

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, Maryland 21244-1850



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' 1st 2021 Biannual HCPCS Coding Cycle

**Zoom Meeting, for remote participation
Wednesday, July 7, 2021 9:00 am – 5:00 pm, eastern daylight time (edt)**

8:45 am, edt:

- Zoom meeting login:
https://cms.zoomgov.com/webinar/register/WN_ukTCxcctSReHO2RJaD5O6w
- Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

9:00 am, edt:

- Welcome
- Background and purpose of meeting
- Meeting format and ground rules

For each agenda item, a written overview of the request and CMS' 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 meeting provides an opportunity for stakeholders 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 decisions will be published on CMS' HCPCS website at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelIII-Coding-Decisions-Narrative-Summary> around the end of July 2021, and will be effective October 1, 2021, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Wednesday, July 7, 2021. 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.

July 7, 2021

CMS HCPCS Virtual Public Meeting

Agenda Item # 1

Request # 21.053

Request to establish a new HCPCS Level II code to identify Ottobock 4R57 Rotation Adapter.

Applicant's suggested language: L5XXX "All lower extremity prostheses, positional torsion rotation unit."

Agenda Item # 2

Request # 21.031

Request to establish a new HCPCS Level II code to identify the Exsufflation Belt.

No suggested language.

Agenda Item # 3

Request # 21.032

Request to revise existing HCPCS Level II code E0652 to remove the word "pneumatic" from the long description that currently states: "Pneumatic compressor, segmental home model with calibrated gradient pressure."

Applicant's suggested language: E0652 "Compressor, segmental home model with calibrated gradient pressure."

Request # 21.070

Request to revise the long description of HCPCS Level II code E0668 "Segmental pneumatic appliance for use with pneumatic compressor, full arm".

Agenda Item # 4

Request # 21.033

Request to establish a new HCPCS Level II code to identify Nerivio

Applicant's suggested language: XXXXX "Remote Neuromodulation Device for the acute treatment of (episodic and chronic) migraine."

Agenda Item # 5

Request # 21.001

Request to establish a new HCPCS Level II code to identify segesterone acetate and ethinyl estradiol vaginal system.

Applicant's suggested language: J7XXX "Annovera (segesterone acetate and ethinyl estradiol vaginal system), each."

Agenda Item # 6

Request # 20.146

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

Applicant's suggested language: J9XXX "Injection, Romidepsin non-lyophilized (e.g. liquid), per IMG." Recommended short descriptor: "Romidepsin Injection, liquid."

Agenda Item # 7

Request # 21.001i

Request to replace J2505 with a new code with a small dose descriptor similar to its biosimilars.

Suggested language: "Injection, pegfilgrastim, 0.5 mg."

Agenda Item # 8

Request # 21.023

Request to revise three existing HCPCS Level II codes for Chaplain spiritual care:

1. Existing language: HCPCS Level II code Q4251 "Assessment by Department of Veterans Affairs chaplain services."

Applicant's suggested language: HCPCS Level II code "Assessment by chaplain services."

2. Existing language: HCPCS Level II code Q4252 "Counseling, individual, by Department of Veterans Affairs chaplain services."

Applicant's suggested language: "Counseling, individual by chaplain services."

3. Existing language: HCPCS Level II code Q4253 "Counseling, group, by Department of Veterans Affairs chaplain services."

Applicant's suggested language: "Counseling, group by chaplain services."

Agenda Item # 9

Request # 21.025

Request to establish a new HCPCS Level II code to identify a large volume delayed sampling (LVDS)-tested leukocyte reduced whole blood-derived platelets.

Applicant's suggested language: P9XXX "Platelets, whole blood-derived, leukocytes reduced, large volume delayed sampling (LVDS)-tested, each unit."

Request # 21.027

Request to establish a new HCPCS Level II code to identify large volume delayed sampling (LVDS)-tested leukocyte reduced apheresis platelets.

Applicant's suggested language: P9XXX "Platelets, pheresis, leukocytes reduced, large volume delayed sampling (LVDS)-tested, each unit."

Agenda Item # 10

Request # 21.026

Request to establish a new HCPCS Level II code to identify Cryoprecipitated fibrinogen complex, pathogen reduced (CFCPR).

Applicant's suggested language: XXXXX "Cryoprecipitated fibrinogen complex, pathogen reduced, each unit (CFCPR)."

Request # 21.028

Request to establish a new HCPCS Level II code to identify a blood component product.

Applicant's suggested language: "Plasma, cryoprecipitate reduced, pathogen reduced, each unit (PCRPR)."

Agenda Item # 11

Request # 21.037

Request to establish two new HCPCS Level II codes for Apollo Revise Systems:

1. Apollo Revise Dual Channel System used to perform the endoluminal flexible Endoscopic revision of bariatric surgical procedures.

Applicant's suggested language: "Revision device, insertable endoscopic gastrointestinal, dual channel."

2. Apollo Revise SX (Single Channel) System used to perform the endoluminal flexible Endoscopic Revision of Bariatric Surgical Procedures.

Applicant's suggested language: "Revision device, insertable endoscopic gastrointestinal, single channel."

Request # 21.038

Request to establish a new HCPCS Level II code to identify the Orbera Intra gastric Balloon System.

Applicant's suggested language: "Fluid filled Intra gastric balloon, insertable."

Request # 21.039

Request to establish two new HCPCS Level II codes to identify each version of the X-TACK I Endoscopic HeliX Tacking System.

Applicant's suggested language:

1. "Repair, endoscopic gastrointestinal insertable tack placement device 160mm."
2. "Repair, endoscopic gastrointestinal insertable tack placement device 235mm."

Request # 21.040

Request to establish two new HCPCS Level II codes to identify Apollo ESG Systems

Applicant's suggested language:

1. Alteration device, endoscopic insertable gastrointestinal, dual channel
2. Alteration device, endoscopic insertable gastrointestinal, single channel

Request # 21.041

Request to establish two new HCPCS Level II codes to identify OverStitch SX (Single Channel) Endoscopic Suturing System and OverStitch Dual Channel Endoscopic Suturing System

No suggested language

Agenda Item # 12

Request # 21.048

Request to establish a new Level II HCPCS to identify Alzair Allergy Blocker.

Applicant's suggested language: Axxxx "Alzair Allergy Blocker Powder, per 800 mg bottle."

Agenda Item # 13

Request # 21.049

Request to establish a new HCPCS Level II code to identify the Lotus No Balloon Catheter, a novel catheter that encompasses three types of urological catheters.

No suggested language.

Agenda Item # 14

Request # 21.054

Request to establish a new HCPCS Level II code to identify for IB-Stim, a percutaneous electrical nerve field stimulator (PENFS) device.

Applicant's suggested language: L86XX "Percutaneous electrical nerve field stimulator (PENFS)."

Agenda Item # 15

Request # 21.035

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

Applicant's suggested language: LXXXX "Percutaneous Nerve Stimulator for Opioid Withdrawal."

Agenda Item # 16

Request # 21.060

Request to revise HCPCS Level II code C1753 to include language for the use of the optical coherence tomography (OCT) imaging catheter.

No suggested language.

Agenda Item # 17

Request # 21.061

Request to establish a new HCPCS Level II code to describe a structured lipid matrix powder fororal administration (Encala).

Applicant's suggested language: B4XXX "structured lipid matrix, orally administered, per dose."

Agenda Item # 18

Request # 21.062

Request to modify/revise an existing HCPCS Level II code for ENU Complete Nutrition Shakes from B4150 to B4153, based on a modification to the product formulation and the inclusion of hydrolyzed whey protein, and the removal of two complete proteins. This change in formula aligns the product to the definition of B4153.

No suggested language.

Agenda Item # 19

Request # 21.063

Request to establish a new HCPCS Level II code to identify PeDIA. PeDIA assists with inducing anesthesia in children ages 3 and over. It replaces the anesthesia mask which can cause anxiety and problems during anesthesia induction.

No suggested language.

Agenda Item # 20

Request # 21.064

Request to establish a new HCPCS Level II code to identify the Sonography-Guided Transcervical Fibroid Ablation System Probe.

No suggested language.

Agenda Item # 21

Request # 21.057

Request to establish a new HCPCS Level II code to identify Peristeen Rectal Balloon.

Applicant's suggested language: AXXXX "Rectal catheter, with or without balloon, any type."

Request # 20.165

1) Request to establish a new HCPCS Level II code to identify an irrigation supply.

