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

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

Zoom Meeting, for remote participation
Friday, June 10, 2022, 9:00 am – 5:00 pm, eastern daylight time (e.d.t.)

8:45 am, e.d.t.:
• Zoom meeting login:
https://cms.zoomgov.com/meeting/register/vJIsd-mgpz4jEvObPtTKB0-BGiFBQ80CuHQ
• Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

9:00 am, e.d.t.:
• 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 (if any). Speaker presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for stakeholders and interested parties to provide additional input related to requests to modify the HCPCS code set.

Final decisions are not made at the public meeting. CMS' final coding, benefit category, and payment decisions will be published on CMS' HCPCS website at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelII-Coding-Decisions-Narrative-Summary around September 2022 and will be effective October 1, 2022, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Friday, June 10, 2022. The information provided in each summary reflects information provided by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

Table of Contents

This is the CMS HCPCS Virtual Public Meeting agenda for Friday, June 10, 2022.

Agenda Item # 1

Exersides™ Refraint™ System - HCP211227F8TPL

Topic/Issue

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

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

Applicant's Summary

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

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0710, "Restraints, any type (body, chest, wrist or ankle)" describes the Exersides™ Refraint™ System and existing HCPCS Level II code A9300, "Exercise equipment" describes the optional bed straps of the Exersides™ Refraint™ System, when appropriate. Medicare and other payers would not separately pay for the Exersides™ Refraint™ System for inpatient use. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claims would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0710 and A9300 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0710 and A9300 apply to this product. Items or services described by HCPCS code E0710 and A9300 are not covered under Medicare Part B.

Pricing for E0710 = 57; Pricing for A9300 = 00.

Agenda Item # 2

SecurAcath - HCP211223CXNXW

Topic/Issue

Request to establish new HCPCS Level II code to identify SecurAcath.

Applicant's suggested language: XXXXX, "Subcutaneous anchoring securement systems"

Applicant's Summary

Interrad Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify SecurAcath. SecurAcath is a single use securement device used to hold percutaneous catheters. The subcutaneous anchoring securement system consists of two components. The base contains two small blunt flexible securement prongs, which are placed subcutaneously at the insertion site of the external catheter or tube. The cover snaps onto the base outside of the body to hold the shaft of the external device according to its specific diameter. The SecurAcath remains with the external device for the duration of need from days to years without the need to replace. External device placement and replacement are coded in the current publication. Securement of these external devices is not categorized. For the most part, temporary adhesive-based or suture-based securement is replaced weekly or used beyond recommendations for use. During care of the external devices temporary securement is removed at which time the device may migrate in or out of its optimal position. Incidental retraction or removal may require replacement of the device. SecurAcath is a system that stabilizes the external device throughout the duration of need. No code for this form of device securement is available. The SecurAcath is similar to external fixation, implanted temporary spacers or interdental fixation. A SecurAcath can withstand repeated dressing changes while maintaining the catheters targeted position. Some codes exist for adhesive based securement of ostomy bags. Central venous access devices that are tunneled and cuffed are coded as a higher level for reimbursement base on the increased securement made possible by the cuff that encourages skin to adhere subcutaneously. These cuffs have variable ability to actually secure the device based on the patient's ability to heal. SecurAcath is a more reliable subcutaneous securement not related to the patient's healing rate. SecurAcath is an engineered, FDA approved, securement device.

Preliminary CMS HCPCS Coding Recommendation

Our understanding is that the SecurAcath securement device would generally be used in a procedure reported with a HCPCS Level I (CPT) code. 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.

Agenda Item # 3

Disposable Catheter Guidewire Holder - HCP2112201BUWA

Topic/Issue

Request to establish a new HCPCS Level II code to identify Disposable Catheter Exchange Guidewire Holder.

Applicant's suggested language: XXXXX, "Disposable Catheter Exchange Guidewire Holder (Sterile) for use with CorPath GRX System"

Applicant's Summary

Siemens Healthineers submitted a request to establish a new HCPCS Level II code to identify Disposable Catheter Exchange Guidewire Holder, Sterile (the "Cassette"). It is used with the CorPath GRX system during percutaneous coronary and vascular procedures. The CorPath GRX System is intended for patients with vascular diseases. Specific patient populations vary and are dependent upon the type of interventional devices selected to be used with the system. The cassette functions to facilitate guidance and delivery of interventional devices during coronary and vascular procedures. The cassette is delivered sterile and ready for use. The CorPath GRX System is a combination of durable equipment and disposable supplies that allow for the remote delivery and manipulation of interventional devices in percutaneous coronary, peripheral vascular, and neurovascular procedures. This request for new HCPCS Level II code reflects the disposable component only (the "Cassette"). The CorPath GRX System allows physicians to deliver and manipulate commercially available guidewires, rapid exchange catheters, guide catheters, microcatheters, embolization coils, and coil assist stents during vascular interventional procedures via use of the disposable cassette. During the use of the CorPath GRX System, the physician maneuvers interventional devices using intuitive controls under independent angiographic fluoroscopy. The system allows the physician, seated at the Remote Workspace, to manipulate interventional devices at the patient bedside using joysticks or touch-screen controls on the Control Console. Commercially available interventional devices (guidewires, rapid exchange catheters, guide catheters, embolization coils and or stents) are loaded into the Single Use Cassette, attached to a Robotic Drive. The physician can then control the Robotic Drive to advance, retract, and rotate the guidewire, advance and retract the rapid exchange catheter, embolization coil, and/or coil assist stent, and advance, retract and rotate the guide catheter or microcatheter. The Robotic Drive and Control Console communicate via a single communication cable. The CorPath GRX software ensures that no movement of the commercially available interventional devices can be initiated, except by the controls at the Control Console. The CorPath GRX System is an apparatus intended to be used on human beings for treatment and alleviation of disease states, not intended by pharmacological, immunological, or metabolic means in or on the human body, but may be assisted by such means.

