Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Agenda
DME and Accessories; O & P; Supplies and Other
Thursday, June 8, 2017 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

8:15-9:00 a.m. Arrival and sign-in

9:00 a.m. Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS' preliminary coding decision is provided. Preliminary decisions are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about the agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

The agenda includes a summary of each HCPCS code application on the agenda. 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.

Agenda Item # 1

APPLICATION# 17.092

Repeat request to establish a new Level II HCPCS code to identify the Power Module Patient Cable for the use with a Left Ventricular Assist Device (LVAD). Trade Name: HeartMate Power Module Patient Cable.

No Primary Speaker

Agenda Item # 2

APPLICATION# 17.066

Request to assign existing Level II HCPCS code B4153 to an enteral formula, nutritionally complete, hydrolized protein, Trade Name: Ultrient.

APPLICATION# 17.097

Request to assign existing Level II HCPCS code B4161 to a Ready-to-Feed Peptide Formula for enteral feeding, Trade Name: Ultrient Junior Peptide 1.0 Calorie Pediatric Enteral Nutrition Formula.

APPLICATION# 17.099

Request to assign existing Level II HCPCS code B4154 to Ultrient Junior 2.0, Trade Name: Ultrient for Renal Health.

APPLICATION# 17.079

Request to assign existing Level II HCPCS code B4150 "Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories=1unit" to a nutritional shake for medical malnutrition, Trade Name: ENU Complete Meal Replacement Powder Mix.

Agenda Item # 2 (continued)

APPLICATION# 17.112

Request to assign existing Level II HCPCS code B4150 to a nutritional shake for medical malnutrition, Trade Name: ENU Nutritional Shake.

APPLICATION# 17.096

Request to establish a new Level II HCPCS code to identify an enteral feeding supply kit, full closed for bolus or gravity feeding, with no-spill valve. Trade Name: Safe-T Feed Ready-to-Feed Pouch with ENFit Safety Connector.

Applicant’s suggested language: BXXXX "Enteral feeding supply kit, full closed for bolus or gravity feeding, with no-spill valve." Disposable, single-use feeding pouch (with pre-filled formula), includes Enfit nutrition connector and a spill-proof valve to prevent leakage and allow for storage after opening if the formula is not completely used."

No Primary Speaker

Agenda Item # 3

APPLICATION# 17.068

Request to establish a new Level II HCPCS code to identify a rechargeable lithium-ion battery for use with the portable pneumatic driver of the SynCardia Total Artificial Heart (TAH-t). Trade Name: Freedom Onboard Battery.

Applicant's suggested language: QXXXX: "Battery (Li-Ion) for use with portable pneumatic biventricular driver, total artificial heart, each."

APPLICATION# 17.069

Request to establish a new Level II HCPCS code to identify a power spupply system for use with the Freedom portable driver of the Syncardia Total Artificail Heart (TAH-t). Trade Name: Freedom Home AC Power Supply System.

Applicant's suggested language: QXXXX: "Power supply system for use with portable pneumatic biventricular total artificial heart."

APPLICATION# 17.070

Request to establish 5 new Level II HCPCS codes to identify supplies and accessories for the Freedom Portable Driver System that operates the SynCardia Total Artificial heart (TAH-t) for use outside the hospital.

Applicant's suggested language:

QXXX1 Miscellaneous supply or accessory for use with an implanted total artificial heart;

QXXX2 Miscellaneous supply or accessory for use with any implanted total artificial heart for which payment was not made under Medicare Part A

QXXX3 Filters for use with total artificial heart, replacement only.

QXXX4 Power adaptor for use with total artificial heart, vehicle type.

QXXX5 Backpack/bag for use with total artificial heart, replacement only.

Agenda Item # 3 (continued)

APPLICATION# 17.077

Request to establish a new Level II HCPCS code to identify the SynCardia Freedom portable driver used with the SynCardia Total Artificial Heart (TAH-t), Trade Name: Freedom Portable Driver

Applicant's suggested language: QXXXX "Pneumatic biventricular driver, portable, total artificial heart."

Primary Speaker: Mary Pat Sloan

Agenda Item # 4

APPLICATION# 17.084

Repeat request to establish a new Level II HCPCS code to identify a digestive enzyme (immobilized lipase) packed cartridge, Trade Name: RELiZoRB.

Applicant's suggested language: "BXXXX, "RELiZORB, immobilized lipase cartridge."

Primary Speaker: Mr. Daniel Tasse'

Agenda Item # 5

APPLICATION# 17.087

Request to establish a new Level II HCPCS code to identify a software controlled, pulsatile pressure, off-loading boot and shin device for the treatment of lower limb wounds, Trade Name: PulseFlow DF

Applicant's suggested language: "EXXXX, Software controlled, ambulatory limb salvage device with an internal pneumatic pump applying pulsatile pressure in the medical aspect of the foot within an off-loading boot and a shin device for the treatment of diabetic and non-diabetic lower limb wounds."

Primary Speaker: Dr. Larry Lavery

Agenda Item # 6

APPLICATION# 17.088

Request to establish 2 new Level II HCPCS codes to identify a blood pressure lowering device used to treat hypertension, Trade Name: RESPeRATE.

Applicant's suggested language:

(1) XXXXX: Non-invasive respiratory modulation assist device (RESPeRATE), including respiratory effort belt, directing patient respiration rate, and patterns of inhalation and exhalation.

(2) XXXXX: Respiratory effort belt kit and accessories used with the non-invasive respiratory modulation assist device (RESPeRATE).

Primary Speaker: Dr. Henry Black

Agenda Item # 7

APPLICATION# 17.091

Request to revise existing Level II HCPCS code P9072, which currently reads, “Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit,” to instead read, “Platelets, pheresis, pathogen reduced, each unit”.

No Primary Speaker

Agenda Item # 8

APPLICATION# 17.093

Request to establish a new Level II HCPCS code to identify a high-precision weight monitoring scale with cellular transmission capability to health care entities. Trade Name: BodyTrace BT004.

Primary Speaker: Mrs. Shira Lee

Agenda Item # 9

APPLICATION# 17.095

Request to establish a new Level II HCPCS code to identify an alternating pressure geri chair cushion, Trade Name: Relief Chair Alternating Pressure Geri Chair Cushion.

Applicant did not suggest language for a code.

Primary Speaker: Ms. Lorinda White

Agenda Item # 10

APPLICATION# 17.100

Third request to establish a new Level II HCPCS code to identify a replaceable pump device used to empty the female urinary bladder, Trade Name: InFlow Intraurethral Valve-Pump and Activator.

Applicant's suggested language: LXXXX, Female Urinary Prosthesis, replaceable.

Primary Speaker: Mr. Jerry Stringham

Agenda Item # 11

APPLICATION# 17.102

Request to establish a new Level II HCPCS code to identify wearable moist-heat or cooling breastfeeding relief packs. Trade Name: Rachel's Remedy.

Applicant's suggested language: "Moist heat device for use prior to or during use with breast pump."

Primary Speaker: Ms. Rachel Jackson

Agenda Item # 12

APPLICATION# 17.103

Repeat request to establish two new Level II HCPCS codes and to revise two existing Level II HCPCS codes in order to distinguish SpeediCath and other hydrophilic-coated intermittent urinary catheters from intermittent urinary catheters that are not coated, and currently share the same codes.

Applicants suggested language:

Establish "AXXXX - Hydrophilic-coated intermittent urinary catheter; straight tip, with sterile lubricating coating, each".

"Establish AXXXX - Hydrophilic-coated intermittent urinary catheter; Coudé tip, with sterile lubricating coating, each".

Revise A4351, which currently reads, "Intermittent urinary catheter; straight tip, with or without coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each", to instead read, "Intermittent urinary catheter; straight tip, without coating (Teflon, silicone, silicone elastomer, etc.), each."

Revise A4352, which currently reads, "Intermittent urinary catheter; Coudé tip, with or without coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each", to instead read, "Intermittent urinary catheter; Coudé tip, without coating (Teflon, silicone, silicone elastomer, etc.), each."

Primary Speaker: Dr. C. Lowell Parsons

Agenda Item # 13

APPLICATION# 17.105

Request to revise existing Level II HCPCS codes L8618 and L8628 to include auditory osseointegrated implants (AOI) devices. Trade name: Cochlear Baha Coil Cables and Cochlear Baha Remote Control 2.

