



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

**Zoom Meeting - Remote participation
Tuesday, May 28, 2024 9:00 am – 5:00 pm, eastern time (ET)**

8:45 am, ET:

- Zoom meeting login:

<https://cms.zoomgov.com/s/1605121459>

- 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 August 2024 and will be effective October 1, 2024, unless otherwise specified.

This agenda includes a summary of each HCPCS Level II code application being presented on Tuesday, May 28, 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.

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Agenda Item # 1
Intermittent Urinary Catheters - HCP220701G0DRV, HCP220701Q1RK8, and
HCP220701EYPYU

Topic/Issue

Request to discontinue three existing HCPCS Level II codes A4351, “Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each,” A4352, “Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each,” and A4353, “Intermittent urinary catheter, with insertion supplies” and establish nineteen new codes.

Applicant's suggested language:

1. AXXXX, “Intermittent urinary catheter; straight tip, without coating, each”
2. AXXXX, “Intermittent urinary catheter; straight tip, with pre-lubricated gel coating, without protective elements, each”
3. AXXXX “Intermittent urinary catheter; straight tip, with pre-lubricated gel coating, with protective elements (e.g., gripper, partial sleeve, full length sleeve, etc.), each”
4. AXXXX, “Intermittent urinary catheter; straight tip, with manually activated hydrophilic coating, without protective elements, each”
5. AXXXX, “Intermittent urinary catheter; straight tip, with manually activated hydrophilic coating, with protective elements (e.g., gripper, partial sleeve, full length sleeve, etc.), each”
6. AXXXX, “Intermittent urinary catheter; straight tip, with pre-activated hydrophilic coating, without protective elements, each”
7. AXXXX, “Intermittent urinary catheter; straight tip, with pre-activated hydrophilic coating, with protective elements (e.g., gripper, partial sleeve, full length sleeve, etc.), each”
8. XXXX, “Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), without coating, each”
9. AXXXX, “Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-lubricated gel coating, without protective elements, each”
10. AXXXX, “Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-lubricated gel coating, with protective elements (e.g. gripper, partial sleeve, full length sleeve, etc.), each”
11. AXXXX, “Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with manually activated hydrophilic coating, without protective elements, each”

12. AXXXX, “Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with manually activated hydrophilic coating, with protective elements (e.g. gripper, partial sleeve, full length sleeve, etc.), each”
13. AXXXX, “Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-activated hydrophilic coating, without protective elements, each”
14. AXXXX, “Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-activated hydrophilic coating, with protective elements (e.g. gripper, partial sleeve, full length sleeve, etc.), each”
15. AXXXX, “Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter without coating, each”
16. AXXXX, “Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter with pre-lubricated gel coating, each”
17. AXXXX, “Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter with manually activated hydrophilic coating, each”
18. AXXXX, “Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter with pre-activated hydrophilic coating, each”
19. AXXXX, “Sterile no-touch catheter system, each”

Summary of Applicant's Submission

The American Association for Homecare and its incontinence care manufacturer members, Coloplast, Hollister, and Wellspect submitted a request to discontinue existing HCPCS Level II codes A4351, A4352, and A4353. The requested nineteen new HCPCS Level II codes are to further distinguish the functionalities of straight tip intermittent urinary catheters, curved tip intermittent urinary catheters, and insertion supplies. The wide variation in functionality between products currently classified under HCPCS Level II codes A4351 A4352, and A4353 creates a lack of transparency, which may result in patients receiving the least expensive intermittent urinary catheter or supply. However, this catheter or supply may not meet the patient’s clinical needs to consistently perform successful self-catheterization. Lastly, because HCPCS Level II codes A4351, A4352, and A4353 do not accurately reflect the different features and functionalities of various intermittent urinary catheters, payors other than the Medicare program have been forced to implement a variety of coding “workarounds” in order to better identify and separately reimburse for catheters with different features. This conflicts with the federal requirement and purpose of the uniform code set that CMS has been charged with overseeing for the benefit of all payors, not just the Medicare program. The nineteen recommended HCPCS Level II codes for straight tip, curved tip, and supplies for urinary catheters identify differences in catheters that are not coated; require a coating to be separately provided and manually applied; pre-coated catheters that need to be manually activated; ready-to-use catheters that include hydrophilic technology that reduce the risk of urethral trauma; and catheters that have protective elements, which helps aid with insertion into the urethra.

CMS Preliminary HCPCS Coding Recommendation

CMS has been extensively evaluating this application. To inform our deliberation, CMS contracted with the Health Federally Funded Research and Development Center (FFRDC), operated by MITRE, to conduct an environmental scan and inform our clinical understanding of the use of intermittent urinary catheters. MITRE provided a [report](#) to CMS with their findings. The report represents MITRE's expertise and information available to MITRE (for instance, page 24 of the report may not reflect more recent experience) and should not be construed as CMS coding policy.

The report provides a number of findings and observations. Among the most salient to our preliminary HCPCS coding recommendation are the following:

- There is good evidence that, for some patients, hydrophilic catheters may reduce the incidence of a urinary tract infection (UTI).
- ...for most of the potential codes considered [from the applicant's request] there is a lack of evidence to support performance differentiation when compared to current catheter codes.
- Coding is not a barrier to writing an accurate prescription or for revising a prescription for urinary catheters. However, suppliers do have latitude in what is supplied unless the prescribing physician includes a "dispense as written" notation on the written order. Physicians hesitate to take this step since doing may result in increased costs for patients who may not have sufficient insurance to fully cover the cost of the ordered supplies.
- From its systematic review, MITRE concluded that the evidence base is insufficient to determine that all coatings impact health outcomes, but there was evidence supporting that hydrophilic coating may influence health outcomes. Specifically, it identified studies demonstrating that catheters with hydrophilic coating can reduce the risk of UTIs and hematuria. MITRE could not identify studies that differentiated between hydrophilic coating catheter types (i.e., pre-activated, manually activated) or discern the impact of hydrophilic coating on quality-of-life outcomes.
- Further, MITRE could not identify any studies that assessed whether catheter shape, tip configuration (i.e., straight, coudé), or firmness led to differences in patient outcomes. While MITRE identified studies that assessed whether protective elements (i.e., introducer tip, no-touch sleeve) and re-use (vs. single use) catheters influenced health outcomes, the evidence was inconclusive. MITRE also examined whether patient characteristics led to differences in health outcomes, but it could not identify studies that assessed differences by patient age, sex, disease, or condition, or whether administration assistance was present.

