

**Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Application Summaries for DME and Accessories; O & P; Supplies and Other**

June 8, 2017

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the June 8, 2017 HCPCS Public Meeting for DME and Accessories; O & P; Supplies and Others HCPCS code applications are presented within the summary document in the same sequence as the Agenda for this Public Meeting. Each individual summary includes: the application number, topic; background/discussion of the applicant's request; CMS' published preliminary HCPCS coding recommendation; CMS' published preliminary Medicare payment recommendation; a summary of comments offered on behalf of each applicant at CMS' HCPCS public meeting in response to our preliminary recommendations; and CMS' final HCPCS coding decision. We publish a separate HCPCS Code Application Summary document for each HCPCS Public Meeting held. This is one of a series of five HCPCS Code Application Summaries for CMS' 2017-2018 HCPCS coding cycle.

Introduction and Overview

Approximately 74 people attended. The agenda included 18 items.

Cindy Hake, Director, CMS National Level II HCPCS Coding Program and Deputy Director, Division of DMEPOS Policy, provided an overview of the HCPCS public meeting procedures as it relates to the overall HCPCS coding process.

Joel Kaiser, the Director of the Division of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy, presented an overview of the methods used for setting the payment amount for DME, prosthetics, orthotics and supplies and when the different payment categories are used. The overview was also provided as a written document along with the agenda for today's meeting. For additional information, the DME payment rules are located at Section 1834(a) of the Social Security Act. The Medicare fee schedule for DME, Prosthetics, Orthotics and Supplies, and background information can be accessed and downloaded free of charge at:
<http://www.cms.gov/DMEPOSFeeSched/>.

Prior to the Public Meetings, over the course of several months, the CMS HCPCS Workgroup convene, discuss, and establish preliminary coding recommendations on all HCPCS code applications and make preliminary coding recommendations. At the same time, CMS assigns preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the CMS HCPCS web site, specifically at www.cms.gov/medhpcpsgeninfo/08_HCPCSPublicMeetings.asp#TopOfPage, as part of the HCPCS public meeting agendas.

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings, and reconsiders its preliminary coding recommendations in light of any new information provided, and formulates its final coding decisions.

CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

All requestors will be notified in writing of the final decision regarding the HCPCS code modification request(s) they submitted. At about the same time, the HCPCS Annual Update is published at: www.cms.gov/HCPCSReleaseCodeSets/ANHCPCS/itemdetail.asp.

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as the Guidelines for Proceedings at these CMS' Public Meetings, can be found on the CMS HCPCS web site, specifically at:

www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.html.

In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completion and background information regarding the HCPCS Level II coding process is available at:

http://cms.gov/medhcpcsgeninfo/01_overview.asp#TopOfPage. The application form is updated annually and posted on the CMS HCPCS website sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: [HCPCS Decision Tree - cms.gov](#).

June 8, 2017

Agenda Item # 1

Application# 17.092

TOPIC

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 bridge 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant submitted written comments agreeing with CMS' preliminary decision and thanking the workgroup.

FINAL DECISION

Establish Q0477, "Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only". Effective 1/1/18.

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

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.

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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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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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

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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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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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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

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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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.

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

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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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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

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.

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 B4034 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 classifications 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, contact the individual private insurance entity. For Medicaid contact the Medicaid agency in the state in which the claim would be filed. For Medicare contact the Medicare contractor.

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 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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

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 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.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagrees with CMS' preliminary recommendation not to create the 4 requested codes for the Freedom Driver and the external components related to the TAH-t for the following reasons: 1) to ensure that TAH-T coverage by Medicare and other payers is meaningful for discharged patients; 2) to provide a uniform and accurate means for suppliers to bill for these items; 3) for payers to have a means for accurately identifying these items for payment for tracking purposes.

FINAL DECISION

This request to establish a new Level II HCPCS code to separately identify this product has not been approved. Reported sales volume is insufficient to support a request for a revision to the national code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding a new code enhances the efficiency of the system and justifies the administrative burden of adding the code.

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) 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.

Agenda Item # 3

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagrees with CMS' preliminary recommendation not to create the 4 requested codes for the Freedom Driver and the external components related to the TAH-t for the following reasons: 1) to ensure that TAH-T coverage by Medicare and other payers is meaningful for discharged patients; 2) to provide a uniform and accurate means for suppliers to bill for these items; 3) for payers to have a means for accurately identifying these items for payment for tracking purposes.

FINAL DECISION

This request to establish a new Level II HCPCS code to separately identify this product has not been approved. Reported sales volume is insufficient to support a request for a revision to the national code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding a new code enhances the efficiency of the system and justifies the administrative burden of adding the code.

