



Centers for Medicare & Medicaid Services (CMS) Agenda for Healthcare Common Procedure Coding System (HCPCS) Public Meeting for Code Applications for Non-Drug and Non-Biological Items and Services Submitted to CMS' 2nd 2021 Biannual HCPCS Coding Cycle

**Zoom Meeting, for remote participation
Thursday, December 2, 2021 9:00 am – 5:00 pm, eastern standard time (est)**

8:45 am, est:

- Zoom meeting login:

<https://cms.zoomgov.com/meeting/register/vJlTf-mtpjsrGmPUe9EFh3kSrpwZX1tVtVE>.

- Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

9:00 am, est:

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

For each agenda item, a written overview of the request and CMS' preliminary coding recommendation or other review status is provided. Preliminary recommendations are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for stakeholders to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meeting. CMS' final coding decisions will be published on CMS' HCPCS website at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelIII-Coding-Decisions-Narrative-Summary> around the beginning of January 2022 and will be effective April 1, 2022, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Thursday, December 2, 2021. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

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December 2, 2021

CMS HCPCS Virtual Public Meeting

Agenda Item # 1

Supra SDRM - HCP210913KT8N0

Request to establish a new HCPCS Level II code to identify the Supra SDRM.

Applicant's suggested language: Q4XXX "Supra SDRM, per sq. cm."

Suprathel - HCP210914Q5TVE

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

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

Agenda Item #2

InnovaMatrix FS - HCP2109145U5NH

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

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

Agenda Item #3

Delete S codes - HCP210813XRPKE

Request to delete three existing codes S2066, S2067, and S2068

Agenda Item # 4

reSET - HCP21090135K6E

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

Applicant's suggested language: QXXXX "12-week, outpatient prescription digital cognitive behavioral therapy for substance use disorder as an adjunct to contingency management."

reSET-O - HCP210902RNB7C

Request to establish a new HCPCS Level II code to identify reSET-O.

Applicant's suggested language: QXXXX "12-week, outpatient prescription digital cognitive behavioral therapy for opioid use disorder as an adjunct to transmucosal buprenorphine and contingency management."

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Somryst - HCP2109034KYG9

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

Applicant's suggested language: QXXXX "9-week, outpatient prescription digital cognitive therapy for chronic insomnia."

Agenda Item # 5

MiSight 1 day- HCP210904KY8NE

Request to establish a new HCPCS Level II code to identify the MiSight 1 day contact lens.

Applicant's suggested language: VXXXX "Contact lens, hydrophilic, dual-focus, myopia control."

Agenda Item # 6

Willow Wearable Breast Pump - HCP210914A4XQA

Request to establish a HCPCS Level II code modifier to add to existing code E0603 "Breast pump, electric (ac and/or dc), any type."

Applicant's suggested language: E0603 XX "Breast pump, electric, with continuous latch technology."

Agenda Item # 7

Cymedica - HCP210914Q1AXK

Request to establish a new HCPCS Level II codes to identify IntelliHab system.

Applicant's suggested language: "Neuromuscular electrical stimulation system for treatment of pain, with conductive garment, integrated goniometer and supplies."

Agenda Item # 8

CardioBra- HCP2109010E9X7

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

PLEASE REVIEW THE FULL WRITEUP FOR THE AGENDA ITEM ON SUBSEQUENT
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Applicant's suggested language: XXXXX "Radiolucent external chest wall electrode positioner to accommodate breast tissue, with electrodes, single use (external electrode positioner)."

Agenda Item # 9

Bandgrip Micro-Anchor Skin Closure- HCP210908WYT1H

Request to establish a new HCPCS Level II code to identify the Bandgrip Micro-Anchor Skin. Closure.

Applicant's suggested language: XXXXX "Micro-anchor adhesive strip, more than 2 sq. in. but less than or equal to 16 sq. in., with any size adhesive border, each dressing."

Agenda Item # 10

InVoCell - HCP210913Y2C5W

Request to establish a new HCPCS Level II codes to identify InVoCell.

Applicant's suggested language: SXXXX "Intravaginal culture (IVC) system, single use."

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Agenda Item # 1

Supra SDRM - HCP210913KT8N0

Topic

Request to establish a new HCPCS Level II code to identify the Supra SDRM.