Preliminary CMS HCPCS Coding Recommendation

Our understanding is that the Disposable Catheter Exchange Guidewire Holder would generally be used in a procedure reported with a HCPCS Level I (CPT) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance,

Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 4

Allura® Vaginal Stent - HCP210920UCYP7

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Allura® Vaginal Stent.

Applicant's suggested language: XXXXX, "Vaginal Stent for use in creating, enlarging or restoring a vagina/vaginal canal"

Applicant's Summary

PMP Corporation submitted a request to establish a new HCPCS Level II code to identify the Allura® Vaginal Stent to cover its use in vaginal procedures, including plastic surgery, gynecological procedures, genitourinary procedures and gender affirmation procedures. The function of the product is to maintain the vaginal canal following radiological or surgical procedures and assist in restoring, enlarging or creating a vagina. Currently, there is no comparable product on the market to the PMT® Allura® Vaginal Stent, and currently available codes regarding stents are related to cardiac or other non-applicable procedures and products. There are also no vaginal, gynecological, urological, genitourinary codes currently listed that apply represent the Allura® Vaginal Stent. The intended uses for the Allura® Vaginal Stent are (a) "As a pressure dressing after vaginal surgery to hold pedicle flaps or free skin grafts in close apposition to the receptor site," and (b) "As an obturator or dilator to maintain the vaginal canal and reduce the possibility of contracture and stenosis following vaginal surgery and/or radiological treatment." The Allura® Vaginal Stent is only available through a prescription from a licensed medical professional. The Allura® Vaginal Stent is considered to be a single patient-use product, intended for 90 days of use. The schedule of use is determined by the licensed medical professional. The route of administration is insertion through the vaginal canal, either during surgery or post-op. The Allura® Vaginal Stent is sold sterile, delivered in doubled-packed Tyvek® bags.

Preliminary CMS HCPCS Coding Recommendation

Our understanding is that the Allura® Vaginal Stent would generally be used in a procedure reported with a HCPCS Level I (CPT) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 5

BandGrip® Micro-Anchor® Skin Closure - HCP2201045HMQY

Topic/Issue

Request to establish a new HCPCS Level II code to identify the BandGrip® Micro-Anchor® Skin Closure.

Applicant's suggested language: XXXXX, "Micro-anchor adhesive strip, more than 2 sq. in. but less than or equal to 16 sq. in., with any size adhesive border, each dressing"

Applicant's Summary

BandGrip Inc. submitted a request to establish a new HCPCS Level II code to identify the BandGrip strips. This skin closure product includes skin microanchors and adhesive binding technology, that through insertion of the strip anchors into the upper skin layers, creates tension required to approximate the skin on opposite sides of wounds of varying sizes and depths. Current wound care product codes describe wound care products that cover, fill, or dress a wound or have separately inserted skin anchors to create the tension necessary for wound closure.

Preliminary CMS HCPCS Coding Recommendation

This application was reviewed in the second biannual (B2) 2021 coding cycle and was included in the public meeting agenda. However, the applicant did not attend the B2 2021 public meeting held on December 1-2, 2021. CMS re-reviewed this application and did not identify new or different information from what was submitted in Bandgrip Inc.'s B2 2021 application. Our understanding is that the BandGrip® Micro-Anchor® Skin Closure would generally be used in a procedure reported with a HCPCS Level I (CPT) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable

Agenda Item # 6

AlertWet® system - HCP211001DP8XX

Topic/Issue

Request to establish a new HCPCS Level II code to identify the AlertWet® system.

