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 2023 Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda

Zoom Meeting, for remote participation
Wednesday, May 31, 2023 9:00 am – 5:00 pm, eastern time (ET)

8:45 am, ET:
• Zoom meeting login:
https://cms.zoomgov.com/webinar/register/WN_r_Xpc62cSt-p9CdWjBYhhA
• 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 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 August 2023 and will be effective October 1, 2023, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Wednesday, May 31, 2023. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

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Preliminary decisions for the HCPCS Virtual Public Meeting on May 31, 2023.[1]

[1] Revised agenda on May 16, 2023 to remove HCPCS Level II application, HCP230103DWLJF, which will no long be considered in the B1 2023 cycle.

Agenda Item #1
Self-Measured Blood Pressure (SMBP) Devices - IHC221222X2AHC

Topic/Issue

Request for benefit category determination for self-measured blood pressure (SMBP) devices.

Applicant's Summary

The American Heart Association (AHA) and American Medical Association (AMA) submitted a combined request for a Benefit Category Determination of the use of self-measured blood pressure (SMBP) devices. Use of SMBP devices is an evidence-based intervention to help patients with hypertension achieve and maintain blood pressure (BP) control. SMBP devices are used by patients in their homes to monitor their BP. Understanding where their BP is in relation to their target BP level enables patients to adjust their behavior to lower their BP. The information also helps patients understand when they need to communicate with their physician about adjusting medications. According to the applicant, SMBPs should be classified by CMS as durable medical equipment (DME). Hypertension is the number one chronic condition of Medicare beneficiaries. Monitoring BP at home using a SMBP device is a key component in managing hypertension. When SMBP devices are used to manage hypertension there is evidence to support improved medication adherence, reduction in BP and improved BP. SMBP devices calculate systolic (top) and diastolic (bottom) BP values and provide patients with a digital display of their BP readings. The devices include an adjustable cuff that wraps around the patient's upper arm. A variety of cuff sizes are available to ensure accuracy. There are two main types of SMBP devices: manual and automatic. Manual SMBP devices consist of a cuff, an inflation bulb and a gauge that is read by looking at a pointer on the dial. Manual BP monitors require the use of a stethoscope to listen to the blood pulsing through the artery. Due to the training and skill required to accurately measure BP with manual SMBP devices, they are not recommended for home use. Automatic BP monitors have upper arm cuffs that automatically inflate, deflate, and calculate a patient's BP. The SMBP device's screen displays a digital readout of the patient's BP. The devices are available for purchase directly from device manufacturers through retail stores such as CVS, Walgreens, Walmart, and Costco, as well as online marketplaces like Amazon. SMBP devices may be equipped with one or more types of connectivity functions to transfer or store BP readings. These functions include WiFi, Bluetooth, or cellular connectivity. The devices can also vary in terms of the number of BP readings that can be stored on the device, as well as software compatibility with patient or clinic-level management software to compile and analyze BP readings and trends.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

1. Can withstand repeated use.

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

All five of these conditions must be met in order for equipment to be classified as DME. With respect to the third condition the item must be useful to a person for the treatment of an illness or injury, and be expected to make a meaningful contribution to the treatment of the individual's illness or injury. It is our understanding that SMBPs, when generally used in the home, are used to monitor BP and to report results to the clinician to determine the course of treatment. 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. For example, the SPEAC® System, which is not DME, is a recording and monitoring system in which the physician receives a summary report to help with clinical decisions. Items that are DME are used by the patient in the home for therapeutic and self-management purposes. SMBPs are generally not used by the patient to self-manage hypertension, but rather require clinical intervention to manage their medical condition, which is the basis for our determination.

The applicants suggested that SMBPs are comparable to glucose monitoring devices because they both provide information for patients and their physicians to take actions based on the readings. We do not agree that they are comparable. Section 1861(n) of the Social Security Act specifically states that glucose monitors are DME. Glucose monitors are home monitoring devices in which the patient immediately self-manages their medical condition in the home based on the readings from the monitor. They do not need to rely on their physician to determine a course of action.

However, we recognize the benefits to improving care in the home. To the degree that there is well accepted medical practice in which SMBPs are used in the home in a way that is similar to the use of glucose monitors to affect treatment actions by the patient, and the FDA has approved this specific use/indication as safe and effective, CMS would be interested in receiving information about those circumstances to information our final determination.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item #2
Myriad Matrix™ - HCP230103Q66RU

Topic/Issue

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

Applicant's suggested language: QXXXX, "Myriad Matrix, per square centimeter"

