

**Centers for Medicare & Medicaid Services (CMS) Agenda for Healthcare
Common Procedure Coding System (HCPCS) Public Meeting for Code
Applications for Non-Drug and Non-Biological Items and Services Submitted to
CMS' 2nd 2020 Biannual HCPCS Coding Cycle**

Zoom Meeting, for remote participation

Tuesday, December 22, 2020 9:00 am – 5:00 pm

8:45 a.m.:

- Zoom Meeting Login
- <https://cms.zoomgov.com/j/1610701817?pwd=R3hYaWtPaGVVREh2YVNMSkFQMThEQT09>
- Or join by phone: Dial US: +1 669 254 5252 or +1 646 828 7666
- Webinar ID: 161 070 1817
- Password: 083822

9:00 a.m.:

- Welcome
- Background and purpose of meeting
- Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS's preliminary coding recommendation or other review status is provided. 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 other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. CMS' final coding decisions will be published on CMS HCPCS web site at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelII-Coding-Decisions-Narrative-Summary> on or about January 2021, and will be effective April 1, 2021, unless otherwise specified.

This document includes a summary of each HCPCS code application on the agenda. 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.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 1

Application # 20.070

Request to establish a new Level II HCPCS code to identify Monarch external Trigeminal Nerve Stimulation (eTNS) System.

Application # 20.071

Request to establish a new Level II HCPCS code to identify Monarch NS-2 Electric Patch Pouch.

Agenda Item # 2

Application # 20.086

Request to establish a new Level II HCPCS code to identify the Cala Trio nerve stimulating device.

Application # 20.087

Request to establish a new Level II HCPCS code to identify a supply that is associated with the Cala Trio device.

Agenda Item # 3

Application # 20.173

Request to establish a new Level II HCPCS code to identify a therapy to prevent and acutely treat cluster headaches in adult patients, gammaCore Sapphire D, non-invasive vagus nerve stimulator.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item #4

CMS request for additional input pertaining to our establishment of three new Level II HCPCS codes to identify replacement components of the inFlow device manufactured by Vesiflo, Inc., that became effective Oct. 1, 2020.

Agenda Item # 5

Application # 20.111

Request to establish a new Level II HCPCS code to identify NovoSorb SynPath

Agenda Item # 6

Application # 20.120

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

Agenda Item # 7

Application # 20.142

Request to establish a new Level II HCPCS code to identify Selenious Acid Injection.

Agenda Item # 8

Application # 20.123

Request to establish a new Level II HCPCS code to identify Dilapan-S.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 9

Application # 20.161

Request to establish a new Level II HCPCS code to identify a low Coefficient of Friction (COF ≤ 0.35) Skin Interface device system. Trade Name: DermaTherapy.

Agenda Item # 10

Application # 20.162

Request to: 1) Modify Level II HCPCS code E0787 descriptor “External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing” to clarify that it excludes systems that only suspend insulin delivery based on continuous glucose sensing; (2) Clarify that Level II HCPCS code E0784 includes insulin pumps that suspend insulin delivery based on continuous glucose sensing along with other items classified to that code; and (3) Eliminate code A4226.

Agenda Item # 11

Application # 20.170

Request to establish a new Level II HCPCS code to identify a subscription-based software application, Natural Cycles.

Agenda Item # 12

Application # 20.163

Request to establish a new Level II HCPCS code to identify the S.T. Genesis Percutaneous Nerve Field Stimulatory (PNFS) system.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 1

Application # 20.070

TOPIC

Request to establish a new Level II HCPCS code to identify Monarch external Trigeminal Nerve Stimulation (eTNS) System.

APPLICANT'S SUMMARY

NeuroSigma Inc, submitted a request to establish a new Level II HCPCS code to identify Monarch external Trigeminal Nerve Stimulation (eTNS) System. The applicant requested the addition of a new code to the HCPCS code set for a non-implantable Trigeminal Nerve Stimulation device for the treatment for pediatric attention deficit hyperactivity disorder (ADHD). This code will be used for the Monarch external Trigeminal Nerve Stimulation (eTNS) System. It is indicated for the treatment of pediatric ADHD as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications. The device is by prescription only and intended to be used in the home under the caregiver supervision during periods of sleep. This system acts by providing therapeutic electrical stimulation of the V1 branch of the Trigeminal Nerve in the forehead. Neuroimaging and EEG studies have demonstrated that use of the device increases metabolic activity in regions of the brain associated with executive function, attention and mood. To administer therapy with the Monarch, patients place a custom disposable electric patch in the center of their forehead just above the eyebrows. The patch is connected to a hand held Pulse generator that creates and transmits a proprietary electrical signal to the patch. Patients initiate the therapy immediately prior to sleep and stop the treatment upon wakening in the morning. According to the applicant, there are no existing codes to describe devices used for this indication, as this is the only medical device to receive an FDA indication for treating pediatric ADHD.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code KXXXX “Transcutaneous electrical nerve stimulator for electrical stimulation of the Trigeminal nerve”.

