

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



**Centers for Medicare & Medicaid Services' (CMS') First Biannual 2023 Healthcare
Common Procedure Coding System (HCPCS) Public Meeting Agenda**

**Zoom Meeting, for remote participation
Thursday, June 1, 2023 9:00 am – 5:00 pm, eastern time (ET)**

8:45 am, ET:

- Zoom meeting login:
https://cms.zoomgov.com/webinar/register/WN_r_Xpc62cSt-p9CdWjBYhhA
- Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

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 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-HCPCSLevelIII-Coding-Decisions-Narrative-Summary> around August 2023 and will be effective October 1, 2023, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Thursday, June 1, 2023. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

Table of Contents

Preliminary decisions for the HCPCS Virtual Public Meeting on June 1, 2023.¹

1. Reconsideration of S codes Associated with Breast Reconstruction Procedures - HCP210813XRPKE.....	3
2. Transportation of Physician/Health Care Professional and Equipment for a Home Visit Evaluation and Management (E/M), Per Trip to Location, One Patient Seen - HCP221230N9KE4	6
Transportation of Physician/Health Care Professional and Equipment for a Home Visit Evaluation and Management (E/M), Per Trip to Location, More Than One Patient Seen - HCP221230W07Q8.....	8
3. Portable X-ray and/or Other Portable Diagnostic Imaging Supplier - HCP230102B51B5	9
Portable X-ray and/or Other Portable Diagnostic Imaging Supplier - HCP2301034XATF	10
Portable X-ray and/or Other Portable Diagnostic Imaging Supplier- HCP230102T6B2A.....	11
4. Bilateral Hip Orthosis - HCP211020YXAK3.....	12
5. PainShield® MD - HCP230103WP355.....	14
Painshield® MD, Monthly Disposable Ultrasound Kit - HCP230103MU5DT	16
6. RelieVRx - HCP220701K2H96.....	17
7. Sodium Phenylacetate and Sodium Benzoate Injection - HCP230103BD8AQ.....	20
8. HCPCS Level II Codes for Various FDA Approvals under the 505(b)(2) or Biologics License Application Pathways and Products “Not Otherwise Classified” - HCP220517FAENJ.....	21
9. Migration of Temporary Codes	23
Appendix A: HCPCS Level II Codes for Products Approved by the FDA Under the 505(b)(2) NDA or BLA Pathways and Products “Not Otherwise Classified”	24
Appendix B: HCPCS Level II Temporary (“K” codes) Coding Revision.....	26
Appendix C: DMEPOS Payment Categories.....	28

¹ Updated May 9th, 2023 to remove Axor™ II from the June 1, 2023 public meeting agenda.

Agenda Item #1
Reconsideration of S codes Associated with Breast Reconstruction Procedures -
HCP210813XRPKE

Topic/Issue

CMS has received input from multiple parties regarding the coding decision issued on February 16, 2022, to discontinue HCPCS Level II codes S2066, S2067, and S2068 effective December 31, 2024, and is interested in receiving further feedback with regard to whether CMS should:

- 1) Extend the effective date to allow additional time for a transition, or
- 2) Retain these codes in the HCPCS Level II code set.

CMS Summary

The Healthcare Common Procedure Coding System (HCPCS) is a standardized coding system used to identify particular items and services on claims submitted to Medicare, Medicaid, and other health insurance programs in a consistent and orderly manner under the Health Insurance Portability and Accountability Act and implementing regulations. The HCPCS is divided into two principal subsystems, referred to as HCPCS Level I and HCPCS Level II. The American Medical Association (AMA) develops and maintains the HCPCS Level I codes, also known as Current Procedural Terminology (CPT®) codes. CMS develops and maintains HCPCS Level II codes, which identify items and certain services that are generally not identified by CPT® codes. To the extent possible, CMS and AMA strive to have complementary code sets to facilitate access to healthcare items and services and to minimize duplication or repetition of items or services in the respective code sets.

In the Second Biannual session of the 2021 HCPCS Coding Cycle, CMS reviewed a request that the Blue Cross and Blue Shield Association submitted to discontinue three S codes related to breast reconstruction: S2066 Breast reconstruction with gluteal artery perforator (GAP) flap; including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral; S2067 Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral; and S2068 Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral.

The preliminary and final decisions are available:

<https://www.cms.gov/files/document/hcpcs-public-meeting-agenda-non-drug-and-non-biological-items-and-services-december-2-2021-updated.pdf>

<https://www.cms.gov/files/document/2021-hcpcs-application-summary-biannual-2-2021-non-drug-and-non-biological-items-and-services.pdf>

In 2006, CMS established HCPCS Level II code S2068 to describe breast reconstruction with Deep Inferior Epigastric Perforator (DIEP) and other flap procedures, as well as S2066 and

S2077, at the request of the Blue Cross and Blue Shield Association for use principally by private payers. Medicare and other government payers, to the best of CMS' knowledge, do not use S2066-S2068 for payment.

In 2010, the AMA published coding guidance stating that CPT® code 19364 was an appropriate code for DIEP flap breast reconstruction procedures. However, in subsequent years various uncertainty remained about what breast reconstruction procedures were appropriate to bill to insurers using CPT® code 19364. Thus, in 2019, the CPT® Editorial Panel convened by the AMA reviewed broadly a series of codes associated with breast reconstruction procedures and specifically considered whether existing CPT® code 19364 should more clearly state that DIEP and other flap procedures are described by the code. As a result of that review, the CPT® Editorial Panel revised the description of CPT® code 19364 to expressly include DIEP and other similarly advanced flap procedures that had historically been considered to be described by the code. Following this action, CMS was again approached by the Blue Cross and Blue Shield Association, though in this case, to discontinue S2066-S2068.

