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 2024 Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda

Zoom Meeting - Remote participation
Thursday, May 30, 2024 9:00 am – 5:00 pm, eastern time (ET)

8:45 am, ET:
• Zoom meeting login:
https://cms.zoomgov.com/s/1605121459
Passcode: 327890
Webinar ID: 160 512 1459
• 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 Thursday, May 30, 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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Preliminary decisions for the HCPCS Virtual Public Meeting on Thursday, May 30, 2024.[1]

[1] Updated on May 16, 2024 to remove IndeeLift® (HCP2311125H5TT) from the agenda, as this application will be reviewed in a subsequent coding cycle.

Agenda Item # 1
Walkasins® Receptor Sole - HCP230630JGDD5

Topic/Issue

Request to establish a new HCPCS Level II code to identify Walkasins® receptor sole.

Applicant's suggested language: LXXXX, “Receptor Sole for use with LXXXX, six-month replacement, each”

Summary of Applicant's Submission

RxFunction, Inc. submitted a request to establish a new HCPCS Level II code to identify Walkasins® receptor sole. Walkasins® receptor sole is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This request is associated with the external lower extremity sensory prosthesis. Walkasins® receptor sole is part of a non-invasive prosthetic device available by prescription for long-term daily use. Walkasins® replaces a part of the lost function of plantar mechanoreceptors, which are internal to the skin. It detects touch and pressure and is an integral part of the integumentary system. Walkasins® is intended for patients with sensory peripheral neuropathy (PN), a condition where plantar mechanoreceptors are permanently inoperative or malfunctioned. Sensory PN leads to uncoordinated balance with unsteady gait and interferes with ambulation, daily activities, and increase risk for falls. Walkasins® detects pressure between the foot and the ground during standing and walking, signaling sensory (afferent) plantar pressure information to the brain that is critical for the subconscious non-voluntary and automatic control of balance and gait function. The Walkasins® system consists of two components per leg: receptor sole and haptic module. Receptor Soles placed in the shoes have embedded sensors that measure foot pressure. Haptic modules worn around the lower leg above the ankle receive and analyze the measured pressure information through a real-time algorithm that runs on a microprocessor, continuously calculating a representation of the instantaneous balance point of the body. At relevant times during standing and walking, the algorithm activates vibratory actuators embedded in the Haptic Module, to provide non-invasive tactile sensory cutaneous stimulation to the lower leg. This stimulation creates new sensory balance stimuli that transmit signals along the same afferent pathways previously served by the plantar mechanoreceptors, thereby replacing part of the lost plantar sensation. The receptor soles worn in shoes receives extensive wear. The sensitivity of the sensors embedded in the soles decline with use. The effectiveness of the system depends on the receptor sole's ability to detect and measure plantar pressure. The receptor sole should be replaced every six months.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, “Receptor sole for use with LXXXX, replacement, each” to describe Walkasins® receptor sole.

Final Medicare Benefit Category Determination

Prosthetic Device.

Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

In the Second Biannual 2023 HCPCS Level II coding cycle CMS made a conditional benefit category determination that the Walkasins® receptor sole is a prosthetic device, pending evidence that the device replaces the permanent inoperative/malfunctioning receptors caused by sensory peripheral neuropathy. In April 2024, the applicant furnished extensive and detailed information regarding the operation of the Walkasins® system. Specifically, it addresses partially replacing the permanent loss of the plantar mechanoreceptor function in individuals diagnosed with sensory peripheral neuropathy (SPN). This is achieved by delivering crucial sensory pressure information to the brain, essential for maintaining gait and balance, through stimulation of a different set of healthy mechanoreceptors above the ankle. Based on the newly provided information and evidence, CMS has concluded that Walkasins® functions as a prosthetic device replacing the part of function of permanently malfunctioning internal body organs, specifically the damaged plantar cutaneous mechanoreceptors within the peripheral nervous system, utilizing healthy mechanoreceptors above the ankle.

Preliminary Medicare Payment Determination

No determination. More time is needed to evaluate and determine how this item is priced under Medicare Part B. The payment determination for this item will be addressed at a subsequent HCPCS public meeting. RxFunction, Inc. has already submitted some payment-related information to CMS to assist in development of a payment determination; however, the applicant is welcome to provide any updated or new information.

Agenda Item # 1
Walkasins® Lower Extremity Sensory Prosthesis – HCP230630P62DH

Topic/Issue

Request to establish a new HCPCS Level II code to identify Walkasins® lower extremity sensory prosthesis.

Applicant's suggested language: LXXXX, "External Lower Extremity Sensory Prosthesis, Cutaneous Stimulation of Mechanoreceptors, Per Leg"

Summary of Applicant's Submission

RxFunction, Inc. submitted a request to establish a new HCPCS Level II code to identify Walkasins® lower extremity sensory prosthesis. Walkasins® lower extremity sensory prosthesis is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Walkasins® lower extremity sensory prosthesis is a non-invasive prosthetic device available by prescription for long-term daily use. Walkasins® replaces a part of the lost function of plantar mechanoreceptors, which are internal to the skin. It detects touch and pressure and is an integral part of the integumentary system. Walkasins® is intended for patients with sensory peripheral neuropathy (PN), a condition where plantar mechanoreceptors are permanently inoperative or malfunctioned. Sensory PN leads to uncoordinated balance with unsteady gait and interferes with ambulation, daily activities, and increase risk for falls. Walkasins® detects pressure between the foot and the ground during standing and walking, signaling sensory (afferent) plantar pressure information to the brain that is critical for the subconscious non-voluntary and automatic control of balance and gait function. The Walkasins® system consists of two components per leg: receptor sole and haptic module. Haptic modules worn around the lower leg above the ankle receive and analyze the measured pressure information through a real-time algorithm that runs on a microprocessor, continuously calculating a representation of the instantaneous balance point of the body. At relevant times during standing and walking, the algorithm activates vibratory actuators embedded in the Haptic Module, to provide non-invasive tactile sensory cutaneous stimulation to the lower leg. This stimulation creates new sensory balance stimuli that transmit signals along the same afferent pathways previously served by the plantar mechanoreceptors, thereby replacing part of the lost plantar sensation.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, "External lower extremity sensory prosthesis, cutaneous stimulation of planter mechanoreceptors, per leg" to describe Walkasins®.