CMS notes that MITRE did not observe significant workarounds by payers in regard to extensive use of modifiers to differentiate what types of catheters were covered and paid, in a way that was otherwise distinct from HCPCS Level II codes. CMS also notes that MITRE identified circumstances in which a history of UTIs or infection control (e.g., sterile techniques) may guide payer coverage, including prior authorization and step therapy.

Considering the information presented by MITRE and our review of the application, CMS believes that clinical evidence and current payer policies would support HCPCS Level II codes to identify hydrophilic coatings, particularly as there is evidence that, for some patients, hydrophilic catheters may reduce the incidence of UTIs. As such, we propose to:

1. Establish a new HCPCS Level II code AXXXX, “Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, etc.), each”
2. Establish a new HCPCS Level II code AXXXX, “Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, etc.), each”
3. Establish a new HCPCS Level II code AXXXX, “Intermittent urinary catheter; straight tip, hydrophilic coating, each”
4. Establish a new HCPCS Level II code AXXXX, “Intermittent urinary catheter; coude (curved) tip, hydrophilic coating, each”
5. Establish a new HCPCS Level II code AXXXX, Intermittent urinary catheter; hydrophilic coating, with insertion supplies”
6. Discontinue existing HCPCS Level II code A4351, “Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each”
7. Discontinue existing HCPCS Level II code A4352, “Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each”

We do not see a claims processing need to discontinue or modify existing HCPCS Level II code A4353, “Intermittent urinary catheter, with insertion supplies.”

CMS also recognizes that adoption of these codes would likely necessitate updating long-established coverage policies and/or payment instructions across nearly every payer. As such, we believe it would be prudent to implement these coding changes effective on January 1, 2026, to allow for a seamless transition. We welcome comment on this timeline.

Considering the likelihood for significant comments on this recommendation and the considerable information presented in the MITRE report, CMS is likely to issue a final determination at a date later than our anticipated July/August 2024 timeframe for this cycle.

Preliminary Medicare Benefit Category Determination

The prior established benefit category determination for HCPCS Level II code A4351 applies to new HCPCS Level II code AXXXX, “Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, etc.), each”, and to new HCPCS Level II code AXXXX, “Intermittent urinary catheter; straight tip, hydrophilic coating, each”.

The prior established benefit category determination for HCPCS Level II code A4352 applies to new HCPCS Level II code AXXXX, “Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, etc.), each” and to new HCPCS Level II code AXXXX, “Intermittent urinary catheter; coude (curved) tip, hydrophilic coating, each”

The prior established benefit category determination for HCPCS Level II code A4353 applies to new HCPCS Level II code AXXXX, “Intermittent urinary catheter; hydrophilic coating, with insertion supplies”.

Preliminary Medicare Payment Determination

Our regulations at 42 CFR 414.236 require continuity of pricing when HCPCS Level II codes are divided or combined. Specifically, § 414.236(a) holds that if a new HCPCS Level II code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

Additionally, § 414.236(b) specifies that when the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.

In the Second Biannual 2022 HCPCS Level II coding cycle public meeting, a speaker for this application confirmed their understanding of these regulations and said that it was not their objective to modify the payment levels for these items.

We will be following our continuity of pricing regulations at § 414.236 for this preliminary payment determination as follows:

1. New HCPCS Level II code AXXXX, “Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, etc.), each” will have a fee that is mapped from existing HCPCS Level II code A4351.

The payment rules and pricing associated with HCPCS Level II code A4351 apply to new HCPCS Level II code AXXXX, if covered. The average 2024 fee schedule for HCPCS Level II code A4351 is \$2.30. 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 = 37

2. New HCPCS Level II code AXXXX, “Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, etc.), each” will have a fee that is mapped from existing HCPCS Level II code A4352.

The payment rules and pricing associated with HCPCS Level II code A4352 apply to new HCPCS Level II code AXXXX, if covered. The average 2024 fee schedule for HCPCS Level II code A4352 is \$8.48. 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 = 37

3. New HCPCS Level II code AXXXX, “Intermittent urinary catheter; straight tip, hydrophilic coating, each” will have a fee that is mapped from existing HCPCS Level II code A4351.

The payment rules and pricing associated with HCPCS Level II code A4351 apply to new HCPCS Level II code AXXXX, if covered. The average 2024 fee schedule for HCPCS Level II code A4351 is \$2.30. 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 = 37

4. New HCPCS Level II code AXXXX, “Intermittent urinary catheter; coude (curved) tip, hydrophilic coating, each” will have a fee that is mapped from existing HCPCS Level II code A4352.

The payment rules and pricing associated with HCPCS Level II code A4352 apply to new HCPCS Level II code AXXXX, if covered. The average 2024 fee schedule for A4352 is \$8.48. 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 = 37

5. New HCPCS Level II code AXXXX, “Intermittent urinary catheter; hydrophilic coating, with insertion supplies” will have a fee that is mapped from existing HCPCS Level II code A4353.

The payment rules and pricing associated with HCPCS Level II code A4353 apply to new HCPCS Level II code AXXXX, if covered. The average 2024 fee schedule for A4353 is \$9.59. 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 = 37

Agenda Item # 2
Lower Body Rehabilitation Kit - HCP231213W7UMD

Topic/Issue

Request to establish a new HCPCS Level II code to identify Lower Body Rehabilitation Kit.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

PT Pro Shop submitted a request to establish a new HCPCS Level II code to identify Lower Body Rehabilitation Kit for lumbar, hip, and knee body regions. The Lower Body Rehabilitation Kit is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Lower Body Kit is an all-in-one kit that includes a towel, 65 cm yoga ball, 8-loop stretch strap, foam roller, foam peanut, foam ball, 5-piece loop band set, 11-piece resistance tube set, and a set of 3 resistance bands. The equipment is necessary for provider prescribed rehabilitation and/or pre-habilitation of the lumbar, hip and knee regions. Existing codes describe individual items in the Lower Body Kit, but do not describe the kit as a whole.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to establish a bundled, unique HCPCS Level II code to describe Lower Body Rehabilitation Kit. We welcome information from the applicant and other insurers who are currently paying for this kit to demonstrate a claims processing need for a unique HCPCS Level II code. The Lower Body Rehabilitation Kit consists of equipment that is considered to be exercise equipment. As such, existing HCPCS Level II code A9300, "Exercise equipment" describes the Lower Body Rehabilitation Kit.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

There is not a benefit category under Medicare Part B for exercise equipment used in the home. The current Medicare policy and prior established benefit category determination for HCPCS Level II code A9300 apply to this item.

In addition, 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 Lower Body Rehabilitation Kit does not meet three of these conditions as follows:

Can withstand repeated use – The Lower Body Rehabilitation Kit is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. 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.

