



Centers for Medicare & Medicaid Services' (CMS') Second Biannual 2024 Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda

Zoom Meeting - Remote participation
Wednesday, November 6, 2024, 9:00 am – 5:00 pm, eastern time (ET)

8:45 am, ET:

- Zoom meeting login:
<https://cms.zoomgov.com/j/1602260511?pwd=hoK9eXztvwuVhSHLLReBBaVnlwiuaC.1>
- Passcode: 132470; Dial: 833 435 1820 US Toll Free; Webinar ID: 160 226 0511
- Individuals who plan to speak as a primary or 5-minute speaker must register by emailing HCPCS@cms.hhs.gov, by the published deadline. All attendees can access the virtual public meeting through the Zoom link above.

9:00 am, ET:

- Welcome
- Background and purpose of meeting
- Meeting format and ground rules

Provided for each agenda item is a written overview of the applicant's request, CMS' preliminary coding recommendation, as well as CMS' preliminary benefit category and payment determination, if applicable. Preliminary recommendations are not final or binding upon any payer and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and any registered 5-minute speakers. Speaker presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for interested parties to provide additional input related to requests to modify the HCPCS Level II code set. Final decisions are not made at the public meeting. CMS' final coding, benefit category, and payment decisions will be published on CMS' HCPCS website at:

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCSLevelII-Coding-Decisions-Narrative-Summary> around January 2025 and will be effective April 1, 2025, unless otherwise specified.

This agenda includes a summary of each HCPCS Level II code application being presented on Wednesday, November 6, 2024. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

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Agenda Item # 1
Chemo Mouthpiece™ - HCP240627CH4KV

Topic/Issue

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

Applicant's suggested language: XXXXX, "Intra-oral cryotherapy device for patients who receive stomatotoxic chemotherapy administration, kit of 6 plus accessories"

Summary of Applicant's Submission

ChemoMouthpiece, LLC submitted a request to establish a new HCPCS Level II code to identify Chemo Mouthpiece™. Chemo Mouthpiece™ received the Food and Drug Administration's (FDA's) 510(k) clearance on January 23, 2024. Chemo Mouthpiece™ is a medical device that is intended for use in adult individuals to cool the oral mucosa, causing vasoconstriction that decreases the flow of chemotherapy, thus reducing the incidence and severity of chemotherapy-induced oral mucositis. The device is indicated for use in the clinical and home settings in adult individuals who are receiving chemotherapy. The Chemo Mouthpiece™ device is a single-patient, multiple-use item that is supplied in a kit containing six identical devices (intended for the same individual). The devices are placed in a freezer six hours prior to the individual being administered chemotherapy. Ten minutes prior to chemotherapy, the individual is instructed to use the device, which will remain in the individual's mouth for the duration of the chemotherapy administration. Each device maintains a temperature of 31.8 degrees to 35.5 degrees Fahrenheit for 30 minutes and the individual is instructed to switch to another frozen device every 30 minutes for the duration of chemotherapy infusion. Individuals are instructed to use the device at home (post-administration of chemotherapy) a minimum of two times per day for the following five days to keep the oral cavity cool to reduce the incidence and severity of chemotherapy-induced mucositis.

CMS Preliminary HCPCS Coding Recommendation

The Chemo Mouthpiece™ is not suitable for coding in HCPCS Level II for Medicare purposes because this product, if covered, would be expected to be included within the payment for the professional service. 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 # 2
Flexi-Q DV Auto-Injector - HCP240701MKHXP

Topic/Issue

Request to establish a new HCPCS Level II code to describe the Flexi-Q DV Auto-Injector.

Applicant's suggested language: XXXXX, "Prefilled syringes and vials, featuring reusable for chronic disease that require frequent injection"

Summary of Applicant's Submission

Vanguard Health Management LLC submitted a request to establish a new HCPCS Level II code to describe the Flexi-Q DV Auto-Injector. The Flexi-Q DV Auto-Injector received the Food and Drug Administration's (FDA's) 510(k) clearance on February 9, 2012. The Flexi-Q DV Auto-Injector is a multi-use auto-injector with a reusable driving unit and cost-effective needle protection disposable cassette for use with standard pre-filled syringes and vials. The Flexi-Q DV Auto-Injector is intended for use in chronic diseases that require frequent injections, and its partially reusable design lowers the cost per injection and reduces the volume for storage and disposal. The Flexi-Q DV Auto-Injector offers automatic needle insertion with customizable preset needle penetration depths, preset injection speeds, and fixed delivery volumes. The Flexi-Q DV Auto-Injector has windows for visual inspection of the syringe content along the full length of the barrel. Drug reconstitution and mixing from a vial can be performed using Flexi-Q's optional vial adaptor or dual-chamber prefilled syringe which permit reconstitution of hard-to-dissolve drugs by allowing swirling and time delays followed by user inspection prior to injection.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4211, "Supplies for self-administered injections" describes the Flexi-Q DV Auto-Injector. Flexi-Q DV Auto-Injector is similar to other devices in HCPCS Level II code A4211.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for HCPCS Level II code A4211 applies to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4211 apply to this product. Items or services described by HCPCS Level II code A4211 are not covered under the Medicare Part B DMEPOS benefit.