Final Medicare Benefit Category Determination

Prosthetic Device.

Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

In the Second Biannual 2023 HCPCS Level II coding cycle CMS made a conditional benefit category determination that the Walkasins® receptor sole is a prosthetic device, pending evidence that the device replaces the permanent inoperative/malfunctioning receptors caused by sensory peripheral neuropathy. In April 2024, the applicant furnished extensive and detailed information regarding the operation of the Walkasins® system. Specifically, it addresses partially replacing the permanent loss of the plantar mechanoreceptor function in individuals diagnosed with sensory peripheral neuropathy (SPN). This is achieved by delivering crucial sensory pressure information to the brain, essential for maintaining gait and balance, through stimulation of a different set of healthy mechanoreceptors above the ankle. Based on the newly provided information and evidence, CMS has concluded that Walkasins® functions as a prosthetic device replacing the part of function of permanently malfunctioning internal body organs, specifically the damaged plantar cutaneous mechanoreceptors within the peripheral nervous system, utilizing healthy mechanoreceptors above the ankle.

Preliminary Medicare Payment Determination

No determination. More time is needed to evaluate and determine how this item is priced under Medicare Part B. The payment determination for this item will be addressed at a subsequent HCPCS public meeting. RxFunction, Inc. has already submitted some payment-related information to CMS to assist in development of a payment determination; however, the applicant is welcome to provide any updated or new information during the public meeting.

Agenda Item # 2
SurgiLock® Tray - HCP2401023N82N

Topic/Issue

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

Applicant's suggested language: JXXXX, “Surgical Safety Tray; designed to clip onto a metal stand with articulation top and will hold surgical instruments in place during a surgical procedure.”

Summary of Applicant's Submission

Medical Lock Corporation submitted a request to establish a new HCPCS Level II code to identify SurgiLock® Tray. SurgiLock® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). SurgiLock® Tray is a single use, disposable polypropylene plastic tray with adhesive elastomer surface that is designed to clip onto a metal stand to hold sterile instruments in place during surgery. The ElasTak technology creates unprecedented cost savings to the hospitals/payers by providing new efficiencies. SurgiLock® Tray will eliminate several sharps related injuries, therefore needing a J code.

CMS Preliminary HCPCS Coding Recommendation

CMS’ understanding is that SurgiLock® Tray 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.

Agenda Item # 3
SNOO Smart Sleeper - HCP2312290MNL5

Topic/Issue

Request to establish a new HCPCS Level II code to identify the SNOO Smart Sleeper.

Applicant's suggested language: XXXXX, "Infant Supine Sleep System consisting of a powered bed with motion and sound functions that respond to crying and sleep disturbances, 360-degree side enclosures, mattress, attachable swaddle sacks to securely position babies on the back, and a mobile app for sleep analytics and feedback"

Summary of Applicant's Submission

Happiest Baby submitted a request to establish a new HCPCS Level II code to identify the SNOO Smart Sleeper. The SNOO Smart Sleeper received the Food and Drug Administration's (FDA's) De Novo clearance on March 30, 2023. The SNOO Smart Sleeper is a class II medical device for home use by caregivers of infants from birth to 6 months of age, who are not yet able to roll over consistently during sleep. The SNOO Smart Sleeper's bassinet plus the SNOO Sleep Sack are jointly intended to facilitate a supine position during sleep. Infants who are placed in a supine sleep position are at lower risk of sudden infant death syndrome (SIDS) or sudden unexpected infant death (SUID). SNOO Smart Sleeper is used exclusively by infants as an innovative sleep system that provides responsive soothing and a safe sleep environment. The SNOO Smart Sleeper's womb-like sound and motion reduce fussing, excessive crying and infant sleep disruptions. In response to fussing and sleep disruptions, SNOO deploys a unique algorithm to provide incrementally greater sound and motion to calm excessive crying and reduce sleep interruptions. Fussing and excessive crying lead to approximately 20% of pediatric consultations. In addition, many infants experience sleep disruptions in the first 6 months (65% of 3-month-olds wake one or more times per night and 9% wake three or more times per night; more than 50% of 6-month-olds wake one or more times per night, 21% wake three or more times per night). Approximately 3,400 healthy infants in the U.S. die suddenly every year from SIDS and SUID, with no reduction in the last 20 years. The Centers for Disease Control and Prevention (CDC), the National Institutes of Health, the FDA, and the American Academy of Pediatrics (AAP) all note that infants that sleep in a supine position are at lower risk of SIDS/SUID. The SNOO sleep sack has wings that attach to safety clips on the bed's platform to secure sleeping infants in the supine position, this offers the benefits of swaddling (reduced fussing, excessive crying and sleep disruptions) while reducing a baby's ability to roll to an unsafe position. The AAP notes that rolling over while swaddled is associated with a markedly increased risk of SIDS/SUID. SNOO's mobile app adjusts the bed's motion and sound to allow monitoring of crying and sleep and provide daily sleep reports to show progress in reducing crying and sleep disruptions.