Summary of Applicant's Submission

Aroa Biosurgery Limited submitted a request to establish a new HCPCS Level II code to identify Myriad Matrix™. Myriad Matrix™ is an advanced extracellular matrix (ECM) scaffold derived from Ovine (sheep) forestomach tissue. This advanced ECM scaffold is a non-reconstituted collagen; thus, it retains the innate biological structure and function of the native ECM associated macromolecules, including elastin, fibronectin, glycosaminoglycans and laminin. Myriad Matrix™ is a bioengineered scaffold derived from Ovine (sheep) forestomach tissue. Myriad Matrix™ absorbs cells, blood, and blood components into the matrix to form a reservoir. Fibroblast, endothelial and immune cells infiltrate the entire matrix and build new tissue. Overtime, Myriad Matrix™ is then completely replaced by the patient's own tissue. According to the applicant, there is no unique HCPCS code assigned to Myriad Matrix™ that properly identifies its dual indications for use in both soft tissue reinforcement and wound care management. According to the applicant, currently, providers are limited to using Q4100, (skin substitute, not otherwise specified) resulting in delayed claims processing, and the inability to specifically report the product being used for treatment. Myriad Matrix™ is indicated for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery, or for management of the following wounds: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, draining wounds. Myriad Matrix™ contain the natural porous structure of AROA ECM™, engineered with interstitial perforations to enable cell infiltration to facilitate rapid healing. Myriad Matrix™ is available in a range of sizes, up to 400 sq cm. Myriad Matrix™ is "delivered" via cutaneous application, or soft tissue implantation, and is packaged as a terminally sterilized single use graft. According to the applicant, the Myriad device manufactured by Aroa Biosurgery Ltd. is cleared in for use in plastic and reconstructive surgery under 510(k) (K162461, decided upon on 12/20/2016) under the name Endoform Plastic and Reconstructive Matrix, and in dermal application under 510(k) (K171231, decided upon 6/14/2017) under the name Endoform Topical Matrix. Per the applicant, the aforementioned devices are identical, and have been branded as a single device under the name Myriad Matrix and labelled in accordance with both clearances.

CMS Preliminary HCPCS Coding Decision

CMS could not identify information in the application confirming that Endoform Plastic and Reconstructive Matrix and Endoform Topical Matrix are identical products to be branded as a single device called "Myriad Matrix™". The Endoform Plastic and Reconstructive Matrix and Endoform Topical Matrix have received separate 510(k) clearances from the Food and Drug Administration (FDA), which were included as part of the HCPCS Level II application. CMS would expect Myriad Matrix™ to receive similar clearance from the FDA. As a result, CMS is unable to establish a new HCPCS Level II code for Myriad Matrix™.

Agenda Item #3
InnovaBurn® and InnovaMatrix® XL - HCP230103KC768

Topic/Issue

Request to establish a new HCPCS Level II code to identify InnovaBurn® and InnovaMatrix® XL.

Applicant's suggested language: AXXXX, "InnovaBurn or InnovaMatrix XL, per square centimeter"

Summary of Applicant's Submission

Convatec Triad Life Sciences, LLC submitted a request to establish a new HCPCS Level II code to identify InnovaBurn® and InnovaMatrix® XL. InnovaBurn® received the Food and Drug Administration's (FDA) 510(k) clearance on September 29, 2022. InnovaMatrix® XL received the FDA's 510(k) clearance on October 21, 2020. According to the applicant, InnovaBurn® will also have the commercial name InnovaMatrix® XL. InnovaBurn® is a sterile, single-use, medical device consisting of extracellular matrix derived from porcine placental material used for safe and effective wound treatment. InnovaBurn® and InnovaMatrix® XL are composed of collagen, elastin, laminin, fibronectin, hyaluronic acid, and sulfated glycosaminoglycans and is produced in sheet form in a variety of sizes. This biodegradable wound matrix provides a protective cover to the wound. InnovaBurn® and InnovaMatrix® XL are 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, and skin tears), partial-thickness second degree burns, and draining wounds. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product fully resorbs and does not have to be removed. InnovaBurn® and InnovaMatrix® XL are supplied terminally sterile, in a single use package, and in a variety of sizes up to 400 square centimeters.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Innovaburn or innovamatrix xl, 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 #3
InnovaMatrix® PD - HCP230103W0Q0W

Topic/Issue

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

Applicant's suggested language: AXXXX, “InnovaMatrix PD, 1 mg”

Summary of Applicant’s Submission

Convatec Triad Life Sciences, LLC submitted a request to establish a new HCPCS Level II code to identify InnovaMatrix® PD. InnovaMatrix® PD received the Food and Drug Administration’s 510(k) clearance on September 28, 2022. InnovaMatrix® PD is a sterile, single use, medical device consisting of extracellular matrix derived from porcine placental material used for safe and effective wound treatment. InnovaMatrix® PD is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans and is produced in particulate form in a variety of sizes. This biodegradable wound matrix provides a protective cover to the wound. InnovaMatrix® PD 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, and skin tears), draining wounds, and partial-thickness second-degree burns. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product fully resorbs and does not have to be removed. InnovaMatrix® PD is supplied terminally sterile, in a single use package, and in a variety of sizes up to 500 mg.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, “Innovamatrix pd, 1 mg”

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 #4
Resolve Matrix™ - HCP22121960DPF

Topic/Issue

Request to establish a new HCPCS Level II code to identify Resolve Matrix™ acellular peritoneum.