CMS is also considering an alternative, new Level II HCPCS code KXXXX: “Transcutaneous electrical nerve stimulator for electrical stimulation through electrodes placed on the forehead.”

CMS has been considering this issue based on comments and input from the previous public meeting. CMS notes that FDA identifies this device as a “transcutaneous electrical nerve stimulator”.

CMS continues to consider the most appropriate manner to describe the distinctions of these products, recognizing that clinical indications may change over time. We are seeking input from stakeholders, the general public, and insurers regarding what product distinctions would warrant a separate code. For example, should CMS specify the codes based on its application to the body rather than a nerve, considering the complexity of the nervous system(s)?

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 1

Application # 20.071

TOPIC

Request to establish a new Level II HCPCS code to identify Monarch NS-2 Electric Patch Pouch.

APPLICANT'S SUMMARY

NeuroSigma Inc., submitted a request to establish a new Level II HCPCS code to identify Monarch NS-2 Electric Patch Pouch. The applicant requested to establish a new Level II HCPCS code for disposable electric patches for a non-implantable Trigeminal Nerve Stimulation device for the treatment for pediatric ADHD. According to the applicant, this code will be used for a pouch of seven refill disposable electric patches for the Monarch external Trigeminal Nerve Stimulation device. The device is indicated for treatment of pediatric ADHD as a monotherapy in patients ages 7 through 12 years who are currently not taking any ADHD medications. The device is available by prescription only and is used in home under the supervision of a caregiver during periods of sleep. The Monarch system acts by providing therapeutic electrical stimulation of the V1 branch of the Trigeminal Nerve in the forehead. Neuroimaging and EEG studies have demonstrated use of the device increases metabolic activity in regions of the brain associated with executive function, attention and mood. To administer therapy with the Monarch, patients place a custom disposable electric patch in the center of their forehead just above the eyebrow. The patch is connected to a hand held Monarch Pulse Generator that creates and transmits proprietary electrical signal to the patch. Patients initiate therapy immediately prior to sleep and stop the treatment upon wakening in the morning. According to the applicant, the existing codes do not describe devices used for this indication as this is the only medical device to receive an FDA indication for treating pediatric ADHD.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4595 “Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes)” describes the refill disposable electric patches that are the subject of this application.

CMS is also considering an alternative, new Level II HCPCS code KXXX: “Electrical nerve stimulator supplies per lead, per month (e.g., for electrical transcutaneous nerve stimulation, nmes)”; and discontinuing the following existing code, as it would be redundant:

Discontinue existing code A4595 “Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes).”

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 2

Application # 20.086

TOPIC

Request to establish a new Level II HCPCS code to identify the Cala Trio nerve stimulating device.

Applicant's suggested language: "Wrist-worn peripheral nerve stimulating device providing transcutaneous afferent patterned stimulation (including charging station)"

APPLICANT'S SUMMARY

Cala Health, Inc. submitted a request to establish a new Level II HCPCS code to identify the Cala Trio nerve stimulating device. The Cala Trio device is provided with two components: rechargeable stimulator that generates electrical impulses during times of active therapy together with a base station to recharge the stimulator; and wrist-worn connector that securely attaches the stimulator to the patient's wrist and assures that electrical impulses are properly targeted to each individual patient's nerves. Cala Trio is prescribed by a physician for use by patients in their home. It is the only peripherally worn device that is FDA-cleared to treat essential tremors, a chronic and progressive movement disorder. Cala Trio is a non-invasive, wrist-worn stimulator that delivers electrical stimulation to the nerves in the wrist to stimulate the Central Tremor Network via the peripheral nervous system. On-board sensors are used to measure the patient's tremor frequency during an initial calibration to individualize the stimulation delivered by the device.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code KXXXX "External Upper Limb Tremor Stimulator of the peripheral nerves of the wrist".