No Medicare Payment. Pricing Indicator = 00

Agenda Item # 3
iHealth® COVID-19/Flu A&B Rapid Test - HCP240530Q0P9A

Topic/Issue

Request to establish a new HCPCS Level II code to identify iHealth® COVID-19/Flu A&B Rapid Test.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

iHealth Labs, Inc submitted a request to establish a new HCPCS Level II code to identify iHealth® COVID-19/Flu A&B Rapid Test. iHealth® non-prescription home use self-collected COVID-19/Flu A&B Rapid Test received the Food and Drug Administration's (FDA's) Emergency Use Authorization (EUA) on May 7, 2024. The iHealth® COVID-19/Flu A&B Rapid Test is a non-prescription, self-collected, nasal swab for individuals aged 14 years or older, or with adult-collected nasal swab specimen from individuals 2 to 14 years old. This test is only authorized for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first four days of symptom onset when tested at least twice over three days, with at least 48 hours between tests.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code to describe iHealth® COVID-19/Flu A&B Rapid Test. iHealth® COVID-19/Flu A&B Rapid Test would not be payable by Medicare as there is no Medicare Benefit Category for at-home COVID-19/Flu A&B Rapid tests. CMS is not aware of other insurers potentially paying for this non-prescription home use self-collected COVID-19/Flu A&B Rapid tests. Please contact non-Medicare payers for coding and payment guidance. If information regarding payers who are currently paying for these COVID-19/Flu A&B Rapid tests becomes available to describe a claims processing need for a unique HCPCS Level II code, the applicant is welcome to submit a new application.

Agenda Item # 4
Missing and Murdered Indigenous Persons (MMIP) and Historical Trauma (HT) -
IHC240819DMW1D

Topic/Issue

Request to establish two new HCPCS Level II codes to identify Missing and Murdered Indigenous Persons (MMIP) and Historical Trauma (HT) services.

Applicant's suggested language:

1. XXXXX, "Missing and murdered indigenous persons (MMIP) mental health and clinical care"
2. XXXXX, "Historical Trauma (HT) mental health and clinical care"

Summary of Applicant's Submission

The Not Invisible Act Commission recommended the Department of Health & Human Services establish two HCPCS Level II codes to describe Missing and Murdered Indigenous Persons (MMIP) and Historical Trauma (HT) services. These new codes could be used for American Indian and Alaska Native Tribal members and other ethnicities to receive and bill for services rendered for MMIP and HT related conditions. The types of services that could be included under these codes may be related to behavioral health services for individuals affected by an unacknowledged death or missing indigenous or other person and for care related to HT for American Indians and Alaska Natives.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code H0052, "Missing and murdered indigenous persons (mmip) mental health and clinical care"
2. Establish a new HCPCS Level II code H0053, "Historical trauma (ht) mental health and clinical care for indigenous persons"

Effective January 1, 2025.

We are requesting public comment on the language in the code descriptor for these new HCPCS Level II codes.

Agenda Item # 5
S3 Uplifter Toilet Chair - HCP240701719RN

Topic/Issue

Request to establish a new HCPCS Level II code to identify S3 Uplifter Toilet Chair.

Applicant's suggested language: EXXXX, "Sit to stand feature with weight activated hydraulic dual control lever system"

Summary of Applicant's Submission

S3 Secure Sit to Stand, LLC submitted a request for a new HCPCS Level II code to identify the S3 Uplifter Toilet Chair. The S3 Uplifter Toilet Chair is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Secure Sit to Stand patented technology has been incorporated into a toilet/showering chair to assist the individual with sitting and standing while toileting or showering. The S3 Uplifter Toilet Chair operates by a two-way hydraulic dual lever system and weight activated arm paddles to allow one to sit down with appropriate resistance and stand with hydraulic lever assisted lift mechanism. This feature allows the individual to softly descend when sitting and stand up with safety and support, decreasing the likelihood of a fall. As one prepares to sit, the individual applies a force on the seat base as they lower themselves into the chair. During this time, one may continue to apply a desired amount of downward force on the front ends of the arms to counteract the force of their weight on the seat base. Since the seat base is tilted upwardly in the extended position, the distance an individual must lower themselves before contacting the chair is significantly decreased relative to a traditional toilet chair. There are also safety locks on the left and right side under the handles that allow you to lock the seat into place while cleaning yourself by simply pushing the left and right knob. As one prepares to stand, they can pull out the safety knob allowing the lever mechanisms to re-engage. Then they can apply a downward force on the front ends of the arms as they apply an upward force on the seat base that activates the hydraulic lever system to tilt the seat base upwardly from a depressed position to an extended position. As the individual begins to stand, the seat base will continue moving upwardly to assist the individual to stand up from a seated position. These features offer a solution for individuals with cognitive impairments and frailty who may otherwise be unable to use existing toileting solutions. Similar technology has been used in the Uplifter Chairs for the dining and living room which has been shown to improve safety and independence with 'sit-to-stand' activities for adults with conditions such as amyotrophic lateral sclerosis, multiple sclerosis, and lower extremity amputations.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E0172, "Seat lift mechanism placed over or on top of toilet, any type" describes the S3 Uplifter Toilet Chair. The S3 Uplifter Toilet Chair is similar in nature to other devices in HCPCS Level II code E0172.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The S3 Uplifter Toilet Chair does not meet one condition as follows:

- **Not primarily and customarily used to serve a medical purpose** – The S3 Uplifter Toilet Chair is a seat lift device that is placed over on or on top of a toilet. It does not provide treatment for a medical condition.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 6
IndeeLift® - HCP2311125H5TT

Topic/Issue

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

Applicant's suggested language: XXXXX, "Multipositional patient transfer system, with integrated lift, patient accessible controls, transfer and/or lift in a seated position from floor to sit or to stand, <400 pounds"