1. Revise existing Level II HCPCS code L8618, which currently reads, "Transmitter cable for use with cochlear implant device, replacement", to instead read, "Transmitter cable for use with cochlear implant device and auditory osseointegrated devices (AOI), replacement (each)."

2. Revise existing Level II HCPCS code L8628, which currently reads, "Cochlear implant, external controller component, replacement", to instead read, "Cochlear implant and auditory osseointegrated devices (AOI), external controller component, replacement".

APPLICATION# 17.106

Request to revise existing Level II HCPCS code L8624 to include use with auditory osseointegrated (AOI) devices, Trade Name: CP910 and CP920 Rechargeable batteries; standard and compact.

Applicant's suggest language:

1) Revise existing Level II HCPCS code L8624, which currently reads, "Lithium ion battery for use with cochlear implant device speech processor, ear level, replacement, each", to instead read, "Lithium ion battery for use with cochlear implant and auditory osseointegrated device speech processor, ear level, replacement, each".

2) Request to establish a new Level II HCPCS code to identify a Lithium Ion battery charger, Trade Name: Cochlear Nucleus CP800 Series Battery Charger.

Applicant's suggested language:

LXXXX:" Battery charger for Lithium rechargeable battery for cochlear implant speech processor and AOI".

Agenda Item # 13 (continued)

APPLICATION# 17.107

Request to establish a new Level II HCPCS code to identify a replacement actuator (transducer) for use with the Baha 5 SuperPower Sound Processor system auditory osseointegrated (AOI) device. Trade Name: Baha 5 SuperPower Actuator unit

Applicant's suggested language: LXXXX "auditory osseointegrated device (AOI) actuator, replacement (each)".

Primary Speaker: Ms. Kalisha Barrett

Agenda Item # 14

APPLICATION# 17.108

Request to establish a new Level II HCPCS code to identify a movable Hypobaric Membrane suspension system for transtibial and transfemoral amputees. Trade Name: Ossurr Movable Hypobaric Membrane.

Applicant's suggested language: LXXXX, "Addition to lower extremity, below knee/above knee movable hypobaric membrane suspension mechanism with proximal and distal adjustability, excludes socket insert."

No Primary Speaker

Agenda Item # 15

APPLICATION# 17.113

Request to establish a new Level II HCPCS code to identify a wearable, adjustable pelvic compression device used in the treatment of menstrual pain symptoms, Trade Name: Ziivaa.

Applicant's suggested language:

hip orthosis, prefabricated, plastic, abduction control of hip joints, flexible, prefabricated, padded, trochanteric pad, ultra-light material pelvic band, lock pelvic control, hip joint, band and belt, micro adjustment, macro adjustment.

Primary Speaker: Dr. Aileen Caceres

Agenda Item # 16

APPLICATION# 17.114

Request to establish 2 new Level II HCPCS codes, one each, to identify the head mounted telemetry and video data collection system, and the Video Processing Unit (VPU), for use with an implanted Epiretinal Prothesis System, Trade Name: Argus II Retinal System.

Applicant's suggested language:

LXXXX Head mounted telemetry and video data collection system;

LXXXX Video processing unit (VPU) for use with an implanted retinal prosthesis

Primary Speaker: Mr. Stuart Langbein

Agenda Item # 17

APPLICATION# 17.064

Request to establish a series of 5 new Level II HCPCS codes to identify an oral electronic vision aid system and its components, Trade Name: BrainPort V100

Applicant's suggested languages:

Lxxx1 Vision Aid Prosthetic System, including intra-oral stimulation device, headset with integrated digital video camera, and patient controller.

Lxxx2 Headset with integrated digital video camera, for use with vision aid prosthetic system, replacement

Lxxx3 Intra-oral stimulation device, for the use with vision and prosthetic system, replacement

Lxxx4 Patient controller for use with vision aid prosthetic system, replacement

Lxxx5 Vision aid prosthetic system training services, individual, up to 10 hours

No Primary Speaker

Agenda Item # 18

APPLICATION# 17.117

Request to:

(1) establish a new Level II HCPCS code to identify a Prosthetic Arm Cover, Trade Name: Freedom Arm Cover;

(2) establish a new Level II HCPCS code to identify an Ankle Foot Orthosis, Trade Name: James' Ankle Foot Orthotic (JAFO);

(3) assign existing code L2820 "Addition to the lower extremity orthosis, soft interface for molded plastic, below knee section" to the JAFO pad (as a soft interface); and

(4) assign existing codes L5704 "Custom shaped protective cover, below knee" and L5705 "Custom shaped protective cover, above knee" to the JAFO.

No coding language was suggested by the applicant.

Primary Speaker: Mr. James Devito

HCPCS Public Meeting Agenda Item # 1

Application# 17.092

TOPIC

Repeat request to establish a new Level II HCPCS code to identify the Power Module Patient Cable for the use with a Left Ventricular Assist Device (LVAD). Trade Name: HeartMate Power Module Patient Cable.

BACKGROUND

St. Jude's Medical, Inc. submitted a request to establish a new Level II HCPCS code to identify the HeartMate Power Module Patient Cable. According to the applicant, this cable provides a direct connection between the main power source, the Power Module and the LVAD microprocessor/controller, thus providing power to the implanted LVAD pump. The patient population indicated for LVAD therapy consists of advanced heart failure patients Class IIIB and IV end-stage left ventricular failure that requires mechanical circulatory support therapy for either ridge to Transplantation (BTT) to support patients until a heart becomes available or Destination Therapy (DT) for patients who are not medically appropriate candidates for cardiac transplantation. The Power Module Patient Cable is furnished at the time of the LVAD implant. It is replaced annually per the instructions for use, and has a useful lifetime of 1 year.

The applicant comments that currently, this item is reported under HCPCS Q0508 (miscellaneous supply or accessory for use with an implanted ventricular assist device); and that an increase in volume of sales supports establishment of a new unique code.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only". Effective 1/1/18.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

For the new QXXXX code, we believe that the item would be paid in accordance with the payment rules that apply to Orthotics, Prosthetics, Prosthetic Devices, and Vision Services if covered. Payment for Q0479 would be modified to reflect the addition of the new cable code.

HCPCS Public Meeting Agenda Item # 2

Application# 17.066

TOPIC

Request to assign existing Level II HCPCS code B4153 to an enteral formula, nutritionally complete, hydrolyzed protein, Trade Name: Ultrient.

BACKGROUND

Trovita Health Sciences submitted a request to assign existing Level II HCPCS code B4153 "Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may also include fiber, administered through an enteral feeding tube, 100 calories=1 unit" to Ultrient Ready-to-feed peptide formula (1.5kcal/mL). According to the applicant, this is a new non-soy enteral formula containing a hydrolyzed whey protein isolate (WPI) as a primary protein source. Ultrient also includes fats, carbohydrates, a vitamin and mineral blend, as well as fiber that is administered only through an enteral feeding tube. The product is primarily used as a sole source meal replacement option for anyone with a medical condition that will require enteral/tube feeding for a prolonged period of time.

The applicant comments that Ultrient would be adequately described under existing HCPCS code B4153.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code B4153 "Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit" adequately describes Ultrient Ready-to-Feed 1.5 KCal/mL Peptide Formula and it is available for assignment by insurers if they deem appropriate. When the product is administered orally, the HCPCS modifier BO "Orally administered nutrition, not by feeding tube" should also be used.

The HCPCS Level II codes describe categories of like items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code B4153 describes this product, as a general rule CMS does not classify individual items into code categories on behalf of insurers. Individual insurers have the necessary flexibility to classify specific products into HCPCS Level II code categories and establish their own coding instructions in accordance with their policies and program operating needs. Questions regarding classification of products into HCPCS Level II code categories should be submitted to the insurer in whose jurisdiction a claim would be filed. For private sector health insurance systems, please contact the individual private insurance entity. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) contractor provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS, which lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing = 39

HCPCS Public Meeting Agenda Item # 2 (continued)

Application# 17.097

TOPIC

Request to assign existing Level II HCPCS code B4161 to a Ready-to-Feed Peptide Formula for enteral feeding, Trade Name: Ultrient Junior Peptide 1.0 Calorie Pediatric Enteral Nutrition Formula.

