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

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

Zoom Meeting, for remote participation
Wednesday, November 30, 2022 9:00 am – 5:00 pm, eastern time (ET)

8:45 am, ET:
• Zoom meeting login:
https://cms.zoomgov.com/webinar/register/WN_v9r9lfW_QZimHUNq__AXrg
• Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

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 stakeholders and interested parties to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meeting. CMS' final coding, benefit category, and payment decisions will be published on CMS' HCPCS website at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCSLevelII-Coding-Decisions-Narrative-Summary around January 2023 and will be effective April 1, 2023, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Wednesday, November 30, 2022. 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 November 30, 2022.

Agenda Item # 1
AMMA - HCP220704AAQ4D

Topic/Issue

Request to establish a new HCPCS Level II code to identify AMMA Portable Scalp Cooling System.

Applicant's suggested language: "Portable scalp coolant generator for therapeutic temperature and duration to reduce chemotherapy-induced alopecia synchronized with single-patient use responding head worn cooling cap for uniform consistent scalp cooling therapy"

Applicant's Summary

Cooler Heads submitted a request to establish a new HCPCS Level II code to identify Portable Scalp Cooling System (PSCS). The PSCS is a wearable device having two device components. The portable coolant generating system cooling unit is synchronized with the one patient use Cooling Cap custom fitted to the patient's scalp to maintain 64.4°F cooling. The PSCS is used by adult patients 21 years of age and older, undergoing chemotherapy treatment (CT) for solid tumor cancer who want to avoid chemotherapy-induced hair loss, or alopecia (CIA). PSCS received the Food and Drug Administration's (FDA's) 510(k) clearance on October 21, 2021. The FDA's indication for use states, "PSCS is used to reduce the likelihood of CIA in adult cancer patients with solid tumors and is compliant with 21 CFR 878.4360." Scalp cooling prevents CIA in 53-66.3% of patients. According to the applicant, the novel materials of the Cooling Cap allow it to be custom molded to adequately cover each patient's unique scalp contours. The materials and wrap method are unique to AMMA and necessary to deliver uniformly dispersed cooling to prevent patchy hair loss. Once the Cooling Wrap has been well molded to the patient's scalp, the Compression Cap is securely fitted to the patient's head, constituting the AMMA head cooling device or the Cooling Cap. The temperature sensors in the Portable Cooling Unit are synchronized to monitor and adjust cooling to maintain a consistent controlled delivery of therapeutic cooling for the duration of the prescribed therapy. The PSCS is intended to lower the scalp temperature to an average of 64.4°F (18°C), reducing blood flow to the hair follicles which may protect them from the effect of chemotherapy drugs, preserve existing hair, and safeguard new growth. The circulation of the refrigerated coolant through the cap extracts heat from the patient's scalp. The PSCS is a prescription only device and therefore can only be used if prescribed by a healthcare provider. Treatment with the PSCS is administered by the user, their caregiver, or assisted by a nurse in a healthcare treatment center, for use in a home setting, and during transit to home from the treatment center. The AMMA PSCS is taken by the patient to the CT infusion center where clinical staff may assist the patient with final set up, supplies for the coolant generator. AMMA is started 30 minutes before CT infusion, used during the infusion, and continued for 2 hours thereafter in the patient's residence, work, or at another location outside of the infusion center. The Portable Cooling Unit monitors and maintains the therapeutic temperature of 64.4°F for the duration of the device's use. The PSCS is delivered to the patient by either the infusion center at the start of the patients CT, or the PSCS may be delivered to the patient's house. The PSCS and its accessories are packaged in a custom constructed transport case.

CMS Preliminary HCPCS Coding Recommendation

The AMMA Portable Scalp Cooling System is not suitable for coding in HCPCS Level II because this product, if covered, would be expected to be included within the payment for the professional service.

Agenda Item # 1
AMMA - HCP220704P7W3Y

Topic/Issue

Request to establish a new HCPCS Level II code to identify AMMA, Cooling Cap.

Applicant's suggested language: XXXXX, "Single-patient use head worn cooling cap receiving unit, for the Cooling Unit to deliver portable uniform consistent scalp cooling therapy"

