Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Application Summaries for
DME and Accessories; O & P; Supplies and Other
June 1, 2016

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at CMS' June 1, 2016, HCPCS Public Meeting for Durable Medical Equipment (DME) and Accessories; Orthotics and Prosthetics (O & P); Supplies and Other. 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' 2016-2017 HCPCS coding cycle.

Introduction and Overview

Approximately 60 people attended. The agenda included 14 items.

Cindy Hake, Director of the CMS National Level II HCPCS Coding Program, 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 to the agenda. 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 Coding Workgroup convene, discuss, and establish preliminary coding recommendations, on all HCPCS code applications. CMS also 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 at: http://www.cms.gov/MedHCPCSGenInfo/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 recommendation 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.

In November, all requestors were notified in writing of the final decision regarding the HCPCS code request(s) they submitted. In addition, the HCPCS Annual Update was published at: www.cms.hhs.gov/HCPCSReleaseCodeSets/ANHCPCS/itemdetail.asp.

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as Guidelines for Proceedings at CMS' Public Meetings can be found on the CMS HCPCS web site specifically at: http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage. In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completing the application, and background information regarding the HCPCS Level II coding process is available at: http://www.cms.gov/MedHCPCSGenInfo/01_Overview.asp#TopOfPage. The application form is updated annually and posted on the CMS HCPCS web site sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: http://www.cms.gov/MedHCPCSGenInfo/Downloads/decisiontree/pdf .

HCPCS Public Meeting Agenda Item # 1

June 1, 2016 Public Meeting

Application# 16.002

TOPIC

Request to establish a new Level II HCPCS code to identify the Cervical Thoracic Lumbar Disk Decompression and Sleep Therapy Orthosis (CTLDDSTO).

Applicant's suggested language: "Exxxx, STUD Total CTLDDSTO".

BACKGROUND

On behalf of Stud Medical Ltd., an application was submitted to establish a new Level II HCPCS code to identify the Sleep Therapy under Disk Decompression (STUD) device. According to the applicant, the STUD treats and heals numerous sleep disorders, particularly mild-to-moderate Obstructive Sleep Apnea (OSA), and assists in lowering Positive Airway Pressure (PAP) when treating moderate-to-severe sleep apnea, when using PAP therapy.

The prefabricated, over-the-counter STUD device is comprised of a head band that is made of soft, flexible interface material. The head band attaches via elastic straps to the "upper extremity Orthosis" or yoke that is made of stretchable neoprene foam-based materials, which runs behind the neck and attaches to over-the-shoulder elastic straps, which, in turn, attach to leg bands worn on the upper thigh. Together, these components provide cervical disk decompression by arching the cervical vertebrae posteriorly, which produces interactive pressure and reduces the load on the intervertebral cervical disks. This repositions and opens the airway, elongating and firming the pharyngeal tissue, treating OSA and snoring while optimizing oxygen intake. The STUD is worn at night during sleep, providing therapy for sleep disorders. It can also be worn during the day for more aggressive daytime treatment for posture improvement, or as a preventive measure.

The applicant comments that a new code is warranted because the STUD is unique technology. Unlike other devices which distinctly treat either sleep apnea or compressed disks, the STUD treats both at the same time and potentially heals the entire body.

PRELIMINARY HCPCS CODING RECOMMENDATION

1) Discontinue A4466 "Garment, belt, sleeve or other covering, elastic or similar stretchable material, any type, each".

2) Establish A44XX "belt, strap, sleeve, garment, or covering, any type". The STUD device would be adequately described by this proposed new code.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant submitted written comments disagreeing with CMS' preliminary decision, stating that "even though the STUD device incorporates" belt, strap, sleeve, garment or covering, any type, it also incorporates additional "items for attachments, such as buckles, tri-glide slides, webbing and hook and loop materials for sizing and fitting, and the finished prefabricated product makes up a particular design to be used for particular purposes". The applicant offered examples of durable medical equipment and accessory code categories that may also incorporate belts, straps, sleeves, garment or other covering such as CPAP headgear and sling seats for patient lifts. The applicant reiterated the original request that (1) the STUD be considered an orthotic device; and (2) a code be established that identifies the STUD as an orthotic.

FINAL DECISION

CMS' HCPCS workgroup reconvened to reconsider your application and your input in response to our preliminary code recommendation. CMS upheld its decision. The following modifications have been made to the HCPCS Level II standard, national code set:

1) Discontinue A4466 "Garment, belt, sleeve or other covering, elastic or similar stretchable material, any type, each".

2) Establish A4467 "belt, strap, sleeve, garment, or covering, any type".

Existing code A4466 also adequately describes the STUD device and is available for assignment by insurers until its discontinuance, on 12/31/16.

Newly established code A4467 adequately describes the STUD device and is available for assignment by insurers effective 1/1/17.

