. Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered. The Surgical Dressing benefit limits coverage to wounds of the skin. Treatments used for injuries to the oral mucosa are not eligible for coverage under this benefit as oral mucosa is not skin. It is a different tissue type and thus is excluded from this benefit. Although these products may serve a beneficial purpose in the treatment of oral mucosal injuries, there is no coverage available under the Surgical Dressings benefit for these items.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Venowave VW5 and Supplies - HCP220922Q7MR0

Topic/Issue

Request to establish two new HCPCS Level II codes to identify Venowave VW5 and supplies.

Applicant's suggested language:

1. XXXXX, “Peristalsis; non-pneumatic compression pump, limb, mobile”
2. XXXXX, “Peristalsis; non-pneumatic compression wrap, limb, mobile”

Summary of Applicant’s Submission

Venowave Inc. submitted a request to establish a new HCPCS Level II code to identify Venowave VW5. Venowave VW5 received the Food and Drug Administration’s (FDA’s) 510(k) clearance on March 7, 2008. The Venowave VW5 is a series of compact, battery-operated peristaltic pumps that generate a wave-form motion, and when worn below the knee strapped firmly to the calf, result in compression of the calf and consequently an increased upward volumetric displacement of venous and lymph fluid. According to the applicant, the Venowave VW5 series induces improved vascular and lymphatic flow of the lower limbs. According to the applicant, current existing HCPCS Level II codes are for pneumatic or for non-pneumatic sequential with gradient compression devices and are not appropriate for the Venowave VW5 to be billed. The Venowave VW5 generates a mechanical wave which starts at the lower pivot point and travels to the upper pivot point, a distance of 14cm (wavelength) traveled for each cycle of the crank. The swept volume or volume of blood or lymph fluid displaced upwards for each cycle is the product of the wavelength (14cm), the width of the wave sheet (7.5cm) and the depth of the wave (0.95cm) or approximately 0.1 L/cycle. Operating by way of a single rechargeable 1.5 V NiMh AA battery, this single-patient use device enables the user to receive treatment anywhere, while remaining active. Indications for use as approved by the FDA are the following: management of the symptoms of post thrombotic syndrome (PTS), prevention of deep vein thrombosis (DVT), prevention of primary thrombosis, treatment of lymphedema, diminishing post-operative pain and swelling, treatment of leg swelling due to vascular insufficiency, treatment of varicose veins, treatment of chronic venous insufficiency, enhancing blood circulation, and treatment of intermittent claudication.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E0676, “Intermittent limb compression device (includes all accessories), not otherwise specified” describes Venowave VW5. For HCPCS Level II code E0676, discontinue Berenson-Eggers Type of Service (BETOS) D1E, “Other DME” and apply BETOS Z2, “Undefined”

At this time, the clinical information provided with this application does not support the claim of significant therapeutic distinction that would warrant a new HCPCS Level II code when the Venowave is used in comparison to other intermittent limb compression devices that share a code category. In addition, no clinical published studies were provided in support of Venowave’s effect on lymphedema.

However, additional information could be provided for CMS consideration to inform whether to create a new code to describe Venowave. Accordingly, we are interested in gaining a better understanding of how the Venowave is distinguishable from other products on the market. Specifically, whether and exactly how the difference in design from other intermittent limb compression devices confers a different function and/or a significant therapeutic distinction when compared with the use of other products on the market. Also, what are the additional therapeutic advantages and capabilities that are not provided or available through traditional pneumatic device formats that are provided by Venowave. Clinical studies that demonstrate such comparison and distinction would be welcome.

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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.

Venowave is a single-patient use item and therefore would not fall under a DMEPOS benefit category. In both the HCPCS and 510(k) application for FDA the applicant indicates that Venowave is “Operating by way of a single rechargeable 1.5 V NiMh AA battery, this single-patient use device enables the user to receive treatment anywhere, while remaining active.”

Lymphedema is a chronic medical problem that involves an accumulation of lymphatic fluid in the extremities along with progressive and pathologic structural changes that arise from an ongoing inflammatory response produced by that fluid and its contents in the interstitial space. The goal of lymphedema treatment is to reduce the amount of retained lymphatic fluid in an extremity or tissue space. A key component of lymphedema treatment requires applying graded compression to the affected limb where higher pressure is applied distally to move fluid more proximally “down” a pressure gradient. We were unable to locate any studies using Venowave in the treatment of lymphedema or information that the device establishes the pressure gradient needed to treat lymphedema. There is a reference to the use of the device in a preliminary study of 10 patients, some of which had lymphedema. Unfortunately, we were unable to locate this study during a literature search. Nonetheless, this small sample size cannot be considered high certainty evidence. As such, we have not found any documented evidence to support the assertions that Venowave can effectively treat the symptoms of lymphedema. In light of the lymphedema compression treatment items benefit passed under the Consolidated Appropriations Act of 2023 and effective January 1, 2024, we encourage Venowave Inc. to provide us with evidence, if available.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

Venowave Inc., the manufacturer of this product, disagreed with part of CMS' published preliminary recommendation. The speaker did not comment on the preliminary coding language, but disagreed with the lack of Medicare benefit category. The speaker commented that the FDA 510(k) wording of "single use" was from 2008. The speaker stated the device can be used and rented by successive patients, and it was designed with a minimum lifetime requirement of 3 years. According to the speaker, Venowave is primarily and customarily used to service a medical purpose; it was developed and is used for patient with an illness or injury at home. In response to CMS' question regarding the treatment of leg swelling due to vascular insufficiency, the speaker stated that the venous, vascular, and related issues are all very correlated in pathophysiology and presentation and all have varying degree of symptoms that closely mimic one another. According to the speaker, secondary lymphedema is a disorder of lymphatic flow that is caused by some other disease or condition. It is more common than primary lymphedema. It is most commonly caused by surgery (especially lymph node dissection, such as for breast cancer), radiation therapy (especially axillary or inguinal), trauma, lymphatic obstruction by tumor, and, in developing countries, lymphatic filariasis. Secondary lymphedema may also result from compression of the lymphatic and venous channels resulting from leakage of fluid into interstitial tissues in patients with chronic venous insufficiency. Lymphedema may also be caused by chronic venous insufficiency (CVI) when fluid leaks into the tissues from the venous system. CVI of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers. The incidence of lymphedema from CVI is not well established.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendations. 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 E0676, "Intermittent limb compression device (includes all accessories), not otherwise specified" to describe Venowave VW5. For HCPCS Level II code E0676, CMS will discontinue Berenson-Eggers Type of Service (BETOS) D1E, "Other DME" and apply BETOS Z2, "Undefined".

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination of no Medicare DMEPOS benefit category for code E0676 apply to this item.

In both the HCPCS application and the 510(k) application for FDA the applicant indicates that Venowave is "Operating by way of a single rechargeable 1.5 V NiMh AA battery, this

single-patient use device enables the user to receive treatment anywhere, while remaining active.” A device must meet all of the conditions listed in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 to be DME, including being able to withstand repeated use by successive patients. Therefore, single-patient use devices do not fall under a DMEPOS benefit category. During the public meeting Venowave Inc. clarified that the device is capable of use by successive patients and indicated that they are seeking FDA approval for Venowave VW5 as a multi-patient use device. The applicant is welcome to submit a new HCPCS Level II coding or benefit category determination application in a subsequent coding cycle if and when new information becomes available related to multi-patient use by the FDA.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

VIBRANT® System - HCP2212200H7AK

Topic/Issue

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

Applicant's suggested language: XXXXX, “Programable pod to activate the non-pharmacologic, orally ingested, recipient capsule, causing intracolonic peristalsis to induce bowel movements”

Summary of Applicant’s Submission

Vibrant Gastro System submitted a request to establish a new HCPCS Level II code to identify VIBRANT® System. VIBRANT® System received the Food and Drug Administration’s (FDA’s) De Novo clearance on August 26, 2022. VIBRANT® System is prescribed for home use to relieve symptoms related to chronic idiopathic constipation (CIC). VIBRANT® System consists of a base unit (Pod) and a naïve capsule. The VIBRANT® Pod is pre-programmed via the Pod and can be monitored and altered by the physician to deliver a patient specific treatment. The naïve capsule is placed into the Pod then activated and calibrated to deliver CIC treatment. The Pod and naïve capsule are an integrated therapeutic solution. The Pod must activate the capsule to deliver the treatment. According to the applicant, the Pod has a useful life of at least 3 years. It is reprogrammed for use by other patients. The programmed capsule is an orally ingested, non-pharmacologic, capsule that is thought to induce mechanical stimulation via vibration of the colonic wall synced with the circadian rhythm of colonic contractile activity thereby increasing complete spontaneous bowel movements (CSBM). The Pod delivered program causes the synced capsule to initiate vibrations at a specific time and duration delivering the treatment in the colon planned by the physician, (using specific vibration mode of work proposed by VIBRANT®), then the capsule is naturally excreted. Dosage is 5 activated capsules weekly, packaged in 20-dose blister packs per month of use. As a supply item the Pod is a component of the therapeutic system. According to the applicant, the VIBRANT® System phase 3 randomized, placebo-controlled trial (RCT) led to the FDA De Novo clearance. Per the applicant, VIBRANT® System treatment efficacy and safety were validated in a phase 3, prospective, double-blind, placebo-RCT of patients with CIC who received blinded treatment once daily, five days a week for 8 weeks. The primary efficacy endpoints were an increase of at least one more CSBM per week (CSBM1 responder) or at least two more CSBMs per week (CSBM2) from baseline. Responder was defined as subject who had an improvement of CSBM1 or CSBM2 during at least 6 of the 8 weeks. Safety analyses were performed, and 904 patients were screened, 312 were enrolled meeting inclusion and exclusion criteria. A greater percentage of patients receiving the vibrating capsule achieved both primary efficacy endpoints compared to placebo (39.3% vs. 22.1%, $p=0.001$ CSBM1; and 22.7% vs. 11.4%, $p=0.008$ CSBM2). Patients had at least 14 years of CIC; of these 56% had severe CIC defined as 0 CSBM for 2 weeks at baseline. According to the applicant, significantly greater improvements in treatment were seen for the secondary endpoints of straining, stool consistency, and quality of life measures compared to placebo. Per the applicant, adverse events were mild, gastrointestinal in nature and similar between groups. A mild vibrating sensation was reported by 11% of patients in the vibrating capsule group, and no patients withdrew from the trial. According to the applicant, patient experience using the VIBRANT® System was favorable across all ages. According to the applicant, VIBRANT® System offers

a solution that is well tolerated and helped treat patients 65 years old and over where 1/3 of them experience CIC.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Programmer for transient, orally ingested capsule, each"

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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.

When clarifying the meaning of “durable” in regulations (CMS-1577-F, November 10, 2011), we noted that a multi-component device may be a system consisting of durable and nondurable components that together serve a medical purpose (like the VIBRANT® System and VIBRANT® Capsule). As explained in that regulation, a multi-component device consisting of durable and non-durable components is considered non-durable if the component that performs the medically necessary function of the device (the VIBRANT® Capsule) is nondurable, even if other components that are part of the device are durable (the VIBRANT® System). Therefore, the VIBRANT® Capsule component of the multi-component device, which performs the medically necessary function of the device, needs to meet the 3-year minimum lifetime requirement and the requirement to withstand repeated use. As the VIBRANT® Capsule does not meet these requirements, the VIBRANT® System is not DME.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

The primary speaker disagreed with CMS’ published preliminary recommendations. According to the speaker, two new unique HCPCS Level II codes are being requested. One G or A code to describe the capsule as a medical supply to carry out the treatment and a second DME E code to describe the programmable Pod. The VIBRANT® System, or Pod, has a pre-programmed treatment algorithm that is given to the patient as capsules. According to the speakers, the VIBRANT® System includes a Pod, a USB cable, an AC/DC USB adapter, and 20 capsules (2 packs of 10). The capsule must receive the treatment instruction from the Pod,

then be swallowed by the patient. According to the speaker, the treatment is pre-programmed to have four sessions at different times during the day. The VIBRANT® System is a three-part system consisting of the Pod, the capsule, and the optional phone application. According to the speakers, without the Pod, the capsule cannot work and without the capsule the Pod is useless.