Summary of Applicant's Submission

IndeeLift Inc. submitted a request for a new HCPCS Level II code to identify the IndeeLift®. IndeeLift® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). IndeeLift® human floor lifts are multipositional electric patient seat lifts intended for lifting an individual who has fallen, who is either ambulatory or non-ambulatory, weighing up to 400 pounds, from the ground to a seated height, 21 inches, to enable them to either stand up or to transfer to a chair/wheelchair (Models PPU and HFL-400-D), or to a standing height, 30 inches, for those individuals who are not able to rise-up from a seated position but can walk with or without an assistive device once they are in a standing position (Model PPU-S and FTS-400). IndeeLift® devices are self-operational or can be used with the aid of a single caregiver depending on the mobility level of the individual. Existing HCPCS Level II codes that partially, but not adequately, describe the IndeeLift® are E0630, E0635, and E0636; however, the lifts described under these codes require at least one assistant to operate the device and assist in maneuvering an individual, and may require supine positioning of the individual. IndeeLift® is designed to be self-operated by the individual, who may or may not be ambulatory, so these requirements would not apply. IndeeLift® helps mitigate deterioration of the neuromuscular condition of an individual with a diagnosis such as severe arthritis of the hips or knees, or a neuromuscular disease, so they are not bed confined.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe the IndeeLift®. CMS believes the IndeeLift® is precautionary in nature and does not replace a capacity that an individual previously had.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

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

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.

4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. The IndeeLift® does not meet one condition as follows:

- **Is primarily and customarily used to serve a medical purpose** – In accordance with section 110.1.B.2 of chapter 15 of the Medicare Benefit Policy Manual, equipment that is precautionary-type equipment is considered nonmedical. The IndeeLift® is used as standby or precautionary equipment in the event of a fall and therefore is considered nonmedical. Thus, the preliminary BCD for this item would be no DMEPOS benefit category.

In addition, we have questions regarding whether the IndeeLift® meets two other conditions:

- **Generally is not useful to an individual in the absence of an illness or injury** - The applicant stated that the IndeeLift® may be used as a patient transfer system as well as an independent fall recovery system after an individual has fallen. This device also appears to be useful to an individual in the absence of an illness or injury to move heavy items such as boxes, small pieces of furniture, and small appliances in the same manner that a dolly would be used for non-medical residential and business purposes.
- **Is appropriate for use in the home** – If an individual falls and needs to be lifted off the floor, it may not be appropriate to use equipment such as the IndeeLift® in the home because the individual or caregiver may be unaware that the individual was injured in the fall and using the equipment may create further harm or injury to the individual. We are requesting more information to ascertain how the risk of use of IndeeLift® if the individual has been injured has an impact on the use of IndeeLift® in the home.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 7
munevo DRIVE - HCP240628F7PWV

Topic/Issue

Request to establish a new HCPCS Level II code to identify munevo DRIVE.

Applicant's suggested language: EXXXX, "Power wheelchair accessory, wearable smart glass based, integrated sensors, proportional, specialty control interface"

Summary of Applicant's Submission

Munevo Inc. submitted a request for a new HCPCS Level II code to identify the munevo DRIVE. The munevo DRIVE is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The munevo DRIVE uses integrated sensors to calibrate head gestures which allow an individual who uses a wheelchair to navigate their power wheelchair. The device is intended for individuals who cannot use a joystick but are able to slightly tilt and turn their head (5 degrees). This alternative input technology, also referred to as an interface control, provides a means for independent operation of complex rehab technology (CRT) power wheelchairs. This device can be used for an individual with, but not limited to, amyotrophic lateral sclerosis, high level spinal cord injuries (C1-C4/5), and progressive diseases such as: multiple sclerosis, muscular atrophy, muscular dystrophy and cerebral palsy. Individuals who use power wheelchairs are often unable to use their hands to operate a joystick or other alternative input device. These individuals may also require adjustment or programming of the device's performance and sensitivity to the user's movement based on the user's needs, physical condition, setting, time of day, and physical condition of the user. These adjustments may need to be made multiple times each day. Non-wearable, mechanical devices require third-party or external support by a CRT supplier, caregiver, or therapist. In contrast, the user can calibrate the munevo DRIVE at any time and within 15 seconds. The munevo DRIVE consists of two hardware components; a smart glass that can be worn like eyeglasses, and an adapter box which integrates with the power wheelchair electronics. For individuals who require simultaneous use of eyeglasses to correct vision impairment, special frames are available. There is specialized software inside the hardware that allows for safe and secure navigation of the wheelchair, power seating systems, and allows connectivity to other devices. Many individuals who use power wheelchairs requiring this type of input device use it to operate additional power seating systems. Frequent repositioning of the body and head can result in the user losing contact with the input device when they use non-wearable input devices. This creates a risk of the user being in a position where they cannot reach/access the input device or separate button/switch needed to activate a power seating function. This is not a concern with the munevo DRIVE, as it is a wearable input device.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E2328, "Power wheelchair accessory, head control or extremity control interface, electronic, proportional, including all related electronics and fixed mounting hardware" describes the munevo DRIVE wheelchair accessory. We believe the munevo DRIVE is a technological refinement of a proportional head control interface, which allows the user to move the wheelchair in any direction, and is similar to other devices coded within HCPCS Level II code E2328.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The information submitted by the applicant was reviewed and was determined to meet the requirements to be classified as DME.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E2328, “Power wheelchair accessory, head control or extremity control interface, electronic, proportional, including all related electronics and fixed mounting hardware” apply to the munevo DRIVE wheelchair accessory.

Note that the applicant has confirmed for CMS that while the munevo DRIVE wheelchair accessory includes add-on functions using Bluetooth® technology to permit wheelchair users to perform non-mobility-related functions, such as to operate a computer and smartphone, these add-on functions are disabled at initial issue of the wheelchair accessory and can be purchased separately by the individual. As these add-ons are not primarily and customarily used to serve a medical purpose, they would not be payable under a DMEPOS benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E2328 apply to this product, if covered. Payment for existing HCPCS Level II code E2328 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately \$582.27 on average for months 1 through 3, and approximately \$436.70 on average for months 4 through 13, resulting in a total capped payment of \$6,113.81 should there be 13 months of continuous use. Fee schedules are updated annually.