CMS Preliminary HCPCS Coding Recommendation

According to the FDA's website[2] as part of the SNOO's evaluation, "the FDA reviewed data comparing the incidence of reported SIDS/SUID in SNOO users to historical CDC SIDS/SUID data. Although this data comparison was not sufficient to determine whether the

[2]"FDA Roundup: March 31, 2023," www.FDA.gov, U.S. Food and Drug Administration. 03/31/2024. https://www.fda.gov/news-events/press-announcements/fda-roundup-march-31-2023

device could prevent SIDS/SUID, the data did demonstrate the device did not increase the risk of SIDS/SUID in the study population. Therefore, the device is not intended to prevent or reduce the risk of SIDS/SUID. At this time, we are not aware of any medical devices that are no infant sleep systems or infant positioners authorized for marketing by the FDA to prevent or reduce the risk of SIDS/SUID."

While CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe an infant supine sleep system, 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[3] # 4
Red Blood Cells, Leukocytes Reduced, Oxygen/Carbon Dioxide Reduced - HCP231002Y5WRL

Topic/Issue

Request to establish a new HCPCS Level II code to identify red blood cells (RBCs), Leukocytes Reduced (LR), O2/CO2 reduced.

Applicant's suggested language: XXXXX, "Red Blood Cells, Leukocytes Reduced, Oxygen/Carbon Dioxide Reduced, Each Unit (RBCs LR, O2/CO2 Reduced, Each Unit)"

Summary of Applicant's Submission

Hemanext Inc. submitted a request to establish a new HCPCS Level II code to identify red blood cells, leukocytes reduced, O2/CO2 reduced. Hemanext's red blood cells, leukocytes reduced, O2/CO2 reduced was approved by the Food and Drug Administration (FDA) under De Novo classification on September 15, 2023. Hemanext's red blood cells, leukocytes reduced, O2/CO2 reduced product is intended for transfusion. Hemanext's ONE® RBC processing and storage system is a standard leukocyte-reduced RBC (LR RBC) product unit processed to reduce oxygen in the RBC storage environment and is packaged in the FDA-authorized Hemanext's Storage Bag (HSB) to maintain RBCs in a hypoxic state over the entire storage period up to 42 days. The three-part HSB comprises an inner oxygen-permeable bag containing the RBCs, an iron-based O2 and CO2 sorbent material, and an outer O2- and CO2-impermeable outer bag. Reduction and strict maintenance of limited oxygen saturation of the RBC storage environment minimizes oxidative damage to the RBCs, known generally as the RBC storage lesion. Similarly to standard LR RBCs, RBCs LR, O2/CO2 reduced are intravenously transfused to restore and maintain oxygen delivery to body tissues and vital organs of any patient experiencing acute or chronic anemia who requires RBC transfusion in the judgment of the attending physician. The unit dosage of RBCs, LR, O2/CO2 reduced is based on the extent of the individual patient's acute or chronic anemia and clinical status.

CMS Preliminary HCPCS Coding Recommendation

The applicant made a claim for clinical therapeutic distinction compared to standard leukocyte reduced RBCs, currently coded under HCPCS Level II code P9016, "Red blood cells, leukocytes reduced, each unit." The applicant submitted clinical studies designed to evaluate biochemical, morphological and functional oxidative damage as compared to standard LR RBCs in animals. CMS believes that the applicant did not provide adequate support for the claim of significant therapeutic distinction for the storage and processing of RBCs up to 42 days that would result in a unique HCPCS Level II code. Red blood cells, leukocytes reduced, O2/CO2 is used in facility settings during procedures reported using a HCPCS Level I Current Procedural Terminology (CPT®) code. We have not identified a specific need for this device to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

[3] Revised on May 16, 2024 to include Red Blood Cells in the title of the agenda item.

Agenda Item # 5
Steripath® Gen2 Blood Collection System - HCP24010208L4M

Topic/Issue

Request to establish a new HCPCS Level II code to identify Steripath® Gen2 Blood Collection System.

Applicant's suggested language: PXXXX, "Specimen collection for blood culture using a pre-assembled, disposable, and integrated sterile device with active initial blood sample diversion and sequestration (>0.5mL), each collection site"

Summary of Applicant's Submission

Magnolia Medical Technologies Inc. submitted a request to establish a new HCPCS Level II code to identify Steripath® Gen2 Blood Collection System. Steripath® Gen2 Blood Collection System was approved by the Food and Drug Administration (FDA) under the 510(k) pathway on February 28, 2020. Steripath® Gen2 Blood Collection System service includes a blood draw from a patient with signs or symptoms of a potential bloodstream infection that may progress to sepsis. The service also includes the use of a specialized device that is a blood collection system that diverts and sequesters an initial aliquot of the blood draw to ensure a clean subsequent blood sample is inoculated into the blood culture bottles. The system is intended to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion. The devices include the Steripath® family of products (commercialized under the trade names Steripath® Gen2 Blood Collection System and Steripath® Micro Blood Collection System).

CMS Preliminary HCPCS Coding Recommendation

The Steripath® Gen2 Blood Collection System is not suitable for inclusion in the HCPCS Level II code set because it is used during blood collection and certain items are considered bundled into the facility payment. We have not identified a specific need for this Steripath® Gen2 Blood Collection System to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 6
VasQ™ - HCP2312298HHUR

Topic/Issue

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

Applicant's suggested language: CXXXX, "External support device for arteriovenous-fistula"

Summary of Applicant's Submission

Laminate Medical Inc. submitted a request to establish a new HCPCS Level II code to identify VasQ™. VasQ™ was granted De Novo clearance as a class II device by the Food and Drug Administration (FDA) on September 26, 2023. VasQ™ is a permanently implanted device intended to provide extravascular support for upper extremity arteriovenous fistulas created for vascular access by means of vascular surgery. VasQ™ is supplied in a sterile package as a single-use device for surgical implantation in persons who need renal dialysis. Vascular surgeons have asked for a code that their facilities can use to identify arteriovenous fistula procedures when the VasQ™ device is implanted.