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 A9268, "Programmer for transient, orally ingested capsule" to describe the VIBRANT® System Pod.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

CMS affirms the preliminary determination of no DMEPOS benefit category for both the VIBRANT® System and the VIBRANT® capsule. During the benefit category determination process for multi-component devices, CMS has a longstanding policy of first determining which specific component provides the medically necessary function of rendering direct treatment. The VIBRANT® System's components consist of a multi-use activation pod, a disposable drug-free capsule, and an accompanying app for patients to track progress. Of the components listed, the disposable and orally administered VIBRANT® capsule is the sole component that provides a medically necessary function by traveling throughout the patient's digestive system while creating vibrations at programmed times that lead to peristalsis in the large intestine and colon to induce bowel movements. Although the capsule serves a medical purpose, it is disposable and not durable in nature. Therefore, the capsule cannot withstand repeated use and does not meet the 3-year useful lifetime requirement of the DME benefit category. Also, while the activation pod is durable, this information does not alter the fact that the capsule is disposable. Therefore, the VIBRANT® system cannot be defined as durable medical equipment.

With respect to VIBRANT® capsule, CMS does not question the efficacy, utility, or usefulness of similar disposable devices; however, they do not meet the definition of DME. For an item such as the VIBRANT® capsule to be covered by Medicare, a change in the law would be needed to create a benefit category for disposable medical devices.

This determination is consistent with previous decisions that were provided for other multi-component systems such as the Omnipod Insulin Delivery System (in which the disposable pod pumps the insulin) and the Altera® Nebulizer (in which the disposable handset nebulizes the medicine). These systems do not meet the definition of durable medical equipment because they rely on disposable components of the system to provide the medically necessary function.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

VIBRANT® Capsule - HCP221222CTE53

Topic/Issue

Request to establish a new HCPCS Level II code to identify VIBRANT®

Applicant's suggested language: XXXXX, “Pod programmed recipient capsule, produce intracolonic peristalsis to induce bowel movements”

Summary of Applicant’s Submission

Vibrant Gastro Capsule submitted a request to establish a new HCPCS Level II code to identify VIBRANT® capsule. VIBRANT® received the Food and Drug Administration’s (FDA’s) De Novo clearance on August 26, 2022. The VIBRANT® solution includes an activated capsule as a medically necessary integrated component of the VIBRANT® System prescribed for home use to relieve symptoms related to chronic idiopathic constipation (CIC). As a naïve capsule it receives the therapeutic program from the VIBRANT® Pod. The capsule is now calibrated to deliver CIC treatment. It can be monitored and altered by the physician to deliver a patient-specific treatment. According to the applicant, the Pod has a useful life of at least 3 years. Once the capsule is used to provide the programmed treatment it is expelled from the body. The Pod can be reprogrammed for use by other patients. The programmed capsule is an orally ingested, non-pharmacologic, capsule that induces mechanical stimulation via vibration of the colonic wall synced with the circadian rhythm of colonic contractile activity thereby increasing complete spontaneous bowel movements (CSBM). The capsule received program from the Pod causes the synced capsule to initiate vibrations at a specific time and duration delivering the treatment in the colon planned by the physician, (using specific vibration mode created by Vibrant®), then the capsule is naturally excreted. Dosage is 5 activated capsules weekly, packaged in 20-dose blister packs per month of use. As a supply item the capsule is a component of the therapeutic system. According to the applicant, the capsule used in the VIBRANT® phase 3 double-blind randomized, placebo-controlled trial (RCT) led to the FDA De Novo clearance of the system inclusive of the capsule. According to the applicant, data reviewed by the FDA included the capsule’s treatment efficacy and safety from a prospective phase 3 RCT of patients with CIC treated and those who received blinded placebo treatment once daily, five days a week for 8 weeks. The primary efficacy endpoints were an increase of at least one more CSBM per week (CSBM1 responder) or at least two more CSBMs per week (CSBM2) from baseline. Responder was defined as subjects who had an improvement of CSBM1 or CSBM2 during at least 6 of the 8 weeks. Safety analyses were performed, and 904 patients were screened, 312 were enrolled meeting inclusion and exclusion criteria. Per the applicant, a greater percentage of patients receiving the treatment from the capsule achieved both primary efficacy endpoints compared to placebo (39.3% vs. 22.1%, p=0.001 CSBM1; and 22.7% vs. 11.4%, p=0.008 CSBM2). Patients had at least 14 years of CIC; of these 56% had severe CIC defined as 0 CSBM for 2 weeks at baseline. According to the applicant, significantly greater improvements in treatment were seen for the secondary endpoints of straining, stool consistency, and quality of life measures compared to placebo. Per the applicant, adverse events were mild, gastrointestinal in nature and similar between groups. A mild vibrating sensation was reported by 11% of patients in the vibrating capsule group. According to the applicant, patient compliance was 90%, and patient experience using the VIBRANT® was favorable across all ages. VIBRANT® offers a solution that is well tolerated and helped treat patients 65 years old and over where 1/3 of them experience CIC.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, “Programmable, transient, orally ingested capsule, for use with external programmer, each”

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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.

The VIBRANT® capsule is a one-time use item that provides direct mechanical stimulation of the intestines as part of VIBRANT’s® multi-component system to treat chronic idiopathic constipation. The capsule cannot be used repeatedly and does not have a life of at least 3 years. Therefore, the VIBRANT® capsule does not meet the definition of DME.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

The primary speaker disagreed with CMS’ published preliminary recommendations. According to the speaker, two new unique HCPCS Level II codes are being requested. One G or A code to describe the capsule as a medical supply to carry out the treatment and a second DME E code to describe the programmable Pod. The VIBRANT® System, or Pod, has a pre-programmed treatment algorithm that’s given to the patient as capsules. According to the speakers, the VIBRANT® System includes a Pod, a USB cable, an AC/DC USB adapter, and 20 capsules (2 packs of 10). The capsule must receive the treatment instruction from the Pod, then swallowed by the patient for repeat use. According to the speakers, the treatment is pre-programmed to have four sessions at different times during the day. The VIBRANT® System is a three-part system consisting of the Pod, the capsule, and the optional phone application. According to the speakers, without the Pod, the capsule cannot work and without the capsule the Pod is useless.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS’ published preliminary recommendations. 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 A9269, “Programmable, transient, orally ingested capsule, for use with external programmer, per month” to describe the VIBRANT® System capsule.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

CMS affirms the preliminary determination of no DMEPOS benefit category for both the VIBRANT® System and the VIBRANT® capsule. During the benefit category determination process for multi-component devices, CMS has a longstanding policy of first determining which specific component provides the medically necessary function of rendering direct treatment. The VIBRANT® System’s components consist of a multi-use activation pod, a disposable drug-free capsule, and an accompanying app for patients to track progress. Of the components listed, the disposable and orally administered VIBRANT® capsule is the sole component that provides a medically necessary function by traveling throughout the patient’s digestive system while creating vibrations at programmed times that lead to peristalsis in the large intestine and colon to induce bowel movements. Although the capsule serves a medical purpose, it is disposable and not durable in nature. Therefore, the capsule cannot withstand repeated use and does not meet the 3-year useful lifetime requirement of the DME benefit category. Also, while the activation pod is durable, this information does not alter the fact that the capsule is disposable. Therefore, the VIBRANT® system cannot be defined as durable medical equipment.

With respect to VIBRANT® capsule, CMS does not question the efficacy, utility, or usefulness of similar disposable devices; however, they do not meet the definition of DME. For an item such as the VIBRANT® capsule to be covered by Medicare, a change in the law would be needed to create a benefit category for disposable medical devices.

This determination is consistent with previous decisions that were provided for other multi-component systems such as the Omnipod Insulin Delivery System (in which the disposable pod pumps the insulin) and the Altera® Nebulizer (in which the disposable handset nebulizes the medicine). These systems do not meet the definition of durable medical equipment because they rely on disposable components of the system to provide the medically necessary function.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Luminopia – HCP221003J1TKP

Topic/Issue

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

Applicant's suggested language: AXXXX, "Software-only digital therapy for amblyopia with a billing unit of 30 days"

Summary of Applicant's Submission

Luminopia, Inc. submitted a request to establish a new HCPCS Level II code to identify Luminopia. Luminopia received the Food and Drug Administration's (FDA's) De Novo clearance on October 20, 2021, as a Class II device. According to the applicant, as part of the as part of the De Novo review process, the FDA determined that there is no legally marketed device substantially equivalent to it and that a new device type needed to be established. Per the applicant, Luminopia does not meet the definition of durable medical equipment. According to the applicant, a new unique A code is requested to facilitate reimbursement and avoid billing errors and delays. Luminopia, Inc. appreciates that CMS created the HCPCS Level II code A9291, but that code describes a cognitive or behavioral therapy. Luminopia is not a cognitive or behavioral therapy as it improves vision in amblyopia patients by presenting modified visual stimuli. Luminopia does not have any elements of cognitive or behavioral therapy. Luminopia is a software-only digital therapeutic designed to be used with commercially available Head-Mounted Displays (HMDs) which are compatible with the software application. Luminopia is indicated for improvement in visual acuity in amblyopia patients, aged 4-7 years old, associated with anisometropia and/or with mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eye-care professional. Luminopia is intended for both previously treated and untreated patients; however, patients with more than 12 months of prior treatment (other than refractive correction) have not been studied. Luminopia is intended to be used as an adjunct to full-time refractive correction, such as glasses, which should also be worn under the HMD during Luminopia therapy. Luminopia is intended for prescription use only, in an at-home environment. According to the applicant, therapeutic algorithms improve vision by breaking interocular suppression, encouraging amblyopic eye usage, and promoting binocular combination. They are applied to patient-selected video content in the same manner for every video. The algorithms reduce contrast to the stronger eye's input to break interocular suppression and encourage amblyopic eye usage. Additionally, parts of each eye's input are occluded by dichoptic masks superimposed over the video content to promote binocular combination. The masks rotate through predefined pairs over the course of treatment to treat the entire visual field. Patients undergo 1 hour of treatment per day, six days per week. Luminopia is self-administered in an at-home environment, under the supervision of a trained eye-care professional. Luminopia is a software-only digital therapeutic that is downloaded onto off-the-shelf hardware.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Prescription digital visual therapy, software-only, fda cleared, per course of treatment"

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category.

Luminopia, Inc. indicated in its application that it supports this determination, stating that “Luminopia does not meet the definition of durable medical equipment.”

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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.

Software-only items (digital therapies and computer software) are not devices, equipment, or supplies and therefore would not fall under a DMEPOS benefit category. Whether or not the item could fall under some other Medicare benefit category can be considered, but would not be addressed under the DMEPOS benefit category determination process.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

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 a new HCPCS Level II code A9292, “Prescription digital visual therapy, software-only, fda cleared, per course of treatment” to describe Luminopia.