Applicant's suggested language: Q4XXX "Supra SDRM, per sq. cm."

Applicant's Summary

PolyMedics Innovations Inc. (PMI) requested a new Level II Healthcare Common Procedure Coding System (HCPCS) code for Supra SDRM: Q4XXX "Supra SDRM, per sq. cm." Supra SDRM is a resorbable synthetic skin substitute used to treat epidermal and dermal wounds, including those caused by burns, pressure ulcers, and venous ulcers, among other wounds. Supra SDRM is composed of a tripolymer of polylactide, trimethylene carbonate, E-caprolactone and polyvinyl alcohol. It is highly permeable to oxygen and water vapor, providing a favorable environment for wound healing. Supra SDRM is fully malleable at room temperature and becomes more pliable at body temperature and can be conformed three dimensionally to multiple anatomical orientations. Supra SDRM is available in eight sheet membrane sizes: • 1 x 1 cm • 18 mm disk • 2 x 2 cm • 5.1 x 5.1 cm • 9 x 9 cm • 9 x 12 cm • 18 x 9 cm • 18 x 18 cm. While HCPCS code C1849 (Skin substitute, synthetic, resorbable, per square centimeter) may be used to report Supra SDRM when used in the hospital outpatient department, there is no existing HCPCS Q code that describes Supra SDRM when used in the physician office setting. Therefore, a new unique Q code is needed to help facilitate claims processing for providers that wish to treat patients in the physician office setting.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Supra sdrm, per square centimeter."

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Agenda Item # 1

Suprathel - HCP210914Q5TVE

Topic

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

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

Applicant's Summary

PolyMedics Innovations Inc. requested a new Level II Healthcare Common Procedure Coding System (HCPCS) code for Suprathel: Q4XXX "Suprathel, per sq. cm." Suprathel is a resorbable synthetic skin substitute used to treat epidermal and dermal wounds, including those caused by burns, pressure ulcers, and venous ulcers, among other wounds. Suprathel is composed of a tripolymer of polylactide, trimethylene carbonate, and E-caprolactone. It is highly permeable to oxygen and water vapor, providing a favorable environment for wound healing. Suprathel is fully malleable at room temperature, becomes more pliable at body temperature and can be conformed three dimensionally to multiple anatomical orientations. Suprathel is available in four sheet membrane sizes: 5 x 5 cm; 9 x 10 cm; 18 x 10 cm; and 18 x 23 cm. While HCPCS code C1849 (Skin substitute, synthetic, resorbable, per square centimeter) may be used to report Suprathel when used in the hospital outpatient department, there is no existing HCPCS Q code that describes Suprathel when used in the physician office setting. Therefore, a new unique Q code is needed to help facilitate claims processing for providers that wish to treat patients in the physician office setting.

Preliminary CMS HCPCS Coding Recommendation

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

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Agenda Item # 2

InnovaMatrix FS - HCP2109145U5NH

Topic

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

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

Applicant's Summary

Triad Life Sciences, Inc. requested a unique Q code under the Level II HCPCS code set for InnovaMatrix FS. InnovaMatrix FS is a sterile, single use, medical device consisting of extracellular matrix derived from porcine placental material used for safe and effective wound treatment. InnovaMatrix FS is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans and is produced in fenestrated sheets in a variety of sizes. This biodegradable wound matrix provides a protective cover to the wound. There are no current specific HCPCS codes that define a fenestrated skin substitute composed of an extracellular matrix derived from porcine placental material. InnovaMatrix FS is the first Food and Drug Administration cleared fenestrated medical device sourced from pig placenta. Therefore, we request a new HCPCS code category code: Q4XXX InnovaMatrix FS, per sq. cm to facilitate proper billing and coding to all payers in the full range of site of care settings. InnovaMatrix FS 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 FS is supplied terminally sterile, in a single use package, and in a variety of sizes of fenestrated sheets.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Innovamatrix fs, per square centimeter."

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Agenda Item # 3

Delete S codes - HCP210813XRPKE

Topic

Request to delete three existing HCPCS Level II codes S2066, S2067, and S2068.