On February 16, 2022, after receiving public comment, CMS decided to discontinue HCPCS codes S2066, S2067, and S2068 on December 31, 2024. Our typical approach is to establish or discontinue codes on the next quarter. However, we established a transition period to allow time for any entities that currently list these codes in their written policies or contracts to make any necessary updates, including facilitating a transition period for negotiations between providers and payers.

We have subsequently received correspondence from multiple parties that there are significant transition complexities and that the transition may be affecting access to care. A primary concern seems to be that CPT® code 19364 may be different enough from S2068, in particular, in which negotiations between providers and private payers may warrant CMS to reconsider the scheduled December 31, 2024, end date.

CMS Preliminary HCPCS Coding Recommendation

CMS seeks written feedback and/or input during the public meeting from interested parties. We raise the following questions for consideration:

1. Should CMS extend the scheduled end date of December 31, 2024, for HCPCS codes S2066-S2068? If so, for how long?
2. Should CMS retain HCPCS codes S2066-S2068 and not end their availability on December 31, 2024? In particular, we seek input from private payers about whether they would continue to use S2066-S2068 in lieu of other codes, such as CPT® code 19364.
3. Are any parties approaching the CPT® Editorial Panel to seek revisions or refinements to the CPT® code set? Are any parties approaching another body, such as the AMA/Specialty Society RVS Update Committee (RUC)? If so, how long may be necessary for this process to occur and be allowed for any subsequent transition period, if any revisions are made by the CPT® Editorial Panel or other entity? In other words, if revisions or refinements are sought, how long would it be beneficial for codes S2066-S2068 to remain effective?

CMS welcomes input from all interested parties, including providers and health insurers. CMS understands that a cancer diagnosis is extremely challenging, both physically and emotionally, for patients and their loved ones and works to ensure that coding decision support providers and payers in efficiently and effectively submitting and processing claims in the provision of access to care for their patients.

CMS notes that this particular process is not a vehicle in which CMS can make an endorsement or statement in regard to the appropriate payment amount for any particular code by a non-government payer. With regard to the applicability of Federal laws, such as the Women's Health and Cancer Rights Act of 1998, balance billing, or the No Surprise Act and how those may apply to payment amounts available to providers from private payers:

Concerns regarding consumers who are covered by a private-sector, employer-sponsored group health plan and have concerns about their plan's compliance with market-wide requirements may contact the Department of Labor's Employee Benefits Security Administration (EBSA) at <https://www.askebsa.dol.gov/>, <https://www.dol.gov/agencies/ebsa/about-ebsa/ask-a-question/ask-ebsa>, or call toll free at [1-866-444-3272](tel:1-866-444-3272).

Concerns regarding consumers who are covered by a non-federal public-sector employer-sponsored plan, such as a state or local government employee plan, and have concerns about their plan's compliance with these requirements may contact the CMS Center for Consumer Information and Insurance Oversight (CCIIO) at NonFed@cms.hhs.gov for further assistance with a question or issue.

Concerns about an [health reimbursement arrangements or health reimbursement accounts](#) provided by a private-sector or public-sector employer may also contact the Department of Labor or CMS/CCIIO, respectively.

Agenda Item #2
Transportation of Physician/Health Care Professional and Equipment for a Home Visit
Evaluation and Management (E/M), Per Trip to Location, One Patient Seen -
HCP221230N9KE4

Topic/Issue

Request to establish a new HCPCS Level II code to identify payment for transportation for the physician or other qualified health care professional, personnel, and medical equipment for home visit for one patient.

Applicant's suggested language: XXXXX, "Transportation of the physician or other qualified health care professional, personnel, and medical equipment for a home visit e/m, per trip to location"

Summary of Applicant's Submission

Home Visiting Providers submitted a request to establish a new HCPCS Level II code to identify payment for transportation for the physician or other qualified health care professional, personnel, and medical equipment for home visit for one patient. This service represents the transportation of the physician or other qualified health care professional, personnel, and medical equipment to a location with one patient for a home visit. The service must be billed in conjunction with home visit E/M Current Procedural Terminology (CPT®) codes. According to the applicant, there is currently no code that describes this service. Per the applicant, home visit E/M CPT® codes do not include transportation in the description. According to the applicant, since transportation is not described in the home visit E/M CPT® codes, Medicare has stated that transportation expenses are not included in calculating the reimbursement for home visits E/Ms. Per the applicant, this application is for a code that will allow transportation to be reimbursed for home visit E/Ms. The applicant implied that transportation is a significant expense that is necessary for a home visit E/M and should be reimbursed.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that for Medicare, beginning January 1, 2023, physicians and qualified nonphysician practitioners furnishing E/M services to a patient residing in their home, in an assisted living facility, in a group home (that is not licensed as an intermediate care facility for individuals with intellectual disabilities), in a custodial care facility, or in a residential substance abuse treatment facility must use the level of service code in the CPT® code range 99341 - 99350 to report the service they provide.² Historically, travel costs incurred by the physician or practitioner are not included in the valuation of E/M codes, since travel time and/or mileage is not considered a resource involved in furnishing the service, and they are not included in establishing payment rates under the PFS in accordance with section 1848 of the Social Security Act.

We welcome information from the applicant and other insurers who are currently paying for this service to describe a claims processing interest for a unique HCPCS Level II code to

² <https://www.cms.gov/files/document/r11732cp.pdf>

describe transportation of the physician or other qualified health care professional, personnel, and medical equipment for a home visit E/M.

Agenda Item #2

Transportation of Physician/Health Care Professional and Equipment for a Home Visit Evaluation and Management (E/M), Per Trip to Location, More Than One Patient Seen - HCP221230W07Q8

Topic/Issue

Request to establish a new HCPCS Level II code to identify payment for transportation for the physician or other qualified health care professional, personnel, and medical equipment for home visit for more than one patient.