Applicant's Summary

Cooler Heads submitted a request to establish a new HCPCS Level II code to identify Cooling Cap used with the Portable Scalp Cooling System (PSCS). The Cooling Cap is for the single-patient use and worn on the head. According to the applicant, the durable portable coolant generating system, Cooling Unit, is synchronized with the single-patient use Cooling Cap custom fitted to the patient's scalp to maintain 64.4°F. AMMA is used by adult patients 21 years of age and older, undergoing chemotherapy treatment (CT) for solid tumor cancer who want to avoid chemotherapy-induced hair loss, or alopecia (CIA). PSCS received the Food and Drug Administration's (FDA's) 510(k) clearance on October 21, 2021. The FDA's indication for use states PSCS is used to reduce the likelihood of CIA in adult cancer patients with solid tumors and is compliant with 21 CFR 878.4360. Scalp cooling prevents CIA in 53-66.3% of patients. According to the applicant, the Cooling Cap's novel materials allow it to be custom molded to adequately cover each patient's unique scalp contours. According to the applicant, the materials and wrap method used to construct this AMMA device are unique to AMMA and necessary to deliver uniformly dispersed cooling to prevent patchy hair loss. Once the Cooling Wrap has been well molded to the patient's scalp, the Compression Cap is securely fitted to the patient's head, constituting the AMMA head cooling device or the Cooling Cap. The temperature sensors in the portable Cooling Unit are synchronized to monitor and adjust cooling to maintain a consistent controlled delivery of therapeutic cooling for the duration of the prescribed therapy. The PSCS is intended to lower the scalp temperature to an average of 64.4°F (18°C), reducing blood flow to the hair follicles which may protect them from the effect of chemotherapy drugs, preserve existing hair, and safeguard new growth. The circulation of the refrigerated coolant through the cap extracts heat from the patient's scalp. The PSCS is by prescription only and therefore can only be used if prescribed by a healthcare provider. Placement of the Cooling Cap, necessary for use with the PSCS, is done by the user, their caregiver, or assisted by a nurse in a healthcare treatment center, for later use in a home setting, and during transit to home from the treatment center. The AMMA Cooling Cap is taken by the patient to the CT infusion center where clinical staff may assist the patient with the final set up and supplies for the coolant generator. AMMA is started 30 minutes before CT infusion, used during the infusion, and continued for 2 hours thereafter at the patient's residence, work, or at another location outside of the infusion center. The Portable Cooling Unit monitors temperature to maintain scalp cooling at 64.4° F for the duration of the PSCS device use. The PSCS is delivered to the patient by either the infusion center at the start of the patients CT, or more often the PSCS is delivered to the patient's house. The Cooling Cap and accessories are packaged in a custom constructed transport case.

CMS Preliminary HCPCS Coding Recommendation

The AMMA Cooling Cap is not suitable for coding in HCPCS Level II because this product, if covered, would be expected to be included within the payment for the professional service.

Agenda Item # 2
FOOTBAR® Walker - HCP220704VX6MB

Topic/Issue

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

Applicant's suggested language: XXXXX, "Sit-to-stand transfer walker, folding, adjustable or fixed height, with or without wheels"

Applicant's Summary

GANM, LLC submitted a request to establish a new HCPCS Level II code to identify FOOTBAR® Walker. The FOOTBAR® Walker is class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. This patented walker features a pull bar designed to improve, retrain or regain sit-to-stand (STS) transfer function often lost due to: temporary injury, surgery (hip/knee replacement), chronic medical conditions or disease progression that may be physical or neurological in nature. The FOOTBAR® Walker functions as an assistive device when sit-to-stand movement (an important and proven medically necessary basic skill) is impaired preventing mobility and/or activities of daily living. According to the applicant, there are no current codes that adequately describe the FOOTBAR® Walker and its therapeutic function. Walkers as a whole describe ambulation mobility function only (if a person cannot stand, they cannot use a walker). A walker by definition cannot meet this functional need that enables a person to safely move from a seated position to a standing position. Lifts are used for individuals who are not able to perform sit to stand for themselves or ambulate and are authorized if a patient meets the specific criteria. According to the applicant, if a lift is approved, per CMS LCD, other MAE such as canes, walkers, wheelchairs, crutches, etc. are no longer approved in conjunction with an approved lift. The applicant stated that the HCPCS codes for lifts also do not accurately describe the STS function and are limited in their description to very specific conditions. The applicant asserted, a lift is approved by CMS if the patient is "bed confined" or requires "supine positioning for transfers". When a lift is approved for a patient, it removes CMS coverage for any other MAE such as canes, walkers, wheelchairs, etc. due to a patient's defined medical condition and in most cases inability to ambulate. Patients of the FOOTBAR® Walker are mobile and able to ambulate. The applicant has applied for inclusion of current HCPCS codes on the original accessory design. After a recent appeal, the applicant was awarded under DCN# 22136003000010 codes E0143+A9900 and A9999 on June 16, 2022. According to the applicant, these are miscellaneous accessory codes that apply to the original model. Accessories were added and permanently affixed to an existing walker of another manufacturer. According to the applicant, these do not accurately align with the new 1-unit model and its fully integrated design all manufactured in line at the factory. Over the past 4 years, the applicant claims to have proven the original model's concept, function and market acceptance through both public and medical professional approval.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E0143, "Walker, folding, wheeled, adjustable or fixed height" describes the FOOTBAR®. Wheeled walkers are typically furnished with brakes since they have wheels. The types of brakes included with the walker is not specified in the code

descriptor and therefore folding wheeled walkers with any type of brakes are described by code E0143.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment

The current Medicare policy and prior established benefit category determination for code E0143 applies to the design of the FOOTBAR® Walker.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0143 apply to the FOOTBAR® Walker, if covered. The current average fee schedule amount for E0143 is $78.69.

The average fee schedule amount is the average of the 2022 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

Agenda Item # 3
geko™ T-3 and geko™ W-3 - HCP22063010MT6

Topic/Issue

Request to establish a new HCPCS Level II code to identify geko™ T-3 and geko™ W-3.