Applicant's Summary

AlertWet submitted a request to establish a new HCPCS Level II code to identify the AlertWet® system. The AlertWet® system delivers a high-quality, cost-effective, innovative medical system that helps caregivers know when a disposable moisture-absorbing underpad product is wet and requires changing. The new innovative system alerts caregivers when patients' disposable products are dry, damp, wet, wetter, soaked, and requires attention before scheduled checks to reduce skin wounds, linen changes, and liabilities. Caregivers and patients need and now have available with this system an automated "patients disposable underpads are wet" alert system, critical to keep patients safe from acquiring wounds and reduce care providers' unrecoverable costs. Further, wet patients tend to get out of bed to go to the toilet, leading to unaccompanied falls and injury, extending the care improvement value of our system. The AlertWet® system performs a function that not even manual checking can achieve today. Today, caregivers try to check patients' underpads and diapers regularly (every 2 hours). But, unfortunately, patients often have voids immediately after checking and lie in wetness for long times; while skin is breaking down. Therefore, it is unrealistic and impossible for caregivers to check as often as patients can potentially soil underpads or diapers. Instead, this system checks every ten seconds to ensure patient care occurs on time and when required using a single disposable breathable underpad that moves patients 350 pounds plus and works on airbeds. Most caregivers use washable underpads, large disposable underpads, and a diaper on each patient. The AlertPad replaces all of these products with a single pad accompanying an automated checking and wet-alerting system. Dry patients also reduce the need for ointments while reducing incontinent falls. While there are codes currently for incontinence pads there are no codes that cover the benefits and value and function that AlertWet® provides. It is not coverable under A4520, or T4541 or others like it as it is not just a pad to collect urine, rather a system that allows for the reduction in wounds, and, therefore, a possible shortening of patient stays due to this reduction and improving patient care in multiple areas.

Preliminary CMS HCPCS Coding Recommendation

Our understanding is that the AlertWet® system would generally be used in a procedure reported with a HCPCS Level I (CPT) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable

Based on the reported settings of use for the AlertWet® System, CMS believes existing HCPCS Level II codes A4520, "Incontinence garment, any type, (e.g., brief, diaper), each" or T4541, "Incontinence product, disposable underpad, large, each" could be used to describe the disposable moisture-absorbing underpad component of the AlertWet® System in

conjuction with existing HCPCS Level II code A9280, "Alert or alarm device, not otherwise classified" to describe the alert/alarm component of the AlertWet® System. These codes are available for assignment by insurers if they deem it appropriate.

We welcome information from the applicant explaining why the referenced HCPCS codes do not work for Medicaid or other insurers and demonstrating the need for a new HCPCS Level II "T" code to identify an incontinence pad that incorporates wetness sensor monitoring technology, compatible with AlertWet® system.

Preliminary Benefit Category Determination

The current Medicare policy and prior established benefit category determinations for T4541, A4520 and A9280 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing codes T4541, A4520 and A9280 apply to this product. Items or services described by HCPCS code T4541, A4520 and A9280 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 7

Magtrace® - HCP211224JJ1BQ

Topic/Issue

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

Applicant's suggested language: QXXXX, "Carboxydextran-coated superparamagnetic iron oxide particles in water containing 0.3% w/v sodium chloride, diagnostic, 2ml study dose"

Applicant's Summary

Endomag submitted a request to establish a new HCPCS Level II code to identify the single use 2ml vial of Magtrace®. Magtrace® is a non-radioactive combination device/drug product and assists in localizing lymph nodes draining a breast cancer tumor site as part of a sentinel lymph node biopsy in patients with breast cancer undergoing a mastectomy. Magtrace® is a solution of iron nanoparticles coated with a carboxydextran shell which maps lymphatic drainage to the axilla. It is injected subcutaneously into interstitial breast tissue days or weeks before, or during, the surgery. Magtrace® use eliminates radiation exposure by replacing the use of the radioisotope and the blue dye that may cause severe allergic reactions. Magtrace® consists of a sterile aqueous suspension of carboxydextran-coated superparamagnetic iron oxide particles in water for injection (WFI) containing 0.3% w/v sodium chloride. Magtrace® does not quickly decay and is retained in the sentinel node, which allows injection from 20 minutes, to weeks before surgery. Injection may occur prior to the surgery in the physician practice, including freestanding radiology centers, and in the hospital outpatient setting, by a radiologist or surgeon. There is no HCPCS code to report Magtrace®. The codes for non-radioactive, non-contrast visualization adjuncts (Q9968) or nonradioactive contrast imaging material, not otherwise classified, per study (A9698) are not appropriate. Magtrace® is not a visualization adjunct or contrast agent. Magtrace® should not be included in Current Procedural Terminology (CPT) coding (as suggested by CMS in the prior HCPCS application). This request is only to establish a unique HCPCS code for Magtrace® just as radioisotopes (Technetium/Lymphoseek) have a unique product code for separate reporting from the administration procedure.

Preliminary CMS HCPCS Coding Recommendation

Our understanding is that Magtrace® would generally be used in a procedure reported with a HCPCS Level I (CPT) code. We have not identified a specific need for Magtrace® to be separately paid, since we believe that a particular payer may elect to pay for the service in which Magtrace® is used. For instance, Medicare would typically reflect the costs of Magtrace® in the payment for the procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 8

Social Determinants of Health (SDOH) Assessment - HCP22010430R11

Topic/Issue

Request to establish a new HCPCS Level II code to identify Social Determinants of Health (SDOH) assessment.