Expected life of at least 3 years – While the applicant has stated that the Lower Body Rehabilitation Kit has an expected lifetime of three years, it is unclear whether the entire kit is, in fact, durable especially given the inclusion of the towel in the kit.

Generally not useful to an individual in the absence of an illness or injury – The Lower Body Rehabilitation Kit contains exercise equipment that can be useful to an individual in the absence of an illness or injury.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9300 apply to this product. Items or services described by HCPCS Level II code A9300 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 2
Shoulder Rehabilitation Kit - HCP231213LDUD1

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

PT Pro Shop submitted a request to establish a new HCPCS Level II code to identify Shoulder Rehabilitation Kit. The Shoulder Rehabilitation Kit is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Shoulder Kit is an all-in-one kit that includes a towel, door frame mounted shoulder pulley, 8-loop stretch strap, collapsible cane, 5-piece loop band set, 11-piece resistance tube set, and a set of 3 resistance bands. The equipment is necessary for doctor prescribed or nonprescribed rehabilitation and/or pre-habilitation of the shoulder region. Existing codes describe individual items in the Shoulder Kit, but do not describe the kit as a whole.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to establish a bundled, new unique HCPCS Level II code to describe Shoulder Rehabilitation Kit. We welcome information from the applicant and other insurers who are currently paying for this kit to demonstrate a claims processing need for a unique HCPCS Level II code. The Shoulder Rehabilitation Kit consists of equipment that is considered to be exercise equipment. As such, existing HCPCS Level II code A9300, "Exercise equipment" describes the Shoulder Rehabilitation Kit.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

There is not a benefit category under Medicare Part B for exercise equipment used in the home. The current Medicare policy and prior established benefit category determination for HCPCS Level II code A9300 apply to this item.

In addition, 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 Shoulder Rehabilitation Kit does not meet three of these conditions as follows:

Can withstand repeated use – The Shoulder Rehabilitation Kit is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. 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.

Expected life of at least 3 years – While the applicant has stated that the Shoulder Rehabilitation Kit has an expected lifetime of three years, it is unclear whether the entire kit is, in fact, durable especially given the inclusion of the towel in the kit.

Generally not useful to an individual in the absence of an illness or injury – The Shoulder Rehabilitation Kit contains exercise equipment that can be useful to an individual in the absence of an illness or injury.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9300 apply to this product. Items or services described by HCPCS Level II code A9300 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 2
Wrist Rehabilitation Kit - HCP231213NNX41

Topic/Issue

Request to establish a new HCPCS Level II code to identify Wrist Rehabilitation Kit.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

PT Pro Shop submitted a request to establish a new HCPCS Level II code to identify Wrist Rehabilitation Kit. The Wrist Rehabilitation Kit is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Wrist Kit is an all-in-one kit that includes a towel, bend and twist bar, finger extension with cuff, 6-piece grip strength set, and a 3-piece finger web set. The equipment is necessary for provider prescribed rehabilitation and/or pre-habilitation of the wrist region. Existing codes describe individual items in the Wrist Kit, but do not describe the kit as a whole.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to establish a bundled, new unique HCPCS Level II code to describe Wrist Rehabilitation Kit. We welcome information from the applicant and other insurers who are currently paying for this kit to demonstrate a claims processing need for a unique HCPCS Level II code. The Wrist Rehabilitation Kit consists of equipment that is considered to be exercise equipment. As such, existing HCPCS Level II code A9300, "Exercise equipment" describes the Wrist Rehabilitation Kit.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

There is not a benefit category under Medicare Part B for exercise equipment used in the home. The current Medicare policy and prior established benefit category determination for HCPCS Level II code A9300 apply to this item.

In addition, 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 Wrist Rehabilitation Kit does not meet three of these conditions as follows:

Can withstand repeated use – The Wrist Rehabilitation Kit is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. 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.

Expected life of at least 3 years – While the applicant has stated that the Wrist Rehabilitation Kit has an expected lifetime of three years, it is unclear whether the entire kit is, in fact, durable especially given the inclusion of the towel in the kit.

Generally not useful to an individual in the absence of an illness or injury – The Wrist Rehabilitation Kit contains exercise equipment that can be useful to an individual in the absence of an illness or injury.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9300 apply to this product. Items or services described by HCPCS Level II code A9300 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 3
Dynasplint, Adjustable Elbow Extension/Flexion Device - HCP230630HDBV8

Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Elbow Extension/Flexion Device.

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code E1800, "Dynamic adjustable elbow extension/flexion device, includes soft interface material." Dynasplint dynamic adjustable elbow extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The elbow is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). HCPCS Level II code E1800 is an inadequate and confusing description. The short and long descriptors for HCPCS Level II code E1800 create the assumption that one device described by HCPCS Level II code E1800 can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension, and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, HCPCS Level II code E1800 can be billed with the modifiers RT and LT to indicate the right elbow and left elbow respectively (E1800RRRT & E1800RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (HCPCS Level II codes E1800 and E1800). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1800RRRTXT (right elbow extension) and E1800RRRTFL (right elbow flexion).

CMS HCPCS Final Coding Decision

On February 29, 2024, CMS published the decision to:

1. Revise existing HCPCS Level II code E1800, "Dynamic adjustable elbow extension/flexion device, includes soft interface material" to instead read "Dynamic adjustable elbow extension and flexion device, includes soft interface material"
2. Establish a new HCPCS Level II code E1803, "Dynamic adjustable elbow extension only device, includes soft interface material"
3. Establish a new HCPCS Level II code E1804, "Dynamic adjustable elbow flexion only device, includes soft interface material"

These three coding actions will be effective January 1, 2025.

Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Elbow Extension/Flexion Device is DME and published that determination on February 29, 2024.

Preliminary Medicare Payment Determination

For HCPCS Level II code E1800, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for HCPCS Level II code E1800 would be approximately \$156.04 for months 1 through 3 and approximately \$117.03 for months 4 through 13, for a total of \$1,638.42 after 13 months of continuous use.

For HCPCS Level II codes E1803 and E1804, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or the DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new HCPCS Level II codes E1803 and E1804 have a pricing history based on HCPCS Level II code E1800. When there is a single code that describes two or more distinct complete items (with HCPCS Level II code E1800, that would be flexion and extension), and separate codes are subsequently established for each item (HCPCS Level II code E1804 for flexion and HCPCS Level II code E1803 for extension), the payment amounts that applied to the single code are applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new HCPCS Level II codes E1803 and E1804 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1800.