Applicant's suggested language: A4XXX "Irrigation supply; sleeve, disposable, each."

2) Request to modify HCPCS Level II code A4397 "Irrigation supply; sleeve, each" to instead read "Irrigation supply; sleeve, reusable, each."

Agenda Item # 22

Request # 21.007

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

Applicant's suggested language: Q4XXX "InnovaMatrix AC, per sq. cm."

Agenda Item # 23

Request # 21.010

Request to establish a new HCPCS Level II code to identify Mirragen Advanced Wound Matrix

Applicant's suggested language: Q42XX "Mirragen Advanced Wound Matrix, per square centimeter."

Agenda Item # 24

Request # 21.018

Request to establish a new HCPCS Level II code to identify bio-ConneKt

Applicant's suggested language: "bio-ConneKt Wound Matrix, per sq. cm."

Agenda Item # 25

Request # 21.022

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

No suggested language.

Agenda Item # 26

Request # 21.024

Request to establish a new HCPCS Level II code to identify Microlyte Matrix and a request to delete Microlyte Matrix from the A6460 HCPCS code.

No suggested language.

Agenda Item # 27

Request # 20.111

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

Applicant's suggested language: QXXXX “NovoSorb SynPath Dermal Matrix.”

Agenda Item # 28

Request # 20.120

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

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

Agenda Item # 29

Request # 21.020

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

No suggested language.

Agenda Item # 1

Request # 21.053

TOPIC

Request to establish a new level II code to identify Ottobock 4R57 Rotation Adapter.

Applicant's suggested language: L5XXX "All lower extremity prostheses, positional torsion rotation unit"

APPLICANT'S SUMMARY

The positional rotation adapter provides medically necessary rotation of the prosthetic limb to accommodate specific environmental situations such as (not all-inclusive): Performing activities in confined spaces like small kitchens and walkways; entering and exiting a vehicle and while driving, enabling the user to swing the prosthesis out of the way; switching prosthetic feet, putting on shoes or changing socks because it brings the prosthetic foot within reach. This feature also allows the user to adjust their limb to the surroundings without putting additional torsional loads and strains on the socket and residual limb. Previously, we have coded this adapter as L5984 "All endoskeletal lower extremity prosthesis, axial rotation unit, with or without adjustability," but with the new clarification of that code, the L5984 is no longer applicable to use as it is not providing the torsional rotation during ambulation.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish a new HCPCS Level II code KXXXX "Endoskeletal system, knee disarticulation, above knee, hip disarticulation, positional unit, any type."

Agenda Item # 2

Request # 21.031

TOPIC

Request to establish a new HCPCS Level II code to identify the Exsufflation Belt

APPLICANT'S SUMMARY

Lung Assist II, Inc. submitted a request to establish a new code for a stand-alone intermittent abdominal daytime pressure ventilator device, the Exsufflation Belt.

The device administers a unique mode of reverse ventilation with active forced exhalation and passive inhalation. Benefits of the Exsufflation Belt that are not available and not capable when using conventional positive pressure by a face mask, mouthpiece, or artificial airway may include: improves quality of life, dignity and confidence in the work place, eating and in public settings, enhanced seating posture, ability to sit up for extended hours, decreased work of breathing with increased tidal volume, fully inflated lungs while resting of respiratory muscles during continued use, alternative to full time use of facial masks or mouth piece allowing the patient to speak and eat freely, reduced mid-facial hyperplasia and facial necrosis from long-term use of a mask, aids in swallowing and cough. The Exsufflation Belt is a body wearable non-invasive device. The device works by forcing diaphragmatic exhalation. Inhalation occurs passively. A fabric corset contains a specialized air/sac bladder that is inflated by a patient-supplied self-cycling positive pressure ventilator. This is an external device to administer daytime abdominal pressure ventilation support for pulmonary restrictive or pulmonary obstructive breathing. The device is intended to administer up to 18 breaths per minute (BPM) and pressures up to 50 cm H2O. Positive pressure from the patient supplied ventilator compresses the abdomen causing the diaphragm to rise resulting in active exhalation. When the bladder is deflated, natural and passive inhalation occurs.

As per the applicant, currently there is no specific assigned coding for abdominal pressure ventilation devices.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish a new HCPCS Level II code KXXXX "Exsufflation belt, includes all supplies and accessories."

Agenda Item # 3

Request # 21.032

TOPIC

Request to revise existing HCPCS Level II code E0652 to remove the word "pneumatic" from the long description that currently states: "Pneumatic compressor, segmental home model with calibrated gradient pressure."

Applicant's suggested language: E0652 "Compressor, segmental home model with calibrated gradient pressure."

APPLICANT'S SUMMARY

Koya Medical, Inc. submitted a request to revise the HCPCS Level II code E0652 to remove the word "pneumatic" from the long description that currently states: "Pneumatic compressor, segmental home model with calibrated gradient pressure."

The Koya Dayspring system is an FDA-cleared medical device that employs sequential gradient compression to treat and manage lymphedema and provides patients with mobility during treatment. The Koya Dayspring system is also clinically indicated for venous insufficiency and is used to promote wound healing. The Koya Dayspring system consists of a segmental gradient compression device that provides comparable compression to existing pneumatic pumps through segments that contract and relax flexible frames in a segmental appliance (separate application) without the use of air. When a patient uses the compressor (subject of this application) in conjunction with the appliance, the device creates the desired, calibrated, gradient pressures in the appliance and moves excess fluid in a rhythmic, distal to proximal manner. The function of the Dayspring system (non-pneumatic) allows patients to be mobile during treatment. Clinicians and patients report improved compliance since daily activities and tasks are not interrupted by the therapy (Rockson et al, "Clinical Evaluation of a Novel Wearable Compression Technology in the Treatment of Lymphedema, An Open-Label Controlled Study", presented at the 34th Annual Conference of American Vein & Lymphatic Society, October 16, 2020 and manuscript under review with Lymphatic Research & Biology, January 2021). Lymphedema is a chronic condition caused by a blockage in the lymphatic system, part of the immune and circulatory systems. Lymphedema is most commonly caused by lymph node removal or damage due to cancer treatment. The main symptom of lymphedema is 2 swelling in an arm or leg that is accompanied by pain and/or discomfort. Compression treatment has been clinically proven to alleviate the swelling and pain. Current compressors included in HCPCS code E0652 provide compression using a pneumatic compressor that inflates and deflates the segmental appliance, generating and applying the recommended pressures and rhythms to move excess fluid in a distal to proximal direction. The Koya Dayspring compressor provides therapeutically similar compression as devices in the current HCPCS codes E0652. The substantive difference is that Koya's new technology is non-pneumatic, but it treats the same conditions as traditional pneumatic compression devices using the same compression modality. The new non-pneumatic technology also allows the patient to be mobile while receiving treatment – a marked

improvement in compression therapy. The original E0652 HCPCS code was established in 1988 and the long description was modified in January 1994. The current HCPCS code description reflects the compression technology available 30 years ago. The applicant's recommendation is to update the long description of HCPCS code E0652 to reflect and include non-pneumatic compression technology that is proven to successfully treat the same conditions as pneumatic compression systems currently coded as HCPCS code E0652.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish a new HCPCS Level II code KXXXX “Non-pneumatic compression system, full arm, sequential calibrated gradient pressure, includes all components and accessories.”

Agenda Item # 3

Request # 21.070

TOPIC

Request to revise the long description of HCPCS Level II code E0668 "Segmental pneumatic appliance for use with pneumatic compressor, full arm".

Applicant suggested language: "Segmental appliance for use with compressor, full arm."

APPLICANT'S SUMMARY

This code description specifically limits the method of sequential gradient compression to "pneumatic". Our specific request is to modify the description of the HCPCS code to allow compression devices that provide the same therapy through innovative technology to meet the code requirements. Our request is to remove the word "pneumatic" so the revised description for HCPCS code E0668 would state: "Segmental appliance for use with compressor, full arm."

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish a new HCPCS Level II code KXXXXX "Non-pneumatic compression system, full arm, sequential calibrated gradient pressure, includes all components and accessories."

Agenda Item # 4

Request # 21.033

TOPIC

Request to establish a new HCPCS Level II code to identify Nerivio

Applicant's suggested Language: XXXXX "Remote Neuromodulation Device for the acute treatment of (episodic and chronic) migraine."