HCPCS Public Meeting Agenda Item # 2

June 1, 2016 Public Meeting

Application# 16.016, 16.017, 16.018

TOPIC

Separate requests to establish a total of three new Level II HCPCS codes, one each to identify three independently variable adjustment components of the NEURO SWING (NSW) System: 1) adjustable alignment of the shank ankle; 2) orthosis configurator; and 3) exchangeable high-force disc spring units for regulation of plantar/dorsiflexion assistance/resistance.

Applicant's suggested language:

16.016: "Adjustable Alignment of the Shank Ankle"

16.017: "Extra-strength ankle joint for monolateral use selected with the assistance of an orthosis configurator"

16.018: "Exchangeable High-force Disc Spring Units for Regulation of Plantar/Dorsiflexion Assistance/Resistance"

BACKGROUND

FIOR & GENTZ GmbH submitted a request to establish 3 new Level II HCPCS codes: one each to identify three independently variable adjustment components of the NEURO SWING (NSW) System: 1) adjustable alignment of the shank ankle (SA); 2) orthosis configurator; and 3) exchangeable high-force disc spring units for regulation of plantar/dorsiflexion assistance/resistance.

According to the applicant, the NSW Ankle Joint is an "ankle joint for the fabrication of custom-made lower limb orthoses, extra-strength, torsion and bending-resistant ankle joint for mololateral use." It is a modular ankle joint orthotic device that can be individually fitted to the patient's pathological gait. The NSW Ankle Joint has an improved medical benefit when compared to the use of similar products, due to the possibilities given by the three independently variable adjustments: shank angle alignment; ROM limitation; and exchangeable high-force disc spring units for plantar and dorsiflexion control. The independently adjustable settings and the high-force disc springs make the NSW Ankle Joint unique in orthotics, allowing for adjustability to the patient's pathology without extensive work on the orthosis.

With the NSW Ankle Joint, the movement and position of the anatomical ankle is controlled, providing dynamic stability of the leg during ambulation. The ankle joint is made of aluminum, titanium and steel with quality machining of thicker metals. The NSW Ankle Joint is indicated

for the orthotic management of neurological patients experiencing motor dysfunction of the lower extremity (e.g., cerebral palsy, stroke, spinal cord injury). The NSW Ankle Joint is a rehabilitation aid and must be prescribed by a physician, perhaps in coordination with a physical therapist. It is a custom-made item, and, therefore, it is to be produced by a trained orthotist. The independently variable adjustments of the NSW ankle joint facilitate the bench, static and dynamic alignments that are necessary for an ideal orthotic fitting. Therefore, this ankle joint becomes essential for the successful and state-of-the-art orthotic management of neurological patients requiring dynamic stabilization of the lower limb in s strong and durable monolateral design that allows uncomplicated biomechanical optimization of the orthosis at any time.

The ankle joints and orthotic designs currently being used for the orthotic management of neurological patients only partially fulfill the requirements of a biomechanically optimized orthosis. Presently, this optimization is achieved mainly through modifications of the footwear while keeping the foot-shoe-complex in a stable SAFO. Also, presently, ankle joints are available in limited sizes and are not intended for monolateral use. A unilateral design withstands much higher bending and torsion forces than a pair of joints. The FIOR & GENTZ configurators consider all determinant factors affecting the load applied to the ankle and/or knee joints in the selection of components, resulting in a joint choice that is personalized and optimal for the individual patient.

Adjustable alignment of the SA: This allows variation of the tibial position, in order to adjust the SA to the patient's unique pathological position. The lower limb segment can be aligned to optimize the effect of the biomechanical forces applied by the ground reaction force during gait, independent of foot-ware. The SA can be repositioned by simply turning a screw making tedious shoe posting and grinding to realign the limb segment "superfluous". The SA offers infinitely adjustable range of motion (ROM).

Configurator: The NSW ankle is available in 5 sizes and 2 different materials. The configurator is an internet-based software which designates the joints and accessories in the optimal size and material to withstand the load that will be applied by a patient. The configurator bases these designations on patient parameters, such as: indication, weight, height, shoe size, muscular status, angular deviations, leg length discrepancies, design and fabrication techniques of the orthosis, among others.

Exchangeable High-force Disc Spring Units: There are 5 high-force spring units available with the NSW ankle, from soft to extra-strong. The adjustment of the spring counteraction does not alter the Shank Alignment or the Range of Motion. Biomechanical optimization of the lower limb in an orthotic fitting is not only obtained with a proper shank inclination and a limited ROM, but additionally through the action of the springs at each of the 4 rockers during gait.

The applicant commented that new codes are warranted because the existing HCPCS code categories do not independently describe an adjustable alignment of the shank angle, adjustable and exchangeable high-force disc spring units, or configurator assisted selection of optimal joints and accessories.