Applicant's suggested language: XXXXX, "Resolve matrix acellular peritoneum matrix (resolve matrix), 1 sq. cm"

Summary of Applicant's Submission

Parametrics Medical submitted a request to establish a new HCPCS Level II code to identify Resolve Matrix™ acellular peritoneum matrix (Resolve Matrix™). Meso Wound Matrix™ (now Resolve Matrix™) received the Food and Drug Administration's (FDA's) 510(k) clearance on February 10, 2012. According to the applicant, Meso Wound Matrix™ is not and will not be sold under the brand name Meso Wound Matrix™. In early 2022, Parametrics Medical engaged with DSM Biomedical regarding commercializing of the product and has since launch the product under the brand name "Resolve Matrix™." Resolve Matrix™ is a thin, flexible, yet strong acellular biologic dermal substitute which acts to support the body's own regenerative tissue repair process during wound healing. According to the applicant, it is uniquely derived from porcine peritoneum membrane and processed using the optrix tissue cleansing methodology. Resolve Matrix™ is indicated for the management of topical wounds, including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds, trauma wounds, draining wounds, and tunneled or undermined wounds. Resolve Matrix™ has a nominal thickness of ±0.3mm and is supplied in multiple sizes. Parametrics Medical is a licensed distributor for Resolve Matrix™, which is manufactured by DSM Biomedical.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Resolve matrix, 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 #5
Miro3D Wound Matrix - HCP220926BGPQ3

Topic/Issue

Request to establish a new HCPCS Level II code to identify Miro3D wound matrix.

Applicant's suggested language: QXXXX, "Miro3D, per cubed centimeter"

Summary of Applicant's Submission

Reprise Biomedical, Inc. submitted a request to establish a new HCPCS Level II code to identify Miro3D wound matrix. Miro3D received the Food and Drug Administration's (FDA's) 510(k) clearance on August 18, 2022. Miro3D wound matrix is a single use, sterile, porcine-derived non-crosslinked acellular collagen matrix. Miro3D is a porous scaffold, which provides a protective environment for wound management. The device is made by drying perfusion decellularized porcine liver in ambient air, cutting the resulting sponge-like scaffold into four defined sizes. Package is dry in a Polyethylene terephthalate glycol plastic tray with a snap-on lid and sealed Tyvek® lid. The unique three-dimensional shape of Miro3D has potential benefits to apply to deep, tunneling, and irregular wound beds, which may otherwise require multiple layers of other products/treatments or surgical treatment with full-thickness skin grafts. According to the applicant, existing HCPCS Level II codes do not adequately describe Miro3D, especially since Miro3D is measured by cubic cm. Applicant also stated that currently, providers must utilize HCPCS Q4100, "Skin substitute, not otherwise specified", which results in delayed claims processing, additional documentation, and the inability for providers to specifically report which product is being used for treatment. Miro3D is offered in four sizes, all 2cm in thickness which include: 2cm x 2cm x 2cm, 3cm x 3cm x 2cm, 5cm x 5cm x 2cm, and 5cm x 10cm x 2cm.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Miro3d, per square centimeter"

Reprise Medical's instruction for use indicates that Miro3D is hydrated and rehydrated in sterile saline or lactated Ringer's solution prior to use. The device is packaged dry, terminally sterilized in its packaging and is rehydrated with sterile saline or lactated Ringer's solution prior to use. Miro3D wound matrix can be cut to fit a wound size prior to rehydration or application.

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 #6
MuGard™ Oral Mucoadhesive Hydrogel, Single Use - HCP230104E2DY0

Topic/Issue

Request to establish a new HCPCS Level II code to identify Mugard™ Oral Mucoadhesive Liquid Hydrogel.

Applicant's suggested language: XXXXX, "Mugard Oral Mucoadhesive Liquid Hydrogel with or w/o drug/biologic, Single Use (10 mL, Non-Substitutable)"

Summary of Applicant's Submission

Soleva Pharmaceuticals, LLC submitted a request to establish a new HCPCS Level II code to identify MuGard™ Oral Mucoadhesive Hydrogel. Mugard™ received the Food and Drug Administration's (FDA's) 510(k) clearance on December 11, 2006. MuGard™ is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. The mucoadhesive polymers in the hydrogel formulation adhere to the oral mucosa and form a protective coating. Dosage and route of administration is to swish 5 to 10 mL of oral liquid every 4 to 6 hours. It may be swallowed or expelled. For the management of oral mucositis/stomatitis, it is recommended that MuGard™ is used 4–6 times a day. For other ulcerative conditions of the oral cavity, MuGard™ should be used 4–6 times a day or as needed. MuGard™ Oral Mucoadhesive is available in a 10 mL single dose unit and a multiple use, 240 mL bottle with dosage cup.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Oral mucoadhesive, any type (liquid, gel, paste, etc.), per 1 ml"

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category

Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations are covered under Section 1861(s)(5) of the Act. The Medicare definition for surgical dressings is located in section 100 of the Medicare Benefit Policy Manual (CMS 100-02).

Surgical dressings are limited to primary and secondary dressings required for the treatment of a wound. Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered.

The Surgical Dressing benefit limits coverage to wounds of the skin. Treatments used for injuries to the oral mucosa are not eligible for coverage under this benefit as oral mucosa is not skin. It is a different tissue type and thus is excluded from this benefit.

