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

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

Zoom Meeting - Remote participation
Thursday, November 30, 2023 9:00 am – 5:00 pm, eastern time (ET)

8:45 am, ET:
• Zoom meeting login:
https://cms.zoomgov.com/webinar/register/WN_spNk4pWiR2Wb2SZ-TMarxQ
• Individuals who plan to speak as a primary or 5-minute speaker must register, through the link above, by the published deadline. All other attendees can access the virtual public meeting through the Zoom link that we will post on the HCPCS website after speaker registration closes.

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

Provided for each agenda item is a written overview of the applicant's request, CMS' preliminary coding recommendation, as well as CMS' preliminary benefit category and payment determination, if applicable. Preliminary recommendations are not final or binding upon any payer and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and any registered 5-minute speakers. Speaker presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for interested parties to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meeting. CMS' final coding, benefit category, and payment decisions will be published on CMS' HCPCS website at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCSLevelII-Coding-Decisions-Narrative-Summary around February 2024 and will be effective April 1, 2024, unless otherwise specified.

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

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Preliminary decisions for the HCPCS Virtual Public Meeting on Thursday, November 30th, 2023.

Agenda Item # 1
Power Seat Elevation for Complex Rehab Power Wheelchair Bases - HCP2307031B3DD

Topic/Issue

Request to delete existing HCPCS Level II code E2300, "Wheelchair accessory, power seat elevation system, any type" and establish two new HCPCS Level II codes to identify complex rehab technology power seat elevation system.

Applicant's suggested language:

1. EXXXX, "Wheelchair Accessory, Power Seating System, Complex Rehab Seat Elevation, Standard Weight Capacity (Up to and including 300 pounds)"

2. EXXXX, "Wheelchair Accessory, Power Seating System, Complex Rehab Seat Elevation, Heavy Duty Weight Capacity, (301 pounds up to and including 450 pounds)"

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 establish two new HCPCS Level II codes to identify complex rehab technology (CRT) power seat elevation system and the deletion of E2300, "Wheelchair accessory, power seat elevation system, any type." In decision memo CAG-00461N, National Coverage Determination for Power Seat Elevation Equipment on Power Wheelchairs, the Centers for Medicare & Medicaid Services confirmed "power seat elevation equipment is a wheelchair accessory that is added to a power wheelchair" and found that power seat elevation equipment on Medicare-covered power wheelchairs (PWCs) falls within the benefit category for durable medical equipment (DME). To implement this decision, HCPCS codes and code characteristics and requirements must be established that accurately reflect CRT seat elevation. Moreover, it is important to distinguish CRT seat elevation from the seat elevation incorporated into Group 2 Seat Elevation Power Wheelchairs K0830 and K0831. The recommended code characteristic requirements for both of the requested new CRT power seat elevation codes are clinically relevant, supported by evidence, and include: (1) elevation of at least 10 inches, (2) capable of elevating/descending while the power wheelchair moves, (3) capable of moving on a horizontal surface while fully elevated, (4) compatible with other power seating options (i.e., tilt and/or recline). A unique HCPCS code is needed to represent patient weight capacity and accurately reflect the additional complexity associated with elevating a patient weight of 301-450 lbs. To provide the durability, strength, and stability of a CRT heavy duty (HD) seat elevation system for use on CRT HD power wheelchairs, the HD systems require robust components to safely lift the full weight of the patient and any additional power seating systems necessary and other components. These systems must pass different test requirements due to the additional weight capacity. They must be able to maintain stability with a frequently changing center of gravity as the individual shifts to reach and to perform mobility-related activities of daily living.

CMS Preliminary HCPCS Coding Recommendation

Discontinue existing HCPCS Level II code E2300, "Wheelchair accessory, power seat elevation system, any type" and establish two new HCPCS Level II codes:

1. EXXXX, “Complex rehabilitative power wheelchair accessory, power seat elevation system, any type”

2. EXXXX, “Power wheelchair accessory, power seat elevation system, any type”

While the applicant requested different codes for seat elevation equipment on CRT power wheelchairs based on patient weight, our research did not show a significant price difference between power seat elevation systems based on weight class for complex rehabilitative power wheelchairs. Instead, the price differences based on weight class exist between the base CRT power wheelchairs themselves. Thus, we do not believe there is a programmatic need for two new HCPCS Level II codes and only one code for CRT wheelchair power seat elevation systems is being established. We welcome comments on this finding.

The second code listed here, “Power wheelchair accessory, power seat elevation system, any type” describes only the seat elevation system and thus could be billed for use with a non-complex rehabilitative Group 2 power wheelchair base. CMS believes the establishment of this new accessory code may obviate the need for existing non-complex rehabilitative Group 2 codes that describe an integrated seat elevation system and a Group 2 power wheelchair base. As such, CMS also recommends the discontinuation of the following Group 2 power wheelchair codes:

1. K0830, “Power wheelchair, group 2 standard, seat elevator, sling/solid seat/back, patient weight capacity up to and including 300 pounds”

2. K0831, “Power wheelchair, group 2 standard, seat elevator, captains chair, patient weight capacity up to and including 300 pounds”

Medicare Benefit Category Determination

Durable Medical Equipment.

CMS issued a final Benefit Category Determination (BCD) and National Coverage Determination (NCD) for NCD 280.16 for power seat elevation equipment on certain power wheelchairs on May 16, 2023. This determination finds that power seat elevation equipment on Medicare-covered power wheelchairs falls within the benefit category for durable medical equipment. For more information on NCD 280.16, please refer to the information published at https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=376&ncdver=1&keyword=seat%20elevation&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1.

Preliminary Medicare Payment Determination

With respect to the proposed code, EXXXX, “Complex rehabilitative power wheelchair accessory, power seat elevation system, any type:”

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as

internet retail prices) that provide information on commercial pricing for the item. If the only available price information is from a period other than the fee schedule base period (the 12-month period of 1986/1987), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Social Security Act for DME.

We note that the applicant suggested that power seat elevation for a complex rehabilitative power wheelchair should be considered comparable to power seat tilt for a complex rehabilitative power wheelchair. We do not believe this to be an appropriate comparison. Different mechanical components are used to effect seat elevation from seat tilt (for example, seat elevation may use a telescoping seat post or scissor-lift component, while tilt would use a hinged mechanism with a geared connection to the motor), and while seat tilt must accommodate an expected shift in the center of gravity from front-to-back, seat elevation only impacts the center of gravity in the vertical axis. For these reasons, we find that seat elevation is not comparable to any item with an existing fee schedule amount, and so the gap-fill approach is the most appropriate method for making a payment determination.

To ensure an appropriate universe of commercial pricing for seat elevation systems that would be classified in this code, we compiled a list of all complex rehabilitative wheelchairs with power seat elevation options available on the Product Classification List for the relevant base wheelchair codes. We verified the comprehensive nature of this list by comparing against manufacturer websites and websites of wheelchair suppliers. We further ensured that this list included all of the seat elevation options specifically mentioned by the applicants. In total, we identified seat elevation equipment for twenty power wheelchair models (listed in the below table). We then searched for the best pricing available online for each of these seat elevation options. We excluded any supplier that did not advertise a full manufacturer's warrantee or being an "authorized" supplier. We further excluded discounts that appeared to represent a time-limited or unique offer (e.g., "10% off orders received before" a specified date, "10% off your first order"). Finally, we excluded prices for suppliers that did not offer standard customizations, for example, suppliers offering refurbished units or with limited build options (e.g., only pre-build models that could not be further customized to reflect beneficiary needs).

Complex Rehabilitative Wheelchairs with Power Seat Elevation	
Alltrack M3	Alltrack M3 HD
Alltrack R3	Alltrack R3 HD
Alltrack P3	F3 Corpus
F3 Corpus HD	Frontier V6
TDX SP2 Aviva FX	Aviva Storm Rx Quantum Rehab Q6
Rovi X3	Rovi X3 mini
Quantum Rival 3	Quantum 4Front 2
Quickie Q300	Quickie Q500
Quickie Q700 Std	Quickie Q700 HD

The average price across the seat elevation systems we found would be classified in this code was $3,450.60. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of

the Act for DME. Based on these adjustments, the purchase price would be approximately $2,261.89. Under the capped rental rules for complex rehabilitative power wheelchairs, the rental price would be approximately $339.28 for months 1-3 and $135.71 for months 4-13 for a total of $2,374.94 for 13 months of continuous use.

Pricing Indicator = 36

With respect to the proposed code, EXXXX, "Power wheelchair accessory, power seat elevation system, any type:"

No determination.

As an extensive review of evidence to determine the coverage criteria for power seat elevation equipment for non-complex rehabilitative power wheelchairs is not complete, we are unable to determine the appropriate universe of seat elevation equipment that may be covered as a Medicare benefit under this code and, for this reason, we are unable to develop an appropriate payment amount at this time. Given the substantial price difference between seat elevation equipment for various models of non-complex rehabilitative power wheelchairs – ranging from around $600 to over $2,000 – it is critical to have a better understanding of the needs of the users for whom seat elevation equipment on this type of wheelchair would be covered, so as to ensure that the payment amount accurately reflects the type of equipment provided. We welcome additional input so that a payment determination for this item can be addressed at a subsequent HCPCS public meeting.

