Department of Health & Human Services
Centers for Medicare & Medicaid Services
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# Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions

## First Biannual, 2021 HCPCS Coding Cycle

This document presents a summary of each HCPCS code application and CMS' HCPCS coding decision for each application processed in CMS' First Biannual 2021 HCPCS code application review cycle. Each individual summary includes: the request number; topic; a summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS; CMS' preliminary HCPCS coding recommendation; a summary of the primary speaker's comments at the HCPCS public meeting; and CMS' final HCPCS coding decision. All new coding actions will be effective October 1, 2021, unless otherwise indicated.

These HCPCS Level II coding decisions will also be included in the October 2021 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS

**July 7, 2021 Meeting Agenda Items**

**Request # 21.053**

## TOPIC

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"

## 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axial rotation unit, with or without adjustability," but with the new clarification of that code, the L5984 is no longer applicable to use as it is not providing the torsional rotation during ambulation.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Following the HCPCS public meeting, CMS re-reviewed this application. CMS is finalizing its preliminary recommendation to establish a new HCPCS Level II code, and is also revising the proposed code language to include the word "rotation": K1022 "Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type."

**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 H20. 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.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary recommendation to establish a new HCPCS Level II code to identify the Lung Assist Exsufflation Belt. The Exsufflation Belt is a system utilizing reversed breathing action for diaphragmatic failure: active exhalation by applying pressure across the abdomen, elevating the diaphragms and passive inhalation as pressure is removed so the diaphragms "fall" down. This is best applied for daytime ventilation to many patients. The loss of need for continuous facial or tracheostomy interface prevents facial skin breakdown and facial-dental deformities allowing normal speaking and eating. The abdominal

device is covered by clothing allowing unobtrusive use. This is effective over months to years. The lack of invasive tracheostomy and facial interface is cost saving from direct and indirect costs and greatly enhances quality of life. Most, if not all, of the negative consequences of using masks or tracheostomy full time are avoided by the active daytime use of this device. A single currently available ventilator is the power source with the added advantage that it can also be used for nocturnal ventilatory support when a change in posture requires positive pressure inhalation.

**CMS FINAL HCPCS CODING DECISION**

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation to establish a new HCPCS Level II code: K1021 "Exsufflation belt, includes all supplies and accessories."

For Medicare, please consult with the Durable Medical Equipment Medicare Administrative Contractor in the jurisdiction that a claim would be filed for payment guidance related to ventilator accessories.

## 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's 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". The 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. The 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."**

### CMS 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."

### SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

At a minimum, multiple codes should be assigned to the compressor controller and limb garments, as the compressor is designed to work with multiple limb garments. The non-calibrated compressor and full and half leg appliances have been submitted for coding in the next round.

Creating new K codes for a non-pneumatic segmental calibrated gradient compression device creates undue burden on the Medicare Administrative Contractors and commercial payers as they must adjudicate every claim individually and will have to generate new coverage policy and payment for a category of devices that has had coverage and payment policy for decades.

Koya therefore respectfully requests that CMS not finalize its preliminary recommendations for request #21.070. Instead, Koya urges CMS to simply modify the descriptor language in HCPCS code E0668 so that non-pneumatic technology is not excluded from these HCPCS codes. That simple change would ensure that compression devices, that perform the same clinical function for patients with the same clinical needs, are included in the same HCPCS codes. Alternatively, another straightforward solution would be to add the word "non-pneumatic" to the HCPCS code descriptions as follows:

E0668: "Segmental pneumatic and non-pneumatic appliance for use with pneumatic and non-pneumatic compressor, full arm".

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is changing its preliminary recommendation, which was to create one HCPCS Level II code for the entire non-pneumatic compression system, including all components and accessories (i.e., the compression controller – request #21.032, and the full arm compression garment – request #21.070 were included under the same code). CMS re-reviewed this application together with the information provided at the public meeting, and is now finalizing the decision to create separate HCPCS Level II codes for the compression controller and the full arm compression garment. Given the technological differences between pneumatic and non-pneumatic compression technology, CMS is not revising the existing pneumatic compression device code E0668, but is establishing the following new code to describe the non-pneumatic device that is the subject of this application (request #21.070): K1025 "Non-pneumatic sequential compression garment, full arm."

**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." This code description specifically limits the method of programmable sequential gradient compression to "pneumatic". The applicant requested that CMS modify the description of the HCPCS code to allow compression devices that provide the same therapy through innovative technology to meet the code requirements. 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.

## CMS 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."

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

At a minimum, multiple codes should be assigned to the compressor controller and limb garments, as the compressor is designed to work with multiple limb garments. The non-calibrated compressor and full and half leg appliances have been submitted for coding in the next round.

Creating new K codes for a non-pneumatic segmental calibrated gradient compression device creates undue burden on the Medicare Administrative Contractors and commercial payers as they must adjudicate every claim individually and will have to generate new coverage policy and payment for a category of devices that has had coverage and payment policy for decades.

Koya requested that CMS not finalize its preliminary recommendations for request #21.032. Instead, they urged CMS to simply modify the descriptor language in HCPCS code E0652 so that non-pneumatic technology is not excluded from these HCPCS codes. That change would ensure that compression devices, that perform the same clinical function for patients with the same clinical needs, are included in the same HCPCS codes. Alternatively, another solution would be to add the word "non-pneumatic" to the HCPCS code descriptions as follows: E0652: "Pneumatic and non-pneumatic compressor, segmental home model with calibrated gradient pressure".

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is changing its preliminary recommendation, which was to create one HCPCS Level II code for the entire non-pneumatic compression system, including all components and accessories (i.e., the compression controller – request #21.032, and the full arm compression garment – request #21.070 were included under the same code). CMS re-reviewed this application together with the information provided at the public meeting, and is now finalizing the decision to create separate HCPCS Level II codes for the compression controller and the full arm compression garment. Given the technological differences between pneumatic and non-pneumatic compression technology, CMS is not revising the existing pneumatic compression device code E0652, but is establishing the following new code to describe the non-

pneumatic device that is the subject of this application (request #21.032): K1024 “Non-pneumatic compression controller with sequential calibrated gradient pressure.”

**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.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The speaker agreed with CMS' HCPCS Level II preliminary proposed language KXXXX "Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm" with a suggested minor revision to the proposed code language to remove the word "transcutaneous," because the FDA Approval Letter dated May 20, 2019 says "stimulation may be provided transcutaneously or percutaneously." The revised code, as requested by the speaker, would read KXXXX "Distal electrical nerve stimulator, stimulates peripheral nerves of the upper arm".

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation to establish a new HCPCS Level II code K1023 "Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm," as only the term transcutaneous is used in the FDA's 510(k) device description of the Nerivio, and the HCPCS application did not discuss the Nerivio device

performing percutaneous stimulation. CMS would be open to hearing more from the applicant about instances where percutaneous stimulation is performed in the home by the patient.

**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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary recommendations.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is finalizing its decision to establish two new codes and discontinue the existing code in the preliminary recommendation:

1. Establish new HCPCS Level II code J7294 "Segesterone acetate and ethinyl estradiol 0.15mg, 0.013mg per 24 hours; yearly vaginal system, each"

2. Establish new HCPCS Level II code J7295 "Ethinyl estradiol and etonogestrel 0.015mg, 0.12mg per 24 hours; monthly vaginal ring, each"

3. Discontinue HCPCS Level II code J7303 "Contraceptive supply, hormone containing vaginal ring, each," effective September 30, 2021.

**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.

## CMS 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"

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary decision to establish a new HCPCS Level II code for Teva's Romidepsin injection solution, a non-lyophilized (e.g. liquid) formulation. They agreed with the proposed code and description: JXXXX "Injection, romidepsin, non-lyophilized, 0.1 mg." and requested to finalize the preliminary decision and include HCPCS Level II code JXXXX in the coding update with an effective date of October 1, 2021.

## CMS FINAL HCPCS CODING DECISION

CMS is finalizing its decision to establish two new codes and discontinue two existing codes.

1. Establish new HCPCS Level II code J9318 "Injection, romidepsin, non-lyophilized, 0.1 mg"

2. Establish new HCPCS Level II code J9319 "Injection, romidepsin, lyophilized, 0.1 mg"

3. Discontinue existing HCPCS Level II code J9315 "Injection, romidepsin, 1 mg," effective September 30, 2021.

4. Discontinue existing HCPCS Level II code C9065 “Injection, romidepsin, non-lyophilized (e.g. liquid), 1mg,” effective September 30, 2021.

**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.

## CMS 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."

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Request #21.001i is an internal application, so CMS attempted to notify all impacted stakeholders in advance of the public meeting to allow them the opportunity to comment. No oral comments were provided by interested stakeholders at the public meeting, but CMS received written comments from Amgen and its representatives, and also from the Biosimilars Forum ("The Forum") in response to CMS' published preliminary HCPCS coding recommendation. Amgen and its representatives generally disagreed with the proposed coding and dose descriptor change on the basis that it could lead to billing confusion, but asked that if CMS finalizes the change, it delays implementation to January 1, 2022 and publishes coding and billing guidance. The Forum agreed with CMS' preliminary recommendation as a means to align billing units between biosimilars and their reference products, which would facilitate billing accuracy.

Specifically, the written comments from Amgen, manufacturer of Neulasta, and its representatives asked CMS to not implement its proposed code changes because a new code and base dose for Neulasta® would not reflect the product's prescribing information for the vast majority of patients, and it would be confusing and unduly burdensome for physicians and providers. The prescribing information makes clear that dosing for all adult patients is 6 mg. Further, Neulasta® is rarely used in the pediatric setting, which is the only setting where dosing is weight-based and where there would be potential for doses smaller than 6 mg., depending on the patient's weight. The commenters mention that Neulasta® has had the same code and base

dose since January 1, 2004. If the code's base dose were to be changed to 0.5 mg, which is the base dose for the relatively recently released biosimilar codes, a physician or provider would need to bill 12 units of the code to describe a 6 mg dose, as compared to billing 1 unit of the current code with a 6 mg dose descriptor. This would create the potential for billing errors, particularly for many who are long accustomed to the product having a code with a 6 mg base dose. Providers and physicians would need to educate their staff and alter their systems to accommodate a different base dose. Non-Medicare payers may not implement the change within the same timeframe as Medicare, creating additional administrative burden on providers to ensure they are using the correct code and billing units for different payers. Other entities would be impacted too, such as the National Correct Coding Initiative, which would need to revise its Medically Unlikely Edits (MUEs) files to address a change to the base dose of J2505. Of course, there are lag times in revising MUEs, and the proposed changes could lead to denials and appeals due to MUEs. We do not see a value in imposing such administrative burdens. These commenters asked that if CMS decides to make these changes, (1) any new code or base dose not take effect until January 1, 2022, to allow physicians, providers and other payers time to prepare for the new code, and (2) CMS issue coding and billing guidance, such as a Medicare Learning Network (MLN) product, to inform providers about the coding change and how to bill for the new base dose, and to serve as a reference.

The written comments from Forum generally support efforts to align billing units between reference products and biosimilars for purposes of the long descriptors, and state that this type of alignment will facilitate more accurate billing and simplify the comparison of payment units. The Forum supported the proposal to replace J2505 with a new code with a dose descriptor similar to its biosimilars, referred to it as a positive step to align billing units between reference products and biosimilars, and suggested that CMS take a broader approach to align billing units between all reference products and biosimilars for future biosimilars and their reference products. The Forum also suggested that CMS consistently display descriptors for biosimilars that include both the brand name and international nonproprietary name or just list the nonproprietary name for all products, stating that this is currently not standardized, which may result in confusion amongst providers when submitting claims, and acknowledged that this specific issue may fall under the purview of payment, not coding.

**CMS FINAL HCPCS CODING DECISION**

We appreciate the written comments provided in response to our published preliminary recommendation. CMS considered all input, and has decided to revise the effective date associated with the coding changes in the preliminary coding recommendation. As a result, CMS is finalizing the following coding changes, and will consider the need to issue additional coding and billing guidance in regards to these changes.