CMS Preliminary HCPCS Coding Recommendation

VasQ™ can be utilized in various anatomic areas including cephalic, basilic and forearm vein arteriovenous anastomosis transpositions as described by HCPCS Level I, Current Procedural Terminology (CPT®) codes, including but not limited to, 36818, 36819, 36820, and Cimino-type brachial artery to cephalic vein arteriovenous anastomosis (CPT® code 36821). It is our understanding that VasQ™ is not suitable for coding in the HCPCS Level II code set because it is used in facility settings during procedures reported using HCPCS Level I CPT® codes. We have not identified a specific need for this device to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 7
Volara™ System - HCP231218VF0N3

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Volara™ System.

Applicant's suggested language: XXXXX, "Multi-function oscillation and lung expansion airway clearance device, performs functions of continuous positive expiratory pressure, continuous high frequency oscillation, and nebulization, and supports delivery of supplemental oxygen"

Summary of Applicant's Submission

Baxter submitted a request to establish a new HCPCS Level II code to identify the Volara™ System. The Volara™ System received the Food and Drug Administration's (FDA's) 510(k) clearance for home use on January 20, 2020. The Volara™ System is a multi-function airway clearance device that provides oscillation and lung expansion (OLE) therapy, delivering three therapies, continuous positive expiratory pressure (CPEP), continuous high frequency oscillation (CHFO) and nebulization, in one integrated product. The CPEP function treats and helps prevent pulmonary atelectasis by delivering continuous positive pressure to help expand and hold the airways open. When delivering CPEP therapy, the device provides continuous positive pressure to the patient's airway opening regions of the lung that are otherwise closed off during tidal volume breathing. In addition, CPEP helps mobilize peripheral lung secretions into the larger airways and contributes to resolving atelectasis by preventing airway collapse during expiration. The CHFO function delivers continuous pulses of positive pressure. These pulsations shear or break down the mucus, loosen the mucus from the walls of the peripheral airways, and use the airflow to mobilize the mucus toward the central airways. CHFO is a form of chest physiotherapy that provides oscillating airflow to the airways by mouthpiece or mask. Nebulizer function allows for delivery of medication and/or delivery of saline to provide humidification and facilitate airway clearance. The aerosol and nebulizer function can be delivered concurrently with CPEP and CHFO for treatment efficiency or deliver nebulized medication as a stand-alone function. The supplemental oxygen capability supports delivery of oxygen during OLE therapy for patients who dependent on the oxygen. The Volara™ System utilizes a platform from which both CPEP and CHFO can be administered during alternating periods in a single treatment session. The treatments are provided in cycles with alternating intervals of 2.5 minutes of CPEP to open the airways and 2.5 minutes of CHFO to create airflow within the lungs to move retained secretions. Caregivers have the option of adjusting the duration of each interval based on physician's order.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code XXXXX, "Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device" to describe the Volara™ System.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The Volara™ device meets the requirements to be classified as DME.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238, fee schedule amounts for new HCPCS Level II 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. As a result, the preliminary pricing methodology for new HCPCS Level II code EXXXX is to use the existing fee schedule amounts for comparable items described by HCPCS Level II code E0483 (“High frequency chest wall oscillation system, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each”) for the continuous high frequency oscillation function, with additional amounts based on HCPCS Level II code E0482 ("Cough stimulating device, alternating positive and negative airway pressure") and HCPCS Level II code E0570 ("Nebulizer, with compressor") to account for the continuous positive expiratory pressure and nebulizer functions of the device.

CMS has compared the three HCPCS Level II codes to Volara™ as shown in the below comparability table. Volara™ provides three functions in one integrated device: continuous positive expiratory pressure, continuous high frequency oscillation, and nebulization. HCPCS Level II codes E0482, E0483, and E0570 describing the three separate functions of the integrated device are found to be comparable to the Volara™ with respect to physical, mechanical, and electrical components, and function and intended use.

	Volara™	**E0482**	**E0483**	**E0570**
Physical Components	Control Unit Three Therapy ports (Continuous Positive Expiratory Pressure (CPEP), Continuous High Frequency Oscillation	Control Unit One therapy port: Continuous Positive Expiratory Pressure (CPEP)	Control Unit One therapy port: High Frequency Chest Wall Oscillation (HFCWO)	Control Unit One therapy port: Nebulizer

	Volara™	E0482	E0483	E0570
	(CHFO), and Nebulizer Air Filter, Breathing Tube, Nebulizer kit, Mouthpiece, Face Mask	Air Filter, Breathing Tube	Valves, Pistons, Pads	Air Filter, Tubing + Mouthpiece, Nebulizer Chamber
Mechanical Components	Utilizes Automatic Program	Utilizes Automatic and Manual Program	Utilizes Manual Program	Utilizes Automatic Program
Electrical Components	Replaceable Battery	AC Adapter	Rechargeable Battery	AC Adapter
Function and Intended Use	Triple therapy in one: secretion clearance, lung expansion, and nebulizer treatment. It benefits cystic fibrosis, neuromuscular, and bronchiectasis patients.	Lung expansion Treatment It benefits patients with muscle weakness in neurological conditions such as muscular dystrophies and spinal cord lesions	Secretion Clearance therapy It benefits patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging	Breaking the liquid medication into breathable mist or aerosol It benefits patients where inhaled medicines are indicated such as asthma and Chronic Obstructive Pulmonary Disease (COPD)
Additional Aspects and Features	Single Patient Use 10 min therapy Maximum of 90 treatment sessions Features a WiFi module to export system and therapy data	Multiple Patient Use Ranging from 6 to 1200 breaths per minute.	Multiple Patient Use Connected through Mobile App as an option	Multiple Patient Use Can be Ultrasonic or Electronic