Although these products may serve a beneficial purpose in the treatment of oral mucosal injuries, there is no coverage available under the Surgical Dressings benefit for these items. This item would not fall under any other DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item #6
MuGard™ Oral Mucoadhesive Hydrogel, Multiple Use - HCP2301044RWA8

Topic/Issue

Request to establish a new HCPCS Level II code to identify Mugard™ Oral Mucoadhesive Liquid Hydrogel.

Applicant's suggested language: XXXXX, "Mugard Oral Mucoadhesive Liquid Hydrogel with or w/o drug/biologic, Multiple Use (240 mL, Non-Substitutable)"

Summary of Applicant's Submission

Soleva Pharmaceuticals, LLC submitted a request to establish a new HCPCS Level II code to identify MuGard™ Oral Mucoadhesive Hydrogel. Mugard™ received the Food and Drug Administration's (FDA's) 510(k) clearance on December 11, 2006. MuGard™ is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. The mucoadhesive polymers in the hydrogel formulation adhere to the oral mucosa and form a protective coating. Dosage and route of administration is to swish 5 to 10 mL of oral liquid every 4 to 6 hours, it may be swallowed or expelled. For the management of oral mucositis/stomatitis, it is recommended that MuGard™ is used 4–6 times a day. For other ulcerative conditions of the oral cavity, MuGard™ should be used 4–6 times a day or as needed. MuGard™ Oral Mucoadhesive is available in a 10 mL single dose unit and a multiple use, 240 mL bottle with dosage cup.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Oral mucoadhesive, any type (liquid, gel, paste, etc.), per 1 ml"

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category

Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations are covered under Section 1861(s)(5) of the Social Security Act (the Act). The Medicare definition for surgical dressings is located in section 100 of the Medicare Benefit Policy Manual (CMS 100-02).

Surgical dressings are limited to primary and secondary dressings required for the treatment of a wound. Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered.

The Surgical Dressing benefit limits coverage to wounds of the skin. Treatments used for injuries to the oral mucosa are not eligible for coverage under this benefit as oral mucosa is not skin. It is a different tissue type and thus is excluded from this benefit.

Although these products may serve a beneficial purpose in the treatment of oral mucosal injuries, there is no coverage available under the Surgical Dressings benefit for these items. This item would not fall under any other DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item #7
Venowave VW5 and Supplies - HCP220922Q7MR0

Topic/Issue

Request to establish two new HCPCS Level II codes to identify Venowave VW5 and supplies.

Applicant's suggested language:

1. XXXXX, "Peristalsis; non-pneumatic compression pump, limb, mobile"

2. XXXXX, "Peristalsis; non-pneumatic compression wrap, limb, mobile"

Summary of Applicant's Submission

Venowave Inc. submitted a request to establish a new HCPCS Level II code to identify Venowave VW5. Venowave VW5 received the Food and Drug Administration's (FDA's) 510(k) clearance on March 7, 2008. The Venowave VW5 is a series of compact, battery-operated peristaltic pumps that generate a wave-form motion, and when worn below the knee strapped firmly to the calf, result in compression of the calf and consequently an increased upward volumetric displacement of venous and lymph fluid. According to the applicant, the Venowave VW5 series induces improved vascular and lymphatic flow of the lower limbs. According to the applicant, current existing HCPCS Level II codes are for pneumatic or for non-pneumatic sequential with gradient compression devices and are not appropriate for the Venowave VW5 to be billed. The Venowave VW5 generates a mechanical wave which starts at the lower pivot point and travels to the upper pivot point, a distance of 14cm (wavelength) traveled for each cycle of the crank. The swept volume or volume of blood or lymph fluid displaced upwards for each cycle is the product of the wavelength (14cm), the width of the wave sheet (7.5cm) and the depth of the wave (0.95cm) or approximately 0.1 L/cycle. Operating by way of a single rechargeable 1.5 V NiMh AA battery, this single-patient use device enables the user to receive treatment anywhere, while remaining active. Indications for use as approved by the FDA are the following: management of the symptoms of post thrombotic syndrome (PTS), prevention of deep vein thrombosis (DVT), prevention of primary thrombosis, treatment of lymphedema, diminishing post-operative pain and swelling, treatment of leg swelling due to vascular insufficiency, treatment of varicose veins, treatment of chronic venous insufficiency, enhancing blood circulation, and treatment of intermittent claudication.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E0676, "Intermittent limb compression device (includes all accessories), not otherwise specified" describes Venowave VW5. For HCPCS Level II code E0676, discontinue Berenson-Eggers Type of Service (BETOS) D1E, "Other DME" and apply BETOS Z2, "Undefined"

At this time, the clinical information provided with this application does not support the claim of significant therapeutic distinction that would warrant a new HCPCS Level II code when the Venowave is used in comparison to other intermittent limb compression devices

that share a code category. In addition, no clinical published studies were provided in support of Venowave's effect on lymphedema.

However, additional information could be provided in which CMS may consider to inform whether to create a new code to describe Venowave. Accordingly, we are interested in gaining a better understanding of how the Venowave is distinguishable from other products on the market. Specifically, whether and exactly how the difference in design from other intermittent limb compression devices confers a different function and/or a significant therapeutic distinction when compared with the use of other products on the market. Also, what are the additional therapeutic advantages and capabilities that are not provided or available through traditional pneumatic device formats that are provided by Venowave. Clinical studies that demonstrate such comparison and distinction would be welcome.