The HCPCS modifier KU can be included when billing certain wheelchair accessories furnished in connection with Group 3 power wheelchairs for complex rehabilitative individuals to receive the unadjusted fee schedule amount. The munevo DRIVE wheelchair accessory is applicable.

Pricing Indicator = 36

Agenda Item # 8
Complex Rehabilitative Power Seat Elevation System - HCP2407015PF60

Topic/Issue

Request to revise existing HCPCS Level II code E2298, "Complex rehabilitative power wheelchair accessory, power seat elevation system, any type" to include complex rehabilitative power seat elevation.

Applicant's suggested language: E2298, "Complex Rehabilitative Power Wheelchair Accessory, Power Seating System, Complex Rehab Seat Elevation, any type"

Summary of Applicant's Submission

The National Coalition for Assistive and Rehab Technology (NCART), on behalf of its member manufacturers of power seat elevation systems, submitted a request to revise existing HCPCS Level II code E2298 to identify the advanced technology of complex rehabilitative technology (CRT) power seat elevation (PSE) systems and to re-calculate its fee schedule amount. The current code description for HCPCS Level II code E2298, "Complex rehabilitative power wheelchair accessory, power seat elevation system, any type" does not differentiate CRT PSE systems from a basic PSE accessory and will have long-term unintended consequences if it is not changed. The language "complex rehabilitative power wheelchair accessory" does not define HCPCS Level II code E2298, it merely dictates what base codes a "power seat elevation system, any type" may be billed on. In NCART's prior HCPCS Level II code application from the second biannual 2023 coding cycle, it was requested CMS adopt characteristics to define CRT PSE that included at least 10" of elevation, being capable of elevating/descending while the power wheelchair (PWC) moves and of moving on a horizontal surface while fully elevated, and compatible with other power seating options (power tilt and/or power recline). If CMS' objective is to preclude billing of a CRT PSE system with non-CRT base codes, such as E2300, NCART recommends revising the code description to differentiate clinically relevant CRT PSE characteristics from a basic PSE accessory used on a non-CRT PWC. Use of "power seating system" in the code description for HCPCS Level II code E2298, instead of "power seat elevation system", would be consistent with all other HCPCS codes listed under Group 6, Power Seating Systems in the Wheelchair Options/Accessories Local Coverage Determination (L33792). NCART contends this because the basic physical components of a stand-alone CRT PSE system are the same as the components of a stand-alone power tilt or power recline system. Lastly, a revision to the code description for HCPCS Level II code E2298 will accurately define the scope of CRT PSE products and should serve as the basis for a re-calculation of the fee schedule, considering the three available pricing methodologies, and publicly available pricing information. CMS has three ways to calculate a reimbursement rate when a HCPCS Level II code is added. CMS can use an existing fee schedule amount for comparable items, previous fee schedule amounts for the old code mapped to the new code to ensure continuity of pricing, or gap filling methodology. NCART contends, firstly, that CRT PSE is comparable to a power tilt system, second that a reimbursement rate has already been established for the HCPCS Level II code E2300, "Wheelchair accessory, power seat elevation system, any type" based on thousands of claims paid from May 16, 2023 through March 31, 2024 and finally, that CMS is not mandated to use gap filling as a payment methodology.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E2298, “Complex rehabilitative power wheelchair accessory, power seat elevation system, any type” describes power seat elevation that may be covered for use on a complex rehabilitative power-driven wheelchair in accordance with the Medicare national coverage determination (NCD) for power wheelchair seat elevation equipment.

The request to add specifications for the code (e.g., capable of elevating at least 10 inches) was addressed during the NCD process and is outside the scope of the HCPCS Level II coding process.

Agenda Item # 9
Wheelchair Mounting Hardware - HCP240131PLFW5

Topic/Issue

Request to establish three new codes and revise an existing HCPCS Level II code E1028, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for joystick, other control interface or positioning accessory” to further describe wheelchair mounting hardware.

Applicant's suggested language:

1. E1028, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware, other”
2. EXXX1, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware used with remote joysticks or touchpads”
3. EXXX2, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for headrest, cushioned, any type”
4. EXXX3, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for lateral trunk or hip support, any type”

Summary of Applicant's Submission

Palmetto GBA submitted a request to revise HCPCS Level II code E1028 and establish three new HCPCS Level II codes to further identify wheelchair mounting hardware accessories. Palmetto GBA further requested HCPCS Level II code E1028 be revised to account for any type of mounting hardware that does not fall into the three requested new HCPCS Level II codes. Mounting hardware for a wheelchair is used to attach additional accessories to the wheelchair to assist the beneficiary in which these types of accessories can range from electronic controls to assist in movement to cushions and support. The mounting hardware, itself, usually consists of a metal bracket and some screws, or similar devices to hold the accessory in place. The mounting hardware allows the correct placement of the accessories to support the individual, access controls and/or move accessories out of the way when getting in and out of the wheelchair. An individual will often need multiple accessories to be mounted, and this will require multiple billings of E1028, each needing a narrative description to identify the type of accessory being mounted. E1028 is in the capped rental pricing category so it is billed for up to 13 months of rental. In addition, there is a Medically Unlikely Edit (MUE) edit for E1028. Creation of the new codes will help with multiple billings of E1028, and the need to review the narrative description, manual tracking of the rental months, and correction when MUE edits are applied.