Final Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

EndeavorRx® - HCP230103HDALU

Topic/Issue

Request to establish a new HCPCS Level II code to identify EndeavorRx®

Applicant's suggested language: AXXXX, "Prescription digital therapeutic (PDT) providing sensory stimuli and simultaneous motor challenges for neural attentional control, FDA-cleared, per course of treatment"

Summary of Applicant's Submission

Akili, Inc. submitted a request to establish a new HCPCS Level II code to identify EndeavorRx®. EndeavorRx® received the Food and Drug Administration's (FDA's) De Novo clearance on June 15, 2020. According to the applicant, this code would be for non-Medicare payers to accurately describe prescription digital therapeutics (PDTs) providing sensory stimuli and simultaneous motor challenges for neural attentional control, FDA-cleared, per course of treatment. Per the applicant, such a code will allow payers to implement appropriate coverage parameters consistent with the therapeutically distinct mechanism of action. EndeavorRx® is indicated to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type Attention-Deficit/Hyperactivity Disorder (ADHD), who have a demonstrated attention issue. Patients who engage with EndeavorRx® demonstrate improvements in a digitally assessed objective measure, Test of Variables of Attention (TOVA®), of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity. EndeavorRx® should be considered for use as part of a therapeutic program that may include clinician-directed therapy, cognitive behavioral therapy (CBT), medication, and/or educational programs. According to the applicant, the HCPCS Level II code A9291 does not describe EndeavorRx®, which embodies a mechanism of action therapeutically distinct from cognitive and/or behavioral therapy devices. EndeavorRx® is a PDT that provides sensory stimuli and simultaneous motor challenges for neural attentional control as distinguished from using a CBT mechanism of action. FDA recognized this distinction when it created a separate classification for EndeavorRx® from previously authorized PDTs for CBT. CBT is based on a set of static teaching principles and coping strategies; EndeavorRx® utilizes a proprietary technology that delivers dynamic and adaptive sensory stimuli and simultaneous motor challenges ("interference processing") designed to target attentional control systems to progressively develop new neurological capabilities relating to attentional control. Multiple clinical studies demonstrate that the EndeavorRx® treatment results in improvements in a range of clinically relevant ADHD outcome measures which complement earlier work showing that earlier prototypes result in significant changes in brain functioning in regions associated with attentional control. According to the applicant, categorizing EndeavorRx® as substantially equivalent to CBT devices may result in inappropriate expectations for treatment, clinical use, and the risks/benefits. Per the applicant, differentiating PDTs using the interference processing mechanism of action from PDTs delivering CBT will allow more clear and informed choices about treatment planning. According to the applicant, non-Medicare payers have a demonstrated need for a new HCPCS Level II code to facilitate efficient and accurate claims processing. According to the applicant, without a HCPCS Level II code to distinguish PDTs using the interference processing mechanism of action from PDTs delivering CBT described by HCPCS Level II

code A9291, commercial payers and Medicaid agencies must manually process claims which is an arduous, inefficient, and costly process.

CMS Preliminary HCPCS Coding Recommendation

This is a repeat application, previously submitted in B1 2022, application HCP220103YXJ32. Our prior determination was to revise existing HCPCS Level II code A9291, “Prescription digital behavioral therapy, fda cleared, per course of treatment,” to instead read, “Prescription digital cognitive and/or behavioral therapy, fda cleared, per course of treatment.” However, the applicant believes, and has stated that other payers agree, that their mechanism of action for EndeavorRx® is different than what is described by existing code A9291. CMS continues to believe that HCPCS Level II code A9291, as currently revised, describes EndeavorRx®. We welcome information from the applicant and other insurers to help us better understand what the mechanism of action is and how it is not cognitive and/ or behavioral therapy.

Medicare Benefit Category Determination

The applicant did not request a reconsideration of the benefit category. CMS has previously stated that digital therapies or computer software are not devices, equipment, or supplies and therefore would not fall under a DMEPOS benefit category.

Summary of Public Feedback

Akili, Inc., the manufacturer of this product, disagreed with CMS’ published preliminary coding decision that the HCPCS Level II code A9291 accurately describes EndeavorRx®. According to the speaker, CBT and EndeavorRx® are not equivalent in any way and should thus be coded differently, because CBT is a high-level clinical treatment that is teaching patients about new ways of thinking and feeling, whereas EndeavorRx® is an adaptive, self-adjusting system/treatment, targeted at specific cognitive processes with a clear activity or mechanism of action. According to the speaker, EndeavorRx® is made up of two subtasks. One is navigating, where the patient navigates or races a spaceship down a track, and either avoids or seeks out targets, and to simplify, this requires sustained attention, and continuous motor activity of adjusting the positioning of the device. The other task is targeting, which involves simplifying selective attention, role selection, inhibition, working memory, and an event-driven motor activity of tapping. All this together adjusts the connectivity in specific neural networks by coding them to engender a success state where the patient was previously failing. Therefore, altering these neural pathways help improve the patient's functional capabilities, which allows for improved downstream multi-tasking. The speaker concluded that EndeavorRx® and CBT are again not equivalent, nor even similar, and therefore they should be coded separately, so the A9291 code is not appropriate here.

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 received, CMS is finalizing its preliminary recommendation that existing HCPCS Level II code A9291, “Prescription digital cognitive and/or behavioral therapy, fda cleared, per course of treatment” describes EndeavorRx®.

We agree with the applicant that EndeavorRx® is not considered CBT. However, the current language for A9291 includes digital therapies for behavior, such as CBT, and at the same time also includes other cognitive only therapies, emphasized by the “and/or” within the coding language.

We appreciate the applicant’s information on the mechanism of action as a potential means of distinction. EndeavorRx’s® mechanism of action on cognitive function is included in the term cognitive therapy, currently described in A9291.

Regardless, we are continuing to learn about the emerging field of prescription digital therapeutics approved by the FDA and how various payers may elect to cover and pay for these products. CMS has issued a “Request for Information (RFI) on Digital Therapies, such as, but not limited to, digital Cognitive Behavioral Therapy” in the proposed rule titled “CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program.” We welcome public input on a number of issues discussed in the RFI.

CMS is also interested in other payer preferences with regard to the code structure for PDTs to process claims to pay for PDTs. The applicant provided CMS with a couple of contacts. While one company expressed a mild preference for further coding distinction for EndeavorRx®, we could not identify multiple payers with coverage or claims policies that were definitive or suggestive of further coding differentiation. We welcome input directly from payers with regard to this emerging field.

ACUVUE® OASYS MAX 1-Day Contact Lenses - HCP2301030122B

Topic/Issue

Request to establish two new HCPCS Level II codes to identify ACUVUE® OASYS MAX 1-Day Contact Lenses.

Applicant's suggested language: "Contact lens, hydrophilic, class 1 uv blocker with blue-violet filter > 50% per lens"

Summary of Applicant's Submission

Johnson and Johnson Vision Care, Inc. (JJV) submitted a request to establish a new HCPCS Level II code to identify ACUVUE® OASYS MAX 1-Day Contact Lenses. ACUVUE® OASYS MAX 1-Day received Food and Drug Administration's (FDA's) 510(k) clearance on March 26, 2021. ACUVUE® OASYS MAX 1-Day Contact Lenses indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are presbyopic and may be nearsighted (myopic) or farsighted (hyperopic) and may have 0.75D or less of astigmatism that does not interfere with visual acuity and block more than 50 percent of blue-violet light. According to the applicant, no existing HCPCS code identifies a contact lens with a blue-violet filter. JJV seeks a new code to use with national payers outside of the Medicare program. According to the applicant, ACUVUE® OASYS MAX 1-Day is a first-of-its-kind contact lens that combines a new patented HEV/blue-violet light filter with senofilcon A. ACUVUE® OASYS MAX 1-Day Contact Lenses are soft (hydrophilic) contact lenses available as spherical and multifocal lenses. These lenses are made of a silicone hydrogel material (senofilcon A) containing an internal wetting agent. A benzotriazole ultraviolet (UV) absorbing monomer is used to block UV radiation (280 nm – 380 nm) in combination with a novel fused tricyclic chromophore that also blocks UV radiation and partially filters high energy visible radiation (HEV) in the range of 380 nm to 450 nm. The light transmittance characteristics for these lenses are less than 1 percent in the UVB range of 280 nm to 315 nm and 10% in the UVA range of 315 nm to 380 nm. The thinnest lenses transmit ≤ 45 percent of the radiation in the range from 380 nm to 450 nm. Lenses with light transmittance of less than 10 percent UVA and less than 1% UVB are designated Class 1 UV blocking under the international organization for standards classification system recognized by FDA.

CMS Preliminary HCPCS Coding Decision

Establish a new HCPCS Level II code VXXXX, "Contact lens, hydrophilic, spherical, with blue-violet filter, per lens"

Preliminary Medicare Benefit Category Determination

Prosthetic Device

Refractive lenses are covered when they are used to restore the vision normally provided by the natural lens of the eye of an individual lacking the organic lens because of surgical removal or congenital absence. Covered diagnoses are limited to pseudophakia (condition in which the natural lens has been replaced with an artificial intraocular lens [IOL]), aphakia (condition in which the natural lens has been removed but there is no IOL), and congenital

aphakia. Lenses provided for other diagnoses will be denied as noncovered. Coverage may be limited to one pair of eyeglasses or contact lenses. Because coverage of refractive lenses is based upon the Prosthetic Device benefit category, there is no coverage for frames or lens add-on codes unless there is a covered lens(es). Tinted lenses, including photochromatic lenses, used as sunglasses, which are prescribed in addition to regular prosthetic lenses to a pseudophakic beneficiary, will be denied as noncovered.

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 VXXXX is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS codes V2521 and V2744. The pricing comparative considers the base hydrophilic contact lens, toric (V2521) and adds a photochromatic additive with code V2744.

Pricing for VXXXX is represented by the following formula: $V2521 + V2744$. Therefore, the average 2023 fee schedule amount for VXXXX would be approximately \$255.08. 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 would be on a lump sum purchase basis.

Pricing Indicator = 38

Summary of Public Feedback

Johnson and Johnson Vision Care, Inc., the manufacturer of this product, agreed with the preliminary decision to issue a new HCPCS Level II code for ACUVUE® OASYS MAX 1-Day Contact Lenses, but disagreed with the preliminary decision descriptor. The speaker requested CMS reconsider its coding descriptor to instead read “Contact lens, hydrophilic, class 1 uv blocker with blue-violet filter.” The speaker commented that the use of the word spherical would limit future options, such as a toric lens.

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 to and finalizing the decision to:

Establish a new HCPCS Level II code V2526, “Contact lens, hydrophilic, with blue-violet filter, per lens” to describe ACUVUE® OASYS MAX 1-Day Contact Lenses.

CMS is under the impression that all contact lenses incorporate a class 1 UV blocker; therefore, we believe the inclusion of the phrase “class 1 UV blocker” in the code descriptor is unnecessary. We recognize that there is the potential for lenses to be made in shapes other than spherical, so we agree with removing “spherical” from the cost descriptor.

Final Medicare Benefit Category Determination

No DMEPOS Benefit Category.