Applicant's suggested language: XXXXX, "Low frequency (1 Hz) wearable neuromuscular electro-stimulation (NMES) device to increase local blood circulation, reduce, edema, and prevent venous thrombosis"

Applicant's Summary

Firstkind Ltd. submitted a request to establish a new HCPCS Level II code to identify geko™ T-3 and geko™ W-3. The geko™ devices with OnPulse™ technology are a low-frequency (1 Hz) neuromuscular electro-stimulation (NMES) devices that stimulate the common peroneal nerve activating the calf and foot muscle pumps, resulting in isometric muscle contraction and increased blood flow. The geko™ device stimulates the motor neurons within the nerve bundle that carry signals to the muscle fibers to cause contraction. Stimulating the common peroneal nerve activates the tibialis, peroneus longus and lateral gastrocnemius muscles. Together, their simultaneous contraction compresses the venous system, efficiently evacuating blood in the deep veins of the calf at a rate equal to 60% of walking. The device is worn just below the knee on one or both legs and is available in two versions; geko™ T-3 and geko™ W-3, which can deliver NMES for up to 24 hours per day. The lightweight battery-operated device has integrated electronics composed of a constant pulse generator with embedded software and a lithium-ion battery enclosed in a molded plastic casing, and embedded electrodes that deliver stimulation via an adhesive surface. The devices deliver multiple stimulation levels that increase the electrical charge, muscle contractions are achieved. The settings address the variation in responsiveness of patients to stimulation due to individual specifics. Two buttons control the on/off function and intensity levels of the device output. According to the applicant, there are no HCPCS codes to describe a wearable NMES device that delivers low-frequency stimulation to increase blood circulation, reduce edema, prevent venous thrombosis, or increase microcirculation in the lower limb for the patient's use at home. Indications include increasing local blood circulation, reduction of edema, prevention of venous thrombosis, and increasing microcirculatory blood flow in lower limb with venous insufficiency and/or ischemia to support wound or tissue healing. The devices can deliver an effective stimulation for up to 24 hours per day, depending on the device selected and the indication for use. After use, the device is removed, discarded and a new device is applied and activated as required. The device is applied to the skin and positioned over the peroneal nerve just below the knee. An indicator line on the device is aligned to the fibula head, for optimal electrode placement. The devices are packaged in sealed, easily opened, pouches. The geko™ W-3 devices are supplied as 7 single units in a cardboard wallet along with instructions for use. The geko™ T-3 devices are supplied in pairs of devices as either 3, 4, or 5 pairs in a cardboard wallet or 25 pairs in a carton. Again, the instructions for use are provided with all the devices. geko™ T-3 and geko™ W-3 received the Food and Drug Administration's (FDA's) 510(k) clearance on May 23, 2018.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a single-patient use, disposable NMES device. CMS would like to further understand the geko™ T-3 and geko™ W-3 device indication for use by the FDA to be used as immediate post-surgical stimulation. With regard to Medicare, we do not have a benefit category for single-patient use or disposable devices, as they do not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code. Also, CMS would like to know if other payers would consider the use of the geko™ T-3 and geko™ W-3 device as an "incident to" supply.

Agenda Item # 4
D-Ostomy - HCP220704QETH9

Topic/Issue

Request to establish a new HCPCS Level II code to identify D-Ostomy.

Applicant's suggested language: XXXXX, “Ostomy skin barrier, with flange including substantially straight edge, each”

Applicant’s Summary

Sanguine Technology, LLC submitted a request to establish a new HCPCS Level II code to identify D-Ostomy. D-Ostomy is class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. According to the applicant, the item is a novel ostomy barrier comprising a flange having a substantially straight edge. For example, the flange on the barrier may be D-shaped. The flange with a substantially straight edge permits ostomy barrier placement in close proximity to a wound, negative pressure wound device, or patient feature (such as skin rolls or folds) without overlap. Overlap of traditional ostomy barriers can cause unwanted leaks of stoma effluent, which can raise the risk of infection or further complications. When traditional ostomy barriers are used in close proximity with negative pressure wound devices, the increased pressure can draw stoma effluent with the vacuum pressure, potentially drawing such effluent through a wound. The D-Ostomy barrier is used similar to that of traditional ostomy barriers: the barrier is placed around a patient's stoma. Unlike traditional ostomy barriers, the straight edge of the D-Ostomy barrier is oriented in proximity to the body feature (wound, scar, skin roll or fold) or negative pressure wound device. Pouches with corresponding D-shaped flanges are attached to the barrier to collect effluent.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4361, "Ostomy faceplate, each" describes the D-Ostomy barrier.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4361 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4361 apply to this product, if covered. The current average fee schedule amount for A4361 is $ 21.75.