Based on this preliminary determination, pricing for both HCPCS Level II codes E1803 and E1804 is represented by the following formula: $E1800 * .5$. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes E1803 and E1804 would be approximately \$78.02 for months 1 through 3 and approximately \$58.52 for months 4 through 13, for a total of \$819.21 after 13 months of continuous use.

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 = 36

Agenda Item # 3
Dynasplint, Adjustable Wrist Extension/Flexion Device - HCP2306303YX0F

Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Wrist Extension/Flexion Device.

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code E1805, “Dynamic adjustable wrist extension / flexion device, includes soft interface material.” Dynasplint dynamic adjustable wrist extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The wrist is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). HCPCS Level II code E1805 is an inadequate and confusing description. The short and long descriptors for HCPCS Level II code E1805 create the assumption that one device described by HCPCS Level II code E1805 can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension, and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, HCPCS Level II code E1805 can be billed with the modifiers RT and LT to indicate the right wrist and left wrist respectively (E1805RRRT & E1805RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (HCPCS Level II codes E1805 and E1805). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1805RRRTXT (right wrist extension) and E1805RRRTFL (right wrist flexion).

CMS HCPCS Final Coding Decision

On February 29, 2024, CMS published the decision to:

1. Revise existing HCPCS Level II code E1805, “Dynamic adjustable wrist extension / flexion device, includes soft interface material” to instead read “Dynamic adjustable wrist extension and flexion device, includes soft interface material”
2. Establish a new HCPCS Level II code E1807, “Dynamic adjustable wrist extension only device, includes soft interface material”
3. Establish a new HCPCS Level II code E1808, “Dynamic adjustable wrist flexion only device, includes soft interface material”

These three coding actions will be effective January 1, 2025.

Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Wrist Extension/Flexion Device is DME and published that determination on February 29, 2024.

Preliminary Medicare Payment Determination

For HCPCS Level II code E1805, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for HCPCS Level II code E1805 would be approximately \$163.08 for months 1 through 3 and approximately \$122.31 for months 4 through 13, for a total of \$1,712.34 after 13 months of continuous use.

For HCPCS Level II codes E1807 and E1808, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or the DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new HCPCS Level II codes E1807 and E1808 have a pricing history based on HCPCS Level II code E1805. When there is a single code that describes two or more distinct complete items (with E1805, that would be flexion and extension), and separate codes are subsequently established for each item (HCPCS Level II code E1808 for flexion and HCPCS Level II code E1807 for extension), the payment amounts that applied to the single code applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new HCPCS Level II codes E1807 and E1808 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1805.

Based on this preliminary determination, pricing for both HCPCS Level II codes E1807 and E1808 is represented by the following formula: $E1805 * .5$. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes E1807 and E1808 would be approximately \$81.54 for months 1 through 3 and approximately \$61.16 for months 4 through 13, for a total of \$856.17 after 13 months of continuous use.

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 = 36

Agenda Item # 3
Dynasplint, Adjustable Knee Extension/Flexion Device - HCP230630T4NRE

Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Knee Extension/Flexion Device.

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code E1810, “Dynamic adjustable knee extension / flexion device, includes soft interface material.” Dynasplint dynamic adjustable knee extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The knee is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). HCPCS Level II code E1810 is an inadequate and confusing description. The short and long descriptors for HCPCS Level II code E1810 create the assumption that one device described by HCPCS Level II code E1810 can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, HCPCS Level II code E1810 can be billed with the modifiers RT and LT to indicate the right knee and left knee respectively (E1810RRRT & E1810RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (HCPCS Level II codes E1810 and E1810). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1810RRRTXT (right knee extension) and E1810RRRTFL (right knee flexion).

CMS HCPCS Final Coding Decision

On February 29, 2024, CMS published the decision to:

1. Revise existing HCPCS Level II code E1810, “Dynamic adjustable knee extension / flexion device, includes soft interface material” to instead read “Dynamic adjustable knee extension and flexion device, includes soft interface material”
2. Establish a new HCPCS Level II code E1813, “Dynamic adjustable knee extension only device, includes soft interface material”
3. Establish a new HCPCS Level II code E1814, “Dynamic adjustable knee flexion only device, includes soft interface material”

These three coding actions will be effective January 1, 2025.

Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Knee Extension/Flexion Device is DME and published that determination on February 29, 2024.

Preliminary Medicare Payment Determination

For HCPCS Level II code E1810, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for HCPCS Level II code E1810 would be approximately \$160.35 for months 1 through 3 and approximately \$120.26 for months 4 through 13, for a total of \$1,683.65 after 13 months of continuous use.

For HCPCS Level II codes E1813 and E1814, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or the DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new HCPCS Level II codes E1813 and E1814 have a pricing history based on HCPCS Level II code E1810. When there is a single code that describes two or more distinct complete items (with E1810, that would be flexion and extension), and separate codes are subsequently established for each item (HCPCS Level II codes E1814 for flexion and E1813 for extension), the payment amounts that applied to the single code applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new HCPCS Level II codes E1813 and E1814 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1810.

Based on this preliminary determination, pricing for both HCPCS Level II codes E1813 and E1814 is represented by the following formula: $E1810 \times .5$. Therefore the 2024 average capped rental fee schedule amount for both E1813 and E1814 would be approximately \$80.18 for months 1 through 3 and approximately \$60.13 for months 4 through 13, for a total of \$841.83 after 13 months of continuous use.

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 = 36

Agenda Item # 3
Dynasplint, Adjustable Ankle Extension/Flexion Device - HCP23063066K8A

Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Ankle Extension/Flexion Device.

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code E1815, “Dynamic adjustable ankle extension/flexion device, includes soft interface material.” Dynasplint dynamic adjustable ankle extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The ankle is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The descriptor for HCPCS Level II code E1815 code is inadequate and confusing. The short and long descriptors for HCPCS Level II code E1815 create the assumption that one device described by HCPCS Level II code E1815 can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, HCPCS Level II code E1815 can be billed with the modifiers RT and LT to indicate the right ankle and left ankle respectively (E1815RRRT & E1815RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (HCPCS Level II codes E1815 and E1815). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1815RRRTXT (right ankle extension) and E1815RRRTFL (right ankle flexion).

CMS HCPCS Final Coding Decision

On February 29, 2024, CMS published the decision to:

1. Revise existing HCPCS Level II code E1815, “Dynamic adjustable ankle extension/flexion device, includes soft interface material” to instead read “Dynamic adjustable ankle extension and flexion device, includes soft interface material”
2. Establish a new HCPCS Level II code E1822, “Dynamic adjustable ankle extension only device, includes soft interface material”
3. Establish a new HCPCS Level II code E1823, “Dynamic adjustable ankle flexion only device, includes soft interface material”

These three coding actions will be effective January 1, 2025.

Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Knee Extension/Flexion Device is DME and published that determination on February 29, 2024.

Preliminary Medicare Payment Determination

For HCPCS Level II code E1815, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for HCPCS Level II code E1815 would be approximately \$163.59 for months 1 through 3 and approximately \$122.69 for months 4 through 13, for a total of \$1,717.67 after 13 months of continuous use.

For HCPCS Level II codes E1822 and E1823, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or the DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new HCPCS Level II codes E1822 and E1823 have a pricing history based on HCPCS Level II code E1815. When there is a single code that describes two or more distinct complete items (with E1815, that would be flexion and extension), and separate codes are subsequently established for each item (HCPCS Level II code E1823 for flexion and HCPCS Level II code E1822 for extension), the payment amounts that applied to the single code are applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new HCPCS Level II codes E1822 and E1823 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1815.

Based on this preliminary determination, pricing for both HCPCS Level II codes E1822 and E1823 is represented by the following formula: $E1815 * .5$. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes E1822 and E1823 would be approximately \$81.80 for months 1 through 3 and approximately \$61.35 for months 4 through 13, for a total of \$858.84 after 13 months of continuous use.

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 = 36

Agenda Item # 3
Dynasplint, Adjustable Finger Extension/Flexion Device - HCP230630U7JWP

Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Finger Extension/Flexion Device.

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code E1825, “Dynamic adjustable finger extension/flexion device, includes soft interface material.” Dynasplint dynamic adjustable finger extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The finger is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The descriptor for HCPCS Level II code E1825 code is inadequate and confusing. The short and long descriptors for HCPCS Level II code E1825 create the assumption that one device described by HCPCS Level II code E1825 can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of 2 of the same HCPCS Level II codes for the same patient on the same date of service. For example, HCPCS Level II code E1825 can be billed with the modifiers RT and LT to indicate the right finger and left finger respectively (E1825RRRT & E1825RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (HCPCS Level II codes E1825 and E1825). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1825RRRTXT (right finger extension) and E1825RRRTFL (right finger flexion).

CMS HCPCS Final Coding Decision

On February 29, 2024, CMS published the decision to:

1. Revise existing HCPCS Level II code E1825, “Dynamic adjustable finger extension/flexion device, includes soft interface material” to instead read “Dynamic adjustable finger extension and flexion device, includes soft interface material”
2. Establish a new HCPCS Level II code E1826, “Dynamic adjustable finger extension only device, includes soft interface material”
3. Establish a new HCPCS Level II code E1827, “Dynamic adjustable finger flexion only device, includes soft interface material”

These three coding actions will be effective January 1, 2025.

Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Finger Extension/Flexion Device is DME and published that determination on February 29, 2024.

Preliminary Medicare Payment Determination

For HCPCS Level II code E1825, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for HCPCS Level II code E1825 would be approximately \$163.08 for months 1 through 3 and approximately \$122.31 for months 4 through 13, for a total of \$1,712.34 after 13 months of continuous use.

For HCPCS Level II codes E1826 and E1827, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or the DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new HCPCS Level II codes E1826 and E1827 have a pricing history based on HCPCS Level II code E1825. When there is a single code that describes two or more distinct complete items (with HCPCS Level II code E1825, that would be flexion and extension), and separate codes are subsequently established for each item (HCPCS Level II code E1827 for flexion and HCPCS Level II code E1826 for extension), the payment amounts that applied to the single code are applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new HCPCS Level II codes E1826 and E1827 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1825.

Based on this preliminary determination, pricing for both HCPCS Level II codes E1826 and E1827 is represented by the following formula: $E1825 * .5$. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes E1826 and E1827 would be approximately \$81.54 for months 1 through 3 and approximately \$61.16 for months 4 through 13, for a total of \$856.17 after 13 months of continuous use.

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 = 36

Agenda Item # 3
Dynasplint, Adjustable Toe Extension/Flexion Device - HCP230630UCV21

Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Toe Extension/Flexion Device.

Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code E1830, “Dynamic adjustable toe extension/flexion device, includes soft interface material.” Dynasplint dynamic adjustable toe extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The toe is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The descriptor for HCPCS Level II code E1830 code is inadequate and confusing. The short and long descriptors for HCPCS Level II code E1830 create the assumption that one device described by HCPCS Level II code E1830 can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1830 can be billed with the modifiers RT and LT to indicate the right toe and left toe respectively (E1830RRRT & E1830RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (HCPCS Level II codes E1830 and E1830). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1830RRRTXT (right toe extension) and E1830RRRTFL (right toe flexion).

CMS HCPCS Final Coding Decision

On February 29, 2024, CMS published the decision to:

1. Revise existing HCPCS Level II code E1830, “Dynamic adjustable toe extension/flexion device, includes soft interface material” to instead read “Dynamic adjustable toe extension and flexion device, includes soft interface material”
2. Establish a new HCPCS Level II code E1828, “Dynamic adjustable toe extension only device, includes soft interface material”
3. Establish a new HCPCS Level II code E1829, “Dynamic adjustable toe flexion only device, includes soft interface material”

These three coding actions will be effective January 1, 2025.

Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Toe Extension/Flexion Device is DME and published that determination on February 29, 2024.

Preliminary Medicare Payment Determination

For HCPCS Level II code E1830, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for E1830 would be approximately \$163.08 for months 1 through 3 and approximately \$122.31 for months 4 through 13, for a total of \$1,712.34 after 13 months of continuous use.

For HCPCS Level II codes E1828 and E1829, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or the DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new HCPCS Level II codes E1828 and E1829 have a pricing history based on HCPCS Level II code E1830. When there is a single code that describes two or more distinct complete items (with HCPCS Level II code E1830, that would be flexion and extension), and separate codes are subsequently established for each item (HCPCS Level II code E1829 for flexion and HCPCS Level II code E1828 for extension), the payment amounts that applied to the single code are applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new HCPCS Level II codes E1828 and E1829 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1830.

Based on this preliminary determination, pricing for both HCPCS Level II codes E1828 and E1829 is represented by the following formula: $E1830 \times .5$. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes E1828 and E1829 would be approximately \$81.54 for months 1 through 3 and approximately \$61.16 for months 4 through 13, for a total of \$856.17 after 13 months of continuous use.

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 = 36

Agenda Item # 4
Off the Shelf Orthotics, Not Otherwise Classified (NOC) - HCP220222L7KH2

Topic/Issue

Request to establish two new HCPCS Level II codes to identify prefabricated off the shelf orthotics that will parallel the current custom fitted codes L1820 and L1652.