PRELIMINARY HCPCS CODING RECOMMENDATION

These requests to establish new Level II HCPCS codes to separately identify components of the NEURO SWING System Ankle Joint have not been approved:

Existing joint base code L2220 "Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint" captures all components and features of the joint, including adjustable alignment (shank ankle feature, subject of application #16.016); any fitting and set-up tools (online configurator, subject of application #16.017); and features for Regulation of Plantar/Dorsiflexion Assistance/Resistance" (disc springs, subject of application #16.018). Separate codes for any of these items would be redundant and duplicative. Existing code L9900 "Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L" code" may be used to identify the separate components.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision, stating that L2220 is a “one size fits all” code, and "does not describe the unique and totally different features of the NEURO SWING system orthotic ankle joint". The speaker claimed significantly improved knee and hip extension at the most critical stage of gait when "the 5 disk springs of the NEURO SWING System selected by the orthotic configurator using the patient's gait condition, weight, height, and activity level, range of motion and manual muscle test of the foot-ankle complex" is used, when compared with the use of joints coded at L2220, which utilize torque force in coil springs.

FINAL DECISION

CMS HCPCS upheld its decision. Existing code L2220 “Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint” adequately captures all components and features of the NEURO SWING joint that are the subject of these three incoming requests.

HCPCS Public Meeting Agenda Item # 3

June 1, 2016 Public Meeting

Application# 16.019

TOPIC

Request to establish a new Level II HCPCS code to identify the Patient Electronics System.

Applicant's suggested language: "LXXXX – Patient electronics system (external) for use with implanted pulmonary artery pressure and heart rate sensor, replacement only."

BACKGROUND

St. Jude Medical Inc. submitted a request to establish a Level II HCPCS code to identify the Patient Electronics System (PES), which is a component of the CardioMEMS™ Heart Failure System. According to the applicant, CardioMEMS is a wireless pulmonary artery pressure and heart rate monitoring system or an implantable hemodynamic system. CardioMEMS provides pulmonary artery hemodynamic data that is used for monitoring and the management of New York Heart Association Class III Heart Failure patients who have been hospitalized for heart failure in the previous year and who have had a wireless sensor implanted.

CardioMEMS includes an implantable wireless censor; a PES; and a secure website, which provides access to the pulmonary artery pressure database. All components are provided on initial issue and have a 5-year warranty. The PES is used to interrogate the implantable, wireless sensor, record and transmit the pulmonary artery sensor's hemodynamic measurements from the patient's home to the secure database for clinician review. The PES includes an antenna, and an electronics unit which powers the implanted sensor, receives and converts information into pressure waveforms, pulmonary artery pressure values, and heart rate measurements.

The applicant commented that a unique code is warranted to identify the replacement PES. This technology is new and no existing HCPCS codes describe it.

PRELIMINARY HCPCS CODING RECOMMENDATION

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were offered at CMS' HCPCS public meeting in reaction to our published, preliminary decision.

FINAL DECISION

CMS upheld its 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.

HCPCS Public Meeting Agenda Item # 4

June 1, 2016 Public Meeting

Application# 16.020

TOPIC

Request to establish a new Level II HCPCS code to identify a rectal insert for patient self-management of fecal incontinence, Trade Name: Renew Insert.

Applicant's suggested language: "AXXXX – Incontinence supply, rectal insert, any type, each".

BACKGROUND

Renew Medical Inc. submitted a request to establish a new Level II HCPCS code to identify the Renew Insert. According to the applicant, the Renew Insert is placed across the anal sphincter, acting as a barrier to the passage of fecal matter through the rectum. The Renew Insert is indicated for self-management of accidental bowel leakage, for patients who have fecal incontinence.

Renew Insert is designed for self-insertion. It is comprised of a soft silicone insert and a plastic fingertip applicator. Once inserted, the top disc of the Renew Insert occludes the lower rectum and creates a seal that keeps bowel contents in an incontinent rectum. The Renew Insert is available by prescription only, after a formal diagnosis of "incontinence of feces." The recommended replacement frequency is once per bowel movement.

The applicant comments that a new code is warranted because the Renew Insert is not described by any existing HCPCS code.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Renew rectal insert has not been approved. Existing code A4337 "Incontinence supply, rectal insert, any type, each" adequately describes the product that is the subject of this request.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were offered at CMS' HCPCS public meeting in reaction to our published preliminary decision.

FINAL DECISION

CMS upheld its decision. This request to establish a new Level II HCPCS code to separately identify the Renew rectal insert has not been approved. Existing code A4337 "Incontinence

supply, rectal insert, any type, each" adequately describes the product that is the subject of this request.

HCPCS Public Meeting Agenda Item # 5

Application# 16.070

TOPIC

Request to establish a new Level II HCPCS code to identify a three-wheeled, manually leg propelled chair/vehicle/cycle, Trade Name: Profhand Pedal Chair.

BACKGROUND

Harmony Hill International Co., Ltd. submitted a request to establish a Level II HCPCS code to identify the Profhand Pedal Chair in the K0001-K0009 range. According to the applicant, the Profhand Pedal Chair is a disability vehicle, cycle, tricycle, foot propelled aide, used to provide a disabled user with a means of transportation, typically without the attendance of another person. The device is designed as a three wheeled foot-propelled vehicle to be used and/or operated by a disabled person who pedals it. This device will enhance the user's independence to get around from one place to another.