1. Establish new HCPCS Level II code J2506 "Injection, pegfilgrastim, excludes biosimilar, 0.5 mg"

Effective January 1, 2022

2. Discontinue existing HCPCS Level II code J2505 "Injection, pegfilgrastim, 6 mg"

Effective December 31, 2021

**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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

These codes will help provide valuable and economical care to beneficiaries in all sites of care. This is the care that beneficiaries want, which can also be cost effective when provided properly. To fulfill the promise this care affords, it must be measurable and accountable. Currently it is generally neither. These codes are a critical step in making spiritual care not only an important component of care given to beneficiaries but one that will be delivered with highly verifiable and replicable quality.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation, and we understand the desire for HCPCS Level II codes to assist with the collection of standardized data for chaplain spiritual care. However, CMS is still not aware of a claims processing need on the part of other insurers for reporting chaplain activity other than the Department of Veterans Affairs. CMS' final decision is to maintain the existing Chaplain codes for use by the Department of Veterans Affairs.

## 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 HCPCS Level II code for large volume delayed sampling (LVDS)-tested leukocyte reduced 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 recognized 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 Outpatient Prospective Payment System final rule.

### CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant is no longer asking CMS to create new HCPCS codes for LVDS-tested platelets, but requests that CMS issue updated billing guidance for HCPCS code P9100 to account for LVDS testing. CMS previously included billing guidance for P9100 in the January 2018 OPPS update transmittal and corresponding Medicare Learning Network (MLN) Matters Article, each of which included the following statement: "Note that HCPCS code P9100 should be reported to describe the test used for the detection of bacterial contamination in platelets as well as any other test that may be used to detect pathogen contamination."

The applicant asked that CMS include updated billing guidance for P9100 in a future outpatient prospective payment system update transmittal and MLN Matters Article; and suggested the following language for this updated guidance:

"HCPCS code P9100 should be reported to describe the test used for the detection of bacterial contamination in platelets, large volume-delayed sampling (LVDS) testing of platelets, and any other test that may be used to detect pathogen contamination. Note that P9100 is a testing code that should be reported separately from the applicable platelet product code."

## CMS FINAL HCPCS CODING DECISION

CMS re-reviewed this application together with the information provided during the public meeting, and is finalizing its preliminary decision that existing code P9031 – "Platelets, leukocytes, reduced each unit" + 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.

We appreciate the applicant's request for CMS to issue updated billing guidance for P9100, and we will take this into consideration.

**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 recognized 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 Outpatient Prospective Payment System final rule.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant is no longer asking CMS to create new HCPCS codes for LVDS-tested platelets, but requests that CMS issue updated billing guidance for HCPCS code P9100 to account for LVDS testing. CMS previously included billing guidance for P9100 in the January 2018 OPPS update transmittal and corresponding Medicare Learning Network (MLN) Matters Article, each of which included the following statement: "Note that HCPCS code P9100 should be reported to describe the test used for the detection of bacterial contamination in platelets as well as any other test that may be used to detect pathogen contamination."

The applicant asked that CMS include updated billing guidance for P9100 in a future outpatient prospective payment system update transmittal and MLN Matters Article; and suggested the following language for this updated guidance:

"HCPCS code P9100 should be reported to describe the test used for the detection of bacterial contamination in platelets, large volume-delayed sampling (LVDS) testing of platelets, and any other test that may be used to detect pathogen contamination. Note that P9100 is a testing code that should be reported separately from the applicable platelet product code."

## CMS FINAL HCPCS CODING DECISION

CMS re-reviewed this application together with the information provided during the public meeting, and is finalizing its preliminary decision that existing code P9035 – "Platelets, pheresis, leukocytes reduced, each unit" + 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.

We appreciate the applicant's request for CMS to issue updated billing guidance for P9100, and we will take this into consideration.

**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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker stated the scientific data illustrating how this product is pathogen reduced compared to the current code on the market (HCPCS P9012; Cryoprecipitate, each unit).

This FDA-approved pathogen reduced product is distinguished from the current code (HCPCS P9012; Cryoprecipitate, each unit) due to its development process. Cerus was founded in 1991 to investigate a novel psoralen-based pathogen inactivation technology for three unaddressed blood safety risks: 1) Risk of bacterial sepsis from transfusion of platelet products; 2) Risk of transfusion-transmitted viruses/other pathogens that escape screening detection, or for which no screening test is performed; and 3) Risk of newly emergent blood-transmissible pathogens for which effective blood screening tests may not exist (originally HIV in 1980, followed by West Nile virus, Chikungunya virus and Ebolavirus). Cryoprecipitated AHF is prepared by thawing fresh frozen plasma (FFP) between 1-6°C, centrifugation and recovery of the cold-insoluble precipitate with a high content of fibrinogen, Factor VIII, von Willebrand factor (vWF) and Factor XIII.

This product is indicated for:

- Control of bleeding associated with fibrinogen deficiency
- Control of bleeding in patients with hemophilia A (Factor VIII deficiency), von Willebrand disease (vWD) and Factor XIII deficiency when specific factor concentrates are not available.

This product must be thawed and brought to room temperature (RT) prior to transfusion; thaw plus delivery time from blood bank ranges from 15 minutes to >2 hours. It can be stored at RT for only up to 6 hours, and cannot be immediately on-hand.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS re-reviewed this application together with the information provided. As a result of our consideration of this new information, CMS has decided to establish a new HCPCS Level II code: P9026 "Cryoprecipitated fibrinogen complex, pathogen reduced, each unit."

CMS is interested in hearing from stakeholders regarding alternative terminology, particularly in regard to the term "pathogen reduced" that could be used to more appropriately describe this product, considering that new methods may be produced in the future and that pathogens are mitigated for safety for all blood products.

**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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker described scientific data illustrating how this product is pathogen reduced compared to the current code on the market (HCPCS code P9044; Plasma, cryoprecipitate reduced, each unit).

This FDA-approved pathogen reduced product is distinguished from the current code (HCPCS code P9044; Plasma cryoprecipitate reduced, each unit) due to its development process. PCRPR is characterized by broad spectrum pathogen reduction. Plasma cryoprecipitate reduction, which is described in HCPCS code P9044, is different from pathogen reduction.
Because PCRPR contains very low residual levels of amotosalen, PCRPR is specifically contraindicated for two patient populations: 1) Patients with a history of hypersensitivity of reaction to amotosalen or other psoralens, and 2) Neonatal patients treated with phototherapy

devise that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interaction between ultraviolet light and amotosalen.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS re-reviewed this application together with the information provided. As a result of our consideration of this new information, CMS has decided to establish a new HCPCS Level II code: P9025 "Plasma, cryoprecipitate reduced, pathogen reduced, each unit."

CMS is interested in hearing from stakeholders regarding alternative terminology, particularly in regard to the term "pathogen reduced" that could be used to more appropriately describe this product, considering that new methods may be produced in the future and that pathogens are mitigated for safety for all blood products.

**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.

## CMS 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 applying for 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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary 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 (CPT) code and would not be performed in the home. The applicant may be interested in applying for 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

**Request # 21.038**

## TOPIC

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

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

## APPLICANT'S SUMMARY

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

The system includes components used for endoscopic placement, filling and removal of intragastric 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 Intragastric Balloon. The OREBERA 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.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

The Orbera Intragastric 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 (Current Procedural Terminology (CPT)) code and would not be performed in the home. The applicant may be interested in applying for 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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary recommendation. The Orbera Intragastric 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 applying for 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

**Request # 21.039**

## TOPIC

Request to establish two new HCPCS Level II codes to identify each version of the X-Tack 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 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.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

The X-Tack Endoscopic HeliX Tacking 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 (Current Procedural Terminology (CPT)) code and would not be performed in the home. The applicant may be interested in applying for 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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary recommendation. The X-Tack Endoscopic HeliX Tacking 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 applying for 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

**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.

## CMS 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 (Current Procedural Terminology (CPT)) code and would not be performed in the home. The applicant may be interested in applying for 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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary 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 applying for 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

**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.

The applicant did not provide recommended language for the requested new code.

## 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.

## CMS 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 (Current Procedural Terminology (CPT)) code and would not be performed in the home. The applicant may be interested in applying for 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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary 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 applying for 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

**Request # 21.048**

## TOPIC

Request to establish a new HCPCS Level II code 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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant agreed that their product is not a drug. However, they have reviewed the recommendation and disagree that a HCPCS Level II code would be redundant and unnecessary. The manufacturer sponsored assignment of an NDC and registration with the FDA is purely for identification purposes in the software system during distribution. It is not utilized nor intended to be the primary identifier for reimbursement. The applicant believes that the NDC is the redundant and unnecessary identifier. HS Pharma requested that CMS assign a new and unique HCPCS code under durable medical equipment (DME) benefits: - XXXXX, Allergy Blocker Powder, per mg. HS Pharma is applying for a unique HCPCS code for Alzair™ Allergy Blocker because Beclomethasone is a prescription nasal spray that is billed with HCPCS Level II code J7622: Beclomethasone, inhalation solution, compounded product, administered through DME, unit dose form, per milligram. Alzair utilizes a patented bottle to create the proper particle size of the product to be effective. The bottle itself is essentially a specialized DME used to administer another mechanical device responsible for the mechanism of action of Alzair.

Most insurers, including Medicare, do not utilize NDC billing codes for medical devices including DME. Other payers are requesting a unique HCPCS code along with the NDC to

process claims. The top six pharmacy benefit managers (PBMs) do not include Alzair on their national formulary due to a lack of appropriate coding. A unique HCPCS code will allow better patient access. The coding application presents the clinical rationale and the cost rationale for assigning a HCPCS code for the product. A HCPCS code in the DME category would be necessary and appropriate for reimbursement as a prescription DME product. For these reasons, the applicant asks that HCPCS coding for Alzair Allergy Blocker be considered under a DME designation as no such HCPCS DME code exists to adequately code or describe the product.

**CMS FINAL HCPCS CODING DECISION**

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is changing its preliminary recommendation, which stated that an existing NDC is available for assignment by insurers to identify the Alzair Allergy Blocker, and establishing a HCPCS Level II code would be redundant and unnecessary. CMS re-reviewed this application together with the information provided at the public meeting, and is now finalizing the decision to establish HCPCS Level II code K1026 "Mechanical allergen particle barrier/inhalation filter, cream, nasal, topical."

**Request # 21.049**

## TOPIC

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

Applicant's suggested language: For new codes, language should include "no balloon type catheter for indwelling use, with or without coating" in the description.

## 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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that the existing HCPCS Level II codes do not describe the Lotus No Balloon Catheter. The FDA has cleared the device through the 510(k) process for: Continuous drainage of fluid, including continuous bladder irrigation and intermittent catheterization. Drainage is generally accomplished by inserting the catheter through the urethra, suprapubically into the bladder or through a nephrostomy tract. Predicate devices include: Malecot catheter, Foley catheter, straight intermittent catheter. The Lotus is the only urological catheter cleared for both intermittent and indwelling use, and use is not limited to the specific organ (bladder, kidney, etc.) or fluid type (chemotherapeutics, urine, etc.). It is designed with a self-contained mechanism for optional indwelling retention, drainage and removal. All other indwelling catheters require accessories for insertion, removal, or retention. The Foley catheter's balloon configuration requires sterile water, two syringes to inflate and deflate the balloon for retention and removal. The Malecot catheter requires a needle or stylet for insertion and removal under vision, contraindicated for urethral bladder access. No additional accessories are required for use with the Lotus, and inadvertent removal or improper placement causes little to no trauma as the lumens are collapsible. More complete drainage is offered by design. The intermittent catheters cannot be used as indwelling catheter. Intermittent catheters must be held while voiding the bladder. A4340 is only covered if medical history justifies its need beyond a standard indwelling catheter, restricting patient use. Example: a 'specialty' coude Foley catheter is prescribed to navigate the male urethra after difficulty with standard Foley catheter insertion. The 'specialty' Malecot catheters are contraindicated for urethral bladder access and prescribed under certain conditions.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation in part, and is removing the reference to A4353 based on feedback brought forth at the public meeting which clarified that the Lotus No Balloon Catheter does not require any supplies for insertion or removal. 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, when it is used as an indwelling catheter. Also, existing code A4351 "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each" adequately describes the Lotus catheter, and is available for assignment by insurers to identify use of the Lotus catheter as the intermittent catheter, when it is used for intermittent catheterization.

