Centers for Medicare & Medicaid Services (CMS)
Agenda for Healthcare Common Procedure Coding System (HCPCS) Public Meeting for code applications for Durable Medical Equipment (DME) and Accessories; Orthotics and Prosthetics (O & P); Supplies and Other Non-Drug and Non-Biological items and services submitted to CMS' first 2020 biannual HCPCS coding cycle

WEBEX MEETING
Tuesday, June 2, 2020
9:00 am – 12:30 pm

8:45 a.m. Webex Meeting Login

9:00 a.m. Welcome
Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS's preliminary coding recommendation is provided. 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 other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Final coding decisions will be published on CMS HCPCS web site at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCS-Coding-Decisions **on or about July 1, 2020, and will be effective October 1, 2020, unless otherwise specified.**

The agenda includes a summary of each HCPCS code application on the agenda. 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.

We are also soliciting public consultation on Medicare use of HCPCS codes for insulin infusion pumps that can also receive and display continuous glucose measurements.

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Agenda Item # 1

Medicare use of HCPCS codes for insulin infusion pumps that can also receive and display continuous glucose measurements

Agenda Item # 2

Application # 20.076

Request to establish a new Level II HCPCS code to identify X10's Interactive pressure modulated device for leg strengthening and active plus passive range of motion (ROM) Knee only.

Agenda Item # 3

Application # 20.077

Request to establish a new Level II HCPCS code to identify the SpeechVive device.

Agenda Item # 4

Application # 20.078

Request to establish a new Level II HCPCS code to identify the PureWick Urine Collection System.

Agenda Item # 5

Application # 20.079

Request to establish a new Level II HCPCS code to identify "HipTrac".

Agenda Item # 6

Application # 20.081

Request to establish a new Level II HCPCS code to identify the Orpyx SI Sensory Insole system.

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Agenda Item # 7

Application # 20.082

Request to revise existing HCPCS code A4467 “Belt, strap, sleeve, garment, or covering, any type” to include the product manufacturer’s name in the code text.

Agenda Item # 8

Application # 20.083

Request to establish a new Level II HCPCS code to identify the Virtual Exercise Rehabilitation Assistant (VERA)

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Agenda Item # 1

TOPIC

Medicare payment for insulin infusion pumps that can also receive and display continuous glucose measurements

BACKGROUND

As part of the annual 2020 HCPCS update cycle last year, a request (application #19.128) was submitted on behalf of Tandem Diabetes, Inc. to establish a new Level II HCPCS code to identify Tandem t-slim X2 insulin pump. The applicant requested the following code:

EXXXX External ambulatory insulin infusion pump and therapeutic CGM receiver

According to the applicant, the t-slim X2 insulin pump is intended for subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t-slim X2 pump can also receive and utilize continuous glucose measurements from the Dexcom G5 and G6 Mobile CGM sensors and transmitters.

In response to this request, the following codes were added to the HCPCS effective January 1, 2020:

E0787 External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing

A4226 Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week

Prior to this change, the only code available for billing for insulin infusion pumps covered under Medicare was code E0784 (External ambulatory infusion pump, insulin). In addition, code K0554 (Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system) was available for billing for equipment used to receive and display continuous glucose measurements. Codes E0784 and K0554 describe separate items of equipment, whereas code E0787 describes one piece of equipment that performs the functions of equipment described by codes E0784 and K0554.

Insulin infusion pumps are paid on a capped rental basis under Medicare. Monthly rental payments are made for the equipment for up to 13 months of continuous use. Following month 13, the supplier of the pump must transfer title to the pump to the beneficiary. Continuous glucose monitors (receivers) are paid on a purchase or rental basis, with total payments capped at the purchase price of the equipment. These payment rules are mandated by the exclusive payment rule for durable medical equipment at section 1834(a) of the Social Security Act.

Medicare also covers continuous glucose monitors (CGMs) under the DME benefit. The Medicare statute and regulations allow for payment on either a rental or purchase basis for this equipment, but total payments cannot exceed the Medicare purchase price for the equipment. This item is identified by code K0554 in the HCPCS.

Under the Local Coverage Determinations for External Infusion Pumps (L33794), Medicare only covers insulin pumps that can also receive and display continuous glucose measurements (pumps described by code E0787) if the beneficiary meets the medical necessity criteria for both an insulin infusion pump and a continuous glucose monitor (CGM).