CMS Preliminary HCPCS Coding Recommendation

We believe there is a claims processing need on behalf of Medicare to address issues related to multiple billings of existing HCPCS Level II code E1028, such as review the narrative description, manual tracking of the rental months, and correction of inappropriate MUE edits. As such, CMS is proposing to:

1. Revise existing HCPCS Level II code E1028, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for joystick, other control interface or positioning accessory” to instead read “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware, other”
2. Establish a new HCPCS Level II code EXXX1, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware used with remote joysticks or touchpads”
3. Establish a new HCPCS Level II code EXXX2, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for headrest, cushioned, any type”
4. Establish a new HCPCS Level II code EXXX3, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for lateral trunk or hip support, any type”

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

CMS established HCPCS Level II code E1028, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for joystick, other control interface or positioning accessory” effective January 1, 2004, and assigned it to the Durable Medical Equipment Medicare benefit category. The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1028 apply when the HCPCS Level II code is revised and new HCPCS Level II codes EXXX1, EXXX2, and EXXX3 are established to more specifically identify mounting hardware: joysticks/touchpads, headrests, and lateral trunk/hip support. Mounting hardware for a wheelchair is used to attach additional accessories to the wheelchair in order to assist the individual.

Preliminary Medicare Payment Determination

For HCPCS Level II codes EXXX1, EXXX2, and EXXX3, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new codes have a pricing history based on HCPCS Level II code E1028. Thus, the preliminary payment determination for new HCPCS Level II codes EXXX1, EXXX2, and EXXX3 is to map the fee schedule amounts for HCPCS Level II code E1028 to each of the new HCPCS Level II codes EXXX1, EXXX2, and EXXX3.

The 2024 average capped rental fee schedule amount for HCPCS Level II codes EXXX1, EXXX2, and EXXX3 would be approximately \$15.99 for months 1 through 3 and approximately \$11.99 for months 4 through 13, for a total of \$167.87 after 13 months of continuous use. Fee schedules are updated annually.

For items furnished in a former Competitive Bidding Area (CBA), the 2024 average capped rental fee schedule amount for HCPCS Level II codes EXXX1, EXXX2, and EXXX3 across all CBAs would be approximately \$15.59 for months 1 through 3 and approximately \$11.69 for months 4 through 13, for a total of \$163.67 after 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Agenda Item # 10
Wheelchair Transit Accessories - HCP220624G4XCH

Topic/Issue

Request to establish two new HCPCS Level II codes to identify wheelchair transit accessories.

Applicant's suggested language:

1. XXXXX, "Transportation tie down system used in a motor vehicle during transportation"
2. XXXXX, "Dot approved occupant wheelchair restraint system"

Summary of Applicant's Submission

Palmetto GBA submitted a request to establish two HCPCS Level II codes to identify wheelchair transit accessories. The best practice for individuals in wheelchairs when traveling is to use occupant restraint systems. These securement methods are collectively known as wheelchair tiedown and occupant restraint systems (WTORS). Currently, transportation tie down straps and wheelchair restraint systems are billed under existing HCPCS Level II code K0108, "Wheelchair component or accessory, not otherwise specified." Hundreds of claim lines are billed to Medicare each quarter, which require manual adjudication. For Medicare, these items are statutorily excluded and always denied. Defined codes would automate the process.

CMS Preliminary HCPCS Coding Recommendation

We believe there is a claims processing need on behalf of Medicare to help reduce the manual adjudication process for existing HCPCS Level II code K0108 for wheelchair tiedowns and occupant restraint systems. As such, CMS is proposing to:

1. Establish a new HCPCS Level II code EXXXX, "Wheelchair transportation securement system, includes all components and accessories"
2. Establish a new HCPCS Level II code EXXXX, "Department of transportation approved wheelchair transit securement system, includes all components and accessories"

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The wheelchair transit accessory does not meet three of the conditions that must be met for equipment to be classified as DME:

Is primarily and customarily used to serve a medical purpose – The wheelchair transit accessory is a personal safety item for use during vehicle transport and is not intended to treat a medical condition. Therefore, it is not primarily serving a medical purpose.

Generally is not useful to an individual in the absence of an illness or injury - The wheelchair transit accessory is a personal safety item for use during vehicle transport and is not intended to treat an illness or injury. Therefore, it is useful to an individual in the absence of an illness or injury.

Is appropriate for use in the home – As stated in the application, the setting of use for the wheelchair transit accessory is 100% outside the home. It is intended for use during vehicle transport.

Therefore, the wheelchair transit accessory cannot be defined as durable medical equipment.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 11
Rollz Motion - HCP240628PHWKW

Topic/Issue

Request to establish a new HCPCS Level II code to describe Rollz Motion.

Applicant's suggested language: XXXXX, "Walker, transport chair, folding, wheeled, adjustable or fixed height, convertible from walker to wheelchair and back"

Summary of Applicant's Submission

Rollz Mobility US Inc. submitted a request to establish a new HCPCS Level II Code to describe Rollz Motion. The Rollz Motion is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Rollz Motion is a rollator and wheelchair combination. It has four large wheels, is heavy duty, foldable, has adjustable handlebars and a solid seat. As a wheelchair, this product has an adjustable solid back in addition to the previous mentioned features. This allows users to stay as active as possible using the Rollz Motion as a rollator and can transform it into a wheelchair whenever they need more support. This benefits rehabilitation and achieving a more active lifestyle. Over 8.5 million people in the United States of all ages with diseases like Multiple Sclerosis, Parkinson's, Amyotrophic Lateral Sclerosis, or simply having serious mobility issues may benefit greatly from a combination product like the Rollz Motion. The Rollz Motion provides the user with a product for well over five years up to ten years, which they can use in multiple stages of mobility.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E0143, "Walker, folding, wheeled, adjustable or fixed height" along with E0156, "Seat attachment, walker" describes the Rollz Motion when used as a walker. However, when used as a transport chair, existing HCPCS Level II code E1038, "Transport chair, adult size, patient weight capacity up to and including 300 pounds" describes the Rollz Motion.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II codes E0143 ("Walker, folding, wheeled, adjustable or fixed height") and E0156 ("Seat attachment, walker") apply to the Rollz Motion, when used as a walker. Also, the current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1038 ("Transport chair, adult size, patient weight capacity up to and including 300 pounds") apply to Rollz Motion when used as a transport chair.