APPLICANT'S SUMMARY

Theranica Bio-Electronics Ltd, Israel, submitted a request to establish a unique HCPCS code (single code) for Nerivio, a unique neuromodulation device for the acute treatment of episodic and chronic migraine. HCPCS Code E0720 includes transcutaneous electrical nerve stimulation (TENS) devices, employing two-lead, localized stimulation. Nerivio is fundamentally distinct from TENS units. It employs a distinct mechanism of action, called Conditioned Pain Modulation, which is an endogenous, descending, analgesic mechanism, triggered by remote stimulation of nociceptive (not mechanical) nerve fibers. Nerivio uses unique stimulation parameters and has a distinct application location (on the upper arm, remote from the trigeminal nerve). Nerivio uses a smartphone application to control stimulation intensity and track treatment efficacy. The FDA deemed Nerivio a De Novo device, asserting that TENS units (e. g, Cefaly and others) under the E0720 code cannot be considered predicate devices of Nerivio. Specifically, the FDA emphasized the differences between Nerivio and TENS devices in the location of stimulation and the mechanism of action.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish a new HCPCS Level II code KXXXX "Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm"

Agenda Item # 5

Request # 21.001

TOPIC

Request to establish a new HCPCS Level II code to identify segesterone acetate and ethinyl estradiol vaginal system.

Applicant's suggested language: J7XXX "Annovera (segesterone acetate and ethinyl estradiol vaginal system), each"

APPLICANT'S SUMMARY

Annovera is a hormonal birth control method that is used for 3 out of 4 weeks every month. The same vaginal system is reusable for up to 1 full year (1 year includes 13 cycles; each cycle is 28 days). After the patient inserts Annovera for the first time, she will remove it at the end of week 3 and leave it out for 7 days. She will then reinsert Annovera at the end of week 4 of each 4 week cycle.

PRELIMINARY HCPCS CODING RECOMMENDATION

1. Establish new HCPCS Level II code JXXXX "Segesterone acetate and ethinyl estradiol 0.15mg, 0.013mg per 24 hours; yearly vaginal system, each"
2. Establish a new HCPCS Level II code JXXXX "Ethinyl estradiol and etonogestrel 0.015mg, 0.12mg per 24 hours; monthly vaginal ring, each"
3. Discontinue HCPCS Level II J7303 "Contraceptive supply, hormone containing vaginal ring, each"

We recognize this coding recommendation may affect multiple manufacturers and payers. We seek a broad range of input on any implications.

Agenda Item # 6

Request # 20.146

TOPIC

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

Applicant's suggested language: J9XXX "Injection, Romidepsin non-lyophilized (e.g. liquid), per 1mg"

APPLICANT'S SUMMARY

Romidepsin Injection, liquid is a histone deacetylase (HDAC) inhibitor drug. Romidepsin is a drug used in the treatment of certain types of lymphoma cancer. A new HCPCS code for Romidepsin Injection, non-lyophilized liquid is needed because it is a single source drug approved under a unique NDC number, and it needs to be differentiated from the existing HCPCS code for a multi-sourced Romidepsin drug in lyophilized powder form. Indications for use: Treatment of cutaneous T-cell lymphoma (CTCL) in adult patients who have received at least one prior systemic therapy; and treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy. The recommended dosage of Romidepsin is 14 mg/m² administered intravenously over a 4-hour period on days 1, 8, and 15 of a 28-day cycle. Cycles should be repeated every 28 days provided that the patient continues to benefit from and tolerates the drug. Romidepsin is administered intravenously.

PRELIMINARY HCPCS CODING RECOMMENDATION

1. Establish new HCPCS Level II code JXXXX "Injection, romidepsin, non-lyophilized, 0.1 mg"
2. Establish new HCPCS Level II code JXXXX "Injection, romidepsin, lyophilized, 0.1 mg"
3. Discontinue existing HCPCS Level II code J9315 "Injection, romidepsin, 1 mg"

Agenda # 7

Request # 21.001i

TOPIC

Request to replace J2505 with a new code with a small dose descriptor similar to its biosimilars.

Suggested language: “Injection, pegfilgrastim, 0.5 mg”

SUMMARY

According to the published prescribing information, pegfilgrastim dosing could be 1.5mg to 6mg depending on the patient’s weight. In order to facilitate more accurate billing and to simplify the comparison of payment amounts for pegfilgrastim and its biosimilar products, CMS would like to discontinue J2505 and replace it with a code that utilizes a descriptor that matches the amount of drug in the pegfilgrastim biosimilar codes.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS recommends the following coding changes:

1. Establish new HCPCS Level II code JXXXX “Injection, pegfilgrastim, excludes biosimilar, 0.5 mg.”
2. Discontinue existing HCPCS Level II code J2505 “Injection, pegfilgrastim, 6 mg.”

Agenda Item # 8

Request # 21.023

TOPIC

Request to revise three existing HCPCS Level II codes for Chaplain spiritual care:

1. Existing language: HCPCS Level II code Q4251 "Assessment by Department of Veterans Affairs chaplain services."

Applicant's suggested language: HCPCS Level II code. "Assessment by chaplain services."

2. Existing language: HCPCS Level II code Q4252 "Counseling, individual, by Department of Veterans Affairs chaplain services."

Applicant's suggested language: "Counseling, individual by chaplain services."

3. Existing language: HCPCS Level II code Q4253 "Counseling, group, by Department of Veterans Affairs chaplain services."

Applicant's suggested language: "Counseling, group by chaplain services."

APPLICANT'S SUMMARY

HealthCare Chaplaincy Network submitted a request for Chaplain spiritual care.

Chaplain spiritual care provides in-depth specialist spiritual and pastoral care and counseling, which is integrated into the total care and treatment program. Chaplains provide a full range of spiritual and pastoral care and counseling that is characterized by in-depth assessment, evaluation and treatment of patients with many different spiritual and religious needs as part of an integrated and comprehensive bio-psycho-social-spiritual approach, ascertaining a patient's spiritual preference and practices and how they wish those integrated into their care, and developing appropriate goals and outcomes of spiritual care. The chaplain also provides consultation, counseling and support to family members and staff. Professional chaplains are clinically trained to provide this care. The existing codes only apply to chaplaincy services in the Veterans Health Administration (VHA). However, the need for standardized data for budgeting and quality purposes that was identified by the VHA as a justification for the original codes also applies to all US health care institutions. Emerging models of care such as those being proposed by the Center for Medicare and Medicaid Innovation (CMMI) often include chaplaincy care and thus require the collection of standardized data. At present, there are no standardized chaplaincy care data sets essential to this data collection.

PRELIMINARY HCPCS CODING RECOMMENDATION

The Department of Veterans Affairs is using its authority to specifically include clinically-trained chaplains in their provision of medical services to veterans. CMS is not aware of any claims-based need on the part of other insurers for reporting chaplain activity. CMS' recommendation is to maintain the existing Chaplain codes for Veterans Affairs use.

Agenda Item # 9

Request # 21.025

TOPIC

Request to establish a new HCPCS Level II code to identify a large volume delayed sampling (LVDS)-tested leukocyte reduced whole blood-derived platelets.

Applicant's suggested language: P9XXX "Platelets, whole blood-derived, leukocytes reduced, large volume delayed sampling (LVDS)-tested, each unit."

APPLICANT'S SUMMARY

bioMérieux submitted a request to establish a new Level II HCPCS code for large volume delayed sampling (LVDS)-tested leukocytereduced whole blood-derived platelets.

LVDS-tested leukocyte-reduced whole blood-derived platelets are a transfused platelet product subject to a new enhanced bacterial testing approach called large volume delayed sampling. On May 20, 2020, bioMérieux's BACT/ALERT® BPA and BACT/ALERT BPN culture bottles received 510(k) clearance from the FDA for LVDS of leukocyte-reduced whole blood platelet concentrates and leukocyte-reduced apheresis platelets when used with BACT/ALERT Microbial Detection Systems (BACT/ALERT 3D and BACT/ALERT VIRTUO). The use of these culture bottles allows U.S. blood centers to offer LVDS tested leukocyte-reduced whole blood-derived platelets and leukocyte-reduced apheresis platelets. Platelets are particularly prone to contamination since they are stored at room temperature (unlike red blood cells or plasma, which can be refrigerated to prevent bacterial growth). Therefore, routine testing for bacterial contamination is critical to detect those units that are contaminated and could potentially cause harm to transfused patients. In a September 2019 final guidance document (updated in December 2020), the FDA officially recognizes LVDS as an effective testing strategy to control the risk of bacterial contamination in platelets with a single-step approach. This results in improved safety as well as increased availability of these life-saving products. There currently is no HCPCS code that specifically describes LVDS-tested leukocyte-reduced whole blood derived platelets. A specific code is needed to allow CMS and other stakeholders to track utilization of LVDS-tested leukocyte-reduced whole blood-derived platelets, and to provide payment that sufficiently accounts for the additional costs associated with LVDS testing. Both of these factors – tracking utilization and providing appropriate payment for new blood products – were recently identified as priorities by CMS in the CY 2021 OPPS final rule.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code P9031 "Platelets, leukocytes, reduced each unit" plus P9100 "Pathogen test[s] for platelets," adequately describes this product. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.

