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
Wednesday, November 29, 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 Wednesday, November 29, 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.

Table of Contents

Preliminary decisions for the HCPCS Virtual Public Meeting on Wednesday, November 29th, 2023.

Agenda Item # 1
MyoPro® – 18.118

Topic/Issue

Request for Medicare payment determination for MyoPro®.

Applicant's Summary

Manufactured by Myomo, Inc., the MyoPro® is a wearable, motorized, microprocessor controlled, elbow-wrist-hand device used for patients experiencing complications of stroke or other neurological/neuromuscular injury and illness. The MyoPro® Motion E is an elbow-wrist-hand device that has one degree of freedom and a fixed wrist joint. The MyoPro® Motion W is an elbow-wrist-hand device that has one degree of freedom and a multi-articulating wrist joint. Motion E and Motion W cover the upper end of the humerus to the palm of the hand. Common components are upper-arm shell, harness attachment, upper-arm sensor cuff, upper arm closure, battery compartment, forearm closure, forearm bar, forearm shell, control panel, elbow motor, wrist joint (fixed or flexion), and hand support shell. The wrist and hand shells are attached by a rigid wrist extension and is at a fixed angle. The entire device for Motion E and Motion W utilizes a single rigid metal upright linking all components to the joints into a single device. Straps and padding are used to anchor the device to the patient's upper extremity. Both models have two replaceable batteries with charging stand, circuit board, and a motor mounted at the elbow joint, permitting microprocessor mediated, volitionally controlled, elbow flexion and extension. Patients can also use a laptop with software-based, settings-control interface accessed through wireless connectivity to adjust the input settings/sensitivity in real-time when needed. Patients use their muscle signals to control movements of a paretic or weakened limb. When the patient tries to bend the arm, precision sensors in the brace detect the weak muscle signals which activate motors to move the arm in the desired directions. The surface EMG sensors continuously monitors and senses, but does not stimulate, the patient's muscles. The MyoPro® filters and processes the EMG signal and translates this information into motor movement. The power assist moves the motor with speed proportional to patient's exertion. The direction of motion is determined by which set of sensors are triggered. A microprocessor amplifies the acquired signal to power electric motors to initiate and complete desired movement in the elbow. The primary purpose of the MyoPro® is to assist upper extremity joint motion in a weakened body member to improve the beneficiary's functional activities of daily living.

The MyoPro® Motion G is an elbow-wrist-hand-finger device that has two degrees of freedom and a multi-articulating wrist joint. Common components are upper-arm shell, harness attachment, upper-arm sensor cuff, upper arm closure, battery compartment, forearm closure, forearm bar, forearm shell, control panel, elbow motor, wrist joint, hand motor and hand support shell. The wrist and hand shells are attached by a rigid wrist extension and is at a fixed angle. The entire device for utilizes a single rigid metal upright linking all components to the joints into a single device. Straps and padding are used to anchor the device to the patient's upper extremity. This device has two replaceable batteries with charging stand, circuit board, and a motor mounted at the elbow joint, permitting microprocessor mediated, volitionally controlled, elbow flexion and extension. Patients can also use a laptop with software-based, settings-control interface accessed through wireless connectivity to adjust the input settings/sensitivity in real-time when needed. Patients use

their muscle signals to control movements of a paretic or weakened limb. When the patient tries to bend their arm, or open and close their hand, precision sensors in the brace detect the weak muscle signals which activate motors to move the hand and arm in the desired directions. The surface EMG sensors continuously monitors and senses, but does not stimulate, the patient's muscles. The MyoPro® filters and processes the EMG signal and translates this information into motor movement. The power assist moves the motor with speed proportional to patient's exertion. The direction of motion is determined by which set of sensors are triggered. A microprocessor amplifies the acquired signal to power electric motors to initiate and complete desired movement in the elbow and fingers. The primary purpose of the MyoPro® is to assist upper extremity joint motion in a weakened body member to improve the beneficiary's functional activities of daily living.

CMS HCPCS Coding

CMS established HCPCS Level II code L8701, "Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated" to describe MyoPro® Motion E and Motion W and L8702, "Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated" to describe MyoPro® Motion G, effective January 1, 2019.

Medicare Benefit Category Determination

CMS determined through rulemaking that MyoPro® is an arm brace (CMS-1780-F).

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. If the only available price information is from a period other than the fee schedule base period (for supplies, the 12-month period of 1986/1987), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Social Security Act for prosthetic devices and orthotics and prosthetics.

In determining whether the devices described by L8701 and L8702 are comparable to items with existing codes and fee schedule amounts, we undertook a detailed examination of the physical, mechanical, and electrical components along with the function and intended use. Although we believe that portions of the devices could be comparable to a combination of products described by existing codes, we believe that the overall form and function of these upper extremity exoskeletons incorporate revolutionary features (such as self-powered responses to myoelectric inputs) and cannot be compared to any other devices. For this reason, we have determined that it is most appropriate to determine the Medicare payment amount in accordance with the "gap filling" procedure outlined in 42 CFR 414.238(c).

In order to develop an appropriate Medicare payment amount in accordance with this procedure, we must identify appropriate commercial pricing for the underlying items. We would emphasize that a Manufacturer Suggested Retail Price (MSRP) is not, by itself, an adequate source of commercial pricing. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60648).

For L8701, the most recent commercial pricing we have found is that which was submitted as part of the original application in 2018. This application demonstrated an average price of $40,148 for the two models described by L8701. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Act. The average 2023 purchase fee schedule amount for L8701 would be approximately $31,745.42.

For L8702, the most recent commercial pricing we have found is from 2023, with an average price of $95,281 for the model described by L8702. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Act. The average 2023 purchase fee schedule amount for L8701 would be approximately $62,457.28.

Pricing indicator = 38

Agenda Item # 2
ReWalk Personal Prosthetic Exoskeleton System – 20.085

Topic/Issue

Request for Medicare payment determination for ReWalk.