Preliminary Medicare Payment Determination

Note that based on the requirements for Medicare, suppliers must not bill both HCPCS Level II code E0143 and HCPCS Level II code E1038 for the same Medicare beneficiary for Rollz Motion.

For HCPCS Level II code E0143 along with HCPCS Level II code E0156:

The payment rules and pricing associated with existing HCPCS Level II codes E1043 and E0156 apply to this product, if covered. The current average 2024 rural fee schedule amount for HCPCS Level II codes E1043 + E0156 in the contiguous United States is \$123.76. The current average 2024 non-rural fee schedule amount in the contiguous United States is \$74.15.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 32

For HCPCS Level II code E1038:

The payment rules and pricing associated with existing HCPCS Level II codes E1038 apply to this product, if covered. Payment for existing HCPCS Level II code E1038 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately \$19.41 on average for months 1 through 3, and approximately \$14.56 on average for months 4 through 13, resulting in a total capped payment of \$203.83 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Agenda Item # 12
NYRC Brace™ - HCP2407013T365

Topic/Issue

Request to establish a new HCPCS Level II code to describe the NYRC Brace™.

Applicant's suggested language: LXXXX, "Tension based scoliosis orthosis with integrated Smart Brace technology for recording and transmitting proper wear and patient compliance monitoring, custom fabricated"

Summary of Applicant's Submission

Secured Ortho Manufacturing of America, LLC submitted a request to establish a new HCPCS Level II code to identify the NYRC Brace™. The NYRC Brace™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The NYRC Brace™ is a custom fabricated rigid shell Rigo-Cheneau style tension-based spinal orthosis with integrated smart technology for the treatment of individuals with adolescent idiopathic scoliosis. The custom-made NYRC Brace™ achieves a more intimate fit with three-dimensional corrective forces to prevent scoliosis progression and axial rotation of the spine. Proper fitting is achieved by affixing X-ray and palpation-guided anatomical markers to the individual's body prior to 3D surface scanning. Individual-specific pelvic parameters and scoliosis classification system of the 3D curve pattern influence the design and custom fabrication. The pre-fabrication process includes a clinician consultation with NYRC Brace™ biomedical engineers to determine the brace design and strap placement configuration. Proprietary algorithm design software helps create an individualized brace. The NYRC Brace™ is differentiated from other scoliosis braces by the integrated smart device technology and connectivity via a mobile app. The smart device technology guides the fitting of the brace and the education to the individual of the proper use as well as captures usage data of the individual's adherence to proper/adequate strap tensioning (brace tightness), daily hours of proper and improper brace use, and balance patterns when wearing the brace. The mobile app generates real-time (live) and look-back (week, month, year) analytics in easily understood visual formats to educate and benefit the individual while assisting medical providers in more effective management of the individual's treatment plan. The NYRC Brace™ is custom fabricated and made for a specific individual using their own body geometry. The NYRC Brace™ requires intensive individual evaluation and precise body scanning imagery to support the custom fabrication, strap locations and fitting refinements. The NYRC Brace™ also has an anterior trim that overlaps when the straps are tightened with purposeful relief voids built into the shell to allow for adequate tension and comfortable application of corrective forces. Smart hardware and customized setup of the individual protocols, including mobile app-based individual education and self-guided practice sessions, enhance the individual experience and create opportunities for improved compliance and outcomes.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code L1300, "Other scoliosis procedure, body jacket molded to patient model" describes the NYRC Brace™ and existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories,

components and electronics, not otherwise classified” describes the integrated monitoring smart device technology.

The NYRC Brace™ uses a computer-aided design - computer-aided manufacturing (CAD-CAM) technique to custom fabricate the brace. Appendix C of the DMEPOS Quality Standards¹ indicates that CAD-CAM is one of the techniques used to make a molded to individual model brace. HCPCS Level II code L1300, therefore, includes braces, such as the NYRC Brace™, that are custom fabricated using the CAD-CAM technique.

Preliminary Medicare Benefit Category Determination

Back Brace.

The NYRC Brace™ meets the definition of a brace. Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians’ services or on a physician’s order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. This definition is also in Medicare regulations at 42 CFR 410.2. The NYRC Brace™ is a rigid device that is used to treat scoliosis in adolescents.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code L1300 apply to this product. Payment is made on a lump sum purchase basis. The average of the 2024 fee schedule amounts for HCPCS Level II code L1300 is \$2,104.12.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

¹ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html>.

Agenda Item # 13
ExoBand - HCP240701FNQJ2

Topic/Issue

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

Applicant's suggested language: KXXXX, "Hip orthosis, including abduction orthosis consisting of a belt, two leg loops and two tensioners which together with a toothed guide join all these elements"

Summary of Applicant's Submission

Moveo SRL submitted a request to establish a new HCPCS Level II code to identify ExoBand. ExoBand is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). ExoBand is a hip orthosis including abduction orthosis device which is designed to support human walking for individuals with motor impairments caused by disabling diseases and health conditions including those with neurodegenerative diseases such as Parkinson's disease and multiple sclerosis or those who experienced acute events like stroke, or spinal cord injury. ExoBand is a walking device consisting of a belt and two leg loops. These three independent elements are connected to each other by a mechanism that stores energy generated in the first phase of the gait cycle to return it in the second phase, enhancing the thrust of the hip flexors and leading to functional improvement in walking.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes ExoBand. ExoBand is primarily made of elastic material and is similar to other devices in existing HCPCS Level II code A4467.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. This definition is also in Medicare regulations at 42 CFR 410.2. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based in this definition, the preliminary determination is that the ExoBand is not a brace. There is no indication that this product uses rigid or semi-rigid materials that would qualify it as a brace.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 14
WalkOn - HCP240630DETBH

Topic/Issue

Request to establish a new HCPCS Level II code to describe the WalkOn ankle foot orthosis.