Applicant's suggested language:

LXXXX: "Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, off the shelf"

LXXXX: "Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, off the shelf"

Summary of Applicant's Submission

Palmetto GBA submitted a request to establish two orthotic HCPCS Level II codes to describe a prefabricated off the shelf (OTS) hip and knee orthosis. These two new OTS orthotics HCPCS Level II codes would parallel the current custom fitted HCPCS Level II codes L1820, "Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, includes fitting and adjustment" and L1652, "Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, includes fitting and adjustment, any type." There has been a significant increase in claim submissions using HCPCS Level II code L2999 ("Lower extremity orthoses, not otherwise specified") to describe the OTS version of HCPCS Level II codes L1820 and L1652. This increase in HCPCS Level II code L2999 claim submissions has increased the workload burden on the Durable Medical Equipment Medicare Administrative Contractors.

CMS Preliminary HCPCS Coding Recommendation

We believe there is a claims processing need to split the codes, as suppliers are already billing the OTS versions of the braces under NOC/miscellaneous codes (HCPCS Level II code L2999) and then each claim needs to go through manual review. This will eliminate the need for manual review. In addition, we would further revise the existing HCPCS Level II codes to be clear they are now for custom-fitted items. As such, CMS proposes to:

1. Establish a new HCPCS Level II code LXXX1, "Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, off the shelf"
2. Establish a new HCPCS Level II code LXXX2, "Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, off the shelf"
3. Revise existing HCPCS Level II code L1820, "Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, includes fitting and adjustment" to instead read "Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise"

4. Revise existing HCPCS Level II code L1652, “Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, includes fitting and adjustment, any type” to instead read “Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, includes fitting and adjustment, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise”

Preliminary Medicare Benefit Category Determination

Orthotic

Preliminary Medicare Payment Determination

For new HCPCS Level II codes LXXX1 and LXXX2, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS makes an effort to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new HCPCS Level II codes LXXX1 and LXXX2 have a pricing history. For HCPCS Level II code LXXX1, the pricing history is based on L1820. For HCPCS Level II code LXXX2, the pricing history is based on L1652.

When there is a single code that describes two or more distinct complete items (that would be off-the-shelf and custom-fitted items), and separate codes are subsequently established for each item (using the original HCPCS Level II codes L1820 and L1652 for custom fitted and establishing HCPCS Level II codes LXXX1 and LXXX2 for off-the-shelf), the payment amount that applied to the original code is also applied to the new code. Thus, the preliminary payment determination for new HCPCS Level II codes LXXX1 and LXXX2 is to establish the fee schedule amount by mapping the existing fee schedule amount for the related item described by HCPCS Level II codes L1820 and L1652.

The average 2024 purchase fee schedule amount for HCPCS Level II codes L1820 and LXXX1 is \$159.97. The average 2024 purchase fee schedule amount for HCPCS Level II codes L1652 and LXXX2 is \$417.34.

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 = 38

Agenda Item # 5
Scoliosis Brace - HCP211020YNN4T

Topic/Issue

Request to establish a new HCPCS Level II code to identify spinal orthosis designed to support the adult scoliotic spinal curve deformities in the adult patient population.

Applicant's suggested language: LXXXX, "Scoliosis orthosis, sagittal-coronal control provided by a rigid lateral frame, extends from axilla to trochanter, includes all accessory pads, straps and interface, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise"

Summary of Applicant's Submission

Palmetto GBA submitted a request to establish a new HCPCS Level II code to identify spinal orthosis designed to support adult scoliotic spinal curve deformities in the adult patient population. The new code would describe a prefabricated spinal orthosis designed to support the scoliotic curvature in the adult patient population to immobilize and aid in support of the spine for pain control associated with a scoliotic curve deformity. The design parameters would include a rigid lateral frame extending from the axilla to the trochanter with a lumbar sacral support to stabilize the position of the rigid lateral frame. Two manufacturers submitted four different devices for Pricing, Data Analysis and Coding (PDAC) contractor HCPCS Level II code verification and two of these devices (Peak Scoliosis Bracing System and TechnoSpine TLSO-Scoliosis Brace) have products that include a rigid lateral frame extending from the axilla to the trochanter with a lumbar sacral support that stabilizes the position of the rigid lateral frame. A new HCPCS Level II code LXXXX would more accurately describe the Peak Scoliosis Bracing System and TechnoSpine TLSO-Scoliosis Brace rather than HCPCS Level II code L1005, "Tension based scoliosis orthosis and accessory pads, includes fitting and adjustment." Other products listed on the product classification list, maintained by PDAC, under HCPCS Level II code L1005 were not submitted for review. If new HCPCS Level II code LXXXX is established, the PDAC plans to determine if the products currently coded in HCPCS Level II code L1005 should be coded under the new HCPCS Level II code.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, "Scoliosis orthosis, sagittal-coronal control provided by a rigid lateral frame, extends from axilla to trochanter, includes all accessory pads, straps and interface, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise"

The FLEXPineBrace, manufactured by StandingTall, is currently coded under HCPCS Level II code L1005. We believe that the proposed HCPCS Level II code LXXXX would describe FLEXPineBrace.

Preliminary Medicare Benefit Category Determination¹

Back Brace.

The Peak Scoliosis Bracing System and the TechnoSpine TLSO-Scoliosis Brace fall under the definition of a brace. Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. These devices are a prefabricated rigid spinal orthosis designed to support the scoliotic curvature in the adult patient population to immobilize and aid in support of the spine for pain control associated with a scoliotic curve deformity.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II codes 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, deflation factors are applied against current pricing in order 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 orthotics and prosthetics.

In determining whether the items that would be classified in HCPCS Level II code LXXXX are comparable to items with existing codes, we undertook a detailed examination of its physical, mechanical, and components along with its function and intended use.

The Peak Scoliosis Bracing System and the TechnoSpine TLSO-Scoliosis Brace are fabricated from non-elastic and heat-moldable materials, integrating rigid panels. Currently, the assigned existing code for these items (HCPCS Level II code L1005) pertains to orthoses made from elastic materials. Furthermore, aside from the material contrast, the existing code primarily focuses on addressing scoliosis and hyperkyphosis in the pediatric population, whereas these new products primarily cater to scoliosis treatment in adults.

Taking into account these noted differences, we have concluded that while the two items falling under HCPCS Level II code LXXXX share some similarities with devices described in HCPCS Level II code L1005, they are not fully comparable. Therefore, we have decided that it is most appropriate to establish the Medicare payment amount using the "gap filling" procedure outlined in 42 CFR 414.238(c).