Agenda Item # 9

Request # 21.027

TOPIC

Request to establish a new HCPCS Level II code to identify large volume delayed sampling (LVDS)-tested leukocyte reduced apheresis platelets.

Applicant's suggested language: P9XXX "Platelets, pheresis, leukocytes reduced, large volume delayed sampling (LVDS)-tested, each unit."

APPLICANT'S SUMMARY

bioMérieux requests a new HCPCS code for large volume delayed sampling (LVDS)-tested leukocyte reduced apheresis platelets.

LVDS-tested leukocyte-reduced apheresis platelets are a transfused platelet product subject to a new enhanced bacterial testing approach called large volume delayed sampling. On May 20, 2020, bioMérieux's BACT/ALERT BPA and BACT/ALERT BPN culture bottles received 510(k) clearance from the FDA for LVDS of leukocyte-reduced apheresis platelets and leukocyte-reduced whole blood platelet concentrates when used with BACT/ALERT® Microbial Detection Systems (BACT/ALERT 3D and BACT/ALERT VIRTUO). The use of these culture bottles allows U.S. blood centers to offer LVDS-tested leukocyte reduced apheresis platelets and leukocyte-reduced whole blood-derived platelets. Platelets are particularly prone to contamination since they are stored at room temperature (unlike red blood cells or plasma, which can be refrigerated to prevent bacterial growth). Therefore, routine testing for bacterial contamination is critical to detect those units that are contaminated and could potentially cause harm to transfused patients. In a September 2019 final guidance document (updated in December 2020), the FDA officially recognizes LVDS as an effective testing strategy to control the risk of bacterial contamination in platelets and extend their shelf life to 7 days with a single-step approach. This results in improved safety as well as increased availability of these life-saving products. There currently is no HCPCS code that specifically describes LVDS-tested leukocyte-reduced apheresis platelets. A specific code is needed to allow CMS and other stakeholders to track utilization of LVDS tested leukocyte-reduced apheresis platelets, and to provide payment that sufficiently accounts for the additional costs associated with LVDS testing. Both of these factors – tracking utilization and providing appropriate payment for new blood products – were recently identified as priorities by CMS in the CY 2021 OPSS final rule.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code P9035 "Platelets, pheresis, leukocytes reduced, each unit" plus P9100 "Pathogen test[s] for platelets," adequately describes this product. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.

Agenda Item # 10

Request # 21.026

TOPIC

Request to establish a new HCPCS Level II code to identify Cryoprecipitated fibrinogen complex, pathogen reduced (CFCPR).

Applicant's suggested language: XXXXX "Cryoprecipitated fibrinogen complex, pathogen reduced, each unit (CFCPR)."

APPLICANT'S SUMMARY

Cerus Corporation submitted a request to establish a single new HCPCS National Level II code to facilitate accurate insurance billing of a new blood component product; Cryoprecipitated fibrinogen complex, pathogen reduced (CFCPR).

A single unit of CFCPR comprises a concentrate of pathogen reduced human plasma clotting factors, specifically enriched for fibrinogen, factor XIII and von Willebrand factor (vWF), in a volume ranging from 60 to 100 milliliters (mL). CFCPR is indicated for treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. CFCPR is additionally indicated for control of bleeding when recombinant and/or specific virally inactivated preparations of factor XIII or vWF are not available, and as second-line therapy for (1) von Willebrand disease and (2) control of uremic bleeding after other treatment modalities have failed. While both CFCPR and an existing HCPCS-coded product (HCPCS P9012, Cryoprecipitate, each unit) serve as a source of fibrinogen and are indicated for the control of bleeding associated with fibrinogen deficiency, CFCPR differs in several important respects from HCPCS P9012/cryoprecipitate: (1) Unlike HCPCS 9012/cryoprecipitate, which has a high factor VIII concentration per mL and is indicated for treatment of hemophilia A, CFCPR has a lower factor VIII concentration and the product labeling accordingly instructs that CFCPR should not be used for replacement of factor VIII; (2) CFCPR is pathogen reduced with an FDA-approved pathogen inactivation system, while HCPCS P9012/cryoprecipitate is not pathogen reduced; and (3) pathogen inactivation and processing in a functionally closed system enables thawed CFCPR to be stored at room temperature and immediately available for transfusion for up to 5 days, while thawed HCPCS P9012/cryoprecipitate can be stored at room temperature for only up to 6 hours before it must be transfused or discarded.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS remains very interested in ensuring the safety of our blood supply, and that we continue to develop a HCPCS Level II code structure that supports blood safety and shelf life, and facilitates the production of new products that provide a new clinical benefit that may be distinct from others on the market. We would like to better understand the scientific data that the applicant has to illustrate how this product is pathogen reduced compared to current codes on the market. Additionally, while the process itself was approved by the FDA, we do not know how the

product is distinguished from others due to the process. CMS is interested in learning more from the applicant related to the science behind the product, as well as other experts on blood safety and supply.

Agenda Item # 10

Request # 21.028

TOPIC

Request to establish a new HCPCS Level II code to identify a blood component product.

Applicant's suggested language: "Plasma, cryoprecipitate reduced, pathogen reduced, each unit (PCRPR)."

APPLICANT'S SUMMARY

PCRPR is indicated for transfusion or therapeutic plasma exchange (TPE) in patients with thrombotic thrombocytopenic purpura (TTP). It may be used to provide coagulation factors, except fibrinogen, factor VIII, factor XIII, and vWF, for transfusion support of patients with appropriate clinical indications. While both PCRPR and an existing HCPCS-coded product (HCPCS P9044, Plasma, cryoprecipitate reduced, each unit) serve as a source of specific clotting factors for transfusion or TPE, PCRPR is pathogen reduced with an FDA-approved pathogen inactivation system to reduce the risk of transmission of viruses, Gram-positive and Gram-negative bacteria, spirochetes and parasites, while HCPCS P9044/Plasma, cryoprecipitate reduced is not pathogen reduced.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS remains very interested in ensuring the safety of our blood supply, and that we continue to develop a HCPCS Level II code structure that supports blood safety and shelf life, and facilitates the production of new products that provide a new clinical benefit that may be distinct from others on the market. We would like to better understand the scientific data that the applicant has to illustrate how this product is pathogen reduced compared to current codes on the market. Additionally, while the process itself was approved by the FDA, we do not know how the product is distinguished from others due to the process. CMS is interested in learning more from the applicant related to the science behind the product, as well as other experts on blood safety and supply.

Agenda Item # 11

Request # 21.037

TOPIC

Request to establish two new HCPCS Level II codes for Apollo Revise Systems:

1. Apollo Revise Dual Channel System used to perform the endoluminal flexible Endoscopic revision of bariatric surgical procedures.

Applicant's suggested language: "Revision device, insertable endoscopic gastrointestinal, dual channel."

2. Apollo Revise SX (Single Channel) System used to perform the endoluminal flexible Endoscopic Revision of Bariatric Surgical Procedures.

Applicant's suggested language: "Revision device, insertable endoscopic gastrointestinal, single channel."

APPLICANT'S SUMMARY

Apollo submitted a request to establish two new HCPCS Level II codes for Apollo Revise Systems.

The Apollo Revise System is an endoscopic endoluminal system used to revise previously done bariatric procedures that have failed. Often the patient requires revision of anatomic abnormalities- enlarged gastric pouch after Roux-en-Y gastric bypass (RYGB) or Sleeve Gastrectomy (LSG). There are no HCPCS that represent a device for revising bariatric procedures. Endoscopic endoluminal revisions for previous bariatric surgeries is a recent innovation and has no established coding. The device used in the procedure currently does not have coding. The Apollo Revise System enables endoscopic endoluminal revisions of prior bariatric procedures. The Apollo Revise System restores the functionality of the original bariatric procedure by tightening the gastric pouch. Both Apollo Revise System includes: OverStitch Endoscopic Suturing System (1); OverStitch Suture Cinch (6); OverTube Endoscopic Access System (1); OverStitch 2-0 Polypropylene Suture (6); Tissue Helix (1). The difference in the single and dual channels are the attachment mechanisms which are specific to the type of endoscope. The original version was developed to be used with a dual channel endoscope. The single channel device was cleared in 2017 works only with single channel endoscopes. Both systems perform the same revision procedure.