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category

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

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

All five of these conditions must be met in order for equipment to be classified as DME.

Venowave is a is a single-patient use item and therefore would not fall under a DMEPOS benefit category. In both the HCPCS and 510K[5] application for FDA the applicant indicates that Venowave is "Operating by way of a single rechargeable 1.5 V NiMh AA battery, this single-patient use device enables the user to receive treatment anywhere, while remaining active."

Lymphedema is a chronic medical problem that involves an accumulation of lymphatic fluid in the extremities along with progressive and pathologic structural changes that arise from an ongoing inflammatory response produced by that fluid and its contents in the interstitial space. The goal of lymphedema treatment is to reduce the amount of retained lymphatic fluid in an extremity or tissue space. A key component of lymphedema treatment requires applying graded compression to the affected limb where higher pressure is applied distally to move fluid more proximally "down" a pressure gradient. We were unable to locate any studies using Venowave in the treatment of lymphedema or information that the device establishes the pressure gradient needed to treat lymphedema. There is a reference to the use of the device in a preliminary study of 10 patients, some of which had lymphedema. Unfortunately, we were unable to locate this study during a literature search. Nonetheless, this small sample size cannot be considered high certainty evidence. As such, we have not found any documented evidence to support the assertions that Venowave can effectively treat the symptoms of lymphedema. In light of the lymphedema compression treatment items benefit

passed under the Consolidated Appropriations Act of 2023 and effective January 1, 2024, we encourage Venowave Inc. to provide us with evidence, if available.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item #8
VIBRANT® System - HCP2212200H7AK

Topic/Issue

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

Applicant's suggested language: XXXXX, "Programable pod to activate the non-pharmacologic, orally ingested, recipient capsule, causing intracolonic peristalsis to induce bowel movements"

Summary of Applicant's Submission

Vibrant Gastro System submitted a request to establish a new HCPCS Level II code to identify VIBRANT® System. VIBRANT® System received the Food and Drug Administration's (FDA's) De Novo clearance on August 26, 2022. VIBRANT® System is prescribed for home use to relieve symptoms related to chronic idiopathic constipation (CIC). VIBRANT® System consists of a base unit (Pod) and a naïve capsule. The VIBRANT® Pod is pre-programmed via the Pod and can be monitored and altered by the physician to deliver a patient specific treatment. The naïve capsule is placed into the Pod then activated and calibrated to deliver CIC treatment. The Pod and naïve capsule are an integrated therapeutic solution. The Pod must activate the capsule to deliver the treatment. According to the applicant, the Pod has a useful life of at least 3 years. It is reprogrammed for use by other patients. The programmed capsule is an orally ingested, non-pharmacologic, capsule that is thought to induce mechanical stimulation via vibration of the colonic wall synced with the circadian rhythm of colonic contractile activity thereby increasing complete spontaneous bowel movements (CSBM). The Pod delivered program causes the synced capsule to initiate vibrations at a specific time and duration delivering the treatment in the colon planned by the physician, (using specific vibration mode of work proposed by VIBRANT®), then the capsule is naturally excreted. Dosage is 5 activated capsules weekly, packaged in 20-dose blister packs per month of use. As a supply item the Pod is a component of the therapeutic system. According to the applicant, the VIBRANT® System phase 3 randomized, placebo-controlled trial (RCT) led to the FDA De Novo clearance. Per the applicant, VIBRANT® System treatment efficacy and safety were validated in a phase 3, prospective, double-blind, placebo-RCT of patients with CIC who received blinded treatment once daily, five days a week for 8 weeks. The primary efficacy endpoints were an increase of at least one more CSBM per week (CSBM1 responder) or at least two more CSBMs per week (CSBM2) from baseline. Responder was defined as subject who had an improvement of CSBM1 or CSBM2 during at least 6 of the 8 weeks. Safety analyses were performed, and 904 patients were screened, 312 were enrolled meeting inclusion and exclusion criteria. A greater percentage of patients receiving the vibrating capsule achieved both primary efficacy endpoints compared to placebo (39.3% vs. 22.1%, p=0.001 CSBM1; and 22.7% vs. 11.4%, p=0.008 CSBM2). Patients had at least 14 years of CIC; of these 56% had severe CIC defined as 0 CSBM for 2 weeks at baseline. According to the applicant, significantly greater improvements in treatment were seen for the secondary endpoints of straining, stool consistency, and quality of life measures compared to placebo. Per the applicant, adverse events were mild, gastrointestinal in nature and similar between groups. A mild vibrating sensation was reported by 11% of patients in the vibrating capsule group, and no patients withdrew from the trial. According to the applicant, patient experience using the VIBRANT® System was favorable across all ages. According to the applicant, VIBRANT® System offers

a solution that is well tolerated, and helped treat patients 65 years old and over where 1/3 of them experience CIC.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Programmer for transient, orally ingested capsule, each"

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category

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

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

All five of these conditions must be met in order for equipment to be classified as DME.