During the May 31, 2023, HCPCS Public Meeting, CMS determined that ACUVUE® OASYS MAX 1-Day Contact Lenses are not intended to treat pseudophakia, aphakia, or congenital aphakia. Refractive lenses are covered by Medicare when they are used to restore the vision normally provided by the natural lens of the eye of an individual lacking the organic lens because of surgical removal or congenital absence. Covered diagnoses are limited to pseudophakia, aphakia, or congenital aphakia. Lenses provided for other diagnoses are denied by Medicare as noncovered.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Reconsideration of S Codes Associated with Breast Reconstruction Procedures - HCP210813XRPKE

Topic/Issue

CMS has received input from multiple parties regarding the coding decision issued on February 16, 2022, to discontinue HCPCS Level II codes S2066, S2067, and S2068 effective December 31, 2024, and is interested in receiving further feedback with regard to whether CMS should:

1. Extend the effective date to allow additional time for a transition, or
2. Retain these codes in the HCPCS Level II code set.

CMS Summary

The Healthcare Common Procedure Coding System (HCPCS) is a standardized coding system used to identify particular items and services on claims submitted to Medicare, Medicaid, and other health insurance programs in a consistent and orderly manner under the Health Insurance Portability and Accountability Act and implementing regulations. The HCPCS is divided into two principal subsystems, referred to as HCPCS Level I and HCPCS Level II. The American Medical Association (AMA) develops and maintains the HCPCS Level I codes, also known as Current Procedural Terminology (CPT®) codes. CMS develops and maintains HCPCS Level II codes, which identify items and certain services that are generally not identified by CPT® codes. To the extent possible, CMS and AMA strive to have complementary code sets to facilitate access to healthcare items and services and to minimize duplication or repetition of items or services in the respective code sets.

In the Second Biannual session of the 2021 HCPCS Coding Cycle, CMS reviewed a request that the Blue Cross and Blue Shield Association submitted to discontinue three S codes related to breast reconstruction: S2066 Breast reconstruction with gluteal artery perforator (GAP) flap; including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral; S2067 Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral; and S2068 Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral.

The preliminary and final decisions are available:

<https://www.cms.gov/files/document/hcpcs-public-meeting-agenda-non-drug-and-non-biological-items-and-services-december-2-2021-updated.pdf>

<https://www.cms.gov/files/document/2021-hcpcs-application-summary-biannual-2-2021-non-drug-and-non-biological-items-and-services.pdf>

In 2006, CMS established HCPCS Level II code S2068 to describe breast reconstruction with Deep Inferior Epigastric Perforator (DIEP) and other flap procedures, as well as S2066 and S2077, at the request of the Blue Cross and Blue Shield Association for use principally by

private payers. Medicare and other government payers, to the best of CMS' knowledge, do not use S2066-S2068 for payment.

In 2011, the AMA published coding guidance stating that CPT® code 19364 was an appropriate code for DIEP flap breast reconstruction procedures. However, in subsequent years various uncertainty remained about what breast reconstruction procedures were appropriate to bill to insurers using CPT® code 19364. Thus, in 2019, the CPT® Editorial Panel convened by the AMA reviewed broadly a series of codes associated with breast reconstruction procedures and specifically considered whether existing CPT® code 19364 should more clearly state that DIEP and other flap procedures are described by the code. As a result of that review, the CPT® Editorial Panel revised the description of CPT® code 19364 to expressly include DIEP and other similarly advanced flap procedures that had historically been considered to be described by the code. Following this action, CMS was again approached by the Blue Cross and Blue Shield Association, though in this case, to discontinue S2066-S2068.

On February 16, 2022, after receiving public comment, CMS decided to discontinue HCPCS codes S2066, S2067, and S2068 on December 31, 2024. Our typical approach is to establish or discontinue codes on the next quarter. However, we established a transition period to allow time for any entities that currently list these codes in their written policies or contracts to make any necessary updates, including facilitating a transition period for negotiations between providers and payers.

We have subsequently received correspondence from multiple parties that there are significant transition complexities and that the transition may be affecting access to care. A primary concern seems to be that CPT® code 19364 may be different enough from S2068 in which negotiations between providers and private payers may warrant CMS to reconsider the scheduled December 31, 2024, end date.

CMS Preliminary HCPCS Coding Recommendation

CMS seeks written feedback and/or input during the public meeting from interested parties. We raise the following questions for consideration:

1. Should CMS extend the scheduled end date of December 31, 2024, for HCPCS codes S2066-S2068? If so, for how long?
2. Should CMS retain HCPCS codes S2066-S2068 and not end their availability on December 31, 2024? In particular, we seek input from private payers about whether they would continue to use S2066-S2068 in lieu of other codes, such as CPT® code 19364.
3. Are any parties approaching the CPT® Editorial Panel to seek revisions or refinements to the CPT® code set? Are any parties approaching another body, such as the AMA/Specialty Society RVS Update Committee (RUC)? If so, how long may be necessary for this process to occur and be allowed for any subsequent transition period, if any revisions are made by the CPT® Editorial Panel or other entity? In other words, if revisions or refinements are sought, how long would it be beneficial for codes S2066-S2068 to remain effective?

CMS welcomes input from all interested parties, including providers and health insurers. CMS understands that a cancer diagnosis is extremely challenging, both physically and emotionally, for patients and their loved ones and works to ensure that coding decision support providers and payers in efficiently and effectively submitting and processing claims in the provision of access to care for their patients.

CMS notes that the Healthcare Common Procedure Coding System is a standardized coding system used to identify particular items and services on claims submitted to Medicare, Medicaid, and other health insurance programs in a consistent and orderly manner. While these codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are made independent of the process for making determinations regarding coverage and payment.

Consumers who are covered by a private-sector, employer-sponsored group health plan and have concerns about compliance with market-wide requirements may contact the Department of Labor's [Employee Benefits Security Administration online or by calling 1-866-444-3272](#).

Consumers who are covered by a non-federal public-sector employer-sponsored plan, such as a state or local government employee plan, and have concerns about their plan's compliance with these requirements may contact the CMS Center for Consumer Information and Insurance Oversight (CCIIO) at NonFed@cms.hhs.gov for further assistance with a question or issue.

Summary of Public Feedback

CMS received a substantial number of responses, both verbal and written, requesting to retain HCPCS Level II codes S2066, S2067, and S2068 and not end their availability on December 31, 2024. One commenter noted a preference for a transition through 2028. Comments were received from providers, patients, and various associations, including the American Society of Plastic Surgeons. The majority of the commenters feel their accessibility will be, or has already been, impacted by the decision to eliminate the S codes. Concerns raised by commenters included that various payers have been difficult to reach or engage to discuss a transition and have adjusted payment unilaterally. Commenters also described payment reductions up to 80 percent in the transition to CPT® code 19364 and described that they would not be able to provide certain services at those payment levels. In some cases, commenters noted that payers have paused or rolled back certain payment adjustments when there has been engagement between payers and providers. Commenters also noted that certain S codes describe procedures that necessitate complex, skilled expertise.

CMS notes this excerpt from the written comments of the American Society of Plastic Surgeons (ASPS), which summarizes many of the comments:

ASPS is deeply concerned that the private insurance industry is treating the sunset of the S-codes as an opportunity to reclassify microsurgical breast reconstruction as a lower-level procedure. There should be no difference between payers' internal value for the procedure variations covered under S2066-68 and their value for CPT® 19364 with the transition in coding. The same perforator flap techniques are covered under

both types of code. The clinical resources and level of surgical skill required do not change simply because the procedure is described with a different code. Yet, we hear from our microsurgeon members – particularly those in private, community-based practices – that private insurance companies are not transferring the current value for microsurgical breast reconstruction along with the change in the code used to report it; instead, they are shifting to a lower value wherever there is a lower value associated with CPT® 19364.

Commenters noted that this transition is not impacting Original Medicare (fee-for-service) prospective payment or access for beneficiaries enrolled in Original Medicare.

CMS asked the participants if they believed that permanent retention of the S codes in the HCPCS Level II code set would result in outcomes that commenters believed were most likely to ensure access. CMS noted that payers may set payer-by-payer policies in terms of whether to recognize certain codes. For instance, CMS has a long-standing policy to recognize and pay for these procedures using CPT® code 19364, and there are not identified access challenges for Medicare beneficiaries in Original Medicare. CMS specifically noted that some payers may choose to transition to CPT® code 19364, even if the S codes are retained. Commenters replied generally that they believed more coding options would facilitate a range of potential outcomes with different payers and more likely result in the retention of current payment amounts for the procedures described by the S codes.

Blue Cross and Blue Shield Association, the applicant of the original application, provided written comments in support of CMS' published final decision from the Second Biannual session of the 2021 HCPCS Coding Cycle to discontinue the above mentioned S codes on December 31, 2024. Blue Cross and Blue Shield Association commented they are not aware of anyone approaching the CPT® Editorial Panel or the RUC regarding these procedures, these codes, or their deletion. They further commented that the CPT®/RUC process would be the appropriate avenue for providers if they do not agree with the CPT® Editorial Panel regarding CPT® code 19364 being the correct code for DIEP, GAP, and SIEA flaps. Blue Cross and Blue Shield Association suggested that plastic surgeons who disagree with the retirement of S2066, S2067, and S2068 could apply, either alone or in conjunction with the American Society of Plastic Surgeons, to the CPT® Editorial Panel for dedicated codes for DIEP, GAP, and SIEA and then submit them for valuation through the official pathway of the AMA/Specialty Society Relative Value Scale Update Committee. No other payers commented in writing or verbally.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. We recognize the importance of the patient-provider relationship and the practice of medicine in determining the most appropriate breast reconstruction procedure for each patient. The intent of HCPCS codes is to facilitate the practice of medicine, while providing a standardized approach to identify particular items and services on claims submitted to Medicare, Medicaid, and other health insurance programs in a consistent and orderly manner under the Health Insurance Portability and Accountability Act and implementing regulations. In our original decision in 2022, CMS established a transition period to allow time for any entities that currently list these codes in their written policies or contracts to make any necessary updates, including facilitating a transition period for negotiations between providers and payers. While it was not a CMS instruction or

expectation that negotiations must occur, as CMS does not have such authority to do so through this process, it was anticipated that there would be engagement among payers and providers to facilitate a smooth transition.

Based on the public comment, we are persuaded that the transition period through 2024 is not sufficient. Consistent with the comments CMS received, we have observed press reports of various private payers pausing or reversing their transition or payment policies for CPT® code 19364 after engagement with providers. We also heard reports of difficulties for providers in reaching private payers to discuss a transition. We received only one comment from private payers, providing limited insight for CMS in regard to the transition plans of private payers.

As such, we will be maintaining HCPCS Level II codes S2066, S2067, and S2068 and will not sunset their availability on December 31, 2024.

CMS notes that while the clarification from the CPT® Editorial Panel with regard to CPT® code 19364 was intended to reduce confusion (among other purposes) by expressly stating the long-standing position of the CPT® Editorial Panel that CPT® code 19364 describes DIEP, it is now unambiguous that multiple codes describe procedures such as DIEP, GAP, and SEIA. As a result, payers have flexibility to determine their coverage and payment policies with regard to what code(s) may be reported on a claim to describe these procedures (DIEP, GAP, SEIA).

CMS notes that the Healthcare Common Procedure Coding System is a standardized coding system used to identify particular items and services on claims submitted to Medicare, Medicaid, and other health insurance programs in a consistent and orderly manner. While these codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are made independent of the process for making determinations regarding coverage and payment.

Consumers who are covered by a private-sector, employer-sponsored group health plan and have concerns about compliance with market-wide requirements may contact the Department of Labor's [Employee Benefits Security Administration online or by calling 1-866-444-3272](#).