**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.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

CMS refers the applicant back to the American Medical Association (AMA) Current Procedural Terminology (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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

This is a single-use disposable (new De Novo FDA classification) Percutaneous Electrical Nerve Field Stimulator (PENFS) system, used in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS). It has a battery-operated stimulator applied to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves. It is placed behind the patient's ear and connected to stimulation needles on the auricle, and used for 120 hours over 5 days per week, for up to 3 consecutive weeks.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. 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. Per the public meeting, it is our understanding that the applicant is currently engaging with the AMA, which we believe is the appropriate route for coding the PENFS.

## 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.

### CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Request # 21.035 is a resubmission of request # 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Speranza Therapeutics disagreed with CMS' preliminary recommendation. The S.T. Genesis is an FDA cleared and regulated neuromodulation device, and is designed to administer auricular neurostimulation treatment while allowing the patient comfort and mobility during the detox process. 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 5 days or a maximum of 120 hours. Each patient's treatment is determined by frequent measurement of Clinical Opiate Withdrawal Scale (COWS) feedback. Speranza has data from a clinical trial that is not yet published, which shows a 93% reduction in COWS score, that on average went from 19.1 to 2.6, and 100% of the patients involved in the study accelerated into treatment.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS re-reviewed this application together with the information provided, and 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. In our prior coding decision from the second bi-annual 2020 coding cycle, we recommended that Speranza Therapeutics engage with the AMA on Level I coding. We were not provided information about the status of that engagement.

**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.

Applicant's suggested language: C1753 "Catheter, intravascular ultrasound or optical coherence tomography."

## APPLICANT'S SUMMARY

Since 2004, the current HCPCS Level II 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 HCPCS Level II 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".

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Both technologies support percutaneous revascularization procedures. OCT is used to support approximately 21,000 revascularization procedures annually. Below are codes that describe procedures that are applicable to OCT:

> Applicable HCPCS Level I and Level II Codes C1753 Catheter, intravascular ultrasound, CPT code 92978 Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel.
>
> CPT 92979 Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel. Outpatient Reimbursement, Percutaneous Coronary Intervention, Procedure PCI with Drug Eluting Stent, single major coronary artery C9600.
>
> C-APC Assignment 5193 – Level 3 Endovascular Procedures, PCI with Drug Eluting Stent, single major coronary artery, with IVUS guidance, C9600, C1753
>
> C-APC Assignment 5193 – Level 3 Endovascular Procedures, PCI with Drug Eluting Stent, single major coronary artery, with OCT guidance C9600
>
> C-APC Assignment 5193 – Level 3 Endovascular Procedures. 2020 Estimated average charge per procedure for C1753: $4,087.

The speaker requests a revision to the code description for C1753, which currently reads, "catheter, intravascular ultrasound," to instead read, "catheter, intravascular ultrasound or optical coherence tomography, catheter, intravascular imaging."

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS re-reviewed this application together with the information provided, and is finalizing the decision to not revise HCPCS Level II code C1753 to include language for the use of the OCT imaging catheter. However, the applicant may contact the Division of Outpatient Care within CMS' Hospital and Ambulatory Policy Group to further discuss this request.

**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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker noted that, first, although S9435 is typically associated with payers where inborn errors of metabolism (IEM) are mandated by the state for coverage, not all states have mandates, which causes confusion. Commercial and Medicaid insurers tend to follow the mandate of the state. Second, payers differ on inclusion of cystic fibrosis as an inborn error of metabolism. As documented in their application, the speaker noted that Encala is proven to be particularly effective in addressing fat malabsorption in patients with cystic fibrosis (CF). And third, in addition to state mandates, some payer policies also cover medical foods to treat fat

malabsorption that is diagnosed at any stage of life and is associated with various diseases and disorders.

In 38 states and the District of Columbia, there is limited or no mandated coverage of IEMs and not all payers classify CF as an inborn error of metabolism. IEMs are not mandated for either commercial or Medicaid payers in some states (e.g., Virginia, Georgia); are mandated for commercial plans only (not Medicaid) in others (e.g., Minnesota, Connecticut); are mandated for Medicaid plans only (not commercial) in others (e.g., North Carolina, Ohio) and are mandated for both commercial and Medicaid plans in others (e.g., New York, Florida). Finally, IEMs are mandated but states do not clearly include CF as an IEM (e.g., Texas, California). The primary speaker believes that assigning the code S9435 is insufficient for use broadly in the case of fat malabsorption, even in some cases when associated with CF.

**CMS FINAL HCPCS CODING DECISION**

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. The applicant provided CMS with specific insurer's policy that directs coding for Encala, and justification for why no existing HCPCS Level II code adequately describes Encala. As a result of our consideration of this new information, CMS has changed its preliminary coding recommendation, and decided to establish a new HCPCS Level II code: S9432 "Medical foods for non-inborn errors of metabolism."

**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.

The applicant did not provide recommended language for the requested new code.

## 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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its decision to recommend the use of 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.

## 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.

The applicant did not provide recommended language for the requested new code.

### 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 form 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; i.e., 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.

### CMS 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.

### SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary 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 generally be expected to be bundled into the appropriate hospital payment.

**Request # 21.064**

## TOPIC

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

The applicant did not provide recommended language for the requested new code.

## 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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary recommendation. 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.

**Request # 21.057**

## TOPIC

1. 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."

2. Request to modify existing code A4459 Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type to read A4459 Manual pump-operated trans-anal irrigation system, reusable, 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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Neurogenic bowel dysfunction leads to: poor health from complications, loss of independence, decreased psychological welfare, and loss of ability to work and participate in daily life activities. Trans anal irrigation is a highly effective bowel emptying technique. Prior to defecation there is stool throughout the colon, and post TAI results in good stool evacuation descending from the colon and rectum. Trans anal irrigation vs. standard of care shows a 28% reduction in mean neurogenic bowel dysfunction score, 54% fewer urinary tract infections, 50% improvement in quality of life, more independence, improved psychological welfare, and less time spent on bowel management allows the ability to work.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS re-reviewed this application together with the information provided, and is changing its preliminary coding recommendation. While existing code A4459 describes the TAI system, CMS recognizes that the rectal catheter is a single use item and may need to be billed more frequently than the other components of the system. As a result, CMS has

decided to retain the descriptor language in code A4459, and establish new HCPCS Level II code A4453 "Rectal catheter for use with the manual pump-operated enema system, replacement only."

**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 HCPCS Level II 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.

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 hours 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

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The Medicare local coverage determination (LCD) limits A4397 to only four a month and therefore does not recognize the clinical use, patient population, and frequency in use difference between reusable (which are disposed weekly) and single-use disposable (which are disposed daily and cannot functionally be reused) – thus, most Medicare beneficiaries described in this presentation stop irrigating, even though this is their colostomy management preference of choice that suits their needs and lifestyle.

Private payers do follow Medicare guidelines. It is likely that some private payers also limit the monthly quantity to 4 irrigation sleeves, thus keeping colostomy users from using disposable irrigation sleeves. There are also some private payers that do not place this restriction.

Colostomy patients need access to products that meet their needs. A coding distinction would reflect how these products operate differently.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS re-reviewed this application together with the information provided. Rather than defer this application to a subsequent coding cycle, we decided to take the following coding actions:

1. Establish two new HCPCS Level II Codes:

A4436: “Irrigation supply; sleeve, reusable, per month”

A4437: “Irrigation supply; sleeve, disposable, per month”

Effective date: January 1, 2022

2. Discontinue HCPCS Level II code A4397 “Irrigation supply; sleeve, each.”

Effective date: December 31, 2021

We believe a January 1, 2022, start date will allow appropriate time for engaging with insurers and the medical community on claims processing.

**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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary HCPCS code recommendation to defer, for a second time, the application to establish a code to identify InnovaMatrix AC. The speaker commented that the delay is not justified, because the decision should be relatively routine and straightforward since InnovaMatrix AC is neither an HCT/P nor a synthetic device, and the decision should be consistent with prior decisions to establish new Q codes for other sheet skin substitute products that are cleared by the FDA as medical devices and are neither an HCT/P nor a synthetic device. The speaker commented that the decision delay fosters an unlevel playing field among similarly situated products, makes coding unpredictable, creates an impediment to

the use of this new technology and discourages innovation. The speaker reiterated the request for a new Q code for InnovaMatrix AC, effective October 1, 2021.

**CMS FINAL HCPCS CODING DECISION**

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation 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.

**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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The speaker appreciated that CMS has determined that these synthetic, resorbable products should be treated as skin substitutes for Medicare payment purposes. However, the speaker noted that the creation of the HCPCS code C1849 has some serious unintended consequences. In order to address the coding confusion and the unintended consequences of the C1849 HCPCS codes, the speaker asked that CMS:

1. Assign unique "Q" codes, by brand, to the products, such as Mirragen Advanced Wound Matrix, that meet the definition of synthetic, resorbable skin substitutes. This "Q" code will equip physicians and qualified health practitioners with the ability to apply Mirragen in the appropriate place of service for the Medicare beneficiary, rather than potentially transferring the beneficiary to a more expensive site of care, or delaying care in order to transfer to a location capable of reporting the C1849 code on their Medicare claims.

2. Delete the following HCPCS codes: A6460 and A6461, which do not correctly describe synthetic, resorbable skin substitutes.

3. Put an end to the unintended consequences surrounding the synthetic, resorbable skin substitutes by not delaying this and other similar applications to a subsequent coding cycle.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation 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.

**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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that the use of collagen to effect hemostasis and wound healing is well documented. The bio-ConneKt Wound Matrix is a novel embodiment in that for the first time it offers a collagen matrix that can be bio-available for the entire wound healing cascade. The product's safety is evidenced by its FDA clearance (K140456 – July 2014) as an advanced wound dressing for a variety of acute and chronic wounds and burns. More than five years of successful clinical results from the commercial use of this product (including civilian, VA and Military hospitals) have already proven that it is safe and effective for the management of complex wounds in adult, pediatric and geriatric populations. The stabilization technology enables this collagen matrix to heal most skin deficits without the need for re-application, as it integrates and remodels with host tissue over time, making the bio-available scaffold utilized for "wound closure", not "wound management". The ability to absorb up to 50 times its weight in fluids, porous structure, cell-friendly architecture, and resistance to rapid proteolysis makes the MLM collagen a versatile tool for wound closure, especially for chronic wounds. Additionally, the product has a six-year shelf life and retains stability when tested at extreme environmental conditions (-29$^{o}$ C to 60$^{o}$ C).

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation 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.

**Request # 21.022**

## TOPIC

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

The applicant did not provide recommended language for the requested new code.

## 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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary 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.

**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.

The applicant did not provide recommended language for the requested new code.

## APPLICANT'S SUMMARY

Imbed Biosciences, Inc. submitted a request to establish a new HCPCS Level II 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 OPPS 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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that Imbed Biosciences has applied for a "Q" code for Microlyte Matrix, a synthetic resorbable skin substitute. The current code (C1849) does not meet the needs of beneficiaries and its availability is limited to outpatient settings. Microlyte Matrix is a synthetic, resorbable wound matrix which was cleared by FDA 510(k) on August 4, 2016.

Microlyte Matrix functions as a wound granulation matrix: Polyelectrolyte multilayer acts as a 2-D molecular template to support granulation; Hydrophilic PVA layer helps maintain moisture at wound bed; Contours tightly to the wound bed.

Microlyte Matrix is currently aligned to HCPCS code C1849 "Synthetic Resorbable Skin Substitutes." It is available only in the hospital-owned outpatient wound clinic POS, forces beneficiaries to be sent from the physician office to the wound clinic for Microlyte Matrix application and it limits overall availability to the beneficiaries.

A single code representing multiple synthetic skin substitutes creates confusion to the PBDs, unlike other skin substitutes with branded codes. A branded "Q" code for Microlyte Matrix would expand the places of service and availability of to the beneficiaries, reduce confusion for PBD billers and treat Microlyte Matrix the same as other skin substitutes, per CMS revised definition of skin substitutes (p. 611, CY2021 OPPS Final Rule).

In summary, Microlyte Matrix is highly effective at assisting in closing challenging chronic wounds. It should be made more widely available to all beneficiaries in both the outpatient wound clinic and physician office settings and it should be assigned its own unique "Q" code to reduce confusion for the provider-based departments and to enable physicians to apply it in the physician office.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation 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.