Applicant's suggested language: QXXXX, "Social determinants of health (SDOH)"

Applicant's Summary

The American Psychological Association submitted a request to establish a new HCPCS Level II code to identify SDOH assessment (e.g., education/history, employment/unemployment, occupational exposure, housing/economic circumstances, social environment, upbringing, family support group/family circumstance, psychosocial), with scoring and documentation. An assessment provides a vital opportunity for qualified healthcare providers to assess the needs of patients, on an ongoing basis, in order to promote emotional, behavioral and medical health. The age-appropriate SDOH assessment is administered, scored and documented by the qualified healthcare professional. SDOH assessments include the following areas of interest, education/history, employment/unemployment, occupational exposure, housing/economic circumstances, social environment, upbringing, family support group/family circumstance and psychosocial. While SDOH ICD-10 diagnosis codes exist, a universally recognized HCPCS code does not exist to report an assessment of SDOH by a qualified healthcare professional. HCPCS code H0025 "Behavioral health prevention education service (delivery of services with target population to affect knowledge, attitude and/or behavior)" is recognized by some payers, as are SDOH ICD-10 codes, but HCPCS code H0025 has a Medicare Status I "Not Valid for Medicare Purposes." Physicians may include their time for SDOH screening in evaluation and management (E/M) CPT Codes (i.e. 99212-99215). However, qualified health care professionals, other than Doctors of Medicine and Doctors of Osteopathic Medicine, cannot report E/M CPT Codes 99212-99215.

Preliminary CMS HCPCS Coding Recommendation

CMS believes the work done by qualified health care professionals to perform SDOH assessments is consistent with the type of provider services described by HCPCS Level I (CPT) codes. CMS refers this applicant to the American Medical Association (AMA) CPT Editorial Panel for coding guidance on reporting SDOH assessments.

Agenda Item # 9

Chaplain Services - HCP220103QGVN8

Topic/Issue

Request to revise existing HCPCS Level II code Q9001 to remove "department of veterans affairs."

Applicant's suggested language: Q9001, which currently reads "Assessment by department of veterans affairs chaplain services" to instead read "Assessment by chaplain services"

Applicant's Summary

HealthCare Chaplaincy Network submitted a request to revise HCPCS Level II code Q9001 to remove "department of veterans affairs." Chaplain spiritual care provides in-depth specialist spiritual and pastoral care and counseling, which is integrated into the total care and treatment program. Chaplains provide a full range of spiritual and pastoral care and counseling that is characterized by in-depth assessment, evaluation and treatment of patients with many different spiritual and religious needs. As part of an integrated and comprehensive bio-psycho-social-spiritual approach, ascertaining a patient's spiritual preference and practices and how they wish those integrated into their care, and developing appropriate goals and outcomes of spiritual care. The chaplain also provides consultation, counseling and support to family members and staff. Professional chaplains are clinically trained to provide this care. The existing codes only apply to hospice and /or chaplaincy services in the Veterans Health Administration (VHA). However, the need for standardized data for budgeting and quality purposes that was identified by the VHA as a justification for the original codes also applies to all US health care institutions. Emerging objectives of care such as the needs to drive accountable care and advance health equity as proposed in the Strategy Refresh of the Center for Medicare and Medicaid Innovation (CMMI) can benefit from chaplaincy care and thus require the collection of standardized data. At present, there are no standardized chaplaincy care data sets essential to this data collection.

Preliminary CMS HCPCS Coding Recommendation

This application from the HealthCare Chaplaincy Network is a repeat from 2021 and did not contain any new information in response to the previous HCPCS Level II coding decision. CMS continues to understand the desire for HCPCS Level II codes to assist with the collection of standardized data for chaplain spiritual care. However, CMS is still not aware of a claims processing need on the part of other insurers for reporting chaplain activity other than the Department of Veterans Affairs. CMS' recommendation is to maintain the existing HCPCS Level II chaplain codes for use by the Department of Veterans Affairs.

Agenda Item # 9

Chaplain Services - HCP2201036JBC9

Topic/Issue

Request to revise existing HCPCS Level II code Q9002 to remove "department of veterans affairs."