The average fee schedule amount is the average of the 2022 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 = 37

Agenda Item # 5
Dr. Arthritis, Patella Tendon Knee Strap - HCP220331103NX

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable patella tendon knee strap.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable patella tendon knee strap. This reusable strap comes in one size and is used for the following conditions: sports related injuries and fatigue, patellar tendonitis (jumper's knee), patellofemoral pain syndrome (runner's knee), iliotibial band syndrome (ITBS), chondromalacia, patellar Tracking and Osgood–Schlatter disease. This device is an adjustable patella tendon knee strap, which provides support to the patella tendon insertion point and knee joint itself through compression. The patella tendon knee strap is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable patella tendon knee strap.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Patella Tendon Knee Strap is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 5
Dr. Arthritis, Shoulder Support Brace - HCP220331DKCD6

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable shoulder strap.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable shoulder strap. This reusable brace comes in one size and used the following conditions: chronic shoulder pain, dislocated, shoulder, rotator cuff injury, tendon inflammation (bursitis or tendinitis) or tendon tears, shoulder instability, frozen shoulder syndrome. This device is an adjustable shoulder brace that provides graduated compression and relative immobilization of the shoulder. The shoulder support brace is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable shoulder support brace.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Shoulder Support Brace is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 5
Dr. Arthritis, Elbow Support Strap - HCP220331KEXCD

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable elbow strap.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable elbow strap. This reusable strap comes in one size and used the following conditions: lateral epicondylitis (tennis elbow,) medial epicondylitis (golfers' elbow) and musculoskeletal elbow conditions. This device is an adjustable elbow strap, which provides support to the elbow joint through compression. The elbow support strap is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable elbow support strap.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Elbow Support Strap is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 5
Dr. Arthritis, Wrist Brace - HCP220420WCDD8

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable wrist brace.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable carpal tunnel wrist brace. This reusable brace comes in one size and used the following conditions: carpal tunnel syndrome, sports-related injuries, and fatigue ligament/tendon support, wrist sprains/strains, wrist arthritis basal thumb arthritis and ganglion cysts. This device is a carpal tunnel wrist brace that provides graduated compression and relative immobilization of the wrist joint. The user would wear the device directly over the skin, over the lower arm covering the wrist joint. The user would secure the device in place using a hook and loop fastener. The wrist brace is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable wrist brace.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Wrist Brace is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 5
Dr. Arthritis, Thumb Support Brace - HCP220331EFF4D

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable thumb brace.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable thumb brace. This reusable brace comes in one size and used the following conditions: basal thumb pain, thumb ligament issues, tendinitis/tendinopathy, trigger thumb (stenosing tenosynovitis), repetitive strain injury (RSI), De Quervain's Syndrome (De Quervain's tenosynovitis) and thumb sprains. This device is an adjustable thumb brace that provides graduated compression and relative immobilization of the wrist joint and 1st carpal metacarpal joint (thumb). The user would apply it directly over the skin, across the wrist joint and covering the thumb. The user would secure the device in place using a hook and loop fastener, tightening as appropriate to achieve the desired level of supportive compression. The thumb support brace is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable thumb brace.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Thumb Support Brace is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 5
Dr. Arthritis, Open Finger Compression Gloves - HCP2203319P57X

Topic/Issue

Request to establish a new HCPCS Level II code to identify pair of open finger gloves.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify pair of open finger gloves. The gloves are used with arthritis, carpal tunnel, and musculoskeletal hand conditions. This device is a pair of open finger compression gloves, which provides graduated compression of the wrist, hand and finger. It supports and stabilizes the small joints of the hand, through compression and partial immobilization. User wears the device over the skin; it can be easily removed/reused. The finger compression gloves are exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the pair of open finger compression gloves.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Open Finger Compression Gloves are not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 5
Dr. Arthritis, Elbow Compression Sleeve - HCP2204214YW7G

Topic/Issue

Request to establish a new HCPCS Level II code to identify an elbow sleeve.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an elbow sleeve. This sleeve comes in one size and used the following conditions: sports related injuries and fatigue, elbow arthritis, tennis elbow, golfer's elbow, olecranon bursitis, cubital tunnel syndrome and any other musculoskeletal elbow injuries. This device is an elbow compression sleeve, which provides support to the elbow joint thought stabilization, relative immobilization and compression. The user would wear it directly over the skin, the center of the elbow sleeve should be positioned across the elbow joint itself. The elbow sleeve is easy to remove and reapply. The elbow compression sleeve is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the elbow compression sleeve.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Elbow Compression Sleeve is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 5
Dr. Arthritis, Wrist Brace - HCP220321YBBBP

Topic/Issue

Request to establish a new HCPCS Level II code to identify an adjustable wrist brace.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify an adjustable wrist brace. This reusable brace comes in one size and used the following conditions: for use with arthritis, carpal tunnel, etc. This device is a wrist brace that provides graduated compression and relative immobilization of the wrist joint. It supports and stabilizes the wrist joint, and through compression and partial immobilization promotes recovery for common musculoskeletal injuries. User applies to wrist joint and secures using hook and loop fastener. The device is easy to remove and reapply. The wrist brace is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the adjustable wrist brace.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Wrist Brace is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 5
Dr. Arthritis, Foot Compression Sleeve - HCP220421KT8W1

Topic/Issue

Request to establish a new HCPCS Level II code to identify a foot compression sleeve.