As described above, the preliminary payment determination is to use the pricing for HCPCS Level II code E0483 to account for the continuous high frequency oscillation function and additional amounts to recognize the device's continuous positive expiratory pressure and nebulizer functions using HCPCS Level II codes E0482 and E0570 respectively. We believe the additional cost of the continuous positive expiratory pressure function can be accounted for by dividing the rental fee of HCPCS Level II code E0482 ("Cough stimulating device, alternating positive and negative airway pressure") by two to recognize only the positive pressure since HCPCS Level II code E0482 devices provide both positive and negative pressure. Secondly, we would compute the purchase price of HCPCS Level II code E0482 by multiplying the rental amount by 10 and then dividing that amount by 60 in order to get the cost of the continuous positive expiratory pressure feature added to the device over the course of the five-year reasonable useful lifetime. Similarly, we believe the additional cost of the nebulizer function can be accounted for by calculating the purchase price of HCPCS Level II code E0570 ("Nebulizer, with compressor") by multiplying the rental amount by 10 and then dividing that amount by 60 to obtain the cost of the added function over the device's five-year reasonable useful lifetime.

Therefore, the preliminary payment determination for HCPCS Level II code EXXXX using comparable items is calculated using the following formula: EXXXX= E0483 + ((E0482/2)*10/60) + (E0570*10/60). The 2024 average non-rural capped rental fee schedule amount for HCPCS Level II code EXXXX would be approximately $1,505.16 for months 1 through 3 and approximately $1,128.90 for months 4 through 13.

Pricing Indicator = 36

Agenda Item # 7
Volara™ System Supply Kit - HCP231218VBVAD

Topic/Issue

Request to establish a new HCPCS Level II code to identify disposable supply kit for the Volara™ System.

Applicant's suggested language: XXXXX, "Disposable supply kit for multi-function oscillation and lung expansion airway clearance device, includes but not limited to handset, nebulizer kit, biofilter, adapters, and hose"

Summary of Applicant's Submission

Baxter submitted a request to establish a new HCPCS Level II code to identify disposable supply kit used with the Volara™ System. Volara™ System received the Food and Drug Administration's (FDA's) 510(k) clearance for home use on January 20, 2020. The supply kit is an integral part of the system, required for the patient to receive the therapy. The components in the supply kit connect to the Volara™ System to deliver the oscillation and lung expansion therapy. It has the following components: biofilter, nebulizer kit, handset, hose, and adapters. Biofilter is used as a barrier between patient and device to reduce chance for bioburden contamination. This filter is used for 90 therapy sessions and automatically alerts the patient when a new filter and supply kit are required. Nebulizer kit including nebulizer cup and tubing, transfers pressurized air from device nebulizer port to the nebulizer cup for the nebulization process to occur. Handset serves as the central connection point for the supply kit components and is the ergonomic means for the patient or caregiver to administer therapy. Hose is conduit for therapy air from device therapy port to the patient handset. Adapters allow for different configurations or setups of the supply kit based on the individual patient's clinical needs. The Volara™ System supply kit is configurable via various adapters to adjust to the patient's clinical needs.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code XXXXX, "Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)" to describe the disposable supply kit for the Volara™ System.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The Volara™ supply kit serves as a DME accessory to the durable Volara™ device. The single patient use supply kit is intended for 30 days of treatment or a maximum of 90 treatment session. Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03) indicates that payment may be made for supplies and accessories that are necessary for the effective use of durable medical equipment. Because the Volara™ supply kit is an accessory to an item of DME, the supply kit falls under the DME benefit category.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238, fee schedule amounts for new HCPCS Level II 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. As a result, the preliminary pricing methodology for new HCPCS Level II code AXXXX is to use the existing fee schedule amounts for comparable items described by HCPCS Level II code A7030 ("Full face mask used with positive airway pressure device, each"), HCPCS Level II code A7003 ("Administration set, with small volume nonfiltered pneumatic nebulizer, disposable"), HCPCS Level II code A7004 ("Small volume nonfiltered pneumatic nebulizer, disposable"), HCPCS Level II code A7037 ("Tubing used with positive airway pressure device") and HCPCS Level II code A7039 ("Filter, non disposable, used with positive airway pressure device") to describe the components of the Volara™ supply kit.

CMS has compared the five HCPCS Level II codes to the components of the Volara™ supply kit as shown in the below comparability tables. HCPCS Level II code A7030 describes the Volara™ mask and HCPCS Level II codes A7003 and A7004 recognize the Volara™ handset, mouthpiece, nebulizer cup and tubing. The Volara™ breathing tube and tracheostomy adaptor is described by comparable HCPCS Level II code A7037 and the Volara™ biofilter by HCPCS Level II code A7039. We believe HCPCS Level II codes A7030, A7003, A7004, A7037 and A7039 describe the components of the Volara™ supply kit and are comparable with respect to the physical and mechanical components, function and in the additional aspects and features.

	Volara™ Face Mask	**A7030**
Physical Components	Mask	Mask
Mechanical Components	Contains Silicone	Contains Silicone
Electrical Components	NA	NA
Function and Intended Use	It covers the mouth and nose of the patient tightly. Use is Optional in the Volara™ system	It covers the mouth and nose of the patient tightly. It is used with CPAP ventilation system
Additional Aspects and Features	The narrow end of the mask is over the patient's nose 15mm Outer Diameter (OD) (infant) or 22mm of Internal Diameter (ID) (Adult) Comes in regular or inflatable Single Patient Use	The narrow end of the mask is over the patient's nose 15mm Outer Diameter (OD) (infant) or 22mm of Internal Diameter (ID) (Adult) Comes in small, medium, and large Reusable or Single Patient use