The Profhand Pedal Chair allows users to train both their feet and hands to maneuver, and it is a good training exercise piece of equipment. The target population for the item are patients suffering from either a stroke, cerebral palsy, spinal injury, Parkinson's disease, as well as other related symptoms, to help these patients rehabilitate and move around on their own.

The applicant comments that a new code is warranted because there are currently no codes that describe the Profhand Pedal chair.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Profhand Pedal Chair has not been approved. 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision stating that insurers will be interested in coding the Profhand Pedal Wheelchair because it offers health benefits as it is powered by legs instead of hands or electricity. According to the speaker, pedaling can strengthen muscles, even for the afflicted leg that is strapped in, improves overall circulation and stimulates the afflicted limb as well as providing cardio respiratory fitness.

FINAL DECISION

The CMS HCPCS Workgroup reconvened to reconsider this application together with all input provided and upheld its decision. A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector.

HCPCS Public Meeting Agenda Item # 6

June 1, 2016 Public Meeting

Application# 16.073

TOPIC

Request to establish a new Level II HCPCS code to identify a flexible protective overlay for peripheral IV insertion sties, Trade Name: Dale IV-ARMOR.

BACKGROUND

Dale Medical Products, Inc. submitted a request to establish a new Level II HCPCS code to identify the Dale IV-ARMOR. According to the applicant, the Dale IV-ARMOR helps maintain a continuous IV flow while allowing patient flexibility and mobility, and easy access by clinicians. Dale IV ARMOR provides a protective cover for peripheral IV insertion sites. It improves patient comfort without the need for a stiff immobilizing device. As use of the Dale IV-ARMOR splint the IV in the vein reduces the chances of the IV kinking, its use results in reduced incidence of occlusion and IV restarts, and as such it confers significantly improved medical outcomes and superior clinical outcomes.

Dale IV-ARMOR can be used for pediatric and adult patients, with a peripheral IV.

The applicant comments that a new code is warranted because no existing code describes the functionality offered by the Dale IV-ARMOR.

PRELIMINARY HCPCS CODING RECOMMENDATION

This product is already included in existing code A4221 "Supplies for maintenance of drug infusion catheter, per week (list drug separately)". As such, this product is not separately billable.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. Written comments were submitted by the applicant discussing the following benefits of the Dale IV Armor: (1) splints and provides protection by shielding the IV site and reducing catheter micro-movement and dislodgement; (2) maximizes IV patency while protecting the site from patient tampering; (3) minimizes line occlusions caused by patient movement with needing a stiff immobilizing device; and (4) reduces the introduction of infection associated with IV reinsertion.

FINAL DECISION

The CMS HCPCS Workgroup reconvened to reconsider this application together with all input provided and upheld its preliminary decision. This product is already included in existing code A4221 “Supplies for maintenance of drug infusion catheter, per week (list drug separately)”. As such, this product is not separately billable.

HCPCS Public Meeting Agenda Item # 7

June 1, 2016 Public Meeting

Application# 16.074

TOPIC

Request to establish a new Level II HCPCS code to identify a digestive enzyme cartridge, Trade Name: Relizorb™ Cartridge.

Applicant's suggested language: "BXXXX Relizorb Cartridge"

BACKGROUND

Alcresta Pharmaceuticals submitted a request to establish a Level II HCPCS code to identify the Relizorb Cartridge. According to the applicant, Relizorb is the first-of-its-kind, digestive enzyme cartridge designed to mimic the normal function of the pancreas by breaking down fats in enteral tube feeding formula into their absorbable forms (fatty acids and monoglycerides). Relizorb is designed for use by adults on enteral tube feeding who have trouble breaking down and absorbing fats. The enzyme packed cartridge is an ex vivo prescription device that is used in enzymatic hydrolysis of macronutrients into their essential nutrient forms at the time of delivery. The device consists of an outer casing containing an inert polymer with a covalently bound enzyme through which nutritional formula is directed.

Enteral feeding is used as part of standard of care in a subset of people, typically nocturnally to maintain or gain weight, reduce fatty acid and deficiencies and improve GI symptoms.

The applicant comments that a new code is warranted because no other product on the market resembles the Relizorb cartridge, and because no existing code describes this technology.

PRELIMINARY HCPCS CODING RECOMMENDATION

For purposes of billing Medicare, this device is already included in one of the following existing kit codes, depending on the route of administration.

B4034, "enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape."

B4035, "enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape."

B4036, "enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape."

For coding guidance for non-Medicare insurers, contact the insurer in whose jurisdiction a claim would be filed.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision stating that a unique code should be established to specifically identify Relizorb as a separate item for tracking purposes. A separate code would allow patients who are tube fed and who have fat malabsorption to obtain RELIZORB on a medical necessity basis; provide for more consistent claims data; and provide for separate payment outside the supply kit for only those patients who need Relizorb.