BACKGROUND

Trovita Health Science submitted a request to assign Level II HCPCS code B4161 "Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit" to include Ultrient Junior 1.0. According to the applicant, this product is a new non-soy sole source of complete and balanced nutrition containing hydrolyzed whey protein, carbs and fats designed for tube feeding children ages 1-13. It is administered through a feeding tube for pediatric patients and can deliver 100% of the macro and micro-nutrients they need to stay alive or until they can be weaned off of the feeding tube.

The applicant comments that Ultrient Junior Peptide 1.0 would be adequately described under existing code B4161.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code B4161 "Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit" adequately describes the Ultrient Junior Peptide 1.0 Calorie Pediatric Enteral Nutrition Formula. Code B4161 is available for assignment by insurers if they deem appropriate. When the product is administered orally, the HCPCS modifier BO "Orally administered nutrition, not by feeding tube" should also be used.

The HCPCS Level II codes describe categories of like items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code B4161 describes this product, as a general rule CMS does not classify individual items into code categories on behalf of insurers. Individual insurers have the necessary flexibility to classify specific products into HCPCS Level II code categories and establish their own coding instructions in accordance with their policies and program operating needs. Questions regarding classification of products into HCPCS Level II code categories should be submitted to the insurer in whose jurisdiction a claim would be filed. For private sector health insurance systems, please contact the individual private insurance entity. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed.

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PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing =39

HCPCS Public Meeting Agenda Item # 2 (continued)

Application# 17.099

TOPIC

Request to assign existing Level II HCPCS code B4154 to Ultrient Junior 2.0, Trade Name: Ultrient for Renal Health

BACKGROUND

Trovita Health Sciences submitted a request to assign existing Level II HCPCS code B4154 "Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit" to Ultrient 2.0 for Renal Health. According to the applicant, this product is a new non-soy, complete enteral nutrition formula containing reduced levels of micronutrients (including phosphorous and potassium, etc.). It is intended for use by patients with chronic kidney disease.

The applicant comments that Ultrient 2.0 for Renal Health would be adequately described under B4134.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code B4154 "Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit" adequately describes Ultrient 2.0 Calorie for Renal Health. Code B4154 is available for assignment by insurers if they deem appropriate. When the product is administered orally, the HCPCS modifier BO "Orally administered nutrition, not by feeding tube" should also be used.

The HCPCS Level II codes describe categories of like items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code B4154 describes this product, as a general rule CMS does not classify individual items into code categories on behalf of insurers. Individual insurers have the necessary flexibility to classify specific products into HCPCS Level II code categories and establish their own coding instructions in accordance with their policies and program operating needs. Questions regarding classification of products into HCPCS Level II code categories should be submitted to the insurer in whose jurisdiction a claim would be filed. For private sector health insurance systems, please contact the individual private insurance entity. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed.

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PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing =39

HCPCS Public Meeting Agenda Item # 2 (continued)

Application# 17.079

TOPIC

Request to assign existing Level II HCPCS code B4150 "Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories=1unit" to a nutritional shake for medical malnutrition, Trade Name: ENU Complete Meal Replacement Powder Mix.

BACKGROUND

Trovita Health Science submitted a repeat request to assign existing Level II HCPCS code B4150 to ENU Complete Meal Replacement Powder. According to the applicant, ENU is a conventional food product that is a nutritional shake/beverage made from a powder. The product is a novel, well-balanced macro-nutritional powder formula comprised of a highly bioavailable whey protein isolates, quality carbohydrates and healthy fats. It is designed for beneficiaries with high caloric and protein needs associated with medical malnutrition, because of various medical conditions. It can be administered orally and via enteral tube.

The applicant comments that ENU Meal Replacement Powder would be adequately described under existing code B4150.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code B4150 "Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit" adequately describes the ENU Meal Replacement Powder Mix and it is available for assignment by insurers if they deem appropriate. When the product is administered orally, the HCPCS modifier BO "Orally administered nutrition, not by feeding tube" should also be used.

The HCPCS Level II codes describe categories of like items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code B4150 describes this product, as a general rule CMS does not classify individual items into code categories on behalf of insurers. Individual insurers have the necessary flexibility to classify specific products into HCPCS Level II code categories and establish their own coding instructions in accordance with their policies and program operating needs. Questions regarding classification of products into HCPCS Level II code categories should be submitted to the insurer in whose jurisdiction a claim would be filed. For private sector health insurance systems, please

contact the individual private insurance entity. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed.

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PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing = 39

HCPCS Public Meeting Agenda Item # 2 (continued)

Application# 17.112

TOPIC

Request to assign existing Level II HCPCS code B4150 to a nutritional shake for medical malnutrition, Trade Name: ENU Nutritional Shake.

BACKGROUND

Trovita Health Science submitted a request to assign ENU Nutritional Shake to existing Level II HCPCS code B4150 "Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit." According to the applicant, ENU is a conventional food product which is a nutritional shake/beverage. The applicant states that the product is a novel, well-balanced macro-nutritional formula comprised of a highly bioavailable whey protein isolates, quality carbohydrates and healthy fats. It is designed for beneficiaries with high caloric and protein needs associated with medical malnutrition, because of various medical conditions. It is available in vanilla and chocolate flavors, and is administered orally, or through an enteral tube feeding system in a patient's home by the patient or caregiver, or in an inpatient hospital setting or skilled nursing facility.

The applicant comments that ENU nutritional shake is adequately described under existing code B4150.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code B4150 "Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit" adequately describes the ENU Nutritional Shake. Code B4150 is available for assignment by insurers if they deem appropriate. When the product is administered orally, the HCPCS modifier BO "Orally administered nutrition, not by feeding tube" should also be used.

The HCPCS Level II codes describe categories of like items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code B4150 describes this product, as a general rule CMS does not classify individual items into code categories on behalf of insurers. Individual insurers have the necessary flexibility to classify specific products into HCPCS Level II code categories and establish their own coding instructions in accordance with their policies and program operating needs. Questions regarding classification of products into HCPCS Level II code categories should be submitted to the insurer in whose jurisdiction a claim would be filed. For private sector health insurance systems, please

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PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing =39

HCPCS Public Meeting Agenda Item # 2 (continued)

Application# 17.096

TOPIC

Request to establish a new Level II HCPCS code to identify an enteral feeding supply kit, full closed for bolus or gravity feeding, with no-spill valve. Trade Name: Safe-T Feed Ready-to-Feed Pouch with ENFit Safety Connector.

Applicant's suggested language: BXXXX "Enteral feeding supply kit, full closed for bolus or gravity feeding, with no-spill valve." Disposable, single-use feeding pouch (with pre-filled formula), includes Enfit nutrition connector and a spill-proof valve to prevent leakage and allow for storage after opening if the formula is not completely used."

BACKGROUND

Trovita Health Sciences submitted a request to establish a new Level II HCPCS code to identify the Safe-T Feed Ready-to-Feed Pouch with ENFit Safety Connector (Safe-T Feed System).

According to the applicant, the Safe-T Feed System is a new class II medical device that connects directly to the feeding tube and allows for fully-enclosed, bolus or gravity administration of pre-filled nutrition formulas, without the requirement for syringes or pump systems. The Safe-T Feed System is the first completely closed enteral tube feeding system pre-fit with the new EnFit connector. The unique design elements allow for clean, and spill-free administration of the food formulas. Spillage is a leading reason patients do not achieve their total daily required caloric intake. The client population includes patients with ALS, GI disease, or cancer, who are on enteral feeding and do not meet their daily nutrition goals.

The applicant comments that a new code is warranted because existing codes B4034-B4036 do not adequately describe the Safe-T-Feed System.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Safe-T- Feed Ready-to-Feed Pouch with ENFit Safety Connector has not been approved. Existing code B4034 "Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape" or B4036 "Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape", depending on the type of feeding, adequately describes this product.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to this product if covered. Pricing =39

HCPCS Public Meeting Agenda Item # 3

Application# 17.068

TOPIC

Request to establish a new Level II HCPCS code to identify a rechargeable lithium-ion battery for use with the portable pneumatic driver of the SynCardia Total Artificial Heart (TAH-t). Trade Name: Freedom Onboard Battery.