Applicant's suggested language: XXXXX, "Transportation of the physician or other qualified health care professional, personnel, and medical equipment for a home visit e/m, per trip to location, more than one patient seen"

Summary of Applicant's Submission

Home Visiting Providers, submitted a request to establish a new HCPCS Level II code to identify payment for transportation for the physician or other qualified health care professional, personnel, and medical equipment for home visit for more than one patient. This service represents the transportation of the physician or other qualified health care professional, personnel, and medical equipment to a location with more than one patient for a home visit. According to the applicant, there is currently no code that describes this service. Per the applicant, home visit E/M Current Procedural Terminology (CPT®) codes do not include transportation in the description. According to the applicant, since transportation is not described in the home visit E/M CPT® codes, Medicare has stated that transportation expenses are not included in calculating the reimbursement for home visits E/M's. Per the applicant, this application is for a code that will allow transportation to be reimbursed for home visit E/M's. The applicant implied, transportation is a significant expense that is necessary for a home visit E/M and should be reimbursed.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that for Medicare, beginning January 1, 2023, physicians and qualified nonphysician practitioners furnishing E/M services to a patient residing in their home, in an assisted living facility, in a group home (that is not licensed as an intermediate care facility for individuals with intellectual disabilities), in a custodial care facility, or in a residential substance abuse treatment facility must use the level of service code in the CPT® code range 99341 - 99350 to report the service they provide.³ Historically, travel costs incurred by the physician or practitioner are not included in the valuation of E/M codes, since travel time and/or mileage is not considered a resource involved in furnishing the service, and they are not included in establishing payment rates under the PFS in accordance with section 1848 of the Social Security Act.

We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code to describe transportation of the physician or other qualified health care professional, personnel, and medical equipment for a home visit E/M.

³ <https://www.cms.gov/files/document/r11732cp.pdf>

Agenda Item #3

Portable X-ray and/or Other Portable Diagnostic Imaging Supplier - HCP230102B51B5

Topic/Issue

Request to revise existing HCPCS Level II code R0070, “Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, one patient seen.”

Applicant's suggested language: R0070, “Transportation of portable imaging equipment and personnel to home or nursing home, per trip to facility or location, one patient seen”

Summary of Applicant’s Submission

DispatchHealth Imaging submitted a request to revise an existing HCPCS Level II code R0070, “Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, one patient seen” to instead read “Transportation of portable imaging equipment and personnel to home or nursing home, per trip to facility or location, one patient seen.” The applicant is looking to expand R0070 for other portable diagnostic imaging services such as ultrasound, dopplers and echocardiograms. Per the applicant, a portable imaging supplier moves its X-ray equipment and other portable diagnostic imaging equipment from place to place, performing X-ray, EKG and other diagnostic imaging services such as ultrasound, venous and arterial dopplers and echocardiograms at various locations. According to the applicant, a portable imaging supplier is a supplier using only portable units vs. a mobile unit that is typically described as a vehicle that travels from place to place to perform services inside the vehicle. An example of such a vehicle includes mobile semi-trailers.

CMS Preliminary HCPCS Coding Recommendation

This application is being deferred for additional consideration in a subsequent biannual coding cycle. We believe more time is needed to consider revising existing HCPCS Level II code R0070 and any implications that might occur. We welcome information from the applicant and other insurers who are currently paying for transportation of portable x-ray equipment and personnel to demonstrate a claims processing need for a revision to HCPCS Level II code R0070.

Agenda Item #3
Portable X-ray and/or Other Portable Diagnostic Imaging Supplier -
HCP2301034XATF

Topic/Issue

Request to revise existing HCPCS Level II code R0075, “Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen.”

Applicant's suggested language: R0075, “Transportation of portable x-ray and other diagnostic imaging equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen”

Summary of Applicant’s Submission

DispatchHealth Imaging submitted a request to revise an existing HCPCS Level II code R0075, “Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen” to instead read “Transportation of portable x-ray and other diagnostic imaging equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen.” According to the applicant, this language revision would include the code for the use of cost coverage and billing for the transportation of equipment and personnel for other portable diagnostic imaging examinations such as ultrasound, dopplers and echocardiograms. Per the applicant, a transportation service code (R0075) may only be billed when the X-ray equipment or other diagnostic imaging equipment used is actually transported to the location where the examination was taken. The allowable fee for R0075 will be adjusted based upon the modifier used. Per the applicant, "Portable X-ray and/or Other Portable Diagnostic Imaging Supplier" is defined as a supplier that provides one or more of the following portable services, including but not limited to, X-ray, electrocardiogram (EKG), long-term EKG (Holter Monitor), bone densitometry, sonography, and other imaging services in accordance with all state and federal requirements, under the general supervision of a qualified physician. According to the applicant, R0075 must be billed in conjunction with the Current Procedural Terminology (CPT®) radiology codes (70000 series) and only when the X-ray equipment used was actually transported to the location where the X-ray was taken. Per the applicant, the CPT® 70000 series also includes some ultrasound procedures although the R0075 code is not accepted for transportation of ultrasound equipment and personnel to the facility or location where the exam is taken.

CMS Preliminary HCPCS Coding Recommendation

This application is being deferred for additional consideration in a subsequent biannual coding cycle. We believe more time is needed to consider revising existing HCPCS Level II code R0075 and any implications that might occur. We welcome information from the applicant and other insurers who are currently paying for transportation of portable X-ray equipment and personnel to demonstrate a claims processing need for a revision to HCPCS Level II code R0075.