	Volara™ Nebulizer Kit	A7003	A7004
Physical Components	Nebulizer Cup Nebulizer Tube	Nebulizer Cup Nebulizer Tube	Nebulizer Cup
Mechanical Components	Capacity: 2-10 ml	Capacity: 0.2 ml	Capacity: 0.2 ml
Electrical Components	NA	NA	NA
Function and Intended Use	It is designed to aerosolize medication approved for nebulization and prescribed by a physician. A fill volume of 2.5 ml of medication is expected to last 10 minutes of nebulization.	It is intended for use in the treatment of upper and lower respiratory tract illnesses where aerosolized medication is required. A fill volume of 0.2 ml of medication is expected to last 1 minute of nebulization.	It is intended for use in the treatment of upper and lower respiratory tract illnesses where aerosolized medication is required. A fill volume of 10 ml of medication is expected to last 6-8 minutes of nebulization.
Additional Aspects and Features	Single Use Includes connection for in-line nebulization filter	Single Use (disposable)	Single Use (disposable)

	Volara™ Tubing	A7037
Physical Components	Endotracheal tube or tracheostomy tube.	Endotracheal tube or tracheostomy tube.
Mechanical Components	22 mm x 20 mm adapter	22mm male fitting connectors
Electrical Components	NA	NA
Function and Intended Use	Used in Volara™ System	Used in CPAP system
Additional Aspects and Features		

	Volara™ Bio-Filter	A7039
Physical Components	Connector, Filter, Port	Connector, Filter, Port
Mechanical Components	Poly Propylene Housing Material	Poly Propylene Housing Material Contains Foam
Electrical Components	NA	NA

	Volara™ Bio-Filter	A7039
Function and Intended Use	Used in Volara™ System Attached to the breathing hose	Used in CPAP or BIPAP system Attached to the breathing hose
Additional Aspects and Features	The biofilter has a filtration efficiency of greater than 99% or penetration of less than 1%	The biofilter has a filtration efficiency of greater than 99% or penetration of less than 1%

As described above, the preliminary payment determination is to use the pricing for HCPCS Level II codes A7030, A7003, A7004, A7037 and A7039 to describe the various components of the Volara™ supply kit. We believe that these codes represent the characteristics of the Volara™ supply kit and when the comparable code fees are summed, can be used to establish the fee schedule amounts for new supply HCPCS Level II code AXXXX. Payment for the supply kit would be established by summing the individual fee schedules for the following HCPCS Level II codes: A7030, A7003, A7004, A7037 and A7039.

Therefore, the preliminary payment determination for HCPCS Level II code AXXXX using comparable items is calculated using the following formula: AXXXX = A7030 + A7003 +A7004 +A7037+A7039. The average 2024 non-rural fee schedule amount for code AXXXX would be approximately $137.34.

Pricing Indicator = 34

Agenda Item # 8
TheraBionic® P1 - HCP240102U225T

Topic/Issue

Request to establish a new HCPCS Level II Code to identify TheraBionic® P1.

Applicant's suggested language: EXXXX, "Systemic delivery of amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment"

Summary of Applicant's Submission

TheraBionic, Inc. submitted a request to establish a new HCPCS Level II code to identify the TheraBionic® P1. The TheraBionic® P1 was granted humanitarian device exemption (HDE) as a humanitarian use device (HUD) by the Food and Drug Administration (FDA) on September 26, 2023. The TheraBionic® P1 is intended for use in adults with advanced hepatocellular cancer who have failed first and second-line therapy. The TheraBionic® P1 is a portable battery-driven generator coupled with a spoon shaped antenna placed in the patient's mouth to deliver systemic low-level amplitude-modulated radiofrequency electromagnetic fields for tumor-specific treatment of advanced hepatocellular cancer. Each treatment episode lasts 28 days and consists of one-hour sessions three times per day at home by the patient until progression of malignancy is documented. The TheraBionic® P1 does not fit the existing HCPCS Level II code E0766 ("Electrical stimulation device used for cancer treatment, includes all accessories, any type") because the code has been associated in clinical practice guidelines and payer policies with other home-use devices that deliver localized tumor treatment fields via electrodes applied to the skin (scalp or chest) for the treatment of glioblastoma or mesothelioma. The TheraBionic® P1 also does not fit HCPCS Level II code E0761 ("Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device") because the TheraBionic® P1 does not deliver high peak power or pulsed electromagnetic energy.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code EXXXX, "Intrabuccal, systemic delivery of amplitude-modulated, low-level radiofrequency electromagnetic field device, for cancer treatment, includes all accessories" to describe TheraBionic® P1.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

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

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

5. Is appropriate for use in the home.

The TheraBionic® P1 device meets all five of the conditions that must be met in order for equipment to be classified as DME.

Preliminary Medicare Payment Determination

No determination.

As this device is marketed under an HDE (Humanitarian Device Exemption), there are specific rules laid out in the Food and Drug Administration Amendments Act of 2007 that may impact the establishment of a national Medicare payment amount. Specifically, only certain devices with HDE approval may be sold at a profit, and that profit is limited to a certain quantity based on the Annual Distribution Number established by the FDA as part of the HDE process. Therefore, we are consulting with the Food and Drug Administration to determine whether this statute would impact a Medicare payment determination.

Pricing Indicator = 46

Agenda Item # 9
medibottle - HCP240102C0A2T

Topic/Issue

Request for a new HCPCS Level II code to identify the medibottle.