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Applicant's Summary

The Blue Cross and Blue Shield Association submitted a request to discontinue three S codes related to breast reconstruction: S2066 Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral; S2067 Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral; and S2068 Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral S codes are temporary national codes established by private payers. They are not recognized by Medicare or other federal payers and are not assigned a fee schedule. These codes were established in 2006 (S2068) and in 2007 (S2066 and S2067) to describe a new method of breast reconstruction that had not reached the sufficient literature and utilization threshold to apply for CPT Category I Code status. Since that time, the procedures represented by these three codes have grown in acceptance, and in 2021, CPT code 19364 was modified to report these procedures. As of January 1, 2021, the descriptor for CPT code 19364 now reads "Breast reconstruction; with free flap (e.g., fTRAM, DIEP, SIEA, GAP flap). As there is now an established Category I CPT code that represents these services, the S codes are no longer needed, and the Blue Cross and Blue Shield Association requests their discontinuation. This surgical procedure does not involve any drugs or biologicals.

Preliminary CMS HCPCS Coding Recommendation

We appreciate that methods of breast reconstruction have advanced to the point where the procedures described by HCPCS codes S2066, S2067, and S2068 are now described by CPT code 19364; however, we note that discontinuing the S codes may affect multiple manufacturers and payers. We seek a broad range of input on any implications of discontinuing S2066, S2067, and S2068, including whether we should consider a later effective date for discontinuing the codes for claims processing or other purposes.

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Agenda Item # 4

reSET - HCP21090135K6E

Topic

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

Applicant's suggested language: QXXXX "12-week, outpatient prescription digital cognitive behavioral therapy for substance use disorder as an adjunct to contingency management."

Applicant's Summary

Pear Therapeutics' reSET is intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients 18 years of age and older who are currently enrolled in outpatient treatment under the supervision of a clinician. reSET is indicated as a 12-week (90-day) prescription-only treatment for patients with substance use disorder (SUD) who are not currently on opioid replacement therapy, who do not abuse alcohol solely or who do not abuse opioids as their primary substance of abuse. It is intended to increase abstinence from a patient's substances of abuse during treatment and increase retention in the outpatient treatment program. Delivers therapy based on the community reinforcement approach, an intensive form of validated neurobehavioral therapy for SUD, along with contingency management and fluency training to enhance learning. reSET is currently comprised of 62 interactive modules: 32 core modules and 30 supplemental modules. reSET was cleared as the first in class of a rapidly emerging field of prescription digital therapeutics (PDTs), a new therapeutic class that leverages regulated and clinically validated prescription software, as determined by the Food and Drug Administration, to treat human disease. There are currently no HCPCS codes that describe PDTs. The lack of a unique HCPCS code for PDTs has contributed to patient access concerns because government/commercial payers lack the necessary coding infrastructure to appropriately cover and pay for PDTs. As coverage and payment for PDTs among government/commercial payers continue to evolve, a unique Q code for reSET will facilitate claims billing/processing across diverse payer claims processing and billing systems, thereby improving patient access.

Preliminary CMS HCPCS Coding Recommendation

We understand that this application is intended to be used in conjunction with face-to-face treatment delivered by the clinician. HCPCS Level I (CPT) coding is the typical approach for physician services. Please let us know about any previous engagement that you may have had thus far with the AMA about potential HCPCS Level I (CPT) coding. Please also inform us if you have any more information that describes the role of the practitioner relative to this device, and if a HCPCS Level I (CPT) code covers this device.

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Agenda Item # 4

reSET-O - HCP210902RNB7C

Topic

Request to establish a new HCPCS Level II code to identify reSET-O.

Applicant's suggested language: QXXXX "12-week, outpatient prescription digital cognitive behavioral therapy for opioid use disorder as an adjunct to transmucosal buprenorphine and contingency management."