Applicant's suggested language: Q9002, which currently reads "Counseling, individual, by department of veterans affairs chaplain services" to instead read "Counseling, individual, by chaplain services"

Applicant's Summary

HealthCare Chaplaincy Network submitted a request to revise HCPCS Level II code Q9002 to remove "department of veterans affairs." Chaplain spiritual care provides in-depth specialist spiritual and pastoral care and counseling, which is integrated into the total care and treatment program. Chaplains provide a full range of spiritual and pastoral care and counseling that is characterized by in-depth assessment, evaluation and treatment of patients with many different spiritual and religious needs. As part of an integrated and comprehensive bio-psycho-social-spiritual approach, ascertaining a patient's spiritual preference and practices and how they wish those integrated into their care, and developing appropriate goals and outcomes of spiritual care. The chaplain also provides consultation, counseling and support to family members and staff. Professional chaplains are clinically trained to provide this care. The existing codes only apply to hospice and /or chaplaincy services in the Veterans Health Administration (VHA). However, the need for standardized data for budgeting and quality purposes that was identified by the VHA as a justification for the original codes also applies to all US health care institutions. Emerging objectives of care such as the needs to drive accountable care and advance health equity as proposed in the Strategy Refresh of the Center for Medicare and Medicaid Innovation (CMMI) can benefit from chaplaincy care and thus require the collection of standardized data. At present, there are no standardized chaplaincy care data sets essential to this data collection.

Preliminary CMS HCPCS Coding Recommendation

This application from the HealthCare Chaplaincy Network is a repeat from 2021 and did not contain any new information in response to the previous HCPCS Level II coding decision. CMS continues to understand the desire for HCPCS Level II codes to assist with the collection of standardized data for chaplain spiritual care. However, CMS is still not aware of a claims processing need on the part of other insurers for reporting chaplain activity other than the Department of Veterans Affairs. CMS' recommendation is to maintain the existing HCPCS Level II Chaplain codes for use by the Department of Veterans Affairs.

Agenda Item # 9

Chaplain Services - HCP2201034JRL4

Topic/Issue

Request to revise existing HCPCS Level II code Q9003 to remove "department of veterans affairs."

Applicant's suggested language: Q9003, which currently reads "Counseling, group, by department of veterans affairs chaplain services" to instead read "Counseling, group, by chaplain services"

Applicant's Summary

HealthCare Chaplaincy Network submitted a request to revise HCPCS Level II code Q9003 to remove "department of veterans affairs." Chaplain spiritual care provides in-depth specialist spiritual and pastoral care and counseling, which is integrated into the total care and treatment program. Chaplains provide a full range of spiritual and pastoral care and counseling that is characterized by in-depth assessment, evaluation and treatment of patients with many different spiritual and religious needs. As part of an integrated and comprehensive bio-psycho-social-spiritual approach, ascertaining a patient's spiritual preference and practices and how they wish those integrated into their care, and developing appropriate goals and outcomes of spiritual care. The chaplain also provides consultation, counseling and support to family members and staff. Professional chaplains are clinically trained to provide this care. The existing codes only apply to hospice and /or chaplaincy services in the Veterans Health Administration (VHA). However, the need for standardized data for budgeting and quality purposes that was identified by the VHA as a justification for the original codes also applies to all US health care institutions. Emerging objectives of care such as the needs to drive accountable care and advance health equity as proposed in the Strategy Refresh of the Center for Medicare and Medicaid Innovation (CMMI) can benefit from chaplaincy care and thus require the collection of standardized data. At present, there are no standardized chaplaincy care data sets essential to this data collection.

Preliminary CMS HCPCS Coding Recommendation

This application from the HealthCare Chaplaincy Network is a repeat from 2021 and did not contain any new information in response to the previous HCPCS Level II coding decision. CMS continues to understand the desire for HCPCS Level II codes to assist with the collection of standardized data for chaplain spiritual care. However, CMS is still not aware of a claims processing need on the part of other insurers for reporting chaplain activity other than the Department of Veterans Affairs. CMS' recommendation is to maintain the existing HCPCS Level II Chaplain codes for use by the Department of Veterans Affairs.

Agenda Item # 10

VibraCool - HCP220103PBVLQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify a vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to skin surface directly under compression or indirectly when attached to a rigid brace, with frequency 80-300 Hz.

Applicant's suggested language: XXXXX, "Vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to skin surface directly under compression or indirectly when attached to a rigid brace, with frequency 80-300 Hz, each"