When clarifying the meaning of "durable" in regulations (CMS-1577-F, November 10, 2011), we noted that a multi-component device may be a system consisting of durable and nondurable components that together serve a medical purpose (like the VIBRANT® System and VIBRANT® Capsule). As explained in that regulation, a multi-component device consisting of durable and non-durable components is considered non-durable if the component that performs the medically necessary function of the device (the VIBRANT® Capsule) is nondurable, even if other components that are part of the device are durable (the VIBRANT® System). Therefore, the VIBRANT® Capsule component of the multi-component device, which performs the medically necessary function of the device, needs to meet the 3-year minimum lifetime requirement and the requirement to withstand repeated use. As the VIBRANT® Capsule does not meet these requirements, the VIBRANT® System is not DME.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item #8
VIBRANT® Capsule - HCP221222CTE53

Topic/Issue

Request to establish a new HCPCS Level II code to identify VIBRANT®

Applicant's suggested language: XXXXX, "Pod programmed recipient capsule, produce intracolonic peristalsis to induce bowel movements"

Summary of Applicant's Submission

Vibrant Gastro Capsule submitted a request to establish a new HCPCS Level II code to identify VIBRANT® capsule. VIBRANT® received the Food and Drug Administration's (FDA's) De Novo clearance on August 26, 2022. The VIBRANT® solution includes an activated capsule as a medically necessary integrated component of the VIBRANT® System prescribed for home use to relieve symptoms related to chronic idiopathic constipation (CIC). As a naïve capsule it receives the therapeutic program from the VIBRANT® Pod. The capsule is now calibrated to deliver CIC treatment. It can be monitored and altered by the physician to deliver a patient-specific treatment. According to the applicant, the Pod has a useful life of at least 3 years. Once the capsule is used to provide the programmed treatment it is expelled from the body. The Pod can be reprogrammed for use by other patients. The programmed capsule is an orally ingested, non-pharmacologic, capsule that induces mechanical stimulation via vibration of the colonic wall synced with the circadian rhythm of colonic contractile activity thereby increasing complete spontaneous bowel movements (CSBM). The capsule received program from the Pod causes the synced capsule to initiate vibrations at a specific time and duration delivering the treatment in the colon planned by the physician, (using specific vibration mode created by Vibrant®), then the capsule is naturally excreted. Dosage is 5 activated capsules weekly, packaged in 20-dose blister packs per month of use. As a supply item the capsule is a component of the therapeutic system. According to the applicant, the capsule used in the VIBRANT® phase 3 double-blind randomized, placebo-controlled trial (RCT) led to the FDA De Novo clearance of the system inclusive of the capsule. According to the applicant, data reviewed by the FDA included the capsule's treatment efficacy and safety from a prospective phase 3 RCT of patients with CIC treated and those who received blinded placebo treatment once daily, five days a week for 8 weeks. The primary efficacy endpoints were an increase of at least one more CSBM per week (CSBM1 responder) or at least two more CSBMs per week (CSBM2) from baseline. Responder was defined as subjects who had an improvement of CSBM1 or CSBM2 during at least 6 of the 8 weeks. Safety analyses were performed, and 904 patients were screened, 312 were enrolled meeting inclusion and exclusion criteria. Per the applicant, a greater percentage of patients receiving the treatment from the capsule achieved both primary efficacy endpoints compared to placebo (39.3% vs. 22.1%, p=0.001 CSBM1; and 22.7% vs. 11.4%, p=0.008 CSBM2). Patients had at least 14 years of CIC; of these 56% had severe CIC defined as 0 CSBM for 2 weeks at baseline. According to the applicant, significantly greater improvements in treatment were seen for the secondary endpoints of straining, stool consistency, and quality of life measures compared to placebo. Per the applicant, adverse events were mild, gastrointestinal in nature and similar between groups. A mild vibrating sensation was reported by 11% of patients in the vibrating capsule group. According to the applicant, patient compliance was 90%, and patient experience using the VIBRANT® was

favorable across all ages. VIBRANT® offers a solution that is well tolerated, and helped treat patients 65 years old and over where 1/3 of them experience CIC.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Programable, transient, orally ingested capsule, for use with external programmer, each"

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category

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

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

All five of these conditions must be met in order for equipment to be classified as DME.

The VIBRANT® capsule is a one-time use item that provides direct mechanical stimulation of the intestines as part of VIBRANT's® multi-component system to treat chronic idiopathic constipation. The capsule cannot be used repeatedly and does not have a life of at least 3 years. Therefore, the VIBRANT® capsule does not the meet the definition of DME.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item #9
Luminopia - HCP221003J1TKP

Topic/Issue

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

Applicant's suggested language: AXXXX, "Software-only digital therapy for amblyopia with a billing unit of 30 days"