Applicant's suggested language: QXXXX: "Battery (Li-Ion) for use with portable pneumatic biventricular driver, total artificial heart, each."

BACKGROUND

SynCardia Systems, LLC, submitted a request to establish a new Level II HCPCS code to identify the Freedom Onboard Lithium Ion Battery. According to the applicant, this battery powers the Freedom portable driver that operates the Syncardia Total Artificial Heart (TAH-t), a bridge to heart transplant for transplant-eligible patients at risk of death from biventricular failure. This battery is unique to the TAH-t and is not interchangeable with other batteries. The Freedom Onboard rechargeable lithium Ion Batteries power the Freedom Portable Driver when the driver is not connected to external power. According to the applicant, the batteries are rented. Two fully charged Freedom Onboard batteries provide approximately two hours of support. A total of six Freedom Onboard batteries are supplied to the patient; this allows for the availability of four charged batteries to replace the two that are powering the Freedom portable driver when they need to be recharged.

Suppliers have been billing using either existing code Q0508 "Miscellaneous Supply or accessory for use with an implanted ventricular assist device" or Q0509 "Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare part A"; based on pre-authorization with the individual's third-party health plan.

The applicant comments that a new code is warranted because there are no existing codes uniquely describe the Freedom Onboard Battery that specifically powers the Freedom portable drive that operates the TAH-t. These batteries are unique to the TAH-t and are not interchangeable with other batteries.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify the lithium-ion battery for use with the SynCardia Total Artificial heart. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

HCPCS Public Meeting Agenda Item # 3 (continued)

Application# 17.069

TOPIC

Request to establish a new Level II HCPCS code to identify a power supply system for use with the Freedom portable driver of the Syncardia Total Artificial Heart (TAH-t). Trade Name: Freedom Home AC Power Supply System.

Applicant's suggested language: QXXXX: "Power supply system for use with portable pneumatic biventricular total artificial heart."

BACKGROUND

SynCardia Systems, LLC submitted a request to establish a new Level II HCPCS code to identify a Home AC Power Supply System which consists of 2 Home AC Power Supplies with integrated cord, a 4-well battery charger and an AC Power Adaptor backup. This power adaptor routes external power to the Freedom portable driver. It must be connected to an external power source. This device is continuously used to power the Freedom portable driver when the Onboard Batteries are not providing sole power. This device is only used by patients who have been implanted with a TAH-t or these are patients either awaiting heart transplant or have been implanted with the TAH-t as a destination.

The applicant comments that DMEPOS suppliers bill the Freedom Home AC Power Supply System using either code Q0508, "Miscellaneous supply or accessory for use with any implanted ventricular assist device" or Q0509, "Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A."

The applicant comments that a new code is warranted because no existing HCPCS code describes this Home AC Power Supply System or its specific use.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify the power supply system for use with a portable pneumatic biventricular total artificial heart. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

HCPCS Public Meeting Agenda Item # 3 (continued)

Application# 17.070

TOPIC

Request to establish 5 new Level II HCPCS codes to identify supplies and accessories for the Freedom Portable Driver System that operates the SynCardia Total Artificial heart (TAH-t) for use outside the hospital.

Applicant's suggested language:

QXXX1 Miscellaneous supply or accessory for use with an implanted total artificial heart;

QXXX2 Miscellaneous supply or accessory for use with any implanted total artificial heart for which payment was not made under Medicare Part A;

QXXX3 Filters for use with total artificial heart, replacement only;

QXXX4 Power adaptor for use with total artificial heart, vehicle type;

QXXX5 Backpack/bag for use with total artificial heart, replacement only.

BACKGROUND

SynCardia Systems, LLC, submitted a request to establish 5 new Level II HCPCS codes to identify the supplies and accessories used with the Freedom Portable Driver System. According to the applicant, these items may require replacement during the time the patient is living outside of a hospital awaiting a transplant, or for whom treatment is Destination Therapy. These items assure that a patient can function and live with the TAH-t outside the hospital setting. The following items are included in this request: Freedom Shoulder Bag; Freedom Backpack; Freedom Accessory Bag; Freedom Car Charger; Freedom Filter Pack; and Freedom Miscellaneous Supplies including the Freedom Patient Tool Kit, handles and straps for the backpack, shoulder bag, Freedom driver and accessory bags.

The applicant states that each of these items are currently reported using either existing code Q0508, "Miscellaneous supply or accessory for use with an implanted ventricular assist device" or Q0509, "Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A."

The applicant comments that new codes are warranted because no existing codes describe these specific TAH-t accessories.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify the supplies and accessories for use with the Portable Driver System that operates the SynCardia Total Artificial Hearts that are the subject of this request. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

HCPCS Public Meeting Agenda Item # 3 (continued)

Application# 17.077

TOPIC

Request to establish a new Level II HCPCS code to identify the SynCardia Freedom portable driver used with the SynCardia Total Artificial Heart (TAH-t), Trade Name: Freedom Portable Driver

Applicant's suggested language: QXXXX "Pneumatic biventricular driver, portable, total artificial heart."

BACKGROUND

SynCardia Systems, LLC, submitted a request to establish a new Level II HCPCS code to identify a pneumatic, biventricular portable driver for use with the Syncardia Total Artificial Heart, (TAH-t). The portable driver is a piston-driven, pneumatic compressor that delivers regulated pressures and vacuum to the TAH-t drivelines. It is used to continuously operate the TAH-t. According to the applicant, the use of Freedom Portable Driver enables patients who are eligible, to be discharged from the hospital as they are awaiting a heart transplant. In addition, the FDA granted this TAH-t an Investigational Device Exemption (IDE) for "destination therapy" for persons who are ineligible for heart transplant. The applicant states that a patient is provided 2 portable drivers to ensure there is one always available to the patient. Patients are expected to return to the hospital with their portable drivers every 120 days at which time the patient is connected to their second driver; receives a newly supplied back-up portable driver; and the previously connected driver is returned for maintenance.

The applicant comments that a new code is warranted because no existing HCPCS code describes the Freedom Portable Driver

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify the Portable driver used with the Syncardia Total Artificial Heart. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

HCPCS Public Meeting Agenda Item # 4

Application# 17.084

TOPIC

Repeat request to establish a new Level II HCPCS code to identify a digestive enzyme (immobilized lipase) packed cartridge, Trade Name: RELiZoRB.

Applicant's suggested language: "BXXXX, "RELiZORB, immobilized lipase cartridge."

BACKGROUND

Alcresta Therapeutics, Inc. submitted a request to establish a new HCPCS Level II code to identify RELiZORB, an enzyme packed cartridge indicated for use in adults to hydrolyze fats in entral formula. The cartridge fits in line with enteral feeding systems, and is connected between the infusion pump and the feeding tube. The active ingredient is the digestive enzyme lipase, attached to polymetric carriers together called iLipase. As the formula passes through RELiZORB, it makes contact with the iLipase, and fats in the formula are modified to more absorbable forms prior to ingestion. Fat malabsorption is most common in individuals who cannot produce or secrete adequate amounts of digestive enzymes because of compromised pancreatic function. According to the applicant, RELiZORB is a "first-of-its kind digestive enzyme cartridge designed to mimic normal pancreatic function by breaking down fats in enteral tube feeding formula" The applicant comments that, "since the last application was submitted, data was published at the most recent North American Cystic Fibrosis Conference. The results of the study demonstrate that RELiZORB is safe and effective in patients with pancreatic enzymatic insufficiency (EPI) that are receiving enteral feeding."

The applicant comments that a new code is needed to facilitate separate billing of the RELiZORB. "Unlike supplies which are inert materials used to administer formula during enteral tube feeding, RELiZORB actively modifies the composition of the formula by hydrolyzing fats into an absorbable form. RELiZORB provides proven therapeutic benefit and should not be considered a supply." "Currently, providers must utilize HCPCS code B9998 "Noc for enteral supplies", resulting in delayed claims processing."