CMS is also considering an alternative, new Level II HCPCS code KXXX: "wrist-worn nerve stimulating device."

CMS has been considering this issue based on comments and input from the previous public meeting. CMS notes that FDA identifies this device as an "external upper limb tremor stimulator". CMS continues to consider the most appropriate manner to describe the distinctions of these products, recognizing that clinical indications may change over time. We are seeking input from stakeholders, the general public, and insurers regarding what product distinctions would warrant a separate code. For example, should CMS specify the codes based on its application to the body rather than a nerve, considering the complexity of the nervous system(s)?

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 2

Application # 20.087

TOPIC

Request to establish a new Level II HCPCS code to identify a supply that is associated with the Cala Trio device.

Applicant's suggested language: "Wrist-worn connectors for use with transcutaneous afferent patterned stimulation device"

APPLICANT'S SUMMARY

Cala Health, Inc. submitted a request to establish a new Level II HCPCS code to identify Cala Trio Wrist-Worn Connector. The stimulator/charging station (different application) and the wrist-worn connector are supplied initially, but replacement component of the wrist-worn connector can be provided as needed by the patient. The wrist-worn connector is only associated with the Cala Trio device. Cala Trio device is a non-invasive, wrist-worn stimulation that delivers electrical stimulation to the nerves in the wrist to stimulate the central tremor network via the peripheral nervous system. The wrist-worn connector is good for 90 days.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4595 "Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes)" describes the refill disposable electric patches that are the subject of this application.

CMS is also considering an alternative, new Level II HCPCS code KXXX: "Electrical nerve stimulator supplies per lead, per month (e.g., for electrical transcutaneous nerve stimulation, nmes)"; and discontinuing the following existing code, as it would be redundant:

Discontinue existing code A4595 "Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes)."

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 3

Application # 20.173

TOPIC

Request is to establish a new Level II HCPCS code to identify a non-invasive vagus nerve stimulator that provides therapy to prevent and acutely treat cluster headaches in adult patients, trade name: GammaCore Sapphire D.

APPLICANT'S SUMMARY

Electrocore, Inc. submitted a request to establish a new Level II HCPCS code to identify the GammaCore Sapphire D device, a non-invasive vagus nerve stimulator that externally stimulates the cervical branch of the vagus nerve to reduce the number of cluster headaches when used preventively and decrease the severity of cluster attacks when used acutely. Existing code categories are inadequate to describe the product. This is primarily due to miscellaneous coding requiring manual intervention for every claim submission. This delays patient care, does not allow for consistent and standardized reimbursement and leads to additional administrative and logistical support and expense.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new code KXXXX “Non-invasive vagus nerve stimulator”

CMS is also considering an alternative, new Level II HCPCS code KXXX: “neck worn nerve stimulating device.”

Existing code A4595 “Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes)” describes the refill disposable electric patches that are the subject of this application.

CMS is also considering an alternative, new Level II HCPCS code KXXX: “Electrical nerve stimulator supplies per lead, per month (e.g., for electrical transcutaneous nerve stimulation, nmes)”; and discontinuing the following existing code, as it would be redundant:

Discontinue existing code A4595 “Electrical stimulator supplies, 2 lead, per month, (e.g., for tens, nmes).”

CMS continues to consider the most appropriate manner to describe the distinctions of these products, recognizing that clinical indications may change over time. We are seeking input from stakeholders, the general public, and insurers regarding what product distinctions would warrant

a separate code. For example, should CMS specify the codes based on its application to the body rather than a nerve, considering the complexity of the nervous system(s)?

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 4

InFlow® device by Vesiflo, Inc.

TOPIC

CMS requests additional input pertaining to our establishment of three new Level II HCPCS codes to identify replacement components of the inFlow device manufactured by Vesiflo, Inc.. These codes were implemented Oct. 1, 2020.

SUMMARY

CMS is seeking additional input pertaining to the establishment of three new Level II HCPCS codes effective October 1, 2020, to identify replacement components of the inFlow device manufactured by Vesiflo, Inc., specifically, the replacement urethral drainage device with valve; replacement hand-held activation device; and replacement charger and base station for the activation device.

