DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Centers for Medicare & Medicaid Services' (CMS') Second Biannual 2024 Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda

Zoom Meeting - Remote participation
Thursday, November 7, 2024, 9:00 am – 5:00 pm, eastern time (ET)

8:45 am, ET:
• Zoom meeting login:
https://cms.zoomgov.com/j/1602260511?pwd=hoK9eXztvwuVhSHLLReBBaVnlwiuaC.1
• Passcode: 132470; Dial: 833 435 1820 US Toll Free; Webinar ID: 160 226 0511
• Individuals who plan to speak as a primary or 5-minute speaker must register by emailing HCPCS@cms.hhs.gov, by the published deadline. All attendees can access the virtual public meeting through the Zoom link above.

9:00 am, ET:
• Welcome
• Background and purpose of meeting
• Meeting format and ground rules

Provided for each agenda item is a written overview of the applicant's request, CMS' preliminary coding recommendation, as well as CMS' preliminary benefit category and payment determination, if applicable. Preliminary recommendations are not final or binding upon any payer and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and any registered 5-minute speakers. Speaker presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for interested parties to provide additional input related to requests to modify the HCPCS Level II code set. Final decisions are not made at the public meeting. CMS' final coding, benefit category, and payment decisions will be published on CMS' HCPCS website at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCSLevelII-Coding-Decisions-Narrative-Summary around January 2025 and will be effective April 1, 2025, unless otherwise specified.

This agenda includes a summary of each HCPCS Level II code application being presented on Thursday, November 7, 2024. 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.

Table of Contents

Preliminary decisions for the HCPCS Virtual Public Meeting on Thursday, November 7, 2024.

Agenda Item # 1
Urocycler® - HCP2406308PQY6

Topic/Issue

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

Applicant's suggested language: XXXXX, “External prosthetic urinary sphincter, capable of automatic bladder cycling, sterile, each”

Summary of Applicant's Submission

TekGenius, Incorporated submitted a request to establish a new HCPCS Level II code to identify Urocycler®. Urocycler® is class II exempt from premarket notification requirements by the Food and Drug Administration (FDA). Urocycler® is an external prosthetic artificial urinary sphincter capable of sterile automatic bladder cycling. The device functions as a self-contained sterile automatically cycling external bladder sphincter. The Urocycler® is a low pressure-sensitive magnetic valve system, made of ceramic permanent magnets to create a controlled magnetic field that holds the valve closed initially when attached to any urinary catheter. This stops the constant “drip-drain” of foley catheters, allowing physiologic urine pressure buildup within the filling bladder. The clinical trials and documented outcomes show decreased catheter-associated urinary tract infection (CAUTI) by 96% without oral/parenteral antibiotics. Further analysis indicated use of the device correlated with decreased maintenance times, adverse events and hospital length of stay, while eliminating the 10% fatality rate of CAUTI and lowering the annual costs for hospitals by the reduction of morbidity and mortality rates. Controlled clinical trials of catheterized individuals demonstrated a 96% reduction in urinary tract infection, reduced catheter care nursing time, decreased pain and bladder spasm while also aiding in normal bladder retraining. Additionally, individuals had a 90% reduction in catheter biofilms, decreased post-void residual, normalized urine pH, avoided retrograde bacterial infection, and decreased inpatient admissions or readmission by over 95%.

CMS Preliminary HCPCS Coding Recommendation

The Urocycler® Bladder Management System with collection bag is an external, single-use, disposable urological supply. Urocycler® is a thumb-sized tubed disposable one-use sterile item, packaged in sterile peel-pack, that is placed at the distal end of any urinary catheter with the urinary drainage tubing to a urinary drainage bag. The applicant requested a new code for valve(s). Since May 1, 2015, the Urocycler® has been coded under existing HCPCS Level II codes A9900, A4357 and A9270. CMS believes that:

Existing HCPCS Level II code A4357, “Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each” used in conjunction with existing HCPCS Level II code A9900, “Miscellaneous dme supply, accessory, and/or service component of another hcpcs code” describes Urocycler’s® urine drainage bag and anti-reflux valve. In accordance with contractor coding guidance established in 2015, HCPCS Level II code A9270, “Non-covered item or service” is available for billing the Urocycler’s® magnetic release valve.

Preliminary Medicare Benefit Category Determination

Prosthetic device (Urological supply).

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A4357 apply to this product, if covered. The current average fee schedule amount for HCPCS Level II code A4357 is $12.65.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 37

For the anti-reflux valve, the payment rules and pricing associated with the existing HCPCS Level II code A9900 apply to this product. HCPCS Level II code A9900 is a non-covered item.

No Medicare Payment. Pricing Indicator = 00

For the magnetic release valve, the payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. HCPCS Level II code A9270 is a non-covered item.

No Medicare Payment. Pricing Indicator = 00

Agenda Item # 2
ProVate Vaginal Support - HCP230628N8LUJ

Topic/Issue

Request for Medicare payment determination for ProVate vaginal support.

Summary of Applicant's Submission

Indegene previously submitted a request to establish a new HCPCS Level II code to identify ProVate vaginal support. ProVate vaginal support received the Food and Drug Administration's (FDA's) 510(k) clearance on July 8, 2019. The ProVate vaginal support is indicated for the temporary, nonsurgical management of pelvic organ prolapse in females. The device is made of a flexible skeleton covered by a soft elastomer. ProVate is a disposable, single-use, prescription only device. Each unit is intended to be used for up to seven days. The ProVate box will contain 10 individually packaged devices. Each individual may be provided with up to 80 devices per year, 20 devices delivered to their home every 3 months. ProVate size-fitting is performed by a healthcare professional. The ProVate device comes in 6 sizes to accommodate various vaginal dimensions. The device is supplied in its compact (slender) mode, ready for use within a disposable applicator intended for the insertion of the device. The ProVate support is inserted into the vagina in a compacted mode within an applicator for comfortable insertion. When in the vagina, the plunger of the applicator is pressed (like with a tampon applicator) and the ProVate support expands into its ring shape to support the vaginal walls, and the applicator is removed and thrown away. At the end of its use (up to 7 days), the individual pulls the removal string, which collapses the device into its compact configuration, facilitating easy and painless removal. The device is then thrown away, and a new device can be inserted by the individual as needed. Once inserted, the circular shape of the ProVate is comparable to that of the predicate device (the currently available ring pessary), and the ring provides mechanical support to the prolapsed organs. Vaginal ring pessaries are currently the widely used pessary. However, ring pessaries are generally reusable and can contribute to various adverse symptoms (including discomfort, pain, discharge, bleeding, etc.) and with sexual disturbances, and in most cases require healthcare provider assistance to insert and remove, hence causing dependency upon the clinic.

