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 2022 Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda

Zoom Meeting, for remote participation
Wednesday, June 8, 2022 9:00 am – 5:00 pm, eastern daylight time (e.d.t)

8:45 am, e.d.t:
• Zoom meeting login:
https://cms.zoomgov.com/meeting/register/vJIsd-mgpz4jEvObPtTKB0-BGiFBQ80CuHQ
• Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

9:00 am, e.d.t:
• Welcome
• Background and purpose of meeting
• Meeting format and ground rules

On December 21, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that establishes procedures for making benefit category determinations and payment determinations for new DMEPOS items and services under Medicare Part B. The final rule is available on CMS.gov: https://www.cms.gov/medicare/durable-medical-equipment-prostheticsorthotics-and-supplies-fee-schedule/dmepos-federal-regulations-and-notices. This new process will be used to address the benefit category and payment status of codes added to the HCPCS from 2020 through 2022 as well as new items in 2022 and future years.

The HCPCS day one and day two agenda provide preliminary benefit and payment decisions for items and services described by new codes created before the rule was effective from January 2020 through April 2022. In addition, the agenda for these two days includes continuous glucose monitor and related supplies and accessories coding and payment determinations and additional items added by CMS to address Medicare benefit category or payment determinations.

Provided for each agenda item is a written overview of the applicant's request, CMS' final coding determination, 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 stakeholders and interested parties to provide additional input related to the preliminary benefit category and payment determinations and requests to modify the HCPCS code set, where applicable. Final decisions are not made at the public meeting. CMS' final benefit category and payment decisions will be published on CMS' HCPCS website at:

https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelII-Coding-Decisions-Narrative-Summary around September 2022 and will be effective October 1, 2022, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Wednesday, June 8, 2022. 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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This is the CMS HCPCS Virtual Public Meeting agenda for Wednesday, June 8, 2022.

Agenda Item # 1

Alpha-Stim® Cranial Electrotherapy Stimulation – 19.117

Topic

Medicare Benefit Category and Payment Determination for Alpha-Stim® Cranial Electrotherapy Stimulation.

Temporary HCPCS code: K1002 "Cranial electrotherapy stimulation (ces) system, includes all supplies and accessories, any type."

Applicant's Summary

According to information submitted by Electromedical Products International, Inc., the Alpha-Stim® Cranial Electrotherapy Stimulation (CES) device utilizes a microcurrent to deliver proprietary low-level electrical signals and applied trans cranially. The device is intended to treat insomnia, depression, anxiety, and pain. The device consists of an electric pulse generator operated with two AAA batteries, and patient connect hardware which consist of ear clip electrodes and an electro conductive solution for moistening the electrodes to assure good electrical contract through the skin. The device transmits the waveform through small clips attached to the ear lobes sending a microcurrent through the brain, modulating specific groups of nerve cells. The Alpha-Stim® CES has a pulsed, rectangular wave form and frequency range up to 100 Hz. The Alpha-Stim® CES device may be used as an adjunct or replacement to medication and/or physiotherapy. The stimulator lasts 5-years, ear clips 1-year, conducting solution 1 month, and the ear clip electrode pads are one-time use.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1002 effective January 1, 2020, "Cranial electrotherapy stimulation (ces) system, includes all supplies and accessories, any type."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets 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 information for the Alpha-Stim® Cranial Electrotherapy Stimulation (CES) was reviewed extensively and supports the preliminary durable medical equipment benefit category determination. As explained in more detail below, Medicare makes payment under the existing DME fee schedule for durable electrical stimulation devices used primarily and customarily for medical purposes and this device is comparable to these other electrical stimulation devices.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238(b) regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history, the fee schedule amounts for code K1002 for this particular electrical stimulation device would be established using the existing fee schedule amounts for comparable items (electrical stimulation devices) described by HCPCS code E0720.

Electrical nerve stimulation uses electrical current to activate or decrease activity of nerves to achieve a specific result to the body. The Alpha-Stim® Cranial Electrotherapy Stimulation and devices under E0720 are external, non-invasive electrical nerve stimulation devices that utilize electrodes placed on the skin for delivery of electrical stimulation. Devices under E0720 have a range of intensity, frequency, pulse width, adjustable or fixed, waveform, and treatment times which the Alpha-Stim® Cranial Electrotherapy Stimulation device is comparable to.

	E0720	**Alpha-Stim® CES**
Physical Components	-Electrodes (quantity can vary) -Stimulator	-Electrode -Stimulator
Mechanical Components		
Electrical Components	-Variable frequency range, commonly less than 200 Hz -Could have adjustable frequency by the patient -Multiple wave patterns available (direct, alternating, or pulsed), (square, sine) -Pulsed, burst or continuous treatment -Has an anode and cathode electrode -Usually has a battery or could be rechargeable	-Frequency up to 100 Hz -Battery operated -Rectangular wave -Pulsed treatment
Function and Intended Use	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves	-Provides electrical stimulation using skin surface electrodes

	-Can be placed almost any location on the body -Typical indication is to treat pain -Commonly stimulates peripheral nerves	which has the intention of stimulating nerves -Worn on behind the ear -Indication to treat insomnia, depression, anxiety, and pain -Stimulates various nerves
Additional Aspects and Features	-Non-invasive -Self-administered -Time worn can vary	-Non-invasive -Self-administered -20 to 60-minute session

CMS recognizes the new indications through our preliminary valuation to compare the technology to E0720 devices prior to competitive bidding, when devices to treat a range of conditions like insomnia, depression, anxiety, and pain were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for K1002 using fees for E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program. Based on this preliminary determination, the average 2022 fee schedule amount for K1002 would be based on the unadjusted purchase fee schedule amounts for E0720 of approximately $429 on average. Since the purchase price for this item are more than $150, payment for this device would be made on a capped rental basis in accordance with 42 CFR §414.229, with the capped rental fee schedule amounts for months 1 thru 3 based on 10 percent of the purchase price or approximately $42.90 on average. The capped rental fee schedule amounts for months 4 thru 13 based on 7.5 percent of the purchase price or approximately $32.17 on average. Total payments after 13 months would be approximately $450.40 on average.

Pricing = 36

Agenda Item # 2

Monarch external Trigeminal Nerve Stimulation (eTNS) System® – 20.070

Topic

Medicare Benefit Category and Payment Determination for Monarch external Trigeminal Nerve Stimulation (eTNS) System®.