PRELIMINARY HCPCS CODING RECOMMENDATION

The Apollo Revise Systems are not suitable for HCPCS Level II coding due to its setting of use. CMS believes this device would typically be bundled within a HCPCS Level I (Current Procedural Terminology [CPT]) code, and would not be performed in the home. The applicant

may be interested in Medicare hospital outpatient pass-through. For information regarding pass-through please refer to CMS' pass-through application procedures as detailed on:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>

Agenda Item # 11

Request # 21.038

TOPIC

Request to establish a new HCPCS Level II code to identify the Orbera Intra-gastric Balloon System.

Applicant's suggested language: "Fluid filled Intra-gastric balloon, insertable."

APPLICANT'S SUMMARY

Apollo Endosurgery submitted a request to establish a new HCPCS Level II code for Orbera Intra-gastric Balloon System.

The system includes components used for endoscopic placement, filling and removal of intra-gastric balloon device. The fluid filled balloon is designed to occupy space and move freely within the stomach. There are no HCPCS that represent the placement and removal of a fluid-filled Intra-gastric Balloon. The ORBERA BALLOON SYSTEM is indicated for weight reduction for adults with obesity with a Body Mass Index (BMI) of >30 and <40 kg/m² who have previously failed more conservative weight reduction alternatives. Orbera is to be used in conjunction with a long-term diet and behavior modification program designed to increase the possibility of significant weight loss and maintenance of that weight loss. The maximum placement period is 6 months. ORBERA is designed to assist weight loss by partially filling the stomach. The expandable design of ORBERA permits a fill volume range of 400cc (minimum) to a maximum of 700cc. Endoscopic route of administration. The ORBERA balloon is positioned within the Placement Catheter Assembly. The Placement Catheter Assembly (Figure 3) consists of a 6.5mm external diameter silicone catheter, one end of which is connected to a sheath in which the collapsed balloon resides. The opposite end is connected to a luer lock connector for attachment to a filling system. A filling system consisting of an IV spike, fill tube and filling valve is provided to assist in the balloon deployment.

PRELIMINARY HCPCS CODING RECOMMENDATION

The Orbera Intra-gastric Balloon System is not suitable for HCPCS Level II coding due to its setting of use. CMS believes this device would typically be bundled within a HCPCS Level I (CPT) code, and would not be performed in the home. The applicant may be interested in Medicare hospital outpatient pass-through. For information regarding pass-through please refer to CMS' pass-through application procedures as detailed on:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>

Agenda Item # 11

Request # 21.039

TOPIC

Request to establish two new HCPCS Level II codes to identify each version of the X-TACK I Endoscopic HeliX Tacking System.

Applicant's suggested language:

1. "Repair, endoscopic gastrointestinal insertable tack placement device 160mm."
2. "Repair, endoscopic gastrointestinal insertable tack placement device 235mm."

APPLICANT'S SUMMARY

Apollo Endosurgery submitted a request to establish two codes for each version of the X-TACK I Endoscopic HeliX Tacking System.

The X-Tack Endoscopic HeliX Tacking System is a sterile, single-use device that enables the user to approximate soft tissue in the gastrointestinal (GI) tract using helix tacks and a 3-0 suture through a 2.8 mm or larger working channel of an endoscope (e.g. gastroscope or colonoscope). Both devices can be inserted orally and anally, however the X-Tack 235 is anticipated to be used predominantly through the anus. The X-Tack Endoscopic HeliX Tacking System is intended for approximation of soft tissue in minimally invasive gastroenterology procedures (e.g. closure and healing of ESD/EMR sites, and closing of fistula, perforation or leaks). X-Tack is not intended for hemostasis of acute bleeding ulcers. This is a newly cleared device and no other currently cleared devices use the same mechanism of action as X-Tack. The X-Tack Endoscopic HeliX Tacking System is intended for approximation of soft tissue in minimally invasive gastroenterology procedures (e.g. closure and healing of ESD/EMR sites, and closing of fistula, perforation or leaks). X-Tack is not intended for hemostasis of acute bleeding ulcers. Action; Repair and Closure of tissue. The X-Tack Endoscopic Helix System is placed endoscopically through either the oral or the anal cavity.

PRELIMINARY HCPCS CODING RECOMMENDATION

The X-Tacking Endoscopic System is not suitable for HCPCS Level II coding due to its setting of use. CMS believes this device would typically be bundled within a HCPCS Level I (CPT) code, and would not be performed in the home. The applicant may be interested in Medicare hospital outpatient pass-through. For information regarding pass-through please refer to CMS' pass-through application procedures as detailed on:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>

Agenda Item # 11

Request # 21.040

TOPIC

Request to establish two new HCPCS Level II codes to identify Apollo ESG Systems

Applicant's suggested language:

1. Alteration device, endoscopic insertable gastrointestinal, dual channel
2. Alteration device, endoscopic insertable gastrointestinal, single channel

APPLICANT'S SUMMARY

Apollo Endosurgery submitted a request to establish two new HCPCS Level II codes for Apollo ESG Systems used to perform the endoluminal flexible Endoscopic Sleeve Gastroplasty Procedure.

The Apollo ESG System is used to reduce the volumetric capacity of the stomach for the purpose of weight loss. There are no HCPCS codes that represent a device for creating a gastric sleeve by endoluminal flexible endoscopy. This is a new procedure with no coding for the physician, procedure or device. That is why we are seeking a HCPCS code to ensure resources for the procedure are properly captured. The Apollo ESG System enables the Endoscopic Sleeve Gastroplasty, a flexible endoscopic bariatric procedure that reduces the stomach volume. The Apollo ESG System reduces the stomach volume by up to 80%. Both Apollo ESG Systems include: OverStitch Endoscopic Suturing Device (1); OverStitch Suture Cinch (8); OverTube Endoscopic Access Device (1); OverStitch 2-0 Polypropylene Suture Material (8); Tissue Helix (1). The difference in the single and dual channels are the attachment mechanisms which are specific to the type of flexible endoscope. The original version was developed to be used with a dual channel endoscope. The single channel device was cleared in 2017 works only with single channel endoscopes. Both systems perform the same ESG procedure.

PRELIMINARY HCPCS CODING RECOMMENDATION

The Apollo ESG System is not suitable for HCPCS Level II coding due to its setting of use. CMS believes this device would typically be bundled within a HCPCS Level I (CPT) code, and would not be performed in the home. The applicant may be interested in Medicare hospital outpatient pass-through. For information regarding pass-through please refer to CMS' pass-through application procedures as detailed on:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>

Agenda Item # 11

Request # 21.041

TOPIC

Request to establish two new HCPCS Level II codes to identify OverStitch SX (Single Channel) Endoscopic Suturing System and OverStitch Dual Channel Endoscopic Suturing System.

No suggested language

APPLICANT'S SUMMARY

Apollo Endosurgery submitted a request to establish two new codes for OverStitch SX (Single Channel) Endoscopic Suturing System and OverStitch Dual Channel Endoscopic Suturing System.

The Apollo Endosurgery OverStitch Endoscopic Suture System provides physicians the ability to perform different types of tissue apposition within the Gastrointestinal (GI) Tract. The Apollo Endosurgery OverStitch Endoscopic Suture System is intended for endoscopic placement of suture(s) and approximation of soft tissue. The Apollo OverStitch endoscopic suturing device has been used in a variety of applications including closure of perforations, closure of full thickness defects in the gastrointestinal wall created during endoscopic full thickness resection, closure of mucosectomies during peroral endoscopic myotomy, stent fixation, fistula closure, post endoscopic submucosal dissection, endoscopic mucosal resection and Natural Orifice Transluminal Endoscopic Surgery (NOTES) defect closures. The OverStitch endoscopic suturing system (Apollo Endosurgery, Austin, Texas) is currently the only available full-thickness suturing device, and the only Food and Drug Administration cleared and commercially available device in the United States. Therefore, there are no HCPCS that represent an endoscopic suturing device. The OverStitch Endoscopic Suturing System is intended for endoscopic placement of suture(s) and approximation of soft tissue (Regulation Name: Endoscope and Accessories Regulatory Class: Class II). The OverStitch System performs endoscopic surgical procedures. Both OVERSTITCH System is placed endoscopically through either the oral or the anal cavity.