The applicant did not submit any suggested language.

Applicant's Summary

Dr. Arthritis submitted a request to establish a new HCPCS Level II code to identify a foot compression sleeve. This sleeve provides support to the ankle and foot joint, through compression, relative immobilization and joint stabilization. This would promote the recovery during sport or strenuous exercise, sports related injuries and fatigue, ligament/tendon support, ankle sprains/strains, ankle arthritis, heel/arch support. The user would wear it directly over the skin and it would be positioned to cover the lower leg, ankle joint and midfoot. The foot compression sleeve is easy to remove and reapply. The foot compression sleeve is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the foot compression sleeve.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4467 apply to this item.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based on this definition, the preliminary determination is that the Dr. Arthritis Foot Compression Sleeve is not a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4467 apply to this product. Items or services described by HCPCS code A4467 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 6
HEMIGARD® ASRD - HCP220628EJE62

Topic/Issue

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

Applicant's suggested language: XXXXX, "HEMIGARD, 12 pairs of adhesive suture retention devices per box"

Applicant's Summary

Suturegard submitted a request to establish a new HCPCS Level II code to identify HEMIGARD® ASRD. HEMIGARD® ASRD is a class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. HEMIGARD® ASRD is a sterile, single use device. The HEMIGARD® ASRD is a wound closure device comprised of two 60x15 mm sterile, single use, adhesive strips, placed on either side of a wound. It is used in combination with suture, which is passed through its' apertures before the suture enters and exits the skin. It is made of nonwoven polyester, transparent polyethylene film and a PETG plastic insert with two apertures for suture passage. It has peel away paper backing and has an acrylate based hypoallergenic skin adhesive for attachment.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the Hemigard® ASRD would generally be used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer would pay for the service in which this product is used.

Agenda Item # 7
Keragel® 20gm Tube - HCP2207049R6X6

Topic/Issue

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

Applicant's suggested language: XXXXX, "KERATIN - Keragel 20gm sterile tube, each"

Applicant's Summary

Molecular Biologicals Inc. submitted a request to establish a new HCPCS Level II code to identify Keragel® 20gm tube. Keragel® received the Food and Drug Administration's (FDA's) 510(k) clearance on February 11, 2009. It is a patient self-administered gel in a tube consisting of bioactive keratin, Replicine™, as the clinically predominant and distinguishing ingredient. Keragel® is a topical gel product designed for acute/chronic partial and full thickness wounds with low to moderate exudate in conditions such as: venous leg ulcers, arterial ulcers, diabetic foot ulcers, skin graft donor sites, and first and second-degree burns. Keragel® can be self-applied topically to the wound bed surface. Keragel® is applied with dressing changes to the wound bed, commonly daily. The clinically predominant function of Keragel® is to deliver bioactive keratin to the wound bed to facilitate wound healing, as well as establish more durable skin structure. Exogenous Keratin has demonstrated activation and proliferation of keratinocytes by upregulating Keratin 6, 16, and 17 and activating fibroblasts, collagen IV and collagen VII. By activating keratinocytes, a scaffold is developed to allow for epithelial cell migration and granulation of the wound bed. Keragel® is beneficial in patients suffering from chronic, recalcitrant wounds such as diabetic foot ulcer, venous leg ulcer, pressure ulcers, wounds from dystrophic epidermolysis bullosa among others.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A6248 "Hydrogel dressing, wound filler, gel, per fluid ounce," describes Keragel®.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A6248 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A6248 apply to this product, if covered. The current average fee schedule amount for A6248 is $19.99.

The average fee schedule amount is the average of the 2022 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 = 35

Agenda Item # 7
KeragelT® 20gm Tube - HCP2207053M4YQ

Topic/Issue

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

Applicant's suggested language: XXXXX, "Keratin - KeragelT 20gm sterile tube, each"

Applicant's Summary

Molecular Biologicals Inc. submitted a request to establish a new HCPCS Level II code to identify KeragelT®. KeragelT® received the Food and Drug Administration's (FDA's) 510(k) clearance on February 11, 2009. KeragelT® 20gm tube is a patient self-administered gel in a tube consisting of bioactive keratin, Replicine™, as the clinically predominant and distinguishing ingredient. KeragelT® is a topical gel product designed for acute/chronic partial and full thickness wounds with low to moderate exudate in conditions such as: venous leg ulcers, arterial ulcers, diabetic foot ulcers, skin graft donor sites, and first and second-degree burns. KeragelT® can be self-applied topically to the wound bed surface. KeragelT® is applied with dressing changes to the wound bed, commonly daily. The clinically predominant function of KeragelT® is to deliver bioactive keratin to the wound bed to facilitate wound healing, as well as establish more durable skin structure. Exogenous Keratin has demonstrated activation and proliferation of keratinocytes by upregulating Keratin 6, 16, and 17 and activating fibroblasts, collagen IV and collagen VII. By activating keratinocytes, a scaffold is developed to allow for epithelial cell migration and granulation of the wound bed. KeragelT® is beneficial in patients suffering from chronic, recalcitrant wounds such as diabetic foot ulcer, venous leg ulcer, pressure ulcers, wounds from dystrophic epidermolysis bullosa among others.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A6248 "Hydrogel dressing, wound filler, gel, per fluid ounce," describes KeragelT®.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A6248 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A6248 apply to this product, if covered. The current average fee schedule amount for A6248 is $19.99.