CMS Final HCPCS Coding Decision

CMS established HCPCS Level II code A4564, "Pessary, disposable, any type" to describe ProVate, effective April 1, 2024.

Medicare Benefit Category Determination

CMS determined that ProVate vaginal support is a prosthetic device, effective April 1, 2024

Preliminary Medicare Payment Determination

There are currently no commercial prices for this item when furnished in the United States. Therefore, interim local fee schedule amounts for this item would be established by the DME MACs for any covered claims until commercial pricing information for items furnished in the United States becomes available. Section 60 of Chapter 23 of the Medicare

Claims Processing Manual states that MACs shall establish interim local fee schedule amounts for use in paying claims on an interim basis until the national fee schedule amounts are established for new DMEPOS items paid for on a fee schedule basis.

Pricing Indicator = 46

Agenda Item # 3
RestoreX - HCP2406287KDEG

Topic/Issue

Request for benefit category determination for RestoreX.

Summary of Applicant's Submission

PathRight Medical submitted a request to revise existing HCPCS Level II code S4988, to an E alpha numeric code for a new Medicare benefit category determination. RestoreX is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This current resubmission is in follow-up to a HCPCS Level II code application submitted last year in the Second Biannual 2023 HCPCS Level II Coding Cycle (RestoreX Penile Traction Device - HCP23061702CGD). The final decision was to establish new HCPCS Level II code S4988, “Penile contracture device, manual, greater than 3 lbs. traction force.” It was also stated at that time that this device would not meet the criteria for Medicare reimbursement, and additional information was requested: "Based on the information in the application and provided during the public meeting process, the applicant discussed recent changes to the device instructions for use (IFU) to support repeated use by successive individuals, and an expected useful life of at least 3 years. However, a text update to the IFU is not sufficient to establish successive repeated use and expected useful life of at least 3 years. We welcome more information demonstrating how RestoreX Penile Traction Device meets these classification conditions. Currently, the information for this item has not demonstrated these conditions, and thus the device is not considered DME." Included in this application are the requested validation studies/data confirming the 3-year durability and sanitation testing to ensure that the device is able to be safely transferred between individuals. With these additional tests, PathRight Medical believes that there is sufficient objective information now to fully qualify for all five required elements for DME status. Specifically, the device can withstand repeated use (shown in the validation data provided) and has an expected life of at least 3 years (shown again in the validation data). RestoreX is primarily and customarily used to serve a medical purpose (used to treat Peyronie's disease primarily), is generally not useful to an individual in the absence of an illness or injury and is appropriate for use in the home. With this context, PathRight Medical requests that this new resubmission be reconsidered for DME qualification and reimbursement.

CMS Preliminary/Final HCPCS Coding Decision

CMS established a new HCPCS Level II code S4988, “Penile contracture device, manual, greater than 3 lbs traction force” to describe RestoreX Penile Traction Device, effective April 1, 2024. With this application’s submission, the applicant provided additional information to support a preliminary Medicare benefit category determination of Durable Medical Equipment. To support this preliminary Medicare benefit category determination, we recommend to:

1. Establish a new HCPCS Level II code EXXXX, “Penile contracture device, manual, greater than 3 lbs traction force” to describe RestoreX.

   Effective April 1, 2025

2. Discontinue existing HCPCS Level II code S4988, “Penile contracture device, manual, greater than 3 lbs traction force”

   Effective March 31, 2025

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. This application is a follow up to a previous application (HCP23061702CGD) in which we determined the device did not meet the requirement for withstanding repeated use and did not have an expected life of at least 3 years. With this application’s submission, the applicant provided additional information regarding these conditions. Based on the submitted information, we believe this device can withstand repeated use and has an expected life of at least 3 years. Therefore, the RestoreX Penile Traction Device meets the requirements to be classified as DME.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c)(1), fee schedule amounts for items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors also listed in these program instructions.

In determining whether RestoreX is comparable to items with existing codes, we undertook a detailed examination of its physical, mechanical, and electrical components along with its function and intended use and additional attributes and features. We carefully reviewed the existing HCPCS Level II codes as part of our payment review for RestoreX and did not find any codes that adequately compare to the features of RestoreX. We believe this device is not comparable to any existing coded device and for this reason, have determined that the gap-

filling methodology is appropriate for establishing fees for this device. For this reason, we have determined that it is most appropriate to determine the Medicare payment amount in accordance with the gap filling procedure.

To develop an appropriate Medicare payment amount in accordance with the gap filling procedure, we must identify appropriate commercial pricing for the underlying items. We emphasize that a Manufacturer Suggested Retail Price (MSRP) is not, by itself, an adequate source of commercial pricing. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60739). The applicant provided paid claims data from private payers, which we used in our calculation. The claims data covers the years 2020 through 2022. In calculating the fee schedule amount, we are not using the paid claim from 2020 as it is almost 48% lower than lowest paid claims in 2021 and 2022 and we therefore believe it is no longer representative of what private payers are currently paying for RestoreX.

In accordance with regulations at 42 CFR 414.238(c), the allowable amount for the 2021 and 2022 private payer claims are deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The 2021 and 2022 private payer claim payments, when deflated to the 1986 fee schedule base period, are less than $150. Since these price used in calculating the fee schedule amounts are less than $150, payment would be made on an inexpensive or routinely purchased items basis in accordance with our regulations at 42 CFR 414.220. Using these deflated figures the price is then updated to the current year using the covered item update factors specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3). The resulting 2024 fee schedule amount for HCPCS Level II code EXXXX, when covered, would be $140.28. Payment would be made on a purchase or rental basis in accordance with section 1834(a)(2)(A) of the Social Security Act. Fee schedules are updated annually.

Pricing Indicator = 32

Agenda Item # 4
Peristeen® Plus Transanal Irrigation System - HCP2406251AW47

Topic/Issue

Request to establish a new HCPCS Level II code to identify Peristeen® Plus Transanal Irrigation System.