Applicant's Summary

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify a vibrating motor for focal mechanical simulation, capable of applying torque perpendicular to skin surface directly under compression or indirectly when attached to a rigid brace, with frequency 80-300 Hz. The code would describe a mechanical simulation (m-stim) motor used for focal mechanical stimulation, usually in conjunction with cold or heat packs. To be effective, the motor must vibrate at a high rate (80 - 300 Hz) and at a non-traumatic amplitude, and the vibration energy must be applied perpendicularly, conforming continuously to the skin overlaying the affected area (i.e., not at a single point). Pocketed compression accessories are used to ensure vibrations travel perpendicularly in the target area; alternatively, if the patient is using a rigid brace for joint stabilization, the motor may be attached to the brace. The effect of using the motor is supported and amplified by reusable cold or heat pack accessories configured for use with the motor, as needed. (The accessories are subject to separate applications.) Pain Care Labs currently distributes its patented motor configuration, which vibrates at 200 HZ, under the trade name VibraCool. With respect to function, studies support use of m-stim for treatment of (1) joint instability or weakness, with or without pain (resulting from, e.g., tendinopathies, inactivity, stroke, osteoarthritis, post-operative weakness, post-ligamentous injury, or muscular or bony injury); (2) chronic pain or spasms (osteoarthritis, stroke, or post-operative spasms); (3) acute pain (post-operative inflammation, post-operative skin disruption, itching from healing, or physical therapy); or (4) inflammatory pain (injury or rheumatoid arthritis). Under a National Institutes of Health grant, Pain Care Labs is extending research to the effectiveness of its m-stim configuration in decreasing opioid use for lower-back pain. No existing codes describe this item. Indications for use as cleared by FDA relevant to this application are for the temporary relief of minor injuries (muscle or tendon aches) and to treat myofascial pain caused by trigger points, restricted motion and muscle tension. The method of action is to apply high-frequency low-amplitude mechanical stimulation to a target body part, accompanied as appropriate by application of heat or cold. Application perpendicular to the skin surface ensures mechanical energy penetrates the muscles, stimulating production of growth and repair hormones by muscle and bone cells while mechanically separating muscle fibers contracted by energy or spasm, facilitating increased mobility. Vibratory energy transmitted in conformity to a contiguous surface area stimulates deep Pacinian mechanoreceptors, overring the A-Delta pain signal transmission in the spine (gate control). Heat aids in central and peripheral pain and spasm reduction, while cold acts centrally and locally to reduce pain and inflammation.

Preliminary CMS 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 vibrating motor for focal mechanical simulation, capable of applying torque perpendicular to skin surface directly under compression or indirectly when attached to a rigid brace, with frequency 80-300 Hz. With regard to Medicare, we do not have a benefit category for massage devices such as VibraCool, as they do not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Agenda Item # 10

VibraCool - HCP220103PAHMY

Topic/Issue

Request to establish a new HCPCS Level II code to identify a cold pack accessory used in conjunction with a vibrating motor for focal mechanical stimulation.

Applicant's suggested language: XXXXX, "Cold pack accessory capable of transmitting vibration when frozen, configured for use with vibrating motor for focal mechanical stimulation, reusable, each"

Applicant's Summary

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify a cold pack accessory used in conjunction with a vibrating motor for focal mechanical stimulation. (This vibrating motor is subject to a separate application.) The code sought in this application would be used to describe a cold pack accessory designed to apply cryotherapy to a specific target area subject to focal mechanical stimulation. This item is frozen solid to be used, so that it transmits rather than dampens the transmission of mechanical energy to the target area. The accessory is configured to fit the footprint of the vibrating motor and to be held in place between the vibrating motor and the skin surface when the motor is activated. With respect to function, mechanical stimulation with cold may be used for treatment of (1) weakness with or without pain due to stroke, or pain due to tendinopathies, rheumatoid arthritis or osteoarthritis, post-operative pain, post-ligamentous injury, or muscular or bony injury); (2) chronic pain (osteoarthritis, stroke,); (3) acute pain (post-operative inflammation, post-operative skin disruption, itching from healing, or physical therapy); or (4) inflammatory pain (injury or rheumatoid arthritis). Cold acts centrally and locally to reduce pain and inflammation, and the physiological effects of mechanical stimulation are synergistically maximized by simultaneous application of cold. An existing code could describe this item, but the items it describes are not covered by Medicare. This accessory is a critical element of the vibrating motor's system for pain or inflammation, and to be able to provide coverage, payers must be able to distinguish this item from other, non-covered items. Indications for use as cleared by FDA relevant to this application are for temporary relief of minor injuries (muscle or tendon aches) and to treat myofascial pain caused by trigger points, restricted motion and muscle tension. The method of action is application of cryotherapy in conjunction with vibration; the transmission of vibration requires that the cold pack accessory be rigid when applied, to ensure that vibrations are transmitted effectively rather than dampened by the accessory. The system is usually applied to the target area for 20 minutes; the accessory thaws after that time. Pain Care Labs makes the item available as part of a kit with the motor and other accessories or separately as needed for replacement.

Preliminary CMS 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 cold pack accessory used in conjunction with a vibrating motor for focal mechanical simulation. With regard to Medicare, we do not have a benefit category for massage devices such as VibraCool, as they do not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are

currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Agenda Item # 10

VibraCool - HCP220103JC42V

Topic/Issue

Request to establish a new HCPCS Level II code to identify a heat pack accessory used in conjunction with a vibrating motor for focal mechanical stimulation.