Consumers who are covered by a non-federal public-sector employer-sponsored plan, such as a state or local government employee plan, and have concerns about their plan's compliance with these requirements may contact the CMS Center for Consumer Information and Insurance Oversight (CCIIO) at NonFed@cms.hhs.gov for further assistance with a question or issue.

**Transportation of Physician/Health Care Professional and Equipment for a Home Visit
Evaluation and Management (E/M), Per Trip to Location, One Patient Seen -
HCP221230N9KE4**

Topic/Issue

Request to establish a new HCPCS Level II code to identify payment for transportation for the physician or other qualified health care professional, personnel, and medical equipment for home visit for one patient.

Applicant's suggested language: XXXXX, "Transportation of the physician or other qualified health care professional, personnel, and medical equipment for a home visit e/m, per trip to location"

Summary of Applicant's Submission

Home Visiting Providers submitted a request to establish a new HCPCS Level II code to identify payment for transportation for the physician or other qualified health care professional, personnel, and medical equipment for home visit for one patient. This service represents the transportation of the physician or other qualified health care professional, personnel, and medical equipment to a location with one patient for a home visit. The service must be billed in conjunction with home visit E/M Current Procedural Terminology (CPT®) codes. According to the applicant, there is currently no code that describes this service. Per the applicant, home visit E/M CPT® codes do not include transportation in the description. According to the applicant, since transportation is not described in the home visit E/M CPT® codes, Medicare has stated that transportation expenses are not included in calculating the reimbursement for home visits E/Ms. Per the applicant, this application is for a code that will allow transportation to be reimbursed for home visit E/Ms. The applicant implied that transportation is a significant expense that is necessary for a home visit E/M and should be reimbursed.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that for Medicare, beginning January 1, 2023, physicians and qualified nonphysician practitioners furnishing E/M services to a patient residing in their home, in an assisted living facility, in a group home (that is not licensed as an intermediate care facility for individuals with intellectual disabilities), in a custodial care facility, or in a residential substance abuse treatment facility must use the level of service code in the CPT® code range 99341 - 99350 to report the service they provide.² Historically, travel costs incurred by the physician or practitioner are not included in the valuation of E/M codes, since travel time and/or mileage is not considered a resource involved in furnishing the service, and they are not included in establishing payment rates under the Physician Fee Schedule (PFS) in accordance with section 1848 of the Social Security Act.

We welcome information from the applicant and other insurers who are currently paying for this service to describe a claims processing interest for a unique HCPCS Level II code to describe transportation of the physician or other qualified health care professional, personnel, and medical equipment for a home visit E/M.

² <https://www.cms.gov/files/document/r11732cp.pdf>

Summary of Public Feedback

Home Visiting Providers, the applicant, disagreed with CMS' published preliminary recommendation. The speakers stated that travel time and expense are not included in the existing CPT® code descriptors for 99341-99350. The speakers explained that physicians and other qualified healthcare professionals who do home visits are required to donate their time and money for travel expense, paid at a much lower rate than providers for any other medical care, and spend more time during visits just to be reimbursed at a lower rate for time spent. The speakers stated that X-ray transportation codes cover the cost of transportation for both personnel time and equipment and sets precedent for why CMS should honor this current request. The speakers requested CMS review the stance from the PFS that travel costs incurred by the physician or practitioner are not included in the valuation of E/M codes. Commenters indicated that a clinician who stays in the office can see three patients in the same amount of time a clinician who drives to the home can see only one, yet the reimbursement for the office visit is the same as the home visit.

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 received, CMS is finalizing its preliminary recommendation. We have not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code to describe transportation of the physician or other qualified health care professional, personnel, and medical equipment for a home visit E/M. For Medicare, travel costs incurred by the physician or practitioner are not included in the valuation of E/M codes, since travel time and/or mileage is not considered a resource involved in furnishing the service, and they are not included in establishing payment rates under the PFS in accordance with section 1848 of the Social Security Act. In addition, we are not aware of other payers that would have a need for a code with the suggested language.

**Transportation of Physician/Health Care Professional and Equipment for a Home Visit Evaluation and Management (E/M), Per Trip to Location, More Than One Patient Seen
- HCP221230W07Q8**

Topic/Issue

Request to establish a new HCPCS Level II code to identify payment for transportation for the physician or other qualified health care professional, personnel, and medical equipment for home visit for more than one patient.

Applicant's suggested language: XXXXX, "Transportation of the physician or other qualified health care professional, personnel, and medical equipment for a home visit e/m, per trip to location, more than one patient seen"

Summary of Applicant's Submission

Home Visiting Providers, submitted a request to establish a new HCPCS Level II code to identify payment for transportation for the physician or other qualified health care professional, personnel, and medical equipment for home visit for more than one patient. This service represents the transportation of the physician or other qualified health care professional, personnel, and medical equipment to a location with more than one patient for a home visit. According to the applicant, there is currently no code that describes this service. Per the applicant, home visit E/M Current Procedural Terminology (CPT®) codes do not include transportation in the description. According to the applicant, since transportation is not described in the home visit E/M CPT® codes, Medicare has stated that transportation expenses are not included in calculating the reimbursement for home visits E/M's. Per the applicant, this application is for a code that will allow transportation to be reimbursed for home visit E/M's. The applicant implied, transportation is a significant expense that is necessary for a home visit E/M and should be reimbursed.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that for Medicare, beginning January 1, 2023, physicians and qualified nonphysician practitioners furnishing E/M services to a patient residing in their home, in an assisted living facility, in a group home (that is not licensed as an intermediate care facility for individuals with intellectual disabilities), in a custodial care facility, or in a residential substance abuse treatment facility must use the level of service code in the CPT® code range 99341 - 99350 to report the service they provide.³ Historically, travel costs incurred by the physician or practitioner are not included in the valuation of E/M codes, since travel time and/or mileage is not considered a resource involved in furnishing the service, and they are not included in establishing payment rates under the Physician Fee Schedule (PFS) in accordance with section 1848 of the Social Security Act.

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 to describe transportation of the physician or other qualified health care professional, personnel, and medical equipment for a home visit E/M.

³ <https://www.cms.gov/files/document/r11732cp.pdf>

Summary of Public Feedback

Home Visiting Providers, the applicant, disagreed with CMS' published preliminary recommendation. The speakers stated that travel time and expense are not included in the existing CPT® code descriptors for 99341-99350. The speakers explained that physicians and other qualified healthcare professionals who do home visits are required to donate their time and money for travel expense, paid at a much lower rate than providers for any other medical care, and spend more time during visits just to be reimbursed at a lower rate for time spent. The speakers stated that X-ray transportation codes cover the cost of transportation for both personnel time and equipment and sets precedent for why CMS should honor this current request. The speakers requested CMS review the stance from the PFS that travel costs incurred by the physician or practitioner are not included in the valuation of E/M codes. Commenters indicated that a clinician who stays in the office can see three patients in the same amount of time a clinician who drives to the home can see only one, yet the reimbursement for the office visit is the same as the home visit.

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 establish a new HCPCS Level II code to describe transportation of the physician or other qualified health care professional, personnel, and medical equipment for a home visit E/M. For Medicare, travel costs incurred by the physician or practitioner are not included in the valuation of E/M codes, since travel time and/or mileage is not considered a resource involved in furnishing the service, and they are not included in establishing payment rates under the PFS in accordance with section 1848 of the Social Security Act. In addition, we are not aware of other payers that would have a need for a code with the suggested language.

Portable X-ray and/or Other Portable Diagnostic Imaging Supplier - HCP230102B51B5

Topic/Issue

Request to revise existing HCPCS Level II code R0070, “Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, one patient seen.”

Applicant's suggested language: R0070, “Transportation of portable imaging equipment and personnel to home or nursing home, per trip to facility or location, one patient seen”

Summary of Applicant’s Submission

DispatchHealth Imaging submitted a request to revise an existing HCPCS Level II code R0070, “Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, one patient seen” to instead read “Transportation of portable imaging equipment and personnel to home or nursing home, per trip to facility or location, one patient seen.” The applicant is looking to expand R0070 for other portable diagnostic imaging services such as ultrasound, dopplers and echocardiograms. Per the applicant, a portable imaging supplier moves its X-ray equipment and other portable diagnostic imaging equipment from place to place, performing X-ray, EKG and other diagnostic imaging services such as ultrasound, venous and arterial dopplers and echocardiograms at various locations. According to the applicant, a portable imaging supplier is a supplier using only portable units vs. a mobile unit that is typically described as a vehicle that travels from place to place to perform services inside the vehicle. An example of such a vehicle includes mobile semi-trailers.

CMS Preliminary HCPCS Coding Recommendation

This application is being deferred for additional consideration in a subsequent biannual coding cycle. We believe more time is needed to consider revising existing HCPCS Level II code R0070 and any implications that might occur. We welcome information from the applicant and other insurers who are currently paying for transportation of portable X-ray equipment and personnel to demonstrate a claims processing need for a revision to HCPCS Level II code R0070.

Summary of Public Feedback

DispatchHealth Imaging, the applicant, urged CMS to expand the transportation component of HCPCS Level II code R0070 to include portable ultrasound, doppler, and echocardiogram procedures. According to the speakers, there is no reason why these services should be excluded from the transportation code, as they are no less medically necessary for clinical diagnostics, no less expensive to own and transport, and no less valuable to a pertinent medical decision-making process. Commenters stated that Medicare provides coverage for ambulance transportation; however, Medicare does not provide provisions for transportation coverage for the portable services such as ultrasound, dopplers, and echocardiograms when the equipment is transported to the patient location and the diagnostic procedure is performed on site. Commenters stated that portable diagnostic imaging suppliers are similar to urgent care providers, where the location or the date and time of a necessary service is unpredictable.

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 deferring this application to a subsequent coding cycle for additional consideration. We believe more time is needed to consider revising existing HCPCS Level II code R0070 and any implications that might occur.

Portable X-ray and/or Other Portable Diagnostic Imaging Supplier - HCP2301034XATF

Topic/Issue

Request to revise existing HCPCS Level II code R0075, “Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen.”

Applicant's suggested language: R0075, “Transportation of portable x-ray and other diagnostic imaging equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen”

Summary of Applicant’s Submission

DispatchHealth Imaging submitted a request to revise an existing HCPCS Level II code R0075, “Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen” to instead read “Transportation of portable x-ray and other diagnostic imaging equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen.” According to the applicant, this language revision would include the transportation of equipment and personnel for other portable diagnostic imaging examinations such as ultrasound, dopplers and echocardiograms. Per the applicant, a transportation service code (R0075) may only be billed when the X-ray equipment or other diagnostic imaging equipment used is transported to the location where the examination was taken. The allowable fee for R0075 will be adjusted based upon the modifier used. Per the applicant, "Portable X-ray and/or Other Portable Diagnostic Imaging Supplier" is defined as a supplier that provides one or more of the following portable services, including but not limited to, X-ray, electrocardiogram (EKG), long-term EKG (Holter Monitor), bone densitometry, sonography, and other imaging services in accordance with all state and federal requirements, under the general supervision of a qualified physician. According to the applicant, R0075 must be billed in conjunction with the Current Procedural Terminology (CPT®) radiology codes (70000 series) and only when the X-ray equipment used was actually transported to the location where the X-ray was taken. Per the applicant, the CPT® 70000 series also includes some ultrasound procedures although the R0075 code is not accepted for transportation of ultrasound equipment and personnel to the facility or location where the exam is taken.