Summary of Applicant's Submission

Luminopia, Inc. submitted a request to establish a new HCPCS Level II code to identify Luminopia. Luminopia received the Food and Drug Administration's (FDA's) De Novo clearance on October 20, 2021, as a Class II device. According to the applicant, as part of the as part of the De Novo review process, the FDA determined that there is no legally marketed device substantially equivalent to it and that a new device type needed to be established. Per the applicant, Luminopia does not meet the definition of durable medical equipment. According to the applicant, a new unique A code is requested to facilitate reimbursement and avoid billing errors and delays. Luminopia, Inc. appreciates that CMS created the HCPCS Level II code A9291, but that code describes a cognitive or behavioral therapy. Luminopia is not a cognitive or behavioral therapy as it improves vision in amblyopia patients by presenting modified visual stimuli. Luminopia does not have any elements of cognitive or behavioral therapy. Luminopia is a software-only digital therapeutic designed to be used with commercially available Head-Mounted Displays (HMDs) which are compatible with the software application. Luminopia is indicated for improvement in visual acuity in amblyopia patients, aged 4-7 years old, associated with anisometropia and/or with mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eye-care professional. Luminopia is intended for both previously treated and untreated patients; however, patients with more than 12 months of prior treatment (other than refractive correction) have not been studied. Luminopia is intended to be used as an adjunct to full-time refractive correction, such as glasses, which should also be worn under the HMD during Luminopia therapy. Luminopia is intended for prescription use only, in an at-home environment. According to the applicant, therapeutic algorithms improve vision by breaking interocular suppression, encouraging amblyopic eye usage, and promoting binocular combination. They are applied to patient-selected video content in the same manner for every video. The algorithms reduce contrast to the stronger eye's input to break interocular suppression and encourage amblyopic eye usage. Additionally, parts of each eye's input are occluded by dichoptic masks superimposed over the video content to promote binocular combination. The masks rotate through predefined pairs over the course of treatment to treat the entire visual field. Patients undergo 1 hour of treatment per day, six days per week. Luminopia is self-administered in an at-home environment, under the supervision of a trained eye-care professional. Luminopia is a software-only digital therapeutic that is downloaded onto off-the-shelf hardware.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Prescription digital visual therapy, software-only, fda cleared, per course of treatment"

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category. Luminopia, Inc. indicated in its application that it supports this determination, stating that "Luminopia does not meet the definition of durable medical equipment."

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

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

All five of these conditions must be met in order for equipment to be classified as DME.

Software-only items (digital therapies and computer software) are not devices, equipment, or supplies and therefore would not fall under a DMEPOS benefit category. Whether or not the item could fall under some other Medicare benefit category can be considered, but would not be addressed under the DMEPOS benefit category determination process.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item #10
EndeavorRx® - HCP230103HDALU

Topic/Issue

Request to establish a new HCPCS Level II code to identify EndeavorRx®

Applicant's suggested language: AXXXX, "Prescription digital therapeutic (PDT) providing sensory stimuli and simultaneous motor challenges for neural attentional control, FDA-cleared, per course of treatment"

Summary of Applicant's Submission

Akili, Inc. submitted a request to establish a new HCPCS Level II code to identify EndeavorRx®. EndeavorRx® received the Food and Drug Administration's (FDA's) De Novo clearance on June 15, 2020. According to the applicant, this code would be for non-Medicare payers to accurately describe prescription digital therapeutics (PDTs) providing sensory stimuli and simultaneous motor challenges for neural attentional control, FDA-cleared, per course of treatment. Per the applicant, such a code will allow payers to implement appropriate coverage parameters consistent with the therapeutically distinct mechanism of action. EndeavorRx® is indicated to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type Attention-Deficit/Hyperactivity Disorder (ADHD), who have a demonstrated attention issue. Patients who engage with EndeavorRx® demonstrate improvements in a digitally assessed objective measure, Test of Variables of Attention (TOVA®), of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity. EndeavorRx® should be considered for use as part of a therapeutic program that may include clinician-directed therapy, cognitive behavioral therapy (CBT), medication, and/or educational programs. According to the applicant, the HCPCS Level II code A9291 does not describe EndeavorRx®, which embodies a mechanism of action therapeutically distinct from cognitive and/or behavioral therapy devices. EndeavorRx® is a PDT that provides sensory stimuli and simultaneous motor challenges for neural attentional control as distinguished from using a CBT mechanism of action. FDA recognized this distinction when it created a separate classification for EndeavorRx® from previously authorized PDTs for CBT. CBT is based on a set of static teaching principles and coping strategies; EndeavorRx® utilizes a proprietary technology that delivers dynamic and adaptive sensory stimuli and simultaneous motor challenges ("interference processing") designed to target attentional control systems to progressively develop new neurological capabilities relating to attentional control. Multiple clinical studies demonstrate that the EndeavorRx® treatment results in improvements in a range of clinically relevant ADHD outcome measures which complement earlier work showing that earlier prototypes result in significant changes in brain functioning in regions associated with attentional control. According to the applicant, categorizing EndeavorRx® as substantially equivalent to CBT devices may result in inappropriate expectations for treatment, clinical use, and the risks/benefits. Per the applicant, differentiating PDTs using the interference processing mechanism of action from PDTs delivering CBT will allow more clear and informed choices about treatment planning. According to the applicant, non-Medicare payers have a demonstrated need for a new HCPCS Level II code to facilitate efficient and accurate claims processing. According to the applicant, without a HCPCS Level II code to distinguish PDTs using the interference processing mechanism of action from PDTs delivering CBT described by HCPCS Level II

code A9291, commercial payers and Medicaid agencies must manually process claims which is an arduous, inefficient, and costly process.