PRELIMINARY HCPCS CODING RECOMMENDATION

Three new Level II HCPCS codes implemented Oct. 1, 2020:

K1010 (Indwelling intraurethral drainage device with valve, replacement only, each)

K1011 (Activation device for intraurethral drainage device with valve, replacement only, each)

K1012 (Charger and base station for intraurethral activation device, replacement only)

It is CMS' understanding that the initial issuance of the device includes fitting and placement by the provider and issuance of all components. Thus, all components provided on initial issue would be included in the practice expense amount paid to a professional, submitted using the appropriate CPT code, and would not be separately billable. As a result, CMS established these three new codes, effective October 1, for the replacement components. CMS seeks comment on this approach.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 5

Application # 20.111

TOPIC

Request to establish a new Level II HCPCS code to identify NovoSorb SynPath

Applicant's suggested language: QXXXX: NovoSorb SynPath Dermal Matrix

APPLICANT'S SUMMARY

PolyNovo North America, LLC requests to establish a new Level II HCPCS code to identify NovoSorb SynPath.

NovoSorb SynPath is a sterile, acellular, synthetic dermal matrix made from the proprietary NovoSorb technology. The porous network of non-toxic, biodegradable synthetic polymers act as a template to support the proliferation of vital cells involved in cellular repair. As the matrix integrates into the wound bed, it supports the creation of a neodermal structure. The fenestrated matrix allows excess exudate from the wound to pass through to a secondary absorbent dressing to prevent maceration. The matrix is covered by a sealing membrane that reduces water vapor loss, helps maintain a moist wound environment, and acts as a barrier to prevent external contamination of the wound. The membrane remains intact with the dermal matrix until the clinician determines when to remove it based on the wound progression, the need for surgical closure or grafting, or application of another dermal template. It is indicated for management of partial and full thickness wounds, chronic ulcers (pressure, venous, diabetic), surgical wounds, and traumatic wounds. The device provides a dermal template to support the development of a neodermis for wound healing. Dosing does not apply to the device. After preparing the wound site, the clinician applies the textured side of the matrix directly into the wound surface flush against the wound bed. The device can be further fenestrated with a scalpel to facilitate drainage. The clinician secures the matrix using their choice of fixation. The product is presented in a sterile, inner transparent pouch encased by an outer aluminized pouch. The product is available in a range of sizes from 2cm x 2cm square to 20cm X 40cm square.

There is no current HCPCS code to describe an acellular, biodegradable synthetic polymer-based template (dermal matrix) with a sealing membrane for cellular repair of wounds.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request is being deferred to the subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Comment is particularly welcome on how different insurers would typically make a payment for this type of device.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 6

Application # 20.120

TOPIC

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

Applicant's suggested language: Q42XX Restrata per square centimeter.

APPLICANT'S SUMMARY

Acera Surgical, Inc. requests a unique Level II HCPCS Q code to describe Restrata Wound Matrix, a fully-synthetic, nanofiber wound matrix.

Restrata functions as a matrix for treating wounds and is engineered utilizing nano-scale materials to provide a resorbable scaffolding to initiate cell migration, revascularization, and soft tissue formation and reinforcement in the prepared wound bed. CMS classifies Restrata as a skin substitute: "We have determined that the product may be treated as a skin substitute for Medicare payment purposes." Restrata is currently described by the code C1849 Skin substitute, synthetic, resorbable, per square centimeter. This code can be used by hospitals to report use of Restrata but is not recognized by Medicare in other sites of service, including sites which are paid under the Medicare Physician Fee Schedule, such as physician offices and ambulatory wound care clinics. Restrata will commonly be administered in those sites of service and a product-specific Q code, comparable to the codes available for other skin substitute products, is necessary to report the product. The HCPCS codes previously assigned by CMS in response to Acera's 2018 HCPCS application, A6460 and A6461, do not appropriately describe the product, which functions like other skin substitutes and is implanted by a physician into the wound bed, and completely resorbed into the wound. Additional product applications follow as clinically necessary and prescribed by the provider. Restrata is indicated for use in management of wounds, including partial and full thickness wounds, pressure sores, venous, diabetic and chronic vascular ulcers, wounds with tunneling or undermining, surgical (e.g. donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma and draining wounds. The fibrous structure of Restrata is highly porous. It has a structure similar to native extracellular matrix of the skin and has a defined rate of resorption which provides a scaffold for cellular infiltration and vascularization before completely degrading via hydrolysis in the wound bed. Restrata permits the migration of cells and formation of soft tissue in the wound bed and does not contain any human or animal materials or tissues. The dosage includes size selection appropriate to the prepared wound bed and is reapplied every 7 days or as necessary. The product is cut to the desired shape of the wound bed and hydrated before being anchored securely using the physician's preferred fixation method based on wound type/location. Restrata is supplied in a single use double peel package in a variety of sizes.