CMS Preliminary HCPCS Coding Recommendation

This application is being deferred for additional consideration in a subsequent biannual coding cycle. We believe more time is needed to consider revising existing HCPCS Level II code R0075 and any implications that might occur. We welcome information from the applicant and other insurers who are currently paying for transportation of portable X-ray equipment and personnel to demonstrate a claims processing need for a revision to HCPCS Level II code R0075.

Summary of Public Feedback

DispatchHealth Imaging, the applicant, urged CMS to expand the transportation component of HCPCS Level II code R0075 to include other portable diagnostic procedures. According to

the speakers, there is no reason why these services should be excluded from the transportation code, as they are no less medically necessary for clinical diagnostics, no less expensive to own and transport, and no less valuable to a pertinent medical decision-making process. Commenters stated that Medicare provides coverage for ambulance transportation; however, Medicare does not provide provisions for transportation coverage for the portable services such as ultrasound, dopplers, and echocardiograms when the equipment is transported to the patient location and the diagnostic procedure is performed on site. Commenters stated that portable diagnostic imaging suppliers are similar to urgent care providers, where the location or the date and time of a necessary service is unpredictable.

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 received, CMS is deferring this application to a subsequent coding cycle for additional consideration. We believe more time is needed to consider revising existing HCPCS Level II code R0075 and any implications that might occur.

Portable X-ray and/or Other Portable Diagnostic Imaging Supplier- HCP230102T6B2A

Topic/Issue

Request to revise existing HCPCS Level II code R0076, “Transportation of portable ekg to facility or location, per patient.”

Applicant's suggested language: R0076, “Transportation of portable EKG to facility or location, per one patient seen”

Summary of Applicant’s Submission

DispatchHealth Imaging submitted a request to revise an existing HCPCS Level II code R0076, “Transportation of portable ekg to facility or location, per patient” to instead read “Transportation of portable EKG to facility or location, per one patient seen.” According to the applicant, R0076 appears available with a description, although when used for codification on a claim there is no reimbursement. The applicant is requesting the code language revision and to revise, re-instate, and update the policy and coverage provision for R0076. According to the applicant, HCPCS code R0076 must be billed with one of the following modifiers, UN, UP, UQ, UR, US, to indicate how many patients were served on that trip to the facility or location. According to the applicant, R0076 must be billed in conjunction with a Current Procedural Terminology (CPT®) code, and only when the diagnostic equipment used was actually transported to the location where the test was taken. Per the applicant, if only one patient is served, R0076 should be reported with no modifier for any EKG procedure. According to the applicant, R0076 would not apply when the diagnostic testing equipment is stored in the location where the diagnostic test was taken. Per the applicant, R0076 would not apply when EKG procedure is performed in conjunction with an X-ray procedure, such as a chest x-ray and EKG were performed together during the visit. Only the X-ray transportation code would apply to the claim. According to the applicant, the function of the transportation code, R0076, would be for the portable X-ray supplier to capture reimbursement that covers the cost of the vehicle, maintenance, labor, supplies, insurance, and other direct cost applicable to providing the portable EKG service.

CMS Preliminary HCPCS Coding Recommendation

This application is being deferred for additional consideration in a subsequent biannual coding cycle. We believe more time is needed to consider revising existing HCPCS Level II code R0076 and any implications that might occur. We welcome information from the applicant and other insurers who are currently paying for transportation of portable X-ray equipment and personnel to demonstrate a claims processing need for a revision to HCPCS Level II code R0076.

Summary of Public Feedback

DispatchHealth Imaging, the applicant, urged CMS to expand the transportation component of HCPCS Level II code R0076 to include other portable diagnostic procedures. According to the speakers, there is no reason why these services should be excluded from the transportation code, as they are no less medically necessary for clinical diagnostics, no less expensive to own and transport, and no less valuable to a pertinent medical decision-making process. Commenters stated that Medicare provides coverage for ambulance transportation;

however, Medicare does not provide provisions for transportation coverage for the portable services such as ultrasound, dopplers, and echocardiograms when the equipment is transported to the patient location and the diagnostic procedure is performed on site. Commenters stated that portable diagnostic imaging suppliers are similar to urgent care providers, where the location or the date and time of a necessary service is unpredictable.

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 received, CMS is deferring this application to a subsequent coding cycle for additional consideration. We believe more time is needed to consider revising existing HCPCS Level II code R0076 and any implications that might occur.

Bilateral Hip Orthosis - HCP211020YXAK3

Topic/Issue

Request to establish a new HCPCS Level II code to identify a bilateral hip orthosis.

Applicant's suggested language: LXXXX, "Hip orthosis, bilateral hip joints and thigh cuffs, adjustable flexion, extension, abduction control of hip joint, postoperative hip abduction type, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise"

Summary of Applicant's Submission

Palmetto GBA submitted a request to establish a new HCPCS Level II code to identify a hip orthosis designed for bilateral post-operative range of motion control. According to the Medicare Contractor for Pricing, Data Analysis and Coding of HCPCS Level II DMEPOS Codes (PDAC), there is apparent supplier confusion about the use of L1690, "Combination, bilateral, lumbo-sacral, hip, femur orthosis providing adduction and internal rotation control, prefabricated, includes fitting and adjustment." HCPCS Level II code L1690 was established in 1999 for the predicate/historical product SWASH (Sitting, Walking, And Standing Hip) Orthosis. The SWASH Orthotic enhanced the position and function of the femur by providing hip abduction and external rotation for the pediatric population. This was done by limiting hip and internal femur rotation to resist a bilateral lower limb scissoring gait pattern for the pediatric population. According to the applicant, a new code would describe a prefabricated, custom fitted, hip orthosis designed for bilateral post-operative hip range of motion control. The design parameters would include a pelvic band, bilateral hip joints and thigh cuffs designed to provide adjustable flexion, extension, and abduction control of the hip joint.

CMS Preliminary HCPCS Coding Decision

Establish a new HCPCS Level II code LXXXX, "Hip orthosis, bilateral hip joints and thigh cuffs, adjustable flexion, extension, abduction control of hip joint, postoperative hip abduction type, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise"

Preliminary Medicare Benefit Category Determination

Leg brace (Orthotic)

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 is to establish the fee schedule amount by doubling the existing fee schedule amounts for the related item described by HCPCS code L1686 ("Hip

Orthosis, Abduction Control of Hip Joint, Postoperative Hip Abduction Type, Prefabricated, Includes Fitting and Adjustment”).

Pricing for LXXXX is represented by the following formula: $2 * L1686$. Therefore, the average 2023 fee schedule amount for LXXXX would be approximately \$2,249.62. 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 would be on a lump sum purchase basis.

Pricing Indicator = 38

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. Based on the information provided in the application and in the written comment, CMS is finalizing its preliminary recommendation to:

Establish a new HCPCS Level II code L1681, “Hip orthosis, bilateral hip joints and thigh cuffs, adjustable flexion, extension, abduction control of hip joint, postoperative hip abduction type, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise” to describe a bilateral hip orthosis.

Final Medicare Benefit Category Determination

Leg Brace (orthotic)

Final Medicare Payment Determination

Pricing for L1681 is represented by the following formula: $2 * L1686$. Therefore, the average 2023 fee schedule amount for L1681 would be approximately \$2,249.62. 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 would be on a lump sum purchase basis.

Pricing Indicator = 38

PainShield® MD - HCP230103WP355

Topic/Issue

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

Applicant's suggested language: XXXXX, “Low frequency ultrasonic treatment device, single transducer/actuator, includes all components and accessories for initial use”

Summary of Applicant’s Submission

Nanovibronix Inc. submitted a request to establish a new HCPCS Level II code to identify PainShield® MD. PainShield® MD received the Food and Drug Administration’s (FDA’s) 510(k) clearance on August 22, 2008. The PainShield® MD is an ultrasonic device used to apply heat to the tissues in the body for the treatment of medical conditions such as pain relief, muscle spasms, and joint contractures. The device includes a transducer/actuator rechargeable battery-powered driver unit and a cable that connects the driver to the transducer. The PainShield® MD provides intermittent ultrasonic output at a preset, low intensity frequency of 90 kHz, which cannot be modified by the user. When the device is on, it alternates between two phases: an active phase and an idle phase, both lasting 30 minutes each. The device automatically turns off after 6.5 hours of treatment, after which the battery needs to be recharged. Treatment is delivered through an ultrasound actuator which is applied and secured to the surface of the body using adhesive patches. According to the applicant, the life expectancy of the driver is at least three years. The PainShield® MD is approved by the FDA for home use. According to the applicant, the PainShield® MD meets all the criteria for durable medical equipment (DME). Per the applicant, an independent testing firm is conducting durability testing to demonstrate that the PainShield® MD has an expected life of at least three years. According to the applicant, the PainShield® MD therefore meets all the DME requirements: it can withstand repeated use, it has an expected life of at least 3 years, it is primarily and customarily used to serve a medical purpose, it is not usually useful to an individual in the absence of illness or injury, and it is appropriate for use in the home.

CMS Preliminary HCPCS Coding Recommendation

This is a repeat application, with our prior decisions published on September 26, 2022 and March 8, 2023. The decision published on September 26, 2022 questioned whether the device has a lifetime of at least 3 years. We suggested that the applicant presents a lifetime durability test over the entire device/system 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 with the redesigned battery. While CMS received this current application by the January 2, 2023 deadline for this biannual cycle, it was submitted when test results were in process and not yet complete. CMS did not receive final test results until March 29, 2023. Generally, when an application is submitted as incomplete, CMS will defer the application to a future HCPCS coding cycle when the submitter can complete the application. Nevertheless, while CMS has not had sufficient time to thoroughly review all test results, in our initial review we did note that we have some comments/questions about the results, as follows:

1. The IEC report published by Carmel Lab does not describe how the test was set up, or conducted. It also does not specify any parameters besides the voltage. A durability

test is not a pass or fail type of test and this missing information will strengthen the outcome of the testing protocol on the device lifetime. What was the testing criteria for the device durability?

2. According to the current application, patients typically use PainShield® for one treatment/charge cycle (6.5 hours) every day for the first week. The test stated that the devices were used for 21 cycles for the first week which means three treatments per day. What was the rationale behind not replicating the same usage as outlined in the application?
3. The report stated that the testing was continued with a device that was shut down after a week. The report also stated that the issue was deemed not related to the life test but did not specify what the issue was. The exclusion criteria were not listed in the report therefore we have the following questions:
 - a. What were the inclusion and exclusion criteria for the test?
 - b. What happened to the device to cause it to shut down?
 - c. Why was the device that shut down brought back into testing?
4. At the end, the report stated that the devices behaved within defined limits and carried out cycles in accordance with the anticipated behaviors. What is the definition of the “anticipated behavior”? It would be best if the report included a brief “results” or “discussion” section.
5. In the “Li-Polymer Battery Technology⁴” document, different voltage and current ranges were applied for the battery life expectancy tests than the IEC Test report by Carmel Lab. For example, the voltage range in the IEC test was between 12-13 V as compared to 10.5- 13.0 V for the battery tests. What is the rationale for the differences in voltage and current ranges?
6. Comparing the IEC report to the “Li-Polymer Battery Technology³” document, the testing methodologies seemed to be different. The tests on the upgraded batteries had more interventions and cycle changes to validate the life expectancy. What was the reason for using different methodologies?

