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

Wednesday, June 6, 2018

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the June 6, 2018 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.

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.

Wednesday, June 6, 2018

Agenda Item # 1

Application# 18.120

TOPIC

Request to establish a series of 5 new level II HCPCS codes, one each to identify 5 levels of Hospital at Home comprehensive episode of care, for use for reporting, as specified, to private insurers participating in a bundled payment model.

Applicant's suggested language:

XXXX1- Hospital at Home comprehensive episode of care with bundled payment model-Level 1

XXXX2- Hospital at Home comprehensive episode of care with bundled payment model-Level 2

XXXX3- Hospital at Home comprehensive episode of care with bundled payment model-Level 3

XXXX4- Hospital at Home comprehensive episode of care with bundled payment model-Level 4

XXXX5- Hospital at Home comprehensive episode of care with bundled payment model-Level 5

BACKGROUND

Request to establish a series of five new level II HCPCS codes, one each to identify 5 levels of Hospital at Home comprehensive episode of care, for use for reporting, as specified, to private insurers participating in a bundled payment model.

Hospital at Home is a high tech/hi touch program, for both medical and surgical services, deflects emergency room visits, inpatient admissions, reduces length of stay, and skilled nursing facilities or rehabilitation hospital admissions. In addition, it provides immediate post-op recuperation services in the home for surgical services. This program also incorporates pharmacy medications and certain services traditionally performed in outpatient settings by the physician, lab, DME, PT, etc. However, services that need or are required to be rendered in an accredited outpatient/inpatient setting are excluded from the program such as high tech imaging, surgery in an ambulatory surgical center, blood transfusions etc. A severity structure from low to high complexity (Level 1 to Level 5) is utilized. One claim is submitted with the code holding the total reimbursement amount for all of the home-based services for the member and the duration of the services is defined by the health plan.

The five levels of severity/complexity and corresponding proposed code for each level are as follows:

1. Level 1: A severity/complexity level with the diagnoses and procedures that require **straightforward** medical decision making and usually, the presenting problem(s) being **self-limited or minor** for the intensity of services required.

2. Level 2: A severity/complexity level with the diagnoses and procedures that require **straightforward** medical decision making and the presenting problem(s) are **low to moderate** severity for the intensity of services required.

3. Level 3: Medical decision making of **low** complexity with the diagnoses and procedures and the presenting problem(s) are usually of **moderate** severity for the intensity of services required.

4. Level 4: Medical decision making of **moderate** complexity with the diagnoses and procedures and the presenting problem(s) are usually of **moderate to high** severity for the intensity of services required.

5. Level 5: Medical decision making of **high** complexity with the diagnoses and procedures and the presenting problem(s) are usually of **moderate to high** severity for the intensity of services required.

For this particular model a member's eligibility is determined through a prescreening criteria and the members must voluntarily enter into the Hospital at Home program. Ideally, the member is identified as "at risk" by a primary or specialty care physician before an acute crisis. In addition, when a limited non-intensive care unit (ICU) hospital level need is identified, a care unit will be set up in the member's home by a Hospital at Home coordinator.

There are no existing bundled payment codes for a Hospital at Home comprehensive episode of care with bundled payment model. CPT codes that are "close but too limited to fully capture the program's scope" are Home Services-99341-99350, Comprehensive Care for Joint Replacement Model-G9481-G9490 and BPCI Services-Bundled Payment for Care improvement Initiative-G9187.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing HCPCS modifiers V1, "Demonstration modifier 1", V2, "Demonstration modifier 2", and V3, "Demonstration modifier 3", are available for assignment by insurers, (and for definition within in their own policies), to report levels of care.

CMS proposes adding 2 additional modifiers in the series: V0, "Demonstration modifier 0", and V4, "demonstration modifier 4", in order to make available enough modifiers to distinguish 5 levels of care per the incoming request.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS for the recommendation to create 2 new demonstration modifiers, but respectfully request 5 new HCPCS codes. The speaker indicated that having the 5

requested codes are the most simplistic way to identify, utilize billing and reimbursement, and to track better patient outcomes and reduce confusion as well as ensure accuracy of billing. In addition, assigning a specific code to capture the unique services rendered is a holistic approach to patient care.

FINAL DECISION

CMS revised its decision. CMS refers the applicant to the American Medical Association for CPT coding guidance for the patient care service bundles described in this application. These services are not suitable for coding in HCPCS Level II.

Wednesday, June 6, 2018

Agenda Item # 2

Application# 18.091

TOPIC

Request to establish a new Level II HCPCS code to identify a non-powered orthopedic traction apparatus with accessories, Trade Name: HipTrac

Applicant's suggested language: Exxxx-"Hip joint traction equipment."

BACKGROUND

MedRock Inc. submitted a request to establish a new Level II HCPCS code to identify HipTrac. According to the applicant, HipTrac is a medical device used by the patient at home and in clinical settings to perform long axis hip (acetabular-femoral) joint traction without assistance from a healthcare provider or care giver. The applicant comments that HipTrac replicates widely-used manual therapy (hands-on) technique used by health care providers in the clinic setting to improve hip joint capsular restrictions and pain control due to hip osteoarthritis and other intra-articular hip joint pathologies.

The applicant comments that HipTrac meets the growing demand for alternative, less costly, non-pharmaceutical treatments for hip osteoarthritis. In addition, HipTrac performs joint mobilization to the hip joint capsule increasing mobility, decreasing pain and intra-articular pressure, and improving overall activity tolerance to get people moving again. The applicant comments that the HipTrac is a medical device, not exercise equipment.