Applicant's Summary

Manufactured by ReWalk Robotics, the ReWalk Personal Prosthetic Exoskeleton System (ReWalk) is a wearable, motorized, computerized, personal lower body exoskeleton system with adjustable ankle joints. The ReWalk is used by individuals with lower body paralysis due to spinal cord injury (SCI) at levels T7 to L5 to restore the function of motor movement controlled by the spinal cord. The device enables individuals with SCI to stand upright and walk again. The ReWalk is placed over a patient's paralyzed or weakened limbs for the purpose of providing ambulation. Patients can control walking initiation, speed, and direction through a combination of controller commands and shifts in their body weight. The ReWalk is configured and custom fit for each patient. A personal computer is provided with the device and used for installation/configuration, upgrading and servicing of the ReWalk device. The ReWalk allows for multiple patient uses through adjustments in length and or weight to align with the patient's joints. The ReWalk is programed to the patient by a trained healthcare professional. It consists of three main parts: remote control communicator, exoskeleton, and control unit. The remote-control communicator is a small wireless device that provides two-way communication between the user and the ReWalk unit. The remote control allows the user to select different modes and presents a visual indication of the status of the system, which includes the mode in which the device is operating (walking, standing, sitting, etc.). The exoskeleton consists of four components: the articulating legs, the pelvic band, the straps, padding, and knee bracket and the ankle-foot plate. The control unit is attached to the pelvic band of the exoskeleton. The control unit consists of an outer shell and an inner compartmentalized shell with power management and computer control system components. The main battery is a lithium-ion battery that can allow the patient to walk continuously for more than three hours on a charge. The ReWalk must be used with supervision of a specially trained companion.

CMS HCPCS Coding

CMS established HCPCS Level II code K1007, "Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors" to describe ReWalk, effective October 1, 2020.

Medicare Benefit Category Determination

CMS determined through rulemaking that ReWalk is a leg brace (CMS-1780-F).

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established

using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. If the only available price information is from a period other than the fee schedule base period (for supplies, the 12-month period of 1986/1987), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Social Security Act for prosthetic devices and orthotics and prosthetics.

In determining whether the devices described by this code are comparable to items with existing codes and fee schedule amounts, we undertook a detailed examination of the physical, mechanical, and electrical components along with the function and intended use. Although we believe that portions of the devices could be comparableto a combination of existing products described by existing codes, we believe that the overall form and function of these lower extremity exoskeletons incorporate revolutionary features (such as self-powered responses to inputs) and cannot be described by any existing codes. For this reason, we have determined it is most appropriate to determine the Medicare payment amount in accordance with the "gap filling" procedure outlined in 42 CFR 414.238(c).

We understand that since the original application, ReWalk has increased the MSRP for their device described by this code. We would note that for gap filling purposes, we can only use verifiable supplier or commercial pricing – that is, there must be evidence of genuine market transactions at a certain price. We have verifiable commercial pricing from the original application; the average of the prices of these 2020 market transactions was $125,500. We note that ReWalk is not the only device on the market described by K1007. We welcome any information from other makers of bilateral, lower limb exoskeletons to ensure that the Medicare payment amount for this code accurately reflects the full market of devices that would be classified in this code.

The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Act. Based on available, verifiable commercial pricing, the average 2023 purchase fee schedule amount for K1007 would be approximately $94,616.95.

Pricing indicator = 38

Agenda Item # 3
External Chest Compressor - HCP230628J67H1

Topic/Issue

Request to establish a new HCPCS Level II code to identify external chest compressor.

Applicant's suggested language: XXXXX, “External chest compressor, anterior and posterior sagittal control, produces intracavitary pressure, anterior extends from 3 inches superior to pectus prominence to 3 inches inferior to pectus prominence, rigid circumferential frame with rigid pads, anteriorly and posteriorly, custom fabricated”

Summary of Applicant's Submission

Children’s Healthcare of Atlanta submitted a request to establish a new HCPCS Level II code to identify custom pectus carinatum orthosis for non-surgical treatment of pectus carinatum. While there is some variation in a pectus carinatum deformity, the most frequent type consists of anterior displacement of the mid and lower sternum and the attached costal cartilage (the cartilage that connects the sternum and the ends of the ribs; its elasticity allows the chest to move when breathing). There is an overgrowth of cartilage that causes the cartilage to buckle and push the sternum forward. During puberty, the chest wall is compliant, making non-surgical treatment an effective option. Non-surgical treatment involves a compressive pectus carinatum orthosis that is worn for most of the day and night. The orthosis applies pressure over the apex of the deformity. The most used method, the Calgary protocol, recommends wearing the brace 23 hours a day until a 48-hour out of brace correction is maintained. At that time the patients are transitioned to wearing the orthosis 8 hours a day until skeletal maturity is achieved. The compliance with custom orthoses yields deformity correction, minimal reoccurrence, quality of life improvement, and self-esteem improvement. Orthotic treatment has been shown to be successful in peer reviewed literature, and avoids the substantial risk and cost associated with major chest wall surgery.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, “Thoracic, pectus carinatum orthosis, sternal compression, rigid circumferential frame with anterior and posterior rigid pads, custom fabricated.”

The new HCPCS Level II code, LXXXX, describes all features of the external chest compressor for non-surgical treatment of pectus carinatum.

Preliminary Medicare Benefit Category Determination

Back Brace (Orthotic).

The application supports a preliminary benefit category determination that the Custom Pectus Carinatum Orthosis is used as a brace. 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 Custom Pectus Carinatum Orthosis is a rigid device that is used to treat and correct pectus carinatum.

Preliminary Medicare Payment Determination

No determination.

As a code representing custom products without a claims history, no payment basis exists on which to develop an appropriate fee schedule amount for LXXXX. We invite the applicant to provide any documentation or claims examples that would demonstrate current commercial pricing for this item.

At this time, 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 # 4
Sure Stance Knee - HCP2306308HLHL

Topic/Issue

Request to establish a new HCPCS Level II code to identify Sure Stance Knee.