Applicant's suggested language: LXXXX, "Ankle foot orthosis (AFO), spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, off-the-shelf"

Summary of Applicant's Submission

Ottobock submitted a request to establish a new HCPCS Level II code to describe the WalkOn ankle foot orthosis (AFO). The WalkOn is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The WalkOn is an off the shelf, posterior leaf design, ankle foot orthosis made from prepreg carbon graphite composite material. The WalkOn allows for compression of the heel at heel strike, dynamic response, floor reaction forces, and energy storage from mid-stance to toe off. The WalkOn and similar designs assist in the control of knee hyperextension and provide dorsiflexion assist to clear the foot/toe during the swing phase of gait. The design of the WalkOn ankle foot orthosis does not allow for much bending or molding. Substantial modification could include adding a supination correction strap, grinding or trimming the footplate, or adding a custom foot orthosis which all should be performed by a certified Orthotist or certified Fitter. The WalkOn is the predicate device for the HCPCS Level II code L1951, "Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, includes fitting and adjustment," which was established January 1, 2004. At that time, there was not a distinction between prefabricated, custom fit with substantial modification versus prefabricated, off-the-shelf with minimal modifications. Since that time, HCPCS Level II code L1951 has been categorized as a prefabricated, custom fitted item requiring substantial modifications and customized to fit a specific patient by an individual with expertise that includes fitting and adjustment. Most individuals fitted with a L1951 device will not require substantial modifications. In the absence of a unique code, HCPCS Level II code L2999, "Lower extremity orthoses, not otherwise specified" has been the most appropriate code for billing prefabricated, off-the-shelf, minimal self-adjustment AFOs.

CMS Preliminary HCPCS Coding Recommendation

CMS believes a revision to the existing HCPCS Level II code L1951 and the establishment of a new HCPCS Level II code for the prefabricated, off-the-shelf, requiring minimal self-adjustment leg brace is necessary for claims processing. As such, CMS is proposing the following coding actions:

1. Revise existing HCPCS Level II code L1951, "Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, includes fitting and adjustment" to instead read "Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise."

2. Establish new HCPCS Level II code LXXXX, “Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, off-the-shelf” to describe WalkOn.

Preliminary Medicare Benefit Category Determination

Leg Brace.

Preliminary Medicare Payment Determination

For new HCPCS Level II code LXXXX, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS makes an effort to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new HCPCS Level II code LXXXX has a pricing history. For HCPCS Level II code LXXXX, the pricing history is based on HCPCS Level II code L1951. When there is a single code that describes two or more distinct complete items (that would be off-the-shelf and custom-fitted items), and separate codes are subsequently established for each item, the payment amount that applied to the original code is also applied to the new code. Thus, the preliminary payment determination for new HCPCS Level II code LXXXX is to establish the fee schedule amount by mapping the existing fee schedule amount for the related item described by HCPCS Level II code L1951.

The average 2024 purchase fee schedule amount for HCPCS Level II codes L1951 and LXXXX is \$983.23. The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 14
WalkOn Reaction - HCP240630953Y7

Topic/Issue

Request to establish a new HCPCS Level II code to describe the WalkOn Reaction.

Applicant's suggested language: LXXXX, "Ankle foot orthosis (AFO), rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf"

Summary of Applicant's Submission

Ottobock submitted a request to establish a new HCPCS Level II code to describe the WalkOn Reaction prefabricated, off-the-shelf ankle foot orthosis (AFO). The WalkOn Reaction is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The WalkOn Reaction is an ankle foot orthosis designed for ambulatory individuals needing support with dorsiflexor weakness with no or slight-to-moderate spasticity. It can also be used for individuals with slight impairment of the plantar flexion muscles, for individuals with foot deformities that can be corrected with insoles and a lateral support element and for individuals with a slight impairment of knee extension, for example, individuals with constant fatigue of the knee extensors during long periods of standing or walking. The indication frequently occurs after an individual experiences a stroke, traumatic brain injury, multiple sclerosis, neuromuscular atrophy or peroneal paralysis. The WalkOn Reaction is suitable for individuals with a high level of activity, who need support for knee extension or flexion in the mid-stance phase and during toe-off or heel strike. The frontal support element allows the WalkOn Reaction to influence the knee with the help of ground reaction forces. The support element makes it possible to exert influence on deviations of the frontal axes in the knee and ankle joint. The WalkOn Reaction is made from prepreg carbon graphite composite material and can be molded and bent slightly. Additionally, the WalkOn Reaction can be substantially modified by adding a supination correction strap, grinding or trimming the footplate, or adding a custom foot orthosis, which all should be performed by a certified Orthotist or certified Fitter. The WalkOn Reaction is currently assigned by the Medicare Contractor for Pricing, Data Analysis and Coding (PDAC) to HCPCS Level II code L1932, "Afo, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, includes fitting and adjustment," which was established on January 1, 2005. At that time, there was not a distinction between prefabricated, custom fit with substantial modification versus prefabricated, off-the-shelf with minimal modifications. Since that time, HCPCS Level II code L1932 has been categorized as a prefabricated, custom fitted item requiring substantial modifications and customized to fit a specific patient by an individual with expertise that includes fitting and adjustment. Most individuals fitted with an L1932 device will not require substantial modifications. In the absence of unique code, HCPCS Level II code L2999, "Lower extremity orthoses, not otherwise specified" has been the appropriate code for billing prefabricated, off-the-shelf, minimal self-adjustment AFOs.