Applicant also requested that CMS delete HCPCS codes A6460 and A6461 as they serve no purpose and may create confusion.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request is being deferred to the subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision. Comment is particularly welcome on how different insurers would typically make a payment for this type of device.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 7

Application # 20.142

TOPIC

Request to establish a new Level II HCPCS code to identify Selenious Acid Injection.

Applicants suggested language: B42XX: Selenious Acid Injection, trace element, parenteral nutrition, admixture

APPLICANT'S SUMMARY

American Regent Inc. submitted a request to establish a new Level II HCPCS code to separately identify Selenious Acid Injection. Currently, there is no code specifically, separately identify Selenious Acid Injection as an admixture in parenteral nutrition (PN) solutions. A new HCPCS code is required to specify the use of Selenious Acid Injection as an admixture in PN solutions, as current coding specifying "home mix" is not appropriate for Selenious Acid Injection. The FDA approved the NDA for Selenious Acid Injection on April 30, 2019 for adult and pediatric patients as a source of selenium for PN when oral or enteral nutrition is not possible, insufficient, or contraindicated. Selenious Acid Injection is supplied as a pharmacy bulk package for admixing use only. It is not for direct intravenous infusion. Prior to administration, Selenious Acid Injection must be transferred to a separate PN container, prepared and used as an admixture in PN solutions. Selenious Acid Injection should be added to the parenteral nutrition solution only in a suitable work area such as a laminar flow hood (or an equivalent clear air compounding area). The key factor in the preparation is careful aseptic technique to avoid inadvertent touch contamination during mixing of solutions and addition of other nutrients. The dosage of Selenious Acid Injection is individualized based on the patient's clinical condition, nutritional requirements, and the contribution of oral or enteral selenium intake. Selenious Acid Injection is a clear, colorless solution packaged as 600 mcg/10 mL (60 mcg/mL) of selenium in a 10 mL pharmacy bulk package vial.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code B4189 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 grams of protein - premix", B4193 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 52 to 73 grams of protein - premix", B4197 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, 74 to 100 grams of protein - premix", B4199 "Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and

vitamins, including preparation, any strength, over 100 grams of protein - premix", B5000 "Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal-aminosyn-rf, nephramine, renamine-premix", B5100 "Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic, hepatamine-premix" or B5200 "Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, stress-branch chain amino acids-freamine-hbc-premix" depending on content, adequately describes the complete formula, including the trace element that is the subject of this application.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 8

Application # 20.123

TOPIC

Request to establish a new Level II HCPCS code to identify Dilapan-S.

Applicant's suggested language: JXXXX Synthetic hydrogel cervical dilator; each hydrogel dilator

APPLICANT'S SUMMARY

Medicem Inc. submitted a request to establish a new Level II HCPCS code to identify Dilapan-S. According to the applicant, Dilapan-S is a mechanical, non-pharmacologic firm hygroscopic cervical dilator rod composed of Aquacryl, a synthetic patented hydrogel.

Placement is performed by OB/GYN-trained healthcare providers. Typically 3-5 rods are inserted into the cervix. Post-insertion, Dilapan-S initiates a cascade of biophysical, mechanical, and physiological changes in the cervical tissue that continue until removal. Each rod absorbs fluid from the surrounding cervical tissue and expands to several times its original diameter, gradually dilating the cervical canal by exerting evenly distributed radial pressure. This mechanical stretch leads to the release of endogenous prostaglandins that initiate collagen degradation and cervical softening and ripening. Dilapan-S may remain in-situ for up to 24 hours. The majority of rod expansion occurs in 4-6 hours. Average cervical ripening time is 12-15 hours.