In order to allow access to this innovative technology for all Medicare beneficiaries, CMS is seeking public consultation to more fully consider how we can address the likely conflicting payment provisions and adhere to the payment limits in the statute. In addition, we need to consider what happens in cases where the patient wants to utilize this newer technology pump but already owns a CGM receiver and/or insulin pump paid for by Medicare or has been renting an insulin infusion pump without an integrated CGM receiver for less than 13 months of continuous use.

As we engage in this public consultation, we believe the best course of action may be to make code E0787 invalid for Medicare use and have suppliers bill for the rental of the equipment described by code E0787 using the separate codes E0784 with the RR (rental) modifier and K0554 with the RR modifier. This would allow for the correct application of the payment rules for insulin pumps and CGM receivers while allowing beneficiaries to receive and use this new technology. Code E0787 would still be valid for use by other payers. In addition, code A4226 would still be valid for use in billing for the supplies used with the pumps described by code E0787, which would not be billed for using a combination of codes E0784RR and K0554RR. We are soliciting public consultation on this option as well as any other ideas for coding and payment of this equipment.

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Agenda Item # 2

Application # 20.076

TOPIC

Request to establish a new Level II HCPCS code to identify X10's Interactive pressure modulated device for leg strengthening and active plus passive range of motion (ROM) Knee only.

Applicant's suggested language: EXXXX, Interactive pressure modulated DEVICE FOR leg strengthening and active plus ROM KNEE ONLY

SUMMARY

Application submitted on behalf of Harnessed Motion, LLC, to establish a new HCPCS Level II code to identify X10 Knee Rehabilitation machine. According to the applicant, the X10 therapy system consist of X10 machine is robotic, integrated with computer, touch screen, and a specific therapy protocol. The therapy is managed between patient and the licensed X10 personal physical therapy coach. Patient's progress is monitored by the coach in-person or via telemedicine daily and adjust therapy as needed. Weekly patient progress report is sent to the surgeon for therapy recommendations. The X10 therapy system is for range of motion and strengthening exercises after knee replacement surgery. According to applicant, the X10 therapy rapidly improves strength and range of motion utilizing clinical approach that is pain-free. The X10 uses precise controlled pressure to bend and straighten the leg. As a result, the X10 slows down and creeps when it senses the pressure is approaching the patient's preset limit, it will then stop and reverse and reverse when the limit is reached. Patient's pain is maintained below threshold and it builds patients' confidence and therefore are able to engage in more therapy sessions up to 21 per week, compared with standard physical therapy, which is 3 per week. The X10 system gently and effectively pumps the fluid into the lymph and excretes out. The X10 therapy system is primarily for knee arthroplasty (single or bilateral), patients with other knee surgeries, and knee injury. It is effective for all patients, including those who typically do not respond to traditional therapy. Designed to use multiple times a day and several weeks at a time. The X10 can easily be cleaned between therapy treatment plans. The roller pads and the thigh straps are replaced following each rental period.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code E0935 "Continuous passive motion exercise device for use on knee only" adequately describes the device; and existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the monitoring feature. These codes are available for assignment by insurers if they deem appropriate.

While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735- 1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

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Agenda Item # 3

Application # 20.077

TOPIC

Request to establish a new Level II HCPCS code to identify the SpeechVive device.

Applicant's suggested language: XXXXX, "Speech volume modulation device"