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a unique Level II HCPCS code to separately identify the RELiZORB (immobilized lipase) cartridge has not been approved. Existing codes B4034 "Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape", B4035 "Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape", or B4036 "Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape", depending of the type of feeding, adequately describes this product.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to this product if covered. Pricing = 39

HCPCS Public Meeting Agenda Item # 5

Application# 17.087

TOPIC

Request to establish a new Level II HCPCS code to identify a software controlled, pulsatile pressure, off-loading boot and shin device for the treatment of lower limb wounds, Trade Name: PulseFlow DF

Applicant's suggested language: "EXXXX, Software controlled, ambulatory limb salvage device with an internal pneumatic pump applying pulsatile pressure in the medical aspect of the foot within an off-loading boot and a shin device for the treatment of diabetic and non-diabetic lower limb wounds."

BACKGROUND

Pulse Flow Technologies, Inc, submitted a request to establish a new Level II HCPCS code to identify the PulseFlowDF. According to the applicant, this product is a software controlled, prescription medical device which is clinically equivalent to existing hospital outpatient pressure treatment in connection with diabetic limb salvage. It consists of a shin housing with a bladder, a computer-controlled electric pump and exterior battery charger with a built-in monitor for data capture; and a wide boot with a built-in off-loader, integral intermittent pneumatic plantar compression inflation via an inflatable bladder in the insole, shock absorption and impact protection. The applicant states that the PulseFlowDF is "designed to heal diabetic foot ulcers" by stimulating blood flow; protecting the foot wound; and stabilizing and off-loading the foot. It's intended clinical term of use is 12 weeks, after which the pumping mechanism can be removed and the boots can be used as street shoes.

The applicant commented that a new code is warranted to align the devices to the correct DME category and because no existing code adequately describe the PulseFlow DF.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the PulseFlowDF has not been approved. Existing code A9283 "Foot pressure off loading/supportive device, any type, each" plus A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" together adequately describes the product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to this product. Pricing = 00

HCPCS Public Meeting Agenda Item # 6

Application# 17.088

TOPIC

Request to establish 2 new Level II HCPCS codes to identify a blood pressure lowering device used to treat hypertension, Trade Name: RESPeRATE.

Applicant's suggested language:

(1) XXXXX: Non-invasive respiratory modulation assist device (RESPeRATE), including respiratory effort belt, directing patient respiration rate, and patterns of inhalation and exhalation.

(2) XXXXX: Respiratory effort belt kit and accessories used with the non-invasive respiratory modulation assist device (RESPeRATE).

BACKGROUND

Boston MedTech Advisors, Inc. submitted a request to establish a new Level II HCPCS code to identify the RESPeRATE device manufactured by 2breath Technologies, Ltd. According to the applicant, the product is a safe non-invasive non-pharmaceutical medical device that lowers blood pressure in hypertensive patients by modulating and controlling a patient's breathing rate and inhalation and exhalation duration ratio. This device is used by patients daily in the home for 15 minutes per day. It is cleared as a biofeedback device. The device consists of a computerized control unit, a breathing sensor and a set of ear buds. The patient places the breathing sensor on their upper abdomen. The sensor analyzes the patient's breathing pattern and creates a personalized melody composed of 2 distinct inhale and exhale "guiding tones." The patient hears the tones via the headphones. The body's natural response is to follow external rhythms to synchronize breathing to the tones by gradually slowing breathing and prolonging exhalation. The muscles surrounding the small blood vessels of the body relax; blood flows more freely; and blood pressure is reduced.

The applicant commented that a new code is warranted because there is no HCPCS code to describe this device or similar devices operating in a similar manner and patients are required to pay for this device out of pocket. Existing code E1399 "Durable Medical Equipment, miscellaneous" is being billed, but this code is not accompanied with a coverage policy and has no established fee.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish two new Level II HCPCS codes to identify the RESPeRATE device has not been approved, because this product is an integral part of a procedure and payments for that service includes payment for the RESPeRATE device if it is used.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

HCPCS Public Meeting Agenda Item # 7

Application# 17.091

TOPIC

Request to revise existing Level II HCPCS code P9072, which currently reads, “Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit,” to instead read, “Platelets, pheresis, pathogen reduced, each unit”.

BACKGROUND

The Cerus Corporation submitted a request to revise the code descriptor for P9072 to omit the phrase "or rapid bacterial tested." According to the applicant, the pathogen reduced aphersis platelet product is prepared from platelets collected by apheresis from a single healthy platelet donor and manufactured using a recently FDA-approved pathogen reduction process to reduce the risk of transfusion-transmitted infection (TTI), including sepsis, and potentially reduce the risk of transfusion-associated graft-versus-host disease (TA-GVHD).

The applicant comments that a revision to the code descriptor to omit "rapid bacterial tested" is warranted because intermixing into a single HCPCS code introduces coding problems; a barrier to patient access; and payment incentives to use RBT units instead of pathogen reduced units.

PRELIMINARY HCPCS CODING RECOMMENDATION

1) Existing code P9072 "Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit" made not billable to Medicare. Effective 7/1/17.

2) Newly established code Q9988 "Platelets, Pheresis, Pathogen-Reduced, each unit", effective 7/1/17, adequately describes pathogen reduced apheresis platelets.

3) Discontinue code P9072. Effective 12/31/17.

4) Discontinue code Q9988. Effective 12/31/17.

5) Establish new code PXXXX to replace Q9988 using the same language. Effective 1/1/18.

6) Establish Q9987 "Pathogen(s) Test for Platelets". Effective 7/1/17.

7) Discontinue code Q9987. Effective 12/31/17.

8) Establish new code XXXXX to replace Q9987 using the same language. Effective 1/1/18.

HCPCS Public Meeting Agenda Item # 8

Application# 17.093

TOPIC

Request to establish a new Level II HCPCS code to identify a high-precision weight monitoring scale with cellular transmission capability to health care entities. Trade Name: BodyTrace BT004.

BACKGROUND

Omada Health, Inc., submitted a request to establish a new Level II HCPCS code to identify a cellular-enabled medical bathroom scale to be used in Diabetes Prevention Programs in a beneficiary's home. According to the applicant, the scale is intended for use by adults who are overweight with at least one additional risk factor for cardiovascular disease or type 2 diabetes. Real time weight data is automatically transmitted to a program provider to inform clinical care; and enables communication between the patient and the care provider. The applicant comments that there is one existing DME code for a scale E1639, but it is a dialysis scale.

The applicant comments that a new code is warranted because there is no existing code to identify this unique medical product that is distinguishable from an ordinary drugstore scale of unknown accuracy and no secure cellular communications properties.

PRELIMINARY HCPCS CODING RECOMMENDATION

1) Existing code E1639 "Scale, each" adequately describes the scale that is the subject of this request and it is available for assignment by insurers if they deem appropriate.

2) Revise the short descriptor of existing code E1639, which currently reads, "Dialysis scale", to instead read, "scale, each" (removing the word "dialysis"). Effective 1/1/17.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product. Pricing = 00

HCPCS Public Meeting Agenda Item # 9

Application# 17.095

TOPIC

Request to establish a new Level II HCPCS code to identify an alternating pressure geri chair cushion, Trade Name: Relief Chair Alternating Pressure Geri Chair Cushion.

Applicant did not suggest language for a code.

BACKGROUND

H&R Healthcare, LP, submitted a request to establish a new Level II HCPCS code to identify the Relief Chair Alternating Pressure Geri Chair Cushion with Low Air Loss and Intelligent Pressure Sensing (IPS) technology. According to the applicant, this cushion is designed for use with a rollabout chair. Its use aids in the prevention/treatment of pressure ulcers while a patient is in the chair. The cushion's Intelligent Pressure Sensing Technology responds to patient movements by automatically adjusting the internal cushion pressure, allowing the cushion to regulate airflow and continuously provide therapy. This approximately 71" X 20" X 5.5", waterproof, skid-resistant cushion has 26 air cells covering the entire back and leg section of the Rollabout chair, geriatric chair or recliner. The cushion provides head to toe protection of patients in a sitting position.

The applicant comments that, as there are existing codes for support surfaces, mattresses and overlays including wheelchair cushions; a new code is warranted for a Rollabout chair cushion.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Relief Chair Alternating Pressure w/LAL and IPS Geri Chair Cushion has not been approved. Existing code E2610 "Wheelchair seat cushion, powered" adequately describes this product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing = 32

HCPCS Public Meeting Agenda Item # 10

Application# 17.100

TOPIC

Third request to establish a new Level II HCPCS code to identify a replaceable pump device used to empty the female urinary bladder, Trade Name: InFlow Intraurethral Valve-Pump and Activator.