PRELIMINARY HCPCS CODING RECOMMENDATION

Dilapan-S is not suitable for coding in Level II HCPCS. It is our understanding that Dilapan-S would likely be included by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) as a supply in the existing CPT code(s). In making such determinations, the AMA considers evidence that use of Dilapan-S has become a typical supply provided (greater than 50% of the time) during the relevant procedure(s). We recommend that the applicant work with the AMA RUC to determine whether this item should be included as a supply for existing CPT codes.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 9

Application # 20.161

TOPIC

Request to establish a new Level II HCPCS code to identify a low coefficient of friction (COF \leq 0.35) skin interface device system. Trade Name: DermaTherapy. In addition, as indicated by the request for a code in the EXXXX section of the code, the applicant is also asking that the product be deemed Durable Medical Equipment.

Applicant's suggested language: EXXXX: Low Friction (COF \leq 0.35) Skin Interface System.

APPLICANT'S SUMMARY

Precision Fabrics Group, Inc. submitted a request to establish a new HCPCS code to identify DermaTherapy.

DermaTherapy is a low COF skin protective interface system with four components: 1) mattress/overlay interface cover with elasticized edge and depth to accommodate a mattress plus an overlay, 2) pillow interface cover, 3) skin interface overlay, and 4) an absorbent interface underpad. All four components function to provide a low COF interface between the mattress surface and/or overlay and the patients' skin to protect against shear and friction forces on the skin and wick moisture away from skin. These are the major contributors to development of pressure injuries. In addition, the interface material has a durable antimicrobial finish to reduce bacterial growth. Currently no HCPCS codes describe an interface system with a low COF \leq 0.35 for use with Pressure Reduction Support Surfaces Groups 1, 2 or 3 or hospital beds used in the home. The system is indicated to protect the skin from development of pressure ulcers for patients that are immobilized or have limited mobility due to disease, surgery, trauma or injury.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS has not identified a need on the part of any insurance sector to establish a unique code to identify low coefficient of friction bed and pillow covers and pads, which are available without a prescription.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 10

Application # 20.162

TOPIC

Request to:

- 1) Modify Level II HCPCS code E0787 descriptor “External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing” to clarify that it excludes systems that only suspend insulin delivery based on continuous glucose sensing;
- (2) Clarify that E0784 includes insulin pumps that suspend insulin delivery based on continuous glucose sensing along with other items classified to that code; and
- (3) Eliminate code A4226.

APPLICANT'S SUMMARY

Tandem Diabetes Care, Inc., submitted a request to: 1) Modify Level II HCPCS code E0787 descriptor “External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing” to clarify that it excludes systems that only suspend insulin delivery based on continuous glucose sensing;

- (2) Clarify that E0784 includes insulin pumps that suspend insulin delivery based on continuous glucose sensing along with other items classified to that code; and
- (3) Eliminate the code A4226.

Tandem t:slim X2 insulin pumps are the only items classified to E0787. The t:slim X2 pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 pump can also be used as part of a system to receive and display continuous glucose measurements from the Dexcom G6 CGM. If granted, this request would reclassify the t:slim X2 with embedded Basal-IQ technology to E0784 and the t:slim X2 with embedded Control-IQ™ technology would remain classified to E0787. This request is the same as the request Tandem made at the June 2, 2020, HCPCS public meeting. Presently, Medicare beneficiaries lack access to updateable Tandem pumps under E0784 unless they also meet Medicare requirements for continuous glucose monitoring and qualify for an E0787. According to the applicant, these recommendations would ensure that Medicare beneficiaries could use a Tandem pump even if they do not use a CGM, in the same way they were able to obtain a Tandem pump before CMS created code E0787. Elimination of the A4226 bundled supply code and use of the three existing codes that describe the same

supplies: A4224 (infusion sets), A4225 (insulin reservoirs), and K0553 (CGM supplies) would accommodate Medicare beneficiaries who often do not begin insulin pump and CGM therapy simultaneously or who purchase supplies from more than one supplier.

PRELIMINARY HCPCS CODING RECOMMENDATION

This application was submitted on June 29, 2020. Following this submission, CMS issued biannual determinations in July (<https://www.cms.gov/files/document/2020-hcpcs-application-summary-bi-annual-1-2020-durable-medical-equipment-dme-and-accessories.pdf>). CMS understands that the applicant is engaging with the Pricing, Data Analysis and Coding (PDAC) contractor, and we believe that is an appropriate avenue at this time.

In addition, CMS has subsequently issued a proposed rule on CGMs. We believe it is most appropriate to review the public comments that will be submitted on the proposed rule before taking further action in regard to the codes that are the subject of this application. CMS appreciates the stakeholder engagement as we continue to consider how to develop and refine HCPCS Level II coding for use by all payers and ensure access to medically necessary devices and supplies for Medicare beneficiaries with diabetes.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 11

Application # 20.170

TOPIC

Request to establish a new Level II HCPCS code to identify a subscription-based software application, Natural Cycles.