Applicant's suggested language: XXXXX, "Heat pack accessory, solid and capable of transmitting vibration when activated, configured for use with vibrating motor for focal mechanical stimulation, reusable, each"

Applicant's Summary

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify a heat pack accessory used in conjunction with a vibrating motor for focal mechanical stimulation. (This vibrating motor is subject to a separate application.) The code sought in this application would be used to describe a heat pack accessory designed to apply heat to a specific target area subject to focal mechanical stimulation. This item is solid when heated, so that it transmits rather than dampens the transmission of mechanical energy to the target area. The accessory is configured to fit the footprint of the vibrating motor and to be held in place between the vibrating motor and the skin surface when the motor is activated. With respect to function, studies support use of mechanical stimulation with heat for treatment of (1) joint pain (resulting from, e.g., tendinopathies, inactivity, stroke, osteoarthritis, post-operative weakness, post-ligamentous injury, or muscular or bony injury); (2) chronic pain or spasms (osteoarthritis, stroke, or post-operative spasms); (3) acute pain (post-operative skin disruption, itching from healing, or physical therapy); or (4) injury pain after inactivity. Heat aids in central and peripheral pain relief and local spasm reduction, and the physiological effects of mechanical stimulation are synergistically maximized by simultaneous application of heat. An existing code could describe this item, but the items it describes are not covered by Medicare. This accessory is a critical element of the vibrating motor's system, and to be able to provide coverage, payers must be able to distinguish this item from other, non-covered items. Indications for use of the VibraCool system relevant to this application are for temporary relief of minor injuries (muscle or tendon aches) and to treat myofascial pain caused by trigger points, restricted motion and muscle tension. The method of action is application of heat in conjunction with vibration; the transmission of vibration requires that the heat pack accessory be solid when applied, to ensure that mechanical stimulation frequency is transmitted effectively rather than dampened by the accessory. The system is usually applied to the target area for about 20 minutes. Pain Care Labs makes the item available as part of a kit with the motor and other accessories or separately as needed for replacement, both reusable and disposable packs.

Preliminary CMS 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 heat pack accessory used in conjunction with a vibrating motor for focal mechanical simulation. With regard to Medicare, we do not have a benefit category for massage devices such as VibraCool, as they do not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are

currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Agenda Item # 10

VibraCool - HCP220103RYF4M

Topic/Issue

Request to establish a new HCPCS Level II code to identify a pocketed compression accessory used in conjunction with a vibrating motor for focal mechanical stimulation.

Applicant's suggested language: XXXXX, "Pocketed compression accessory for use with vibrating motor for focal mechanical stimulation, each"

Applicant's Summary

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify a pocketed compression accessory for use with vibrating motor for focal mechanical stimulation. The code sought in this application would be used to describe a pocketed compression accessory appropriately configured for the target therapeutic area and designed to hold in place a vibrating motor and a cold pack accessory or heat pack accessory (as used), while compressing them against the skin surface on or near the target area to ensure that mechanical energy is transmitted perpendicularly to the skin without loss of force. With respect to function, studies support use of mechanical stimulation for treatment of (1) joint instability or weakness, with or without pain (resulting from, e.g., tendinopathies, inactivity, stroke, osteoarthritis, post-operative weakness, post-ligamentous injury, or muscular or bony injury); (2) chronic pain or spasms (osteoarthritis, stroke, or post-operative spasms); (3) acute pain (post-operative inflammation, post-operative skin disruption, itching from healing, or physical therapy); or (4) inflammatory pain (injury or rheumatoid arthritis). No existing codes describe this item. The pocketed compression accessory would be used for any of these conditions. Indications for use as cleared by FDA relevant to this application are for temporary relief of minor injuries (muscle or tendon aches) and to treat myofascial pain caused by trigger points, restricted motion and muscle tension. The method of action of the pocketed compression accessory is to compress the vibrating motor and heat pack accessory or cold pack accessory (as used) to a target body part. Pain Care Labs makes the item available as part of a kit with the motor and other accessories or separately as needed for replacement.

Preliminary CMS 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 pocketed compression accessory for use with vibrating motor for focal mechanical stimulation. With regard to Medicare, we do not have a benefit category for massage devices such as VibraCool, as they do not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Agenda Item # 11

Zipline - HCP21122159KTB

Topic/Issue

Request to establish a new HCPCS Level II code to identify transportation of laboratory specimens from point of care to an appropriate laboratory via automated unmanned aerial vehicle.

Applicant's suggested language: XXXXX, "Stat lab request, specimen delivery by automated unmanned aerial vehicle"

Applicant's Summary

Zipline International Inc. submitted a request to establish a new HCPCS Level II code to identify transportation of laboratory specimens from point of care to an appropriate laboratory via automated unmanned aerial vehicle. This service uses small, electric, fixed-wing airplanes with vertical take-off and landing capabilities to automatically transport lab samples from patient facilities to laboratory facilities. This functionality provides two significant clinical benefits beyond services covered by existing codes: 1) dramatically improved speed to result in time-critical cases and 2) access to test results that are otherwise unavailable in remote or underserved care settings. Existing codes (e.g. S3600) do not adequately describe this service in the same way that non-emergency transportation codes do not adequately describe air ambulance services.