Applicant's suggested language: XXXXX, "Manual Transanal Irrigation Device, includes water reservoir, pump, tubing, and all accessories (not including catheter)"

Summary of Applicant's Submission

Coloplast, Corp. submitted a request to establish a new HCPCS Level II code to identify Peristeen® Plus Transanal Irrigation System (TAI). Peristeen® Plus TAI received the Food and Drug Administration's (FDA'S) 510(k) clearance on November 23, 2009. Coloplast, Corp. also submitted related HCPCS application HCP240625E95UJ to establish a new HCPCS code for single use rectal balloon catheter for manual transanal irrigation. Existing HCPCS Level II code A4459, "Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type", is currently used for billing TAI devices; however, the code describes enemas and does not accurately describe TAI devices used with rectal balloon catheters. TAI devices with a rectal balloon catheter are a minimally invasive, non-surgical treatment for individuals with neurogenic bowel dysfunction (NBD) for whom conservative bowel management, including enemas, has produced insufficient results. Additionally, TAI devices are indicated for the treatment of NBD that results from lesions on the central nervous system from spinal cord injury or disease. TAI with a rectal balloon catheter has a prosthetic mechanism of action, replacing the function of malfunctioning anal sphincters that have been damaged by NBD. When the balloon inflates it creates water pressure in the bowel sufficient to activate the gut "pacemaker" cells stimulating peristalsis, propelling bowel contents forward, and eliciting a reflex, relaxing (opening) the anal sphincter to support bowel control. When the balloon deflates, the obstruction is removed, and evacuation occurs. The applicant maintains that TAI devices with rectal balloon catheters are different from other devices coded under HCPCS Level II code A4459 based on their design, indications for use and mechanism of action. The initial kit includes a water reservoir with temperature indicator, a screw top, a pump for instilling water and air into the balloon catheter and tubing, and a control unit. The rectal balloon catheters are single use and separately packaged.

CMS Preliminary HCPCS Coding Recommendation

On January 1, 2015, CMS established HCPCS Level II code A4459, "Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type" to identify the Peristeen® Transanal Irrigation System (TAI). TAI systems are a device used to empty the lower bowel and to prevent chronic constipation and fecal incontinence or as a method of bowel management. The system consisted of an enema bag, a rectal catheter with an inflatable balloon and a pump. According to the applicant, the Peristeen® Plus Transanal Irrigation System's initial kit includes a water reservoir with temperature indicator, a screw top, a pump for instilling water and air into the balloon catheter and tubing, and a control unit. The single use rectal balloon catheters are separately packaged. While CMS continues to believe existing code A4459, "Manual pump-operated enema system, includes balloon,

catheter and all accessories, reusable, any type" adequately describes TAI devices, based on the applicant's explanation of the initial device kit, we believe it is necessary to revise the description of HCPCS Level II code A4459 because the device does not include single use balloon catheters; therefore, the description is no longer accurate. As such, CMS is proposing to:

Revise existing HCPCS Level II code A4459, "Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type" to instead read, "Manual transanal irrigation system, includes water reservoir, pump, tubing, and accessories, without catheter" because the balloon catheters are packaged separately from the device and to differentiate between enema systems and transanal irrigation systems.

CMS believes revising the description of existing HCPCS Level II code A4459 will accurately capture manual transanal irrigation systems used in the treatment of neurogenic bowel dysfunction.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The TAI devices for use with rectal balloon catheters do not meet two of the conditions that must be met for equipment to be classified as DME:

- **Can withstand repeated use** –A TAI device with a rectal balloon catheter system consists of a manual control unit and pump, tubing, a water container, and a single-use rectal balloon catheter. Since the rectal balloon catheter is single use; the control unit, pump and tubing last for 90 - 100 uses; and the water container for 15 uses, the system cannot withstand repeated use by successive patients.

- **Has an expected life of 3 years –** Since the rectal balloon catheter is single use; the control unit, pump and tubing last for 90 - 100 uses; and the water container for 15 uses, the system does not have a life of at least 3 years.

In addition, Section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual indicates that irrigation kits are non-reusable supplies that are not DME. Therefore, TAI device systems do not meet the definition of DME.

The applicants suggest that TAI devices with rectal balloon catheters meet the requirements to be considered a prosthetic device (Social Security Act § 1861(s)(8)) by replacing the function of the anal sphincters. Specifically, they indicate that TAI devices replace the function of malfunctioning anal sphincters by creating water pressure in the bowel sufficient to activate the gut "pacemaker" cells stimulating peristalsis, and by eliciting a reflex relaxing of the anal sphincter to support bowel emptying. In accordance with Medicare program instructions at Chapter 15, Section 120 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), prosthetic devices (other than dental) are devices which replace all or part of an internal body organ (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. We do not believe TAI devices with rectal balloon catheters are appropriately classified as prosthetic devices under the Medicare definition as they do not replace the function or structure of an internal body organ. Once inserted into the bowel and inflated, the TAI rectal balloon catheter provides a temporary seal for retaining the water instilled during the irrigation. The activation of peristalsis and the reflex relaxing of the anal sphincters by the increased water flow in the lower bowel is the body's own reflex mechanism to pass stool and not viewed as a replacement of the structure or function of a permanently inoperative or malfunctioning internal body organ. We note that this reflex action occurs in the body with the existing bowel elements and sphincters, even with degrees of defect, several minutes after the rectal balloon catheter is removed from the body. This reflex mechanism is also initiated by other forms of treatment such as digital rectal stimulation.

The applicants further suggested that intermittent urinary catheters are comparable to TAI devices with balloon catheters because they both replace a malfunctioning portion of the body. They indicated that the catheters replace the function of an impaired urinary sphincter and bladder detrusor muscle to allow emptying of the bladder. We do not agree that they are comparable. Catheters provide a passage to drain the urine from the bladder through the urethra. TAI devices that instill water into the lower bowel do not provide this replacement structure. The rectal balloon catheter is already removed from the body several minutes before the bowel motion occurs.

CMS understands that the applicant may present further information about the device's mechanism of action and the functions of the inner and external anal sphincters. This preliminary determination reflects CMS' understanding prior to review of the further information, and CMS will consider all information provided by the applicant and other commenters to inform our final determination.

Preliminary Medicare Payment Determination

No Medicare DMEPOS Payment. Pricing Indicator = 00

Agenda Item # 4
Peristeen® Plus Transanal Irrigation System - HCP240625E95UJ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Peristeen® Plus Transanal Irrigation System.