Temporary HCPCS code: K1016 "Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve."

Applicant's Summary

According to information submitted by NeuroSigma Inc., the Monarch external Trigeminal Nerve Stimulation (eTNS) System® is a non-implantable trigeminal nerve stimulation device for the treatment for pediatric attention deficit hyperactivity disorder (ADHD). This device is used during periods of sleep. This system acts by providing therapeutic electrical stimulation of the V1 branch of the trigeminal nerve in the forehead. To administer therapy with the Monarch eTNS System®, a patient places a disposable electric patch in the center of their forehead just above the eyebrows. When applied in this manner, the electrodes within the patch will be oriented on top of the Supraorbital and Supratrochlear nerves located above the eyes. The patch is secured to the skin of the forehead by hypoallergenic hydrogel and medical grade foam and adhesive. The patch is connected to a hand-held pulse generator that creates and transmits an electrical signal to the patch with two lead wires. The Monarch eTNS System® has been tested to withstand 5 years of nightly use.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1016 effective April 1, 2021, "Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets 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.

Monarch external Trigeminal Nerve Stimulation System® meets the definition of durable medical equipment. As explained in more detail below, Medicare makes payment under the existing DME fee schedule for durable electrical stimulation devices used primarily and customarily for medical purposes and this device is comparable to these other electrical stimulation devices.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238(b) regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history, the fee schedule amounts for code K1016 for this particular electrical stimulation device would be established using the existing fee schedule amounts for comparable items (electrical stimulation devices) described by HCPCS code E0720.

Electrical nerve stimulation uses electrical current to activate or decrease activity of nerves to achieve a specific result to the body. The Monarch eTNS System® and devices under E0720 are external, non-invasive electrical nerve stimulation devices that utilize electrodes placed on the skin for delivery of electrical stimulation. Devices under E0720 have a range of intensity, frequency, pulse width, adjustable or fixed, waveform, and treatment times which the Monarch eTNS System® can be compared to.

	E0720	**Monarch eTNS®**
Physical Components	-Electrodes (quantity can vary) -Charger, if needed -Stimulator	-Electrode -Charging station -Stimulator
Mechanical Components		
Electrical Components	-Variable frequency range, commonly less than 200 Hz -Could have adjustable frequency by the patient -Multiple wave patterns available (direct, alternating, or pulsed), (square, sine) -Pulsed, burst or continuous treatment -Has an anode and cathode electrode -Usually has a battery or could be rechargeable	-Frequency of 120 Hz -Fixed frequency -Rechargeable battery -Square wave -Pulsed stimulation
Function and Intended Use	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Can be placed almost any location on the body -Typical indication is to treat pain	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Worn on the forehead -Indication to treat ADHD

	-Commonly stimulates peripheral nerves	-Stimulates trigeminal nerve
Additional Aspects and Features	-Non-invasive -Self-administered -Time worn can vary	-Non-invasive -Self-administered -7 to 8-hour session

CMS recognizes the new indications through our preliminary valuation to compare the technology to E0720 devices prior to competitive bidding, when devices to treat conditions like ADHD were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for K1016 using fees for E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program. Based on this preliminary determination, the average 2022 fee schedule amount for K1016 would be based on the unadjusted purchase fee schedule amounts for E0720 of approximately $429 on average. Since the purchase price for this item are more than $150, payment for this device would be made on a capped rental basis in accordance with 42 CFR §414.229, with the capped rental fee schedule amounts for months 1 thru 3 based on 10 percent of the purchase price or approximately $42.90 on average. The capped rental fee schedule amounts for months 4 thru 13 based on 7.5 percent of the purchase price or approximately $32.17 on average. Total payments after 13 months would be approximately $450.40 on average.

Pricing = 36

Agenda Item # 2

Monarch external Trigeminal Nerve Stimulation (eTNS)® Supplies – 20.070

Topic

Medicare Benefit Category and Payment Determination for Monarch external Trigeminal Nerve Stimulation (eTNS) System® supplies.

Temporary HCPCS code: K1017 "Monthly supplies for use of device coded at K1016."

Applicant's Summary

According to information submitted by NeuroSigma Inc., the Monarch external Trigeminal Nerve Stimulation (eTNS) System® is a non-implantable trigeminal nerve stimulation device for the treatment for pediatric attention deficit hyperactivity disorder (ADHD). This device is to be used during periods of sleep. This system acts by providing therapeutic electrical stimulation of the V1 branch of the trigeminal nerve in the forehead. To administer therapy with the Monarch eTNS System®, a patient places a disposable electric patch (called NS-2 electric patches) in the center of their forehead just above the eyebrows. When applied in this manner, the electrodes within the patch will be oriented on top of the Supraorbital and Supratrochlear nerves located above the eyes. The patch is secured to the skin of the forehead by hypoallergenic hydrogel and medical grade foam and adhesive. The patch is connected to a hand-held pulse generator that creates and transmits an electrical signal to the patch with two lead wires. The patches are single use disposable.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1017 effective April 1, 2021, "Monthly supplies for use of device coded at K1016."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

The preliminary benefit category determination for the Monarch eTNS® equipment (code K1016) is that it meets the definition of durable medical equipment (DME) found in 42 Code of Federal Regulations (CFR) 414.202. Chapter 15, section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-02) states payment may be made for supplies that are necessary for the effective use of durable medical equipment.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238(b) regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history the fee schedule amounts for HCPCS code K1017 for supplies for electrical

stimulation devices described by HCPCS code K1016 would be established using the existing fee schedule amounts for comparable items (supplies for electrical stimulation devices) under code A4595. Electrical stimulation supplies coded under A4595 covers a wide range of sizes (e.g., 4cm and 4" x 7"), shapes (e.g., round, oval, and butterfly), and materials which Monarch eTNS is comparable to.

A monthly payment would be made for all supplies necessary for one month.

Pricing = 34

Agenda Item # 3

Cala Trio™ – 20.086

Topic

Medicare Benefit Category and Payment Determination for Cala Trio™.

Temporary HCPCS code: K1018 "External upper limb tremor stimulator of the peripheral nerves of the wrist."