SUMMARY

SpeechVive, Inc. submitted an application for one new Level II HCPCS code to identify its SpeechVive device ("SpeechVive"). According to the applicant, the SpeechVive is a wearable technology comprised of an ear-worn device, charging station and charging cord. SpeechVive is regulated by 21 CFR 874.5840 and is recognized by FDA under Product Code KTH: Class I 510(k) exempt device. SpeechVive treats Parkinson's patients diagnosed with the medical condition that is identified by ICD 10 Code – R47.1: Dysarthria and Anarthria. SpeechVive utilizes an in-ear device that plays noise (multi-talker babble) only when the patient speaks. The noise elicits the Lombard Effect, automatically increasing the patient's vocal intensity, slowing their speech rate, and/or increasing the clarity of their speech. The function and impact of the product on vocal intensity has been demonstrated in randomized clinical trial with delayed treatment groups and multiple baselines that are included as attachments to the application. The SpeechVice device is an innovative new technology and as such there is no current HCPCS code that fits the product's description and function. This lack of an existing HCPCS code has been validated in e-mail discussions with the Pricing, Data and Analysis Committee (PDAC) and through the submission and payment of the unlisted HCPCS code. To date, the Veterans Administration (VA), Durable Medical Equipment Medicare Administrative Contractors (DME MAC) and Commercial Insurers have questioned the lack of a SpeechVive specific code, have not been able to offer alternative HCPCS codes, and have agreed that, in absence of a code, the miscellaneous code should be used. SpeechVive is currently being billed and reimbursed using HCPCS miscellaneous code: E1399 - durable medical equipment, miscellaneous. In addition, the lack of an appropriate HCPCS code has hindered VA, DME MAC and commercial insurers' ability to track SpeechVive financial and other associated metrics within their respective systems. As a result of the clinical benefit of the SpeechVive device, and payer inquiries about a unique code, there is a programmatic need for CMS to assign a unique code for the device.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish a new Level II HCPCS code KXXXX "Speech volume modulation system, any type, including all components and accessories"

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Agenda Item # 4

Application # 20.078

TOPIC

Request to establish a new Level II HCPCS code to identify the PureWick Urine Collection System.

Applicant's suggested language: E06XX, “Urine Collection pump, home model, portable or stationary, battery powered or electric”

SUMMARY

BD submitted an application for a new Level II HCPCS code for its PureWick Urine Collection System.

According to the applicant, the PureWick System is an alternative to an indwelling catheter for female adult patients suffering from permanent urinary incontinence. It is indicated for non-invasive urine output management in females and is contraindicated in patients with urinary retention. It funnels the urine and removes it to the Collection Canister once it passes through the patient tubing. Suction enables efficient removal of urine from the Female External Catheter (FEC). According to the applicant 2018, the CMS PDAC responded to a coding verification request for various items of the PureWick System. Correspondence with the PDAC Medical Director led the applicant to believe that the powered urine collection pump was an item of DME that could not be assigned to a Level II HCPCS code that would describe a urine collection pump; however, the other components of the PureWick System could potentially be assigned to existing Level II HCPCS codes. As per the applicant, the PDAC Medical Director acknowledged that the applicant could submit a HCPCS application to CMS HCPCS Workgroup for the powered urine collection pump, then resubmit the entire PureWick System to Pdac for reconsideration. The applicant believes that HCPCS codes exist for other components of the PureWick System: Collection Canister; A5102; Patient Tubing; A4331; PureWick FEC; A4328.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code KXXXX "Suction pump, home model, portable or stationary, electric, any type for use with external urine management system"

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Agenda Item # 5

Application # 20.079

TOPIC

Request to establish a new Level II HCPCS code to identify the "HipTrac".

Applicant's suggested language: EXXXX, “Hip (femoral-acetabular) joint traction equipment (e.g. HipTrac)”

SUMMARY

MedRock, Inc. requested a new HCPCS code to identify the HipTrac. According to the applicant, the HipTrac is used in the treatment of pain and joint capsule restriction commonly associated with hip osteoarthritis. HipTrac replicates the manual therapy technique in clinics by physical therapists, physicians and chiropractors, it is independent – used by the patient at home between visits and after discharge from the clinic to decrease pain while increasing mobility and exercise – tolerance of the patient. MedRock have stated that PDAC and HCPCS do not just place products by the title description alone, but rather evaluates the primary and customary medical use, therapeutic distinctions, mechanical engineering and capable predicates. E0880 was established 26 years ago and provides the example Bucks Traction as a device that would be under this code. Bucks use 15 lbs. of force HipTrac uses 90 – 180lbs. of force.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing Level II HCPCS code E0880 "Traction stand, free standing, extremity traction, (e.g., buck's)” adequately describes the HipTrac.

While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735- 1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may

request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

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Agenda Item # 6

Application # 20.081

TOPIC

Request to establish a new Level II HCPCS code to identify the Orpyx SI Sensory Insole system.