In the meantime, the DME fee schedule amounts for this item would be established by the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240. We establish fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history in accordance with regulations at 42 CFR § 414.238. In particular, for new HCPCS codes for items and services without a fee schedule pricing history we use the existing fee schedule amounts for comparable items when these items are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, then we establish the fee schedule using supplier or commercial price lists. If the purchase price used in calculating the fee schedule amounts is greater than $150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the purchase price used in calculating the fee schedule amounts is $150 or less, then payment would be made on a rental or purchase basis in accordance with our regulations at 42 CFR 414.220.

Pricing Indicator = 46

Agenda Item # 2[1]
Information Only: Final Determination for Dynamic Seating Component - Application #19.120

Topic/Issues

Request for Medicare payment determination for existing HCPCS Level II code E2398, "Wheelchair accessory, dynamic positioning hardware for back"

Summary of Applicant's Submission

The Dynamic Back consists of dynamic components, joints, linkages and elastomers, and is designed to be attached to a wheelchair frame. The system is designed to accommodate the wheelchair user's flexion and extension with minimal displacement at the pelvis during movement, and the variable spring returns the individual back to their initial posture. Static wheelchair frame components do not allow for an individual's abnormal and uncontrolled movement within the system and cannot withstand the high level of repeated force these individuals can exert. As the person extends, flexes, stretches, and shifts his or her weight due to high tone, uncontrolled movement, or relieve discomfort or pressure, the dynamic component responds to the forces that movement produces.

Final CMS HCPCS Coding Action

CMS established a new HCPCS Level II code E2398, "Wheelchair accessory, dynamic positioning hardware for back" effective January 1, 2020.

Final Benefit Category Determination

CMS determined that the Dynamic Back is DME, effective October 1, 2022.

Preliminary Medicare Payment Determination

CMS published the following preliminary Medicare payment determination in May 2022, in advance of the June 2022 public meeting:

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. The preliminary payment determination for code E2398, for this particular wheelchair dynamic hardware, is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS code E1015.

Dynamic positioning back hardware absorbs and diffuses the wheelchair user's uncontrolled movements and forces using elastomers, joints, linkages, and other components. Devices that fall under E1015 absorb the impact of a force at the point of vibration, energy, or where the

[1] Revised on November 21, 2023 to clarify that this is a final determination for information purposes only.

force occurs and disperses the energy through the frame, with minimal displacement of the patient. Both the dynamic positioning back hardware and devices under E1015 reduce shear forces and allows movement with return to a neutral position. Also, both the dynamic positioning back hardware and devices under E1015 are mounted directly to the frame of a wheelchair. Common components include rubber, polymer, elastomer, hardware componentry (spring, screws, washers, etc.).

	E1015	**Dynamic Back Hardware**
Physical Components	Mounted directly to the frame of a wheelchair Rubber/polymer/elastomer Hardware componentry	Mounted directly to the frame of a wheelchair Rubber/polymer/elastomer Hardware componentry
Mechanical Components	Spring Gas filled cylinder	Spring
Electrical Components	N/A	N/A
Function and Intended Use	Shock absorber Reduces vibration Minimal displacement of the patient Allows movement with return to a neutral position	Shock absorber Reduces vibration Minimal displacement of the patient Allows movement with return to a neutral position
Additional Aspects and Features	Reduction of shear forces	Reduction of shear forces

The 2022 fee schedule amounts for code E1015 when used with complex rehabilitative wheelchairs range from $140.34 to $168.37. The 2022 fee schedule amounts for code E1015 when used with standard wheelchairs furnished in rural and noncontiguous areas range from $137.55 to $152.59. The 2022 fee schedule amount for code E1015 when used with standard wheelchairs furnished in other areas ranges from $121.07 to $133.07. The fee schedule amounts for this item are generally less than $150 and therefore this item is inexpensive DME. Payment for the item would be made on a purchase or rental basis with total payments for any combination of claims for rental and/or purchase would be capped at the purchase fee schedule amount.

Pricing Indicator = 32

Summary of Public Feedback

In the June 2022 public meeting, three manufacturers and the National Coalition for Assistive and Rehab Technology (NCART) provided comments that the dynamic back hardware is not comparable to the E1015 (shock absorber for manual wheelchair), indicating that the dynamic back hardware is not comparable in function, strength, or durability and handles a vastly different set of forces than shock absorbing devices described by HCPCS code E1015. Additional comments were provided by an occupational therapist familiar with the items who is also a consultant for several organizations and manufacturers, including Seating Dynamics, one of the three manufacturers of the item. The consultant provided written comments that items described by code E1015 are intended to provide suspension, which can reduce vibration and jarring from uneven terrain, but is different from dynamic seating, which is

activated by client forces and then returns a client to a preferred starting position. All speakers asked CMS to delay a payment decision until they could provide a further analysis of the materials to CMS.

NCART followed up in writing to CMS both in June and October 2022, re-iterating that the dynamic back hardware is not comparable to devices described by HCPCS code E1015. They stated that the dynamic back hardware is potentially comparable to E2295 ("manual wheelchair accessory, for pediatric size wheelchair, dynamic seating frame, allows coordinated movement of multiple positioning features") but that there is insufficient utilization of the code from which to establish pricing. Therefore, they suggested that a gap-fill pricing methodology be used for E2398, but that the establishment of pricing through this methodology be deferred until there is sufficient payment history with which to establish a price. CMS also met with NCART in May 2023 for further discussion and received additional supporting materials later that month.

Final Medicare Payment Determination

While we appreciate NCART's analysis and suggestion that the dynamic back hardware may be comparable to HCPCS code E2295, we do not agree. HCPCS code E2295 is used to describe the wheelchair back and shock absorbing or dynamic seating hardware; it is not used to only describe the dynamic back hardware feature. The code E2295 was first verified for the Kids Rock Active Component with an effective date of 1/1/2009. This device, unlike the Dynamic Back, was a complete seating frame with active hip, knee, and ankle pivot points. In addition, we believe that NCART did not demonstrate significant evidence or studies to suggest that Dynamic Back differs from shock absorption and is not comparable to E1015, "Shock absorber for manual wheelchair, each".

The final determination is as outlined in our preliminary payment determination, that for this particular wheelchair dynamic hardware, HCPCS code E2398 is comparable to items described by HCPCS code E1015. Regardless of the source of the force (from the ground/terrain below the wheelchair frame or from the patient sitting above the wheelchair base), when that force is applied, both the dynamic positioning back hardware and devices under E1015 reduce the shear forces and allow movement with return to a neutral or starting position. In addition, regardless of where the shock or force is absorbed (near the rails and frame or above the base of the wheelchair), the absorbing action minimizes patient displacement and allows movement to return to a more neutral or starting position. The dynamic positioning back hardware and devices under E1015, as well as this particular wheelchair dynamic hardware, absorb and reduce the fluctuation and oscillation to allow a return to a more neutral or starting position.

In the supplemental information provided to CMS after the June 2022 public meeting, NCART again stated that Dynamic Back hardware is not comparable to devices described by HCPCS code E1015. However, the mechanism of both dynamic back hardware and E1015 (for example Retro Fit Suspension Kit) is to absorb the shock impact. The goal for both E1015 devices and Dynamic Back is to protect spinal alignment. They may absorb different types of forces but that will not impact the overall functionality. Dynamic Back diffuses the force that could otherwise lead to patient injury which is the same as the E1015 Retro Fit Suspension Kit, as it reduces and adjusts the mobility shock.

The supplemental information also states that code E1015 is intended to provide suspension, which can reduce vibration and jarring from uneven terrain, but is different from dynamic seating, which is activated by client forces and then returns a client to a preferred starting position. However, CMS has not received evidence that supports the claim that Dynamic Back returns the patient to the neutral position but E1015 devices do not. The E1015 devices reduce the forces caused by unstable transportation such as uneven terrain. These systems can convert air suspension to coil springs and it is important that as the chair goes over each bump, that this bump is not felt by the patient or is limited as much as possible. If each bump is transmitted up to the user, then the user will likely not maintain their seated position. And this is the point of having a suspension system to provide as minimum displacement as possible. These wheelchairs aim to maintain the patient's position at their preferred starting point.

Therefore, the final payment determination for code E2398 is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS code E1015.

The current 2023 fee schedule amount ranges for code E1015 are as follows:

- when used with complex rehabilitative wheelchairs: $152.55 to $183.02;
- when used with standard wheelchairs furnished in rural and noncontiguous areas: $149.79 to $166.14;
- when used with standard wheelchairs furnished in other areas: $131.95 to $145.04.

This item meets the definition of inexpensive DME in the regulations at 42 CFR 414.220(a)(1). Payment for the item would be made on a purchase or rental basis with total payments for any combination of claims for rental and/or purchase would be capped at the purchase fee schedule amount.

Pricing Indicator = 32

Agenda Item # 3
Sully Walker - HCP23051165PKK

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Sully Walker.

The applicant did not provide any suggested language.

Summary of Applicant's Submission

Sully Walker LLC submitted a request to establish a new HCPCS Level II code to identify a powered walking aid, the Sully Walker. The Sully Walker received the Food and Drug Administration's (FDA's) 510(k) clearance on October 25, 2021. Most walking aid products, like geriatric walkers and rollators, require pushing to propel the device. The Sully Walker leverages electronic power to replace the lift-and-thrust or push actions by providing forward motion by controlled power through a thumb throttle for forward motion. It has built-in speed limiting controls matched to the user's capability.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code EXXXX, "Battery powered walking aid attachment for walker, per pair" to be used in conjunction with existing HCPCS Level II code E0143, "Walker, folding, wheeled, adjustable or fixed height" to describe the Sully Walker.