CMS Preliminary HCPCS Coding Recommendation

CMS believes a revision to the existing HCPCS Level II code L1932 and the establishment of a new HCPCS Level II code for the prefabricated, off-the-shelf, requiring minimal self-adjustment leg brace is necessary for claims processing. As such, CMS is proposing the following coding actions:

1. Revise existing HCPCS Level II code, L1932, “Afo, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, includes fitting and adjustment” to instead read as “Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.”
2. Establish new HCPCS Level II code, LXXXX, “Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf” to describe the WalkOn Reaction.

Preliminary Medicare Benefit Category Determination

Leg Brace.

Preliminary Medicare Payment Determination

For new HCPCS Level II code LXXXX, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS makes an effort to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new HCPCS Level II code LXXXX has a pricing history. For HCPCS Level II code LXXXX, the pricing history is based on HCPCS Level II code L1932. When there is a single code that describes two or more distinct complete items (that would be off-the-shelf and custom-fitted items), and separate codes are subsequently established for each item, the payment amount that applied to the original code is also applied to the new code. Thus, the preliminary payment determination for new HCPCS Level II code LXXXX is to establish the fee schedule amount by mapping the existing fee schedule amount for the related item described by HCPCS Level II code L1932.

The average 2024 purchase fee schedule amount for HCPCS Level II codes L1932 and LXXXX is \$1,044.74. The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 15
InTandem - HCP231229HB5QU

Topic/Issue

Request for Medicare payment determination for InTandem.

Summary of Applicant's Submission

MedRhythms Inc. previously submitted a request to establish a new HCPCS Level II code to identify InTandem. InTandem is a class II device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). InTandem delivers rhythmic auditory stimulation (RAS), using real-time gait data from shoe-worn sensors, a durable control unit containing proprietary RAS based treatment algorithms in a closed-loop system to unconsciously improve gait quality and speed in individuals with stroke-related gait impairments. RAS targets automatic processes in the brainstem, cerebellum, and spinal cord to induce auditory motor entrainment (the unconscious synchronization of the auditory and motor systems). InTandem is intended for individuals who are six months or more post stroke event for gait impairment, specifically, slow walking speed, asymmetry, and effortful gait. In clinical literature, these factors are associated with fall risk, reduced ability to perform ambulation-related activities of daily living, and long-term health outcomes, including frequent hospitalizations and mortality. InTandem is typically used three times per week for 30 minutes each session. InTandem consists of three components: the shoe-worn sensors, a durable control unit preloaded RAS software with a locked music library, and a bone-conduction headset. The sensors collect baseline information about the individual's gait, which is processed by the control unit with the proprietary RAS based treatment algorithms to automatically adjust the music-based rhythmic cues in real time, per the RAS protocol. Depending on response, the control unit may overlay a synchronized rhythm track to engage the auditory-motor response more strongly or slow the tempo. When auditory-motor entrainment is reestablished with sufficient quality of gait, the control unit will automatically detect and increase the tempo. InTandem is a prescription only medical device.

CMS Final HCPCS Coding Decision

CMS established HCPCS Level II code E3200, “Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories, prescription only” to describe InTandem, effective October 1, 2024.

Medicare Benefit Category Determination

CMS determined that InTandem is DME, effective October 1, 2024.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by

Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors also listed in these program instructions.

In determining whether InTandem is comparable to items with existing codes and fee schedule amounts, we undertook a detailed examination of the physical, mechanical, and electrical components along with the function and intended use. Although portions of this device may be comparable to a combination of existing products described by existing codes, we believe that the overall form and function of InTandem, in particular the auditory stimulation features, cannot be described by any existing codes. For this reason, we have determined it is most appropriate to determine the Medicare payment amount in accordance with the “gap filling” procedure.

To develop an appropriate Medicare payment amount in accordance with the “gap filling” procedure, we must identify appropriate commercial pricing for the underlying items. We emphasize that a Manufacturer Suggested Retail Price (MSRP) is not, by itself, an adequate source of commercial pricing. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60739). The applicant provided us with 2023 payment information from the Veterans Administration (VA), which we have verified against the Federal Supply Schedule, and which we have used to establish the payment determination. We divided the VA two-month rental price of \$3,467.34 to obtain a monthly rental price of \$1,731.67. This would be the basis for establishing the capped rental fee schedule amounts for months one through three, which would then be reduced by 25 percent beginning with rental month four in accordance with the statute and regulations. This results in an estimated purchase price equivalent of \$17,336.70.

In accordance with regulations at 42 CFR 414.238(c), the \$17,336.70 is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to the current year using the covered item update factors listed in Chapter 23, Section 60.3 of the Medicare Claims Processing Manual (Pub. 100-04). As the price used in calculating the fee schedule amounts is greater than \$150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. Therefore, the monthly capped rental fee schedule amount for new HCPCS Level II code E3200 would be approximately \$1,099.87 for months 1 through 3, and approximately \$824.90 for months 4 through 13, resulting in a total capped payment of \$11,548.61 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Appendix A: DMEPOS Payment Categories

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

Pricing = 00 Service Not Separately Priced

Items or services described by the HCPCS Level II 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 = 40 Lymphedema Compression Treatment Items

Payment is made on a purchase basis for lymphedema compression treatment items.

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).