Applicant's Summary

According to information submitted by Cala Health Inc., the Cala Trio™ is a non-invasive, wrist-worn stimulator that delivers electrical stimulation to the nerves in the wrist to stimulate the peripheral nervous system for the treatment of essential tremors. The Cala Trio™ device is provided with two components: rechargeable stimulator that generates electrical impulses during times of active therapy together with a base station to recharge the stimulator; and wrist-worn connector that securely attaches the stimulator to the patient's wrist and assures that electrical impulses are properly targeted to each individual patient's nerves. The Cala Trio™ uses circumferential stimulation with three access points to target the median and radial nerves at the wrist. The Cala Trio™ stimulator can last up to 3 years. The wrist worn connector and electrodes has a useful life of 90 days. The stimulator is powered with a lithium-ion rechargeable battery, which can be recharged with the base station. The current is delivered to alternating electrode pairs in the band that target the peripheral nerves on the wrist. The tremor frequency is measured by motion sensors (accelerometer and gyroscope) contained within the stimulator which gathers kinematic data. An on-board microcontroller alternates the current between the electrode pairs.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1018 effective April 1, 2021, "External upper limb tremor stimulator of the peripheral nerves of the wrist."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets 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.

Cala Trio™ device meets the definition of durable medical equipment. As explained in more detail below, Medicare makes payment under the existing DME fee schedule for durable electrical stimulation devices used primarily and customarily for medical purposes and this device is comparable to these other electrical stimulation devices.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238(b) regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history, the fee schedule amounts for code K1018 for this particular electrical stimulation device would be established using the existing fee schedule amounts for comparable items (electrical stimulation devices) described by HCPCS code E0720.

Electrical nerve stimulation uses electrical current to activate or decrease activity of nerves to achieve a specific result to the body. The Cala Trio™ and devices under E0720 are external, non-invasive electrical nerve stimulation devices that utilize electrodes placed on the skin for delivery of electrical stimulation. Devices under E0720 have a range of intensity, frequency, pulse width, adjustable or fixed, waveform, and treatment times which the Cala Trio™ can be compared to.

	E0720	**Cala Trio™**
Physical Components	-Electrodes (quantity can vary) -Charger, if needed -Stimulator	-Electrodes (three) -Charging station -Stimulator
Mechanical Components	-Could contain an accelerometer. One such device provides a measurement of shock impact that indicates when the electrode impedance has changed and adjusts the level of therapy accordingly.	-Gyroscope -Accelerometer
Electrical Components	-Variable frequency range, commonly less than 200 Hz -Could have adjustable stimulation by the patient -Multiple wave patterns available (direct, alternating, or pulsed), (square, sine) -Pulsed, burst or continuous treatment -Has an anode and cathode electrode -Could contain a microprocessor. We are aware of other devices that incorporate microprocessors with real-	-Frequency of 150 Hz -Adjustable stimulation by the patient -Square wave -Burst frequency -Lithium rechargeable battery -Alternating electrode pairs stimulated at any moment; always an anode and cathode at any moment. -Microcontroller

	time biofeedback functions built-in that read a patient's electrical parameters and make constant adjustments to match the patient's immediate nerve function. -Usually has a battery or could be rechargeable	
Function and Intended Use	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Can be placed almost any location on the body -Typical indication is to treat pain -Commonly stimulates peripheral nerves	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Worn on the wrist -Indication to reduce tremors -Stimulates peripheral nerves
Additional Aspects and Features	-Non-invasive -Self-administered -Time worn can vary	-Non-invasive -Self-administered -40-minute session

In our preliminary view, Cala Trio™ has utilized and applied comparable technologies to now generate a specific clinical outcome to effect treatment of essential tremors.

CMS recognizes the new indications through our preliminary valuation to compare the technology to E0720 devices prior to competitive bidding, when devices to treat conditions like essential tremors were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for K1018 using fees for E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program. Based on this preliminary determination, the average 2022 fee schedule amount for K1018 would be based on the unadjusted purchase fee schedule amounts for E0720 of approximately $429 on average. Since the purchase price for this item are more than $150, payment for this device would be made on a capped rental basis in accordance with 42 CFR §414.229, with the capped rental fee schedule amounts for months 1 thru 3 based on 10 percent of the purchase price or approximately $42.90 on average. The capped rental fee schedule amounts for months 4 thru 13 based on 7.5 percent of the purchase price or approximately $32.17 on average. Total payments after 13 months would be approximately $450.40 on average.

Pricing = 36

Agenda Item # 3

Cala Trio™ Supplies– 20.086

Topic

Medicare Benefit Category and Payment Determination for Cala Trio™ supplies.

Temporary HCPCS code: K1019 "Monthly supplies for use of device coded at K1018."

Applicant's Summary

According to information submitted by Cala Health Inc., the Cala Trio™ is a non-invasive, wrist-worn stimulator that delivers electrical stimulation to the nerves in the wrist to stimulate the peripheral nervous system for the treatment of essential tremors. The Cala Trio™ device is provided with two components: rechargeable stimulator that generates electrical impulses during times of active therapy together with a base station to recharge the stimulator; and wrist-worn connector that securely attaches the stimulator to the patient's wrist and assures that electrical impulses are properly targeted to each individual patient's nerves. The Cala Trio™ uses circumferential stimulation with three access points to target the median and radial nerves at the wrist embedded in the band. The band is available in left or right handed to target the appropriate nerve locations. The wrist worn connector electrodes has a useful life of 90 days. The current is delivered to alternating electrode pairs in the band that target the nerves. The tremor frequency is measured by motion sensors (accelerometer and gyroscope) contained within the stimulator which gathers kinematic data. An on-board microcontroller alternates the current between the electrode pairs.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1019 effective April 1, 2021, "Monthly supplies for use of device coded at K1018."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

The preliminary benefit category determination for the Cala Trio™ (code K1018) is that this equipment meets the definition of durable medical equipment (DME) found in 42 Code of Federal Regulations (CFR) 414.202. Chapter 15, section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-02) states payment may be made for supplies, that are necessary for the effective use of durable medical equipment.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238 regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule

pricing history, the fee schedule amounts for HCPCS code K1019 for supplies for electrical stimulation devices described by HCPCS code K1018 would be established using the existing fee schedule amounts for comparable items (supplies for electrical stimulation devices) under code A4595.

The Cala Trio™ connector has alternating electrode pair, only two of the three electrodes are used at a given moment. Electrical stimulation supplies coded under A4595 covers a wide range of sizes (e.g., 4cm and 4" x 7"), shapes (e.g., round, oval, and butterfly), and materials.