FINAL DECISION

The CMS HCPCS Workgroup reconvened to reconsider your application, together with all input provided at the public meeting. CMS revised its decision. This request to establish a new Level II HCPCS code to separately identify the Relizorb Cartridge has not been approved. A national program operating need was not identified by Medicare, Medicaid, or the Private Insurance sector to establish a new code to identify the Relizorb Cartridge.

HCPCS Public Meeting Agenda Item # 8

June 1, 2016 Public Meeting

Application# 16.075

TOPIC

Request to establish a new HCPCS Level II code to identify the SpaceOAR® perirectal spacer system.

Applicant's suggested language: "AXXXX Absorbable perirectal polyethylene glycol hydrogel spacer; 10ml; includes supplies".

BACKGROUND

Augmenix, Inc. submitted a request to establish a new Level II HCPCS code to identify the SpaceOAR system. According to the applicant, the SpaceOAR system is an absorbable polyethylene glycol (PEG) hydrogel. It is designed to temporarily position the anterior rectal wall away from the prostate for men with prostate cancer who are undergoing radiation therapy treatment. The system allows for a reduction in the radiation dose delivered to the anterior rectum.

The spacer is composed of a biodegradable PEG hydrogel that maintains space for the entire course of prostate radiotherapy treatment (approximately 3 months), after which it liquefies by hydrolysis, is absorbed by the body, and cleared via renal filtration. The product is only useful to patients undergoing radiotherapy.

The applicant commented that a new code for the SpaceOAR is necessary to complement existing code C9743 "Injection/Implantation of bulking or spacer material (any type) with or without imaging guidance". Code C9743 is for reporting use of the SpaceOAR system in the HOPD and ASC settings. However, the C code cannot be used for physician office billing. It is anticipated that this system will be used more in physician offices than in HOPDs and ASCs combined.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the SpaceOAR perirectal spacer system has not been approved, because this product is an integral part of a procedure and payments for that service includes payment for the SpaceOAR if it is used.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision, commenting that a new code is warranted for the following reasons: (1) as of July 1, 2016, the only code available to bill for the service of implanting the SpaceOAR will be CPT code 0438T; (2) SpaceOAR must be reported

separately from CPT code 0438T, according to the language of the CPT code; (3) a new code is needed for such reporting and a HCPCS code is the only option; and (4) therefore, CMS should create a new A code for use to bill for SpaceOAR.

FINAL DECISION

The CMS HCPCS Workgroup reconvened to reconsider this application, together with all input provided. CMS upheld its decision. This request to establish a new Level II HCPCS code to separately identify the SpaceOAR perirectal spacer system has not been approved, because this product is an integral part of a procedure and payments for that service includes payment for the SpaceOAR if it is used.

HCPCS Public Meeting Agenda Item # 9

June 1, 2016 Public Meeting

Application# 16.077

TOPIC

Request to establish a new HCPCS Level II code to identify an Upper Esophageal Sphincter (UES) device, Trade Name: Reza Band®.

Applicant's suggested language: “A9XXX – External Upper Esophageal Sphincter Compression Device”.

BACKGROUND

Somna Therapeutics, Inc. submitted a request to establish a new Level II HCPCS code to identify the Reza Band Upper Esophageal (UES) Assist Device. According to the applicant, the Reza Band is a single-patient use, non-invasive, non-sterile medical device, worn by the patient while sleeping. It is indicated for patients 18 years and older to reduce the symptoms of LPR disease due to the presence of stomach refluxate in the laryngopharynx. When positioned at the cricoid (as externally worn around the neck), the Reza Band applies slight external pressure to a weak or dysfunctional UES, thereby blocking the regurgitation of acid and non-acidic stomach contents from rising above the UES into the laryngopharynx. Reza Band includes a Cushion, Comfort Band, Frame, Comfort Dial and Clasp.

The applicant comments that the Reza Band is a unique, non-invasive medical device, and no existing HCPCS codes describe it.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish A44XX "belt, strap, sleeve, garment, or covering, any type".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary decision to establish a new HCPCS code, but asked that either the code language be modified to more precisely describe the product as an “Upper esophageal sphincter (UES) compression device", or that a separate additional code or modifier be established to capture that description.

FINAL DECISION

The CMS HCPCS Workgroup reconvened to reconsider this application together with all input provided. CMS upheld its decision. The following modification has been made to the HCPCS Level II standard, national code set:

Establish code A4467 “Belt, strap, sleeve, garment, or covering, any type”.

New code A4467 adequately describes the Reza Band.

HCPCS Public Meeting Agenda Item # 10

June 1, 2016 Public Meeting

Application# 16.078

TOPIC

Repeat request to establish a new Level II HCPCS code to identify an iodine-containing ointment, Trade Name: Iodosorb Cadexomer Iodine Ointment.