**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 HCPCS Level II 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 acts 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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary HCPCS code recommendation to defer, for the next coding cycle to establish a code to identify NovoSorb SynPath. The speaker commented that the wound care community needs this technology as an option for the care of chronic wounds. The speaker also commented that based on his experience with diabetic foot ulcers, SynPath appears to require less applications of the material to elicit a positive clinical response in the wound than we have seen with many other skin substitutes products. This is positive as it can help to reduce cost for the patients and the health system. To facilitate use of the device, clinicians need a product specific HCPCS code to be able to process claims efficiently, when used in other settings than the hospital outpatient clinic, for Medicaid recipients, the VA and patients with Private Insurance. The applicant urged CMS to move forward in assigning a HCPCS-Q code for the SynPath.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at CMS' HCPCS public meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation 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.

**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 HCPCS Level II 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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary applicant commented that CMS has expanded skin substitute benefit category to include synthetic skin substitutes and designated Restrata as a skin substitute (85 Fed. Reg. 86064). Restrata is currently described by the general HCPCS code C1849 "Skin substitute, synthetic, resorbable, per square centimeter." Acera is requesting a Restrata-specific Q code consistent with treatment other skin substitutes that will permit payment for Restrata in the physician-office setting. Restrata is a synthetic matrix composed of electrospun matrices of polymer fibers whose architecture resembles that of native tissue; it possesses a hybrid-scale fiber architecture similar to native extracellular matrix (ECM) architecture; offers fibroblasts a scaffold for proliferation and differentiation necessary for wound healing; and it provides a scaffold and conduit for cellular infiltration, migration and neovascularization. Restrata received 510(k) clearance on April 26, 2017 for use in the management of wounds. Clinical efficacy and utility in treating various wounds is demonstrated and confirmed by clinical trials and peer-reviewed published studies submitted to CMS Division of Outpatient Care. Restrata's use is similar to other FDA 510(k) cleared skin substitutes. There are currently 22 other skin substitutes FDA cleared via medical device 510(k) pathway with Q codes. CMS created A codes to describe Restrata effective Jan. 1, 2019: A6460 "Synthetic resorbable wound dressing, sterile, pad size 16 sq. in. or less, without adhesive border, each dressing" and A6461 "Synthetic resorbable wound dressing, sterile pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing." Restrata is a skin substitute (according to CMS) and is not a dressing, Restrata requires application by a physician, Restrata is not removed as it is absorbed into the wound bed, Restrata is not DMEPOS, Restrata is furnished by a physician in the office or HOPD, Restrata is not self-applied by the beneficiary in the home setting, CMS confirmed not DMEPOS via email Feb. 12, 2019, CMS has determined that Restrata is a skin substitute and not a dressing: "Our new description defines 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." "Finally, we note that our definition of skin substitutes does not include bandages or standard dressings and therefore, these items cannot be assigned to either the high cost or low-cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278."

Acera requests that CMS assign a product-specific Q code to Restrata similar to all other skin substitutes (including products cleared by FDA as devices). Q code will also allow for payment in the physician office site of service. Many skin substitutes formerly considered HCT/P products must be reevaluated. Given the unavailability of many skin substitutes in light of the FDA guidance, patients need access to advanced wound treatments like Restrata, and physicians are also requesting this access.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation 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.

**Request # 21.020**

## TOPIC

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

Applicant's suggested language: Q42XX "TheraGenesis, per sq. cm.".

## 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 (TREX) 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.

## CMS 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker respectfully disagreed with the CMS' preliminary HCPCS recommendation of deferral and requested the issuance of specific HCPCS Code Q42XX "TheraGenesis, per sq. cm."

The speaker commented that based on discussions with the HCPCS Team, they believe their application is complete; however, if the HCPCS Team has any questions or clarifications they asked that a HCPCS Team member follow-up with same, and they will promptly respond.

The speaker requested that CMS issue for TheraGenesis a specific HCPCS Code "Q42XX-TheraGenesis, per sq. cm." in its next coding cycle effective October 1, 2021.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in response to our published preliminary recommendation. CMS is finalizing its preliminary recommendation 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.

**July 8, 2021 Meeting Agenda Items**

**Request # 21.036**

## TOPIC

Request to establish a new HCPCS Level II code to identify the Pressure Offloading System.

## APPLICANT'S SUMMARY

Advanced Brace submitted a request to establish a new HCPCS Level II code for the Pressure Offloading System as each one is made custom to the Patient Model. The technology within the device suspends the Patient's foot in a way that the wound being addressed is offloaded which allows for optimum healing. The diagnoses that qualify a patient for the Pressure Offloading System AFO (P.O.S. AFO) are going to be as follows: Charcot Foot, Ankle Instability, Various Wounds, Absence of toe(s), Partial foot Amputation, etc. The current codes being used are: L1904 Ankle Gauntlet Custom Fabricated, L3030 Custom Insert, L2820 Soft Interface, L2275 Varus / Valgus Correction, L2330 Lacer Molded to Patient Model. The P.O.S. AFO is a custom product that is designed specifically for each patient's needs. Due to the custom process, Advanced Brace is able to fabricate this unique device--regardless of wound location, size, or shape of foot. This device is designed for anyone who has one or more of the previously listed conditions, and has developed an ulcer on the plantar surface, anterior, or even top of foot. The P.O.S. AFO is fabricated with a custom 3/8th inch tri-lam diabetic industry standard material insole, with an additional 1/8th neoprene to prevent drainage from wound. This custom insert is modified to apply pressure directly posterior, medial, or lateral to the wound site--which is key in the offloading, which allows the wound to heal. Our device achieves an additional 1/2-inch pressure reduction by utilizing the actual sole of the P.O.S AFO. This can be accomplished due to its fabrication process. Finally, a non-slip rubber sole is added to enhance the patient's safety. This device is lightweight, breathable, washable, and overall effective. Our P.O.S. AFO redistributes pressure over the entire plantar surface of the foot where the foot will tolerate, in order to offload existing pressure off of the wound site. It can serve any patient with a stubborn foot wound that will not heal correctly. Regardless of any underlying condition, due to the constant pressure of day to day activities. By reducing pressure, the wound should heal, without causing any other issues along the way. Due to the custom nature of the device, each P.O.S AFO is different as it is molded and created around the patient model and the Patient's needs. The current codes that are available make it very challenging in billing and reimbursement as Insurance Providers don't understand that the product contains: L1904 Ankle Gauntlet Custom Fabricated, L3030 Custom Insert, L2820 Soft Interface, L2275 Varus / Valgus Correction, L2330 Lacer Molded to Patient Model. It would be best to have an umbrella code that covered all of these specifically for the P.O.S AFO.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A9283 "Foot Pressure off loading/ supportive device, any type each," 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Following the public meeting, CMS re-reviewed this application and finalized its preliminary coding recommendation that existing code A9283 – "Foot Pressure off loading/supportive device, any type, each," describes this product. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be filed. For Medicare, contact the Medicare Administrative Contractor in whose jurisdiction 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.

**Request # 21.047**

## TOPIC

Request to discontinue existing HCPCS Level II code L5610 "Addition to lower extremity, endoskeletal system, above knee, hydracadence system".

## APPLICANT'S SUMMARY

This code was originally created for the Hydracadence hydraulic knee and ankle system. This consisted of a steel frame that was ordered in a specific length for the intended user. It was not modular for height adjustments. The hydraulic system of the Hydracadence consisted of a dual chambered mechanism that provided independent function/resistance of both the knee and the ankle, but also allowed for these joints to move synergistically with each other in swing phase. It includes a dedicated foot that is similar in function to a SACH (Solid Ankle Cushion Heel) foot. Heel height adjustability is included.

During normal ambulation, as the knee flexes in swing phase, the ankle actively dorsiflexes to assist in clearing the toes. The ankle provides the user the ability to adjust heel height to accommodate different shoes. The ankle also provides approximately 20 degrees of plantar flexion to accommodate slope descent.

The reason for the request of the retirement or change of L5610 is multifaceted. The Hydracadence has long been discontinued and is no longer available for purchase anywhere in the world. The average utilization of L5610 has been less than 5 units annually for the last several years. Proteor was the only company to create a knee of similar function (Hydracadence 2), but it has also been discontinued due to low sales caused by low reimbursement rates.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

CMS is considering discontinuing existing HCPCS Level II code L5610 "Addition to lower extremity, endoskeletal system, above knee, hydracadence system" as very few claims are being processed for L5610. We are actively seeking input from all stakeholders regarding any impact of discontinuing this code and the necessary amount of lead-time before effectuating the discontinuation.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with the preliminary coding recommendation and wanted to address any concerns that might come up contrary to the preliminary coding recommendation to discontinue HCPCS Level II code L5610. The applicant mentioned that the original Hydracadence hydraulic knee and ankle system has not been manufactured since 2003. Proteor acquired the intellectual property for the Hydracadence, and created the higher cadence which was available until last year and then discontinued because the reimbursement did not cover the cost of the item. There are no other devices currently on the market that utilize code L5610. The

primary speaker also stated that one unique aspect to the Hydracadence is that the hydraulic knee is a kinematic knee coupled with the ankle, which is its primary differentiating factor. The speaker mentioned that the system is "retired," and that a code to describe this system is no longer necessary.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. We note that existing code L5610 "Addition to lower extremity, endoskeletal system, above knee, hydracadence system," like all HCPCS codes, is intended to represent categories of same and similar items. While the applicant stated that L5610 is no longer necessary, other Federal payers have expressed a need for this code to remain active at this time. Thus, CMS has decided to retain code L5610 and will continue to monitor its usage to confirm that no products available now or in the near future are described by this code.

**Request # 21.067**

## TOPIC

Request to establish a new HCPCS Level II code to identify an innovative external penile rigidity device that works with and not against the natural physiology of an erection.

## APPLICANT'S SUMMARY

Eddie is a unique and innovative FDA Class II registered medical device for erectile dysfunction that was uniquely designed to work in conjunction with the natural physiology of an erection. Eddie does not require a Doctor's visit or a prescription and it has none of the side effects of erectile dysfunction medications (e.g., Viagra, Cialis, Levitra). Eddie provides comparable success to that of an implant without the need for an invasive surgery.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new HCPCS Level II code to separately identify the Eddie has not been approved. Erectile dysfunction devices, such as the Eddie, are considered over-the-counter devices and are not typically paid by insurance. For instance, these types of devices are statutorily excluded from Medicare.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker reiterated the original request for a new code, commenting that their product is the "first of its type" as it utilizes blood flow imaging technology. The primary speaker described the product, its sizing, and its use. The primary speaker did not address the reason for proposed code denial in CMS' preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS re-reviewed this application together with the information provided and continues to believe that the Eddie is not appropriate for HCPCS Level II coding. As a result, CMS is finalizing its preliminary coding recommendation not to establish a new code to separately identify the Eddie. Erectile dysfunction devices, such as the Eddie, are considered over-the-counter devices and are not typically paid by insurance. Per Section 1834(a)(1)(I) of the Social Security Act, these types of devices are statutorily excluded for Medicare. 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 insurers, contact the individual private insurance entity.

**Request # 21.068**

## TOPIC

Request to revise HCPCS Level II code L3000 "Foot insert, removable, molded to patient model, UCB type, Berkeley shell, each."

Applicant's suggested language: L3000 "Prescription custom fabricated foot insert, each, removable, molded to patient model, with minimum of a 10mm heel cup, typically dispensed as pair."

## APPLICANT'S SUMMARY

L3000 coding language has not been updated since the inception of the original HCPCS coding set, prior to modern-day materials and manufacturing techniques currently used in custom foot orthotic production. The reference to "UCB"-Berkeley shell is confusing and antiquated. The introduction of ICD10 and the laterality that accompanies certain codes has created confusion with certain non-Medicare payers. Often, non-Medicare payers provide reimbursement only for the device intended for the symptomatic extremity, which creates an iatrogenically induced limb length discrepancy. The current use of the word, "each" in the descriptor does not sufficiently address this problem. This application does not seek to influence Medicare's current orthopedic footwear policies.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code L3000 "Foot, insert, removable, molded to patient model, 'ucb' type, berkeley shell, each" describes the product of this application.