A monthly payment would be made for all supplies necessary for one month.

Pricing = 34

Agenda Item # 4

gammaCore Sapphire™ – 20.173

Topic

Medicare Benefit Category and Payment Determination for gammaCore Sapphire™.

Temporary HCPCS code: K1020 "Non-invasive vagus nerve stimulator."

Applicant's Summary

According to information submitted by Electrocore, Inc., the gammaCore Sapphire D™ device is a non-invasive vagus nerve stimulator that externally stimulates the cervical branch of the vagus nerve. This stimulation is conducted on the side of the neck. The gammaCore™ device is a multiuse, handheld, rechargeable, portable device consisting of a rechargeable battery, signal-generating and -amplifying electronics, with a control switch for user/operator control of the signal amplitude (stimulation level). The device provides non-invasive vagus nerve stimulation when applied to the side of the neck through two stainless steel stimulation surfaces. The vagus nerve runs through the neck and carries information to the central nervous system. Each stimulation with gammaCore™ lasts 2 minutes. It delivers up to 30 stimulations in a 24-hour period. Once the maximum daily number of treatments has been reached, the device will not deliver any more treatments until the following 24-hour period. The device comes loaded with approximately 36 months (1,116 days) of therapy. It provides visible (light and display) and audible (beep) feedback regarding the device and stimulation status. The number of remaining stimulations available in a 24-hour period is indicated on the display screen as well as the remaining number of months or days available. Each gammaCore comes with 6 tubes of conductive electrode gel.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1020 effective April 1, 2021, "Non-invasive vagus nerve stimulator."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets 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 gammaCore Sapphire D™ device meets the definition of durable medical equipment.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238(b) regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history, the fee schedule amounts for code K1020 for this particular electrical stimulation device would be established using the existing fee schedule amounts for comparable items (electrical stimulation devices) described by HCPCS code E0720.

Electrical nerve stimulation uses electrical current to activate or decrease activity of nerves to achieve a specific result to the body. The gammaCore Sapphire D™ and devices under E0720 are external, non-invasive electrical nerve stimulation devices that utilize electrodes placed on the skin for delivery of electrical stimulation. Types of electrodes can vary from metal plates, rubber, self-adhering, and single-use. Devices under E0720 have a range of intensity, frequency, pulse width, adjustable or fixed, waveform, and treatment times which the gammaCore Sapphire D™ can be compared to.

	E0720	**gammaCore Sapphire D™**
Physical Components	-Electrodes (quantity can vary) -Charger, if needed -Stimulator	-Electrode (metal) -Charging adapter -Stimulator
Mechanical Components		
Electrical Components	-Variable frequency range, commonly less than 200 Hz -Could have adjustable stimulation by the patient -Multiple wave patterns available (direct, alternating, or pulsed), (square, sine) -Pulsed, burst or continuous treatment -Has an anode and cathode electrode -Usually has a battery or could be rechargeable	-Frequency of 25 Hz -Pulsed sine waveform -Burst frequency -Rechargeable battery
Function and Intended Use	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Can be placed almost any location on the body -Typical indication is to treat pain	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Placed on the neck -Indication to treat cluster headaches

	-Commonly stimulates peripheral nerves	-Stimulates vagus nerves
Additional Aspects and Features	-Non-invasive -Self-administered -Time worn can vary	-Non-invasive -Self-administered -2-minute sessions

CMS recognizes the new indications through our preliminary valuation to compare the technology to E0720 devices prior to competitive bidding, when devices to treat conditions like cluster headaches were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for K1020 using fees for E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program. Based on this preliminary determination, the average 2022 fee schedule amount for K1020 would be based on the unadjusted purchase fee schedule amounts for E0720 of approximately $429 on average. Since the purchase price for this item are more than $150, payment for this device would be made on a capped rental basis in accordance with 42 CFR §414.229, with the capped rental fee schedule amounts for months 1 thru 3 based on 10 percent of the purchase price or approximately $42.90 on average. The capped rental fee schedule amounts for months 4 thru 13 based on 7.5 percent of the purchase price or approximately $32.17 on average. Total payments after 13 months would be approximately $450.40 on average.

Pricing = 36

Agenda Item # 5

Nerivio™ – 21.033

Topic

Medicare Benefit Category and Payment Determination for Nerivio™.

Temporary HCPCS code: K1023 "Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm."

Applicant's Summary

According to information submitted by Theranica Bio-Electronics Ltd, Israel, the Nerivio™ device is a neuromodulation device for the acute treatment of episodic and chronic migraine. The device stimulates the peripheral nerves in the upper arm to induce conditioned pain modulation. The Nerivio™ device is a wireless wearable battery-operated stimulation unit controlled by a smartphone software application. Treatments with Nerivio™ are self-administered by the user at the onset of a migraine attack. The system delivers low energy electrical pulses to the upper arm for 45 minutes per treatment, after which the device turns off automatically. The device hardware consists of an armband intended to be worn on a user's upper arm. The armband contains the electronic circuitry and the battery in a plastic storage case as well as two electrodes that are attached to the interior of the armband and placed against the user's skin. The device is operated and controlled via software that is installed and run on a user's personal mobile device such as a mobile phone or tablet. The plastic electronics case contains an on/off switch and an LED indicator. The Nerivio™ device can be used for 12 treatments of 45 minutes each. These treatments can be exercised over an 18-month period.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1023 effective October 1, 2021, "Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets 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.

Once used, the Nerivio™ can support 540 minutes of treatments, or 12 treatments of 45 minutes, but only up to an 18-month period. The Nerivio™ device can be used up to an 18-month period; therefore, the minimum lifetime requirement of three years is not met. According to the Nerivio™ user manual, when there are no more treatments left, the device should be disposed. DME is a benefit for rental of equipment for use in the home and therefore DME items must be able to withstand repeated use by successive patients in accordance with Medicare regulations and as indicated in Medicare program instructions at chapter 15, section 110.1 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) and chapter 1, part 4, section 280.1 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03).

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Agenda Item # 6

Alzair™ Allergy Blocker – 21.048

Topic

Medicare Benefit Category and Payment Determination for Alzair™ Allergy Blocker.

Temporary HCPCS code: K1026 "Mechanical allergen particle barrier/inhalation filter, cream, nasal, topical."