PRELIMINARY HCPCS CODING RECOMMENDATION

The Apollo OverStitch Endoscopic Suture System is not suitable for HCPCS Level II coding due to its setting of use. CMS believes this device would typically be bundled within a HCPCS Level I (CPT) code, and would not be performed in the home. The applicant may be interested in Medicare hospital outpatient pass-through. For information regarding pass-through please refer to CMS' pass-through application procedures as detailed on:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>

Agenda Item # 12

Request # 21.048

TOPIC

Request to establish a new Level II HCPCS to identify Alzair Allergy Blocker.

Applicant's suggested language: Axxxx "Alzair Allergy Blocker Powder, per 800 mg bottle."

APPLICANT'S SUMMARY

The Alzair Allergy Blocker is composed of pharmaceutical grade Hydroxypropyl Methylcellulose (HPMC; 98.5%) and high-quality peppermint (1.5%) formulated into a micronized powder of fine particles of inert cellulose. Alzair is indicated to treat hay fever and allergy sufferers by promoting alleviation of mild allergic symptoms (i.e., mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various airborne allergens including indoor and outdoor environmental pollens, house dust, animal hairs, and dust mites. It is a drug free product that has zero contraindications. It is supplied in a novel patented bottle that produces a specific particle size that allows for the proper efficacy and dose of the Methylcellulose.

PRELIMINARY HCPCS CODING RECOMMENDATION

An existing National Drug Code (NDC) is available for assignment by insurers to identify the Alzair Allergy Blocker, if they deem appropriate. As such, establishing a HCPCS Level II code would be redundant and unnecessary. For instance, the Alzair Allergy Blocker is a self-administered product, and is not reportable under Medicare Part B. It is also not reportable under Medicare Part D because Alzair is not approved by the FDA as a drug.

Agenda Item # 13

Request # 21.049

TOPIC

Request to establish a new HCPCS Level II code to identify the Lotus No Balloon Catheter, a novel catheter that encompasses three types of urological catheters.

No suggested language.

APPLICANT'S SUMMARY

Hakki Medical Technologies, Inc. respectfully requests new codes to adequately describe the Lotus No Balloon Catheter, a novel catheter that encompasses three types of urological catheters. The current recommended coding description, A4340, 4351 and 4353, includes just two types of catheters, the Malecot type and the intermittent, straight tip type catheters, and an intermittent catheter with insertion supplies. The Lotus No Balloon Catheter is the only no balloon catheter with FDA 510(k) clearance for use as a straight intermittent catheter and indwelling catheter similar to a Foley type, and a Malecot drainage catheter. As an indwelling catheter, the Lotus No Balloon Catheter has significant therapeutic distinctions compared to the Malecot and Foley type, therefore requiring a new code. Recommended language for new codes should include "no balloon type catheter for indwelling use, with or without coating" in the description and establish new codes for catheterization trays/kits with and without collection bags. The existing codes refer to an indwelling catheter as "an indwelling, specialty type" that includes Malecot and Mushroom, and specialty Foley type catheters. By design, the Lotus No Balloon Catheter is a safer indwelling catheter as it lacks an inflatable retaining balloon that causes well documented complications of an indwelling Foley catheter, nor does it require additional accessories for placement and removal of a Malecot indwelling catheter under direct vision. The Lotus No Balloon Catheter is the only indwelling catheter that does not require placement by a medical practitioner. A patient can safely insert and remove the indwelling Lotus No Balloon Catheter, decreasing the number of self catheterizations needed per day.

PRELIMINARY HCPCS CODING RECOMMENDATION

As we have previously stated, existing code A4340 "Indwelling catheter; specialty type, (e.g., coude, mushroom, wing, etc.), each" adequately describes the Lotus catheter, and is available for assignment by insurers to identify use of the Lotus catheter as the indwelling catheter if they deem appropriate. Existing code A4351 "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each" or A4353 "Intermittent urinary catheter, with insertion supplies" adequately describe the catheter that is the subject of this application when the Lotus anchoring mechanism is not deployed, and it is used for intermittent catheterization.

Agenda Item # 14

Request # 21.054

TOPIC

Request to establish a new HCPCS Level II code to identify for IB-Stim, a percutaneous electrical nerve field stimulator (PENFS) device.

Applicant's suggested language: L86XX "Percutaneous electrical nerve field stimulator (PENFS)."

APPLICANT'S SUMMARY

IB-Stim is a non-implanted nerve stimulator for functional abdominal pain relief which was cleared by the FDA through the de novo premarket review pathway on June 7, 2019 (DEN180057). The FDA stated this is the "first medical device to aid in the reduction of functional abdominal pain in patients 11-18 years of age with irritable bowel syndrome (IBS) when combined with other therapies for IBS" <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-medical-device-relief-pain-associated-irritable-bowel-syndrome-patients>.

IB-Stim is a prescription only device that consists of a small single-use percutaneous electrical nerve field stimulator that is placed behind the patient's ear. This PENFS device has a battery-operated chip that emits low-frequency electrical pulses to stimulate certain cranial nerves continuously for five days, at which point the device is removed. The underlying mechanism of action of this novel therapy was demonstrated in pre-clinical studies and a randomized controlled trial. IB-Stim is prescribed by and placed by a physician. The device is purchased and billed by the hospital.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS refers the applicant back to the American Medical Association (AMA) CPT Editorial Panel again, for coding guidance for this service, including the device. CMS believes this product is not suitable for a HCPCS Level II code. CMS notes that this product is designed to be applied to the body by or under the supervision of a medical professional, and is also described as a single-use device. This type of supervised service is most consistent with HCPCS Level I (CPT) coding. CMS encourages the applicant to describe their engagement with the AMA.

Agenda Item # 15

Request # 21.035

TOPIC

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

Applicant's suggested language: LXXXX "Percutaneous Nerve Stimulator for Opioid Withdrawal."

APPLICANT'S SUMMARY

On behalf of Speranza Therapeutics, the Wells Health Group submitted a request to establish a new HCPCS Level II code for 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 HCPCS Level II 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 transillumination. 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 120 hours. Each patient's treatment is determined by frequent measurement of Clinical Opiate Withdrawal Scale (COWS). As per the applicant, there are currently HCPCS Level II codes for Implantable neurostimulator, pulse generators e.g. L8679 – up till now, no codes for non-implantable stimulators.

PRELIMINARY HCPCS CODING RECOMMENDATION

Application 21.035 is a resubmission of application 20.163 from 2020. CMS previously referred the applicant to the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel for coding guidance for this service, including the device. CMS continues to believe this product is not suitable for a HCPCS Level II code. CMS notes that this product is designed to be applied to the body by, or under the supervision of, a medical professional, and is also described as a single-use device. This type of supervised service is most consistent with

HCPCS Level I (CPT) coding. We encourage the applicant to describe their engagement with the AMA, and to identify if any new information was presented in application 21.035 when compared to application 20.163.

Agenda Item # 16

Request # 21.060

TOPIC

Request to revise HCPCS Level II code C1753 to include language for the use of the optical coherence tomography (OCT) imaging catheter.

No suggested language.

APPLICANT'S SUMMARY

Since 2004, the current Level II HCPCS code C1753 has documented the use of a catheter for intravascular ultrasound (IVUS) in its description "Catheter, intravascular ultrasound". Abbott is requesting that HCPCS code C1753 be revised to include language for the use of the OCT imaging catheter. Significant similarities exist between the function and use of the IVUS and OCT catheters, which may make the creation of a new Level II HCPCS code unnecessary if the existing code's language is adjusted as requested. Both catheters facilitate intracoronary imaging for the visualization of vessel wall lumen morphology to assess or optimize stent implantation and minimize stent-related complications. Beyond these similarities in function and use, there are important differences in the imaging modalities used for IVUS and OCT catheters. IVUS imaging is based on ultrasound waves that are introduced into the coronary arteries through a transducer that travels through the catheter. The waves echo through the arteries and are converted to greyscale images. In OCT, the catheter delivers an infrared camera to the arterial site which is pulled through the vessel to obtain high resolution, detailed visualization of plaque morphology which can distinguish between fibrous, lipid, and calcified composition of atherosclerotic plaque. Contrasting the two modalities, OCT offers better resolution and rapid image acquisition, resulting in more accurate vessel and plaque measurements.