CMS Preliminary HCPCS Coding Recommendation

This is a repeat application, previously submitted in B1 2022, application HCP220103YXJ32. Our prior determination was to revise existing HCPCS Level II code A9291, "Prescription digital behavioral therapy, fda cleared, per course of treatment," to instead read, "Prescription digital cognitive and/or behavioral therapy, fda cleared, per course of treatment." However, the applicant believes, and has stated that other payers agree, that their mechanism of action for EndeavorRx® is different then what is described by existing code A9291. CMS continues to believe that HCPCS Level II code A9291, as currently revised, describes EndeavorRx®. We welcome information from the applicant and other insurers to help us better understand what the mechanism of action is and how it is not cognitive and/ or behavioral therapy.

Medicare Benefit Category Determination

The applicant did not request a reconsideration of the benefit category. CMS has previously stated that digital therapies or computer software are not devices, equipment, or supplies and therefore would not fall under a DMEPOS benefit category.

Agenda Item #11
ACUVUE® OASYS MAX 1-Day Contact Lenses - HCP2301030122B

Topic/Issue

Request to establish two new HCPCS Level II codes to identify ACUVUE® OASYS MAX 1-Day Contact Lenses.

Applicant's suggested language: "Contact lens, hydrophilic, class 1 uv blocker with blue-violet filter > 50% per lens"

Summary of Applicant's Submission

Johnson and Johnson Vision Care, Inc. (JJV) submitted a request to establish a new HCPCS Level II code to identify ACUVUE® OASYS MAX 1-Day Contact Lenses. ACUVUE® OASYS MAX 1-Day received Food and Drug Administration's (FDA's) 510(k) clearance on March 26, 2021. ACUVUE® OASYS MAX 1- Day Contact Lenses indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are presbyopic and may be nearsighted (myopic) or farsighted (hyperopic) and may have 0.75D or less of astigmatism that does not interfere with visual acuity and block more than 50 percent of blue-violet light. According to the applicant, no existing HCPCS code identifies a contact lens with a blue-violet filter. JJV seeks a new code to use with national payers outside of the Medicare program. According to the applicant, ACUVUE® OASYS MAX 1-Day is a first-of-its-kind contact lens that combines a new patented HEV/blue-violet light filter with senofilcon A. ACUVUE® OASYS MAX 1-Day Contact Lenses are soft (hydrophilic) contact lenses available as spherical and multifocal lenses. These lenses are made of a silicone hydrogel material (senofilcon A) containing an internal wetting agent. A benzotriazole ultraviolet (UV) absorbing monomer is used to block UV radiation (280 nm – 380 nm) in combination with a novel fused tricyclic chromophore that also blocks UV radiation and partially filters high energy visible radiation (HEV) in the range of 380 nm to 450 nm. The light transmittance characteristics for these lenses are less than 1percent in the UVB range of 280 nm to 315 nm and 10% in the UVA range of 315 nm to 380 nm. The thinnest lenses transmit ≤ 45percent of the radiation in the range from 380 nm to 450 nm. Lenses with light transmittance of less than 10 percent UVA and less than 1% UVB are designated Class 1 UV blocking under the international organization for standards classification system recognized by FDA. wear for the correction of vision in people with non-diseased eyes who are nearsighted (myopic) or farsighted (hyperopic) and may have 1.00D or less of astigmatism that does not interfere with visual acuity.

CMS Preliminary HCPCS Coding Decision

Establish a new HCPCS Level II code VXXXX, "Contact lens, hydrophilic, spherical, with blue-violet filter, per lens"

Preliminary Medicare Benefit Category Determination

Prosthetic Device

Refractive lenses are covered when they are used to restore the vision normally provided by the natural lens of the eye of an individual lacking the organic lens because of surgical

removal or congenital absence. Covered diagnoses are limited to pseudophakia (condition in which the natural lens has been replaced with an artificial intraocular lens [IOL]), aphakia (condition in which the natural lens has been removed but there is no IOL), and congenital aphakia. Lenses provided for other diagnoses will be denied as noncovered. Coverage may be limited to one pair of eyeglasses or contact lenses. Because coverage of refractive lenses is based upon the Prosthetic Device benefit category, there is no coverage for frames or lens add-on codes unless there is a covered lens(es). Tinted lenses, including photochromatic lenses, used as sunglasses, which are prescribed in addition to regular prosthetic lenses to a pseudophakic beneficiary, will be denied as noncovered.

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 VXXXX is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS codes V2521 and V2744. The pricing comparative considers the base hydrophilic contact lens, toric (V2521) and adds a photochromatic additive with code V2744.

Pricing for VXXXX is represented by the following formula: V2521 + V2744. Therefore, the average 2023 fee schedule amount for VXXXX would be approximately $255.08. 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.

Payment would be on a lump sum purchase basis.

Pricing Indicator = 38

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.