Applicant's suggested language: XXXXX, “Addition, endoskeletal knee/shin system, 4-bar linkage or multiaxial, pneumatic swing phase control with mechanical stance-phase lock”

Summary of Applicant's Submission

DAW Industries submitted a request to establish a new HCPCS Level II code to identify Sure Stance Knee. The Sure Stance Knee is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Sure Stance Knee has completely unique swing and stance phase features. The Sure Stance Knee is a non-microprocessor-controlled, 4-bar pneumatic swing-phase control knee with a mechanical stance-phase control lock. The weight activated stance feature activates up to 35-degree knee flexion, drastically reducing the instances of the patient falling and injuring themselves during a common stumble or mis-step. HCPCS Level II code L5840, “4-bar pneumatic swing-phase control” serves as the Sure Stance Knee's "base" code, however, L5840 alone, does not fully describe the Sure Stance Knee’s safety features, particularly in the stance phase. A standard 4-bar pneumatic knee, as described by HCPCS Level II code L5840, does not provide any stability past a few degrees of flexion. If a patient bears weight on a basic 4-bar pneumatic knee during flexion (for example, if the patient stubs their toe on the ground) that knee will buckle under the patient, resulting in a fall. Knee buckling like this is a common cause of injury amongst individuals with above knee amputation(s). Code L5816, “Polycentric, mechanical stance-phase lock” is the code that most closely describes the Sure Stance Knee's weight-activated stance control safety feature, but does not make any mention of a function for swing-phase control and therefore, cannot describe the variable cadence swing-phase control provided by the Sure Stance Knee’s pneumatics. Together, codes L5840 and L5816 could be used to describe the swing and stance phase features of the Sure Stance Knee, however CMS has already declared the use of these two codes together as “incorrect coding,” citing Policy Article A52496. In this article, it states that codes L5840 and L5816 are both classified as a “base knee code” which can “fully describe a complete knee-shin system,” and therefore the use of these two codes on the same claim is considered “incorrect coding (unbundling),” again per Policy Article A52496, paragraph 3 of the section entitled "KNEES." CMS’ Medical Administrative Contractors (MACs) will authorize the use of HCPCS Level II code L5840 but will not authorize L5816 to be bundled with it. Due to the classification of L5816 as a “knee base code,” in the policy article referenced above, that code cannot be included with L5840 as used to describe the Sure Stance Knee’s stance-phase control safety feature.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, “Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control”

We agree with the applicant that the device contains features that are not described by any single existing code. There are enough unique features with this product that a new HCPCS Level II code is warranted, because the existing HCPCS Level II codes only describe the base

prosthetic knees, and not the combination of features of the Sure Stance Knee. As explained in more detail under the payment determination below, use of multiple codes would not be appropriate, as this would duplicate payment for certain knee system base characteristics.

Preliminary Medicare Benefit Category Determination

Artificial Leg (Prosthetic).

The application supports a preliminary benefit category determination that the Sure Stance Prosthetic Knee replaces a missing leg through the knee joint or higher (KD through HD) and would fall under the Medicare benefit for artificial legs (prosthetics).

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 described in the application, the Sure Stance Knee is an addition for an endoskeletal knee-shin system containing three key, price-determining features: polycentric linkage, weight-activated stance control locking (safety knee), and pneumatic swing control. All of these features are present in devices covered by existing codes, so we are developing a payment amount by combining appropriate codes in order to cover these key features without duplicating payment for base characteristics.

While the application suggested combining L5840 “addition, endoskeletal knee/shin system, 4-bar linkage or multiaxial, pneumatic swing phase control” and L5816 “addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock” to account for these features, adding the payment amount for these codes would duplicate payment for base characteristics, namely, those described by L5810 “addition, endoskeletal knee-shin system, single axis, manual lock.” These codes would also duplicate payment for the 4-bar polycentric linkage feature, while failing to account for the weight-activated control locking mechanism.

The base characteristics for all devices in the L5810-L5840 range are described by L5810. Therefore, we are subtracting the fee schedule amount for L5810 from the payment amount for L5812 “addition, endoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)” and L5830 “addition, endoskeletal knee-shin system, single axis, pneumatic/ swing phase control” in order to determine an appropriate payment amount for the weight-activated stance control locking (safety knee) and pneumatic swing-control features, respectively. These amounts have been added to the payment amount for L5816 “addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock” in order to represent the complete system and features of the Sure Stance Knee.

	Sure Stance Knee	L5810	L5812	L5830	L5816
Physical Components					
Single axis		X	X	X	
4-Bar Polycentric Linkage	X				X
Mechanical Components					
Pneumatic swing control	X			X	
Stance phase control: Manual Lock		X			X
Stance phase control: Geometric Lock	X			X	
Stance Phase Control: Weight-activated control locking mechanism	X		X		
Electrical Components	n/a	n/a	n/a	n/a	n/a
Function and Intended Use					
Transfemoral and hip disarticulation level	X	X	X	X	X
Lower extremity device/component	X	X	X	X	X
Additional Aspects and Features	n/a	n/a	n/a	n/a	n/a

Example of pricing using 2023 Medicare Fee Schedule Amounts for Alabama

Code and Description	2023 Alabama Fee Schedule Amount	Implied Payment for Feature Alone
L5810, "Addition, endoskeletal knee-shin system, single axis, manual lock"	$556.19	N/A
L5812, "Addition, endoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)"	$645.80	**$89.61** (safety knee feature)
L5830, "Addition, endoskeletal knee-shin system,	$2,167.76	**$1,611.57** (pneumatic swing phase control feature)

single axis, pneumatic/ swing phase control”		
L5816, “Addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock”	**$977.42** (polycentric knee-shin system)	N/A
Preliminary Payment Determination (e.g., Alabama)		
LXXXX, “Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control”	**$2,678.60**	

Therefore, the preliminary payment determination is that the fee schedule amounts for HCPCS code LXXXX will be established using the fee schedule amounts for HCPCS code L5816 plus payment for the safety knee feature (the fee schedule amounts for HCPCS code L5812 minus the fee schedule amounts for HCPCS code L5810) and payment for the pneumatic swing phase control feature (the fee schedule amounts for HCPCS code L5830 minus the fee schedule amounts for HCPCS code L5810).

The average fee schedule amount will be determined 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
RevoFit® - HCP2306296NDGX

Topic/Issue

Request to establish a new HCPCS Level II code to describe RevoFit®.