Applicant's Summary

Pear Therapeutics' reSET-O is a 12-week interval prescription digital therapeutic for opioid use disorder (OUD). reSET-O is modeled on the Community Reinforcement Approach (CRA) and delivers CRA therapy as a series of interactive therapy lessons. Each therapy lesson is comprised of a cognitive behavioral therapy component and skill building exercises. Therapy lesson content is delivered primarily via text or audio, and may include videos, animations and graphics. reSET-O is intended as an adjunct to standard of care for patients with OUD and is limited to persons with a valid prescription from their licensed provider. reSET-O reinforces the importance of using buprenorphine for treatment of OUD. reSET-O was cleared as the second in class of a rapidly emerging field of "prescription digital therapeutics" (PDTs), a new therapeutic class that leverages regulated and clinically validated prescription software, as determined by the Food and Drug Administration, to treat human disease. There are currently no HCPCS codes that describe prescription digital therapeutics (PDTs). The lack of a unique HCPCS code for PDTs, including for reSET-O, contributes to patient access concerns because government/commercial payers lack the necessary coding infrastructure to appropriately cover and pay for PDTs, thereby negatively impacting patient access to these products. As coverage and payment for PDTs among government/commercial payers continue to evolve, a unique Q code for reSET-O will facilitate claims billing/processing across diverse payer claims processing and billing systems, thereby improving patient access.

Preliminary CMS HCPCS Coding Recommendation

We understand that this application is intended to be used in conjunction with face-to-face treatment delivered by the clinician. HCPCS Level I (CPT) coding is the typical approach for physician services. Please let us know about any previous engagement that you may have had thus far with the AMA about potential HCPCS Level I (CPT) coding. Please also inform us if you have any more information that describes the role of the practitioner relative to this device, and if a HCPCS Level I (CPT) code covers this device.

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Agenda Item # 4

Somryst - HCP2109034KYG9

Topic

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

Applicant's suggested language: QXXXX "9-week, outpatient prescription digital cognitive therapy for chronic insomnia."

Applicant's Summary

Pear Therapeutics' Somryst is a 9-week prescription-only digital therapeutic intended to provide a neurobehavioral intervention (Cognitive Behavioral Therapy for Insomnia - CBT-I) in patients 22 years of age and older with chronic insomnia. CBT-I is a neurobehavioral treatment, which focuses on addressing the maladaptive behaviors, routines, and dysfunctional thoughts that perpetuate sleep problems, regardless of the original source of the sleep problem. Somryst is comprised of 6 interactive modules, which consist of text, video, animation and graphics. Somryst belongs to a new therapeutic class that leverages regulated and clinically validated prescription software, as determined by the Food and Drug Administration through its "Software as Medical Device" (SaMD) framework, to treat human disease. There are currently no HCPCS codes that describe any prescription digital therapeutics (PDTs). The lack of a unique HCPCS code for PDTs, including Somryst, contributes to patient access concerns because government/commercial payers lack the necessary coding infrastructure to appropriately cover and pay for PDTs, thereby negatively impacting patient access to these products. As coverage and payment for PDTs among government/commercial payers continue to evolve, a unique Q code for Somryst will facilitate claims billing/processing across diverse payer claims processing and billing systems, thereby improving patient access.

Preliminary CMS HCPCS Coding Recommendation

We understand that this application is intended to be used in conjunction with face-to-face treatment delivered by the clinician. HCPCS Level I (CPT) coding is the typical approach for physician services. Please let us know about any previous engagement that you may have had thus far with the AMA about potential HCPCS Level I (CPT) coding. Please also inform us if you have any more information that describes the role of the practitioner relative to this device, and if a HCPCS Level I (CPT) code covers this device.

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Agenda Item # 5

MiSight 1 day- HCP210904KY8NE

Topic

Request to establish a new HCPCS Level II code to identify the MiSight 1 day contact lens.

Applicant's suggested language: VXXXX "Contact lens, hydrophilic, dual-focus, myopia control."