Preliminary Medicare Benefit Category Determination

Walker: Durable Medical Equipment.

Walking Aid Attachment: 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 traditional walker component of the Sully Walker falls within the DME benefit category. Although the power assist component (walking aid attachment) propels the walker forward while eliminating the need for the patient to lift, push, and thrust the walker, this added feature does not appear to us to serve a medical purpose and thus at this time we consider it to be a convenience item. Our preliminary determination is that the power assist component does not fall within the DME benefit category. We welcome more information demonstrating

how the power assist component is used by the patient primarily and customarily to serve a medical purpose.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0143 apply to the Sully Walker, if covered. The current average fee schedule amount for E0143 is $85.67.

The average fee schedule amount is the average of the 2023 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 32

There is no Medicare payment for new code EXXXX.

Pricing Indicator = 00

Agenda Item # 4
Anvil Walker - HCP230629WFQMH

Topic/Issue

Request to establish a new HCPCS Level II code to identify Anvil Walker.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Advanced Brace Ltd. submitted a request to establish a new HCPCS Level II code to identify Anvil Walker. Anvil Walker is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Anvil Walker is a custom device that is designed specifically for each patient's unique diagnoses. Due to the custom process, this device can be fabricated regardless of deformity location, size, or shape of foot. Patients with one or more of the following conditions: foot amputation(s), Charcot Marie Tooth, severely deformed ankle/foot, lymphedema, Charcot Foot, severe ankle contracture, and severe ankle deformity, would benefit from the Anvil Walker. This device is designed for anyone who has one or more of the previously listed conditions and has developed the inability to return to activities of daily living without rigid support. The Anvil Walker is 100% custom made to the patient model and is made of plastic and other materials. It is fabricated with a custom 3/8th inch tri-lam material insole, with an additional 1/8th neoprene to allow suspension. This custom insert is modified to apply pressure directly posterior, medial, or lateral to the deformity site, which is key in the suspension that allows the deformity to be tolerated and, in some cases, reversed. The device achieves an additional 1/2-inch pressure reduction by utilizing the actual sole of the Anvil Walker which allows patients to walk with ease while their deformity is being corrected. The Anvil Walker is designed with an Ankle Foot Orthosis rigid support, Varus/Valgus Correction to the plastic, complete breathable inner and outer soft interface, with the above-mentioned custom arch support. This device includes at minimum three straps, but due to the custom nature, more straps can be added as needed. A non-slip rocker bottom rubber sole is added to enhance the patient’s safety and ease of walking. The Anvil Walker is lightweight, breathable, washable, and overall, extremely effective. Depending on the referring physician’s preference, it can be made open toe or closed toe.

CMS Preliminary HCPCS Coding Recommendation

The combination of existing HCPCS Level II codes listed below describes the Anvil Walker:

- L1904, “Ankle orthosis, ankle gauntlet or similar, with or without joints, custom fabricated”
- L2275, “Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined”
- L2330, “Addition to lower extremity, lacer molded to patient model, for custom fabricated orthosis only”
- L2820, “Addition to lower extremity orthosis, soft interface for molded plastic, below knee section”
- L3002, “Foot, insert, removable, molded to patient model, plastazote or equal, each”

Preliminary Medicare Benefit Category Determination

Leg brace (Orthotic).

The application supports a preliminary benefit category determination that the Anvil Walker is used as a lower extremity brace and would fall under the Medicare benefit for Leg brace (Orthotic). Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) 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. The information submitted by the applicant was reviewed extensively and supports the preliminary benefit category determination of leg brace, as the Anvil Walker supports a weak leg.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing codes L1904, L2275, L2330, L2820, and L3002 apply to this product, if covered. The current average fee schedule amount is as follows:

L1904: $562.05 + L2275: $151.44 + L2330: $475.28 + L2820: $113.24 + L3002: $184.21 = $1,486.22.

The average fee schedule amount is the average of the 2023 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 5
Scrunch Cloth - HCP2306305DJ7H

Topic/Issue

Request to establish a new HCPCS Level II code to identify Scrunch Cloth.

Applicant's suggested language: XXXXX, "ADL Adaptive Washcloth for people with physical, mental, and visual disabilities to care for themselves and to conduct rehabilitation and maintenance therapies"

Summary of Applicant's Submission

Mr. Paul Barnes, the sole proprietor of Scrunch Cloth, submitted a request to establish a new HCPCS Level II code to identify Scrunch Cloth. Scrunch Cloth is adaptive equipment that makes activities of daily living easier for people with physical, mental, and vision disabilities. Scrunch Cloth is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Scrunch Cloth is a grip-free washcloth that hugs the wrist like a "scrunchie" and slips over the hand with one finger to wash and then slips back onto the wrist. It is also a device for rehabilitation and maintenance therapies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A9286, "Hygienic item or device, disposable or non-disposable, any type, each" describes the Scrunch Cloth.

All washcloths of any type are included in the existing HCPCS Level II code A9286.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for code A9286 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A9286 apply to this product. Items or services described by HCPCS code A9286 are not covered under a Medicare Part B DMEPOS benefit.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 6
OdorNuke™ - HCP230703Q5AW5

Topic/Issue

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

Applicant's suggested language: AXXXX, "Deodorant tablet to neutralize urine odor for use in urine collection devices (e.g., bedpans, urinal bottles, bedside commodes, drainage bags, waterless toilets), solid, per tablet"

Summary of Applicant's Submission

B&B Logical LLC submitted a request to establish a new HCPCS Level II code to identify OdorNuke™. OdorNuke™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). OdorNuke™ is a deodorant tablet used to neutralize powerful urine odor in hospitals, nursing homes, palliative care, and private homes. OdorNuke™ is specially formulated for use in temporary urine collection devices, like bedpans, urinal bottles, travel johns, piddle packs, drainage bags and waterless toilets.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A9270, "Non-covered item or service" describes OdorNuke™.

CMS welcomes information from the applicant and other insurers to demonstrate a claims processing need for a unique HCPCS Level II code to identify OdorNuke™.

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 for equipment to be classified as DME. OdorNuke™ is a disposable, one-time use deodorant tablet. This item cannot withstand repeated use and therefore, is not considered DME.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 7
Curaco Carebidet - HCP230630EVUTF

Topic/Issue

Request to establish a new HCPCS Level II code to identify Curaco Carebidet.

Applicant's suggested language: EXXXX, "Automated toileting system for both urine and feces, for male and female. The Carebidet can also be used by either male or female having a catheter, in which case the Carebidet is used only for the feces"

Summary of Applicant's Submission

Connected Health Solutions, LLC submitted a request to establish a new HCPCS Level II code to identify Curaco Carebidet. Curaco Carebidet is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Curaco Carebidet is a toileting system which uses suction to remove the urine and feces from a diaper cup. The diaper cup is the human interface at the sacral and perineal areas, connected to a waste tank that is inside the main body unit. After collection of the urine and feces, the Carebidet delivers a warm water bidet jet wash, followed by a 5-minute gentle air drying cycle. To manage moisture, the Carebidet automatically performs an hourly air-dry cycle, or other time interval per protocol that is set by the caregiving staff or an institution. This Carebidet system is used mostly for patients who are bedridden. In addition to cleaning, the Carebidet system sanitizes the area of the individual that is using the Carebidet to reduce fungal growth and the development of infections.

CMS Preliminary HCPCS Coding Recommendation

Revise existing HCPCS Level II code K1006, "Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system" to instead read "Suction pump, home model, portable or stationary, electric, any type, for use with external urine and/or fecal management system" to be used in conjunction with existing HCPCS Level II code A9286, "Hygienic item or device, disposable or non-disposable, any type, each" to describe Curaco Carebidet.

Preliminary Medicare Benefit Category Determination

There are two preliminary benefit category decisions for this item, as we believe part of this product meets the definition of DME, while another part does not.

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 for equipment to be classified as DME. The suction function of the Carebidet meets the definition of DME. That is, the Carebidet function of suctioning urine and feces from a diaper cup and into a waste tank meets the definition of DME. We believe this fulfills the function of a home suction pump that is classified as DME. The bidet function of the Carebidet does not have a Medicare DMEPOS benefit category. That is, what the Carebidet does after the collection of the urine and feces, which includes delivering a warm water bidet jet wash and an air drying cycle, does not meet the definition of DME. In particular, Chapter 1, Section 280.1 of the Medicare National Coverage Determinations (NCD) Manual (CMS Pub. 100-03) includes a DME Reference List that is used for determining the coverage status of certain pieces of DME. On this list are bidet toilet seat and toilet seats. This National Coverage Determination states that these items are not DME and to, "Deny not medical equipment (§1861(n) of the Act)." As the Curaco Carebidet uses a bidet, this part of the item would not fall under a DMEPOS benefit category.

Preliminary Medicare Payment Determination

There are two preliminary payment determinations for this item, as we believe part of this item meets the definition of DME, while another part of this item does not.

The payment rules and pricing associated with the existing code K1006 apply to the suction function of the Carebidet, if covered.