Applicant's suggested language: XXXXX, "Rectal balloon catheter for use with a transanal irrigation device, original issue and replacement"

Summary of Applicant's Submission

Coloplast, Corp. submitted a request to establish a new HCPCS Level II code to identify Peristeen® Plus Transanal Irrigation System's (TAI) single use rectal balloon catheter for transanal irrigation. Peristeen® Plus TAI received the Food and Drug Administration's (FDA'S) 510(k) clearance on November 23, 2009. Coloplast, Corp. also submitted related HCPCS Level II application, HCP2406251AW47, to establish a new HCPCS Level II code for manual transanal irrigation devices. TAI devices with a rectal balloon catheter are a minimally invasive, non-surgical treatment for individuals with neurogenic bowel dysfunction (NBD) for whom conservative bowel management, including enemas, has produced insufficient results. Additionally, TAI devices are indicated for the treatment of NBD that results from lesions on the central nervous system from spinal cord injury or disease. TAI with a rectal balloon catheter has a prosthetic mechanism of action, replacing the function of malfunctioning anal sphincters that have been damaged by NBD. When the balloon inflates it creates water pressure in the bowel sufficient to activate the gut "pacemaker" cells stimulating peristalsis, propelling bowel contents forward, and eliciting a reflex, relaxing (opening) the anal sphincter to support bowel control. When the balloon deflates, the obstruction is removed, and evacuation occurs. Existing HCPCS Level II code A4453, "Rectal catheter for use with the manual pump-operated enema system, replacement only", is the existing code currently used for billing the rectal catheter for use with TAI devices. The applicant maintains that TAI devices with rectal balloon catheters are different from other devices coded under HCPCS Level II code A4459 based on their design, indications for use and mechanism of action.

CMS Preliminary HCPCS Coding Recommendation

On October 1, 2021, CMS established HCPCS Level II code A4453, "Rectal catheter for use with the manual pump-operated enema system, replacement only" after consideration of a request by Coloplast to revise HCPCS Level II code A4397, "Irrigation supply; sleeve each." CMS believed at the time that HCPCS Level II code A4453 adequately described single use rectal catheters used with irrigation systems. Although the applicant requested to establish a new HCPCS Level II code to identify single use rectal balloon catheter for transanal irrigation devices, CMS continues to believe that existing HCPCS Level II code A4453, "Rectal catheter for use with the manual pump-operated enema system, replacement only" applies to the Peristeen® Plus Transanal Irrigation System's (TAI) single use rectal balloon catheter for transanal irrigation. However, we observed a need to improve the accuracy in the description of existing code A4453 to reflect balloon catheters and transanal irrigation, respectively. As such, CMS is proposing to:

Revise existing HCPCS Level II code A4453, “Rectal catheter for use with the manual pump-operated enema system, replacement only” to instead read, “Rectal catheter with or without balloon, for use with the manual transanal irrigation system, each”, to differentiate between enema systems and manual transanal irrigation systems.

CMS believes that revising the existing code would adequately describe all catheter types and manual transanal irrigation systems associated with bowel management.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Rectal balloon catheters are single-use supplies used with TAI devices. TAI devices do not meet the definition of a Medicare DMEPOS benefit category and as such, supplies used with these devices would not have a Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for code A4453 apply to this item.

Preliminary Medicare Payment Determination

No Medicare DMEPOS Payment. Pricing Indicator = 00

Agenda Item # 5
Ankle Flexionater+ - HCP240701GYH5C

Topic/Issue

Request to establish a new HCPCS Level II code to identify Ankle Flexionater+.

Applicant's suggested language: EXXXX, “Patient actuated serial ankle extension and flexion device with high-intensity force amplification, knee extension and flexion positioning, and active torso control”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Ankle Flexionater+. The Ankle Flexionater+ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased ankle range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of joint motion. The Flexionater+ devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater+ series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to allow the ankle to be stretched with either a straight or bent knee, enabling the individual to stretch the soleus and gastrocnemius muscle with a single device. It is designed as a step and step out apparatus with a switch to instantly change directions of the force application. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS), and continuous passive motion (CPM). These existing codes, however, do not accurately describe the Ankle Flexionater+. Devices described by the existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and overall discontinuation. These device codes also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Ankle Flexionater+ in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1816, "Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories" describes the Ankle Flexionater+.

HCPCS Level II code E1816 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi Flexionater and Flexionater+ series utilizes a technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an individual. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Ankle Flexionater+ and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1816.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1816 apply to the Ankle Flexionator+.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1816 apply to this product, if covered. Payment for existing HCPCS Level II code E1816 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $181.94 on average for months 1 through 3, and approximately $136.45 on average for months 4 through 13, resulting in a total capped payment of $318.39 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Agenda Item # 5
Elbow Flexionater+ - HCP2407013RPDQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Elbow Flexionater+.

Applicant's suggested language: EXXXX, “Patient actuated serial elbow extension and flexion device with high-intensity force amplification, forearm supination/pronation positioning, and active torso control”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Elbow Flexionater+. The Elbow Flexionater+ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased elbow range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of elbow motion. The Flexionater+ devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater+ series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to stretch both flexion and extension deficits, while also allowing for pronation and supination, with a single device. It is designed as a step and step out apparatus with a switch to instantly change directions of the force application. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS) and continuous passive motion (CPM). These existing HCPCS Level II codes, however, do not accurately describe the Elbow Flexionater+. Devices described by the existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and typical treatment periods. These devices also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person physical therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Elbow Flexionater+ in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1801, “Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories” describes the Elbow Flexionater+.

HCPCS Level II code E1801 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi Flexionater and Flexionater+ series utilizes a technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an indiviudal. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Elbow Flexionater+ and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1801.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1801 apply to the Elbow Flexionator+.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1801 apply to this product, if covered. Payment for existing HCPCS Level II code E1801 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $172.29 on average for months 1 through 3, and approximately $129.22 on average for months 4 through 13, resulting in a total capped payment of $301.51 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Agenda Item # 5
Forearm Flexionater+ - HCP2407016DQVD

Topic/Issue

Request to establish a new HCPCS Level II code to identify Forearm Flexionater+.

Applicant's suggested language: EXXXX, “Patient actuated serial forearm and wrist device with high-intensity force amplification, pronation/supination, flexion/extension, and radial/ulnar deviation planes of motion, and active torso control”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Forearm Flexionater+. The Forearm Flexionater+ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased wrist/forearm range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of joint motion. The Flexionater+ devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater+ series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to allow the wrist and forearm to perform pronation/supination, flexion/extension, and radial/ulnar deviation planes of motion with a single device. It is designed as a step and step out apparatus with a switch to instantly change directions of the force application. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS) and continuous passive motion (CPM). These existing HCPCS Level II codes, however, do not accurately describe the Forearm Flexionater+. Devices described by existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and overall discontinuation. These devices also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Forearm Flexionater+ in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1818, "Static progressive stretch forearm pronation / supination device, with or without range of motion adjustment, includes all components and accessories" describes the Forearm Flexionater+.