¹ Revised on May 7, 2024 to correct the benefit category to reflect back brace.

We have found a number of internet retail prices for items that would be classified in HCPCS Level II code LXXXX, retrieved in September 2023.² The median of these prices is \$1,868. After applying the annual deflation and update factors, the 2024 payment amount for HCPCS Level II code LXXXX would be approximately \$1,368.16.

Pricing Indicator = 38

² For example, <https://www.dme-direct.com/peak-scoliosis-bracing-system>, <https://justbrace.com/product/aspens-peak-scoliosis-bracing-system-adjustable>, <https://www.vitalitymedical.com/aspens-peak-scoliosis-bracing-system.html>, <https://www.scriphessco.com/products/aspens-peak-scoliosis-bracing-system/>, <https://www.alimed.com/peak-scoliosis-bracing-system.html>, <https://www.rehab-store.com/p-aspens-peak-scoliosis-bracing-system.html>

Agenda Item # 6
NeuroNode® - HCP221230PJ0M6

Topic/Issue

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

Applicant's suggested language: EXXXX, "Accessory for speech generating device, sEMG sensor"

Summary of Applicant's Submission

Control Bionics Limited submitted a request to establish a new HCPCS Level II code to identify NeuroNode®. NeuroNode® is a class II device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). NeuroNode® is an augmentative and alternative communication (AAC) device intended to provide noninvasive, electromyographic (EMG) mediated computer access, communication, robotic, and environmental control capability for users with impaired speech and/or motor function. NeuroNode® uses the body's EMG signals or 3D spatial movements to give the user precise control of their AAC device. The user sends an initiating signal from their motor cortex to the fibers of the target muscle. If any action potential is generated along those muscle fibers, or a vector shift occurs in the electrical field, NeuroNode® can generate a coherent, unambiguous command to the target speech generating device (SGD). The NeuroNode® functionally enhances the results of the speech generating system for people with conditions like progressive amyotrophic lateral sclerosis, spinal cord injury, spinal muscular atrophy, cerebral palsy, and certain traumatic brain injury. Individuals can access their technology, including but not limited to, an AAC device, computer, phone or tablet with the device. NeuroNode® interprets coherent volitional commands and these minute bioelectric signals can be detected even if the muscle's ability to contract is significantly diminished. The existing HCPCS Level II code E2599 is a miscellaneous code that is used to describe a variety of speech generating technologies such as joysticks, buttons, and keyguards, which are different from NeuroNode® in terms of technology, functionality, and cost. The other control devices require tactile or physical input from the user, such as the ability to press a button or grasp and maneuver a joystick. NeuroNode® detects EMG to allow the user to control the SGD through any type of intentional, detectable movement, or by using a range of motion or 3D spatial awareness. NeuroNode® can be placed on almost any muscle that the user can control. The NeuroNode® is needed when a patient cannot use, or the prescriber does not recommend, standard input devices. A new unique code will allow health care providers to accurately report, and payers to accurately capture product-specific information to adjudicate claims efficiently.

CMS Preliminary HCPCS Coding Recommendation

This application was deferred from the First Biannual 2023 HCPCS Level II coding cycle for additional consideration. NeuroNode® uses an electromyographic sensor to assist with control for an SGD, and it is an alternative to many other standard input devices such as joysticks, buttons, and keyguards, which are also billable under existing HCPCS Level II code E2599, "Accessory for speech generating device, not otherwise classified." As such, CMS is proposing to:

Establish a new HCPCS Level II code, EXXXX, “Accessory for speech generating device, electromyographic sensor” to describe NeuroNode®.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Speech generating devices are considered to fall within the durable medical equipment (DME) benefit category established by section 1861(n) of the Social Security Act. They are used for patients who suffer from a severe speech impairment and have a medical condition that warrants the use of a device. The NeuroNode® is a DME accessory used with speech generating devices. Section 110.3 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) indicates that payment may be made for supplies and accessories that are necessary for the effective use of durable medical equipment. Because the NeuroNode® is an accessory to an item of DME, the control interface input device falls under the DME benefit category.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II codes 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 Medicare Claims Processing Manual, Chapter 23, Section 60.3 and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Social Security Act for DME.

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 EXXXX and were unable to identify codes that adequately compare to the features of the NeuroNode®. 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 EXXXX, we used verifiable commercial pricing as the source, including non-Medicare payer data. The average 2023 commercial pricing for the NeuroNode® was \$6,783.33. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME. Payment for the HCPCS Level II code EXXXX would be made on a purchase or rental basis in accordance with section 1834(a)(2)(A)(iv) of the Social Security Act because the product is an accessory that is needed for an individual to effectively use a speech generating device. The average 2024 purchase fee schedule amount for HCPCS Level II code EXXXX would be approximately \$4,299.75.

Pricing Indicator = 32

Agenda Item # 7
Serena Nylon ema® FH - HCP2312287XKQL

Topic/Issue

Request to be assigned existing HCPCS Level II code E0486, “Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment” for Serena Nylon ema® FH obstructive sleep apnea (OSA) appliance.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Serena Sleep Solutions submitted a request to be assigned a HCPCS Level II code to identify Serena Nylon ema® FH OSA appliance. Serena Nylon ema® FH OSA appliance was approved by the Food and Drug Administration (FDA) under the 510(k) pathway on March 10, 2021. The Serena Nylon ema® FH OSA appliance is indicated for snoring and OSA. The Serena Nylon ema® FH is a custom fabricated, OSA appliance that utilizes a fixed hinged located on the buccal surfaces of the appliance that holds the mandibular jaw forward, reducing upper airway collapsibility. Originally, the Pricing, Data Analysis and Coding contractor assigned this appliance to HCPCS Level II code K1027, “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment.” Existing HCPCS Level II code K1027 does not adequately describe this item, as it states, “without fixed mechanical hinge.” The Serena Nylon ema® FH OSA appliance meets all the conditions set forth in existing HCPCS Level II code E0486. The Nylon ema® FH can be adjusted by the beneficiary after 90-day period and like a Herbst device, cannot be separated into its basic components inside or outside the mouth.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1027, “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment” describes Serena Nylon ema® FH OSA appliance. CMS believes the Serena Nylon ema® FH OSA appliance does not feature a fixed, inseparable hinge that always remains integrated, including during adjustments. Serena Nylon ema® FH OSA appliance is similar to other devices in existing HCPCS Level II code K1027.

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the Medicare Administrative Contractors (MACs).

Preliminary Medicare Payment Determination

No determination.