CMS does not believe there is a need to revise the code to add "prescription custom fabricated" as the current language, "molded to patient model," indicates the device is custom made and can only fit the patient for which the mold was taken. These devices are by prescription only. Additionally, the billing unit "each" identifies the relevant body part and enables accurate billing when one unit is dispensed, whereas reporting as a pair, and particularly, inclusion of the terms "each" and "pair" together in the same code text, could result in confusion and inaccurate billing. Retaining the "each" unit designation is consistent with testimony provided at a past public meeting that there is a need to retain the ability to accurately report when a single unit is dispensed. For instance, CMS is aware of L3000 claims for a single unit (e.g., patients with an amputation of one foot or lower limb). Retaining the "each" unit designation also enables accurate reporting of two devices when dispensed as a pair, allowing suppliers to bill for two units when appropriate.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

This type of orthotic device is fabricated from a three-dimensional model of the patient's own foot (e.g. cast, foam impression, or virtual true 3-D digital image). It is a functional device, (reducing pathological forces) which has a molded heel cup and trim lines. Most third-party payers have now accepted L3000 to define those devices which have at least a 10 mm heel cup height which provides both medial and lateral directive forces to control the hind and forefoot. It may also have intrinsic or extrinsic posts designed to control foot motion. This device is made of a sufficiently rigid material to control function and reduce pathological forces. HCPCS code L3000 includes additions such as postings, padded top covers, soft tissue supplements, balance padding and lesion or structure accommodations. Other additions may be required as well. These are usually dispensed as a pair. Use of a single limb orthosis on the symptomatic side creates the potential for an iatrogenic limb length discrepancy (LLD) on the "asymptomatic" side. LLD may cause pain from the back distally even on the asymptomatic side. It is rare that the contralateral "asymptomatic" limb would not receive an equivalent device. (Examples –Prosthetic Limb, or replacement of broken device). The American Podiatric Medical Association (APMA), American Orthotic & Prosthetic Association (AOPA) and Pedorthic Footcare Association (PFA) are requesting a HCPCS narrative change so that the description may also include, "typically dispensed as a pair."

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our preliminary recommendation. CMS re-reviewed this application together with the information provided and is finalizing its preliminary coding recommendation. Existing code L3000 – "Foot, insert, removable, molded to patient model, 'ucb' type, berkeley shell, each" describes this product. CMS continues to believe that the unit designation of "each" provides the best means for accurate reporting and accurate payment of the number of units dispensed. The RT (right side) and LT (left side) HCPCS modifiers can be utilized to specify the right and/or left foot on claims. We recommend continuing to engage with payers in regard to the appropriate clinical circumstances for covering a product on the "asymptomatic" side.

**Agenda Item # 4**

**Request # 21.069**

## TOPIC

Request to revise L3020 "Foot insert, molded to patient model, longitudinal/metatarsal support, each."

Applicant suggested language: L3020 "Prescription custom fabricated foot insert, molded to patient model, longitudinal/metatarsal support, each, typically dispensed as a pair."

## APPLICANT'S SUMMARY

The American Podiatric Medical Association is requesting a coding language change for HCPCS L3020. The current coding language mainly dates back to when the HCPCS code set was developed in the 1970's and has not been updated since 1993, both prior to the advent of modern-day materials and manufacturing techniques. With the introduction of ICD10, additional burdens are faced by providers and patients in obtaining reimbursement for custom fabricated foot orthotics, mainly due to laterality issues associated with ICD10 and payers not understanding the medical necessity of dispensing these as a pair, despite the code description including the word "each". This application is being submitted solely for coding language modernization only, not in an attempt to change or influence Medicare reimbursement policy. No brand name products are provided in this application because we are not seeking a separate therapeutic distinction for any specific product.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code L3020 "Foot, insert, removable, molded to patient model, longitudinal/ metatarsal support, each" describes this product.

CMS does not believe there is a need to revise the code to add "prescription custom fabricated" as the current language, "molded to patient model," indicates the device is custom made and can only fit the patient for which the mold was taken. These devices are by prescription only. Additionally, the billing unit "each" identifies the relevant body part and enables accurate billing when one unit is dispensed, whereas reporting as a pair, and particularly, inclusion of the terms "each" and "pair" together in the same code text, could result in confusion and inaccurate billing. Retaining the "each" unit designation is consistent with testimony provided at a past public meeting that there is a need to retain the ability to accurately report when a single unit is dispensed. For instance, CMS is aware of L3020 claims for a single unit (e.g., patients with an amputation of one foot or lower limb). Retaining the "each" unit designation also enables accurate reporting of two devices when dispensed as a pair, allowing suppliers to bill for two units when appropriate.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

This type of orthotic device is fabricated from a three-dimensional model of the patient's own foot (e.g. cast, foam impression, or virtual true 3-D digital image). It is an accommodative/functional device, with most third-party payers accepting this code to describe a device with a heel cup of less than 10 mm and intended to control the forefoot through a longitudinal arch and metatarsal support. It may also have an intrinsic or extrinsic post designed to control foot motion. This device is made of a sufficiently rigid material to reduce pathological forces.

HCPCS L3020 includes additions such as postings, padded top covers, soft tissue supplements, balance padding and lesion or structure accommodations. Other additions may be required. This device is normally dispensed as a pair. Many ICD10 are site (LT/RT) specific and many patients have unilateral symptoms. Failure to provide patients with bilateral orthotics results in iatrogenic limb length discrepancies, heel lifts or OTS Orthotics on the asymptomatic side fail to address the entire limb, hip and spinal column. The overwhelming majority of patients receiving functional foot orthotics are not amputees. Amputees with biomechanical issues on the intact limb often require a custom fabricated device and the prosthetic side may also require one to address issues superior to the amputation site. The narrative inclusive of "each" without further explanation is confusing because patients typically must wear these bilaterally. Use of a single limb orthosis on the symptomatic side creates the potential for an iatrogenic limb length discrepancy (LLD) on the "asymptomatic" side. LLD may cause pain from the back distally even on the asymptomatic side. It is rare that the contralateral "asymptomatic" limb would not receive an equivalent device. (Examples –Prosthetic Limb, or replacement of broken device). The American Podiatric Medical Association (APMA), American Orthotic & Prosthetic Association (AOPA) and Pedorthic Footcare Association (PFA) are requesting a HCPCS narrative change so that the description may also include, "typically dispensed as a pair".

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS re-reviewed this application together with the information provided and is finalizing its preliminary coding recommendation. Existing code L3020 – "Foot, insert, removable, molded to patient model, longitudinal/ metatarsal support, each" describes this product. CMS continues to believe that the unit designation of "each" provides the best means for accurate reporting and accurate payment of the number of units dispensed. The RT (right side) and LT (left side) HCPCS modifiers can be utilized to specify the right and/or left foot on claims. We recommend continuing to engage with payers in regard to the appropriate clinical circumstances for covering a product on the "asymptomatic" side.

**Request # 20.150**

## TOPIC

Request to create a coding distinction between particulate and non-particulate bulking agents by (1) revising existing code L8606 which currently reads "Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies" to instead read "Injectable bulking agent, synthetic implant, particulate combination agent, urinary tract, 1 ml syringe, includes shipping and necessary supplies" and(2) establishing a new HCPCS Level II Code to identify non-particulate injectable bulking agents.

Applicant's suggested language: L86XX "Injectable bulking agent, synthetic implant, non-particulate homogenous agent, urinary tract, 2 ml, includes shipping and necessary supplies."

## APPLICANT'S SUMMARY

PRS Consulting, LLC, is requesting a HCPCS Level II code revision as well as addition of a new code to identify Bulkamid.

Bulkamid is a new polyacrylamide hydrogel bulking agent for stress urinary incontinence (SUI), consisting of cross-linked polyacrylamide (2.5% w/w) and water (97.5% w/w), supplied in sterile pre-filled syringes. Bulkamid is indicated for treatment of SUI or stress predominant mixed incontinence due to intrinsic sphincter deficiency (ISD) in adult women. Bulking is an established procedure in women with SUI. Bulkamid does not contain microparticles and its effect is achieved through the volume of hydrogel injected, which integrates with host tissue to provide durable outcomes. Bulkamid is injected in the urethra under cystoscopic guidance using a specifically designed device for exact placement. It is packaged and shipped as a 2ml kit, containing 2x 1ml syringes, disposable rotatable sheath and 2 injection needles. L8606 is used to report currently approved urethral bulking agents (Macroplastique, Coaptite, Durasphere), all containing microparticles in a carrier gel. Bulking for this class of bulking agent is clinically achieved through the body's reaction to the microparticles once the carrier gel has dissipated. Bulkamid represents a different class and requires a unique code as it is: A hydrogel containing no microparticles; Used in lower volumes than the particulate combination agents; significantly distinct therapeutic, as it is nondegradable and remains unchanged, allowing durability and; Packaged as a delivery system kit, allowing for more accurate injection.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation to defer its coding decision to a subsequent coding cycle. The speaker reiterated the request to establish another L code describing synthetic bulking agents in order to create a distinction, via HCPCS coding, between synthetic bulking agents used for stress urinary incontinence based on product composition (synthetic particulate or synthetic non-particulate), mechanism of action and therapeutic differences. Specifically, the speaker claimed that when compared to synthetic particulate bulking agents, synthetic non-particulate bulking agents have "fewer treatment-related adverse events", "more durable effect" with 67% of patients cured or improved at 7 years of follow-up.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS re-reviewed this application together with all information provided, and has concluded that Bulkamid is described by existing code L8606, "Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies." At this time, there is not sufficient clinical evidence to support a coding distinction between particulate and non-particulate bulking agents. The data presented is of limited quantity and does not directly show the therapeutic superiority of non-particulate bulking agents over particulate bulking agents.

We remain interested in future comparative studies and welcome ongoing dialogue with the applicant.

**Request # 20.153**

## TOPIC

Request to establish a new HCPCS Level II code to identify the additional therapeutic function and benefit of Blatchford's Silcare Breathe Liner.

## APPLICANT'S SUMMARY

Blatchford, Inc. requests one new HCPCS Level II code to describe the additional therapeutic function and benefit of Blatchford's Silcare Breathe Liner.

These liners utilize added technology to prevent/mitigate perspiration of the residual limb and facilitate the removal of this perspiration from the skin surface, reducing risk of tissue injury, enhancing suspension through creation of a natural vacuum in every step taken, and significantly differentiating them from all other prosthetic liners. These liner products are suitable for amputees who participate in a variety of activities and whose prosthesis suspension is compromised due to perspiration/moisture, causing loss of control, unwanted movement of the residual limb in the socket and associated risk of falls, causing tissue health issues and potential additional health costs.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Prosthetic liners provide protective cushioning designed with perforations to allow sweat transfer away from skin so it doesn't cause damage. There are two types of patient outcomes in prosthetics: 1) Clinical experience which is anecdotal evidence based on experience and patient medical histories experienced, and 2) Scientific measures which are scientifically-validated experiments and patient-reported measures. To further explain the scientific evidence, there are case studies that show residual limb wounds and infections heal without limiting prosthesis use. Evaluating real world patient experience shows that patients observe less sweat on their limbs, report less 'smelly' liners – which may be indicative of reduced bacterial growth, and experience less frequent pain and fewer residual limb skin issues.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS re-reviewed this application together with all information provided, and is changing its preliminary coding recommendation to defer this application to a subsequent coding cycle. While we remain interested in moisture reduction technology for prosthetic liners, we do not believe there is sufficient clinical evidence to support separate coding at this time. Therefore, CMS is finalizing the decision to not establish a new HCPCS

Level II code, but encourages the applicant to resubmit in a subsequent cycle if new clinical studies become available. In the meantime, depending on product characteristics, we believe the following codes describe the socket insert that is the subject of this request and can be utilized:

- L5679 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism"
- L5673 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism"
- L5681 “Addition to lower extremity, below knee/above knee, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)”
- L5683 "Addition to lower extremity, below knee/above knee, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)"

**Request # 20.154**

## TOPIC

Request to establish a new HCPCS Level II code to identify the additional therapeutic function and benefit of Uniprox's Softskin Air Liners.

Applicant's suggested language: LXXXX "Addition to lower extremity, moisture prevention/mitigation feature (for use with L5679, L5673, L5681 & L5683)"

## APPLICANT'S SUMMARY

Uniprox GmbH & Co. KG requests one new HCPCS Level II code to describe the additional therapeutic function and benefit of Uniprox's Softskin Air Liners.