Applicant's Summary

According to information submitted by HS Pharma, Alzair™ Allergy Blocker is a gel barrier that blocks inhaled allergens within the nasal cavity. It is administered by insufflation into the nose using a spray bottle, so a fine mist covers the nasal cavity. Alzair™ is composed of pharmaceutical grade Hydroxypropyl Methylcellulose (HPMC; 98.5%) and high-quality peppermint (1.5%) formulated into a micronized powder of fine particles of inert cellulose. Alzair™ is indicated to treat hay fever and allergy sufferers by promoting alleviation of mild allergic symptoms (i.e., mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various airborne allergens including indoor and outdoor environmental pollens, house dust, animal hairs, and dust mites. It is a drug free product that has zero contraindications. It is supplied in a patented bottle that produces a specific particle size that allows for the proper efficacy and dose of the Methylcellulose. The spray bottle enables the powder to be applied evenly as a fine mist. The current bottle size contains 800 mg of powder that equates to approximately 200 inhalations. HS Pharma recommends for Alzair™ to be taken three times a day in both nostrils per day, this equates to 28-33 days of treatment.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1026 effective October 1, 2021, "Mechanical allergen particle barrier/inhalation filter, cream, nasal, topical."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets 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 Alzair™ Allergy Blocker is disposed of after 200 inhalations when used as suggested three times per day per nostril, which equates to 28 to 33 days of use; therefore, the minimum lifetime requirement of three years is not met. DME is a benefit for rental of equipment for use in the home and therefore DME items must be able to withstand repeated use by successive patients as indicated in Medicare program instructions at chapter 15, section 110.1 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) and chapter 1, part 4, section 280.1 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03). The Alzair™ Allergy Blocker device cannot be rented and used by successive patients.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Agenda Item # 7

Slow Wave – 21.034

Topic

Medicare Benefit Category and Payment Determination for Slow Wave.

Temporary HCPCS code: K1027 "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment."

Applicant's Summary

According to information submitted by Slow Wave Inc., the Slow Wave DS8 is an intra-oral device intended to reduce or alleviate snoring and mild to moderate Obstructive Sleep Apnea (OSA) while sleeping in adults. The Slow Wave DS8 consists of two custom fitted trays used to reposition the mandible. The trays are designed to be worn on the upper and lower teeth where they act to increase the patient's pharyngeal space by reducing obstructions of the airway during sleep. The device is designed to be retained on the teeth with saliva and surface tension and functions without any screws or fastening mechanism. The patient-custom devices are 3D print manufactured and made from biocompatible material. The Slow Wave DS8, is a mandibular repositioning device that acts to increase the users' pharyngeal space and improves their ability to exchange air during sleep. The device consists of two separate trays worn on the maxilla and mandible, which allow the user to open and close their jaw when asleep, provide full lateral movement of the mandible, move the tongue naturally forward to enhance air exchange during sleep. The DS8 trays worn on the maxilla and mandible with integrally formed molar extensions forming forward-leaning left and right ramps configured so that when the apparatus is in a users' mouth, the ramps create a tendency for the lower tray, lower dentition and mandible to move in a normal downward position keeping users' airway open by maintaining an anterior gap making more space for the tongue. The Slow Wave DS8 does not utilize fixed mechanical hinges at the sides, front or palate. Nor does it incorporate a mechanism to allow the mandible to be advanced in increments of 1 mm.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1027 effective October 1, 2021, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No determination

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

Preliminary Medicare Payment Determination

No determination

Agenda Item # 8

eXciteOSA® Control Unit - HCP210826HY98M

Topic

Medicare Benefit Category and Payment Determination for eXciteOSA® Control Unit.

Temporary HCPCS code: K1028 "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."

Applicant's Summary

According to information submitted by Signifier Medical Technologies, LLC (SMT), the eXciteOSA® control unit is a tongue neuromuscular stimulation device. The eXciteOSA® starter kit consists of a control unit, disposable one-size fits all flexible silicone mouthpiece, and USB-C charger. A smartphone application is used to control all functions of the device, such as turning the device on and off. The eXciteOSA® functions by delivering neuromuscular electrical stimulation therapy to the tongue during the wakeful state. A patient operates the device by inserting the mouthpiece into the control unit, connecting the device to a patient-controlled phone application, and placing the mouthpiece on the tongue. The neuromuscular electrical stimulation effect is achieved with a low-pulsed frequency whose intensity can be modified by the user. The electrical stimulation is a series of pulsed bursts with a sequence of alternating pulse and rests periods. The control unit can be repurposed for multiple, successive patients.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1028 effective April 1, 2022, "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."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets 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.

As stated in the 2011 final rule, CMS-1577-F (76 FR 70291), a multi-component device consisting of durable and non-durable components is considered non-durable if the component that performs the medically necessary function of the device is non-durable, even if other components that are part of the device are durable. The eXciteOSA® software application and smartphone performs the medically necessary function of driving the neuromuscular electrical stimulation therapy and intensity, which includes starting and stopping the therapy by activating the electrodes. We note that without the software application and phone, the device does not function. Since the component that performs the medically necessary function of the device is a smartphone which is useful to an individual in the absence of an illness or injury and software application which is nondurable, the eXciteOSA® device does not meet the definition of durable medical equipment.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Agenda Item # 8

eXciteOSA® Mouthpiece - HCP210826HY98M

Topic

Medicare Benefit Category and Payment Determination for eXciteOSA® Mouthpiece.

Temporary HCPCS code: K1029 "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."

Applicant's Summary

According to information submitted by Signifier Medical Technologies, LLC (SMT), the eXciteOSA® is a tongue neuromuscular stimulation device with a disposable silicone mouthpiece that contains four electrodes. The mouthpiece is disposable, or considered the non-durable component, and is one-size fits all. The eXciteOSA® functions by delivering neuromuscular electrical stimulation therapy to the tongue during the wakeful state. A patient operates the device by inserting the mouthpiece into the control unit, connecting the device to a patient-controlled phone application, and placing the mouthpiece on the tongue. The electrical stimulation is a series of pulsed bursts with a sequence of alternating pulse and rests periods. The mouthpiece contains four electrodes, two located above (superior and posterior) and two to each side of the tongue. The mouthpiece can be washed after each use and lasts up to 90 days.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1028 effective April 1, 2022, "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."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets 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.