HCPCS Level II code E1818 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi Flexionater and Flexionater+ series utilizes a technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an indiviudal. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Forearm Flexionater+ and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1818.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1818 apply to the Forearm Flexionator+.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1818 apply to this product, if covered. Payment for existing HCPCS Level II code E1818 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $185.73 on average for months 1 through 3, and approximately $139.30 on average for months 4 through 13, resulting in a total capped payment of $325.03 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Agenda Item # 5
Knee Flexionater - HCP240701RY421

Topic/Issue

Request to establish a new HCPCS Level II code to identify Knee Flexionater.

Applicant's suggested language: EXXXX, “Patient actuated serial knee flexion device with high-intensity force amplification, and active torso control”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Knee Flexionater. The Knee Flexionater is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased knee range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of joint motion. The Flexionater devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to allow the knee to be stretched in a natural way as the foot plate moves towards the buttocks. It is designed as a step and step out apparatus. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS) and continuous passive motion (CPM). These existing HCPCS Level II codes, however, do not accurately describe the Knee Flexionater. Devices described by existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and overall discontinuation. These devices also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Knee Flexionater in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1811, “Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories” describes the Knee Flexionater.

HCPCS Level II code E1811 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi Flexionater and Flexionater+ series utilizes a technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an indiviudal. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Knee Flexionater and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1811.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1811 apply to the Knee Flexionator.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1811 apply to this product, if covered. Payment for existing HCPCS Level II code E1811 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $179.11 on average for months 1 through 3, and approximately $134.33 on average for months 4 through 13, resulting in a total capped payment of $313.44 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Agenda Item # 5
Knee Flexionater+ - HCP24070102XAA

Topic/Issue

Request to establish a new HCPCS Level II code to identify Knee Flexionater+.

Applicant's suggested language: EXXXX, “Patient actuated serial knee flexion and extension device with high-intensity force amplification, and active torso control”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Knee Flexionater+. The Ermi Knee Flexionater+ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased knee range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of joint motion. The Flexionater+ devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater+ series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to allow both knee extension and flexion stretches with a single device. It is designed as a step and step out apparatus with a switch to instantly change directions of the force application. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS) and continuous passive motion (CPM). These existing HCPCS Level II codes, however, do not accurately describe the Knee Flexionater+. Devices described by existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and overall discontinuation. These devices also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Knee Flexionater+ in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1811, “Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories” describes the Knee Flexionater+.HCPCS Level II code E1811 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi

Flexionater and Flexionater+ series utilizes a technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an indiviudal. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Knee Flexionater+ and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1811.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1811 apply to the Knee Flexionator+.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1811 apply to this product, if covered. Payment for existing HCPCS Level II code E1811 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $179.11 on average for months 1 through 3, and approximately $134.33 on average for months 4 through 13, resulting in a total capped payment of $313.44 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Agenda Item # 5
Shoulder Flexionater - HCP2407019NJ9Q

Topic/Issue

Request to establish a new HCPCS Level II code to identify Shoulder Flexionater.

Applicant's suggested language: EXXXX, “Patient actuated serial shoulder flexion, abduction, and rotation device with high-intensity force amplification, and active torso control, with or without internal rotation stretching addition”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Shoulder Flexionater. The Ermi Shoulder Flexionater is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased shoulder range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of joint motion. The Flexionater devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to allow the shoulder to perform flexion, abduction, and external rotation with a single device. There is also an add-on kit to allow internal rotation. It is designed as a step and step out apparatus with a switch to instantly change directions of the force application. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS) and continuous passive motion (CPM). These existing HCPCS Level II codes, however, do not accurately describe the Shoulder Flexionater. Devices described by existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and overall discontinuation. These devices also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Shoulder Flexionater in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1841, "Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories" describes the Shoulder Flexionater.

HCPCS Level II code E1841 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi Flexionater and Flexionater+ series utilizes a technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an indiviudal. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Shoulder Flexionater and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1841.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1841 apply to the Shoulder Flexionator.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1841 apply to this product, if covered. Payment for existing HCPCS Level II code E1841 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $620.41 on average for months 1 through 3, and approximately $465.31 on average for months 4 through 13, resulting in a total capped payment of $1,085.72 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Agenda Item # 6
RevoFit® - HCP240627PFAV6

Topic/Issue

Request to revise existing HCPCS Level II code L5783, “Addition to lower extremity, user adjustable, mechanical, residual limb volume management system” to identify RevoFit®.

Applicant's suggested language: L5783, “Addition to upper extremity, user adjustable, mechanical, residual limb volume management system”

Summary of Applicant's Submission

Click Medical submitted a request to revise the existing HCPCS Level II code L5783 to identify RevoFit®. RevoFit® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Click Medical acknowledges the creation of the HCPCS Level II code L5783, “Addition to lower extremity, user adjustable, mechanical, residual limb volume management system.” RevoFit® provides similar benefits for Medicare beneficiaries who are also upper extremity/limb prosthetic users as well. Click Medical previously applied for a lower limb code in the B2 2023 HCPCS Level II coding cycle. Again, the original application materials from B2 2023 were heavily lower limb focused. Subsequently, this current HCPCS Level II code application provides strong evidence for the addition of upper limb prostheses as well, to the recently newly assigned aforementioned HCPCS Level II code L5783. This application builds on many parallel lower-limb concepts but is upper-limb specific. The patented RevoFit® volume management system is a kit of components that a prosthetist adds to a custom fabricated socket which allows the individual to adjust their socket volume throughout the day. RevoFit® enables the individual to increase or decrease the volume of their socket as they experience limb volume changes or as they engage in activities which may require increased or decreased compression of their residual limb. Individuals report decreased limb pain and secondary complications, as well as an increase in device usage and activities of daily living (ADL) when managing socket volume at home. RevoFit® volume management system is available to prosthetists and applied in accordance with established prosthetic principles. The prosthetist determines areas of adjustability and adds the system (kit) to the base or replacement socket during custom fabrication. Once delivered, the individual can tighten their device to reduce socket volume or loosen their device to increase socket volume. The interface between the socket and a residual limb is often considered to be the most important factor in the success or failure of a prosthesis. Traditional sockets cannot be compressed or expanded by the individual and instead require fitting socks, pads or intervention from their prosthetist to adjust socket volume. By contrast, RevoFit® system allows the individual to instantly control socket volume without removal of the prosthesis or ADL interruption. This technology has positively impacted individuals with a residual limb across all functional levels, age groups, and amputation levels. RevoFit® volume management system, introduced nine years ago, provides distinct therapeutic benefits through a unique functional and operational approach. Again, given the precedent set by the recent establishment of the HCPCS Level II code L5783 for lower limb applications, Click Medical requested that this code either be modified/expanded, and revised to include upper limb prostheses, or that a new “addition-to” code and fee schedule be established for upper limb prosthetics.