These liners utilize added technology to prevent/mitigate perspiration of the residual limb, reducing risk of tissue injury and significantly differentiating them from all other prosthetic liners. These liner products are suitable for amputees who participate in a variety of activities and whose prosthesis suspension is compromised due to perspiration/moisture, causing loss of control, unwanted movement of the residual limb in the socket and associated risk of falls, causing tissue health issues and potential additional health costs.

Existing codes describe elastomeric socket inserts in various configurations. No existing codes address residual limb moisture/perspiration management and the improved clinical outcomes provided. The new code is for use in conjunction with the base liner codes.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

As per the speaker, once an L code is assigned, the patient will be able to choose a better liner because the product is made in Germany and the main resistance to selling the liner in US is the cost. The existing L code does not cover full reimbursement and what happens is the patient easily picks cheaper liner with more negative results for the user.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS re-reviewed this application together with all information provided, and is changing its preliminary coding recommendation to defer this application to a subsequent coding cycle. While we remain interested in moisture reduction technology for prosthetic liners, we do not believe there is sufficient clinical evidence to support separate coding at this time. Therefore, CMS is finalizing the decision to not establish a new HCPCS

Level II code, but encourages the applicant to resubmit in a subsequent cycle if new clinical studies become available. In the meantime, depending on product characteristics, we believe the following codes describe the socket insert that is the subject of this request and can be utilized:

- L5679 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism"
- L5673 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism"
- L5681 “Addition to lower extremity, below knee/above knee, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)”
- L5683 "Addition to lower extremity, below knee/above knee, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)"

**Request # 20.156**

**TOPIC**

Request to establish two new Level II HCPCS codes to identify the ALLUX MPK knee.

Applicant's suggested language:

LXXXX "Addition, endoskeletal knee-shin system, 4-bar, fluid swing and stance phase control."

LXXXX "Addition, microprocessor control feature, automatic stance-phase lock, automatic stance-phase lock."

**APPLICANT'S SUMMARY**

Proteor USA requests to establish two new HCPCS L codes to identify the ALLUX MPK knee.

This request is regarding the ALLUX microprocessor controlled knee. It is the only microprocessor-controlled knee, utilizing a 4-bar geometry with hydraulic control of both stance and swing phases of gait. One of its many features is an advanced microprocessor controlled standing function, called the Safety Lock. The ALLUX is intended for use by amputees that are missing their leg through knee joint or higher (KD through HD). It uses a 4-bar knee geometry, paired with a microprocessor controlled hydraulic unit providing varying levels of resistance depending on the phases of gait (stance or swing phase). This combination enhances ROM (Range of Motion) and toe clearance, offering a high level of versatility to the user using up to five different modes. There is an enhanced functionality through the use of an automatic stance-phase lock (called the Safety Lock). This feature will automatically lock knee flexion when the user maintains a load on a flexed, stationary knee. Upon knee extension, the lock is released, and the knee returns to normal function.

Currently, there is no adequate L code(s) to describe any 4-bar knee with hydraulic control of both stance and swing phases of gait. Also, the microprocessor code (L5856) does not describe or incorporate the automatic stance lock feature. That functionality was not included in the predicate product (C-Leg) and is an enhanced safety function providing additional stability to the user while standing on slopes, uneven terrain, and/or crouched positions, like picking objects off the ground or a low shelf.

**CMS PRELIMINARY HCPCS CODING RECOMMENDATION**

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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker acknowledged CMS' decision to push this application to the next meeting for additional consideration.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS re-reviewed this application together with the information provided, and is changing its preliminary coding recommendation. We believe the automatic stance-phase lock is inherently part of the microprocessor control feature included in existing code L5856 "Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type." As a result, CMS is finalizing the decision to not approve the request to establish a new code to identify the automatic stance-phase lock feature. This decision is referencing the second part of the applicant's request under the "topic" section.

**Request # 20.157**

**TOPIC**

Request to establish a new HCPCS Level II code to identify the additional therapeutic function and benefit of WillowWood's Alpha SmartTemp Gel Liner

Applicant's suggested language: LXXXX "Addition to lower extremity socket insert, moisture prevention feature (for use with L5679, L5673, L5681 & L5683)"

**APPLICANT'S SUMMARY**

WillowWood Global requests one new code to describe the additional therapeutic function and benefit of WillowWood's Alpha SmartTemp Gel Liner.

These liners utilize unique technology to prevent perspiration of the residual limb, reducing risk of tissue injury and significantly differentiating them from all other prosthetic liners. These liner products are suitable for amputees who participate in a variety of activities and whose prosthesis suspension is compromised due to perspiration/moisture, causing loss of control, unwanted movement of the residual limb in the socket and associated risk of falls, causing tissue health issues and potential additional health costs.

Existing codes, listed below, describe elastomeric socket inserts in various configurations. No existing codes address residual limb moisture/perspiration reduction and the improved clinical outcomes provided. The new code is for use in conjunction with the base liner codes.

Existing/Associated codes:
L5679 – Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism
L5673 - Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism
L5681 – Addition to lower extremity, below knee/above knee, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)
L5683 - Addition to lower extremity, below knee/above knee, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that WillowWood's Alpha SmartTemp technology reduces moisture, as well as lowers residual limb skin temperature, which , in turn, reduces slipperiness that leads to poor fit, which may result in falls, along with reducing the risk of tissue injury and infections. The speaker reiterated the original request for a new HCPCS Level II code on the basis of unique technology, clinical significance, evidence and product/market adoption.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS re-reviewed this application together with all information provided, and is changing its preliminary coding recommendation to defer this application to a subsequent coding cycle. While we remain interested in moisture reduction technology for prosthetic liners, we do not believe there is sufficient clinical evidence to support separate coding at this time. Therefore, CMS is finalizing the decision to not establish a new HCPCS Level II code, but encourages the applicant to resubmit in a subsequent cycle if new clinical studies become available. In the meantime, depending on product characteristics, we believe the following codes describe the socket insert that is the subject of this request and can be utilized:

- L5679 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism"
- L5673 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism"
- L5681 "Addition to lower extremity, below knee/above knee, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)"
- L5683 "Addition to lower extremity, below knee/above knee, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)"

**Request # 20.158**

## TOPIC

Request to establish a new HCPCS Level II code to identify the additional therapeutic function and benefit of WillowWood's Alpha SmartTemp Liner.

Applicant's suggested language: LXXXX "Addition to lower extremity socket insert, moisture prevention feature (for use with L5679, L5673, L5681 & L5683)"

## APPLICANT'S SUMMARY

WillowWood Global requests one new code to describe the additional therapeutic function and benefit of WillowWood's Alpha SmartTemp Liner.

These liners utilize unique technology to prevent perspiration of the residual limb, reducing risk of tissue injury and significantly differentiating them from all other prosthetic liners. These liner products are suitable for amputees who participate in a variety of activities and whose prosthesis suspension is compromised due to perspiration/moisture, causing loss of control, unwanted movement of the residual limb in the socket and associated risk of falls, causing tissue health issues and potential additional health costs.

Existing codes, listed below, describe elastomeric socket inserts in various configurations. No existing codes address residual limb moisture/perspiration reduction and the improved clinical outcomes provided. The new code is for use in conjunction with the base liner codes.

Existing/Associated codes:
L5679 – Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism
L5673 - Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism
L5681 – Addition to lower extremity, below knee/above knee, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)
L5683 - Addition to lower extremity, below knee/above knee, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that WillowWood's Alpha SmartTemp technology reduces moisture, as well as lowers residual limb skin temperature, which, in turn, reduces slipperiness that leads to poor fit, which may result in falls, along with reducing the risk of tissue injury and infections. The speaker reiterated the original request for a new HCPCS Level II code on the basis of unique technology, clinical significance, evidence and product/market adoption.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS re-reviewed this application together with all information provided, and is changing its preliminary coding recommendation to defer this application to a subsequent coding cycle. While we remain interested in moisture reduction technology for prosthetic liners, we do not believe there is sufficient clinical evidence to support separate coding at this time. Therefore, CMS is finalizing the decision to not establish a new HCPCS Level II code, but encourages the applicant to resubmit in a subsequent cycle if new clinical studies become available. In the meantime, depending on product characteristics, we believe the following codes describe the socket insert that is the subject of this request and can be utilized:

- L5679 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism"
- L5673 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism"
- L5681 "Addition to lower extremity, below knee/above knee, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)"
- L5683 "Addition to lower extremity, below knee/above knee, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)"

**Request # 21.029**

## TOPIC

Request to establish a new HCPCS Level II code to identify GAP-FLEX System, Trade Name: Gap-Flex System.

Applicant's suggested language: EXXXX "Gravity Assisted Passive Flexion and Extension for Use on Knee."

## APPLICANT'S SUMMARY

Xeras Medical Technologic Inc. d.b.a. GAP FLEX Inc. submitted a request to establish a new HCPCS Level II code to identify Gap-flex. According to applicant, GAP-FLEX is a new Durable Medical Equipment (DME) Device. Our device comes in two different sizes, "Regular" and "Tall". We are requesting a code for each size or a combined code for both; whichever is more applicable.

The GAP-FLEX System is sturdy, simple setup, lightweight, compact, and easily stored. The product consists of an aluminum T-bar frame with removable therapeutic foam layers and a separate, integrated foam extension block. The system includes a mobile app to track progress and compliance. GAP-FLEX is designed to accelerate range-of-motion recovery and rehabilitation. Utilizing the simple platform of gravity, patients using our device notice a faster, more comfortable, highly compliant and less painful method of recovery. GAP-FLEX provides patients with contactless (particularly important now with COVID-19 associated risks) knee recovery more quickly, more efficiently, and less costly than any other method available.

There is an existing E0935 code that is used for Continuous Passive Motion (CPM) machines. Upon submission to the Pricing, Data Analysis and Coding (PDAC) review board it was agreed that the GAP-FLEX System met and exceeded the clinical criteria for the code; however, the E0935 code language did not adequately describe the mode of action of our device in that it doesn't allow for a non-powered device despite its superior clinical benefits. The PDAC Medical Director strongly recommended for us to apply for an exclusive code for our device. Our product is specifically more effective and efficient because it's non-powered. Keeping the knee stable in a defined angle and allowing gravity to stretch the ligaments and muscles daily is clinically proven (study attached) to heal more quickly and more effectively.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A9300 "Exercise equipment" describes the GAP-FLEX System, and is available for assignment by insurers if they deem appropriate. In addition, A9300 is consistent with the manufacturer's self-designation with the Food and Drug Administration as exercise equipment. 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary HCPCS coding recommendation. The speaker stated that the FDA device designation as previously made by the manufacturer, "exerciser, non-measuring" is "listed as the only reason in the preliminary coding recommendation as to why the GAP-FLEX System was being put in the A9300 Exercise Equipment", and that the device designation with the FDA has been updated to "non-powered orthopedic traction apparatus and accessories, neurological and physical medicine devices". The speaker commented that the GAP-FLEX System is unique in that it is non-powered and patient operated", "for which there is no HCPCS code". The speaker also commented that the GAP-FLEX System is a "more functional, practical and clinically effective solution for patient use in the home setting when compared to CPM, which has never changed its design from facility use to that in the home setting". Also, in comparison to the CPM, the speaker stated "the clinical benefits of the GAP-FLEX System are far superior than those of the CPM machine, as evidenced by our peer reviewed clinical study." "The GAP-FLEX System being five (5) lbs. and able to be delivered contactless to patients makes it a great option for patients recovering at home…"and a code is needed "to provide patient choice where it doesn't exist now while at the same time saving Medicare a tremendous amount of money…". The speaker added that the mobile app, designed to be used in conjunction with the GAP-FLEX device as a complete system, "increases patient accountability, guidance and compliance… helps track progress and collect important progression data… which can be sent to surgeon and/or Physical Therapist…".

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS re-reviewed this application together with the information provided, and is finalizing its preliminary coding recommendation that existing code A9300 "Exercise equipment" describes the GAP-FLEX System, and is available for assignment by insurers if they deem appropriate. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be filed. For Medicare, contact the Medicare contractor in whose jurisdiction a 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.

**Request # 21.030**

## TOPIC

Request to establish a new HCPCS Level II code to identify a low-magnitude, resonant mechanical stimulator (LMRMS)

Applicant's suggested language: E077X "Low-magnitude, resonant mechanical stimulator (LMRMS)."

## APPLICANT'S SUMMARY

Emerson Consultants submitted a request to establish a new HCPCS Level II code for low-magnitude, resonant mechanical stimulator (LMRMS).