Applicant's suggested language: XXXXX, “Liquid Oral Medication Delivery Device”

Summary of Applicant's Submission

The Medicine Bottle Company Inc. submitted a request is for a new HCPCS Level II code to identify the medibottle®. The medibottle®, Pediatric Medication Delivery System, is exempt from the Food and Drug Administration’s (FDA’s) review and classification. The medibottle® is designed and engineered to deliver an accurate dose of oral, liquid medication to the infant population. From the infant’s perspective, medibottle® appears to be a regular baby bottle. This is helpful because the process begins with something that they are familiar with and helps them get and stay comfortable throughout the administration of the dose. The bottle portion of the device is filled like a regular baby bottle and a preferred nipple is attached. The oral dispenser is filled with the prescribed medicine. The caregiver then inserts the oral dispenser into the sleeve, ready to begin the sip and squirt process. Incorporating fluid dynamic principles, the medicine is transported from the oral dispenser to the tip of the nipple without using any physical structure and remains essentially undiluted. The medibottle® utilizes the infant’s natural desire to take in the familiar liquid. Because the infant controls the flow, the medicine is delivered to the ideal position in the mouth for swallowing, also minimizing the residence time which in turn minimizes the chance for the infant to sense the medicine. The medibottle® is essentially a masking device–delivering the intended dose, undiluted and undetected. Peer-reviewed data state that compliance is a pediatrician’s most important concern and non-compliance to medication regimes directly and adversely affects the health of the infant population. Independent clinical trials conducted both inpatient and outpatient, have proven that the medibottle® device offers a significant therapeutic distinction. From an effectiveness standpoint, the medibottle® measured 93% or better versus the second-place oral dispensers failing 57%. This must be considered a significant therapeutic distinction, and it translates into higher quality and safer care for the infant population. If the infant cannot taste the medicine, then there is nothing to resist. Although not the objective, the infant’s acceptance level is also 329% greater than that of the oral dispenser. When implemented with a bad tasting medicine, the disparity between the oral dispenser and medibottle® widens further. Increasing compliance to equal or approaching 100% was the primary objective. Also, the device eliminates the trauma and upset that are often a part of the process for both infant and caregiver.

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 masking device intended to deliver an accurate dose of oral, liquid medication to an infant population. We welcome information from the applicant and other insurers who are currently paying for this product or any oral medication delivery products to demonstrate a claims processing need for a unique HCPCS Level II code.

Agenda Item # 10
Sea-Long Medical Systems 5000 Series- HCP231025TT2K6

Topic/Issue

Request to establish a new HCPCS Level II code to identify Sea-Long Medical Systems 5000 Series.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Sea-Long Medical Systems LLC submitted a request to establish a new HCPCS Level II code to identify the 5000 Series Helmet and Neckseal Set that is to be used during hyperbaric treatments. The 5000 Series Helmet and Neckseal Set was approved by the Food and Drug Administration (FDA) on August 13, 1991. The sets are for single or multiple patient use. The helmet is connected to an oxygen line or tubing that will provide oxygen during treatments in a clinic or hospital setting. The closest HCPCS Level II code is A4620 ("Variable concentration mask") which is for a mask; however, the 5000 Series Helmet is classified as a helmet. The indications of use are based on the guidelines that the FDA has put into place under K010659 that the treatment hood is intended to be used in any place that a clinician normally uses a mask for medical purposes of supplying gas, oxygen, or air. The treatment hood is connected to gas, oxygen, or air supply. The 5000 Series Helmet and Neckseal Set is prescription use only. The dosage is one helmet per patient. The helmet is put onto the patient's head to receive treatment. The item is packaged into individual bags.

CMS Preliminary HCPCS Coding Recommendation

CMS believes that Sea-Long Medical Systems 5000 Series is not suitable for coding in the HCPCS Level II code set as it is our understanding that the item is used by a clinician during a procedure that would be typically described by a HCPCS Level I Current Procedural Terminology (CPT®) code. CMS encourages the applicant to engage with the American Medical Association about potential HCPCS Level I CPT® coding.

Agenda Item # 11
POGO Automatic® Test Cartridges - HCP2306306L0YM

Topic/Issue

Request to establish a new HCPCS Level II code to identify POGO Automatic® Test Cartridges.

Applicant's suggested language: XXXXX, "Test Cartridge with Automated Blood Sampling, 50 tests"

Summary of Applicant's Submission

Intuity Medical submitted a request to establish a new HCPCS Level II code to identify the POGO Automatic® Test Cartridges, which are supplies used with the POGO Automatic® Blood Glucose Monitoring System (ABGMS). POGO Automatic® Blood Glucose Monitoring System received the Food and Drug Administration's (FDA's) 510(k) clearance on May 18, 2018. POGO ABGMS is currently classified by the Medicare Contractor for Pricing, Data Analysis and Coding (PDAC) as E2101, "Blood glucose monitor with integrated lancing/blood sample." Previously, the POGO Automatic® Test Cartridges were classified by the PDAC as A4253, "Blood glucose/reagent strips, per 50 strips" and A4259, "Lancets per box of 100." However, the POGO ABGMS does not use test strips and lancets. It is not possible for a consumer to insert or use traditional test strips and lancets as supplies for the POGO ABGMS, nor is it possible for suppliers to provide the POGO Automatic® Test Cartridge in quantities associated with the traditional test strip and lancet codes. The test cartridge used to perform the glucose measurement in the POGO ABGMS is significantly different from and not interchangeable with traditional strips and lancets used in existing blood glucose monitor (BGM) systems, all of which are generally similar in design and construction. POGO was given FDA clearance with the product name "POGO Automatic®" because it automates multiple procedural steps in the glucose testing process that must be done manually using a traditional BGM system. Each POGO test is a miniaturized blood acquisition and analysis unit called a "microanalyzer"; the user loads an easy-to-handle foil sealed cartridge containing ten tests into the POGO monitor rather than handling the test strips, lancets, and lancing device necessary to perform a traditional BGM test. The microanalyzer performs the finger prick, acquires the blood sample, transports the blood sample to the reaction zone which then provides an optical signal proportional to the glucose level in the sample, positions the reaction zone at the correct location to allow the monitor optical system to calculate a glucose value, all while the user rests their finger on the test area of the POGO monitor. The design of this cartridge integrates the lancing and testing functions in the cartridge and is not similar to the separate design and function of a solid lancet and a test strip. Because these features present a distinction from the test strips and lancets used in traditional BGM systems, the payment assigned to a new code for the POGO Automatic® Test Cartridge is also requested to be gap-filled rather than cross walked from the payment amount assigned to a BGM test strip and lancet.