As indicated in Medicare program instructions at chapter 15, section 110.3 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), payment may be made for supplies that are necessary for the effective use of covered DME. The preliminary benefit category determination for the eXciteOSA® control unit is no benefit category; therefore, supplies used with this item would also have no benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Agenda Item # 9

Optimizer® Patient Charger - HCP21090362W2D

Topic

Medicare Benefit Category and Payment Determination for Optimizer® Patient Charger.

Temporary HCPCS code: K1030 "External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only."

Applicant's Summary

According to information submitted by Impulse Dynamics, Inc., the Optimizer® Patient Charger is used for the Optimizer® Smart System that delivers cardiac contractility modulation therapy. The Optimizer® Smart System is a hermetically-sealed implantable pulse generator and external battery charger that provides electrical stimulation of the cardiac muscle with the intent to increase exercise tolerance, functional capacity, and quality of life for a subset of heart failure patients with very limited therapeutic options. The energy required to deliver cardiac contractility modulation therapy exceeds the capacity of any available non-rechargeable battery, necessitating use of a rechargeable battery and external charging unit. Patients receive periodic cardiac contractility modulation therapy daily, as programmed by their prescribing physicians, and recharge their device approximately weekly. A typical charging session lasts approximately 45 minutes, during which the device conducts a series of self-checks to confirm appropriate function. Without an external recharging device, a patient's battery will drain and render a cardiac contractility modulation device inoperable after approximately 3 weeks.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1030 effective April 1, 2022, "External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No determination

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

Preliminary Medicare Payment Determination

No determination

Agenda Item # 10

Pear Therapeutics - HCP21090135K6E, HCP210902RNB7C, HCP2109034KYG9

Topic

Medicare Benefit Category and Payment Determination for reSET, reSET-O, and Somryst.

HCPCS code: A9291 "Prescription digital behavioral therapy, fda cleared, per course of treatment."

Applicant's Summary

According to information submitted by Pear Therapeutics, reSET®, reSET-O®, and Somryst® are intended to provide cognitive behavioral therapy or neurobehavior intervention, as an adjunct to a contingency management system, for patients who are currently enrolled in outpatient treatment under the supervision of a clinician. The manufacturer states that prescription digital therapeutics (PDTs) is a therapeutic class that is regulated and clinically validated prescription software. PDTs delivers therapy based on the community reinforcement approach, an intensive form of validated neurobehavioral therapy, along with contingency management and fluency training to enhance learning. PDTs are prescribed in conjunction with outpatient treatment. According to the applicant, the provider does not a) pay for, b) take ownership/title over, or c) dispense Pear's prescription digital therapeutics. The provider writes a prescription which is sent to a specialty pharmacy. The specialty pharmacy is the sole entity who verifies the prescription, submits a claim to an insurer, and dispenses the product to the patient. For the reset-O®, therapy lesson content is delivered primarily via text or audio, and may include videos, animations and graphics.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code A9291 effective April 1, 2022, "Prescription digital behavioral therapy, fda cleared, per course of treatment."

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets 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.

Digital therapies or computer software are not devices, equipment, or supplies and therefore would not fall under a DMEPOS benefit category. Whether or not the item could fall under some other Medicare benefit category can be considered, but would not be addressed under the DMEPOS BCD process.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Agenda Item # 11

MiSight® 1 day - HCP210904KY8NE

Topic

Medicare Benefit Category and Payment Determination for MiSight® 1 day contact lens.

HCPCS code: V2525 "Contact lens, hydrophilic, dual focus, per lens."

Applicant's Summary

According to information submitted CooperVision, Inc., the MiSight® 1-day (omafilcon A) soft contact lens is indicated for the correction of myopic ametropia and for slowing the progression of myopia in children, who at the initiation of treatment, are 8-12 years of age and have a refraction of -0.75 D to -4.00 D (spherical equivalent) with less than or equal to 0.75 diopters of astigmatism. The MiSight® 1-day lens employs a dual-focus design which has a central zone containing distance vision and concentric peripheral zones to provide peripheral myopic defocus. Dual focus design has multiple rings of correction zone and treatment zone. The correction zone is where the light refraction is like a traditional contact lens. It corrects the myopia so one can enjoy clear vision, just like they would in an ordinary single vision contact lens. The treatment zone provides an appropriate signal to slow down the pathologic eye growth.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code V2525 effective April 1, 2022, "Contact lens, hydrophilic, dual focus, per lens."

Requested Benefit Category

Prosthetic Device – section 1861(s)(8) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category

These lenses do not qualify as prosthetic devices under any of the categories for prosthetic lenses under section 120.B of chapter 15 of the Medicare Benefit Policy Manual.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Agenda Item # 12

ReWalk Personal Prosthetic Exoskeleton System – 20.085

Topic

Medicare Benefit Category and Payment Determination for ReWalk Exoskeleton System.

Temporary HCPCS code: K1007 "Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors."

Applicant's Summary

According to information submitted by ReWalk Robotics, the ReWalk Personal Prosthetic Exoskeleton System (ReWalk) is a wearable, motorized, computerized, personal lower body exoskeleton system with adjustable ankle joints. The ReWalk is used by individuals with lower body paralysis due to spinal cord injury (SCI) at levels T7 to L5 to restore the function of motor movement controlled by the spinal cord. The device enables individuals with SCI to stand upright and walk again. The ReWalk is placed over a patient's paralyzed or weakened limbs for the purpose of providing ambulation. Patients can control walking initiation, speed, and direction through a combination of controller commands and shifts in their body weight. The ReWalk is configured and custom fit for each patient. A personal computer is provided with the device and used for installation/configuration, upgrading and servicing of the ReWalk device. The ReWalk allows for multiple patient uses through adjustments in length and or weight to align with the patients joints. The ReWalk is programed to the patient by a trained healthcare professional. It consists of three main parts: remote control communicator, exoskeleton and control unit. The remote control communicator is a small wireless device that provides two-way communication between the user and the ReWalk unit. The remote control allows the user to select different modes and presents a visual indication of the status of the system, which includes the mode in which the device is operating (walking, standing, sitting, etc.). The exoskeleton consists of four components: the articulating legs, the pelvic band, the straps, padding, and knee bracket and the ankle-foot plate. The control unit is attached the pelvic band of the exoskeleton. The control unit consists of an outer shell and an inner compartmentalized shell with power management and computer control system components. The main battery is a lithium-ion battery that is capable of allowing the patient to walk continuously for more than three hours on a charge. The ReWalk must be used with supervision of a specially trained companion.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1007 effective October 1, 2020, "Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors."