Agenda Item #3

Portable X-ray and/or Other Portable Diagnostic Imaging Supplier- HCP230102T6B2A

Topic/Issue

Request to revise existing HCPCS Level II code R0076, “Transportation of portable ekg to facility or location, per patient.”

Applicant's suggested language: R0076, “Transportation of portable EKG to facility or location, per one patient seen”

Summary of Applicant’s Submission

DispatchHealth Imaging submitted a request to revise an existing HCPCS Level II code R0076, “Transportation of portable ekg to facility or location, per patient” to instead read “Transportation of portable EKG to facility or location, per one patient seen.” According to the applicant, R0076 appears available with a description, although when used for codification on a claim there is no reimbursement. The applicant is requesting the code language revision and to revise, re-instate, and update the policy and coverage provision for R0076. According to the applicant, HCPCS code R0075 must be billed with one of the following modifiers, UN, UP, UQ, UR, US, to indicate how many patients were served on that trip to the facility or location. According to the applicant, R0075 must be billed in conjunction with a Current Procedural Terminology (CPT®) code, and only when the diagnostic equipment used was actually transported to the location where the test was taken. Per the applicant, if only one patient is served, R0076 should be reported with no modifier for any EKG procedure. According to the applicant, R0076 would not apply when the diagnostic testing equipment is stored in the location where the diagnostic test was taken. Per the applicant, R0076 would not apply when EKG procedure is performed in conjunction with an X-ray procedure, such as a chest x-ray and EKG were performed together during the visit. Only the X-ray transportation code would apply to the claim. According to the applicant, the function of the transportation code, R0076, would be for the portable X-ray supplier to capture reimbursement that covers the cost of the vehicle, maintenance, labor, supplies, insurance, and other direct cost applicable to providing the portable EKG service.

CMS Preliminary HCPCS Coding Recommendation

This application is being deferred for additional consideration in a subsequent biannual coding cycle. We believe more time is needed to consider revising existing HCPCS Level II code R0076 and any implications that might occur. We welcome information from the applicant and other insurers who are currently paying for transportation of portable X-ray equipment and personnel to demonstrate a claims processing need for a revision to HCPCS Level II code R0076.

Agenda Item #4
Bilateral Hip Orthosis - HCP211020YXAK3

Topic/Issue

Request to establish a new HCPCS Level II code to identify a bilateral hip orthosis.

Applicant's suggested language: LXXXX, "Hip orthosis, bilateral hip joints and thigh cuffs, adjustable flexion, extension, abduction control of hip joint, postoperative hip abduction type, 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 a hip orthosis designed for bilateral post-operative range of motion control. According to the Medicare Contractor for Pricing, Data Analysis and Coding of HCPCS Level II DMEPOS Codes (PDAC), there is apparent supplier confusion about the use of L1690, "Combination, bilateral, lumbo-sacral, hip, femur orthosis providing adduction and internal rotation control, prefabricated, includes fitting and adjustment." HCPCS Level II code L1690 was established in 1999 for the predicate/historical product SWASH (Sitting, Walking, And Standing Hip) Orthosis. The SWASH Orthotic enhanced the position and function of the femur by providing hip abduction and external rotation for the pediatric population. This was done by limiting hip and internal femur rotation in order to resist a bilateral lower limb scissoring gait pattern for the pediatric population. According to the applicant, a new code would describe a prefabricated, custom fitted, hip orthosis designed for bilateral post-operative hip range of motion control. The design parameters would include a pelvic band, bilateral hip joints and thigh cuffs designed to provide adjustable flexion, extension, and abduction control of the hip joint.

CMS Preliminary HCPCS Coding Decision

Establish a new HCPCS Level II code LXXXX, "Hip orthosis, bilateral hip joints and thigh cuffs, adjustable flexion, extension, abduction control of hip joint, postoperative hip abduction type, 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

Leg brace (Orthotic)

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. The preliminary payment determination for code LXXXX is to establish the fee schedule amount by doubling the

existing fee schedule amounts for the related item described by HCPCS code L1686 (“Hip Orthosis, Abduction Control of Hip Joint, Postoperative Hip Abduction Type, Prefabricated, Includes Fitting and Adjustment”).

Pricing for LXXXX is represented by the following formula: $2 * L1686$. Therefore, the average 2023 fee schedule amount for LXXXX would be approximately \$2,249.62. The average fee schedule amount is the average of the 2023 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.

Payment would be on a lump sum purchase basis.

Pricing Indicator = 38

Agenda Item #5
PainShield® MD - HCP230103WP355

Topic/Issue

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

Applicant's suggested language: XXXXX, “Low frequency ultrasonic treatment device, single transducer/actuator, includes all components and accessories for initial use”

Summary of Applicant’s Submission

Nanovibronix Inc. submitted a request to establish a new HCPCS Level II code to identify PainShield® MD. PainShield® MD received the Food and Drug Administration’s (FDA’s) 510(k) clearance on August 22, 2008. The PainShield® MD is an ultrasonic device used to apply heat to the tissues in the body for the treatment of medical conditions such as pain relief, muscle spasms, and joint contractures. The device includes a transducer/actuator rechargeable battery-powered driver unit and a cable that connects the driver to the transducer. The PainShield® MD provides intermittent ultrasonic output at a preset, low intensity frequency of 90 kHz, which cannot be modified by the user. When the device is on, it alternates between two phases: an active phase and an idle phase, both lasting 30 minutes each. The device automatically turns off after 6.5 hours of treatment, after which the battery needs to be recharged. Treatment is delivered through an ultrasound actuator which is applied and secured to the surface of the body using adhesive patches. According to the applicant, the life expectancy of the driver is at least three years. The PainShield® MD is approved by the FDA for home use. According to the applicant, the PainShield® MD meets all the criteria for durable medical equipment (DME). Per the applicant, an independent testing firm is conducting durability testing to demonstrate that the PainShield® MD has an expected life of at least three years. According to the applicant, the PainShield® MD therefore meets all the DME requirements: it can withstand repeated use, it has an expected life of at least 3 years, it is primarily and customarily used to serve a medical purpose, it is not usually useful to an individual in the absence of illness or injury, and it is appropriate for use in the home.