Applicant's suggested language: LXXXX, “Addition to lower limb prosthesis, user adjustable, integrated, mechanical, residual limb volume management system”

Summary of Applicant's Submission

Click Medical submitted a request to establish a new HCPCS Level II code to identify RevoFit®. RevoFit® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The RevoFit® is a system to be used in an addition to current lower extremity base socket and socket replacement codes. The RevoFit® volume management system is a kit of components that a prosthetist adds to a custom-fabricated socket which allows the beneficiary to adjust their socket volume throughout the day. RevoFit® enables the user to increase/decrease the volume of their socket as they experience limb volume changes. Users report decreased limb pain and secondary complications, and an increase in device usage and activities of daily living (ADLs) when managing socket volume at home. The RevoFit® volume management system is available to prosthetists and applied in accordance with established prosthetic principles. The prosthetist determines areas of adjustability and adds the system (kit) to the base or replacement socket during custom fabrication. Once delivered, the beneficiary can tighten their device to reduce socket volume or loosen their device to increase socket volume. The interface between the socket and a residual limb is often considered to be the most important factor in the success or failure of a prosthesis. Traditional sockets cannot be compressed or expanded by the user and instead require a combination of fitting socks, pads, or intervention from a prosthetist to adjust socket volume. By contrast, the addition of the RevoFit® system allows the patient to instantly control socket volume without having to remove their prosthesis or interrupt their ADLs. This technology has positively impacted individuals with above knee amputation(s) across all functional levels, age groups, and amputation levels. Traditional socket HCPCS Level II codes were established more than twenty years ago. These codes have been complemented with “addition-to” codes to describe innovations that did not exist when the base socket codes, replacement socket codes, and fee schedules were originally established. The RevoFit® volume management system, introduced eight years ago, provides distinct therapeutic benefits through a unique functional and operational approach. Accordingly, this technology should be considered for a new “addition-to” code and fee schedule.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, “Addition to lower extremity, user adjustable, mechanical, residual limb volume management system”

RevoFit® is one form of a volume management system that has custom sockets with adjustable elements. These fully laminated sockets are fit to a model of a patient’s limb with one or more adjustable elements added in or fabricated with. This device includes added adjustable features such as the tensioning cable with floating panel or ratchet straps, which apply or release pressure to a cut-out a flexible portion of the socket. Additionally, the

RevoFit® features an existing socket that requires alterations in socket fabrication or disruption to traditional physical structure of sockets. RevoFit® is not intended to replace conventional methods, but rather to serve as an adjunctive option for patients with an unmet need. It aims to reduce the frequency of socket replacements and adjustment visits for patients. Furthermore, this RevoFit® system is not intended to integrate with body tissues or with one's nervous system, like bionic limbs usually do. For these reasons, the applicant's above suggested long descriptor language/word "integrated," does not correctly describe the features provided with this RevoFit® volume management system, for use with this product's intended patient population.

Preliminary Medicare Benefit Category Determination

Artificial Leg (Prosthetic).

The application supports a preliminary benefit category determination that the RevoFit® Volume Management System is used in addition to a lower extremity prosthesis and would fall under the Medicare benefit for artificial legs (prosthetics).

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. If the only available price information is from a period other than the fee schedule base period, 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(h)(4) of the Social Security Act for orthotics and prosthetics.

We have found that while the cost for the RevoFit® kit itself is approximately $270, this does not account for the substantial time required for the Prosthetist/Orthotist to integrate the RevoFit® into a socket. This fabrication time would normally be accounted for in the price of a custom socket, such as one that has been modified to incorporate the RevoFit®. Based on pricing support documents available on the manufacturer's website, we have found that the current price typically charged for the integration of RevoFit® into a socket is approximately $4,495. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Act.

The average 2023 purchase fee schedule amount for LXXXX would be approximately $2,946.49.

Pricing Indicator = 38

Agenda Item # 6
Xtend Foot - HCP230629CERGA

Topic/Issue

Request to establish a new HCPCS Level II code to identify Xtend Foot.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Lindhe Xtend submitted a request to establish a new HCPCS Level II code to identify Xtend Foot. Xtend Foot is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Medicare Contractor for Pricing, Data Analysis and Coding of HCPCS Level II DMEPOS Codes (PDAC) determined the increased coronal plane motion provided by Xtend Foot flexible adhesive component is a dynamic feature intrinsic of the keel design, for which this prosthetic foot system is described in HCPCS Level II code L5981 ("All lower extremity prostheses, flex-walk system or equal") and cannot be used to fully describe an additional feature of the L5981 prosthetic foot system. Code L5986 states that the coronal function cannot solely come from the split toe keel design. PDAC commented that there is no numeric value assigned to the function and that it is more dependent by how the motion is accomplished, i.e., a separate, integrated component. Xtend Foot is not a true split-keel, the top strut is a split design, and the base is a solid construction footplate. This construction allows the flexible urethane adhesive to provide motion. Lindhe Xtend evaluated Dynastar by Proteor, currently coded under L5986, "All lower extremity prostheses, multi-axial rotation unit ('mcp' or equal)" and L5981, and believes Dynastar strongly resembles the Xtend Foot in construction.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code L5981, "All lower extremity prostheses, flex-walk system or equal" describes Xtend Foot.

The Xtend Foot provides the multiaxial motion achieved from the inherent flexibility of the prosthetic keel or a split keel/heel prosthetic foot design. Existing HCPCS Level II code L5986, "All lower extremity prostheses, multi-axial rotation unit ('mcp' or equal)," describes a product that is used as an 'addition to' L code foot system for lower limb prosthesis construction. The Xtend Foot has a flexible adhesive component in the keel which binds the carbon fiber lower keel to glass fiber upper keel. This component is included in the prosthetic foot system described by existing HCPCS Level II code L5981, "All lower extremity prostheses, flex-walk system or equal."

Preliminary Medicare Benefit Category Determination

Artificial Leg (Prosthetic).

The application supports a preliminary benefit category determination that the Xtend Foot replaces a missing foot through the ankle joint and would fall under the Medicare benefit for artificial legs (prosthetics).

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code L5981 will apply to this product, if covered. The current average 2023 fee schedule amount for L5981 is $3,666.92.

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 # 7
Dynasplint, Dynamic Adjustable Elbow Extension/Flexion Device - HCP230630HDBV8

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1800, "Dynamic adjustable elbow extension/flexion device, includes soft interface material"

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

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1800, "Dynamic adjustable elbow extension/flexion device, includes soft interface material." Dynasplint dynamic adjustable elbow extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The elbow is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1800 code is an inadequate and confusing description. The short and long E1800 descriptions create the assumption that one E1800 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension, and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1800 can be billed with the modifiers RT and LT to indicate the right elbow and left elbow respectively (E1800RRRT & E1800RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1800 and E1800). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1800RRRTXT (right elbow extension) and E1800RRRTFL (right elbow flexion).

CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

Agenda Item # 7
Dynasplint, Dynamic Adjustable Wrist Extension/Flexion Device - HCP2306303YX0F

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1805, "Dynamic adjustable wrist extension / flexion device, includes soft interface material"

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

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1805, "Dynamic adjustable wrist extension / flexion device, includes soft interface material." Dynasplint dynamic adjustable wrist extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The wrist is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1805 code is an inadequate and confusing description. The short and long E1805 descriptions create the assumption that one E1805 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension, and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1805 can be billed with the modifiers RT and LT to indicate the right wrist and left wrist respectively (E1805RRRT & E1805RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1805 and E1805). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1805RRRTXT (right wrist extension) and E1805RRRTFL (right wrist flexion).

CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

Agenda Item # 7
Dynasplint, Dynamic Adjustable Knee Extension/Flexion Device - HCP230630T4NRE

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1810, "Dynamic adjustable knee extension / flexion device, includes soft interface material"

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

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1810, "Dynamic adjustable knee extension / flexion device, includes soft interface material." Dynasplint dynamic adjustable knee extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The knee is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1810 code is an inadequate and confusing description. The short and long E1810 descriptions create the assumption that one E1810 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1810 can be billed with the modifiers RT and LT to indicate the right knee and left knee respectively (E1810RRRT & E1810RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1810 and E1810). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1810RRRTXT (right knee extension) and E1810RRRTFL (right knee flexion).

CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

Agenda Item # 7
Dynasplint, Dynamic Adjustable Ankle Extension/Flexion Device - HCP23063066K8A

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1815, "Dynamic adjustable ankle extension/flexion device, includes soft interface material"

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

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1815, "Dynamic adjustable ankle extension/flexion device, includes soft interface material." Dynasplint dynamic adjustable ankle extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The ankle is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1815 code is an inadequate and confusing description. The short and long E1815 descriptions create the assumption that one E1815 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1815 can be billed with the modifiers RT and LT to indicate the right ankle and left ankle respectively (E1815RRRT & E1815RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1815 and E1815). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1815RRRTXT (right ankle extension) and E1815RRRTFL (right ankle flexion).

CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

Agenda Item # 7
Dynasplint, Dynamic Adjustable Finger Extension/Flexion Device - HCP230630U7JWP

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1825, "Dynamic adjustable finger extension/flexion device, includes soft interface material"

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

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1825, "Dynamic adjustable finger extension/flexion device, includes soft interface material." Dynasplint dynamic adjustable finger extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The finger is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1825 code is an inadequate and confusing description. The short and long E1825 descriptions create the assumption that one E1825 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of 2 of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1825 can be billed with the modifiers RT and LT to indicate the right finger and left finger respectively (E1825RRRT & E1825RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1825 and E1825). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1825RRRTXT (right finger extension) and E1825RRRTFL (right finger flexion).

CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

Agenda Item # 7
Dynasplint, Dynamic Adjustable Toe Extension/Flexion Device - HCP230630UCV21

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1830, "Dynamic adjustable toe extension/flexion device, includes soft interface material"

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

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1830, "Dynamic adjustable toe extension/flexion device, includes soft interface material." Dynasplint dynamic adjustable toe extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The toe is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1830 code is an inadequate and confusing description. The short and long E1830 descriptions create the assumption that one E1830 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1830 can be billed with the modifiers RT and LT to indicate the right toe and left toe respectively (E1830RRRT & E1830RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1830 and E1830). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1830RRRTXT (right toe extension) and E1830RRRTFL (right toe flexion).

CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

Agenda Item # 8
Ankle Foot Orthosis - HCP230522KHLFG

Topic/Issue

Request to revise an existing HCPCS Level II code L1971, "Ankle foot orthosis, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment" to expand use of L1971 to patients who do not ambulate.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Restorative Medical submitted a request to revise an existing HCPCS Level II code L1971, "Ankle foot orthosis, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment" for it to be covered for individuals who do not ambulate. The current Policy Article, A52457, and Local Coverage Determination (LCD), L33686, state that HCPCS Level II code L1971 is covered for beneficiaries who can ambulate. Many neurologically involved patients need this orthosis and cannot ambulate. Patients with neurological conditions that have diagnosis of inversion or eversion require ankle foot orthosis that are coded using HCPCS Level II code L1971 to bring their foot into a neutral position. While this ankle foot orthosis holds a patient's foot in a neutral position, they can simultaneously work to improve their dorsiflexion. Improving dorsiflexion is not possible if a patient has inversion or eversion that is not being accommodated. This is all done to improve a patient's functional independence and reduce existing range of motion limitations.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code L1971, "Ankle foot orthosis, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment" describes the Ankle Foot Orthosis by Restorative Medical. The description of L1971 does not distinguish between patients who do or do not ambulate. As such, CMS has not identified a program operating need for Medicare or other payers to revise existing HCPCS Level II code L1971. Inquiries regarding the current Policy Article, A52457, and LCD, L33686, should be directed to the Medicare Administrative Contractor (MAC).

Preliminary Medicare Benefit Category Determination

Leg brace (Orthotic).

The application supports a preliminary benefit category determination that the Ankle Foot Orthosis by Restorative Medical 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. A review of the information submitted by the applicant supports the preliminary benefit category determination of leg brace which requires the item to be used to support a weak or deformed lower extremity.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code L1971 apply to this product, if covered. The current average 2023 fee schedule amount for L1971 is $534.86.

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 # 9
Portable Neuromodulation Stimulator (PoNS™) Controller - HCP2306299CNLN

Topic/Issue

Request to establish a new HCPCS Level II code to identify Portable Neuromodulation Stimulator (PoNS™) Controller.