The average fee schedule amount is the average of the 2022 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 = 35

Agenda Item # 8
Crus Med - HCP220705RM6W4

Topic/Issue

Request to establish a new HCPCS Level II code to identify Crus Med.

Applicant's suggested language: XXXXX, “Ready for use slip-on bandage, for the lower leg”

Applicant’s Summary

Pedilay® Care Inc. submitted a request to establish a new HCPCS Level II code to identify Crus Med. Crus Med is class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. According to the applicant, Crus Med is a new and innovative secondary slip-on bandage, ready for use for the lower leg. This ready to use bandage for the lower leg, covers it from the ankle up to below the knee, provides protection of primary wound care dressing, by covering and fixating the dressing. It has an easy application and removal, by stretching over the foot to the ankle and by employing intuitive fastening tabs without employing scissors and tape. According to the applicant, Crus Med is significantly different from other secondary or tertiary bandaging systems and corresponding application methods used for the same treatments, e.g. venous leg ulcer, surgical wounds, burns etc. It is a ready for use slip-on bandage, with a fast, simple and secure application, that does not require wrapping or fixation. It is not properly described by width or by length, it is preformed to the shape of the body. According to the applicant, current codes are inadequate to reflect this unique characteristic and/or the cost of the product. This difference translates into functional superiority with regard to application (there is no need to wrap the bandage or to secure it, no judgment is required about how tightly to wrap or how to apply smoothly to the body), removal or replacement, and security (there is a diminished chance of the bandage being accidently dislodged or loosened during use).

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4461, “Surgical dressing holder, non-reusable, each,” describes Crus Med Bandage. We have no evidence or information that would enable us to determine that the Crus Med Bandage is functionally superior to other surgical dressing holders classified under A4461. We welcome the applicant to submit any clinical studies that demonstrate such comparison and distinction.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4461 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4461 apply to this product, if covered. The current average fee schedule amount for A4461 is $4.06.

The average fee schedule amount is the average of the 2022 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 = 35

Agenda Item # 8
Pedilay® Med- HCP22070547EEV

Topic/Issue

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

Applicant's suggested language: XXXXX, "Ready for use slip-on bandage, for foot & ankle"

Applicant's Summary

Pedilay® Care Inc. submitted a request to establish a new HCPCS Level II code to identify Pedilay® Med. Pedilay® Med is class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. According to the applicant, Pedilay® Med is a new and innovative secondary slip-on bandage, ready for use for the foot and ankle. This is ready to use foot bandage that encloses the foot up to the ankle, provides protection of primary wound care dressing, by covering and fixating the dressing. It has an easy application and removal, by stretching over the heel and by employing intuitive fastening tabs without employing scissors and tape. According to the applicant, Pedilay® Med is significantly different from other secondary or tertiary bandaging systems and corresponding application methods used for the same treatments, e.g. diabetic foot ulcer. It is a ready for use slip-on bandage, with a fast, simple and secure application, that does not require wrapping or fixation. Pedilay® Med is not properly described by width or by length, it is preformed to the shape of the body. According to the applicant, current codes are inadequate to reflect this unique characteristic and/or the cost of the product. This difference translates into functional superiority with regard to application (there is no need to wrap the bandage or to secure it, no judgment is required about how tightly to wrap or how to apply smoothly to the body), removal or replacement, and security (there is a diminished chance of the bandage being accidently dislodged or loosened during use).

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4461, "Surgical dressing holder, non-reusable, each," describes Pedilay® Med Bandage. We have no evidence or information that would enable us to determine that the Crus Med Bandage is functionally superior to other surgical dressing holders classified under A4461. We welcome the applicant to submit any clinical studies that demonstrate such comparison and distinction.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A4461 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4461 apply to this product, if covered. The current average fee schedule amount for A4461 is $4.06.

The average fee schedule amount is the average of the 2022 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 = 35

Agenda Item # 9
MariGen Shield- HCP220630YGVWG

Topic/Issue

Request to establish a new HCPCS Level II code to identify MariGen Shield.