CMS Preliminary/Final HCPCS Coding Decision

CMS established a new HCPCS Level II code A4271, "Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month" to describe POGO Automatic® Test Cartridges, effective April 1, 2024. However, CMS has been made aware

of a claims processing need on behalf of Medicare to revise the current code language. The descriptor language "per month" insinuates an allowance versus a set quantity. This language was causing providers to refer to our final coding determination in order to understand the code (i.e., descriptors should be stand-alone). As such, we recommend to:

Revise existing HCPCS Level II code A4271, "Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month" to instead read to "Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per 50 tests" to describe POGO Automatic® Test Cartridges.

Final Benefit Category Determination

CMS determined that the POGO Automatic® Test Cartridges are supplies used with Durable Medical Equipment, effective April 1, 2024.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS Level II code A4271 went into effect on April 1, 2024, and were established based on supplies for 100 tests. They will therefore be revised so they are based on supplies for 50 tests. Two units of HCPCS Level II code A4271 would be used to bill for supplies for 100 tests.

Agenda Item # 12
Technegas® Aerosol - HCP230930XY3C1

Topic/Issue

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

Applicant's suggested language: AXXXX, "Technetium Tc 99m-labeled carbon inhalation aerosol, diagnostic, per study dose, up to 27 mCi"

Summary of Applicant's Submission

Cyclomedica Australia Pty. Ltd. submitted a request to establish a new HCPCS Level II code to identify Technegas® Aerosol. Technegas®, a drug/device combination kit for the preparation of Technegas® Aerosol, was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on September 29, 2023. Technegas® Aerosol is a diagnostic radiopharmaceutical drug composed of hydrophobic nanometer size particles of carbon labeled with Technetium-99m (Tc 99m) dispersed in high-purity argon gas as an aerosol for inhalation. Technegas® Aerosol is indicated for use in adults and pediatric patients aged six years or older for visualization of pulmonary ventilation and evaluation of pulmonary embolism when paired with perfusion imaging. Technegas® Aerosol is prepared using the TECHNEGAS® kit containing the Technegas® Crucible, a 1.25 gram single-use graphite carbon crucible. The Technegas® Plus System is an automated module used to prepare and administer Technegas® Aerosol in argon gas from the supplied Technegas® Crucible and the user supplied sodium pertechnetate Tc 99m injection, United States Pharmacopeia (USP). Upon addition of sodium pertechnetate Tc 99m injection, USP to the Technegas® Crucible, the Technegas® Plus System provides Technegas® Aerosol for oral inhalation. For adult patients, the recommended activity of sodium pertechnetate Tc 99m injection to be loaded in the Technegas® Crucible is 10.8 to 27 millicuries (mCi) to achieve a lung count rate between 1,500 and 2,500 counts per second (cps) at the end of the last respiration. For pediatric patients aged six years and older, a sufficient amount of Technegas® Aerosol should be inhaled to achieve between 500 cps and 1,000 cps at the end of the last respiration. Technegas® Aerosol should be administered as soon as possible following preparation, and inhalation should be completed within ten minutes of preparation. Technegas® Aerosol is administered to the patient by oral inhalation using the Technegas® Patient Administration Set, a single-use radionuclide rebreathing device for Technegas® Aerosol that connects directly to the Technegas® Plus System.

CMS Final HCPCS Coding Determination

According to the FDA approved labelling, the Technegas® Aerosol kit includes five blister packs of ten single-use Technegas® Crucibles. According to the applicant, the 50 patient administration sets included in the kit are provided at no additional charge as necessary delivery devices for the drug product, and must be used for the inhalation of Technegas® Aerosol. The existing HCPCS Level II code A9512, "Technetium tc-99m pertechnetate, diagnostic, per millicurie" is not intended to be billed for Technegas® Aerosol. Instead, each single-use Technegas® Crucible and single-use Technegas® Patient Administration Set used in a lung ventilation imaging procedure is intended to be billed with the requested HCPCS Level II code for the Technegas® Aerosol. Therefore, CMS' final coding decision is to:

Establish a new HCPCS Level II code A9506, “Graphite crucible for preparation of technetium tc 99m-labeled carbon aerosol, each” to describe Technegas® Aerosol.

Effective July 1, 2024.

We are requesting public comment on the language in the code descriptor for this new HCPCS Level II code.

Agenda Item # 13
Ranitidine - IHC240125QF8N0

Topic/Issue

Request to discontinue an existing HCPCS Level II code J2780, “Injection, ranitidine hydrochloride, 25 mg.”

Summary of Applicant's Submission

CMS has reviewed the deletion of an existing HCPCS Level II code J2780, “Injection, ranitidine hydrochloride, 25 mg.” HCPCS Level II code J2780 is no longer used because on April 1, 2020, the Food and Drug Administration (FDA) requested all manufacturers to withdraw all products containing ranitidine from the market. The FDA’s Orange Book currently lists all injectable formulations of ranitidine as discontinued from the market.

CMS Final HCPCS Coding Determination

CMS published a final determination for the first quarterly HCPCS coding cycle of 2024 on April 2, 2024 to discontinue existing HCPCS Level II code J2780, “Injection, ranitidine hydrochloride, 25 mg” effective July 1, 2024. Consistent with our usual practice to discontinue a code, we welcome information from other insurers who are currently paying for this product.

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.