The average 2023 rental amount for K1006 is approximately $58.79 for months 1-3 and approximately $44.09 for months 4-13, which results in average 2023 payments over 13 months equaling approximately $617.27.

The average fee schedule amount is the average of the 2023 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

There is no Medicare payment for A9286, the bidet portion of Carebidet.

Pricing Indicator = 00

Agenda Item # 8
Ultrasound, Doppler, Echocardiogram, Holter Monitor, Bone Density - HCP23063085FVF

Topic/Issue

Request to revise an existing HCPCS Level II code Q0092, "Set-up portable x-ray equipment" to include reimbursement for other diagnostic imaging procedure set up.

Applicant's suggested language: Q0092, "A/B MACs (B) must pay a set-up component for each Portable x-ray and/or other portable diagnostic imaging procedure (other than retakes of the same procedure) during both single patient and multiple patient trips under Level II HCPCS code Q0092"

Summary of Applicant's Submission

BioTech X-ray, Inc submitted a request to revise existing HCPCS Level II code Q0092, "Set-up portable x-ray equipment" to include reimbursement for other diagnostic imaging procedure set up. HCPCS Level II code Q0092 is currently a reimbursement code for the set-up of diagnostic X-ray equipment where the procedure is performed at the patient's bedside. This should broaden the scope of Current Procedural Terminology (CPT®) codes for which the code can be reimbursed to include ultrasound, doppler, echocardiogram, bone densitometry, and other imaging studies now performed commonly at the bedside by the same providers that are paid for this code to set up their X-ray equipment. When the program manual instructions were updated last in 2003, the technology was not readily available to perform ultrasound, doppler and echocardiogram studies portably at the patient's bedside. The technology has advanced dramatically, and physician's that order portable X-ray exams on bedridden and home-bound patients in long term care facilities also expect providers to perform ultrasound imaging studies at the bedside. Providers have the ability to do this, but are not reimbursed for their travel (R0070/R0075). Q0092 currently reimburses portable X-ray providers for setting up the X-ray equipment at the patient's bedside, for each exam that is being performed. The reimbursement of Q0092 should similarly apply to setting up the ultrasound equipment for each exam being performed.

CMS Preliminary HCPCS Coding Recommendation

We have received several requests in our recent HCPCS Level II coding cycles to revise existing codes related to X-ray equipment and will be grouping this application with those other similar applications. This application is being deferred for additional consideration in a subsequent biannual coding cycle. We believe more time is needed to consider revising existing HCPCS Level II code Q0092 and any implications that might occur. We welcome information from the applicant and other insurers who are currently paying for the set-up of portable X-ray equipment to demonstrate a claims processing need for a revision to HCPCS Level II code Q0092.

Agenda Item # 8
Portable X-ray and/or Other Portable Diagnostic Imaging Supplier - HCP230702YU2LU and HCP230102B51B5

Topic/Issue

Request to revise an existing HCPCS Level II code R0070, "Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, one patient seen" to identify portable X-ray and/or other portable diagnostic imaging supplier.

Applicant's suggested language: R0070, "Transportation of portable x-ray and other portable imaging equipment and personnel to home or nursing home, per trip to facility or location, one patient seen"

Summary of Applicant's Submission

The American Portable Diagnostic Association submitted a request to revise an existing HCPCS Level II code to identify transportation of portable X-ray and other portable imaging equipment and personnel to home or nursing home, per trip to facility or location, one patient seen. This request is to modify and expand the HCPCS Level II code R0070 transportation of equipment to include other portable diagnostic imaging services, such as ultrasound, dopplers and echocardiograms. Modifying the language for the use of HCPCS Level II transportation code under specialty 63 for the portable X-ray supplier (i.e., portable X-ray and/or other portable diagnostic imaging supplier) will extend the conditions of coverage. This would include the transportation component for portable imaging services, such as ultrasound, dopplers, and echocardiograms, which represents other commonly performed portable services by the portable X-ray suppliers that currently bill under an independent diagnostic testing facilities (IDTF) enrollment. Providers of portable diagnostic imaging services recommend merging the current IDTF enrollment into the portable X-ray and/or other portable diagnostic imaging services, (specialty 63). A portable imaging supplier moves its X-ray equipment and other portable diagnostic imaging equipment from place to place, performing X-ray, EKG and other diagnostic imaging services such as Ultrasound, venous and arterial dopplers and echocardiograms at various locations. A portable imaging supplier is a supplier using only portable unit's in comparison to a mobile unit that is typically described as a vehicle that travels from place to place to perform services inside the vehicle. Examples of such vehicles include mobile semi-trailers. A portable unit exists when a supplier transports medical equipment to a particular location. Unlike with mobile facilities, the equipment - a portable unit is separate from and unattached to the vehicle. The equipment used to perform the test is unloaded from the vehicle and moved to the patient's room, bed or appropriate area within the facility or location where the test is performed.

CMS Preliminary HCPCS Coding Recommendation

These applications are being deferred for additional consideration in a subsequent biannual coding cycle. We continue to believe more time is needed to consider revising existing HCPCS Level II code R0070 and any implications that might occur.

Agenda Item # 8
Portable X-ray and/or Other Portable Diagnostic Imaging Supplier, Transportation Component - HCP2307027BP8W and HCP2301034XATF

Topic/Issue

Request to revise an existing HCPCS Level II code R0075, "Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen" to identify portable X-ray and/or other portable diagnostic imaging supplier, transportation.

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

Summary of Applicant's Submission

The American Portable Diagnostic Association submitted a request to revise an existing HCPCS Level II code R0075, "Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen" to identify portable X-ray and/or other portable diagnostic imaging supplier, transportation. The code expansion should include provisions in the policy language for HCPCS Level II code R0075 and billing guidelines when portable X-ray and or other portable diagnostic imaging suppliers submit claims for other portable diagnostic imaging. Currently, HCPCS Level II code R0075 applies only to portable X-ray procedures performed under a portable X-ray supplier specialty 63. R0075 represents a billing component for portable X-ray transportation of equipment and personnel when more than one patient is seen during a visit to a facility. A transportation service code, R0075, may only be billed when the X-ray equipment are actually transported and used at the location where the examination was taken. The function of the code is to identify how many patients were seen at a single location and prorate the transportation fee across all patients. HCPCS Level II code R0075 must be billed with one of the following modifiers to indicate how many patients were served on that trip to the facility or location. The modifiers are UN (two patients served), UP (three patients served), UQ (four patients served), UR (five patients served), and US (six or more patients served). . The allowable fee for R0075 will be adjusted based upon the modifier used on each patient claim. The supplier of portable X-ray and other portable diagnostic services was changed and updated through the National Uniform Claim Committee in 2016. The current title 'Portable X-ray Supplier and Supplier' description is no longer adequate for billing of the modern-day 'Portable Diagnostic Imaging Supplier'. The title changed from 'Portable X-ray Supplier' to 'Portable X-ray and/or Other Portable Diagnostic Imaging Supplier' along with the new description.

CMS Preliminary HCPCS Coding Recommendation

These applications are being deferred for additional consideration in a subsequent biannual coding cycle. We continue to believe more time is needed to consider revising existing HCPCS Level II code R0075 and any implications that might occur.

Agenda Item # 8
Portable X-ray and/or Other Portable Diagnostic Imaging Supplier, Transportation Component, and Portable EKG - HCP230102T6B2A

Topic/Issue

Request to revise an existing HCPCS Level II code R0076, “Transportation of portable ekg to facility or location, per patient” to identify Portable X-ray and/or other portable diagnostic imaging supplier, transportation component, and portable EKG.

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

Summary of Applicant's Submission

Portable Diagnostic Imaging Supplier, Advocacy Dispatch Health Imaging, submitted a request to revise an existing HCPCS Level II code R0076 to identify transportation of portable EKG to facility or location, per patient. HCPCS Level II code R0076 appears available with a description, although when used for codification on a claim, there is no reimbursement. Therefore, the request for revision to the HCPCS Level II code R0076 is to revise, reinstate, and update the policy and coverage provisions for the code. This includes the ability to use code R0076 to bill for the transportation component of a portable EKG on claims and receive reimbursement for the trip on claims billed by portable X-ray supplier (specialty 63), billing independently. The EKG test is included in the provisions of services provided by portable X-ray suppliers. A modifier must be reported with R0076 when more than one patient is seen per trip. Only one of the following five modifiers shall be reported with R0076 when more than one patient is seen: UN (two patients served), UP (three patients served), UQ (four patients served), UR (five patients served), or US (six or more patients served). Payment for the modifiers must be consistent with the definition of the modifiers. R0076 must be billed in conjunction with the Current Procedural Terminology (CPT®) codes, and only when the diagnostic equipment used was actually transported to the location where the test was taken.

CMS Preliminary HCPCS Coding Recommendation

These applications are being deferred for additional consideration in a subsequent biannual coding cycle. We continue to believe more time is needed to consider revising existing HCPCS Level II code R0076 and any implications that might occur.

Agenda Item # 9
Home Infused Iron Replacement Therapy - HCP230703AJHV1

Topic/Issue

Request to establish a new HCPCS Level II code to identify home infusion of iron replacement therapy.