CMS Preliminary HCPCS Coding Recommendation

Revise existing HCPCS Level II code L5783, "Addition to lower extremity, user adjustable, mechanical, residual limb volume management system", to instead now read, "Addition to upper or lower extremity, user adjustable, mechanical, residual limb volume management system" to describe RevoFit®.

Preliminary Medicare Benefit Category Determination

Prosthetic (Artificial Arm).

The application supports a preliminary benefit category determination that the RevoFit® Volume Management System is used in addition to an upper extremity prosthesis and would fall under the Medicare benefit category for prosthetics (artificial arms).

Preliminary Medicare Payment Determination

Based on information from the manufacturer and invoices provided, the cost of the RevoFit® Volume Management System and services are the same when added to an upper extremity prosthesis as they are when added to a lower extremity prosthesis. Our preliminary payment determination is therefore to make no changes to the fee schedule amounts for HCPCS Level II code L5783. Fee schedules are updated annually.

Agenda Item # 7
Intent Decoding Module (IDM) - HCP240628XTEWE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Intent Decoding Modules (IDMs) using pattern-recognition-based approaches for upper limb myoelectric prostheses.

Applicant's suggested language: XXXXX, "Upper extremity addition, external powered feature, FDA 510k Cleared Class II volitional control module with 3 or more EMG inputs for pattern-based movement-intent decoding to determine prosthesis output"

Summary of Applicant's Submission

Coapt LLC submitted a request to establish a new HCPCS Level II code to identify Intent Decoding Modules (IDMs) using pattern-recognition-based approaches for upper limb myoelectric prostheses. Three commercial systems, including Coapt's Complete Control Gen2, Ottobock's MyoPlus, and Infinite Biomedical Technologies' Sense, have received the Food and Drug Administration's (FDA's) 510(k) clearance. Coapt's Complete Control Gen2 received the FDA's 510(k) clearance on May 24, 2019; Ottobock's MyoPlus on September 27, 2019; and Infinite Biomedical Technologies' Sense on October 5, 2018. IDM uses pattern-recognition-based approaches from three or more electromyographic (EMG) signals to decode complex EMG patterns in determining an individual's real-time movement intent and translate it into command signals for the prosthesis. IDMs use academically developed algorithms with an array of three or more EMG sensors to decode the individual's muscle activity patterns. This module technology enables more intuitive and precise operation of the prosthetic upper limb, allowing individuals to perform a wide range of activities of daily living with greater ease and efficiency. IDMs eliminate the need for mode switching and can use at-home calibration to accommodate muscle signal changes associated with muscle fatigue, co-activity, or electrode impedance changes. According to the applicant, existing HCPCS Level II codes describe conventional myoelectric systems that rely on simple amplitude-based EMG signals. These systems often require cumbersome mode-switching and provide less natural control. IDMs, however, represent a significant technological advancement by adding pattern-based intent decoding for intuitively generated muscle contractions. This allows for seamless operation of multiple degrees of freedom and improved proportional speed commands, which are not captured by current codes. Additionally, IDMs can be recalibrated by the individual without clinical visits, promoting greater independence and long-term use.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, "Upper extremity addition, external powered feature, myoelectronic controlled system, additional emg inputs for pattern-based movement" to describe IDMs.

The applicant's suggested language provided information on Intent Decoding Modules (IDMs), which utilize pattern recognition technology. IDMs enable the analysis of myoelectric signal patterns that represent neurological intent. Given this information, CMS recommends including details about these myoelectric-controlled systems in the proposed HCPCS Level II code description. This inclusion ensures that the codes more accurately

reflect the technology and clinical practices associated with modern upper limb prosthetics, thereby improving the precision and relevance of the coding system. However, historically prosthetic HCPCS Level II codes do not include references to FDA 510(k) clearances in their language, so omission aligns with past practices.

Preliminary Medicare Benefit Category Determination

Artificial Arm (Prosthetic).

The application supports a preliminary benefit category determination that the Intent Decoding Module (IDM) is used in addition to an upper extremity prosthesis and would fall under the Medicare benefit for artificial arms (prosthetics).

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. If the only available price information is from a period other than the fee schedule base period (for supplies, the 12-month period of 1986/1987), deflation factors are applied against current pricing to approximate the base period price. The annual deflation factors are specified in the Medicare Claims Processing Manual, Chapter 23, Section 60.3 and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Social Security Act for prosthetics.

We carefully reviewed the existing HCPCS Level II codes and fee schedule amounts as part of our payment review for new HCPCS Level II code LXXXX and were unable to identify codes that adequately compare to the features of the IDM. We believe this accessory is not comparable to any existing coded device and for this reason, have determined that the gap-filling methodology is appropriate for establishing fees for this device. To gap-fill the fee schedule amount for HCPCS Level II code LXXXX, we used verifiable commercial pricing as the source, including non-Medicare payer data. The average commercial pricing for the IDM was $39,417. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Act. Payment for the HCPCS Level II code LXXXX would be made on a purchase basis. The average 2024 purchase fee schedule amount for HCPCS Level II code LXXXX would be approximately $28,733.81. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 8
Aquoral® - HCP240224XYMK1

Topic/Issue

Request to establish a new HCPCS Level II codes to identify Aquoral®.

Applicant's suggested language: XXXXX, “Aquoral, 20 ml”

Summary of Applicant's Submission

K Pharmaceuticals, LLC submitted a request to establish a HCPCS Level II code to identify Aquoral®. TGO Spray® Artificial Saliva received the Food and Drug Administration’s (FDA’s) 510(k) clearance on September 21, 2005. According to the applicant, the 510(k) clearance for TGO Spray® applies to Aquoral®. TGO Spray® was the trademarked name for the device when its original owner, Laboratoires Carilenè, received the 510(k) clearance for the device. The device was subsequently given a new trademarked name, Aquoral®, for marketing in the United States. Aquoral® is a patented oxidized glycerol triester (OGT) based spray for treatment of chronic and temporary xerostomia (dry mouth). Aquoral® forms a lipid film which bonds with the oral mucosa and lubricates the oral cavity, limiting loss of mucosal water, restoring mucosal viscoelasticity, and protecting against further damage and inflammation.