Applicant's suggested language: "AXXX Cadexomer Iodine Wound Filler, ointment, per ounce."

BACKGROUND

Smith & Nephew, Inc. submitted a second request to establish a new Level II HCPCS code to identify Iodosorb Cadexomer Iodine Ointment (Iodosorb). According to the applicant, Iodosorb is a sterile, dark brown, topical ointment, consisting of cadexomer (modified starch microbeads) polyethylene glycols, poloxamer and iodine. It is supplied in 10 gram and 40 gram tubes. Iodosorb is indicated for use in cleaning wet ulcers and wounds such as venous stasis ulcers, pressure sores, and infected traumatic and surgical wounds. It removes loose slough and debris and is biodegradable. According to the applicant, however; based on revised instructions for use specifying that a wound should be cleaned with water and saline before Iodosorb is used, and because Iodosorb is "not washed off," it should be considered as a wound filler that treats wounds; not a wound cleanser.

The applicant comments that the CMS inaccurately placed Iodosorb in code A6260 "wound cleanser, any type, any size"; but Iodosorb it does not belong in that category and it should be removed from that category and be issued a new code because of the unique technology and indications for use.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A6260 "wound cleaners, any type any size", adequately describes the product of this request.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that, while IODOSORB "desloughs" a wound," it does not fit into the wound cleanser category and belongs in the wound filler category". The speaker offered a citation to a Canadian Skin and Wound committee definition of wound cleansing. The speaker presented information that use of Codexomer Iodine "enhances infection protection" of which "the result is enhanced healing¦" And the speaker also stated that "IODOSORB is a multipurpose dressing and a unique product based on Cadexomer Iodine"; and that all of these factors suggest that IODOSORB should be assigned a unique HCPCS code.

FINAL DECISION

The CMS HCPCS Workgroup reconvened to reconsider this application together with all input provided at CMS' HCPCS public meeting, and additional follow-up comments. CMS upheld its decision: Existing code A6260 "wound cleaners, any type any size", adequately describes the product of this request.

HCPCS Public Meeting Agenda Item # 11

June 1, 2016 Public Meeting

Application# 16.079

TOPIC

Request to EITHER revise CPT codes for dialysis services OR establish a new Level II HCPCS code to identify antimicrobial clothing, Trade Name: Med Zip Up.

BACKGROUND

Med Zip Up, Inc. submitted a request to EITHER revise existing Level I HCPCS Current Procedural Terminology (CPT) codes for dialysis treatment and add $.50 to the cost of the treatment; OR establish a new Level II HCPCS code to identify Med Zip Up garments.

According to the applicant, Med Zip Up clothing is indicted for use by dialysis patients. Med Zip Up pants and shirts allow the patient the benefit of getting dressed for a treatment in the privacy of their own home. The garments are treated with Triclosan, antimicrobial bacteria and serve a medical purpose in helping to prevent HealthCare Associated Infections. The garments also have zippers at the neck, and down the sleeves and legs that provide access (e.g., to Hickman catheter or fistulae). The applicant comments that use of these garments transfers the responsibility of providing fresh sheets from the facility to the patient, who maintains their own garments, thereby reducing facility costs.

The applicant comments that a billing code and a price adjustment is needed in order to provide each patient a new shirt or pants, and to replace the garment every 90 days.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish A44XX "belt, strap, sleeve, garment, or covering, any type".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker stated that "Med Zip Up garments are antimicrobial and assist in prevention of hospital and in-home acquired infections, and should qualify as Durable Medical Equipment since they last for 40 washings".

FINAL DECISION

The CMS HCPCS Workgroup reconvened to reconsider your application, together with all input provided. CMS upheld its decision. The following modification has been made to the HCPCS Level II standard, national code set:

Establish code A4467 “Belt, strap, sleeve, garment, or covering, any type”.

New code A4467 adequately describes MedZipUP clothing.

HCPCS Public Meeting Agenda Item # 12

June 1, 2016 Public Meeting

Application# 16.071

TOPIC

Request to establish two new Level II HCPCS codes: one each to identify two apheresis platelet products.

Applicant's suggested language:

XXXX1 Platelets, pheresis, leukocytes reduced, platelet additive solution (PAS), each unit

XXXX2 Platelets, pheresis, leukocytes reduced, irradiated, platelet additive solution (PAS), each unit

BACKGROUND

Fresenius Kabi USA, LLC submitted a request to establish two new Level II HCPCS codes to identify new apheresis platelet products manufactured and formulated with platelet additive solution (PAS) in place of donor plasma. According to the applicant, both products are transfused into patients with thrombocytopenia, dysfunctional platelet disorders (congenial, metabolic, or medication-induced) and active platelet related bleeding. It has no pharmacological activity as its sole function is to provide an appropriate environment and nutrients to maintain the integrity and functionality of the stored platelets for a period of up to 5 days. Blood centers throughout the US manufacture two licensed conventional Leukocytes Reduced (LR) platelet products collected by apheresis from a single platelet donor, which are similar to the two products that the applicant is requesting the establishment of new HCPCS codes.