Applicant's suggested language: SXXXX, "Home infusion therapy, iron replacement; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem"

Summary of Applicant's Submission

The National Home Infusion Association (NHIA) submitted a request to establish a new HCPCS Level II code to identify home infusion of iron replacement therapy. This new HCPCS Level II code would accurately reflect the items and services being provided and would reduce the use of the HCPCS Level II code S9379, "Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem." The current code set created more than twenty years ago, does not have a unique S code for iron replacement therapy.

CMS Preliminary HCPCS Coding Recommendation

We welcome information from the applicant and any payers who are currently paying for this service to describe a claims processing need for a unique HCPCS Level II code to describe home infusion of iron replacement therapy.

CMS notes that the applicant has proposed a number of more specific home infusion therapy services that payers could use instead of the more general HCPCS Level II code S9379. We can appreciate that there may be more nuanced levels of work and service delivery involved in a range of home infusion services. In evaluating this request, it would be helpful for us to have a holistic understanding of the framework in which NHIA views home infusion services across all currently available Level I and Level II codes and why additional codes are useful for payers. It would also help CMS to hear from one or more payers about their views on the framework.

For instance, it would be helpful to understand why iron replacement therapy is different than antibiotic therapy in terms of how a payer would value the inputs of the service, particularly since the drugs are coded separately. As an example, one way in which we could better understand the program need is to see a chart or table that shows certain payers paying S9379 claims differently based upon the infused product.

Agenda Item # 9
Home Infused Antibiotic, Antiviral and Antifungal Therapies Administered Over Extended Timeframes - HCP230703FRY4H

Topic/Issue

Request to establish a new HCPCS Level II code to identify antibiotic, antiviral or antifungal therapy drugs provided at home via extended infusion.

Applicant's suggested language: SXXXX, “Home infusion therapy, antibiotic, antiviral, or antifungal therapy; extended infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem”

Summary of Applicant's Submission

The National Home Infusion Association submitted a request to establish a new HCPCS Level II code to identify antibiotic, antiviral or antifungal therapy drugs being provided in the home via extended infusion. A new code would be used to differentiate extended infusions from the traditional once a day infusion, to appropriately contract for services. At the time the HCPCS S code set for home infusion was created, more than 20 years ago, home infusion of antibiotic, antiviral or antifungal therapy HCPCS codes were created based on the number of infusions per day (e.g., once a day, every 12 hours, every 8 hours, every 6 hours, and every 4 hours.) These codes allow for per diem contracting based on frequency of administration. Twenty years ago, few, if any, antibiotic, antiviral or antifungal therapies were being infused over extended periods of time. Home infusion providers are increasingly receiving physician/practitioner orders for prolonged daily home infusions of anti-infectives. Drugs infused over extended periods of time are more resource intense than traditional bolus and intermittent infusions over 30 to 60 minutes.

CMS Preliminary HCPCS Coding Recommendation

We welcome information from the applicant and any payers who are currently paying for this service to describe a claims processing need for a unique HCPCS Level II code to describe antibiotic, antiviral, or antifungal home infusion therapy administered over an extended timeframe.

CMS notes that the applicant has proposed a number of more specific home infusion therapy services that payers could use instead of the more general HCPCS Level II codes S9494 and S9500. We can appreciate that there may be more nuanced levels of work and service delivery involved in a range of home infusion services. In evaluating this request, it would be helpful for us to have a holistic understanding of the framework in which NHIA views home infusion services across all currently available Level I and Level II codes and why additional codes are useful for payers. It would also help CMS to hear from one or more payers about their views on the framework.

As an example, one way in which we could better understand the program need is to see a chart or table that shows certain payers paying S9494 and S9500 claims differently based upon the infusion time of a product.

Agenda Item # 9
Service Code Associated with Immunotherapies Infused at Least Every 90 Days - HCP230703HEGEW

Topic/Issue

Request to establish a new HCPCS Level II code to identify home infusion immunotherapy administered at least every 90 days.

Applicant's suggested language: SXXXX, "Home infusion therapy, immunotherapy; administered at least every 90 days; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem"

Summary of Applicant's Submission

The National Home Infusion Association submitted a request to establish a new HCPCS Level II code to identify home infusion immunotherapy administered at least every 90 days. As the number of immunotherapy drugs has risen, so has utilization of "Not otherwise classified" code S9379, "Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem," to over 45,000 claims per month. The addition of a code would greatly aid in the ability to appropriately contract for the per diem items and services based on resource utilization.

CMS Preliminary HCPCS Coding Recommendation

We welcome information from the applicant and any payers who are currently paying for this service to describe a claims processing need for a unique HCPCS Level II code to describe home infusion immunotherapy administered at least every 90 days.

CMS notes that the applicant has proposed a number of more specific home infusion therapy services that payers could use instead of the more general HCPCS Level II code S9379 and S9338. We can appreciate that there may be more nuanced levels of work and service delivery involved in a range of home infusion services. In evaluating this request, it would be helpful for us to have a holistic understanding of the framework in which NHIA views home infusion services across all currently available Level I and Level II codes and why additional codes are useful for payers. It would also help CMS to hear from one or more payers about their views on the framework.

Agenda Item # 9
Home Immunotherapy, Single Dose, or Dosing Interval Greater than 90 Days - HCP230703N55EH

Topic/Issue

Request to establish a new HCPCS Level II code to identify home infusion immunotherapy single dose or administration interval greater than 90 days.

Applicant's suggested language: SXXXX, "Home infusion therapy, immunotherapy; single dose or administration interval greater than 90 days; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem"

Summary of Applicant's Submission

The National Home Infusion Association submitted a request to establish a new HCPCS Level II code to identify home infusion immunotherapy single dose or administration interval greater than 90 days. The current home infusion S code set was created more than twenty years ago and since that time the Food and Drug Administration (FDA) has approved dozens of infused immunotherapies, many of which are administered in the home. The initiation of home infusion services requires an assessment of the patient diagnosis, clinical condition at the time of treatment, and potential for adverse events. When there a is a gap between infusions of more than 90 days, the initial assessment process needs to be repeated - not dissimilar from a home health episode of care where they need to requalify a patient every 60 days. As the number of FDA approved immunotherapy drugs has risen sharply the utilization of "not otherwise classified" HCPCS Level II code S9379, "Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem," has risen to over 45,000 claims per month. A new code would greatly aid in the ability to appropriately contract for the home infusion per diem items and services based on resource utilization.

CMS Preliminary HCPCS Coding Recommendation

We welcome information from the applicant and any payers who are currently paying for this service to describe a claims processing need for a unique HCPCS Level II code to describe home infusion immunotherapy single dose or administration interval greater than 90 days.

CMS notes that the applicant has proposed a number of more specific home infusion therapy services that payers could use instead of the more general HCPCS Level II code S9379 and S9338. We can appreciate that there may be more nuanced levels of work and service delivery involved in a range of home infusion services. In evaluating this request, it would be helpful for us to have a holistic understanding of the framework in which NHIA views home infusion services across all currently available Level I and Level II codes and why additional codes are useful for payers. It would also help CMS to hear from one or more payers about their views on the framework.

Agenda Item # 9
Home Infused Subcutaneous or Intravenous Immune Globulin Therapies – HCP230703K43DD

Topic/Issue

Request to revise existing HCPCS Level II code S9338, which currently reads "Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem" to instead read "Home infusion therapy, subcutaneous or intravenous immune globulin therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem" to limit its use to immune globulin therapies provided in the home.

Applicant's suggested language: S9338, "Home infusion therapy, subcutaneous or intravenous immune globulin therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem"

Summary of Applicant's Submission

The National Home Infusion Association submitted a request to revise an existing HCPCS Level II code S9338, "Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem" to limit its use to immune globulin therapies provided in the home, and to instead read "Home infusion therapy, subcutaneous or intravenous immune globulin therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem." At the time the code was created more than twenty years ago there were few immunotherapy drugs provided in the home. Many payers continue to use HCPCS Level II code S9338 for immune globulin and instruct providers to use the "Not otherwise classified" infusion therapy code, S9379, "Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem," for other immunotherapies. As the number of immunotherapy drugs has risen, so has utilization of HCPCS Level II code S9379, to over 45,000 claims per month. This change would allow for payers and providers to appropriately contract for the provision of immune globulin therapies in the home, as well as facilitate more accurate tracking and trending of utilization.

CMS Preliminary HCPCS Coding Recommendation

We welcome information from the applicant and any payers who are currently paying for this service to describe a claims processing need for a change of HCPCS Level II code S9338, to limit its use to immune globulin therapies provided in the home.

CMS notes that the applicant has proposed a number of more specific home infusion therapy services that payers could use instead of the more general HCPCS Level II code S9379. We can appreciate that there may be more nuanced levels of work and service delivery involved in a range of home infusion services. In evaluating this request, it would be helpful for us to

have a holistic understanding of the framework in which NHIA views home infusion services across all currently available Level I and Level II codes and why additional codes are useful for payers. It would also help CMS to hear from one or more payers about their views on the framework.

Agenda Item # 10
Walkasins® Receptor Sole - HCP230630JGDD5

Topic/Issue

Request to establish a new HCPCS Level II code to identify Walkasins® receptor sole.