Requested Benefit Category

Prosthetic (Artificial Leg) – section 1861(s)(9) of the Social Security Act

Preliminary Benefit Category Determination

No determination

More time is needed to evaluate this complex issue related to the scope of the benefit for artificial legs and arms. We will be providing more information on this topic in the near future. In the meantime, coverage and payment for these items will be made at the discretion of the MACs.

Preliminary Medicare Payment Determination

No determination

Agenda Item # 13

MyoPro® – 18.118

Topic

Medicare Benefit Category and Payment Determination for MyoPro® devices.

HCPCS code: L8701 "Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated."

Applicant's Summary

According to information submitted by Myomo, Inc., the MyoPro® is a wearable, motorized, microprocessor controlled, elbow-wrist-hand device used for patients suffering from complications of stroke or other neurological/neuromuscular injury and illness. The MyoPro® Motion E is an elbow-wrist-hand device that has one degree of freedom and a fixed wrist joint. The MyoPro® Motion W is an elbow-wrist-hand device that has one degree of freedom and a multi-articulating wrist joint. Motion E and Motion W cover the upper end of the humerus to the palm of the hand. Common components are upper-arm shell, harness attachment, upper-arm sensor cuff, upper arm closure, battery compartment, forearm closure, forearm bar, forearm shell, control panel, elbow motor, wrist joint (fixed or flexion), and hand support shell. The wrist and hand shells are attached by a rigid wrist extension and is at a fixed angle. The entire device for Motion E and Motion W utilizes a single rigid metal upright linking all components to the joints into a single device. Straps and padding are used to anchor the device to the patient's upper extremity. Both models have two replaceable batteries with charging stand, circuit board, and a motor mounted at the elbow joint, permitting microprocessor mediated, volitionally controlled, elbow flexion and extension. Patients can also use a laptop with software-based, settings-control interface accessed through wireless connectivity to adjust the input settings/sensitivity in real-time when needed. Patients use their muscle signals to control movements of a paretic or weakened limb. When the patient tries to bend the arm, precision sensors in the brace detect the weak muscle signals which activate motors to move the arm in the desired directions. The surface EMG sensors continuously monitors and senses, but does not stimulate, the patient's muscles. The MyoPro® filters and processes the EMG signal, and translates this information into motor movement. The power assist moves the motor with speed proportional to patient's exertion. The direction of motion is determined by which set of sensors are triggered. A microprocessor amplifies the acquired signal to power electric motors to initiate and complete desired movement in the elbow. The primary purpose of the MyoPro® is to assist upper extremity joint motion in a weakened body member to improve the beneficiary's functional activities of daily living.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code L8701 effective January 1, 2019, "Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated."

Requested Benefit Category

Arm Brace – section 1861(s)(9) of the Social Security Act

Preliminary Benefit Category Determination

No determination

More time is needed to evaluate this complex issue related to the scope of the benefit for leg and arm braces. We will be providing more information on this topic in the near future. In the meantime, coverage and payment for these items will be made at the discretion of the MACs.

Preliminary Medicare Payment Determination

No determination

Agenda Item # 13

MyoPro® – 18.118

Topic

Medicare Benefit Category and Payment Determination for MyoPro® devices.

HCPCS code: L8702 "Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated."

Applicant's Summary

According to information submitted by Myomo, Inc., the MyoPro® is a wearable, motorized, microprocessor controlled, elbow-wrist-hand-finger device used for patients suffering from complications of stroke or other neurological/neuromuscular injury and illness. The MyoPro® Motion G is an elbow-wrist-hand-finger device that has two degrees of freedom and a multi-articulating wrist joint. Common components are upper-arm shell, harness attachment, upper-arm sensor cuff, upper arm closure, battery compartment, forearm closure, forearm bar, forearm shell, control panel, elbow motor, wrist joint, hand motor and hand support shell. The wrist and hand shells are attached by a rigid wrist extension and is at a fixed angle. The entire device for utilizes a single rigid metal upright linking all components to the joints into a single device. Straps and padding are used to anchor the device to the patient's upper extremity. This device has two replaceable batteries with charging stand, circuit board, and a motor mounted at the elbow joint, permitting microprocessor mediated, volitionally controlled, elbow flexion and extension. Patients can also use a laptop with software-based, settings-control interface accessed through wireless connectivity to adjust the input settings/sensitivity in real-time when needed. Patients use their muscle signals to control movements of a paretic or weakened limb. When the patient tries to bend their arm, or open and close their hand, precision sensors in the brace detect the weak muscle signals which activate motors to move the hand and arm in the desired directions. The surface EMG sensors continuously monitors and senses, but does not stimulate, the patient's muscles. The MyoPro® filters and processes the EMG signal, and translates this information into motor movement. The power assist moves the motor with speed proportional to patient's exertion. The direction of motion is determined by which set of sensors are triggered. A microprocessor amplifies the acquired signal to power electric motors to initiate and complete desired movement in the elbow and fingers. The primary purpose of the MyoPro® is to assist upper extremity joint motion in a weakened body member to improve the beneficiary's functional activities of daily living.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code L8701 effective January 1, 2019, "Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated."

Requested Benefit Category

Arm Brace – section 1861(s)(9) of the Social Security Act

Preliminary Benefit Category Determination

No determination

More time is needed to evaluate this complex issue related to the scope of the benefit for leg and arm braces. We will be providing more information on this topic in the near future. In the meantime, coverage and payment for these items will be made at the discretion of the MACs.

Preliminary Medicare Payment Determination

No determination

Continuous Glucose Monitor (CGM) – HCP220201FMV4A

Topic

Request to revise existing Continuous Glucose Monitor (CGM) and related supply and accessory HCPCS Level II codes K0553, K0554, A4238 and E2102 and a discussion of adjunctive CGM pricing.