Applicant's Summary

CooperVision, Inc. submitted a request for a new V-code for the MiSight 1 day (omafilcon A) soft contact lens. MiSight 1 day is an FDA-approved device indicated for the correction of myopic ametropia and for slowing the progression of myopia in children, who at the initiation of treatment, are 8-12 years of age and have a refraction of -0.75 D to -4.00 D (spherical equivalent) with less than or equal to 0.75 diopters of astigmatism. MiSight 1 day is an FDA Class III device with PMA approval, and is the only soft contact lens approved by the FDA to slow the progression of myopia in children. When approved, MiSight 1 day was assigned a unique product classification code, QIT, as it is a novel lens which provides a therapeutic mode of action in addition to a refractive mode of action. Because other contact lenses' mode of action only serves to refract light to correct ametropia, current V-codes for contact lenses (e.g. V2520: contact lens, hydrophilic, spherical, per lens; V2522: contact lens, hydrophilic, bifocal, per lens; V2599: contact lens/es, other type) do not address the novel, therapeutic nature of the MiSight 1 day lens. Additionally, current V-codes do not address the optical design through which the therapeutic action is achieved (the MiSight 1 day lens employs a dual-focus design which has a central zone containing distance vision and concentric peripheral zones to provide peripheral myopic defocus). The proposed code will provide the appropriate differentiation for the MiSight 1 day lens by specifying the design (dual-focus) and the therapeutic nature (myopia control) of the lens.

Preliminary CMS HCPCS Coding Recommendation

Upon review of the information submitted with this application, we are considering whether existing code V2522 "Contact lens, hydrophilic, bifocal, per lens" describes the MiSight 1 day contact lens. We are also considering whether creating a new code to describe MiSight would be warranted. Accordingly, we are interested in gaining a better understanding of how the MiSight lens is distinguishable from other products on the market. Specifically, whether and exactly how the difference in design from other bifocal lenses confers a different function and/or a significant therapeutic distinction when compared with the use of other products on the market, separate FDA authorization notwithstanding. Clinical studies that demonstrate such comparison and distinction would be welcome. We are also interested in learning about emerging technologies in this area of practice. We invite comments from payers regarding whether they perceive a benefit to code distinctions for similar products based on specific indications for use, and how such coding might improve efficiency, accuracy or other programmatic need; how/whether it might add administrative complexity; and what might be preferable, on balance.

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Agenda Item # 6

Willow Wearable Breast Pump - HCP210914A4XQA

Topic

Request to establish a HCPCS Level II code modifier to add to existing code E0603 “Breast pump, electric (ac and/or dc), any type”

Applicant’s suggested language: E0603 XX “Breast pump, electric, with continuous latch technology.”

Applicant’s Summary

Willow Innovations, Inc. is submitted a request to establish one HCPCS code modifier to add to existing code E0603 (breast pump, electric) that specifies the continuous latch technology feature of the pump. Recommended language: E0603 XX Breast pump, electric, with continuous latch technology B) Product Name and Description: The Willow Wearable Breast Pump featuring continuous latch technology is an all-in-one breast pump and collection system worn entirely inside a bra. It is intended for lactating women to express and collect breast milk into a disposable collection storage bag or reusable container. The pump is intended for multiple uses with the individual user and may be operated as a single or double pumping system. Product Function: The Willow Wearable Breast Pump is a battery-powered rechargeable electromechanical device. Willow provides an untethered, hands-free, mobile pumping option where the entire pump and milk collection system is contained in one wearable device. The continuous latch technology feature is novel and functions to maintain latch that very closely mimics the natural suckling action of a breastfeeding baby, in contrast to other pumps which alternate between suction and release. Continuous latch provides the pumping mother the ability to be entirely mobile during her pumping sessions. The technology promotes spill-proof mobility for the mother during pumping; leak disruption and milk loss is minimized with continuous latch. Reason: There are currently no HCPCS code modifiers that describe the continuous latch feature of a wearable breast pump. Mobility for the mother while pumping is not a feature identified by HCPCS E0603, as traditional pumps leverage gravity to allow milk to drain into a bottle or container, requiring the mother to lean forward while pumping and maintain a fixed position often connected to tubes and cords. This HCPCS code modifier is necessary for claim submission, processing and adjudication, offering differentiation from traditional (suction and release, tether based) pumps.

Preliminary CMS HCPCS Coding Recommendation

CMS is interested in hearing from the applicant and other stakeholders regarding the difference between the Willow breast pump and existing products in the market. Also, we are looking to understand the clinical benefits and distinctions between breast pumps, including any data, if available, to support the applicant’s claims of technological advancement. Does the applicant have information about a patient population that utilizes the Willow breast pump in comparison to other pumps on the market? In the meantime, existing code E0603 "Breast pump, electric (ac and/or dc), any type" describes the Willow Breast Pump and is available for assignment by insurers if they deem appropriate.