CMS Preliminary HCPCS Coding Recommendation

This is a repeat application, with our prior decisions published on September 26, 2022 and March 8, 2023. The decision published on September 26, 2022 questioned whether the device has a lifetime of at least 3 years. We suggested that the applicant presents a lifetime durability test over the entire device/system to CMS. For example, the manufacturer can provide standardized test results from an independent testing laboratory demonstrating that the device itself can last for at least 3 years with the redesigned battery. While CMS received this current application by the January 2, 2023 deadline for this biannual cycle, it was submitted when test results were in process and not yet complete. CMS did not receive final test results until March 29, 2023. Generally, when an application is submitted as incomplete, CMS will defer the application to a future HCPCS coding cycle when the submitter can complete the application. Nevertheless, while CMS has not had sufficient time to thoroughly review all test results, in our initial review we did note that we have some comments/questions about the results, as follows:

1. The IEC report published by Carmel Lab does not describe how the test was set up, or conducted. It also does not specify any parameters besides the voltage. A durability test is not a pass or fail type of test and this missing information will strengthen the outcome of the testing protocol on the device life time. What was the testing criteria for the device durability?
2. According to the current application, patients typically use PainShield® for one treatment/charge cycle (6.5 hours) every day for the first week. The test stated that the devices were used for 21 cycles for the first week which means three treatments per day. What was the rationale behind not replicating the same usage as outlined in the application?
3. The report stated that the testing was continued with a device that was shut down after a week. The report also stated that the issue was deemed not related to the life test but did not specify what the issue was. The exclusion criteria were not listed in the report therefore we have the following questions:
 - a. What were the inclusion and exclusion criteria for the test?
 - b. What happened to the device to cause it to shut down?
 - c. Why was the device that shut down brought back into testing?
4. At the end, the report stated that the devices behaved within defined limits and carried out cycles in accordance with the anticipated behaviors. What is the definition of the “anticipated behavior”? It would be best if the report included a brief “results” or “discussion” section.
5. In the “Li-Polymer Battery Technology⁴” document, different voltage and currency ranges were applied for the battery life expectancy tests than the IEC Test report by Carmel Lab. For example, the voltage range in the ICE test was between 12-13 V as compared to .5- 13.0 V for the battery tests. What is the rationale for the differences in voltage and currency ranges?
6. Comparing the IEC report to the “Li-Polymer Battery Technology³” document, the testing methodologies seemed to be different. The tests on the upgraded batteries had more interventions and cycle changes to validate the life expectancy. What was the reason for using different methodologies?

⁴ Shenzhen Pknergy Energy Co. LTD, Li-Polymer Battery Technology Specification, Li-Polymer Battery, Model LIPO703450 1250mAh 3.7V, www.pknergy.com.

Agenda Item #5
Painshield® MD, Monthly Disposable Ultrasound Kit - HCP230103MU5DT

Topic/Issue

Request to establish a new HCPCS Level II code to identify PainShield® MD, monthly disposable ultrasound kit.

Applicant's suggested language: XXXXX, “Monthly disposable supply kit for use with low frequency ultrasonic treatment device [K1004], includes an ultrasound actuator/transducer that plugs into the durable handheld device and 30 adhesive patches”

Summary of Applicant’s Submission

Nanovibronix Inc. submitted a request to establish a new HCPCS Level II code to identify PainShield® MD monthly disposable supply kit. PainShield® MD received the Food and Drug Administration’s (FDA’s) 510(k) clearance on August 22, 2008. The Painshield® MD monthly disposable supply kit includes an ultrasound actuator/transducer and 30 adhesive patches that adhere to the body. Treatment is delivered through the actuator/transducer that provides intermittent ultrasonic output at a preset, low intensity frequency of 90 kHz, which cannot be modified by the user. It is applied and secured to the surface of the body using adhesive patches. Each adhesive is one-time use. The PainShield® actuator/transducer can be used for 30 sessions (one month’s use). Once the actuator/transducer has been used for a total of 30 sessions, the patient must dispose of the actuator/transducer and use a new one. The FDA indications for use are as follows: treatment for pain, muscles spasms and joint contractures.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a disposable supply kit (1 transducer and 30 adhesive bandages) for use with the PainShield®. This follows our prior decisions (published September 26, 2022 and March 28, 2023) that the PainShield® device does not have a durable medical equipment, prosthetics, orthotics, and supplies Medicare benefit category. With regard to Medicare, we do not have a benefit category for PainShield®, a low-frequency ultrasonic diathermy treatment device for home use, as it does not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Agenda Item #6
RelieVRx - HCP220701K2H96

Topic/Issue

Request for Medicare payment determination for RelieVRx.