The applicant comments that LR units incorporating PAS differ from “conventional” units (without PAS) in that each unit of conventional leukocytes reduced LR apheresis platelets and LR irradiated apheresis platelets also contains approximately 200 mL of plasma from the platelet donor. Co-administration of that plasma, which comprises 100 percent of the fluid portion of conventional LR apheresis platelets and LR irradiated apheresis platelets, is frequently associated with allergic, febrile and other donor plasma-mediated transfusion reactions. The two new human platelet products are formulated with a newly FDA-approved platelet additive solution (PAS) in place of 65% of donor plasma; thus in PAS platelets the donor plasma content is reduced to only 35% of the volume of plasma present in conventional LR apheresis platelets and LR irradiated apheresis platelets, resulting in a significant reduction in adverse transfusion events.

The applicant comments new codes are needed because no existing HCPCS codes adequately describe these two new platelet products; and new codes are also needed in order to facilitate a price differential for use of PAS.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code P9035 "Platelets, pheresis, leukocytes reduced, each unit" adequately describes the Platelets, pheresis, leukocytes reduced product that is the subject of this request. Existing code P9037 "Platelets, pheresis, leukocytes reduced, irradiated, each unit" adequately describes the Platelets, pheresis, leukocytes reduced, irradiated product that is the subject of this request. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to distinguish these products based on processing materials or methods.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The speaker disagreed with CMS' preliminary decision stating that "existing codes do not reflect the potential clinical benefits of platelets formulated with platelet additive solution (PAS)". The speaker stated that PAS is an "innovative product", the cost of which "is not adequately reflected by existing codes. Furthermore, creating an appropriate HCPCS code will ensure that this novel product will be provided to patients in need of platelets will receive them with reduced side effects". The speaker reiterated the original request for two new codes to specifically identify this proprietary platelet additive solution.

FINAL DECISION

The CMS HCPCS Workgroup reconvened to reconsider your application together with all input provided. CMS upheld its decision:

Existing code P9035 “Platelets, pheresis, leukocytes reduced, each unit” adequately describes the Platelets, pheresis, leukocytes reduced product that is the subject of this request.

Existing code P9037 “Platelets, pheresis, leukocytes reduced, irradiated, each unit” adequately describes the Platelets, pheresis, leukocytes reduced, irradiated product that is the subject of this request.

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to distinguish these products based on processing materials or methods.

HCPCS Public Meeting Agenda Item # 13

June 1, 2016 Public Meeting

Application# 16.080

TOPIC

Request to establish a series of four new Level II HCPCS codes: one each to distinguish 4 previously coded types of whole blood derived "bacteria tested" platelet units as having been rapid bacterial tested, specifically in a blood collection establishment or transfusion service.

Applicant's suggested language:

P9XX1 – Platelets, bacteria tested by blood collection establishment or transfusion service, each unit

P9XX2 – Platelets, leukocytes reduced, bacteria tested by blood collection establishment or transfusion service, each unit

P9XX3 – Platelets, irradiated, bacteria tested by blood collection establishment or transfusion service, each unit

P9XX4 – Platelets, leukocytes reduced, irradiated, bacteria tested by blood collection establishment or transfusion service, each unit

BACKGROUND

Verax Biomedical submitted a request to establish a series of 4 new Level II HCPCS codes to identify whole blood derived (WBD) “bacteria tested” platelets that have undergone rapid bacterial detection testing within four hours of transfusion, specifically in a blood collection establishment or transfusion service. According to the applicant, WBD platelet units not previously tested by culture and post-storage pools that contain such WBD platelet units should be tested for bacteria using a rapid bacterial detection test, such as the Verax Test, within four hours prior to transfusion. Such tests are designed to be used closer to the time of transfusion to address the threat to the blood supply posed by bacterial contamination of platelets.

Platelet transfusions are primarily required by hematology/oncology patients (particularly those with blood cancers) and by surgical/trauma patients. Platelets are prescribed in hospital inpatient or outpatient settings. Typically, prescribing physicians are hematologists, oncologists, or surgeons, based on the patient populations typically requiring platelet transfusions.

The applicant comments that four new codes are warranted because no existing HCPCS codes define platelets that have undergone rapid bacterial detection testing. Rapid bacteria tested platelets represent new products because they address the considerable risk posed by bacterial

contamination of platelets. They offer a significant therapeutic distinction over platelets that have not been tested for bacterial contamination.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish HCPCS modifier: "Rapid bacterial tested". This new modifier can be appended to existing platelets product code(s), if appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary decision regarding application numbers 16.080 and 16.081.

FINAL DECISION

The CMS HCPCS Workgroup reconvened to reconsider this application together with all input provided, and with the program operating needs of all insurance sectors. CMS revised its decision. The following modification has been made to the HCPCS Level II standard, national code set:

Revise existing code P9072 which currently reads: “Platelets, pheresis, pathogen reduced, each unit”, to instead read: “Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit.” Revised code P9072 adequately describes the products that are the subject of this request.