The Juvent Micro-Impact Platform is a low-magnitude, resonant-high frequency mechanical stimulator platform that patients stand on to receive their treatment. The platform functions by sending calibrated (to each patient, each time) mechanical energy micro-impacts up through the body which mimic the impact from walking 2 to 5 miles. These impacts gently move the body and increase blood flow and lymphatic drainage which improves bone health and increases muscle health. The Juvent platform is DME and we believe should fall under the "stimulation device" section of the HCPCS codes. There are no other codes in this section that describe "low magnitude, resonant, high frequency, mechanical stimulation. The other codes in this section describe "electrical stimulation" or non-thermal pulsed high frequency radio waves. In addition, none of these codes describe a platform type device that the patient stands on to receive treatment. There have been numerous published clinical studies showing the benefit of this technology and it is important to be able to track utilization for this unique device.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A9300 "Exercise Equipment" describes Juvent Micro-Impact Platform, and is available for assignment by insurers if they deem appropriate. In addition, A9300 is consistent with the manufacturer's self-designation with the Food and Drug Administration as exercise equipment. 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary recommendation. Existing code A9300 "Exercise Equipment" describes Juvent Micro-Impact Platform, and is available for assignment by insurers if they deem appropriate. In addition, A9300 is consistent with the manufacturer's self-designation with the Food and Drug Administration as exercise equipment. 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.

**Request # 21.034**

## TOPIC

Request to establish a new HCPCS Level II code to identify Slow Wave DS8

The applicant did not provide recommended language for the requested new code.

## APPLICANT'S SUMMARY

Slow Wave, Inc. submitted a request to establish a new code for Slow Wave DS8, an intra-oral device intended to reduce or alleviate snoring and mild to moderate Obstructive Sleep Apnea while sleeping in adults. DS8 consists of two custom fitted trays used to reposition the mandible. The trays are designed to be worn on the upper and lower teeth where they act to increase the patient's pharyngeal space by reducing obstructions of the airway during sleep. The device is designed to be retained on the teeth with saliva and surface tension and functions without any screws or fastening mechanism. The patient-custom devices are 3D print manufactured and made from biocompatible material. The Slow Wave DS8, is a mandibular repositioning device that acts to increase the users' pharyngeal space and improves their ability to exchange air during sleep. The device consists of two separate trays worn on the maxilla and mandible, which allow the user to open and close their jaw when asleep, provide full lateral movement of the mandible, move the tongue naturally forward to enhance air exchange during sleep. The DS8 trays worn on the maxilla and mandible with integrally formed molar extensions forming forward-leaning left and right ramps configured so that when the apparatus is in a users' mouth, the ramps create a tendency for the lower tray, lower dentition and mandible to move in a normal downward position keeping users' airway open by maintaining an anterior Gap making more space for the tongue. DS8 does not utilize code E0486 requirements for fixed mechanical hinges at the sides, front or palate. Nor does it incorporate a mechanism to allow the mandible to be advanced in increments of 1 mm. Neither of these E0486 code requirements are needed with the Slow Wave DS8 design.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

CMS requests the applicant to explain why they believe a HCPCS Level II code would be more appropriate than a CDT (dental) code and whether there has been any engagement with the ADA.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary HCPCS coding recommendation. The speaker commented that, while its design path and mechanism of action is different, the intended use and therapeutic function of the Slow Wave DS8 device is the same as other devices coded at E0486, that is, to reduce or alleviate snoring in adults with mild to moderate Obstructive Sleep Apnea. Specifically, the Slow Wave DS8 does not incorporate a mechanical hinge, and it vertically opens, rather than advances, the mandible. The speaker requested that either the Medicare coverage and coding policy criteria detailed in Policy Article A52512 pertaining to

HCPCS Level II code E0486 be revised to include the design features of the Slow Wave DS8 device, or that a new code be established with new/revised accompanying coding criteria, to enable billing of the Slow Wave. In either case, the requested change to Medicare policy is to eliminate the specifications that the device 1) have a fixed mechanical hinge, and 2) advances the mandible forward. The speaker also suggested adding two new coding criteria that would enable billing of the Slow Wave DS8, specifically, that the device 1) is created from a digital intraoral scan and 3D digitally printed in a lab or dentist office, and 2) is delivered and billed by a Dentist or DME provider.

**CMS FINAL HCPCS CODING DECISION**

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation, particularly information in response to our request to explain why a HCPCS Level II code would be more appropriate than a Current Dental Terminology (CDT) code. CMS re-reviewed this application together with the information provided, and has decided to establish HCPCS Level II code K1027 "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" as E0486 does not describe this product, which is presumed to be primarily for a medical, non-dental purpose. CMS recognizes that a dentist is the likely provider type but that some payers may not accept a CDT code on an 847D claim type for a primarily medical, non-dental benefit.

**Request # 21.051**

## TOPIC

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

Applicant's suggested language: "Head-worn customizable bi-optic electronic central vision prosthetic with unoccluded peripheral fields."

## APPLICANT'S SUMMARY

The eSight device is an electronic image processing vision prosthetic technology (Class 1) with un-occluded peripheral fields for people with central vision impairment.

The eSight device performs various image modifications in real time such that the information provided to the compromised retina is optimized to generate peak synaptic response. The device can manipulate the temporal/spectral/spatial aspects of retinal stimulation, something not achievable through classical optical magnification. Specific electronic image enhancement strategies depend on the eyes' vestigial retinal function, are unique to each user and must be adjusted according to the users' desired ADLs, ambient conditions (cloudy versus bright sun for example), etc. It is important to note that traditional optical magnification aids, whether handheld or spectacle mounted, cannot achieve similarly effective image enhancement. In fact, optical magnification devices actually reduce contrast through light attenuation, which can degrade functional visual performance.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new HCPCS Level II code to separately identify the eSight has not been approved. We are actively seeking input from non-Medicare insurers regarding a need for a unique HCPCS Level II code to identify eSight.

Otherwise, 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and provided comments in support of the request to establish a new HCPCS Level II code to separately identify the eSight low vision device. The speaker commented that there are no existing codes that describe "clinical improvements" or "improved patient quality of life" enabled by the eSight device, and a HCPCS code, and payment, will enable improved patient access, facilitate patients return to work, classroom or online learning, and maintaining an independent and productive life. The speaker also commented that the eSight is customizable and has unique functional features such as "unoccluded habitual peripheral vision and Bioptic tilt" (required to navigate safely while walking). Also, the device provides significant improvement in visual acuity at all distances. The

speaker claims that there is evidence of payment by the VA and by at least one commercially administered plan.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. We remain interested in this emerging technology, and the full breadth of low vision products that provide similar function. We welcome ongoing dialogue and examples of policy demonstrating insurers' needs for a unique code to identify these devices on electronic medical claims.

In the meantime, existing code V2799 "Vision item or service, miscellaneous" is available for assignment by insurers if they deem appropriate to identify the eSight device on a claim.

For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be filed. For Medicare, contact the Medicare contractor in whose jurisdiction 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.

**Request # 21.055**

## TOPIC

Request to establish a new HCPCS Level II code that accurately reflects the active use and non-continuous motion and strengthening mechanisms of the X10, and the treatment duration.

## APPLICANT'S SUMMARY

The X10 Knee Recovery System is an intelligent pressure-modulated recovery device consisting of a computer-controlled actuator arm with an ultra-sensitive inclinometer and load sensing ability. The X10 is used in-home guided by telehealth therapists and increases range of motion and strength. The X10 is used for patients who are lacking range of motion, have leg muscle weakness or are lacking central nervous system control of leg muscles. The X10 is currently assigned code E0935 "Continuous passive motion exercise device for use on knee only." E0935 applies to a machine that passively forces the patient's leg to move between two preset angles for increasing range of motion.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code E0935 "Continuous passive motion exercise device for use on knee only," and existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified," describe the system. CMS understands that a particular insurer may, on a claim-by-claim review basis, prefer to assign a different code when it is paying for a broader range of services and equipment.

CMS found no new information in this current resubmitted application, and encourages the applicant to point out what new information was included in this application when compared to their previous application submission (20.076).

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Failing to set proper reimbursement that recognizes the costs associated with the technological advancements and capabilities of the X10, including its telehealth and data collection capabilities, has had a negative and detrimental impact on physicians and hospitals recommending the use of the X10. This is greatly due to the lead time for individual approval and the uncertainty of reimbursement. The speaker believes that the current code/codes assigned are inadequate to provide the X10 to the public.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS re-reviewed this application together with the information provided, and is finalizing its preliminary coding recommendation that existing code E0935 "Continuous passive motion exercise device for use on knee only," and existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories,

components and electronics, not otherwise classified," describe the system. CMS understands that a particular insurer may, on a claim-by-claim review basis, prefer to assign a different code when it is paying for a broader range of services and equipment.

**Request # 20.164**

## TOPIC

Request to establish a new HCPCS Level II code to identify the Chait Access Adapter with Connecting Tube.

Applicant's suggested language: AXXXX "Cecostomy irrigation supply; tubing with adapter"

## APPLICANT'S SUMMARY

Cook Medical submitted a request to establish a new HCPCS Level II code to identify the Chait Access Adapter with Connecting Tube.

The Chait Access Adapter with Connecting Tube is a single-patient, reusable connecting tube with a flared fitting on one end and a metal cannula joined to a plastic block at the other end. The Chait Access Adapter with Connecting Tube is a replaceable accessory intended to allow connection between the Chait Cecostomy Catheter and the delivery tubing of an irrigation/enema bag system. The flared fitting of the Chait Access Adapter is connected to the enema delivery system tubing, while the metal cannula of the adapter is inserted into the lumen of the catheter's trap door fitting as needed to flush fluids through. This adapter allows enema solution to flow through the catheter into the cecum. This product is only used by patients who have been implanted with the Chait Cecostomy Catheter.

As per the applicant, there is currently no existing HCPCS Level II code that accurately describes the Chait Access Adapter with Connecting tube or its specific use.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

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

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker stated that the Chait Access Adapter with Connecting Tube supplies a connection between an enema bag system and the trapdoor fitting of the Chait Cecostomy Catheter. The Chait Access Adapter is dissimilar to standard enema tubing, as the adapter (plastic block with metal cannula) is essential to the function of the device in administering an antegrade enema. Standard enema tubing is not compatible with the Chait Catheter. Because of this dissimilarity, the speaker feels that the initially assigned (then subsequently rescinded) K code does not fully capture the Chait Access Adapter's functionality. Currently, miscellaneous codes currently used by DME suppliers, A4421(Ostomy supply; miscellaneous) and A4335 (Incontinence supply; miscellaneous) are being used to describe the Chait Access Adapter. The speaker strongly believes that a new unique HCPCS code for a cecostomy irrigation supply (AXXXX Cecostomy irrigation supply; tubing with adapter) is necessary to facilitate access to

the device. Therefore, the speaker respectfully disagrees with CMS' proposal to delay a coding decision until a subsequent cycle and urges CMS to finalize a coding recommendation.

**CMS FINAL HCPCS CODING DECISION**

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS re-reviewed this application together with the information provided, and has decided to change its preliminary coding recommendation, which was to defer this request to a subsequent coding cycle. CMS is finalizing the decision to revise HCPCS Level II code K1013 to add "with or without adapter" to the descriptor language, which will now be, "Enema tube, with or without adapter, any type, replacement only, each."

CMS understands that the Chait Access Adapter (plastic block with metal cannula) is only compatible with Chait Cecostomy Catheter, but we have been unable to determine a clinical distinction between the Chait Access Adapter with Connecting Tube and other enema extension tubing. We welcome the applicant to provide additional information to CMS describing the clinical superiority of a metal adapter.

**Request # 21.056**

## TOPIC

Request to establish two new HCPCS Level II codes, the first for an EPAP device, which includes a nasal pillow body and two cartridge valves (similar to a CPAP mask A code) and a code for a pair of cartridge valve replacements (similar to a CPAP mask replacement A code). We further request to add "EPAP" to the CPAP Headgear code (A7035) and to the CPAP Replacement Nasal Mask Cushion code (A7033).