CMS Preliminary HCPCS Coding Recommendation

According to the applicant, Aquoral® is dispensed in units of 20 mL; however, the dose descriptor for the existing HCPCS Level II code A9155, which describes the product, and its predicate product is 30 mL. As such, we recommend establishing a new code with the smallest dose descriptor to accommodate all the products and delete the existing code. CMS is proposing to:

1. Establish a new HCPCS Level II code AXXXX, “Artificial saliva, 1 ml” to describe Aquoral®.

   Effective April 1, 2025

2. Discontinue existing HCPCS Level II code A9155, “Artificial saliva, 30 ml”

   Effective March 31, 2025

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The Aquoral® OGT corn-based spray which treats chronic and temporary xerostomia (dry mouth) does not meet two of the conditions that must be met for equipment to be classified as DME:

- **Can withstand repeated use** – The Aquoral® OGT corn-based spray is handheld for single-patient use and is not intended for use by successive patients and thus cannot withstand repeated use. The product is more closely utilized like a mouthwash that serves as a treatment regimen used to prevent or lessen the oral conditions. DME is a benefit for rental of equipment and therefore DME items must be able to withstand repeated use by successive patients. The regulation is in accordance with Section 1861(s)(6) of the Social Security Act which sets forth the DME benefit including rental of DME, although purchase of DME items is allowed in limited situations such as section 1834(a)(4) of the Social Security Act for custom DME.

- **Has an expected life of 3 years –** Since the pump spray canister container that contains the Aquoral® spray 20 ml is applied into the mouth 3 to 4 times a day, the product does not have a life of at least 3 years.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 9
Miro3D Fibers - HCP24063049QXA

Topic/Issue

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

Applicant's suggested language: QXXXX, “Miro3D Fibers, per mg”

Summary of Applicant's Submission

Reprise Biomedical, Inc. submitted a request to establish a new Level II code to identify Miro3D Fibers. Miro3D Fibers received the Food and Drug Administration’s (FDA’s) 510(k) clearance on June 6, 2024. Miro3D Fibers is a three-dimensional wound matrix derived from a highly vascularized porcine liver. It is perfusion decellularized and processed in a phosphate buffered aqueous solution, then dried. The resulting dry, porous material is milled to create Miro3D Fibers. Miro3D Fibers is supplied sterile, packaged in a plastic tray with lid, sealed in a foil pouch, and placed inside a corrugated retail box. Miro3D Fibers is offered in four different tray sizes ranging from 100 mg per tray to 700 mg per tray. Miro3D Fibers is intended for a single individual use and may be applied wet or dry. The dressing is a porous scaffold which provides a protective environment for wound management.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, “Miro3d fibers, per milligram” to describe Miro3D Fibers.

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 10
Allacor P™ - HCP240401K027Q

Topic/Issue

Request to establish a new HCPCS Level II codes to identify Allacor P™.

Applicant's suggested language: QXXXX, "Allacor, per cc"

Summary of Applicant's Submission

Stimlabs LLC submitted a request to establish a HCPCS Level II code to identify Allacor P™. Allacor P™ received the Food and Drug Administration's (FDA's) 510(k) clearance on February 2, 2024. Allacor P™ is a medical device derived from human umbilical cord extracellular matrix (ECM). As a resorbable particulate device, Allacor P™ is lyophilized and packaged in a sterile glass vial, inside a single peel pouch, which allows the device to be rehydrated and applied directly to the wound. Allacor P™ is intended to cover, protect, and provide a moist wound environment. Allacor P™ is indicated for use in the management of chronic and acute wounds such as pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial-thickness burns, and skin tears) and draining wounds. Allacor P™ is for single individual use only. The size of Allacor P™ used is determined based on the size of the wound being treated. Allacor P™ may be applied to the wound in a rehydrated state and may be hydrated upon contact with the recommended volume of 0.9% of sterile saline. Up to 8 cc may be applied per procedure. Allacor P™ is offered in a variety of sizes (1 cc, 2 cc and 4 cc). Allacor P™ is lyophilized and packaged in a sterile glass vial.

CMS Preliminary HCPCS Coding Recommendation

The FDA's 510(k) letter states, "Corplex P™, Theracor P, and Allacor P™ are different brand names of the same product and are entirely identical with no changes or differences to product design, manufacturing, intended use, or indications for use." As such, CMS is proposing to:

1. Establish a new HCPCS Level II code AXXXX, "Corplex p or theracor p or allacor p, per milligram" to describe Corplex P™, Theracor P, and Allacor P™.

   Effective April 1, 2025

2. Discontinue existing HCPCS Level II code Q4231, "Corplex p, per cc"

   Effective March 31, 2025

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 11
Myriad Matrix™ - HCP2406275T7U2

Topic/Issue

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

Applicant's suggested language: XXXXX, “Myriad Matrix, per cm2”

Summary of Applicant's Submission

Aroa Biosurgery Ltd. submitted a request to establish a new HCPCS Level II code to identify Myriad Matrix™ (hereinafter, “Myriad”). Myriad received the Food and Drug Administration’s (FDA’s) 510(k) clearance on December 20, 2016. Myriad is an advanced collagen matrix comprised of natural >70%, non-reconstituted collagen derived from ovine (sheep) forestomach extracellular matrix (ECM). It functions as a porous scaffold for cell infiltration and vascular ingrowth during wound healing and is used for the treatment of certain acute and chronic wounds and to reinforce soft tissue where weakness exists in individuals requiring soft tissue repair or reinforcement in plastic and reconstructive surgery, consistent with its FDA indications for use. As noted, Myriad is indicated for certain acute and chronic wounds (including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds and draining wounds) and plastic and reconstructive surgery procedures. With respect to mechanism of action, once placed in the wound bed, Myriad functions as a scaffold to facilitate wound healing. In terms of mechanism of action, over time, Myriad is completely bio-absorbed (remodeled) into new healthy tissue. The ECM components present in Myriad also provide important biology that is known to aid the healing process. Dosing varies based on wound size. The product is administered via cutaneous application and is designed to be fixed via sutures, staples, or tacks to the surrounding tissue at the discretion of the attending physician. Myriad is currently available in a range of device sizes (up to 20 x 20 cm), and a range of device thicknesses (2-layer, 3-layer and 5-layer) and is packaged and supplied sterile and intended for one-time use.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, “Myriad matrix, per square centimeter”

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 11
Myriad Morcells™ - HCP240627FM0EG

Topic/Issue

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

Applicant's suggested language: XXXXX, "Myriad Morcells, per milligram"