Applicant's suggested language:

1. K0553, which currently reads "Supply allowance for therapeutic continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service" to A423X, to instead read "Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service"

2. K0554, which currently reads "Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system" to E210X, to instead read "Non-adjunctive, non-implanted continuous glucose monitor or receiver"

3. A4238, which currently reads "Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service" to instead read "Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service"

4. E2102, which currently reads "Adjunctive continuous glucose monitor or receiver" to instead read "Adjunctive, non-implanted continuous glucose monitor or receiver"

Applicant's Summary

On December 28, 2021, the Centers for Medicare & Medicaid Services (CMS) published a final rule in the Federal Register entitled "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas" (86 FR 73860) that addressed the classification and payment of continuous glucose monitors (CGMs) under the Medicare Part B benefit for durable medical equipment (DME). The final rule can be downloaded at: https://www.federalregister.gov/documents/2021/12/28/2021-27763/medicare-program-durable-medical-equipment-prosthetics-orthotics-and-supplies-dmepos-policy-issues.

This rule expanded the classification of DME to a larger group of CGMs regardless of whether the CGMs are non-adjunctive (can alert patients when glucose levels are approaching dangerous levels, including while they sleep and also replace blood glucose monitors) or adjunctive (can alert patients when glucose levels are approaching dangerous levels, including while they sleep but do not replace blood glucose monitors), as long as the CGMs satisfy the regulatory definition of DME. As such, adjunctive CGMs and related supplies and accessories with dates of service on or after the effective date of the final rule,

February 28, 2022, can now be covered under the Part B DME benefit category when the system meets the DME definition.

Preliminary CMS HCPCS Coding Recommendations

1. Revise existing HCPCS Level II code K0553, which currently reads "Supply allowance for therapeutic continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service" to A423X, to instead read "Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service"

2. Revise existing HCPCS Level II code K0554, which currently reads "Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system" to E210X, to instead read "Non-adjunctive, non-implanted continuous glucose monitor or receiver"

3. Revise existing HCPCS Level II code A4238, which currently reads "Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service" to instead read "Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service"

4. Revise existing HCPCS Level II code E2102, which currently reads "Adjunctive continuous glucose monitor or receiver" to instead read "Adjunctive, non-implanted continuous glucose monitor or receiver"

Effective: 10/1/2022

Code A4238 "Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service" was added to the HCPCS file effective 4/1/22 to identify one month of adjunctive CGM supplies and accessories. Code E2102 "Adjunctive continuous glucose monitor or receiver" was added to the HCPCS file effective 4/1/22 to identify adjunctive CGM receivers. This request revises the descriptor of A4238 and E2102 to add "non-implanted" to clarify intended use. Implantable CGMs have no durable component, cannot withstand repeated use because they are totally implanted, single patient use devices, and are paid for incident to the implantation procedure. Implantable CGMs therefore do not fall under the Medicare benefit for durable medical equipment and cannot be billed as such; implantable CGMs are typically covered by Medicare under an outpatient benefit, such as Hospital Outpatient. We have heard from providers and suppliers that there is confusion among some payers with regard to whether these codes applied to implantable CGMs, and thus, these coding changes are intended to resolve that confusion.
We are also making conforming changes to the existing K0553 and K0554 codes to revise the code descriptors and to convert them to "A" and "E" codes. These changes include adding "non-implanted" to the code descriptor.

Lastly, we seek feedback on the 4/1/2022 coverage indicator change for the following codes that made them invalid for Medicare use: A9276 "Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply; A9277 Transmitter; external, for use with interstitial continuous glucose monitoring

system; and A9278 Receiver (monitor); external, for use with interstitial continuous glucose monitoring system.

Benefit Category Determination

Durable Medical Equipment

Preliminary Medicare Payment Determination

There is a substantial difference in the utility and capabilities of adjunctive CGMs versus non-adjunctive CGMs. Non-adjunctive CGMs are able to: A) alert the patient about dangerous glucose levels while they sleep; and B) replace the use of a blood glucose monitor (BGM) for accurate glucose measuring/testing purposes. Adjunctive CGMs are able to alert the patient about potentially dangerous glucose levels while they sleep, but the CGM results must be verified by a BGM and all other glucose measuring and testing must be performed by a separate BGM. Because the combination of using an adjunctive CGM (A) and a separate BGM (B) are comparable to the services provided by a non-adjunctive CGM (A + B), the fee schedule amounts for the adjunctive CGM and related supplies can be established using the existing fee schedule amounts for non-adjunctive CGMs and related supplies reduced by the amounts paid separately for the BGM and related supplies. The combination of payments made for the adjunctive CGM and related supplies and BGM and related supplies is then equal to the payments made for the non-adjunctive CGM and related supplies, which performs the functions of both of these separate items.

At this time, we are only aware of class III adjunctive CGMs. Claims for class III DME items are identified using the HCPCS modifier KF. Payment for the monthly CGM supplies used with an FDA Class III adjunctive CGM, described by the HCPCS code and modifier combination of A4238KF, would be established using the fee schedule amounts for the monthly CGM supplies used with an FDA Class III non-adjunctive CGM, described by the HCPCS code and modifier combination of K0553KF minus the average monthly payment for BGM supplies for insulin-treated beneficiaries with diabetes, which according to our November 4, 2020 proposed rule (85 FR 70403) was $34.35 in 2020. Updated to 2022 using the former Competitive Bidding Area update factors of 0.6% (2021) and 5.0% (2022), the average 2022 monthly payment for BGM supplies for insulin-treated beneficiaries with diabetes is $36.29. This calculation is represented below and results in a 2022 monthly fee schedule amount for A4238KF of $236.68:

K0553KF ($272.97) – $36.29 (average monthly payment for BGM supplies for insulin-treated beneficiary with diabetes) = A4238KF ($236.68)

As discussed in the final rule, the fee schedule amounts for the non-adjunctive CGM receiver (K0554KF) were established using the average reasonable charge data for blood glucose monitors from 1986 and 1987, updated to the current year using the Class III update factors. We are establishing lower receiver fees for adjunctive CGMs in accordance with our gap-filling regulations since the adjunctive monitor does not replace the functions of a blood glucose monitor. Payment for the Class III adjunctive CGM receiver, described by the HCPCS code and modifier combination of E2102KF, would be established using the 2022 Class III fee schedule amounts for the non-adjunctive receiver, code K0554KF, minus the 2022 fee schedule amounts for the home blood glucose monitor (E0607). This calculation is

represented below and results in an average 2022 purchase fee schedule amount for E2102KF of $195.66:

K0554KF (average of $278.06) – E0607 (average of $82.39) = E2102KF (average of $195.66)

The 2022 monthly fee schedule amount for A4238KF would be $236.68.

The average 2022 purchase fee schedule amount for E2102KF would be approximately $195.66.

Effective 10/1/2022

Appendix: 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.