For these reasons, the current description for the existing C1753 code is insufficient to describe the use of the OCT catheter due to the specificity of imaging modality stated in the code's description. Due to the specification that the catheter is for use in "intravascular ultrasound", we propose revising the description of C1753 to facilitate the appropriate documentation of OCT within a procedure. Our suggested language is as follows: "Catheter, intravascular ultrasound or optical coherence tomography".

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS' preliminary recommendation is not to revise HCPCS Level II code C1753 to include language for the use of the OCT imaging catheter. However, the applicant may submit a New Technology Ambulatory

Payment Classification (APC) application for their OCT imaging catheter. For information regarding the New Technology APC process, please refer to:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/Downloads/newtechapc.pdf](#). We would appreciate more insight into how the applicant believes C1753 is used for payment purposes and why it should apply to its product.

Agenda Item # 17

Request # 21.061

TOPIC

Request to establish a new HCPCS Level II code to describe a structured lipid matrix powder for oral administration (Encala).

Applicant's suggested language: B4XXX "structured lipid matrix, orally administered, per dose."

APPLICANT'S SUMMARY

Encala has a molecular structure with both hydrophobic and hydrophilic characteristics. Once mixed and ingested with solids or liquids, Encala transits from the stomach to the small intestine and functions as its own intraluminal micelle. Encala digestion and absorption is lipase and bile acid independent and is efficiently absorbed in clinical conditions with decreased or absent lipase and bile acid concentrations such as in patients with EPI. Encala migrates to intestinal mucosal cells (enterocytes) for absorption in the same fashion as native micelles formed from other dietary fats. It is metabolized within the mucosal cells and then transported via the lymphatic system like other dietary fats.

Encala is provided by oral administration. The Encala dose is 18.4 grams with 9.2 grams of the active structured lipid matrix. Please note in an NIH-funded randomized, placebo-controlled, double-blind study, Encala contained 7.2 grams of the active structured lipid 4 matrix per 32 gram dose. The difference is the result of formulation optimization prior to commercial manufacturing to enhance patient adherence reported in a prospective examination.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS' preliminary recommendation is not to establish a HCPCS Level II code to describe this product as it does not require a prescription. Existing HCPCS Level II code S9435 – "Medical foods for inborn errors of metabolism" is available for assignment for insurers if they deem appropriate. For coding guidance, contact the insurers in whose jurisdiction a claim will be filed. We would be interested in learning about any specific insurer's policy that directs coding for Encala.

Agenda Item # 18

Request # 21.062

TOPIC

Request to modify/revise an existing HCPCS Level II code for ENU Complete Nutrition Shakes from B4150 to B4153, based on a modification to the product formulation and the inclusion of hydrolyzed whey protein, and the removal of two complete proteins. This change in formula aligns the product to the definition of B4153.

No suggested language.

APPLICANT'S SUMMARY

ENU Complete Nutrition Shake is an enteral nutrition medical food formulation that can be consumed orally or by enteral feeding tube. ENU Complete Nutrition Shakes are 1.6 kcal/mL and come in two flavors, chocolate and vanilla. The patient population is generally anyone above the age of 2 who is experiencing malnutrition or unwanted weight loss related to an underlying disease, such as cancer, cystic fibrosis, or sarcopenia. The ENU Complete Nutrition Shake has previously been assigned a HCPCS Code of B4150, and we are requesting a code revision to B4153 due to a formulation change to the product to remove complete proteins and change to hydrolyzed protein (See attached product nutrition facts and ingredient list below in Section). The updated nutrition facts and ingredients now include a removal of the two complete proteins (whey protein isolate and soy protein isolate), and now ONLY include hydrolyzed whey protein, making the formula a Peptide Formula.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS agrees with the applicant that existing code B4153 “Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit” describes the ENU Complete Nutrition Shake.

For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare payment purposes, we recommend you contact the Pricing, Data Analysis and Coding (PDAC) Contractor for a code verification review

Agenda Item # 19

Request # 21.063

TOPIC

Request to establish a new HCPCS Level II code to identify PeDIA. PeDIA assists with inducing anesthesia in children ages 3 and over. It replaces the anesthesia mask which can cause anxiety and problems during anesthesia induction

No suggested language.

APPLICANT'S SUMMARY

PeDIA assists with inducing anesthesia in children ages 3 and over. It replaces the anesthesia mask which can cause anxiety and problems during anesthesia induction (bringing a patient from an awake state to a state of anesthesia). It brings anesthesia gases from the anesthesia machine to the child to induce anesthesia, i.e. bring them from an awake state to a depth of anesthesia. The PeDIA is attached to the distal end of the anesthesia circuit where the anesthesia mask would normally go. The anesthesia circuit brings anesthesia gases from the anesthesia machine to fill the PeDIA device. Once primed (filled with gases), the anesthesia provider gives the PeDIA to the child. The child places the mouthpiece of the PeDIA in his/her mouth, then inhales anesthesia gases through it. When the child exhales, gases and carbon dioxide are carried back to the anesthesia machine. As the child inhales and exhales through the balloon, the PeDIA makes a whistling sound and also slightly deflates and inflates, engaging the senses of sight, touch and sound while providing the child a sense of renewed control in the unsettling environment of the operating room. As the child inhales and exhales the anesthesia gases, he/she is induced, ie, passes from the awake state to the anesthetized state, until they can no longer participate, which, at that point, the child is very sedated and anesthetized by the gases.

The PeDIA also distracts the child because it is a colorful medical grade device that resembles a balloon (a familiar toy) and makes a pleasing sound.

PRELIMINARY HCPCS CODING RECOMMENDATION

The PeDIA is not suitable for coding in HCPCS Level II due to its setting of use. For use in Hospital Inpatient, Hospital Outpatient, and Freestanding Ambulatory Surgical settings, this anesthesia supply would be bundled into the appropriate hospital payment.

Agenda Item # 20

Request # 21.064

TOPIC

Request to establish a new HCPCS Level II code to identify the Sonography-Guided Transcervical Fibroid Ablation System Probe.

No suggested language.

APPLICANT'S SUMMARY

The Sonata System combines real-time intrauterine ultrasound guidance with targeted radiofrequency ablation in an incisionless procedure to treat symptomatic uterine fibroids. While other methods for treatment require more invasive approaches including a small or large incision across the abdomen. Sonata offers a breakthrough alternative to hysterectomy and myomectomy. Transcervical delivery avoids the peritoneal cavity and does not require general anesthesia. Transcervical Radiofrequency Ablation (TFA) Treats 80% of all fibroid types including submucous, intramural, transmural, and subserous.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new HCPCS Level II code to separately identify the Sonography-Guided Transcervical Fibroid Ablation System Probe has not been approved. The Sonography-Guided Transcervical Fibroid Ablation System Probe is an integral part of the procedure, and separate coding could be construed as redundant. CMS believes the appropriate starting point for correct coding is for the applicant to approach the AMA for guidance.

Agenda Item # 21

Request # 21.057

TOPIC

Request to establish a new HCPCS Level II code to identify Peristeen Rectal Balloon.

Applicant's suggested language: AXXXX "Rectal catheter, with or without balloon, any type."

APPLICANT'S SUMMARY

The Peristeen Irrigation (TAI) system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system may be purchased with a carrying case (toilet bag). The rectal catheter is single-use, but the other components may be used multiple times. Accessory kits are available for the components.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4459 "Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type" adequately describes the product of this application.

Agenda Item # 21

Request # 20.165

TOPIC

1) Request to establish a new HCPCS Level II code to identify an irrigation supply.

Applicant's suggested language: A4XXX "Irrigation supply; sleeve, disposable, each."

2) Request to modify HCPCS Level II code A4397 "Irrigation supply; sleeve, each" to instead read "Irrigation supply; sleeve, reusable, each."

APPLICANT'S SUMMARY

Coloplast requests a new Level II HCPCS code to identify Disposable Irrigation Sleeves. Coloplast Disposable Irrigation Sleeves serve a clinical purpose for a specific patient population compared to reusable sleeve described by A4397. Therefore, we ask for a new HCPCS code to differentiate the disposable ostomy irrigation sleeve from the reusable ostomy irrigation sleeve. Method of Irrigation.