Applicant's suggested language: EXXXX, "Non-implanted neuromodulation tongue stimulator, controller"

Summary of Applicant's Submission

Helius Medical Inc. submitted a request to establish a new HCPCS Level II code to identify Portable Neuromodulation Stimulator (PoNS™) controller. PoNS™ received the Food and Drug Administration's (FDA's) De Novo clearance on March 25, 2021. PoNS™ is a translingual, non-implantable tongue stimulator. The PoNS™ device provides therapy through two primary components: a controller and a mouthpiece. The controller is a programmable, electronic, durable medical device, when connected to the mouthpiece, orally generates electrical pulses for electrotactile stimulation of the nerves in the tongue. The controller generates and controls the delivery of electrotactile stimulation to the trigeminal and facial nerves through the mouthpiece while the individual is performing prescribed therapeutic exercises to directly activate brainstem areas and trigger neuroplastic changes in the brain (cerebral cortex) over a 14-week therapeutic period. The PoNS™ device is indicated for use as a short-term treatment of gait deficit due to mild to moderate symptoms of multiple sclerosis. The PoNS™ is used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over. It is available by prescription only. The PoNS™ device is prescribed by a health care provider, typically a neurologist. The therapeutic exercise regimen is developed by a separate health care provider, typically a physical rehabilitation professional. The controller is packaged separately from the mouthpiece.

CMS Preliminary HCPCS Coding Recommendation

CMS is seeking additional detailed information to further inform our decision. Please provide responses to the following questions:

1. When using the PoNS™ device, what specific physical activity is the patient performing in the home and in the physical therapist's clinical setting? How long are the sessions (minutes and/or hours) in the home and in the clinical setting? And how many sessions are required per week?
2. Does the patient need any specific equipment to use with the PoNS™ device in the home?
3. May the PoNS™ device be used 100% of the time without a physical therapist's clinical involvement?
4. During the 14-week period of use, how many times does the patient need to see or consult with a physical therapist?
5. After the initial 14-week period, will the patient need to use the device again in the future?

Preliminary Medicare Benefit Category Determination

The preliminary Medicare benefit category determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

Preliminary Medicare Payment Determination

The preliminary Medicare payment determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

Agenda Item # 9
Portable Neuromodulation Stimulator (PoNS™) Mouthpiece - HCP2306294W7HD

Topic/Issue

Request to establish a new HCPCS Level II code to identify Portable Neuromodulation Stimulator (PoNS™).

Applicant's suggested language: AXXXX, "Non-implanted neuromodulation tongue stimulator, mouthpiece"

Summary of Applicant's Submission

Helius Medical Inc. submitted a request to establish a new HCPCS Level II code to identify Portable Neuromodulation Stimulator (PoNS™) mouthpiece. PoNS™ received the Food and Drug Administration's (FDA's) De Novo clearance on March 25, 2021. PoNS™ is a translingual, non-implantable tongue stimulator. PoNS™ device is a translingual, non-implantable tongue stimulator. The PoNS™ device provides therapy through two primary components: a mouthpiece and a controller. The mouthpiece is a disposable device that contains an array of 143 gold-plated electrodes through which electrotactile stimulation is applied to the dorsal surface of the patient's tongue and stimulates the trigeminal and facial nerves. The mouthpiece connects to the controller and receives status messages and instructions from the controller. The mouthpiece delivers the stimulation while the individual is performing prescribed therapeutic exercises to activate brainstem areas and trigger neuroplastic changes in the brain (cerebral cortex) over a 14-week therapeutic period. The PoNS™ device is indicated for use as a short-term treatment of gait deficit due to mild to moderate symptoms of multiple sclerosis. The PoNS™ is used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over. It is available by prescription only. The PoNS™ device is prescribed by a physician, typically a neurologist. The therapeutic exercise regimen is developed by a separate health care provider, typically a physical rehabilitation professional. The mouthpiece is packaged separately from the controller.

CMS Preliminary HCPCS Coding Recommendation

CMS is seeking additional detailed information to further inform our decision. Please provide responses to the following questions:

1. When using the PoNS™ device, what specific physical activity is the patient performing in the home and in the physical therapist's clinical setting? How long are the sessions (minutes and/or hours) in the home and in the clinical setting? And how many sessions are required per week?
2. Does the patient need any specific equipment to use with the PoNS™ device in the home?
3. May the PoNS™ device be used 100% of the time without a physical therapist's clinical involvement?
4. During the 14-week period of use, how many times does the patient need to see or consult with a physical therapist?
5. After the initial 14-week period, will the patient need to use the device again in the future?

Preliminary Medicare Benefit Category Determination

The preliminary Medicare benefit category determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

Preliminary Medicare Payment Determination

The preliminary Medicare payment determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

Agenda Item # 10
IpsiHand™ Upper Extremity Rehabilitation System - HCP230701PDW27

Topic/Issue

Request to establish a new HCPCS Level II code to identify Neurolutions IpsiHand™ Upper Extremity Rehabilitation System.

Applicant's suggested language: XXXXX, "Brain-computer interface (BCI) controlled therapy device including noninvasive EEG headset, powered motion assist device, includes microprocessor, all components and accessories"

Summary of Applicant's Submission

Neurolutions Inc. submitted a request to establish a new HCPCS Level II code to identify Neurolutions IpsiHand™ Upper Extremity Rehabilitation System (IpsiHand™). IpsiHand™ received the Food and Drug Administration's (FDA's) De Novo clearance on April 23, 2021. Neurolutions began marketing IpsiHand™ in 2022 and first sales of the IpsiHand™ were completed in early 2023. IpsiHand™ is the first and only brain-computer interface (BCI) controlled therapy to be awarded an FDA market authorization. IpsiHand™ is a class II medical device, available by prescription only, that consists of a biometric electroencephalogram (EEG) headset, a powered upper extremity range of motion assist device, and a microprocessor control unit containing therapy software. IpsiHand™ allows for delivery of thought-actuated therapy for chronic upper extremity disability in patients with strokes. IpsiHand™ is indicated for use in patients with chronic strokes (6 months or more post-stroke) who are 18 years or older, undergoing stroke rehabilitation to facilitate muscle re-education and for maintaining or increasing range of motion in the upper extremities. The device is locked, which means that it can only be used for treatment of the specified clinical indication by the patient. IpsiHand™ promotes Hebbian learning, a process of tightly coupling motor intent brain signals with hand sensory feedback to induce synaptic plasticity and remodel the brain. A patient is prompted to visualize hand movements; the system detects their intention to move non-invasively using the EEG and instructs the handpiece to complete the intended motion. Handpiece-actuated motion is synchronized with the proprioceptive sensory feedback felt by the patient. The therapeutic effect is accomplished by the patient completing therapy modules where they repeatedly visualize moving their affected hand and the system completes the desired motion. IpsiHand™ is self-administered in the patient's home in one-hour modules for five days per week. Patients who completed 12-weeks of therapy showed an average increase of 7.7 points on the Upper Extremity Fugl-Meyer assessment. It is important to note that the functional gains that are achieved using IpsiHand™ are maintained beyond the completion of therapy. The overall required duration of therapy varies from patient to patient, depending on the severity of the initial impairment. Therapy with IpsiHand™ should continue until functional gains in the upper extremity have plateaued which may take years to achieve. The therapy is not delivered as part of a clinician service.