Applicant's Suggested language: "For diabetics only, multiple density insert, made by direct carving with cam technology from a rectified cad model created from a digitalized scan of the patient, total contact with patient's foot, including arch, base layer minimum of 3/16-inch material, includes all components of plantar sensing system (pressure sensors, temperature sensors, motion sensor and wireless enabled electronics), custom fabricated, each."

SUMMARY

Orpyx Medical Technologies Inc. is requesting the creation of one (1) new HCPCS code for Orpyx SI Sensory Insole system as described below: A5514, but also include sensor that monitors pressure temperature, and activity which can provide real-time audiovisual alerts. The descriptor of the new HCPCS code would be: For diabetics only, multiple density insert, made by direct carving with cam technology from a rectified cad model created from a digitized scan of the patient Orpyx SI Sensory Insole system is prescribed by physicians and attempt to prevent plantar foot ulcerations in the most vulnerable patient population. Patients who are at higher risk to develop foot ulcers and other pedal pathology use this system

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A5514 "For diabetics only, multiple density insert, made by direct carving with cam technology from a rectified cad model created from a digitized scan of the patient, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each" adequately describes the insole; and existing code and A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the sensors and electronics. These codes are available for use by insurers if they deem appropriate.

While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with
their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state

in which the claims would be filed. For private insurance, contact the individual private insurance entity.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735- 1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

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Agenda Item # 7

Application # 20.082

TOPIC

Request to revise existing HCPCS A4467 “Belt, strap, sleeve, garment, or covering, any type” to add the product manufacturer’s name within the code text.

SUMMARY

Medcross Products, LLC. is requesting modification to existing HCPCS to identify Med Zip Up “A4467 Belt, strap, sleeve, garment, or covering, any type” to include the manufacture’s name (Medcross Products LLC.). Name change be corrected in the CMS system and listed in codes system during the next update. Medcross Products, LLC states their uniforms and other clothing protect patients from getting infections at home and in the hospital or nursing homes. Medcross jacket design is the only jacket on the market that is universal allowing access to a portal wherever it may be. Use of a double ended zipper for Hickman Catheter at the neck, simply unzip from the neck, the side of where the portal is located. To access the fistula, simply unzip at the sleeve cuff to allow access to the portal in the forearm while the antimicrobial spikes create a protective barrier from infectious disease during the administering of dialysis treatment.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4467 "Belt, strap, sleeve, garment, or covering, any type" as established in 2017 to identify "med zip up" and other similar products adequately describes this product. The Level II HCPCS codes describe categories of similar items. Manufacturer or Vendor names are not included in code text. Insurers may or may not independently keep product list by make model or vendor relative to HCPCS codes. CMS requests additional information from the applicant about any discussions with the FDA with regard to marketing approval of this product for the clinical indications (antimicrobial, barrier to infectious disease) claimed in this application.

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Agenda Item # 8

Application # 20.083

TOPIC

Request to establish a new Level II HCPCS code to identify the Virtual Exercise Rehabilitation Assistant (VERA)

Applicant's suggested language: EXXXX, "Monitoring Feature/device, stand alone or integrated, to sport virtual physical rehabilitation, includes 3D markerless motion technology for clinician review of quality/completion of physical therapy exercises with patient progress via video records, synchronous telemedicine visits (tele-rehabilitation), report generation, and real-time patient performance feedback."

SUMMARY

Reflexion Health, Inc. is requesting the creation of one (1) new HCPCS code to identify the Virtual Exercise Rehabilitation Assistant (VERA According to the applicant, the VERA is a software system used with Microsoft Kinect v2 intended to support the physical rehabilitation of adults in the clinic at home. The system includes rehabilitation exercises for the upper extremity, trunk and lower extremity with the audio-visual feedback & graphic movement representations for patients as well as remotely accessible patient performance video. Patient assessment, exercise guidance and approval by medical professional is required prior to use. Patients are provided an all-inclusive kit (monitor, cellular wireless access point, 3D motion sensing camera) to enable real accountability while a patient is doing their exercise.

PRELIMINARY HCPCS CODING RECOMMENDATION

It is our understanding that the item that is the subject of this application is factored into the practice expense. For additional details and for coding guidance, CMS refers the applicant to the American Medical Association (AMA).