HCPCS Public Meeting Agenda Item # 13

June 1, 2016 Public Meeting

Application# 16.081

TOPIC

Request to establish a series of seven new Level II HCPCS codes: one each to distinguish previously coded types of platelet units as having been "secondary tested," specifically by a blood collection establishment or transfusion service.

Applicant's suggested language:

P9XX1 – Platelets, pheresis, secondary tested or safety measure tested by blood collection establishment or transfusion service, each unit

P9XX2 – Platelets, pheresis, leukocytes reduced, secondary tested or safety measure tested by blood collection establishment or transfusion service, each unit

P9XX3 – Platelets, pheresis, irradiated, secondary tested or safety measure tested by blood collection establishment or transfusion service, each unit

P9XX4 – Platelets, pheresis, leukocytes reduced, irradiated, secondary tested or safety measure tested by blood collection establishment or transfusion service, each unit

P9XX5 – Platelets, hla-matched, leukocytes reduced, apheresis/pheresis, secondary tested or safety measure tested by blood collection establishment or transfusion service, each unit

P9XX6 – Platelets, pheresis, leukocytes reduced, cmv negative, irradiated, secondary tested or safety measure tested by blood collection establishment or transfusion service, each unit

P9XX7 – Platelets, leukocytes reduced, cmv negative, apheresis/pheresis, secondary tested or safety measure tested by blood collection establishment or transfusion service, each unit

BACKGROUND

Verax Biomedical submitted a request to establish a series of seven new Level II HCPCS codes; one each to distinguish 7 previously coded types of platelet units as having been "secondary tested" specifically by a blood collection establishment or transfusion service. According to the applicant, secondary tested platelet units are those that have undergone testing to detect bacteria missed by primary culture based tests. Secondary testing, using a bacterial detection test with the specified platelet type, should be performed within 24 hours prior to transfusion. Secondary testing on the day of transfusion—with a device cleared and labeled as a "safety measure"—not only enables detection of bacteria missed by early culture testing, but it also enables a 5-day

platelet product to be extended to a 6-day or 7-day platelet product. The extension of platelet dating would have a significantly beneficial impact on platelet supply.

Secondary tested, including safety measure tested, platelet products are primarily transfused to hematology/oncology and trauma/surgical patients, who require platelet transfusion to increase their ability to form clots to stop bleeding.

The applicant comments that new codes are warranted because existing HCPCS codes do not distinguish platelets that are secondary tested.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish HCPCS modifier: "Rapid bacterial tested". This new modifier can be appended to existing platelet product code(s), if appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary decision regarding application numbers 16.080 and 16.081.

FINAL DECISION

The CMS HCPCS Workgroup reconvened to reconsider this application together with all input provided, and with the program operating needs of all insurance sectors. CMS revised its decision. The following modification has been made to the HCPCS Level II standard, national code set:

Revise existing code P9072 which currently reads: “Platelets, pheresis, pathogen reduced, each unit;” to instead read: Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit.” Revised code P9072 adequately describes the products that are the subject of this request.

HCPCS Public Meeting Agenda Item # 14

Application# 16.084

TOPIC

Repeat request to establish a new Level II HCPCS code to identify a solution that rejuvenates stored red blood cell products, Trade Name: Rejuvesol®.

Applicant's suggested language: "PXXXX – Rejuvenation of red blood cells".

BACKGROUND

Zimmer Biomet submitted a request to establish a Level II HCPCS code to identify the use of Rejuvesol solution to rejuvenate red blood concentration. According to the applicant, Rejuvesol Solution is a "single-source drug" and the only commercially available RBC rejuvenation product in the US. Each injection is intended only for the use as an in vitro processing solution for the rejuvenation of stored RBC units, typically after 14 or more days of liquid storage. Rejuvenation extends shelf life.

Rejuvesol Solution is supplied as a 50 mL single-use vial containing sodium pyruvate 0.55g; inosine 1.34g; adenine 0.034g; dibasic sodium phosphate 0.730g; and monobasic sodium phosphate 0.311g, in water for injection, pH 6.7-7.4.

The applicant comments that a new code is warranted to support identification, reporting and separate payment for Rejuvesol Solution, as use of the product and the processing rejuvenation presents additional cost.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing Level II HCPCS codes adequately describe final blood and blood component products. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to distinguish these products based on processing materials or methods.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were offered at CMS' HCPCS public meeting in reaction to our published preliminary decision.

FINAL DECISION

The CMS HCPCS Workgroup reconvened to reconsider this application together with all input provided, and CMS upheld its decision. A national program operating need to establish a code to identify was not identified by Medicare, Medicaid or the Private Insurance Sector to distinguish these products based on processing material or methods. Existing Level II HCPCS codes adequately describe the final blood and blood component products that are the subject of this request.