Summary of Applicant's Submission

AppliedVR, Inc. submitted a request to establish a new HCPCS Level II code to identify RelieVRx. RelieVRx received the Food and Drug Administration's (FDA's) De Novo clearance on March 3, 2021. RelieVRx is an immersive virtual reality (VR) medical device for home use that is indicated for the treatment of chronic low back pain. RelieVRx is available only by prescription, that consists of a modified proprietary Pico G2 4G VR headset, which is not available for retail sale, as well as a patented Breathing Amplifier™ to allow integration of bio-enabled immersive experiences, and preloaded software. The device is locked such that it can only be used for treatment of the specified clinical indication. The device delivers a clinically based multimodal pain self-management program incorporating evidence-based principles of Cognitive Behavioral Therapy (CBT) and other neuroscience-based behavioral health methods to reduce pain intensity and pain interference with daily activities, sleep, mood and stress for patients diagnosed with moderate to severe chronic low back pain. The device engages all four major regions of the brain to address maladaptive neuroplastic changes associated with chronic pain and has been demonstrated in published peer-reviewed literature to produce statistically and clinically significant reductions in pain intensity and pain interference. RelieVRx therapy is administered daily as a 3-16 minute module (averaging 7 minutes per day) over the course of 56 days. The de novo FDA authorization encompasses the integrated hardware and software, as the headset is required to deliver the 3-dimensional 360° multimodal pain self-management curriculum and is tested to meet American National Standards Institute (ANSI) medical device standards. According to the applicant, clinical trial evidence demonstrates that the durable VR hardware is required to deliver significantly greater reductions in pain intensity and pain interference compared to software-only or application-only methods. RelieVRx is self-administered, unsupervised in the patient's home while the patient is in a seated position. The therapy is not delivered as part of a clinician service. The device is returned upon completion of the 56-day course of treatment and is available for reuse. The device has an expected useful life of 3 years or greater, is suitable for repeated use, and does not include non-medical software or allow non-medical use.

CMS Final HCPCS Coding Decision

On March 8, 2023 CMS established HCPCS Level II code E1905, "Virtual reality cognitive behavioral therapy device (cbt), including pre-programmed therapy software" to describe RelieVRx, effective April 1, 2023.

Medicare Benefit Category Determination

CMS determined that RelieVRx is DME and published that determination on March 8, 2023.

Preliminary Medicare Payment Determination

AppliedVR, Inc. requested that CMS classify RelieVRx as an item “requiring frequent and substantial servicing.” These items are defined in 42 CFR §414.222 as “items requiring frequent and substantial servicing in order to avoid risk to the beneficiary’s health.” The request was supported by a detailed explanation of the “servicing, refurbishing, and cleaning required between each treatment to safely provide the device to the next patient.” We do not agree that this servicing is frequent or substantial. All rented equipment is serviced in between rental episodes; therefore, this could not be considered frequent servicing. Furthermore, the actual servicing provided (check the condition of the device hardware and software, install a new breath amplifier and facial liner, upload data from device, perform factory reset, remove and erase memory card, recharge battery if necessary, and clean/disinfect device) is minimal. If this servicing is not provided or is done incorrectly, it is difficult to see how this could result in actual harm to the patient, such as the harm that would result from a ventilator malfunction. Therefore, the DME payment classification for RelieVRx is “other durable medical equipment (capped rental items).”

In accordance with regulations at 42 CFR §414.229, the fee schedule amount for capped rental items must be set based on a purchase price. There is no provision to set the payment amount for capped rental items based on a rental price. While we appreciate the commercial price information and invoices that AppliedVR submitted to us, these clearly represent rental prices based on the typical 2-3 month course of treatment. The information we have separately received from the Veterans Health Administration confirms that RelieVRx devices are being procured exclusively on a rental basis. Unfortunately, as the regulations require payment amounts be set based on a purchase price, we cannot use the commercial price information submitted to us for an 8-week rental of the RelieVRx.

In our search for an appropriate price we found a purchase price from 2017 cited in an article⁵ reviewing an earlier version of the RelieVRx device (then called the “EaseVRx”). This article describes a virtual reality cognitive behavior therapy device, incorporating pre-programmed therapeutic software together with a virtual-reality headset. We accept that there are some physical differences: the current RelieVRx device uses a self-contained VR headset with preloaded software, but the article describes a device performing the same functions with a VR headset driven by a locked smartphone pre-loaded with the therapeutic software (the article notes that aside from the VR app and wifi, “every other function is forbidden”). This article clearly describes this device as available to purchase: “you either buy the standard package for \$2588, or buy the premium one for a little bit more than \$3700.” Despite the physical differences, we believe that the device described by the 2017 article, even if it is not the exact same version as the current model, presents to us the only purchase price known to CMS for an item described by E1905. As such, we believe that our best option for a preliminary payment determination would be to use this 2017 purchase price of \$2588.

As described in 42 CFR §414.229, the monthly fee schedule amount for capped rental items is 10 percent of the adjusted purchase price for the first three months, and 7.5 percent for months four through thirteen. The adjusted purchase price is determined by deflating the purchase price using the CPI-U to the 1986-1987 equivalent. This value is then adjusted to a current purchase price based on the methodology outlined in statute (for recent years, this adjustment is based on the CPI-U adjusted by the change in economy-wide productivity, but

⁵ Escape the Scary and Painful in Healthcare: The AppliedVR Review (2017, September 26). *The Medical Futurist*. Retrieved from <https://medicalfuturist.com/escape-scary-painful-healthcare-appliedvr-review/>.

the statute provides for other adjustment applicable to certain years). Based on this 2017 purchase price of \$2588, the 2023 average capped rental fee schedule amount for E1905 would be approximately \$204.66 for months 1 through 3 and approximately \$153.50 for months 4 through 13, for a total of \$2,148.98 after 13 months of continuous use.

We welcome any information that may provide more recent purchase prices for this device, if available.

Pricing Indicator = 36

Agenda Item #7
Sodium Phenylacetate and Sodium Benzoate Injection - HCP230103BD8AQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Sodium Phenylacetate and Sodium Benzoate injection.