Applicant's suggested language: LXXXX, “Receptor Sole for use with LXXXX, six-month replacement, each”

Summary of Applicant's Submission

RxFunction, Inc. submitted a request to establish a new HCPCS Level II code to identify Walkasins® receptor sole. Walkasins® receptor sole is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This request is associated with the external lower extremity sensory prosthesis. Walkasins® receptor sole is part of a non-invasive prosthetic device available by prescription for long-term daily use. Walkasins® replaces a part of the lost function of plantar mechanoreceptors, which are internal to the skin. It detects touch and pressure and is an integral part of the integumentary system. Walkasins® is intended for patients with sensory peripheral neuropathy (PN), a condition where plantar mechanoreceptors are permanently inoperative or malfunctioned. Sensory PN leads to uncoordinated balance with unsteady gait and interferes with ambulation, daily activities, and increase risk for falls. Walkasins® detects pressure between the foot and the ground during standing and walking, signaling sensory (afferent) plantar pressure information to the brain that is critical for the subconscious non-voluntary and automatic control of balance and gait function. The Walkasins® system consists of two components per leg: receptor sole and haptic module. Receptor Soles placed in the shoes have embedded sensors that measure foot pressure. Haptic modules worn around the lower leg above the ankle receive and analyze the measured pressure information through a real-time algorithm that runs on a microprocessor, continuously calculating a representation of the instantaneous balance point of the body. At relevant times during standing and walking, the algorithm activates vibratory actuators embedded in the Haptic Module, to provide non-invasive tactile sensory cutaneous stimulation to the lower leg. This stimulation creates new sensory balance stimuli that transmit signals along the same afferent pathways previously served by the plantar mechanoreceptors, thereby replacing part of the lost plantar sensation. The receptor soles worn in shoes receives extensive wear. The sensitivity of the sensors embedded in the soles decline with use. The effectiveness of the system depends on the receptor sole's ability to detect and measure plantar pressure. The receptor sole should be replaced every six months.

CMS Preliminary HCPCS Coding Recommendation

CMS does not have clear information that any insurance sector has a claims processing need for a new HCPCS Level II code to identify Walkasins® receptor sole. Existing HCPCS Level II code A9279, “Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified” is available for insurers if they deem appropriate for the Walkasins® receptor sole.

Preliminary Medicare Benefit Category Determination

No determination.

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. Since the Walkasins® Receptor Sole cannot be used by successive patients, it does not fall within the DME benefit category.

Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. Rather than replacing damaged, malfunctioning nerves or any other part of the nervous system or the function thereof that affect balance and sensation in the soles of the feet, the Walkasins® Receptor Sole and the Walkasins® external lower leg sensory attachment operates together to cue or alert the patient via vibrations to make changes in gait in order to improve ambulation and coordination. There are different classifications for the usage areas of "haptic" wearables according to the degree of sensory impairment in the individuals intended to use them (Shull and Damian. 2015)[2]. The first category involves sensory substitution in the situation when patients have completely lost a certain sense and the technology is used to replace the lost function, therefore acting as a prosthesis for the lost sense. In the second category, the concept of sensory augmentation would apply when there is partial sensory impairment where patients would benefit from supplementary sensory cues to enhance motor control during rehabilitation activities. Walkasins® external lower leg device falls under the second category. This device works by presumably emulating signals by fast-adapting cutaneous afferents. The participants in the published studies who went through the clinical trials using Walkasins® had to demonstrate formal diagnosis of sensory peripheral neuropathy.

Peripheral neuropathy develops in stages; during the stages one to three, the patient would show sporadic numbness and pain, persistent symptoms, and debilitating pain. Stages four and five are known for deduction of the pain and moderate to total loss of the sensation. There has been no indication as to which phases of peripheral neuropathy will benefit from utilization of Walkasins®.

Based on the information provided, it seems like Walkasins® is mainly relying on the residual peripheral nerves that are intact after the injury. The device optimizes the balance, gait function, and physical activity utilizing the nerves that are not damaged.

[2] Shull PB, Damian DD. Haptic wearables as sensory replacement, sensory augmentation, and trainer-A review. *J Neuroeng Rehabil*. 2015; 12: 59 10.1186/s12984-015-0055-z

Therefore, we are not able to determine at this time that the Walkasins® device falls within the prosthetic device benefit category or any other DMEPOS benefit category. Further information would be beneficial to CMS, including clarification on the following items:

1. Are there any studies or documents to support and demonstrate how the Walkasins® device replaces the function of the lost or damaged nerves of the peripheral nervous system?

2. What types of peripheral neuropathy symptoms do the patients require to benefit from Walkasins®?

Preliminary Medicare Payment Determination

No determination.

Agenda Item # 10
Walkasins® Lower Extremity Sensory Prosthesis - HCP230630P62DH

Topic/Issue

Request to establish a new HCPCS Level II code to identify Walkasins® lower extremity sensory prosthesis.

Applicant's suggested language: LXXXX, "External Lower Extremity Sensory Prosthesis, Cutaneous Stimulation of Mechanoreceptors, Per Leg"

Summary of Applicant's Submission

RxFunction, Inc. submitted a request to establish a new HCPCS Level II code to identify Walkasins® lower extremity sensory prosthesis. Walkasins® lower extremity sensory prosthesis is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Walkasins® lower extremity sensory prosthesis is a non-invasive prosthetic device available by prescription for long-term daily use. Walkasins® replaces a part of the lost function of plantar mechanoreceptors, which are internal to the skin. It detects touch and pressure and is an integral part of the integumentary system. Walkasins® is intended for patients with sensory peripheral neuropathy (PN), a condition where plantar mechanoreceptors are permanently inoperative or malfunctioned. Sensory PN leads to uncoordinated balance with unsteady gait and interferes with ambulation, daily activities, and increase risk for falls. Walkasins® detects pressure between the foot and the ground during standing and walking, signaling sensory (afferent) plantar pressure information to the brain that is critical for the subconscious non-voluntary and automatic control of balance and gait function. The Walkasins® system consists of two components per leg: receptor sole and haptic module. Haptic modules worn around the lower leg above the ankle receive and analyze the measured pressure information through a real-time algorithm that runs on a microprocessor, continuously calculating a representation of the instantaneous balance point of the body. At relevant times during standing and walking, the algorithm activates vibratory actuators embedded in the Haptic Module, to provide non-invasive tactile sensory cutaneous stimulation to the lower leg. This stimulation creates new sensory balance stimuli that transmit signals along the same afferent pathways previously served by the plantar mechanoreceptors, thereby replacing part of the lost plantar sensation.

CMS Preliminary HCPCS Coding Recommendation

CMS does not have clear information that any insurance sector has a claims processing need for a new HCPCS Level II code to identify Walkasins® lower extremity sensory prosthesis. Existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" is available for insurers if they deem appropriate for the Walkasins® lower extremity sensory prosthesis.

Preliminary Medicare Benefit Category Determination

No determination.

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. Since the Walkasins® external lower extremity sensory device cannot be used by successive patients, it does not fall within the DME benefit category.

Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. Rather than replacing damaged, malfunctioning nerves or any other part of the nervous system or the function thereof that affect balance and sensation in the soles of the feet, the Walkasins® Receptor Sole and the Walkasins® external lower leg sensory attachment operate together to cue or alert the patient via vibrations to make changes in gait in order to improve ambulation and coordination. There are different classifications for the usage areas of "haptic" wearables according to the degree of sensory impairment in the individuals intended to use them (Shull and Damian. 2015)[3]. The first category involves sensory substitution in the situation when patients have completely lost a certain sense and the technology is used to replace the lost function, therefore acting as a prosthesis for the lost sense. In the second category, the concept of sensory augmentation would apply when there is partial sensory impairment where patients would benefit from supplementary sensory cues to enhance motor control during rehabilitation activities. Walkasins® external lower leg device falls under the second category. This device works by presumably emulating signals by fast-adapting cutaneous afferents. The participants in the published studies who went through the clinical trials using Walkasins® had to demonstrate formal diagnosis of sensory peripheral neuropathy.

Peripheral neuropathy develops in stages; during the stages one to three, the patient would show sporadic numbness and pain, persistent symptoms, and debilitating pain. Stages four and five are known for deduction of the pain and moderate to total loss of the sensation. There has been no indication as to which phases of peripheral neuropathy will benefit from utilization of Walkasins®.

Based on the information provided, it seems like Walkasins® is mainly relying on the residual peripheral nerves that are intact after the injury. The device optimizes the balance, gait function, and physical activity utilizing the nerves that are not damaged.

[3] Shull PB, Damian DD. Haptic wearables as sensory replacement, sensory augmentation, and trainer-A review. *J Neuroeng Rehabil*. 2015; 12: 59 10.1186/s12984-015-0055-z

Therefore, we are not able to determine at this time that the Walkasins® device falls within the prosthetic device benefit category or any other DMEPOS benefit category. Further research is needed, including clarification on the following items:

1. Are there any studies or documents to support and demonstrate how the Walkasins® device replaces the function of the lost or damaged nerves of the peripheral nervous system?

2. What types of peripheral neuropathy symptoms do the patients require to have to benefit from Walkasins®?

Preliminary Medicare Payment Determination

No determination.

Agenda Item # 11
DART-Reach and EZ-Spray - HCP230124KCGPN

Topic/Issue

Request to establish a new HCPCS Level II code to identify DART device (nasal atomizer), DART- Reach device (laryngeal atomizer), and EZ-Spray device (gas powered atomizer).

