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

Centers for Medicare & Medicaid Services' (CMS') First Biannual 2023 Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda

Zoom Meeting, for remote participation
Tuesday, May 30, 2023 9:00 am – 5:00 pm, eastern time (ET)

8:45 am, ET:
• Zoom meeting login:
https://cms.zoomgov.com/webinar/register/WN_r_Xpc62cSt-p9CdWjBYhhA
• Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

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

Provided for each agenda item is a written overview of the applicant's request, CMS' preliminary coding recommendation, as well as CMS' preliminary benefit category and payment determination, if applicable. Preliminary recommendations are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and any registered 5-minute speakers. Speaker presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for interested parties to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meeting. CMS' final coding, benefit category, and payment decisions will be published on CMS' HCPCS website at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCSLevelII-Coding-Decisions-Narrative-Summary around August 2023 and will be effective October 1, 2023, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Tuesday, May 30, 2023. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

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Preliminary decisions for the HCPCS Virtual Public Meeting on May 30, 2023[1].

[1] Updated May 9th, 2023 to add Axor™ II to the May 30, 2023 public meeting agenda.

Agenda Item #1
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.

Agenda Item #2
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 in order 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 needy individuals. 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 (Smith, et al., Estimated staff time effort, costs, and Medicaid revenues for coordinated specialty care clinics serving clients with first-episode psychosis. Psychiatric Services, 2019, 70(5), 425-427). 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.

Agenda Item #3
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+ was approved by 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 a with 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.

Agenda Item #4
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 Hummingbird® Tympanostomy Tube System (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 Hummingbird® Tympanostomy Tube System 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 Hummingbird® Tympanostomy Tube System as well as whether any parties have approached the AMA about code revisions.

Agenda Item #5
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 an application 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 800µV; NeuroNode® can generate a coherent command to an SGD in response to an EMG voltage of 0.5µV. According to the applicant, this provides a statistically significant advantage to an otherwise profoundly disabled person. 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 are going to look into 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 a speech generating device (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 look more closely, existing code E2599, "Accessory for speech generating device, not otherwise classified" continues to be available for billing the NeuroNode® accessory for SGDs.

Agenda Item #6
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 in or 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.

Agenda Item #7
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 ≥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 definitely 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 Level II HCPCS 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.

Agenda Item #8
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 = 0

Agenda Item #9
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.

Agenda Item #10
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, 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 neuromusclar 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 EXXXX 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

Agenda Item #10
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.[2] 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

[2] For example, https://cpapsupplies.com/exciteosa-replacement-mouthpiece; https://www.directhomemedical.com/excite-osa-replacement-mountpiece-16049.html

Agenda Item #11
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

Agenda Item #12[3]
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).

[3] Revised on May 9, 2023 to add Axor™ II to May 30, 2023 public meeting agenda from the previous June 1, 2023 date.

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 $5255.18. 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

Appendix A: DMEPOS Payment Categories

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

Pricing = 00 Service Not Separately Priced

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

Pricing = 31 Frequently Serviced Items

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

Pricing = 32 Inexpensive and Other Routinely Purchased Items

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

Pricing = 33 Oxygen and Oxygen Equipment

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

Pricing = 34 Supplies Necessary for the Effective Use of DME

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

Pricing = 35 Surgical Dressings

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

Pricing = 36 Capped Rental Items

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

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

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

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

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

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