Irrigation is a way to manage effluent from a surgically created sigmoid or colostomy stoma. The accessories include a cone, a water bag, a sleeve. Reusable sleeves are either attached to a belt to secure the sleeve or a locking barrier that will adhere to the peristomal skin surrounding the stoma. Disposable sleeves have adhesive that adheres directly to the patient's skin. Once the adhesive is used on the skin, it is not meant to be reused, similar to a disposable band aid. Irrigation is generally accomplished by instillation of lukewarm tap water through the stoma, which stimulates peristalsis and contractions of the colon leading to the evacuation of stool. Once the water is installed, the cone is removed, the user waits for the contents of the colon to be expelled from the stoma to the sleeve and into the toilet. The irrigation process can take from 30 minutes to 1 hour depending on the person and their specific bowel regimen. According to the applicant, In addition to the difference in frequency of usage, the unique clinical rationale supports the need for a new HCPCS code for disposable irrigation sleeves.

Clinical rationale for disposable irrigation sleeves:

1. Difficult pouching situations requiring better fit of disposable irrigation sleeve;
 - a. Challenging abdominal contours
 - b. Concerns with leakage / infection
2. Type of pouching system individual uses when not irrigating is not compatible with reusable sleeves
3. Thick and pasty stool consistency is a clinical reason to use a disposable irrigation sleeve
4. Inability to care for reusable sleeves or lifestyle preference

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS will defer this application to a subsequent coding cycle to provide an opportunity for further consideration of clinical distinction, and to determine how to best implement a coding change, should one be made, for these products.

Agenda Item # 22

Request # 21.007

TOPIC

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

Applicant's suggested language: Q4XXX "InnovaMatrix AC, per sq. cm."

APPLICANT'S SUMMARY

InnovaMatrix AC is a sterile, single use, medical device consisting of extracellular matrix derived from porcine placental material used for safe and effective wound treatment. InnovaMatrix AC is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans. This biodegradable wound matrix provides a protective cover to the wound.

There are no current specific HCPCS codes that define a skin substitute composed of an extracellular matrix derived from porcine placental material. InnovaMatrix AC is the first Food and Drug Administration cleared medical device sourced from pig placenta. Therefore, we request a new HCPCS code category code: Q4XXX "InnovaMatrix AC, per sq. cm" to facilitate proper billing and coding to all payers in the full range of site of care settings.

InnovaMatrix AC is intended for use in the management of wounds, including: partial- and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor site/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds, (abrasions, lacerations, second-degree burns and skin tears), and draining wounds. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product will fully resorb and does not have to be removed. InnovaMatrix AC is supplied terminally sterile, in a single use package, and in a variety of sizes.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS will defer this application to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Agenda Item # 23

Request # 21.010

TOPIC

Request to establish a new HCPCS Level II code to identify Mirragen Advanced Wound Matrix

Applicant's suggested language: Q42XX "Mirragen Advanced Wound Matrix, per square centimeter."

APPLICANT'S SUMMARY

Mirragen Advanced Wound Matrix is composed solely of biocompatible and resorbable borate-based bioactive glass fibers and particulates. It is intended for use in the management of wounds. The product size varies from 1"x1" to 4"x4" and the size is selected according to the wound dimensions. The device is a synthetic resorbable matrix that covers the wound, absorbs exudate, and provides a scaffold upon which cellular migration, revascularization, and soft tissue regeneration can occur within the wound bed. The fiber structure of MIRRAGEN mimics the microstructure of the extracellular matrix, thereby functioning as a skin substitute in the wound healing process.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS will defer this application to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Agenda Item # 24

Request # 21.018

TOPIC

Request to establish a new HCPCS Level II code to identify bio-ConneKt

Applicant's suggested language: "bio-ConneKt Wound Matrix, per sq. cm."

APPLICANT'S SUMMARY

As a bioengineered skin substitute, the FDA 510(k) cleared bio-ConneKt Wound Matrix is clinically indicated for the local management of moderately to heavily exuding wounds, including: partial and full thickness wounds, draining wounds, tunneling wounds, pressure sores/ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds and surgical wounds. It is an all-biologic, xenograft collagen-based scaffold that is supplied sterile and subject to proprietary processing to withstand challenges of wound micro-environment. bio-ConneKt Wound Matrix is fully absorbed into the wound bed where it is vascularized by healing tissue. The product is covered by secondary wound dressings to help keep the wound site clean and protected from infections. Clinical testing indicates no need for product removal of bio-ConneKt Wound Matrix and one-time application for most conditions. The manufacturing process for the bio-ConneKt Wound Matrix meets USA and European Standards for animal tissue sourcing, handling, and inactivation of viruses and transmittable agents.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS will defer this application to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Agenda Item # 25

Request # 21.022

TOPIC

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

No suggested language.

APPLICANT'S SUMMARY

XCelliStem is a proprietary blend of multiple ECM source material, spleen and lung. It is the only product composed of multiple ECM sources. All current products are from a single ECM source and their composition is limited based on the sole source material. Each ECM source material is composed of a unique collection of varying components, such as collagen, elastin, fibronectin, laminin, glycosaminoglycans (GAGs), proteoglycans, and other proteins. Utilizing multiple ECM sources allows for a final composition that contains a broader diverse mix of various ECM components. ECM components have a variety of signaling molecules contained within them, and also have a multitude of binding sites within their structure. Binding sites and signaling molecules can be involved in a wide array of activities within tissue, including binding to existing native ECM material, binding to cells, signaling cell attraction, cell mobility, cell growth, and cell differentiation. Signaling components can also be involved in progenitor cell recruitment to the site, and regulation of progenitor cell activity at the site.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS will defer this application to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Agenda Item # 26

Request # 21.024

TOPIC

Request to establish a new HCPCS Level II code to identify Microlyte Matrix and a request to delete Microlyte Matrix from the A6460 HCPCS code.

No suggested language.

APPLICANT'S SUMMARY

Imbed Biosciences, Inc. submitted a request to establish a new Level II HCPCS code for Microlyte Matrix and delete Microlyte Matrix from A6460.

Microlyte Matrix is composed of an ultrathin polyelectrolyte multilayer matrix coated with a resorbable polymer. It functions as a wound matrix product to enhance wound granulation and maintain a moist wound healing environment which facilitates cell growth, neovascularization, and wound closure. The matrix components of Microlyte serve as a functional molecular template to facilitate the granulation process by masking the disorganized surface chemistry of the wound bed. Microlyte Matrix is currently assigned HCPCS A6460, a code which CMS created for a product now assigned to C1849 "Skin substitute, synthetic, resorbable, per sq cm". In the CY 2021 OPFS Final Rule, CMS defined skin substitutes as "a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers" and that they are products that are "applied to wounds to aid in healing and through various mechanisms of action." Imbed has requested formal assignment to C1849, which accurately describes Microlyte Matrix and its clinical function. While this code may be billed in hospital outpatient departments, it is not recognized by Medicare in other places of service including physician offices. We therefore request that Microlyte Matrix be assigned a unique Q-code and be deleted from code A6460. Microlyte Matrix may be used for the management of: wounds; partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second-degree burns, abrasions and lacerations, donor sites and surgical wounds; and may be used over debrided and grafted partial thickness wounds. The product is applied to wounds as a dry, flexible polymer film; the product size is determined by wound size. Microlyte Matrix is supplied individually packaged in foil pouches in varying sizes.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS will defer this application to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Agenda Item # 27

Request # 20.111

TOPIC

Request to establish a new HCPCS Level II 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

CMS will continue to defer this application to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Agenda Item # 28

Request # 20.120

TOPIC

Request to establish a new HCPCS Level II 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.

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

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS will continue to defer this application to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Agenda Item # 29

Request # 21.020

TOPIC

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

No suggested language.

APPLICANT'S SUMMARY

TheraGenesis is a bilayer wound matrix, meshed and non-meshed. TheraGenesis is a cellular and/or tissue-based product (CTP) that is comprised of two layers: a porcine tendon-derived atelo-collagen layer and a silicone film layer. The silicone film layer also contains a non-adhesive mesh (TRES) to reinforce the silicone film to better hold sutures and staples to adhere TheraGenesis to the wound being treated. The biodegradable collagen matrix provides a scaffold for cellular and capillary in-growth. TheraGenesis will be used to treat patients with chronic and traumatic wounds including but not limited to diabetic foot ulcers, venous leg ulcers, burns, and other chronic and traumatic wounds and tissue deficits, in outpatient wound care clinics, outpatient and inpatient operating rooms, ambulatory surgical centers and physician offices sites of service. TheraGenesis is a single-use, bi-layered wound matrix that is administered by a physician as a wound covering to aid in the repair or replacement of lost or damaged tissue.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS will defer this application to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.