CMS Preliminary HCPCS Coding Recommendation

CMS is interested in understanding how other payers treat therapy devices used by a patient at home for maintaining or restoring some degree of function. Would the use of IpsiHand™ at home be considered providing medical therapy relative to when using an exercise

equipment? Who writes the order and who develops and oversees a plan of care involving IpsiHand™?

Preliminary Medicare Benefit Category Determination

The preliminary Medicare benefit category determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

Preliminary Medicare Payment Determination

The preliminary Medicare payment determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

Agenda Item # 11
Motus Hand and Motus Foot - HCP230314K8EQG

Topic/Issue

Request to establish a new HCPCS Level II Code to identify the Motus Hand and the Motus Foot.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Motus Nova submitted a request to establish a new HCPCS Level II code to identify the Motus Hand and the Motus Foot. The Motus Hand and the Motus Foot are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Motus Hand and Foot are devices comprised of a robotic exoskeleton and a dedicated computer with interactive interface to provide biofeedback on a patient's performance. The Motus devices are for survivors of stroke to use at home or in the clinic; they guide patients through therapeutic activities, provide intuitive robotic assistance to augment weakness helping patients engage in high-dose repetitive task practice, and generate personalized statistics. They are for non-invasive, external use only and are intended to assist patients with engaging in rehabilitative exercises.

CMS Preliminary HCPCS Coding Recommendation

CMS is interested in understanding how payers treat therapy devices used by patients at home for maintaining or restoring some degree of function. Would the use of the Motus Hand and Foot devices at home be considered providing medical therapy relative to when using exercise equipment?

Preliminary Medicare Benefit Category Determination

The preliminary Medicare benefit category determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

Preliminary Medicare Payment Determination

The preliminary Medicare payment determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

Agenda Item # 12
Nalu™ Adhesive Clip - HCP230630M0GF7

Topic/Issue

Request to establish a new HCPCS Level II code to identify Nalu™ Adhesive Clip.

Applicant's suggested language: AXXXX, "Adhesive clip applied to the skin to secure relief therapy disc, each"

Summary of Applicant's Submission

Nalu Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify the Nalu™ Adhesive Clip. The Nalu™ Adhesive Clip received the Food and Drug Administration's (FDA's) 510(k) clearance on March 29, 2019. The Nalu™ Neurostimulation System includes features that are different from all other systems requiring adhesives. The Nalu™ Neurostimulation System comes with an adhesive wearable clip that is a medical supply furnished by the durable medical equipment carrier for beneficiaries outside and separate from the cost and reimbursement of the Nalu™ Neurostimulation System. The adhesive clip assembly includes usability features making it easy for users of the Nalu™ Neurostimulation System to precisely position, align and secure their external therapy disc over their implantable neurostimulator to ensure robust bidirectional wireless communication throughout the day. The physical clip also has retention features that balance convenient therapy disc insertion and removal by users (patients may swap therapy discs multiple times per wear period) while reliably retaining the therapy disc throughout days of normal use activities such as walking, working, exercising, sleeping, showering which can be further monitored by an accelerometer onboard the therapy disc.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each"

Preliminary Medicare Benefit Category Determination

Supply used with Prosthetic Device.

In order for the Nalu™ Neurostimulation System (electrical nerve stimulator) to function properly, the system requires the use of the Nalu™ Adhesive Clip. The system includes an implantable pulse generator and an external therapy disc that includes a controller and a battery. However, the system depends upon the adhesive clip to assist the patient in precisely positioning, aligning, and securing the external therapy disc over the implantable neurostimulator to ensure bidirectional wireless communication. Therefore, the Nalu™ Adhesive Clip is a supply to the electrical nerve stimulator which is a prosthetic device.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a

comparison of: physical components, mechanical components, electrical components, function and intended use, and additional attributes and features. The preliminary payment determination for code AXXXX, for this item, is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS code A5126 "Adhesive or non-adhesive; disk or foam pad."

We note that as an ostomy supply, A5126 uses a different fee schedule base period than prosthetics, and so the payment amount for AXXXX has been adjusted accordingly. Based on this preliminary determination, the 2023 fee schedule amounts for AXXXX would be approximately $1.93 on average.

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 # 13
mRNA and mmRNA - HCP230630CKHA7

Topic/Issue

Request to establish a new HCPCS Level II code to identify mandibular Repositioning Nighttime Appliance (mRNA) and modified mandibular Repositioning Nighttime Appliance (mmRNA).

Applicant's suggested language: XXXXX, "Oral device/appliance, custom fabricated, removable, mandibular advancement and non-surgical jaw expansion, with or without a fixed mechanical hinge"

Summary of Applicant's Submission

Vivos® Therapeutics Inc. submitted a request to establish a new HCPCS level II code to identify mRNA and mmRNA. mRNA and mmRNA received the Food and Drug Administration's (FDA's) 510(k) clearance on August 19, 2021. Both the mRNA and mmRNA are indicated for the adult treatment of mild and moderate Obstructive Sleep Apnea. Both devices (mRNA and mmRNA) represent a significant increase in complexity of design and cost of fabrication versus the mandibular advancement only oral appliances described by the current code set (E0486 or K1027).

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1027, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" describes mRNA.

Existing HCPCS Level II code E0486, "Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment" describes mmRNA.

CMS welcomes more information from the applicant on how the existing codes do not meet the features and functions of their products and how the existing codes do not represent the significant increase in complexity.