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) 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.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagrees with CMS' preliminary recommendation not to create the 4 requested codes for the Freedom Driver and the external components related to the TAH-t for the following reasons: 1) to ensure that TAH-T coverage by Medicare and other payers is meaningful for discharged patients; 2) to provide a uniform and accurate means for suppliers to bill for these items; 3) for payers to have a means for accurately identifying these items for payment for tracking purposes.

FINAL DECISION

This request to establish a new Level II HCPCS code to separately identify this product has not been approved. Reported sales volume is insufficient to support a request for a revision to the national code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding a new code enhances the efficiency of the system and justifies the administrative burden of adding the code.

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) 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.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagrees with CMS' preliminary recommendation not to create the 4 requested codes for the Freedom Driver and the external components related to the TAH-t for the following reasons: 1) to ensure that TAH-T coverage by Medicare and other payers is meaningful for discharged patients; 2) to provide a uniform and accurate means for suppliers to bill for these items; 3) for payers to have a means for accurately identifying these items for payment for tracking purposes.

FINAL DECISION

This request to establish a new Level II HCPCS code to separately identify this product has not been approved. Reported sales volume is insufficient to support a request for a revision to the national code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding a new code enhances the efficiency of the system and justifies the administrative burden of adding the code.

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) 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.

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 medial 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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation, commenting that the language of the proposed codes does not reflect the FDA's product classification or all of the intended uses, functions or technologies of the PulseFlowDF. Specifically, the speaker discussed unique functions of the PulseFlow DF in comparison to predicate products. As one example, the speaker mentioned wound healing, even though the PulseFlow DF does not have an FDA cleared indication for wound healing. The speaker reiterated the original request for a new code and listed the following functions of the PulseFlowDF as not reflected in the proposed codes: 1) intermittent plantar compression which increases peripheral oxygenation and blood flow leading to wound healing; 2) designed to promote normal gait pattern, reduces health complications of immobility, and enhances social mobility; 3) long term use of shoe which provides protection against lower limb and foot injuries post healing.

FINAL DECISION

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 describe the PulseFlowDF. These codes are available for assignment by insurers if they deem appropriate.

Agenda Item # 6

Application# 17.088

TOPIC

Request to establish 2 new Level II HCPCS codes, one each to identify a blood pressure lowering device used to treat hypertension, and the belt kit with accessories. 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation, stating that RESPeRATE: 1) is a well-established, clinically effective treatment to reduce blood pressure in patients with well-established hypertension who are not at goal with other therapies; 2) there is no code for home-use of RESPeRATE; and 3) denying a code impedes patient access to a useful treatment which helps blood pressure management and ultimately helps to prevent serious medical conditions. The speaker reiterated the original request for CMS to issue codes for this device and similar devices.

FINAL DECISION

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.

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 apheresis 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 1/1/17.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with all elements of CMS' preliminary decision that apply to pathogen reduced apheresis platelets.

FINAL DECISION

- 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 P9073 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 P9100 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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation, stating that the existing code is not adequate and does not distinguish the BodyTrace scale from ordinary bathroom scales of unknown accuracy and no secure cellular communication properties. You offered specific language for your requested code, and suggested that the BodyTrace Scale meets the requirements to be considered Durable Medical Equipment (DME).

FINAL DECISION

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.

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation, stating that Relief Chair Alternating Pressure Geri Chair Cushion is different in size and cost from a wheelchair cushion, and the two are not interchangeable. You commented that the Relief Alternating Pressure Geri Chair cushion that is the subject of this application is intended for use with chairs coded as E1031. You also raised the matter of coverage, stating: If you cover a wheelchair and a cushion,

and a rollabout chair, you should cover the GeriChair cushion as well. And you commented that the Relief Chair cushion meets the needs of beneficiaries for whom a Rollabout Chair is appropriate.

FINAL DECISION

Existing code A9900 "Miscellaneous DME supply, accessory, and/or service component of another HCPCS code" is available for assignment by insurers to report the Relief Chair cushion, if they deem appropriate. Separate billing for any cushion could be considered duplicative and inappropriate.

Agenda Item # 10

Application# 17.100

TOPIC

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 Intraurethral 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". The 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary coding recommendation, stating the InFlow Intraurethral-Pump and Activator is geared to a very specific patient population and the volume of use is increasing. You also stated that women with Impaired Detrusor Contractility (IDC) are in need of better and safer bladder drainage solutions.