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Agenda Item # 7

CyMedica - HCP210914Q1AXK

Topic

Request to establish a new HCPCS Level II codes to identify IntelliHab system.

Applicant's suggested language: "Neuromuscular electrical stimulation system for treatment of pain, with conductive garment, integrated goniometer and supplies."

Applicant's Summary

CyMedica requested to create a new HCPCS Level II code for the IntelliHab system, a next generation neuromuscular electrical stimulation (NMES) system with an interconnected "smart" conductive garment indicated for treatment of pain associated with knee osteoarthritis. The IntelliHab system was recently cleared by the FDA for the treatment of knee osteoarthritis pain. Proposed language for new HCPCS code: Neuromuscular electrical stimulation system for treatment of pain, with conductive garment, integrated goniometer and supplies. The IntelliHab system is the first and only NMES system cleared by the FDA for treatment of knee osteoarthritis pain. It is a non-invasive, non-pharmacological prescription treatment for knee osteoarthritis pain for use by patients in their homes. The IntelliHab system is comprised of a novel, power regulated, patented, closed loop feedback NMES therapy with a wireless application for control of electrical stimulation therapy and an interconnected, conductive garment with integrated goniometers to measure range of motion (ROM). The patented waveform technology and interconnected garment deliver a unique therapeutic dose that has been clinically demonstrated and cleared by the FDA for the treatment of osteoarthritis pain. The current codes for NMES and conductive garments do not adequately describe the new interconnected system and advancements in NMES technology that have been shown to provide the clinically therapeutic dose needed to achieve treatment of osteoarthritis pain. Additionally, there is a programmatic need for a distinct code to differentiate the novel therapy of osteoarthritis pain treatment using an advanced NMES system from the crowded field of traditional NMES devices that have neither demonstrated effectiveness in the treatment of osteoarthritis pain nor have been cleared for this therapeutic use by the FDA.

Preliminary CMS HCPCS Coding Recommendation

CMS does not see a clear distinction between the IntelliHab system and the predicate product CyMedica-e-vive system; CY 1000. FDA 510(k) premarket notification determined the device is substantially equivalent to the predicate product. The indication of use for neuromuscular electrical stimulation (NMES) system with interconnected "smart" conductive garment, to treat knee pain from osteoarthritis by increasing quadricep strength. We are unclear how this product is distinct from the e-vive system, which is used for muscle atrophy. CMS believes that it may be appropriate to use existing codes E0745 "Neuromuscular Stimulation Device, electronic shock unit" and E0731 "Form fitting conductive garment".

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Agenda Item # 8

CardioBra - HCP2109010E9X7

Topic

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

Applicant's suggested language: XXXXX "Radiolucent external chest wall electrode positioner to accommodate breast tissue, with electrodes, single use (external electrode positioner)"

Applicant's Summary

CardioBra LLC submitted a request for "radiolucent external chest wall electrode positioner to accommodate breast tissue, with electrodes, single use (external electrode positioner)" for the CardioBra. External electrode positioners (EEPs) address important disparities facing women. EEPs are designed to address significant barriers to exercise stress echocardiogram (ECG) testing for women by promoting accurate placement of ECG leads around breast tissue, protecting ECG lead positioning during exercise testing, and allowing rapid access to the chest wall that is necessary during image acquisition. EEPs also provide breast compression and elevation to help alleviate back, shoulder, and chest pain from exercising during diagnostic testing without breast support. If women are unable to exercise to peak capacity due to non-cardiac pain, the exercise stress echocardiogram results may be non-diagnostic. EEPs can be worn before, during, and after the exercise portion of stress testing, allowing for modesty and dignity that is essential for women with cultural, religious, and personal concerns to participate in medically necessary exercise stress testing. The primary target population is premenopausal women because this cohort has not experienced the improvements in cardiovascular mortality seen in other segments of the population. These women typically are not yet eligible by age for Medicare, and we recommend establishing a new, non-Medicare HCPCS code such as an S-code. The barriers facing women in exercise stress testing are long-standing, predictable, avoidable, and require the HCPCS Workgroup's immediate attention. There are no existing unique codes for any product to address these barriers, and securing a separate, unique code for EEPs is an important, necessary step for addressing the gender-based disparities in diagnostic exercise testing for cardiovascular disease. Instead of deferring to other code sets, the HCPCS Workgroup should move expediently to establish this new code to help remove gender-based disparities in exercise stress testing.