Applicant's suggested language: LXXXX, Female Urinary Prosthesis, replaceable.

BACKGROUND

Medical Technology Partners, Inc., submitted a request to establish a new Level II HCPCS code to identify InFlow Intraurethal Valve-Pump and Activator, manufactured by Vestiflo, Inc. According to the applicant, the inFlow device is indicated for use by adult females with impaired detrusor contractility (IDC) of neurological origin, (e.g., due to MS, stroke, Parkinson's, spinal cord injury, spina bifida, etc). Persons with IDC experience complications including urinary retention, overflow, urinary incontinence, recurrent urinary tract infections (UTIs), bladder stones, and impaired renal function. The inFlow system includes the InFlow device, and an Activator: The InFlow device is a sterile, single-use urethral insert that houses a magnetic metal valve pump mechanism in a biocompatible silicone, packaged with a disposable introducer. The pump device is inserted into the urethra and anchors at the bladder next. It is an indwelling device intended to be removed and replaced every 29 days.The Activator is a hand-held remote control that is required to activate the internal valve-pump mechanism in the InFlow device. "The pump empties the bladder at a normal rate."nThe Activator comes with a Base Station for recharging its internal battery. Use of the InFlow Urinary Prosthesis provides bladder drainage and mimics normal voiding for women whose bladder function is permanently impaired.

The applicant comments that a new code is warranted because no existing HCPCS code adequately describes InFlow, which is a new type of device.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the inFlow Intraurethral Valve-Pump and Activator has not been approved. Existing code A4335 "Incontinence supply; miscellaneous" adequately describes this product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

HCPCS Public Meeting Agenda Item # 11

Application# 17.102

TOPIC

Request to establish a new Level II HCPCS code to identify wearable moist-heat or cooling breastfeeding relief packs. Trade Name: Rachel's Remedy.

Applicant's suggested language: "Moist heat device for use prior to or during use with breast pump."

BACKGROUND

Rachel's Remedies, LLC submitted a request to establish a new Level II HCPCS code to identify wearable Breastfeeding Relief Packs. According to the applicant, this product is for use by breast feeding women as a necessary breast pump supply/accessory for use prior to pumping, to trigger the milk let-down reflex and increase milk flow and supply. In addition, the applicant comments that this product can relieve symptoms of clogged ducts, mastitis, milk blisters, and blebs; and used cold, relieve engorgement after pumping or nursing. It is a natural treatment consisting of microwavable and freezer safe flaxseed filled pillow with a moistening cloth in a waterproof pouch.

The applicant comments that a new code is warranted because existing codes do not incorporate non-electric moist heat.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Rachel's Remedy Breastfeeding Relief Packs has not been approved. Existing code A9273 "Hot water bottle, ice cap or collar, heat and/or cold wrap, any type" adequately describes the product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing =00

HCPCS Public Meeting Agenda Item # 12

Application# 17.103

TOPIC

Repeat request to establish two new Level II HCPCS codes and to revise two existing Level II HCPCS codes in order to distinguish SpeediCath and other hydrophilic-coated intermittent urinary catheters from intermittent urinary catheters that are not coated, and currently share the same codes.

Applicants suggested language:

Establish "AXXXX - Hydrophilic-coated intermittent urinary catheter; straight tip, with sterile lubricating coating, each".

"Establish AXXXX - Hydrophilic-coated intermittent urinary catheter; Coudé tip, with sterile lubricating coating, each".

Revise A4351, which currently reads, "Intermittent urinary catheter; straight tip, with or without coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each", to instead read, "Intermittent urinary catheter; straight tip, without coating (Teflon, silicone, silicone elastomer, etc.), each."

Revise A4352, which currently reads, "Intermittent urinary catheter; Coudé tip, with or without coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each", to instead read, "Intermittent urinary catheter; Coudé tip, without coating (Teflon, silicone, silicone elastomer, etc.), each."

BACKGROUND

Coloplast, Inc., submitted a request to establish 2 new Level II HCPCS code and to revise 2 existing codes in a way that would make a distinction between hydrophilic coated intermittent urinary catheters; and intermittent urinary catheters without coating. Intermittent catheterization is advocated as an effective bladder management strategy for patients with incomplete bladder emptying capacity due to idiopathic or neurogenic bladder dysfunction. Hydrophilic catheters have hydrophilic polymer coating bonded on the catheter surface; when hydrated becomes a smooth lubricant. The applicant points out that existing codes for intermittent catheters include both the uncoated and hydrophilic-coated catheters in the same HCPCS codes.

The applicant claims that there are clinical and functional difference between "conventional uncoated" and hydrophilic intermittent urinary catheters. Specifically, uncoated catheters must be used with a separate gel lubricant, the application of which requires manual dexterity. In contrast, Hydrophilic catheters are "pre-lubricated" and as such, are easier to use by persons with impaired manual dexterity. The applicant also claims that use of hydrophilic catheters is associated with reduced friction when compared with the use of lubricated, non-coated catheters, and the reduced friction is associated with reduced pain on insertion and withdrawal, and less microscopic hematuria. In addition, use of hydrophilic catheters is associated with lower incidence of symptomatic urinary tract infections.

The applicant comments that the current coding structure between hydrophilic and non-coated catheters:

1. does not recognize a difference in materials of manufacture;

2. has resulted in non-uniform coding of hydrophilic intermittent urinary catheters across insurers;

3. does not enable data collection for administrative medical records, ordering and research purposes; and

4. does not facilitate separate billing for "built-in lubricant" on hydrophilic catheters.

The applicant comments that "Hydrophilic coated catheters should not be considered equivalent to uncoated catheters for coding and reimbursement purpose" and coding distinctions between non-coated and hydrophilic-coated intermittent urinary catheters is necessary in order to enable more accurate reimbursement for and improve patient access to hydrophilic catheters; promote prescription compliance; and facilitate data collection.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish two new Level II HCPCS codes to separately identify hydrophilic coated urinary catheters has not been approved. Existing code A4351 "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each" or A4352 "Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each", depending on whether the catheter has a straight or curved tip, adequately describe the products that are subject of this request.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to this product if covered. Pricing =37

HCPCS Public Meeting Agenda Item # 13

Application# 17.105

TOPIC

Request to revise existing Level II HCPCS codes L8618 and L8628 to include auditory osseointegrated implants (AOI) devices. Trade name: Cochlear Baha Coil Cables and Cochlear Baha Remote Control 2.

1. Revise existing Level II HCPCS code L8618, which currently reads, "Transmitter cable for use with cochlear implant device, replacement", to instead read, "Transmitter cable for use with cochlear implant device and auditory osseointegrated devices (AOI), replacement (each)."

2. Revise existing Level Ii HCPCS code L8628, which currently reads, "Cochlear implant, external controller component, replacement", to instead read, "Cochlear implant and auditory osseointegrated devices (AOI), external controller component, replacement".

BACKGROUND

Cochlear Americas, Inc. submitted a request to revise existing codes L8618 and L8628 to include osseointegrated devices (AOI).manufactured by In-Tech Electronics Limited According to the applicant, the coil cable plugs into both the sound processor and either the CI coil or the AOI actuator. It links the various components of the sound processors and facilitates communication with the internals. The signal translated by the sound processor and communicated via electrical (CI) or mechanical (AOI) signals allow the user to hear. The remote assistant is used to control the functions of the Baha sound processor and allows the user to communicate with the processor to optimize the best listening program and run troubleshooting diagnostics to identify a malfunction with the device.

The applicant comments that existing code descriptions limit reporting of both the Coil Cable and the Remote Assistant Controller to cochlear implants only. The applicant states that a revision to the HCPCS definition will allow appropriate reporting of the coil cable and Remote Assistant Controller for both the cochlear implant and AOI processors. The applicant also comments that since the remote assistant is a new component, L9900 Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS L code is the only coding option to report the replacement of the remote assistant. Both of these items are sold separately, as part of implant systems, and/or as part of replacement systems.

PRELIMINARY HCPCS CODING RECOMMENDATION

1) Revise existing L8618, which currently reads, "Transmitter cable for use with cochlear implant device, replacement", to instead read, "Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement". Effective 1/1/18.