As stated in the Preliminary Medicare Benefit Category Determination, in the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

Agenda Item # 8
SnoreHook - HCP2312035AJRX

Topic/Issue

Request to be assigned existing HCPCS Level II code K1027, “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment” for the SnoreHook.

The applicant did not submit any suggested language.

Summary of Applicant’s Submission

Boyd Research submitted a request to be assigned an existing HCPCS Level II code K1027 to describe the SnoreHook. SnoreHook was approved by the Food and Drug Administration (FDA) under the 510(k) pathway on May 3, 2005. SnoreHook is described as an oral device/appliance used to reduce upper airway collapsibility for the treatment of snoring and mild to moderate obstructive sleep apnea.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1027, “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment” describes SnoreHook.

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

Preliminary Medicare Payment Determination

No determination.

As stated in the Preliminary Medicare Benefit Category Determination, more time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

Agenda Item # 9
xenoPATCH - HCP2312290X848

Topic/Issue

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

Applicant's suggested language: AXXXX, "xenoPATCH, 1 sq cm"

Summary of Applicant's Submission

Extremity Care submitted a request to establish a new HCPCS Level II code to identify xenoPATCH. Extremity Care is a licensed distributor for xenoPATCH, which is manufactured by DSM Biomedical. Meso Wound Matrix received the Food and Drug Administration's (FDA's) 510(k) clearance on February 12, 2012; however, "xenoPATCH" has since been added to the FDA's 510(k) listing and is sold under this brand name exclusively by Extremity Care. xenoPATCH is a thin, flexible, yet strong acellular biologic dermal substitute scaffold which acts to support the body's own regenerative tissue repair process during wound healing. xenoPATCH is indicated for the management of topical wounds, including partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds, trauma wounds (including second degree burns), draining wounds, and tunneled/undermined wounds.

CMS Preliminary HCPCS Coding Recommendation

It is our understanding that Meso Wound Matrix was never commercially marketed or sold by DSM Biomedical. Parametrics obtained the rights to license the product from DSM Biomedical and rebranded as "Resolve Matrix" for distribution by Parametrics exclusively; however, Parametrics has since privately labeled the product for exclusive distribution by Extremity Care, who now owns the brand and named the product "xenoPATCH." Resolve Matrix will remain in use. As such, we propose to:

Revise existing HCPCS Level II code A2024, "Resolve matrix, per square centimeter" to instead read "Resolve matrix or xenopatch, per square centimeter" to describe the rebranded product, xenoPATCH.

Agenda Item # 10
MatriDerm - HCP2312299XQ9C

Topic/Issue

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

Applicant's suggested language: AXXXX, "MatriDerm, per square centimeter"

Summary of Applicant's Submission

Access Pro Medical submitted a request to establish a new HCPCS Level II code to identify MatriDerm. MatriDerm received the Food and Drug Administration's (FDA's) 510(k) clearance on January 7, 2021. MatriDerm is a single-use three-dimensional acellular dermal matrix composed of bovine collagen fibers and bovine elastin. MatriDerm provides a moist wound healing environment and scaffold. MatriDerm is indicated for the management of wounds including full thickness and partial thickness wounds, chronic wounds (e.g. pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers), surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), partial thickness burns, trauma wounds (abrasions, lacerations, skin tears) and draining wounds.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Matriderm, per square centimeter" to describe MatriDerm.

Agenda Item # 11
MicroMatrix® Flex - HCP231218YCJEE

Topic/Issue

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

Applicant's suggested language: AXXXX, "MicroMatrix Flex, per cc"

Summary of Applicant's Submission

Integra LifeSciences Corporation submitted a request to establish a new HCPCS Level II code to identify MicroMatrix® Flex. MicroMatrix® Flex received the Food and Drug Administration's (FDA's) 510(k) clearance on September 22, 2023. The MicroMatrix® Flex device is supplied as a dual-syringe system for the mixing and delivery of a MicroMatrix® paste for the management of wounds. The particulate component of the device is composed of porcine-derived extracellular matrix known as urinary bladder matrix. The MicroMatrix® particulate within the MicroMatrix® Flex device is lyophilized (freeze-dried) micronized particles of porcine urinary bladder extracellular matrix. MicroMatrix® Flex is intended for the management of 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.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Micromatrix flex, per mg" to describe MicroMatrix® Flex.

The weight of lyophilized MicroMatrix® Flex particulate component provided in a syringe is between 750-800 mg. In the preparation of the device, the particulate component is mixed with up to 8 mL of saline solution to form the paste.

Agenda Item # 12
MiroTract Wound Matrix - HCP240102AB73B

Topic/Issue

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

Applicant's suggested language: AXXXX, "MiroTract Wound Matrix Sheet, per cm³"

Summary of Applicant's Submission

Reprise Biomedical, Inc. submitted a request to establish a new HCPCS Level II code to identify MiroTract Wound Matrix. MiroTract Wound Matrix received the Food and Drug Administration's (FDA's) 510(k) clearance on December 13, 2023. MiroTract Wound Matrix consists of a segment of dry, decellularized porcine collagen that is radially compressed and provided on a guidewire. Once placed, the matrix can be wetted by the natural wound environment, or it can be hydrated with saline or Lactated Ringer's Solution. This wetting process allows relaxation to a thick sheet-like form and expansion contact with the adjacent wound bed. MiroTract Wound Matrix is supplied sterile and is intended for one-time use in a single patient. MiroTract is available in four size configurations.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Mirotract wound matrix sheet, per cubic centimeter" to describe MiroTract Wound Matrix.

Agenda Item # 13
AceConnex Pre-Sutured Fascia Allograft - HCP231217FK5VQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify AceConnex pre-sutured fascia allograft.

Applicant's suggested language: AXXXX, "AceConnex Pre-Sutured Fascia, per millimeter"

Summary of Applicant's Submission

AlloSource submitted a request to establish a new HCPCS Level II code to identify AceConnex pre-sutured fascia allograft. AceConnex pre-sutured fascia allograft received the Food and Drug Administration's (FDA's) 510(k) clearance on June 27, 2023. AceConnex pre-sutured fascia allograft is used as a component in soft tissue surgical procedures for reconstruction, replacement, or augmentation of the hip labrum. It is applied by using multiple hip labral anchors per surgeon preference. The product is provided in a sterile single unit in various package sizes.

CMS Preliminary HCPCS Coding Recommendation

It is our understanding that AceConnex pre-sutured fascia allograft would generally be used in a procedure reported with a HCPCS Level I Current Procedural Terminology (CPT®) code. We have not identified a specific need for this item to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

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).