Applicant's suggested language: XXXXX, “Medication atomizer”

Summary of Applicant's Submission

Pulmodyne, Inc. submitted a request to establish a new HCPCS Level II code to identify medication atomizer. DART and EZ-Spray are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). DART-Reach (Topical applicator) received the Food and Drug Administration’s (FDA’s) 510(k) clearance on May 25, 2007. Pulmodyne, Inc. makes three products that pertain to the requested medication atomizer code. The DART device (nasal atomizer) sprays medication for delivery and absorption through the nasal passage. The DART-Reach device (laryngeal atomizer) sprays medication laryngeally to topically anesthetize the airway. The EZ-Spray device (gas powered atomizer) can be used in the mouth or the nose to widely anesthetize the upper and lower airway. Each device is used in conjunction with medications for airway topicalization, sedation, pain management, opiate overdoses, anxiolysis, seizure control, awake intubations, etc. All these devices have been used in conjunction with Lidocaine, Midazolam, Naloxone, Fentanyl, Sufentanil, Hydromorphone-opioids, Ketamine, Flumazenil, Glucagon, Insulin, Butorphanol, Precedex, Lorazepam, Haldol, and other medications.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the medication atomizer is not suitable for inclusion in the HCPCS Level II code set because it is used for a procedure and certain items are considered bundled into the facility payment. We have not identified a specific need for the medication atomizer to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 12
HEMIGARD® - HCP2307020DN93

Topic/Issue

Request to establish a new HCPCS Level II code to identify HEMIGARD® Adhesive Suture Retention Device (ASRD).

Applicant's suggested language: XXXXX, "Use of adhesive suture retention device to assist in closure of fragile or at-risk skin wound"

Summary of Applicant's Submission

SUTUREGARD Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify HEMIGARD® ASRD. HEMIGARD® ASRD is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). HEMIGARD® is a sterile single use device that allows surgeons to quickly and safely close and heal high tension or at-risk surgical wounds that normally cannot be closed successfully with standard closure materials. Patients with failed open (or postoperatively dehisced) wounds must undergo prolonged wound care during which time they may require costly products, hospitalization or additional surgery and are at risk for further complications. Surgical wound dehiscence occurs when a surgically repaired wound failing to heal, becoming an open wound. In the recent peer reviewed publication, 131 patients (mean MBI 32) underwent emergent/elective foot and ankle surgery. In this study, postop complications were: 1.5% surgical site infection, 3% dehiscence. A new code is needed to cover the HEMIGARD® device cost. HCPCS Level II supply code A4649, "Surgical supply, miscellaneous" is intended for passive wound dressings and does not account for patient value brought by the HEMIGARD® device, which directly improves surgical outcomes. It is the first of its kind hybrid device combining suture and adhesive technology. It is a simple but very effective load transferring skin anchor that mitigates the risk of conventional suture/staple skin closures. It protects skin edge blood flow and prevents suture-induced skin tearing.

CMS Preliminary HCPCS Coding Recommendation

We appreciate the applicant submitting the study along with the application. Again, our understanding is that the HEMIGARD® ASRD is not suitable for inclusion in the HCPCS Level II code set because it is used for a procedure and certain items are considered bundled into the facility payment. We have not identified a specific need for the HEMIGARD® ASRD to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 13
Hummingbird® Tympanostomy Tube System (HTTS) - HCP2306297BBG1

Topic/Issue

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

Applicant's suggested language: SXXXX, "Insertion of ventilation tube using one-pass tympanostomy tube system in pediatric patients (list separately in addition to code for primary procedure)"

Summary of Applicant's Submission

Preceptis Medical (Preceptis) submitted a request to establish a new HCPCS Level II code to identify HTTS. The HTTS was initially cleared by the Food and Drug Administration (FDA) on June 5, 2020 through a 510(k) pathway for use in patients that are 6 months to 24 months in age. The HTTS received a second 510(k) clearance on July 27, 2022 for use in pediatric patients that are 6 months and older in age. This HCPCS Level II code would describe this device used to place tympanostomy tube(s) in pediatric patients in the physician office setting using an innovative surgical technology that combines the separate functions of creating a myringotomy (incision in the eardrum), and positioning and placing a ventilation tube across the tympanic membrane. The HTTS is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient and is indicated to be used in office settings for pediatric patients 6 months and older. Using the HTTS, the surgeon manually advances the sharpened sheath to create a myringotomy and simultaneously positions the ventilation tube within the myringotomy, always under direct visualization. The user then manually retracts the sharpened sheath away from the myringotomy using the manual actuator located on the handle. The retraction of the sheath releases the tube within the myringotomy. This device allows the tympanostomy service to be furnished to pediatric patients without general anesthesia and the service can therefore be performed in the physician office setting. Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia, as it describes the base procedure and adequately describes the majority of the surgeon's work and facility resources. However, procedures that utilize the HTTS have incremental intra-service work that is meaningful from a resource standpoint, including, the child must be swaddled and/or physically stabilized prior to the procedure, the child's head must be held by a nurse throughout the procedure, and then the surgeon uses this specialized HTTS device to complete the procedure. While the existing American Medical Association (AMA) Current Procedural Terminology (CPT®) Level I code 69433 is not age-specific, the vignette and the Relative Value Units (RVU) associated with this procedure are established for patients who can respond to surgeon direction, and do not have risk of movement during the procedure. The existing CPT® Level I code 69433 without the add-on S code creates a programmatic need for payers, including commercial insurers, Medicaid Fee-for-Service (FFS), and managed Medicaid payers, by not allowing payers to identify services performed using this technology. Private payers and Medicaid managed care plans have consistently expressed the need of a universal code for properly identifying the use of this device when used with the CPT® Level I code 69433.

CMS Preliminary HCPCS Coding Recommendation

The HTTS is not suitable for inclusion in the HCPCS Level II code set because it is used for a procedure and certain items are considered typically bundled into the facility payment. CMS would like to know if other insurers, particularly individual state Medicaid programs and private insurers, would pay for an add-on code if we were to establish one.

We note the following excerpt: While the existing American Medical Association (AMA) Current Procedural Terminology (CPT®) Level I code 69433 is not age-specific, the vignette and the Relative Value Units (RVU) associated with this procedure are established for patients who can respond to surgeon direction, and do not have risk of movement during the procedure.

Why has Preceptis Medical not considered pursuing a more descriptive CPT® code that can be valued more consistently with the age-specific population that is involved in the procedure? CMS is aware of a similar new technology that is used for children 6 months old and older to allow for ear tubes to be placed in the office setting without undergoing general anesthesia that is utilizing a CPT® code (0583T). We understand that CPT® code 0583T may preclude the Hummingbird® Tympanostomy Tube System due to a reference to iontophoresis local anesthesia in the code descriptor language, however, we would suggest the applicant to approach the AMA for an editorial change.

Agenda Item # 14
SurgiLock® - HCP2304138EFP5

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Medical Lock Corporation submitted a request to establish a new HCPCS Level II code to identify SurgiLock®. SurgiLock® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). SurgiLock® instrument platform is a class II medical device used by surgeons in the operating room and cardiologists and technicians in the cath-lab. SurgiLock® Platform has a direct impact in reducing the risk of infection, improving operating room efficiencies, and increasing safety. It improves efficiency and safety by helping to protect the sterile field and keeping instruments and other surgical supplies organized and readily available as well as reducing the need to hand sharps back and forth between surgeon and scrub nurse.

CMS Preliminary HCPCS Coding Recommendation

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

Agenda Item # 15
Pulse Irrigation Evacuation (PIE) - IHC230502YKN10

Topic/Issue

Request for benefit category determination for the PIE device.

Summary of Applicant's Submission

PIEMed submitted a DMEPOS benefit category determination (BCD) request for the Pulse Irrigation Evacuation (PIE) device for classification as durable medical equipment (DME). The PIE Device is an at-home device that uses pulses of water to irrigate the colon and remove stool. PIE is the treatment of choice for patients with neurogenic bowel, recurrent fecal impactions, or severe constipation when traditional bowel maintenance programs are ineffective or not tolerated. The PIE Device is cleared for home use, and is covered by many commercial medical insurance plans and the Veterans Administration, but not by Medicare. The PIE Device lasts more than three years, is rentable, can be used by more than one patient, and has no purpose other than for the treatment of an illness.

CMS HCPCS Coding

The PIE device is currently coded under existing HCPCS Level II codes E0350, “Control unit for electronic bowel irrigation/evacuation system” and E0352, “Disposable pack (water reservoir bag, speculum, valving mechanism and collection bag/box) for use with the electronic bowel irrigation/evacuation system”.

Preliminary Medicare Benefit Category Determination

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.

In order to help decide if the PIE Device can be classified as DME, CMS is interested in finding out more information about how this device is used in the home. CMS has the following questions:

1. The applicant states that the PIE Device is an FDA-cleared Class II at-home medical device. Can the applicant send CMS any FDA documentation indicating this at-home designation?

2. The applicant mentions that the PIE Device is now routinely used in the home setting. Was the PIE Device previously not routinely used in the home setting? If so, what has changed over the years to allow the PIE Device to now be routinely used in the home?

3. Can the applicant explain the type of caregiver needed to help operate this device in the home? Do they need training? Can a caregiver who is not a health care professional, such as a family member or the patient themselves, operate this device?