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the Medicare Administrative Contractors (MACs).

Preliminary Medicare Payment Determination

No determination.

Agenda Item # 13
Daytime Nighttime Appliance (DNA) - HCP2306308TG88

Topic/Issue

Request to establish a new HCPCS Level II code to identify Daytime Nighttime Appliance (DNA).

Applicant's suggested language: XXXXX, "Oral device/appliance, custom fabricated, removable used to treat mild or moderate obstructive sleep apnea by non-surgical jaw expansion"

Summary of Applicant's Submission

Vivos® Therapeutics Inc. submitted a request to establish a new HCPCS Level II code to identify DNA. DNA received the Food and Drug Administration's (FDA's) 510(k) clearance on December 30, 2022. DNA is indicated in the adult treatment of mild and moderate obstructive sleep apnea. DNA is a custom fabricated, removable, oral device/appliance for the treatment of obstructive sleep apnea by non-surgical jaw expansion.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1027, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" describes DNA.

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the Medicare Administrative Contractors (MACs).

Preliminary Medicare Payment Determination

No determination.

Agenda Item # 14
The Slide®- HCP230703WJE8T

Topic/Issue

Request to revise an existing HCPCS Level II code E0486, "Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment" to identify The Slide®.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

LeBlanc Dental Products submitted a request to revise existing HCPCS Level II code E0486, "Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment" to identify The Slide®. The Slide® received the Food and Drug Administration's (FDA's) 510(k) clearance on July 20, 2021. The Slide® is a prescribed intraoral device worn while sleeping to reduce nighttime snoring and mild to moderate obstructive sleep apnea. The fixed hinge is defined as a mechanical joint, containing an inseparable pivot point. Interlocking flanges, tongue and groove mechanisms, hook and loop or hook and eye clasps, elastic straps or bands, mono-block articulation, traction-based articulation, compression-based articulation, etc. (not all-inclusive) do not meet this requirement of CMS' Policy Article A52512 published at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52512.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1027, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" describes The Slide®.

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the Medicare Administrative Contractors (MACs).

Preliminary Medicare Payment Determination

No determination.

Agenda Item # 15
EVO® Sleep and Snore Device - HCP230703YHFLY

Topic/Issue

Request to establish a new HCPCS Level II code to identify EVO® Sleep and Snore Device.

Applicant's suggested language: KXXXX, "Oral device used to reduce upper airway collapsibility, that is iteratively adjustable with interlocking lateral flanges, custom fabricated from US Pharmacopeia Class VI qualified material with a forward engineered and wholly embedded patient monitoring sensor technology"

Summary of Applicant's Submission

ProSomnus® Sleep Technologies submitted a request to establish a new HCPCS Level II code to identify EVO® Sleep and Snore Device. EVO® Sleep and Snore Device received the Food and Drug Administration's (FDA's) 510(k) clearance on November 20, 2020. EVO® Sleep and Snore Device is a custom oral device to reduce upper airway collapsibility and to monitor medically important physiologic patient data. Physiologic data medically relevant to upper airway collapsibility include temperature, blood pressure, pulse rate, heart rate, and oxygen. The available coding for oral devices to reduce upper airway collapsibility, specifically E0486 and K1027, does not provide for patient monitoring. The available coding for patient monitoring devices, including K0554 and E2102, are specific to glucose monitoring. It should be noted that there are similar concepts in the existing codes about glucose monitoring: K0554, "receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system." Also, E2103, "non-adjunctive, non-implanted continuous glucose monitor or receiver" as maintained by CMS falls under miscellaneous pumps and monitors and E2102, "adjunctive continuous glucose monitor or receiver." Both codes are specific to glucose monitoring and are therefore not applicable to EVO® Sleep and Snore Device's technology for reducing upper airway collapsibility. EVO® Sleep and Snore Device's technology will measure physiological metrics relevant to upper airway collapsibility and their effects on the patient including temperature, oxygen levels, blood pressure, heart rate, and/or pulse rate.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1027, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" describes EVO Sleep and Snore Device.

We have not identified a program need to separately identify the monitoring feature associated with this device. We note that items used in the patient's home that provide monitoring and measurements for the physician/practitioner to evaluate the patient's condition and course of treatment do not fall under the Medicare benefit for DME used in the home. CMS welcomes more information from the applicant on how the existing codes do not meet the features and functions of their products.

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the Medicare Administrative Contractors (MACs).

Preliminary Medicare Payment Determination

No determination.

Agenda Item # 15
Docking Station/Power Supply for an Oral Device/Appliance - HCP230703C4XWT

Topic/Issue

Request to establish a new HCPCS Level II code to identify a docking station/power supply for an oral device/appliance.

Applicant's suggested language: KXXXX, “Docking station encompasses power supply, and one or more of feature; transmission data, cleaning, or protection for an oral device/appliance used to reduce upper airway collapsibility with a completely embedded remote patient monitoring sensor/chip component”

Summary of Applicant's Submission

ProSomnus® Sleep Technologies submitted a request to establish a new HCPCS Level II code to identify a docking station/power supply for an oral device/appliance. The purpose of this request is to assign a new HCPCS Level II coding that supports a docking station/power supply for an oral device/appliance used to reduce upper airway collapsibility with a completely embedded remote patient monitoring sensor/chip component. The available coding for oral devices/appliances to reduce upper airway collapsibility, specifically E0486 and K1027, do not provide for remote patient monitoring docking stations/power supply. The docking station may include but is not limited to power supply, transmission data, cleaning, or protection of the device.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code KXXXX, “Docking station for use with oral device/appliance used to reduce upper airway collapsibility”

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the Medicare Administrative Contractors (MACs).

Preliminary Medicare Payment Determination

No determination.

Appendix A: DMEPOS Payment Categories

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

Pricing = 00 Service Not Separately Priced

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

Pricing = 31 Frequently Serviced Items

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

Pricing = 32 Inexpensive and Other Routinely Purchased Items

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

Pricing = 33 Oxygen and Oxygen Equipment

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

Pricing = 34 Supplies Necessary for the Effective Use of DME

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

Pricing = 35 Surgical Dressings

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

Pricing = 36 Capped Rental Items

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

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

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

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

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

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