2) A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to revise existing code L8628 "Cochlear implant, external controller component, replacement" to include the use with auditory osseointegrated devices (AOI). For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

For the coil cable, the payment rules associated with existing code L8618 apply to this product if covered. Pricing =38. For the remote assistant, no separate Medicare payment. Payment for the controls for the prosthetic device are included in the payment for the prosthetic device and no separate payment is allowed for the remote control functions that duplicate the functions paid for as part of the prosthetic device.

HCPCS Public Meeting Agenda Item # 13 (continued)

Application# 17.106

TOPIC

Request to revise existing Level II HCPCS code L8624 to include use with auditory osseointegrated (AOI) devices, Trade Name: CP910 and CP920 Rechargeable batteries; standard and compact.

Applicant's suggest language:

1) Revise existing Level II HCPCS code L8624, which currently reads, "Lithium ion battery for use with cochlear implant device speech processor, ear level, replacement, each", to instead read, "Lithium ion battery for use with cochlear implant and auditory osseointegrated device speech processor, ear level, replacement, each".

2) Establish a new Level II HCPCS code to identify a Lithium Ion battery charger, Trade Name: Cochlear Nucleus CP800 Series Battery Charger.

Applicant's suggested language:

LXXXX:" Battery charger for Lithium rechargeable battery for cochlear implant speech processor and AOI".

BACKGROUND

On behalf of manufacturer Wyon AG, Cochlear Americas, Inc. submitted a request to: 1) revise existing code L8624 to include use of a Lithium ion battery with osseointegrated devices; and 2) establish a new code to identify the battery charger for Lithium rechargeable battery for cochlear implant speech processor and AOI. The battery and battery charger provide a cochlear implant or an AOI sound processor up to 8-16 hours of battery life. The battery charger is the docking station to place the rechargeable batteries to recharge the battery module. These lithium ion batteries are required to maintain the functionality of the device and allow the user to hear.

The applicant comments that no existing code identifies the battery charger, and the descriptor of existing code L8624 limits reporting of the lithium ion battery to cochlear implant. Modification of this code will allow appropriate reporting of lithium ion batteries for both cochlear implant and AOI processors.

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PRELIMINARY HCPCS CODING RECOMMENDATION

1) Revise existing code L8624, which currently reads, "Lithium ion battery for use with cochlear implant device speech processor, ear level, replacement, each", to instead read, "Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each". Effective 1/1/18.

2) Establish LXXXX, "External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each". Effective 1/1/18.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with existing code L8624 apply to this product if covered. Pricing =38. For LXXXX, we believe that the item would be paid in accordance with the payment rules that apply to Orthotics, Prosthetics, Prosthetic Devices, and Vision Services if covered.

HCPCS Public Meeting Agenda Item # 13 (continued)

Application# 17.107

TOPIC

Request to establish a new Level II HCPCS code to identify a replacement actuator (transducer) for use with the Baha 5 SuperPower Sound Processor system auditory (AOI) osseointegrated device. Trade Name: Baha 5 SuperPower Actuator unit

Applicant's suggested language: LXXXX "auditory osseointegrated device (AOI) actuator, replacement (each)."

BACKGROUND

Cochlear Americas, Inc., submitted a request to establish a new Level II HCPCS code to identify the actuator that is utilized in the Baha 5 SuperPower processor system. According to the applicant, the actuator is a separate piece that drives the sound transmission through the bone to the functional parts of the inner ear (cochlea). The external part of the auditory osseointegrated device is for patients who need a stronger amplification for their level of hearing loss. The actuator is separated from the microphone and battery (sound processor) to help provide the necessary amount of power required to drive the device and minimize feedback. Clinicians choose from a portfolio of sound processors to fit the patients hearing needs. The applicant comments that this item is a separate component from the sound processor, microphones, and battery, therefore there is a need for a separate reimbursement code and pathway.

The applicant comments that a new code is warranted to allow for beneficiary access and accurate claims processing.

PRELIMINARY HCPCS CODING RECOMMENDATION

1) Revise existing code L8691, which currently reads, "Auditory osseointegrated device, external sound processor, replacement", to instead read, "Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each". Effective 1/1/18.

2) Establish LXXXX, "Auditory osseointegrated device, transducer/actuator, replacement only, each". Effective 1/1/118.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with existing code L8624 apply to this product if covered. Pricing =38. Payment for L8691 would be revised to back out payment for the transducer/actuator. For LXXXX, we believe that the item would be paid in accordance with the payment rules that apply to Orthotics, Prosthetics, Prosthetic Devices, and Vision Services if covered.

HCPCS Public Meeting Agenda Item # 14

Application# 17.108

TOPIC

Request to establish a new Level II HCPCS code to identify a movable Hypobaric Membrane suspension system for transtibial and transfemoral amputees. Trade Name: Ossurr Movable Hypobaric Membrane.

Applicant's suggested language: LXXXX, "Addition to lower extremity, below knee/above knee movable hypobaric membrane suspension mechanism with proximal and distal adjustability, excludes socket insert."

BACKGROUND

OSSUR Americas, Inc., submitted a request to establish a new Level II HCPCS code to identify a movable Hypobaric Membrane manufactured by Ossur hf. According to the applicant, this product is one part of a 2-part system that allows transtibial and transfemoral amputees to maintain suspension inside a prosthetic socket, ensuring that the prosthetic limb remains safely and securely attached to their body. The applicant states, that it does this by creating a hypobaric lock when it makes contact with the socket's inner wall. The Movable Hypobaric membrane is used in conjunction with an Iceross Seal-In X silicone liner. After the individual dons the liner, they attach the movable Hypobaric Membrane to the liner in the optimal position for their unique anatomy and clinical condition. The user can slide the movable Hypobaric Membrane both proximally and distally within the prosthetic socket on a daily or even hourly basis.

The applicant comments that a new code is warranted because no existing HCPCS code describes a movable Hypobaric Membrane.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish LXXXX "Gasket or seal, for use with prosthetic socket insert, any type, each". Effective 1/1/18.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

We believe that the item would be paid in accordance with the payment rules that apply to Orthotics, Prosthetics, Prosthetic Devices, and Vision Services if covered.

HCPCS Public Meeting Agenda Item # 15

Application# 17.113

TOPIC

Request to establish a new Level II HCPCS code to identify a wearable, adjustable pelvic compression device used in the treatment of menstrual pain symptoms, Trade Name: Ziivaa.

Applicant's suggested language:

hip orthosis, prefabricated, plastic, abduction control of hip joints, flexible, prefabricated, padded, trochanteric pad, ultra-light material pelvic band, lock pelvic control, hip joint, band and belt, micro adjustment, macro adjustment.

BACKGROUND

Ziivaa, LLC, submitted a request to establish a new Level II HCPCS code to identify the Ziivaa wearable, adjustable pelvic compression device. According to the applicant, this device is a customizable truncal "orthosis" consisting of 2 foam pads attached to an adjustable nylon belt. It is worn at the hips, over clothing and delivers 30-40 lbs of pressure to the pelvic region. Its use creates targeted, inward compression to the hips, which slightly adjusts the pelvic bones inward, which reduces tension on the suspensory ligaments at their attachment sites on the pelvis, sacrum, soft tissues and uterus. The device, worn while lying down for 15 minutes per treatment, alleviates and/or eliminates pain from dysmenorrhea, making it a "transient use therapeutic device."

The applicant comments that the Ziiva device qualifies for a primary/base procedure/orthotic code and that a new code is warranted to identify this unique device because it is not described by existing codes.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Ziivaa Adjustable Compression device has not been approved. Existing code A4467 "Belt, strap, sleeve, garment, or covering, any type" adequately describes the product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to these products if covered. Pricing =00

HCPCS Public Meeting Agenda Item # 16

Application# 17.114

TOPIC

Request to establish 2 new Level II HCPCS codes, one each, to identify the head mounted telemetry and video data collection system, and the Video Processing Unit (VPU), for use with an implanted Epiretinal Prothesis System, Trade Name: Argus II Retinal System.