Summary of Public Feedback

Nanovibronix Inc., the applicant of this request, responded to CMS’ published preliminary HCPCS coding recommendation by providing answers to the questions that CMS had raised. According to the speaker, in the first biannual coding cycle of 2022, PainShield® MD was found to meet all but one of the five statutory requirements for DME. The open issue was demonstration of an expected lifetime of 3 years, with tests to be conducted by an independent accredited testing laboratory. The speaker stated that in October 2022, Carmel Labs began a testing program with seven complete systems with new batteries. The test protocol simulates a typical patient treatment, which takes six and a half hours, and battery recharging, which takes one and a half hours. By immediately and continually repeating this process, it was possible to get three complete cycles per day, or a total of 21 cycles per week, which the speaker further explained is similar to an accelerated life test. According to the speaker, the testing criteria for the device durability used the driver and actuator, with a

⁴ Shenzhen Pkenergy Energy Co. LTD, Li-Polymer Battery Technology Specification, Li-Polymer Battery, Model LIPO703450 1250mAh 3.7V, www.pkenergy.com.

power supply connected to a 24-hour repeating timer. The acceptance criteria were that the electrical excitation signal must have the voltage amplitude and frequency that are necessary to activate the applicator and properly treat the patient. The test program also checked for: unintentional shutdowns; low battery faults; disconnection faults; mechanical damage; electronic circuit fault; and malfunction of the OLED display. According to the speaker, one of the batteries failed very soon after the start of the tests (21 cycles) but was concluded not to be an “end of useful life” issue, but a clear internal fault within the battery that caused an early failure. This battery was replaced, and the tests were continued with this system to the end of the test program.

According to the speaker, the final results of this lifetime test were submitted to CMS in March 2023. The speaker commented that the final report shows a lifetime of 420 cycles; however, with continued testing now the devices show a lifetime of 525 cycles. According to the speaker, typical patient use would be 126 cycles per year, so this testing represents over 4 years of use. According to the speaker, the ultimate test criterion was that the driver properly operates the accessory applicator, which is verified by the voltage and frequency of the electrical excitation signal.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS’ published preliminary HCPCS coding 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:

Revise existing HCPCS Level II code K1004, “Low frequency ultrasonic diathermy treatment device for home use, includes all components and accessories” to read “Low frequency ultrasonic diathermy treatment device for home use” to describe the PainShield® MD.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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. Specifically, the PainShield® does not meet the definition of DME because the submitted application and report did not demonstrate that this device has a life of at least 3 years.

CMS had suggested that the manufacturer provide standardized test results from an independent testing laboratory demonstrating that the device itself could last for at least 3 years with the redesigned battery. The manufacturer provided an International Electrotechnical Commission (IEC) test listed as IEC 60601-1 conducted by Carmel Environmental Laboratory. We appreciate the information provided during the public meeting, responding to the questions posed in the preliminary determination regarding the testing techniques and results. The listed IEC test performed by the testing laboratory, IEC 60601-1, is an International Standard Test and applies to the basic safety and essential performance of electrical medical equipment and electrical medical systems. This standard can be used, in part, to show compliance under the U.S. Food and Drug Administration, Canada-Health Canada, and European Union Medical Device Directive 2007/47/EC regulations. This test does not specify any standards on the durability of a medical device application. Therefore, the additional document that was provided by the applicant still does not demonstrate that PainShield® can last for at least 3 years. Additionally, during the public meeting, the manufacturer was asked to provide CMS with a life cycle assessment (LCA) test that was recently conducted, according to the presenters. CMS has not yet been presented with such a report. An LCA test or analysis is a systematic tool that is needed to analyze a product's environmental impacts over its entire life cycle. Durability of an item should be tested over the entire system or device and not just an individual component (e.g., battery), and the lifetime of the battery itself cannot be used alone to justify the lifetime of a device. Since the applicant submitted a report related to the electrical safety rather than a report including information about the device's durability, PainShield® does not fall within a DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Painshield® MD, Monthly Disposable Ultrasound Kit - HCP230103MU5DT

Topic/Issue

Request to establish a new HCPCS Level II code to identify PainShield® MD, monthly disposable ultrasound kit.

Applicant's suggested language: XXXXX, “Monthly disposable supply kit for use with low frequency ultrasonic treatment device [K1004], includes an ultrasound actuator/transducer that plugs into the durable handheld device and 30 adhesive patches”

Summary of Applicant’s Submission

Nanovibronix Inc. submitted a request to establish a new HCPCS Level II code to identify PainShield® MD monthly disposable supply kit. PainShield® MD received the Food and Drug Administration’s (FDA’s) 510(k) clearance on August 22, 2008. The Painshield® MD monthly disposable supply kit includes an ultrasound actuator/transducer and 30 adhesive patches that adhere to the body. Treatment is delivered through the actuator/transducer that provides intermittent ultrasonic output at a preset, low intensity frequency of 90 kHz, which cannot be modified by the user. It is applied and secured to the surface of the body using adhesive patches. Each adhesive is one-time use. The PainShield® actuator/transducer can be used for 30 sessions (one month’s use). Once the actuator/transducer has been used for a total of 30 sessions, the patient must dispose of the actuator/transducer and use a new one. The FDA indications for use are as follows: treatment for pain, muscles spasms and joint contractures.

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 decisions (published September 26, 2022 and March 28, 2023) 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

Nanovibronix Inc., the applicant, responded to CMS’ published preliminary HCPCS coding recommendations by providing answers to the questions that CMS raised. According to the speaker, the initial Painshield® MD kit is supplied with supplies for the patients initial treatment. However, for any additional treatment sessions, the patient will need additional supplies to use with the Painshield® MD. The disposable supply kit is comprised of one ultrasound actuator/transducer and 30 adhesives to adhere the transducer to the body. According to the speaker, providers and suppliers have been utilizing existing HCPCS Level II code A9999, “Miscellaneous dme supply or accessory, not otherwise specified” for the

supply kit. According to the speaker, some payors are paying between \$272 and \$350 per supply kit. These are contracted rates that they have negotiated with the payors.

The suggested language for the disposable supply kits included the term “monthly”; however, the speaker stated that the frequency of use of the PainShield® MD device will vary based upon the individual patient’s needs. Therefore, utilization of the disposable supplies used with the PainShield® device will vary from patient to patient, and thus should not contain the word “monthly.”

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code K1036, “Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month” to describe the PainShield® MD supplies.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

As indicated in Medicare program instructions at chapter 15, section 110.3 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), payment may be made for supplies that are necessary for the effective use of covered DME. The final benefit category determination for PainShield® is no DMEPOS benefit category; therefore, supplies used with this item would also have no benefit category.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

RelieVRx - HCP220701K2H96

Topic/Issue

Request for Medicare payment determination for RelieVRx.

Summary of Applicant's Submission

AppliedVR, Inc. submitted a request to establish a new HCPCS Level II code to identify RelieVRx. RelieVRx received the Food and Drug Administration's (FDA's) De Novo clearance on March 3, 2021. RelieVRx is an immersive virtual reality (VR) medical device for home use that is indicated for the treatment of chronic low back pain. RelieVRx is 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.

CMS Final HCPCS Coding Decision

On March 8, 2023, CMS established HCPCS Level II code E1905, "Virtual reality cognitive behavioral therapy device (cbt), including pre-programmed therapy software" to describe RelieVRx, effective April 1, 2023.

Medicare Benefit Category Determination

CMS determined that RelieVRx is DME and published that determination on March 8, 2023.

Preliminary Medicare Payment Determination

AppliedVR, Inc. requested that CMS classify RelieVRx as an item “requiring frequent and substantial servicing.” These items are defined in 42 CFR §414.222 as “items requiring frequent and substantial servicing in order to avoid risk to the beneficiary’s health.” The request was supported by a detailed explanation of the “servicing, refurbishing, and cleaning required between each treatment to safely provide the device to the next patient.” We do not agree that this servicing is frequent or substantial. All rented equipment is serviced in between rental episodes; therefore, this could not be considered frequent servicing. Furthermore, the actual servicing provided (check the condition of the device hardware and software, install a new breath amplifier and facial liner, upload data from device, perform factory reset, remove and erase memory card, recharge battery if necessary, and clean/disinfect device) is minimal. If this servicing is not provided or is done incorrectly, it is difficult to see how this could result in actual harm to the patient, such as the harm that would result from a ventilator malfunction. Therefore, the DME payment classification for RelieVRx is “other durable medical equipment (capped rental items).”

In accordance with regulations at 42 CFR §414.229, the fee schedule amount for capped rental items must be set based on a purchase price. There is no provision to set the payment amount for capped rental items based on a rental price. While we appreciate the commercial price information and invoices that AppliedVR submitted to us, these clearly represent rental prices based on the typical 2-3 month course of treatment. The information we have separately received from the Veterans Health Administration confirms that RelieVRx devices are being procured exclusively on a rental basis. Unfortunately, as the regulations require payment amounts be set based on a purchase price, we cannot use the commercial price information submitted to us for an 8-week rental of the RelieVRx.

In our search for an appropriate price, we found a purchase price from 2017 cited in an article⁵ reviewing an earlier version of the RelieVRx device (then called the “EaseVRx”). This article describes a virtual reality cognitive behavior therapy device, incorporating pre-programmed therapeutic software together with a virtual-reality headset. We accept that there are some physical differences: the current RelieVRx device uses a self-contained VR headset with preloaded software, but the article describes a device performing the same functions with a VR headset driven by a locked smartphone pre-loaded with the therapeutic software (the article notes that aside from the VR app and Wi-Fi, “every other function is forbidden”). This article clearly describes this device as available to purchase: “you either buy the standard package for \$2,588, or buy the premium one for a little bit more than \$3,700.” Despite the physical differences, we believe that the device described by the 2017 article, even if it is not the exact same version as the current model, presents to us the only purchase price known to CMS for an item described by E1905. As such, we believe that our best option for a preliminary payment determination would be to use this 2017 purchase price of \$2,588.

As described in 42 CFR §414.229, the monthly fee schedule amount for capped rental items is 10 percent of the adjusted purchase price for the first three months, and 7.5 percent for months four through thirteen. The adjusted purchase price is determined by deflating the purchase price using the CPI-U to the 1986-1987 equivalent. This value is then adjusted to a current purchase price based on the methodology outlined in statute (for recent years, this

⁵ Escape the Scary and Painful in Healthcare: The AppliedVR Review (2017, September 26). *The Medical Futurist*. Retrieved from <https://medicalfuturist.com/escape-scary-painful-healthcare-appliedvr-review/>.

adjustment is based on the CPI-U adjusted by the change in economy-wide productivity, but the statute provides for other adjustment applicable to certain years). Based on this 2017 purchase price of \$2,588, the 2023 average capped rental fee schedule amount for E1905 would be approximately \$204.66 for months 1 through 3 and approximately \$153.50 for months 4 through 13, for a total of \$2,148.98 after 13 months of continuous use.

We welcome any information that may provide more recent purchase prices for this device, if available.

Pricing Indicator = 36

Summary of Public Feedback

AppliedVR, Inc., the manufacturer of this product, disagreed with CMS's published preliminary recommendation on pricing and classification of the RelieVRx as "other durable medical equipment (capped rental items)." While CMS had based its preliminary pricing determination on the belief that the price referenced in a 2017 review article was a purchase price for the RelieVRx device, the speaker indicated that this was neither a purchase price, nor was the product in question the RelieVRx device.

The speaker explained that the \$2,588 price referenced in the review article was, in fact, made up of an equipment purchase fee of \$800 together with a software licensing fee of \$1,788. In separate written feedback, AppliedVR, Inc., provided invoices that support this price break-out.