## APPLICANT'S SUMMARY

The ULTepap is an Expiratory Positive Airway Pressure (EPAP) device FDA cleared for the treatment of mild to moderate Obstructive Sleep Apnea (OSA) for adults >66 lbs. EPAP has been clinically proven to be equally efficacious to Continuous Positive Airway Pressure (CPAP) since 1983. Instead of relying on a blower like CPAP, EPAP uses a valve system which allows the patient to inhale with negligible resistance, but exhale with enough resistance to help inflate the upper airway. The ULTepap is comprised of body with nasal pillows which interface with the nose, and a pair of cartridge valves. It is these cartridge valves which produce the resistance on exhalation that creates the therapeutic back pressure. The device is held in place by a standard CPAP mask headgear. The obvious advantage of EPAP vs CPAP is the lack of a tube, blower, humidifier and filters, which can lead to better adherence to therapy and reduced costs.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

CMS understands that no third-party payers pay for any EPAP devices at this time. Thus, this request to establish two new HCPCS Level II codes has not been approved. CMS welcomes input about whether our understanding of third-party payers is incorrect.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Following the public meeting, CMS re-reviewed this application and is finalizing its preliminary coding recommendation. We continue to understand that no third-party payers pay for any EPAP devices at this time.

**Request # 21.065**

## TOPIC

Request to establish a new HCPCS Level II code to identify the provision and remote interpretation of data collected via a purchased or leased FDA-registered at-home uroflow medical device.

The applicant did not provide recommended language for the requested new code.

## APPLICANT'S SUMMARY

The Stream Dx device is a novel point of care uroflow meter that, unlike current office based uroflow meters, allows patients suffering from LUTS, BPH, OAB and UI to have an accurate uroflow test in the comfort of their homes at times when they normally void. This significantly improves the quality of both volume and flow rate data, in turn improving treatment efficacy and outcomes. It also provides for an electronic voiding summary, which is otherwise not currently available to physicians. The data that is collected can either be wirelessly uploaded or recorded on the device and uploaded later. The uploaded data is used to generate volume and flow rate reports, Liverpool nomograms, an IPSS score and an electronic home voiding summary. The reports that are generated are formatted for inclusion in the patient's Electronic Health Record (EHR).

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

This type of product would typically be included in the practice expense for a procedure and not separately coded.

The applicant has identified CPT codes 99453 "Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment" and 99454 "Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; each 30 days" as relevant, but indicated that those codes require at least 16 out of 30 days for remote data collection as a rationale for CMS to develop a separate code. HCPCS Level I (CPT) coding is the typical approach for coding for physician services. CMS believes the appropriate starting point for correct coding is for the applicant to approach the AMA for guidance.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation. The primary speaker provided, that 50% of men over 50 years of age suffer from Lower Urinary Tract Symptoms (LUTS), and this is the most common urological diagnosis for men aged 45 to 74. The American Urological Association (AUA) recommended development of an objective screening tool to measure LUTS. Per AUA guidelines, uroflowmetry (measurement of urine flow) is indicated for Benign Prostatic Hyperplasia (BPH), overactive bladder, LUTS (new and returning), and prior to surgery. Stream Dx is a Home Uroflow Service. Patients use the test at home and ship the data to

Stream Dx headquarters. The Stream Dx Cloud Server prepares and transmits a report to the patient's physician for review of results. The AUA recommends CPT code 51741-26 for professional interpretation. The direct supervision requirement for 51741 was originally established for diagnosis and monitoring and are for in-clinic testing. At home, uroflow testing requires the patient to use a device for 6 to 9 days. The speaker reiterated the request for a Level II HCPCS code for home use of equipment and commented that this would be consistent with establishment of other HCPCS Level II codes. The speaker also commented that home uroflowmetry tests are proven effective for diagnosis and monitoring, and are more accurate than in-clinic testing. The speaker claimed that there is no existing HCPCS Level II code to describe a home uroflowmetry device, there is a "hole in coverage", and establishment of the requested code would increase access to care.

**CMS FINAL HCPCS CODING DECISION**

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS is finalizing its preliminary recommendation. This type of product would typically be included in the practice expense for a procedure and not separately coded.

The applicant has identified CPT codes 99453 "Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment" and 99454 "Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; each 30 days" as relevant, but indicated that those codes require at least 16 out of 30 days for remote data collection as a rationale for CMS to develop a separate code. CMS still believes that HCPCS Level I (CPT) is the appropriate code set for the Stream Dx, and that the applicant should request a unique HCPCS Level I (CPT) code if the Stream Dx is not described under CPT code 99454 due to the associated timeframe. CMS continues to believe that the applicant should reach out to the AMA regarding CPT coding. HCPCS Level I (CPT) coding is the typical approach for services directly involving physician interpretation of the results.

**Request # 21.066**

## TOPIC

Request to establish two new HCPCS Level II codes to identify:

a. Feelix Device Wireless stethoscope with recording device and LED indicators

b. FeelixPro Wireless stethoscope with recording device with headset attachment for physician use only.

## APPLICANT'S SUMMARY

Feelix Device is a digital stethoscope that collects high-fidelity recordings in any environment and transmit data wirelessly. Feelix collects recordings of patient body sounds and allows clinicians to review and share recordings via a HIPAA-compliant cloud. FeelixPro is a connected device used by professional clinicians to collect high-fidelity sounds with a headset feature and EInk screen for point of care use. FeelixPro collects recordings of patient body sounds and allows clinicians to save and transmit those recordings into a HIPAA-compliant cloud.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

It is our understanding that the item that is the subject of this application could be used in furnishing remote monitoring HCPCS Level I Current Procedural Terminology (CPT) codes 99453 "Remote monitoring of physiologic parameters, initial set up and patient education on use of equipment," 99454 "Remote monitoring of physiologic parameters, supply with daily recordings or programmed alert transmission, each 30 days," and 99457 "Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in calendar month requiring interactive communication with the patient/caregiver during the month". HCPCS Level I (CPT) coding is the typical approach for physician services. At this time, we encourage you to engage with the AMA about potential HCPCS Level I (CPT) coding.

CMS encourages the applicant to follow up with additional information shall it become available as a result of communication with the AMA.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that the Feelix stethoscope is the first digital stethoscope designed for clinicians and consumers that uses adaptive noise suppression to transmit high-fidelity audio, enabling remote monitoring of abnormalities in lung and body sounds. It is the first digital stethoscope that listens to lung sounds and transmits patient data from home to care teams anywhere. Feelix stethoscope collects high-fidelity lung and heart sounds and transmits data to secure cloud for analysis. It has a secure Bluetooth connectivity and adaptive noise suppression. It operates in environments when the ambient noise information is not available.

The clinician benefits: 1. Enhanced sound for more accurate diagnosis and treatment; 2. EMR integration for collaboration across the care continuum; 3. Bluetooth connectivity.

**CMS FINAL HCPCS CODING DECISION**

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS is finalizing its preliminary recommendation. It is our understanding that the item that is the subject of this application could be used in furnishing remote monitoring HCPCS Level I (CPT) codes 99453 "Remote monitoring of physiologic parameters, initial set up and patient education on use of equipment," 99454 "Remote monitoring of physiologic parameters, supply with daily recordings or programmed alert transmission, each 30 days," and 99457 "Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in calendar month requiring interactive communication with the patient/caregiver during the month". CMS continues to believe that HCPCS Level I (CPT) is the appropriate code set for the Feelix Device.

**Request # 21.050**

## TOPIC

Request to modify HCPCS Level II code B9998, which reads "Noc for enteral supplies," to include a patented undershirt for children who are fed enterally.

## APPLICANT'S SUMMARY

The *Starberrykids* feeding tube onesie is used exclusively for the gastric/gastro-jejunal (g/gj) tube population. The child will remain comfortable while the caregiver administers medication and feeds the child. It also provides easy access to maintain the cleanliness of the g-tube site.

This bodysuit was created exclusively to keep the child comfortable while the caregiver has access to the g/gj tube. An undershirt is a basic essential need for a child. A child that is not toilet trained typically wears an undershirt that snaps on the bottom. The snap on the bottom undershirts are cumbersome for children who are fed enterally as the caregiver cannot easily access the feeding tube. In such a case many children with g-tubes do not wear undershirts. During winter these undershirts provide an extra layer of warmth. In the summer, many children wear just these g-tube onesies with shorts, for a complete outfit. At night, many children wear these onesies with pajama bottoms, as this is an ideal way for the caregiver to have access for feeding the child throughout the night, and to be able to easily administer the medication without waking the child by moving him around to get to the g-tube. The flap has four snaps so that it can be closed to keep the child from touching the port and extensions.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4467 "Belt, strap, sleeve, garment, or covering, any type," describes this product. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be filed. For Medicare, contact the Medicare contractor in whose jurisdiction a 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.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that the Starberrykids feeding tube undershirt eases the process of feeding children who are fed via g/gj tube. It enables caregiver to administer medication and to clean and dress the stoma easily. With traditional baby undershirts, the child needs to be completely undressed in order to gain access to the g/gj tube. The undershirt features a flap which opens easily to provide access. The primary speaker recommended assignment of HCPCS Level II code B9998 "all items not otherwise classified for enteral supplies" to describe the Starberrykids onesie, as opposed to the suggested HCPCS Level II code A4467 which is for "belt, strap, sleeve, garment or covering." The recommendation is based on the fact that the Starberrykids feeding tube undershirt is specifically made for children on feeding tubes. Children from other populations would not have any need for this item.

## CMS FINAL HCPCS CODING DECISION

We appreciate the comments provided at the public meeting in reaction to our published preliminary recommendation. CMS is finalizing its preliminary recommendation that existing code A4467 "Belt, strap, sleeve, garment, or covering, any type," describes this product. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) the claim would be filed. For Medicare, contact the Medicare contractor in whose jurisdiction 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.

**Request # 21.059**

## TOPIC

Request is to establish a new HCPCS Level II code for a prescription and over-the-counter drug deactivation and disposal pouch. Brand Name: Deterra Drug Deactivation System.

The applicant did not provide recommended language for the requested new code.

## APPLICANT'S SUMMARY

Deterra's purpose is to reduce the risk of substance use disorder, and negative environmental impact through effective deactivation and disposal of unused, unwanted, or expired medications. Available evidence points to Deterra as scientifically proven to render prescription and over-the-counter medicine, including addictive opioids, unavailable for misuse, abuse, and diversion. Deterra helps prevent diversion, misuse, and abuse because the advanced activated carbon system renders active pharmaceutical ingredients inert and non-retrievable for all practical purposes. Its plant-based packaging and non-toxic ingredients prevent harmful chemicals from entering our landfills and water supplies when drugs are disposed.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

As stated previously, CMS still does not have clear information that any insurance sector has a claims processing need for a new HCPCS Level II code to identify a prescription and over-the-counter drug deactivation and disposal pouch. We note that this decision is similar to the approach CMS took for other products that store disposable medical devices, like sharps disposal containers.

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary recommendation. As stated previously, CMS still does not have clear information that any insurance sector has a claims processing need for a new HCPCS Level II code to identify a prescription and over-the-counter drug deactivation and disposal pouch. We note that this decision is similar to the approach CMS took for other products that store disposable medical devices, like sharps disposal containers.

**Request # 21.042 - 21.046**

## TOPIC

Request to establish a new HCPCS Level II code to identify Whole Health Partners within the Veterans Health Administration (VHA).

Applicant's suggested language: QXXXX "Department of veterans affairs whole health partner services."

## APPLICANT'S SUMMARY

Whole Health Partners and related services help veterans navigate the healthcare system to find resources to meet those goals. They provide a safe and trusted environment for patients to share their experiences. They provide an opportunity to reach veterans in their communities and improve access to health education and information. The services they provide represent a critical component of VHA's Whole Health Approach to care. In order to accurately investigate the ongoing delivery of these well-being approaches, there is a need for specificity in coding. This will allow for more large-scale, high-quality trials, as well as the ability to accurately capture costs for provision of these approaches, and the provider type.

## CMS PRELIMINARY HCPCS CODING RECOMMENDATION

Establish HCPCS Level II code QXXXX "Department of veterans affairs whole health partner services."

## SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No oral or written comments were provided by the primary speaker or applicant in response to CMS' published preliminary HCPCS coding recommendation.

## CMS FINAL HCPCS CODING DECISION

Having received no further public input on this application, CMS is finalizing its preliminary recommendation to establish HCPCS Level II code Q9004 "Department of veterans affairs whole health partner services."