Applicant's suggested language: Q4XXX, "MariGen Shield, per sq cm"

Applicant's Summary

Kerecis submitted a request to establish a new HCPCS Level II code to identify MariGen Shield. MariGen Shield received the Food and Drug Administration's (FDA's) 510(k) clearance on June 29, 2022. MariGen Shield is a bilayer of processed resorbable acellular fish dermal matrix skin substitute adhered to a thin, transparent, porous, soft silicone layer. MariGen Shield is composed of a fish dermal matrix layer which is approximately 1 mm in thickness and is porous. The silicone layer is a transparent polyurethane film single-coated with soft, medical grade silicone that is attached to the scaly side of the fish dermal matrix. The silicone layer is porous, soft and conformable to the wound surface. The silicone layer can be peeled off as the fish dermal matrix is resorbed. MariGen Shield is indicated for the management of wounds such as partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds (abrasions, lacerations, partial-thickness burns, skin tears), surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), draining wounds. The product is individually packaged in various sizes and dosed equally to the wound size in centimeters. The fish skin layer is made from wild-caught Atlantic Cod that is minimally processed in order to preserve the natural proteins and structure of the fish skin. The silicone acts to protect the fish dermal matrix layer and is intended to ease the application of the device.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Kerecis omega3 marigen shield, per square centimeter"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 10
AC5® Advanced Wound System - HCP220629RD4XM

Topic/Issue

Request to establish a new HCPCS Level II code to identify AC5® Advanced Wound System.

Applicant's suggested language: XXXXX, "AC5 Advanced Wound System (AC5)"

Applicant's Summary

Arch Therapeutics, Inc. submitted a request to establish a new HCPCS Level II code to identify AC5® Advanced Wound System. AC5® Topical Gel received the Food and Drug Administration's (FDA's) 510(k) clearance on December 14, 2018. A subsequent 510(k) was issued on March 11, 2020 (to add an additional manufacturing process and manufacturer). AC5® is a self-assembling wound care matrix that provides clinicians with multi-modal support and utility across all phases of wound healing. AC5® is made up of biocompatible and resorbable peptides that self-assemble into a nanofiber network which resembles the construct of the extracellular matrix. This self-assembly is a rearrangement of peptide units into a series of higher ordered nanofibril and nanofiber structures, culminating in an entangled network that creates a physical barrier to mitigate contamination and help modulate inflammation. The extracellular matrix-mimicking scaffold provides an environment conducive to cellular migration and soft tissue regeneration within the wound bed. AC5® Advanced Wound System is supplied as a powder that is hydrated at the point of care to form a 3-dimensional wound conforming matrix that allows for full wound contact. AC5® is provided as a kit that includes: 1 x 3 mL syringe with Luer-Lok tip, 1 x vial of lyophilized peptide, 1 x vial of Sterile Water for Injection, USP 2 x 18-gauge, 1.5 inch needles, 1 x 18-gauge 1.5 inch blunt fill needles, 2 x Alcohol Prep pad wipes. AC5® peptide is sterilized by gamma irradiation. All other components of AC5® are sterile and packaged into a kit in a controlled environment. Each kit is for single patient use only and may be used on wounds between 20-25 square centimeters.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Ac5 advanced wound system (ac5)"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 11
NeoMatriX Wound Matrix - HCP220627LXLYC

Topic/Issue

Request to establish a new HCPCS Level II code to identify NeoMatriX Wound Matrix.

Applicant's suggested language: AXXXX, "NeoMatriX, per square centimeter"

Applicant's Summary

NeXtGen Biologics submitted a request to establish a new HCPCS Level II code to identify NeoMatriX Wound Matrix. NeoMatriX Wound Matrix is a single-use, medical device composed of acellular axolotl dermal extracellular matrix intended to support wound healing for chronic and hard-to-heal wounds. NeoMatriX Wound Matrix received the Food and Drug Administration's (FDA's) 510(k) clearance on October 7, 2021. The device is derived from farm raised hybrid amphibian variants sourced from a closed herd in a dedicated facility. NeoMatriX Wound Matrix is intended for use in the management of wounds, including partial- and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor site/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds, (abrasions, lacerations, second-degree burns and skin tears), and draining wounds. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product will fully resorb and does not have to be removed. NeoMatriX Wound Matrix is supplied terminally sterile, in a single-use package, and in a variety of sizes.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Neomatrix, per square centimeter"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 12
OWYN - HCP220629C4ABF

Topic/Issue

Request to revise existing HCPCS Level II code B4150 “Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit” to identify OWYN.

Applicant's suggested language: B4150, “Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit” together with modifier BO “administered orally and not by a feeding tube”

Applicant’s Summary

Only What You Need, Inc. submitted a request to revise existing HCPCS Level II code B4150 “Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit” to identify OWYN. The OWYN Complete Nutrition Shake is a plant base nutritionally balanced oral formula with nutrient-dense calories and includes protein, carbohydrate, fat, vitamins and minerals. Each shake provides 300 calories, 20 grams of protein, 31 grams of carbohydrates, 3 grams of fiber, 10 grams of fat (9 grams of healthy fat), and 23 vitamins and minerals. These shakes are intended for the nutrition management of patients with inadequate nutrient intake, malnutrition, risk of malnutrition associated with cancer, gastrointestinal disease, surgical recovery, chronic and acute illness, and food allergies. It is to be consumed orally a few times per day. The device is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to revise existing HCPCS Level II code B4150. Medicare covers enteral nutritional therapy administered through feeding tubes under the prosthetic device benefit, with the feeding tube being the prosthetic device. Medicare does not cover oral nutrition since this is not a prosthetic device and there are no other DMEPOS benefit categories for these items. In addition, we are not aware of other payers that would have a need for a code with the suggested language.