Applicant's suggested language:

LXXXX Head mounted telemetry and video data collection system;

LXXXX Video processing unit (VPU) for use with an implanted retinal prosthesis

BACKGROUND

Second Sight Medical Products submitted a request to establish two new Level II HCPCS codes, one each to identify the Argus II headmounted telemetry and video data collection system, and the Video Processing Unit used with the Argus II Retinal System. According to the applicant, this product enables blind individuals suffering from severe retinitis pigmentosa (RP) to "regain some functional vision, greater independence and an improved quality of life." According to the applicant, the Argus II is the first and only approved treatment for people with severe to profound retinitis pigmentosa that provides electrical stimulation of the retina to induce visual perception. It consists of 2 major components: (1) surgically implanted retinal prosthesis and (2) external patient-worn system that collects and processes image data and integrates with the surgical implant.

The applicant comments that "providers need product-specific HCPCS codes to facilitate billing when patients need to replace the external, patient-worn Argus II prosthetic components," "to ensure continued patient access to this technology, even if there is a relatively small patient population." In addition, existing code V2799 confuses the Argus II components with conventional eyeglasses and, because it is a miscellaneous code, its use "adds to the administrative burden of providers/suppliers/payers" and results in delays in processing payment.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish two unique Level II HCPCS codes to identify external, patient-worn replacement components for the Argus II Retinal System has not been approved.

Existing code C1841 "Retinal prosthesis, includes all internal and external components" identifies the entire prosthesis, including all internal and external components.

Existing code V2799 "Vision item or service, miscellaneous" is available for assignment by insurers to identify the replacement head mounted telemetry system and the replacement VPU.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply these products if covered. Pricing = 46

HCPCS Public Meeting Agenda Item # 17

Application# 17.064

TOPIC

Request to establish a series of 5 new Level II HCPCS codes to identify an oral electronic vision aid system and its components, Trade Name: BrainPort V100

Applicant's suggested language:

Lxxx1 Vision Aid Prosthetic System, including intra-oral stimulation device, headset with integrated digital video camera, and patient controller.

Lxxx2 Headset with integrated digital video camera, for use with vision aid prosthetic system, replacement

Lxxx3 Intra-oral stimulation device, for the use with vision and prosthetic system, replacement

Lxxx4 Patient controller for use with vision aid prosthetic system, replacement

Lxxx5 Vision aid prosthetic system training services, individual, up to 10 hours

BACKGROUND

Wicab, Inc., submitted a request to establish 5 new Level II HCPCS codes to identify the BrainPort V100, an oral electronic vision aid system and its components. According to the applicant, this device is a prescription vision aid prosthetic device for profoundly blind patients regardless of the cause of blindness, to aid in orientation, mobility, and object recognition in their everyday environment. It is an adjunctive device to other assistive methods such as the white cane or guide dogs. This battery powered device includes an intra-oral 394 electrode stimulation array, a hand-held controller (for user-adjustable settings) a headset (sunglasses with mounted adjustable video camera), reusable lithium batteries with charger, carrying case and user manual. The device translates information from the digital video camera to generate electro-tactile stimulation patterns on the surface of the tongue, which the user interprets as visual information. With training, users are able to interpret the shape, size, location and motion of objects in their environment. As a non-surgical visual prosthetic, the BrainPort V100 preserves the eyes, in the event future research offers better alternatives to remedy blindness.

The applicant comments that "Medicare and private payers administer coverage and payment policies for prosthetic devices that replace all or part of a permanently inoperative or malfunctioning body organ through the HCPCS nomenclature. Therefore, the BrainPort V100 must be issued specific HCPCS codes to facilitate claims submission and reimbursement. There is no existing code to describe BrainPort V100 or its components."

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new HCPCS code to identify the product that is the subject of this request. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Based on the preliminary coding recommendation, a Medicare payment determination would not apply.

HCPCS Public Meeting Agenda Item # 18

Application# 17.117

TOPIC

Request to:

(1) establish a new Level II HCPCS code to identify a Prosthetic Arm Cover, Trade Name: Freedom Arm Cover;

(2) establish a new Level II HCPCS code to identify an Ankle Foot Orthosis, Trade Name: James' Ankle Foot Orthotic (JAFO);

(3) assign existing code L2820 "Addition to the lower extremity orthosis, soft interface for molded plastic, below knee section" to the JAFO pad (as a soft interface); and

(4) assign existing codes L5704 "Custom shaped protective cover, below knee" and L5705 "Custom shaped protective cover, above knee" to the JAFO.

No coding language was suggested by the applicant.

BACKGROUND

My JAFO, LLC, submitted a request to establish 1 new Level II HCPCS code and assign additional Level II HCPCS codes L2820, and L5704 and L5705 to describe the James Ankle Foot Orthotic (JAFO), manufactured by New Option Sports. According to the applicant, the JAFO is used by patients with Foot Drop and/or frail and atrophied legs. The JAFO's design eliminates the need for strapping on AFOs. Use of the JAFO eliminates Peroneal Nerve entrapment; prevents chafing; increases proprioception and balance. The applicant comments that the padding should be considered a soft interface as coded at L2820; and the plastizote foam should be considered a protective cover as coded at L5704 and L5705. The applicant suggests that the JAFO be used as an alternative method of securing an AFO to a limb. The JAFO is zipped on and off using a zipper that starts at the top of the patient's calf in the front and ends at the ankle.

The freedom arm cover is medically necessary to afford shape and protection of the endoskeletal prosthetic components from dirt, debris and other environmental factors that can be encountered during daily use. It is used by patients with prosthetic arms. The Plastizote Arm Cover is zipped on and off using a zipper that starts at the top of the bend in the elbow and ends at the wrist.

The applicant commented that the proposed coding configuration is warranted because existing codes do not adequately describe the JAFO, as it is a brand new concept. In addition, no existing code adequately describes the Freedom Prosthetic Arm Cover.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish four new Level II HCPCS codes to identify the James' Ankle Foot Orthotic (JAFO) and one new code to identify the Freedom Arm Cover has not been approved. Existing code A4467 "Belt, strap, sleeve, garment, or covering, any type" adequately describes all items included in this application and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply these products if covered. Pricing = 00

PAYMENT FOR DMEPOS

DMEPOS

The term DMEPOS, which stands for durable medical equipment (DME), prosthetics, orthotics and supplies, is used in the Medicare program to describe a set of Medicare Part B device and supply benefits for which claims are processed by four DME Medicare Administrative Contractors (DME MACs). The Part B device benefits covered by this term include:

- DME – equipment used in the home which can withstand repeated use, is primarily and customarily used to serve a medical purpose, has an expected life of at least 3 years and is generally not useful in the absence of an illness or injury;
- Prosthetic Devices – devices that replace all or part of an internal body organ, including ostomy, tracheostomy and urological supplies, parenteral and enteral nutrients, equipment and supplies (PEN), intraocular lenses (IOLs), and one pair of conventional eyeglasses or contact lenses after each cataract surgery;
- Prosthetics – artificial legs, arms, and eyes;
- Orthotics – rigid or semi-rigid leg, arm, back, and neck braces;
- Surgical Dressings
- Therapeutic Shoes and Inserts

Fee Schedule Payments

Prior to January 1, 1989, payment for most DMEPOS items and services was made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment for most DMEPOS items and services is now based on the lower of the actual charge for the item or a fee schedule amount. The Part B deductible and 20 percent coinsurance both apply to the DMEPOS items and services described above.

The Social Security Act requires that the DMEPOS fee schedule amounts be established based on average reasonable charges made during a base period (e.g., July 1, 1986 thru June 30, 1987 for prosthetic devices, prosthetics and orthotics). The fee schedule amounts are increased by annual update factors. Additionally, the Social Security Act requires adjustments to the fee schedule amounts for certain items furnished on or after January 1, 2016, in areas that are not competitive bid areas, based on information from competitive bidding programs (CBPs) for DME, enteral nutrients, equipment and supplies. For new items where specific reasonable charge data required by the law in establishing fee schedule amounts does not exist, the fee schedule amounts for comparable items are used for the new items or the fee schedule amounts may be "gap-

filled" using supplier price lists. The gap-filling methodology is used to estimate the average reasonable charge for the item from the base period.

DMEPOS Payment Categories/HCPCS Pricing Indicators

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicators in the HCPCS identify which major payment category a code falls under. The pricing indicators applicable to DMEPOS are as follows:

- **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.