In addition, the speaker described how the device referred to in this article was not the RelieVRx device and would not be classified in E1905. The wellness product referenced in the article was intended exclusively for in-hospital use, did not contain CBT content, and was not organized as a curriculum, but rather as a series of games, movies, and other apps. Furthermore, the wellness product used different physical components (a Samsung Galaxy phone connected to a separate headset). In response to questions, the speaker explained a further difference in that the content of the wellness product was predominantly licensed from other firms, while the CBT-based curriculum of the RelieVRx device was primarily developed in-house by Applied VR, Inc. (while some content in RelieVRx may be licensed, it is further modified for integration into the device software).

Addressing payment classification, the speaker maintained that the rental-only model was consistent with classification as an item requiring frequent and substantial servicing (FSS), and that the servicing necessary between patients was, indeed, substantial. The speaker listed servicing steps required to prevent respiratory infection risk (e.g., through the "breath amplifier" component of the device), skin infection/irritation risk addressed through replacement of foam facial padding, general device sanitation, re-installation of the software (with testing), and management of patient information that may be present on the device upon its return.

In further support of classification under FSS, the speaker cited other devices classified as FSS together with a description based on publicly available information of the servicing process to demonstrate similarity with the process used for the RelieVRx device. The examples cited were continuous passive motion machines (E0935), tumor treatment field therapy (E0766), and ventilators (E0465-67).

Regardless of classification, the speaker argued that the only available price for RelieVRx is the \$2,889.45 paid by the VA for a three-month rental; based on the typical 10 percent rental fee for the first three months of use, this would imply a purchase price of \$9,631.50.

Final Medicare Payment Determination

We appreciate the comments provided in response to CMS's published preliminary recommendation. Based on the information provided in the application, and after consideration of the comments received, CMS is finalizing its preliminary recommendation for classification of the RelieVRx as "other durable medical equipment (capped rental items)," but is modifying the payment determination.

While we appreciate the comparison between the servicing required for FSS items and what is required for the RelieVRx, there are some additional aspects of the examples provided that we believe distinguish these examples as qualifying for classification as FSS. Continuous passive motion machines are covered for a maximum of 21 days, so a supplier would be required to pick up the equipment within the same month it was delivered, often after only two weeks of use. The transducers for tumor treatment field therapy are both a substantial portion of the cost of the device and are required to be replaced every three days. Given the life-threatening complications that may arise from failure of a ventilator, there are strict requirements for servicing at specific intervals while the device is being used by the patient along with very tight response standards for service calls (which suppliers often choose to meet by providing the patient with a back-up ventilator). We do not mean to diminish the important steps taken to ensure that each RelieVRx device is disinfected and wiped of any protected personal information before being provided to another beneficiary; however, these steps are consistent with the standards expected of any supplier of durable medical equipment and, thus, are not unusually frequent or substantial.

We are grateful for the additional detail on the nature of the product referenced in the 2017 article, as well as the payment structure. We agree that, despite references in the text of the article implying a purchase, this device was rented and is substantially different from the RelieVRx device. Although the regulations at 42 CFR § 414.229 for "Other durable medical equipment – capped rental items" specifically refer to a purchase price when describing the establishment of the monthly fee schedule amount, we agree that since there is no available purchase price for this item, one must be estimated based on the best available commercial payment data. As suggested in the public comments, we estimate that the purchase price would be \$9,631.50, assuming the \$963.15 monthly rental amount implied by the Veteran's Affairs payment rate represents 10 percent of the purchase price.

Based on this estimated purchase price and the process outlined in 42 CFR § 414.229 for capped rental items, the 2023 average capped rental fee schedule amount for E1905 would be approximately \$629.66 for months 1 through 3 and approximately \$472.25 for months 4 through 13, for a total of \$2,148.98 after 13 months of continuous use. We note that the estimated capped rental payment for months 1 through 3 are within \$1 of what the estimated payment would have been had we determined this device to be classified under FSS.

Pricing Indicator = 36

Sodium Phenylacetate and Sodium Benzoate Injection - HCP230103BD8AQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Sodium Phenylacetate and Sodium Benzoate injection.

Applicant's suggested language: XXXXX, "Sodium Phenylacetate/Sodium Benzoate 10%, per ml"

Summary of Applicant's Submission

Maia Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify Sodium Phenylacetate and Sodium Benzoate Injection. Sodium Phenylacetate and Sodium Benzoate Injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 10, 2021. Sodium Phenylacetate and Sodium Benzoate Injection is indicated as adjunctive therapy in pediatric and adult patients for the treatment of acute hyperammonemia and associated encephalopathy in patients with deficiencies in enzymes of the urea cycle. Sodium phenylacetate and sodium benzoate are metabolically active compounds that can serve as alternatives to urea for the excretion of waste nitrogen. Phenylacetate conjugates with glutamine in the liver and kidneys to form phenylacetylglutamine, via acetylation. Phenylacetylglutamine is excreted by the kidneys via glomerular filtration and tubular secretion. The nitrogen content of phenylacetylglutamine per mole is identical to that of urea (both contain two moles of nitrogen). Two moles of nitrogen are removed per mole of phenylacetate when it is conjugated with glutamine. Similarly, preceded by acylation, benzoate conjugates with glycine to form hippuric acid, which is rapidly excreted by the kidneys by glomerular filtration and tubular secretion. One mole of hippuric acid contains one mole of waste nitrogen. Thus, one mole of nitrogen is removed per mole of benzoate when it is conjugated with glycine. Sodium Phenylacetate and Sodium Benzoate Injection must be diluted with sterile 10% Dextrose Injection (D10W) before administration. The dilution and dosage of Sodium Phenylacetate and Sodium Benzoate Injection are determined by weight for neonates, infants, and young children, and by body surface area for larger patients, including older children, adolescents, and adults. Sodium phenylacetate and sodium benzoate is administered as an injection. Sodium Phenylacetate and Sodium Benzoate Injection 10% per 10% is a clear and almost colorless solution supplied in a sterile, non-pyrogenic, single-dose glass vial. Both sodium phenylacetate and sodium benzoate solutions are physically and chemically stable for up to 24 hours at room temperature and room lighting conditions.

CMS Final HCPCS Coding Decision

The reference listed drug for this application is Ammonul. Ammonul is approved under an NDA and there are several ANDAs that are therapeutically equivalent. We have noticed none of these products have a unique HCPCS Level II code. It is our understanding there is very little to no Medicare claims volume or utilization for any of products under any of the related NDAs/ANDAs. We welcome information from the applicant, other manufacturers of related NDAs/ANDAs, and other insurers who are currently paying for this product or associated NDAs to describe whether there is interest in HCPCS Level II codes for these products for billing for outpatient use.

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 denying the application to establish a new HCPCS Level II code to identify Sodium Phenylacetate and Sodium Benzoate injection.

The reference listed drug for this application is Ammonul. Ammonul is approved under an NDA and there are several ANDAs that are therapeutically equivalent. We have noticed none of these products have a unique HCPCS Level II code. It is our understanding there is very little to no Medicare claims volume or utilization for any of products under any of the related NDAs/ANDAs.

Migration of Temporary Codes

Topic/Issue

To begin the process of establishing permanent codes for supplies and other products that received a temporary Healthcare Common Procedure Coding System (HCPCS) code (“K” code) that became effective January 1, 2020 through 2022.

Summary

Occasionally CMS will establish temporary HCPCS codes (“K” codes) for supplies and other products for which a national code has not yet been developed. CMS is committed to migrating these codes, when appropriate, into permanent HCPCS code categories. As announced in the Second Biannual (B2) 2022 Guidelines for Participating in the HCPCS Public Meeting, CMS will begin using the public meeting process promulgated through regulations to announce any plans it has to migrate K codes. The final rule outlining this process (86 FR 73902) is available at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposfeesched>.

CMS Preliminary HCPCS Coding Decision

We are revising 25 temporary (“K” codes) HCPCS Level II codes. These changes will be effective January 1, 2024. CMS is seeking written feedback on these changes.

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

Summary of Public Feedback

Written comments were provided in support of CMS’ published preliminary HCPCS Level II coding recommendation to transition codes K1005, K1006, K1028 and K1029 to permanent codes. For K1029, a suggestion was made to consider an “A” code rather than an “E” code.

CMS Final HCPCS Coding Decision

Based on the input received, CMS is finalizing its preliminary recommendation to revise the 25 temporary (“K” codes) HCPCS Level II codes listed in Appendix A to permanent codes effective January 1, 2024. For K1029, CMS is transitioning this code to EXXXX as this assignment keeps the supply in the same alpha-numeric location as the device.

These changes will be effective January 1, 2024. This three-month delay in effective date allows time for billing software and procedures to be updated to reflect the changes to the HCPCS.

Appendix A: HCPCS Level II Temporary (“K” codes) Coding Revision

Application # or MEARIST™ ID	Temporary Code	Permanent Code	Long Descriptor
19.118	K1001	E0530	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
19.117	K1002	E0732	Cranial electrotherapy stimulation (ces) system, any type
19.131	K1003	E1301	Whirlpool tub, walk-in, portable
19.136	K1005	A4287	Disposable collection and storage bag for breast milk, any size, any type, each
20.078	K1006	E2001	Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system
20.077	K1009	E3000	Speech volume modulation system, any type, including all components and accessories
20.172	K1013	A4457	Enema tube, with or without adapter, any type, replacement only, each
20.156	K1014	L5615	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
20.159	K1015	L3161	Foot, adductus positioning device, adjustable
20.07	K1016	E0733	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
20.07	K1017	A4541	Monthly supplies for use of device coded at E0733
20.086	K1018	E0734	External upper limb tremor stimulator of the peripheral nerves of the wrist
20.086	K1019	A4542	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist
20.173	K1020	E0735	Non-invasive vagus nerve stimulator
21.031	K1021	A4468	Exsufflation belt, includes all supplies and accessories
21.053	K1022	L5926	Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type

20.033	K1023	A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm
21.032	K1024	E0680	Non-pneumatic compression controller with sequential calibrated gradient pressure
21.07	K1025	E0682	Non-pneumatic sequential compression garment, full arm
20.048	K1026	A7023	Mechanical allergen particle barrier/inhalation filter, cream, nasal, topical
HCP210826HY98M	K1028	E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application
HCP2108265Y526	K1029	E0493	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
HCP210903LPG21	K1031	E0681	Non-pneumatic compression controller without calibrated gradient pressure
HCP210903PMKF3	K1032	E0678	Non-pneumatic sequential compression garment, full leg
HCP210903WBEG8	K1033	E0679	Non-pneumatic sequential compression garment, half leg

Appendix B: DMEPOS Payment Categories

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

Pricing = 00 Service Not Separately Priced

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

Pricing = 31 Frequently Serviced Items

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

Pricing = 32 Inexpensive and Other Routinely Purchased Items

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

Pricing = 33 Oxygen and Oxygen Equipment

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

Pricing = 34 Supplies Necessary for the Effective Use of DME

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

Pricing = 35 Surgical Dressings

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

Pricing = 36 Capped Rental Items

Payment is made on a monthly rental fee schedule basis. The beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items, other than power wheelchairs, for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. The rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Complex rehabilitative power wheelchairs can also be purchased in the first month.

Pricing = 37 Ostomy, Tracheostomy and Urological Supplies

Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)

Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

Pricing = 39 Parenteral and Enteral Nutrition (PEN)

Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

Pricing = 45 Customized DME

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

Pricing = 46 Carrier Priced Item

The allowed payment amount for covered items is based on local carrier pricing (e.g., local fee schedule amounts or reasonable charges or other carrier pricing method).