Summary of Applicant's Submission

Aroa Biosurgery Ltd. (Aroa) submitted a request to establish a new HCPCS Level II code to identify Myriad Morcells™ (hereinafter, "Morcells"). Morcells received the Food and Drug Administration's (FDA's) 510(k) clearance on March 31, 2021. It is derived from an extracellular matrix (ECM) primarily composed of ovine (sheep) collagen. Myriad Morcells™ is the proprietary (brand) name of the technology, which was cleared under the device name "Myriad Particles." Upon commercialization, the proprietary name "Myriad Morcells™" was added to the device through an update to the FDA Establishment Registration & Device Listing Database. Morcells functions as a porous scaffold for cell infiltration and vascular ingrowth during wound healing and is used for the treatment of certain acute and chronic wounds consistent with its FDA indications for use. Morcells contains more than 150 essential ECM proteins, including structural proteins, adhesion proteins, and signaling proteins—all of which aid the wound healing process. Morcells is fragmented into a dispersible (particulate) form, which allows the device to be dispersed at the wound site and during application applied to soft tissue areas with irregular topography to maximize delivery, including for wounds that might not readily accommodate a sheet form. This provides a conformable ECM graft for management of wounds. Current codes do not adequately describe Morcells. Morcells is indicated for certain acute and chronic wounds, including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. With respect to mechanism of action, once placed in the wound bed, Morcells functions as a scaffold to facilitate wound healing and is incorporated into the wound over time. In terms of mechanism of action, over time, Morcells is completely bio-absorbed ("remodeled") into new healthy tissue. The ECM components present in Morcells also provide important biology that is known to aid the healing process. Dosing varies based on wound size. The device surface area is not measurable in square centimeters given the fragmented form, rather, it is measured by units of mass (i.e., milligrams). Morcells is currently available in a range of sizes, from 200 mg to up to 2000 mg. Morcells is administered via cutaneous application, is packaged in an outer sterile barrier pouch, and supplied as a single use product.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Myriad morcells, 4 milligrams"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors. The current dosage available for Myriad Morcells™ ranges from 200 to 2,000 mg. CMS has a long-standing convention to assign dose descriptors in the smallest amount

that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form.

Agenda Item # 12
Foundation DRS Solo - HCP240626X4WW0

Topic/Issue

Request to establish a new HCPCS Level II code to identify Foundation DRS Solo.

Applicant's suggested language: AXXXX, “Foundation DRS Solo, per sq cm”

Summary of Applicant's Submission

Bionova Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify Foundation DRS Solo. Foundation DRS Solo received the Food and Drug Administration’s (FDA’s) 510(k) clearance on August 11, 2022. Foundation DRS Solo is a sterile, single-use dermal regeneration scaffold comprised of chitosan and chondroitin sulfate. Foundation DRS Solo can be used on partial and full thickness wounds to promote cellular invasion, neovascularization, and neodermis formation. This biodegradable matrix can be used on a variety of wound types and/or prior to definitive treatment. Foundation DRS Solo is intended for use in the management of wounds, including: partial and full thickness wounds, pressure ulcers, venous ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, first degree burns, partial thickness burns (superficial second degree burns), donor sites and other bleeding surface wounds, abrasions, trauma wounds (abrasions, lacerations, skin tears), dehisced wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence). 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. Foundation DRS Solo is supplied terminally sterile, in a single use package, and in a variety of sizes to accommodate most wounds.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Foundation drs solo, per square centimeter"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 13
MiroDry™ Wound Matrix - HCP2406301X889

Topic/Issue

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

Applicant's suggested language: XXXXX, "MiroDry Wound Matrix, per square centimeter"

Summary of Applicant's Submission

Reprise Biomedical, Inc. submitted a request to establish a new HCPCS Level II code to identify MiroDry™ Wound Matrix. MiroDry™ Wound Matrix received the Food and Drug Administration's (FDA's) 510(k) clearance on March 1, 2024. MiroDry™ Wound Matrix is an acellular, collagen sheet scaffold designed to conform to the irregular topography of wound beds. MiroDry™ is made up of porcine liver and utilizes the same perfusion decellularization technology and drying process as Miro3D® wound matrix but is specifically designed to conform to shallow initial wound beds or wounds that have already filled in from previous applications of Miro3D®. As a finished product, MiroDry™ offers a dry, open, and porous collagen graft that is both compressible and conformable into wound beds, providing a protective environment for wound management. MiroDry™ wound matrix is a thin version of Miro3D®. While Miro3D® is 20 mm (2 cm) in thickness and measured by cubic centimeters, MiroDry is a thinner version ranging from 5 mm to 10 mm (0.5 cm – 1 cm) and is measured by square centimeters. MiroDry™ is processed and stored dry in a sterile tray with a plastic snap-on lid and Tyvek® seal. This plastic tray with Tyvek® seal is placed in a foil pouch within a corrugated shelf box. MiroDry™ is individually packaged, with one unit per retail box. The device is supplied sterile, intended for single use only and is available in various sizes.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Mirodry wound matrix, per square centimeter"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Appendix A: DMEPOS Payment Categories

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicator codes in the HCPCS identify which major payment category a HCPCS Level II code falls under. The pricing indicator codes applicable to DMEPOS.

Pricing = 00 Service Not Separately Priced

Items or services described by the HCPCS Level II codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

Pricing = 31 Frequently Serviced Items

Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health. Payment for E0935 is based on a daily rental fee schedule basis since coverage of this device is limited to 21 days.

Pricing = 32 Inexpensive and Other Routinely Purchased Items

Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of $150 or less, were purchased 75 percent of the time or more from July 1986 through June 1987, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or respiratory assist device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

Pricing = 33 Oxygen and Oxygen Equipment

Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after which payment for the ongoing delivery of contents continues for gaseous or liquid systems.

Pricing = 34 Supplies Necessary for the Effective Use of DME

Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

Pricing = 35 Surgical Dressings

Payment is made on a purchase fee schedule basis for surgical dressings.

Pricing = 36 Capped Rental Items

Payment is made on a monthly rental fee schedule basis. The beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items, other than power wheelchairs, for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. The rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Complex rehabilitative power wheelchairs can also be purchased in the first month.

Pricing = 37 Ostomy, Tracheostomy and Urological Supplies
Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)
Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

Pricing = 39 Parenteral and Enteral Nutrition (PEN)
Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

Pricing = 40 Lymphedema Compression Treatment Items
Payment is made on a purchase basis for lymphedema compression treatment items.

Pricing = 45 Customized DME
Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item and judgment of a reasonable payment amount, which, at a minimum, includes a review of the costs of labor and material used in constructing the equipment.

Pricing = 46 Carrier Priced Item
The allowed payment amount for covered items is based on local carrier pricing (e.g., local fee schedule amounts or reasonable charges or other carrier pricing method.