Preliminary CMS HCPCS Coding Recommendation

CMS does not believe there is a claims processing need for a new HCPCS Level II code to identify the transportation of laboratory specimens from point of care to an appropriate laboratory via automated unmanned aerial vehicle. Existing HCPCS Level II code S3600 "Stat laboratory request (situations other than s3601)" was established to describe all urgent laboratory requests outside of those described under code S3601. The timeframe for STAT deliveries will vary from by situation, regardless of the mechanism of delivery, due to the associated circumstances (e.g., travel distance between point of care and laboratory), and code S3600 is intended to account for a broad range of expedited timeframes.

Agenda Item # 12

Dynasplint - HCP2201030HELW

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1810.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1810. Currently, the short description of E1810 is as follows: "Adjust knee ext/flex device" and the long description is as follows: "Dynamic adjustable knee extension / flexion device, includes soft interface material." The knee is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1810 code is an inadequate and confusing description. The short and long E1810 descriptions create the assumption that one E1810 device can work both extension and flexion for a hinge joint. That is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use the requested modifiers. For example, with the modifier, a patient who has been prescribed a knee extension device and a knee flexion device for the left knee would be submitted on the CMS/HCFA 1500 Form as follows: E1810 RR LT XT FL. These modifiers would accurately and adequately describe the E1810 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service.".

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic, CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Agenda Item # 12

Dynasplint - HCP220103LMW31

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1800.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1800. Currently, the short description of E1800 is as follows: "Adjust elbow ext/flex device" and the long description is as follows: "Dynamic adjustable elbow extension / flexion device, includes soft interface material." The elbow is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1800 code is an inadequate and confusing description. The short and long E1800 descriptions create the assumption that one E1800 device can work both extension and flexion for a hinge joint. That is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use these requested modifiers. For example, with the modifier, a patient who has been prescribed an elbow extension device and an elbow flexion device for the left elbow would be submitted on the CMS/HCFA 1500 Form as follows: E1800 RR LT XT FL. These modifiers would accurately and adequately describe the E1800 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service."

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Agenda Item # 12

Dynasplint - HCP220104VM3VW

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1805.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1805. Currently, the short description of E1805 is as follows: "Adjust wrist ext/flex device" and the long description is as follows: "Dynamic adjustable wrist extension / flexion device, includes soft interface material." The wrist and metacarpals are hinge joints which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1805 code is an inadequate and confusing description. The short and long E1805 descriptions create the assumption that one E1805 device can work both extension, flexion, and metacarpal extension and flexion for a hinge joint. That is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use these requested modifiers. For example, with the modifier, a patient who has been prescribed a wrist extension device and a wrist flexion device for the left wrist would be submitted on the CMS/HCFA 1500 Form as follows: E1805 RR LT XT FL. These modifiers would accurately and adequately describe the E1805 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service."

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Agenda Item # 12

Dynasplint - HCP2201042VU1F

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1815.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1815. Currently, the short description of E1815 is as follows: "Adjust ankle ext/flex device" and the long description is as follows: "Dynamic adjustable ankle extension / flexion device, includes soft interface material." The ankle is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1815 code is an inadequate and confusing description. The short and long E1815 descriptions create the assumption that one E1815 device can work both extension and flexion for a hinge joint. That is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use these requested modifiers. For example, with the modifier, a patient who has been prescribed an ankle extension device and an ankle flexion device for the left ankle would be submitted on the CMS/HCFA 1500 Form as follows: E1815 RR LT XT FL. These modifiers would accurately and adequately describe the E1815 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service."

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Agenda Item # 12

Dynasplint - HCP2201044JC64

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1825.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1825. Currently, the short description of E1825 is as follows: "Adjust finger ext/flex device" and the long description is as follows: "Dynamic adjustable finger extension / flexion device, includes soft interface material." The finger is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1825 code is an inadequate and confusing description. The short and long E1825 descriptions create the assumption that one E1825 device can work both extension and flexion for a hinge joint. That is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use these requested modifiers. For example, with the modifier, a patient who has been prescribed a finger extension device and a finger flexion device for the left second digit would be submitted on the CMS/HCFA 1500 Form as follows: E1825 RR LT F1 XT FL. These modifiers would accurately and adequately describe the E1825 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service."

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Agenda Item # 12

Dynasplint - HCP2201047DPYK

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1830.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1830. Currently, the short description of E1830 is as follows: "Adjust toe ext/flexion device" and the long description is as follows: "Dynamic adjustable toe extension / flexion device, includes soft interface material." The toe is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1830 code is an inadequate and confusing description. The short and long E1830 descriptions create the assumption that one E1830 device can work both extension, flexion, hammertoe, and Varus/Valgus extension and flexion for a hinge joint. That is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use these requested modifiers. For example, with the modifier, a patient who has been prescribed a toe extension device and a toe flexion device for the left great toe would be submitted on the CMS/HCFA 1500 Form as follows: E1830 RR LT XT FL. These modifiers would accurately and adequately describe the E1830 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service."

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Appendix: 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.