Applicant's suggested language: XXXXX, "Sodium Phenylacetate/Sodium Benzoate 10%, per ml"

Summary of Applicant's Submission

Maia Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify Sodium Phenylacetate and Sodium Benzoate Injection. Sodium Phenylacetate and Sodium Benzoate Injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 10, 2021. Sodium Phenylacetate and Sodium Benzoate Injection is indicated as adjunctive therapy in pediatric and adult patients for the treatment of acute hyperammonemia and associated encephalopathy in patients with deficiencies in enzymes of the urea cycle. Sodium phenylacetate and sodium benzoate are metabolically active compounds that can serve as alternatives to urea for the excretion of waste nitrogen. Phenylacetate conjugates with glutamine in the liver and kidneys to form phenylacetylglutamine, via acetylation. Phenylacetylglutamine is excreted by the kidneys via glomerular filtration and tubular secretion. The nitrogen content of phenylacetylglutamine per mole is identical to that of urea (both contain two moles of nitrogen). Two moles of nitrogen are removed per mole of phenylacetate when it is conjugated with glutamine. Similarly, preceded by acylation, benzoate conjugates with glycine to form hippuric acid, which is rapidly excreted by the kidneys by glomerular filtration and tubular secretion. One mole of hippuric acid contains one mole of waste nitrogen. Thus, one mole of nitrogen is removed per mole of benzoate when it is conjugated with glycine. Sodium Phenylacetate and Sodium Benzoate Injection must be diluted with sterile 10% Dextrose Injection (D10W) before administration. The dilution and dosage of Sodium Phenylacetate and Sodium Benzoate Injection are determined by weight for neonates, infants, and young children, and by body surface area for larger patients, including older children, adolescents, and adults. Sodium phenylacetate and sodium benzoate is administered as an injection. Sodium Phenylacetate and Sodium Benzoate Injection 10% per 10% is a clear and almost colorless solution supplied in a sterile, non-pyrogenic, single-dose glass vial. Both sodium phenylacetate and sodium benzoate solutions are physically and chemically stable for up to 24 hours at room temperature and room lighting conditions.

CMS Final HCPCS Coding Decision

The reference listed drug for this application is Ammonul. Ammonul is approved under an NDA and there are several ANDAs that are therapeutically equivalent. We have noticed none of these products have a unique HCPCS Level II code. It is our understanding there is very little to no Medicare claims volume or utilization for any of products under any of the related NDAs/ANDAs. We welcome information from the applicant, other manufacturers of related NDAs/ANDAs, and other insurers who are currently paying for this product or associated NDAs to describe whether there is interest in HCPCS Level II codes for these products for billing for outpatient use.

Agenda Item #8
HCPCS Level II Codes for Various FDA Approvals under the 505(b)(2) or Biologics
License Application Pathways and Products “Not Otherwise Classified” -
HCP220517FAENJ

Topic/Issue

We are requesting public comment on the language in the code descriptors for the new HCPCS Level II codes that we established in CMS’ Third Quarter 2022 Drug and Biological HCPCS code application review cycle, effective January 1, 2023, per our posting at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCSLevelIII-Coding-Decisions-Narrative-Summary>.

Applicant’s Summary

CMS reviewed its approach for establishing HCPCS Level II codes to identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration’s (FDA) Orange Book⁶, and are therefore considered single source products. Also, this effort will help reduce use of the not otherwise classified (NOC) codes.

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS codes as described at the following CMS link:

https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_an_noucement.pdf, CMS has made several code changes, including manufacturer specific codes to identify products approved under separate 505(b)(2) NDA or BLA pathways. Since the products are approved under separate 505(b)(2) NDAs and are not rated as therapeutically equivalent by the FDA in the Orange Book, they are single source drugs based on the statutory definition of “single source drug” in section 1847A(c)(6) of the Act. Because these are single source drugs, there was a programmatic need for each product to have a unique billing and payment code.

In cases where certain products met the statutory definition of a “multiple source drug” in section 1847A(c)(6) of the Act, CMS removed the brand name of the drug from any existing HCPCS code as needed (e.g. remove “velcade” from J9041) as it would accommodate any associated generic product(s), if approved and marketed, that are rated as therapeutically equivalent.

Due to the complexity and nuanced nature of the differences between each product, we encourage providers to rely on the Average Sales Price (ASP) HCPCS-NDC crosswalk⁷ to identify the correct billing and payment code for each applicable product.

⁶ The FDA’s Orange Book, officially entitled, *Approved Drug Products With Therapeutic Equivalence Evaluations*, identifies drug products approved on the basis of safety and effectiveness by the FDA, and is published at the following FDA link: <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>.

⁷ The ASP crosswalks are maintained by CMS on a quarterly basis to support ASP-based Medicare Part B payments only. The quarterly ASP crosswalks are published at the following CMS link: <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files>.

CMS HCPCS Coding Decision

We established 6 new HCPCS Level II codes within the fourth quarter (Q4) of 2022, effective April 1, 2023, and established or revised 28 new codes within the first quarter (Q1) of 2023, effective July 1, 2023 to separately identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code and products NOC.

We seek comment on these code descriptors.

See Appendix A for a complete list of new and revised HCPCS Level II codes that we are establishing under this initiative.

Agenda Item #9 Migration of Temporary Codes

Topic/Issue

To begin the process of establishing permanent codes for supplies and other products that received a temporary Healthcare Common Procedure Coding System (HCPCS) code (“K” code) that became effective January 1, 2020 through 2022.

Summary

Occasionally CMS will establish temporary HCPCS codes (“K” codes) for supplies and other products for which a national code has not yet been developed. CMS is committed to migrating these codes, when appropriate, into permanent HCPCS code categories. As announced in the Second Biannual (B2) 2022 Guidelines for Participating in the HCPCS Public Meeting, CMS will begin using the public meeting process promulgated through regulations to announce any plans it has to migrate K codes. The final rule outlining this process (86 FR 73902) is available at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposfeesched>.