APPLICANT'S SUMMARY

Natural Cycles USA Corp submitted a request to establish a new Level II HCPCS code to identify Natural Cycles, a subscription-based software application.

Natural Cycles is a subscription-based software application (app) that runs on mobile phones and is used in conjunction with patient-specific data and a woman's basal temperature taken by a basal thermometer as a method of fertility control, including contraception. Natural Cycles is the first and only app cleared by the FDA as a medical device for birth control. The "brain" behind the app is the dynamic individualized Natural Cycles algorithm. It continuously analyzes patient-specific data to display individualized daily fertility status.

The clearance led the FDA to create a new regulatory category called "Software application for contraception", setting the framework and guidance for future developments in this area. Natural Cycles provided the FDA with evidence to demonstrate the effectiveness of the app for contraception. This included a detailed description of its proprietary algorithm and an analysis of real-world data from 15,570 women who used the app for contraception, for a total exposure time of 7,353 woman-years.

The Patient Protection and Affordable Care Act ("ACA") mandates that private health plans require coverage for all FDA-approved methods of contraception used by women, including female sterilization, along with related counseling and services. It also requires this coverage to be provided with no patient out-of-pocket costs.

As per the applicant, Natural Cycles is first-in-class, having been granted the De Novo classification, none of the existing HCPCS codes apply, which is why Natural Cycles is requesting a new code. In order to enable insurance plans to cover Natural Cycles at no cost for the patient, Natural Cycles requires a new HCPCS code for a stand-alone software application for contraception.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS recognizes the evolving manner of digital health technologies, like Natural Cycles. CMS requests information in regard to how private insurers are currently processing claims and covering this non-prescription product.

December 22, 2020

CMS HCPCS Virtual Public Meeting

Agenda Item # 12

Application # 20.163

TOPIC

Request to establish a new Level II HCPCS code to Identify the S.T. Genesis Percutaneous Nerve Field Stimulatory (PNFS) system.

APPLICANT'S SUMMARY

Wells Health Group, on behalf of DyAnsys, Inc. submitted a request to establish a new Level II HCPCS code to identify S.T. Genesis Percutaneous Nerve Field Stimulatory (PNFS) system.

The function of the S.T. Genesis Percutaneous Nerve Field Stimulatory (PNFS) system is to support reduction of opioid withdrawal symptoms through application to branches of cranial nerves V, VII, IX, and X as well as the occipital nerves. There are no existing Level II HCPCS codes that adequately describe the form and function of a Percutaneous Nerve Stimulator for Opioid Withdrawal. The newly granted FDA Product Code: PZR was effective 2/5/2018, and critical to this HCPCS Application. The new FDA product code was granted to allow for better treatment options for people suffering with Opioid Use Disorders (OUD). However, the consequences of innovative technology and new FDA product categories is the inevitable need for HCPCS coding modifications. FDA Indications For Use: Percutaneous Nerve Field Stimulatory (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX, and X, and the occipital nerves identified by trans illumination. S.T. Genesis PNFS is designed to administer auricular neurostimulation treatment while offering the patient a high degree of comfort and mobility. Stimulation is performed by sending electrical pulses emitted through needles strategically positioned in the ear. Once the device is applied, the therapy begins and continues for a maximum of 120 hours. Each patient's treatment is determined by frequent measurement of Clinical Opiate Withdrawal Scale (COWS) feedback until the opiate cravings have subsided. There are currently level II HCPCS codes for Implantable neurostimulator, pulse generators e.g. L8679 – up till now, no codes for non-implantable stimulators.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS would like to know more about the setting of use for this product. For instance, what type(s) of professionals are necessary for the appropriate application of this single-use product to the patient? Also, why would a Level II HCPCS Code be more appropriate than a CPT code? We would also like to know more about the applicant's claims experience with this product. What types of coverage and payment policies have private insurers adopted in terms of separate or bundled payment with the professional service for this product? We also would find

it helpful to understand how market availability for this product has evolved over time. At this time, it seems to CMS that it would be most appropriate for the applicant to approach the AMA CPT Editorial Panel, though we welcome information to further inform our thinking.