Agenda Item # 13
Injectable Immunotherapies - HCP220705DHHCU

Topic/Issue

Request to revise an existing HCPCS Level II code S9562, “Home injectable therapy, palivizumab, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem” to replace palivizumab with immunotherapies.

Applicant's suggested language: S9562, “Home injectable therapy, immunotherapy, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem”

Applicant’s Summary

National Home Infusion Association submitted a request to revise existing HCPCS Level II code S9562 to replace “palivizumab” with “immunotherapies”. The applicant commented the code should be revised so that it can be used for a growing number of Food and Drug Administration (FDA) approved injectable therapies. According to applicant, at the time the code was created, 20 years ago, palivizumab was the only injectable immunotherapy administered in the home. Since then the FDA has approved additional injectable immunotherapies that are commonly administered in the home. The applicant requested that the description for S9562 be changed to “home injectable therapy, immunotherapy, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem.” According to the applicant, this change would be consistent with the other home infusion therapy S-codes, which are based on therapy type, not a specific drug.

CMS Preliminary HCPCS Coding Recommendation

CMS has been notified by the applicant that the claims volume submitted by non-Medicare payers under the not otherwise classified (NOC) codes for home injectable immunotherapies indicates further coding distinction is appropriate. In light of the developing RSV pediatrics issue, we want to continue to allow for differential code. As such, CMS will establish new HCPCS Level II code SXXXX, “Home injectable therapy, immunotherapy, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem”.

Agenda Item # 14
Shoulder Pacemaker™ - HCP220705H21VT

Topic/Issue

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

Applicant's suggested language: EXXXX, "Motion Activated Neuromuscular Stimulator, Dynamic Transcutaneous Stimulation of Nerve and Muscle Groups, Any Joint, Entire System"

Applicant's Summary

Alyve Medical Inc. submitted a request to establish a new HCPCS Level II code to identify the Shoulder Pacemaker™ device. According to the applicant, Shoulder Pacemaker™ is a therapeutic Motion Activated Stimulation (MAS) device that employs advanced sensor technology, coupled with neuromuscular electrical stimulation to aid patients in recalibrating complex muscle movements in order to restore optimal joint motion and function. The system includes the operating console that is worn on a patients arm by use of a band strapped around the upper arm, lead wires attached to the console with electrodes at the other end that are placed on the patient over areas targeted for treatment, and a tablet-based app that controls the device, guides the patient through the prescribed therapeutic treatment regimen, tracks patient progress over time and conveys the results of a patient's treatment to the health care professional (HCP) overseeing their treatment. According to the applicant, the Shoulder Pacemaker™ is the first device introduced to the market that employs MAS. Shoulder Pacemaker™ received the Food and Drug Administration's (FDA's) 510(k) clearance on August 24, 2021. According to applicant, the use, operation, mechanism of action and resulting therapeutic treatment are different from existing devices classified either as Neuromuscular Electrical Stimulators (E0745) or Functional Electrical Stimulators (E0770). The intelligent components of the device and companion app provide dynamic stimulation the timing and intensity of which is specific to each individual movement by the patient during each individual therapeutic exercise repetition completed in each treatment session. The device and app also provide tri-modal biofeedback (sensory, auditory and visual) to the patient during execution of each exercise movement as well as collect and report data on the patient's progress through assigned treatment programs to both the patient and the attending HCP. According to the applicant, there is no current code category that describes such a device. According to the Shoulder Pacemaker's™ User Manual, Home Version, the expected lifespan of the Shoulder Pacemaker™ device is two years.

CMS Preliminary HCPCS Coding Recommendation

CMS believes the mechanism of action of the Shoulder Pacemaker™ aligns with other neuromuscular electrical stimulation devices. However, the issue of whether the device has a lifetime of at least 3 years is still in question. The manufacturer initially stated in the application to CMS that the device has an expected lifetime of 3 years. However, the Shoulder Pacemaker's™ User Manual, Home Version, attached as supporting documentation by the applicant, states the expected lifespan of the Shoulder Pacemaker™ device is two years. There are many ways to demonstrate lifetime durability of an entire device to CMS. For example, the manufacturer can provide standardized test results from an independent testing laboratory demonstrating that the device itself can last for at least 3 years. If the

lifetime of the Shoulder Pacemaker™ is less than 3 years, then existing code A9270, “Non-covered item or service” is available for Medicare. If the manufacturer can demonstrate lifetime durability of 3 years or more, we would likely determine that the product is described by existing code E0745, “Neuromuscular stimulator, electronic shock unit”. CMS seeks further clarification from the manufacturer.

Appendix: DMEPOS Payment Categories

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

Pricing = 00 Service Not Separately Priced

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

Pricing = 31 Frequently Serviced Items

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

Pricing = 32 Inexpensive and Other Routinely Purchased Items

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

Pricing = 33 Oxygen and Oxygen Equipment

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

Pricing = 34 Supplies Necessary for the Effective Use of DME

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

Pricing = 35 Surgical Dressings

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

Pricing = 36 Capped Rental Items

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

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

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

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

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

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