CMS Preliminary HCPCS Coding Decision

We are revising 25 temporary (“K” codes) HCPCS Level II codes. These changes will be effective January 1, 2024. CMS is seeking written feedback on these changes.

See Appendix B for a complete list of new and revised HCPCS Level II codes that we are establishing under this initiative.

Appendix A: HCPCS Level II Codes for Products Approved by the FDA Under the 505(b)(2) NDA or BLA Pathways and Products “Not Otherwise Classified”

HCPCS Code	Action	Long Descriptor
J0612	Add	Injection, calcium gluconate (fresenius kabi), per 10 mg
J0613	Add	Injection, calcium gluconate (wg critical care), per 10 mg
J9196	Add	Injection, gemcitabine hydrochloride (accord), not
J9294	Add	Injection, pemetrexed (hospira) not therapeutically
J9296	Add	Injection, pemetrexed (accord) not therapeutically
J9297	Add	Injection, pemetrexed (sandoz), not therapeutically
J0137	Add	Injection, acetaminophen (hikma) not therapeutically equivalent to j0131, 10 mg
J0206	Add	Injection, allopurinol sodium, 1 mg
J0216	Add	Injection, alfentanil hydrochloride, 500 micrograms
J0457	Add	Injection, aztreonam, 100 mg
J0665	Add	Injection, bupivacaine, not otherwise specified, 0.5 mg
J0736	Add	Injection, clindamycin phosphate, 300 mg
J0737	Add	Injection, clindamycin phosphate (baxter), not therapeutically equivalent to j0736, 300 mg
J1576	Add	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1805	Add	Injection, esmolol hydrochloride, 10 mg
J1806	Add	Injection, esmolol hydrochloride (wg critical care) not therapeutically equivalent to j1805, 10 mg
J1811	Add	Insulin (fiasp) for administration through dme (i.e., insulin pump) per 50 units
J1812	Add	Insulin (fiasp), per 5 units
J1813	Add	Insulin (lyumjev) for administration through dme (i.e., insulin pump) per 50 units
J1814	Add	Insulin (lyumjev), per 5 units
J1836	Add	Injection, metronidazole, 10 mg
J1920	Add	Injection, labetalol hydrochloride, 5 mg
J1921	Add	Injection, labetalol hydrochloride (hikma) not therapeutically equivalent to j1820, 5 mg
J1941	Add	Injection, furosemide (furoscix), 20 mg
J2305	Add	Injection, nitroglycerin, 5 mg
J2371	Add	Injection, phenylephrine hydrochloride, 20 micrograms
J2372	Add	Injection, phenylephrine hydrochloride (biorphen), 20 micrograms
J2426	Revise	Injection, paliperidone palmitate extended release (invega sustenna), 1 mg
J2427	Add	Injection, paliperidone palmitate extended release (invega hafyera, or invega trinza), 1 mg
J2598	Add	Injection, vasopressin, 1 unit
J2599	Add	Injection, vasopressin (american reagent) not therapeutically equivalent to j2595, 1 unit
J7213	Add	Injection, coagulation factor ix (recombinant), ixinity, 1 i.u.
J9321	Add	Injection, pemetrexed (sandoz) not therapeutically equivalent to j9305, 10 mg

J9322	Add	Injection, pemetrexed (bluepoint) not therapeutically equivalent to j9305, 10 mg
-------	-----	--

Appendix B: HCPCS Level II Temporary (“K” codes) Coding Revision

Application # or MEARIST™ ID	Temporary Code	Permanent Code	Long Descriptor
19.118	K1001	EXXXX	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
19.117	K1002	EXXXX	Cranial electrotherapy stimulation (ces) system, any type
19.131	K1003	AXXXX	Whirlpool tub, walk-in, portable
19.136	K1005	AXXXX	Disposable collection and storage bag for breast milk, any size, any type, each
20.078	K1006	EXXXX	Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system
20.077	K1009	EXXXX	Speech volume modulation system, any type, including all components and accessories
20.172	K1013	AXXXX	Enema tube, with or without adapter, any type, replacement only, each
20.156	K1014	LXXXX	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
20.159	K1015	LXXXX	Foot, adductus positioning device, adjustable
20.07	K1016	EXXXX	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
20.07 ⁸	K1017	AXXXX	Monthly supplies for use of device coded at EXXXX
20.086	K1018	EXXXX	External upper limb tremor stimulator of the peripheral nerves of the wrist
20.086	K1019	AXXXX	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist
20.173	K1020	EXXXX	Non-invasive vagus nerve stimulator
21.031	K1021	AXXXX	Exsufflation belt, includes all supplies and accessories

⁸ The code language for K1017 currently reads “Monthly supplies for use of device coded at k1016.” This would be updated to reflect the new E code established to replace K1016.

21.053	K1022	LXXXX	Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type
20.033	K1023	AXXXX	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm
21.032	K1024	EXXXX	Non-pneumatic compression controller with sequential calibrated gradient pressure
21.07	K1025	EXXXX	Non-pneumatic sequential compression garment, full arm
20.048	K1026	AXXXX	Mechanical allergen particle barrier/inhalation filter, cream, nasal, topical
HCP210826HY98M	K1028	EXXXX	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application
HCP2108265Y526	K1029	EXXXX	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
HCP210903LPG21	K1031	EXXXX	Non-pneumatic compression controller without calibrated gradient pressure
HCP210903PMKF3	K1032	EXXXX	Non-pneumatic sequential compression garment, full leg
HCP210903WBEG8	K1033	EXXXX	Non-pneumatic sequential compression garment, half leg

Appendix C: 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 code falls under. The pricing indicator codes applicable to DMEPOS.

Pricing = 00 Service Not Separately Priced

Items or services described by the HCPCS 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 = 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).