FINAL DECISION

A national program operating need was not identified by Medicare, Medicaid, or the Private Insurance Sector to establish a code to identify the product that is the subject of this request. Existing code A4335 "Incontinence supply; miscellaneous" is available for assignment by insurers if they deem appropriate.

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagrees with CMS' preliminary recommendation, stating that A9273 does not adequately describe the product since it is a "moist heat treatment" prescribed and recommended for use prior to pumping milk and is a breast pump accessory for breast feeding women and "is 3-4 times more expensive to manufacture than a hot water bottle or heat wrap. The applicant stated that "Rachel's Remedy should be categorized with Breastfeeding/breast pump accessories and a code is needed to support data collection."

FINAL DECISION

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.

Agenda Item # 12

Application# 17.103

TOPIC

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 in order to distinguish 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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation, stating that current HCPCS codes do not distinguish between hydrophilic-coated and uncoated catheters and that the preliminary decision bundles codes with and without accessories, and with different compositions. The speaker claimed that there are benefits to establishing separate codes to distinguish hydrophilic catheters from uncoated catheters.

FINAL DECISION

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.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker suggested that the proposed actions might lead to a scenario where miscellaneous codes would need to be used to identify the transducer/activator component in transitional AOIs.

FINAL DECISION

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 use with the 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.

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.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were offered on behalf of Cochlear Americas at CMS' HCPCS Public Meeting in reaction to our published preliminary coding recommendation.

FINAL DECISION

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 L8625, "External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each". Effective 1/1/18.

Agenda Item # 13

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 1/1/18.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary coding and payment recommendation. The speaker asked that CMS keep the language of existing code L8691 as it currently reads, for the following reasons: 1) all AOIs require a transducer/actuator to deliver the mechanical energy resulting from the conversion of sounds into vibrations; 2) exclusion of the transducer/actuator from the description of L8691 and from the related payment would create a void in coding and reimbursement; and 3) this revision would eliminate code L8691's applicability to most AOIs currently available that fall under L8691. The speaker agreed with the preliminary coding recommendation to establish a new code to identify replacement transducer/actuators for AOIs.

FINAL DECISION

- 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 L8694, "Auditory osseointegrated device, transducer/actuator, replacement only, each".

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

Establish L7700, "Gasket or seal, for use with prosthetic socket insert, any type, each". Effective 1/1/18.

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation, stating that "the ZIIVAA characteristics extend beyond the "belt, strap, sleeve, garment or covering, any type" and indicated that the unique features and function are markedly congruent with items in the orthotics category." The speaker stated that the benefit of pelvic compression reduces the stretch sensations originated in the round, cardinal, broad, and uterosacral ligaments. In addition, the speaker indicated that she is "seeking to acquire insurance coding and coverage through assignment of a descriptively comparable orthotic code (LXXXX) equivalent to the unique characteristics of the product and the problem it solves."

FINAL DECISION

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.

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 A4467 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 will be filed. For private sector health insurance systems, contact the individual private insurance entity. For Medicaid, contact the Medicaid agency in the state in which the claim will be filed. For Medicare contact the Medicare contractor.

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 Prosthesis 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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagrees with CMS' preliminary recommendation, and suggests that 2 codes need to be created for the two external components of the Argus II System in the L86XX series for the telemetry system and for the VPU. The speaker stated that item is being treated as vision services rather than prosthetics and the suggestion to use an existing code lacks a real rationale for not establishing a code; V codes characterize vision items or services and does not imply a prosthetic benefit; similarly situated products (e.g., protheses) are treated differently (e.g., and are included in the L section of the codes; and V2799 cannot be processed by the A/B MACS, as that is inconsistent with Medicare policy on jurisdiction for replacement items.

FINAL DECISION

A national program operating need has not been identified by Medicare, Medicaid or the Private Insurance Sector to establish two unique Level II HCPCS codes to identify external, patient-worn replacement components for the Argus II Retinal System.

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.

CMS will consider revising the DMEPOS Jurisdiction List for 2018 to reflect joint jurisdiction for code V2799.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

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.

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagrees with CMS' preliminary recommendation, stating that the JAFO is more than A4467, "belt, strap, sleeve, garment or covering." The applicant stated that a new code is requested for JAFO for the following reasons; 1) eliminates the need for a strap, 2) prevents chaffing, 3) eliminates Peroneal nerve entrapment, 4) increases proprioception and balance, 5) reduces the risk of breaking the AFO strut, and 6) protects the patient's atrophied limb and ankle foot orthotic from external forces.

FINAL DECISION

This request to establish a new Level II HCPCS code 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 the JAFO and the Freedom Arm Cover. These codes are available for assignment by insurers if they deem appropriate.