Preliminary CMS HCPCS Coding Recommendation

This product may not be suitable for inclusion in HCPCS Level II code set because it is a supply used in a procedure reported using HCPCS Level I (CPT) code. It is our understanding that the CardioBra would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physicians' service? If so, what CPT code(s) describe the service(s)?

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Agenda Item # 9

Bandgrip Micro-Anchor Skin Closure - HCP210908WYT1H

Topic

Request to establish a new HCPCS Level II code to identify the Bandgrip Micro-Anchor Skin Closure.

Applicant's suggested language: XXXXX "Micro-anchor adhesive strip, more than 2 sq. in. but less than or equal to 16 sq. in., with any size adhesive border, each dressing."

Applicant's Summary

Bandgrip Inc, submitted a request for a new HCPCS Level II code to identify the Bandgrip Micro-Anchor Skin Closures. The Bandgrip Micro-Anchor Skin Closure is a safe, sterile, Polycarbonate, class I, non-significant risk device for skin closure. The micro-anchor skin closure device is designed for speed of application, simplicity and strength. The device utilizes a novel method which precisely approximates skin edges utilizing several small skin anchors on a clear bandage-type patch. The clear micro-anchors are 0.29 inches in height and do not puncture through the dermis. Available evidence points to Bandgrip as a safe, effective alternative to traditional skin closure techniques such as staples, sutures and skin glues. There are currently no codes that can be used for the effective use for a micro-anchor skin closure device.

Preliminary CMS HCPCS Coding Recommendation

This product may not be suitable for inclusion in HCPCS Level II code set because it is a supply used in a procedure reported using HCPCS Level I (CPT) code. It is our understanding that the Bandgrip would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physicians' service? If so, what CPT code(s) describe the service(s)?

**PLEASE REVIEW THE FULL WRITEUP FOR THE AGENDA ITEM ON
SUBSEQUENT PAGES OF THIS DOCUMENT**

Agenda Item # 10

InVoCell - HCP210913Y2C5W

Topic

Request to establish a new HCPCS Level II codes to identify InVoCell

Applicant's suggested language: SXXXX "Intravaginal culture (IVC) system, single use"

Applicant's Summary

InVoCell Intravaginal Culture System contains the InVoCell Culture Device and InVoCell LL Retention Device. The Culture Device is FDA indicated for use in preparing, holding, and transferring human gametes or embryos during In Vitro Fertilization/Intravaginal Culture (IVF/IVC) and Intra-cytoplasmic Sperm Injection Fertilization/Intravaginal Culture (ICSI/IVC). The Retention Device is used during the incubation period to aid in holding the Culture Device in the vagina. During IVC eggs and sperm are combined in the InVoCell culture device. Then the InVoCell is placed in the patients' vagina, allowing for fertilization and incubation to occur. InVoCell is a new product and there are no other IVC products in the market. The InVoCell Retention Device is a single use, device that includes holes to allow for natural drainage of vaginal fluids (see Figure 3). The retention device is placed into the vaginal cavity with the InVoCell Culture Device to ensure that the InVoCell Culture Device is retained in the vaginal cavity. The retention device comes in a single size: 70mm. The InVoCell Culture Device is a three-part assembly enclosed in two separate packages. The inner vessel holds culture medium, eggs and sperm, or ICSI fertilized embryos. In an InVoCell procedure, the inner vessel is placed into the outer rigid shell, which provides additional resistance to contamination. Following the loading of gametes or embryos, the InVoCell Culture Device is assembled and placed in the vaginal cavity to allow for embryo development.

Preliminary CMS HCPCS Coding Recommendation

This product may not be suitable for inclusion in HCPCS Level II code set because it is used in a procedure reported using HCPCS Level I (CPT) code. It is our understanding that the InVoCell Culture Device and InVoCell Retention Device would typically be bundled into the payment for the procedure if it is used, and as such would not be separately payable. We invite the applicant to provide further information to help us understand when this product would be used. Is this device used primarily in the course of furnishing a physician's service? If so, what CPT code(s) describe the service(s)?