Agenda Item # 16
Mobility+ - HCP221220WF9Y

Topic/Issue

Request for Medicare payment determination for Mobility+.

Summary of Applicant's Submission

Rockfield Medical Devices submitted a request to establish a new HCPCS Level II code to identify Mobility+ in the first biannual 2023 cycle. Mobility+ received the Food and Drug Administration's (FDA's) 510(k) clearance on October 27, 2022. Mobility+ is a portable, lightweight, non-electronic, disposable enteral feeding system intended to deliver commercially available liquid nutrition formula to a patient using a standard feeding tube (or extension tube) with an ENFit connector. Mobility+ can be used in a clinical or home care setting, in patients aged two and older. Mobility+ has an internal elastomeric pouch, filled by the user with formula, that consistently deflates once feeding begins. The deflation of the elastomeric pouch generates a constant, low-pressure force that pushes the formula from the pouch through the supplied tubing set ("Giving Set") to an already implanted feeding tube. The System is self-contained, portable and does not require an external pump, nor a power source, nor an IV pole/clamp which are common among other enteral feeding systems. Mobility+ is designed to provide the patient and caregiver improved mobility, discretion, and ease of use. The Mobility+ Feeding pouch, an elastomeric pump, operates silently, in comparison to the noise generated by many of the current pumps on the market. According to the applicant, existing pump noises can be disruptive not only during the day but also during sleeping hours for patients that are night feeding. According to the applicant, Mobility+ offers the simplicity of a gravity-fed system without the requirements of being sedentary and tethered to an IV pole while feeding. Mobility+ brings mobility and discretion to all patient populations whether gravity/bolus fed or infusion pump fed.

CMS HCPCS Final Coding Decision

On August 23, 2023, CMS published the decision to establish a new HCPCS Level II code B4148, "Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape" to describe Mobility+, effective October 1, 2023.

Medicare Benefit Category Determination

CMS determined that Mobility+ is a Prosthetic Device and published that determination on August 23, 2023.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238, fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. As a result, the preliminary pricing methodology for new HCPCS code B4148 is to use the existing fee schedule amounts

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

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

	Mobility+	**B4035**	**B4036**
Physical Components	Feeding pouch, filling set, giving set, EnFit connector, extension set, and additional supplies (gauze, tape, dressings, etc.) The feeding pouch can hold up to 500ml of feed	Feeding pouch, filling set, giving set, EnFit connector, extension set, and additional supplies (gauze, tape, dressings, etc.) The catheter tip or oral syringe can hold up to 1200 ml of feed	Feeding pouch, filling set, giving set, EnFit connector, extension set, and additional supplies (gauze, tape, dressings, etc.) The catheter tip or oral syringe can hold up to 600 ml of feed
Mechanical Components	Feeding pouch is made using elastomeric material which creates a force to administer the nutrition. Multiple extension sets (tubing) of different lengths are provided to allow for different rates of infusion.	Poly vinyl chloride (PVC) pouch (uses separate pump to control rate of infusion)	Poly vinyl chloride (PVC) pouch (uses gravitational force to administer nutrition without controlling rate of infusion)
Electrical Components	NA	NA	NA
Function and Intended Use	Function: Provide nutritional content to patients unable to eat or drink in a controlled and sterile fashion Intended Use: To treat tube fed patients with swallowing difficulties such as Gastrointestinal dysfunction	Function: Provide nutritional content to patients unable to eat or drink in a controlled and sterile fashion Intended Use: To treat tube fed patients with swallowing difficulties such as Gastrointestinal dysfunction	Function: Provide nutritional content to patients unable to eat or drink in a controlled and sterile fashion Intended Use: To treat tube fed patients with swallowing difficulties such as Gastrointestinal dysfunction

Additional Aspects and Features	Does not require separate equipment.	Requires separate equipment (pump to control rate of infusion)	Requires separate equipment (IV pole)
	Very Portable	Less portable (some pumps can be carried in backpacks)	Least portable (IV pole with wheels)
	Continuous feeding	Can be continuous, dose, or bulbus feeding	Non-continuous feeding
	Disposable feeding set	Disposable feeding set	Disposable feeding set
	No power source/ electricity	Battery power source	No power source/ electricity

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

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

Pricing Indicator = 39

Agenda Item # 17
ONTAK® - HCP230702AUMJK

Topic/Issue

Request to delete an existing HCPCS Level II code J9160, “Injection, denileukin diftitox, 300 micrograms”.

Summary of Applicant's Submission

Citius Pharmaceuticals, Inc. submitted a request to delete an existing HCPCS Level II code J9160, “Injection, denileukin diftitox, 300 micrograms”, which identifies ONTAK® (denileukin diftitox). ONTAK® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on October 15, 2008. This application requests the deletion of an existing HCPCS Level II code that is no longer used. J9160 is no longer used because the item that it previously described was withdrawn from the U.S. market in 2014 and has not been marketed or available in the United States for nearly ten years.

CMS Final HCPCS Coding Decision

CMS published a final determination for Q3 2023 on October 18, 2023 to discontinue existing HCPCS Level II code J9160, “Injection, denileukin diftitox, 300 micrograms” effective January 1, 2024. Consistent with our usual practice for public requests to discontinue a code, we welcome information from other insurers who are currently paying for this product.

Agenda Item # 18
HCPCS Level II Codes for Various FDA Approvals under the 505(b)(2) or Biologics License Application (BLA) Pathways and Products "Not Otherwise Classified" - HCP220517FAENJ

Topic/Issue

We are requesting public comment on the language in the code descriptors for the new HCPCS Level II codes that we established in CMS' Second and Third Quarters of 2023 Drug and Biological HCPCS code application review cycles, per our postings at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMSHCPCSLevelII-Coding-Decisions-Narrative-Summary.

Applicant's Summary

CMS has been reviewing its approach for establishing HCPCS Level II codes to identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book[4], and are therefore considered single source products. Also, this effort will help reduce use of the not otherwise classified (NOC) codes.

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS codes as described at the following CMS link: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf. CMS is making several code changes, including manufacturer specific codes to identify products approved under separate 505(b)(2) NDA or BLA pathways. Since the products are approved under separate 505(b)(2) NDAs and are not rated as therapeutically equivalent by the FDA in the Orange Book, they are single source drugs based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. Because these are single source drugs, there is a programmatic need for each product to have a unique billing and payment code.

In cases where certain products meet the statutory definition of a "multiple source drug" in section 1847A(c)(6) of the Act, CMS will remove the brand name of the drug from any existing HCPCS code as needed as it will accommodate any associated generic product(s), if approved and marketed, that are rated as therapeutically equivalent.

Due to the complexity and nuanced nature of the differences between each product, we encourage providers to rely on the Average Sales Price (ASP) HCPCS-NDC crosswalk[5] to identify the correct billing and payment code for each applicable product.

[4] The FDA's Orange Book, officially entitled, *Approved Drug Products With Therapeutic Equivalence Evaluations,* identifies drug products approved on the basis of safety and effectiveness by the FDA, and is published at the following FDA link: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[5] The ASP crosswalks are maintained by CMS on a quarterly basis to support ASP-based Medicare Part B payments only. The quarterly ASP crosswalks are published at the following CMS link:https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files.

CMS HCPCS Coding Decision

We established two new HCPCS Level II codes within the second quarter (Q2) of 2023, effective October 1, 2023, and established ten new HCPCS Level II codes within the third quarter (Q3) of 2023, effective January 1, 2024, to separately identify products approved by the FDA after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code.

We seek comment on these code descriptors.

See Appendix A for a complete list of new HCPCS Level II codes that we are establishing.

CMS intends to continue our review in subsequent HCPCS code application quarterly cycles to separately identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code, as well as products that have been “not otherwise classified”.

Appendix A: HCPCS Level II Codes for Products Approved by the FDA Under the 505(b)(2) NDA or BLA Pathways and Products "Not Otherwise Classified"

HCPCS Code	Action	Long Descriptor
J0391	Add	Injection, artesunate, 1 mg
J0688	Add	Injection, cefazolin sodium (hikma), not therapeutically equivalent to j0690, 500 mg
J0873	Add	Injection, daptomycin (xellia) not therapeutically equivalent to j0878, 1 mg
J1246	Add	Injection, dinutuximab, 0.1 mg
J1596	Add	Injection, glycopyrrolate, 0.1 mg
J1939	Add	Injection, bumetanide, 0.5 mg
J2404	Add	Injection, nicardipine, 0.1 mg
J2679	Add	Injection, fluphenazine hcl, 1.25 mg
J3425	Add	Injection, hydroxocobalamin, 10 mcg
J9052	Add	Injection, carmustine (accord), not therapeutically equivalent to j9050, 100 mg
J2359	Add	Injection, olanzapine, 0.5 mg
J7519	Add	Injection, mycophenolate mofetil, 10 mg

Appendix B: DMEPOS Payment Categories

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

Pricing = 00 Service Not Separately Priced

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

Pricing = 31 Frequently Serviced Items

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

Pricing = 32 Inexpensive and Other Routinely Purchased Items

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

Pricing = 33 Oxygen and Oxygen Equipment

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

Pricing = 34 Supplies Necessary for the Effective Use of DME

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

Pricing = 35 Surgical Dressings

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

Pricing = 36 Capped Rental Items

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

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

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

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

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

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