The applicant comments that a new code is warranted because there are no other devices that specifically target the hip joint. As "spinal traction devices have HCPCS codes and coverage," so should the HipTrac.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Hip-Trac, has not been approved. Existing code A9300, Exercise equipment, 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. Pricing = 00

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker indicated that he had originally requested a new code in 2014 and that A9300 was assigned to HipTrac. This new application was supplemented with new clinical studies to indicate that this product is not exercise equipment but a medical device that treats disease. This product replicates the same medical technique of mobilization to the joint capsule. In addition, the speaker indicated that exercise equipment does not require a physician prescription and that it is being used by the VA and other health insurers in this country.

FINAL DECISION

This request to establish a new Level II HCPCS code to separately identify Hip-Trac, has not been approved. Existing code A9300, Exercise equipment, is available for assignment by insurers if they deem appropriate. 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. For coding guidance, contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed.

Wednesday, June 6, 2018

Agenda Item # 3

Application# 18.092

TOPIC

Request to establish two new Level II HCPCS codes to identify components of a powered external limb overload warning device, Trade Name: SurroSense Rx.

Applicant's suggested language:

EXXX1- "Plantar pressure sensing system, includes all components (wireless-enabled shoe pads, a smart watch, changing cables, AC adaptor and mobile downloads)

EXXX2- "Plantar pressure sensing shoe inserts, per pair of inserts."

BACKGROUND

Orpyx Medical Technologies, Inc. submitted a request to establish two new Level II HCPCS codes to identify components of the SurroSense Rx system. According to the applicant, the SurroSense Rx system assists in foot pressure offloading. The system includes left and right pressure-sensing shoe inserts, a smart watch, left and right shoe pads, charging cables, smart watch charging cable and AC adaptor. The system is a wearable plantar pressure monitoring device indicated for persons with decreased or absent foot sensation caused by diabetic peripheral neuropathy. The applicant comments that the device measures pressure over time, and based on proprietary algorithms, determines when offloading is required, thereby generating an alert through the display device. It is not intended to replace standard diabetic foot care but rather to act as an adjunct to standard diabetic foot care. It is designed to help prevent complications of the feet due to peripheral neuropathy such as diabetic foot ulcers.

The applicant comments that new codes are warranted because there are no existing codes to adequately describe a multi-component wireless-enabled wearable interactive plantar pressure sensing medical device.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish new Level II HCPCS codes to separately identify SurroSense RX system, has not been approved. Existing code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" 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. Pricing = 00

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation; described SurroSense Rx smart insole technology for use with diabetic foot patients; and reiterated the original request for 2 new HCPCS codes in order to provide access to patients for this life-saving technology. The speaker commented that this technology will reduce the cost of health care as it serves as a neuropathy compliance monitor.

FINAL DECISION

This request to establish 2 new Level II HCPCS codes to separately identify components of the SurroSense RX system, has not been approved. Existing code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" is available for assignment by insurers if they deem appropriate.

Wednesday, June 6, 2018

Agenda Item # 4

Application# 18.109

TOPIC

Request to establish a new Level II HCPCS code to identify an insulin pen for self-injection that connects wirelessly to a cell phone app with dose calculator and diabetes management tools, Trade Name: InPen.

Applicant's suggested language: "Connected Insulin Pen with Dose Calculator"

BACKGROUND

Companion Medical, Inc., submitted a request to establish a new Level II HCPCS code to identify the Connected Insulin Pen with Dose Calculator. According to the applicant, the InPen system is used for the self-injection of insulin by people with diabetes. It consists of a wirelessly connected insulin pen and smartphone app with dose calculator and diabetes management tools. The pen injector transmits insulin dose information wirelessly and automatically to a smartphone to ensure a record of reliable, accurate dosing information. The app includes dose reminders, a logbook, a dose calculator to accurately calculate insulin doses- accounting for active insulin to prevent insulin stacking.

According to the applicant, the InPen system integrates glucose data, tracks insulin temperature and age, and sends alert to the smartphone app. The app includes healthcare provider reports to aggregate insulin dosing and blood glucose data for review before and after patient interactions. The InPen is indicated for use with rapid-acting insulin cartridges, specifically Lilly and NovoNordisk and other conventional pen needles. It is designed for single-patient use and allows the user to dial the desired dose of insulin from 0.5 to 30 units in one-half (1/2) unit increments. The applicant comments that the InPen can be used solely in patient's home by a patient.

The applicant comments that the InPen combines the interface and utility of a reusable insulin pen with the data features found in most insulin pumps.

The applicant comments that a new code is warranted because no existing HCPCS code describes a connected insulin pen with an integrated dose calculator.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code S5561,"Insulin delivery device, reusable pen; 3 ml size", or A4211, "Supplies for self-administered injections" are available for assignments by insurers to describe the pen and/or dosage calculator application, if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing A4211 code apply to this product. Pricing = 00.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The speaker respectfully disagreed with CMS' preliminary recommendation and suggested that a new HCPCS code is needed to describe the InPen since it is a new class of product. The primary speaker indicated that the InPen is similar to an insulin pump in all aspects with the exception that it is not worn on the body and does not provide a pumped basal rate. The speaker indicates that since it provides the same benefits as a pump it should be available to those individuals who do not want to wear their pumps.

FINAL DECISION

Existing code S5561, "Insulin delivery device, reusable pen; 3 ml size", or A4211, "Supplies for self-administered injections" are available for assignments by insurers to describe the pen and/or dosage calculator application, if they deem appropriate.

Wednesday, June 6, 2018

Agenda Item # 5

Application# 18.119

TOPIC

Request to establish a new Level II HCPCS code to identify a wearable, passive, continuous, remote patient monitoring device, Trade Name: TracPatch.

Applicant did not provide suggested language

BACKGROUND

Consensus Orthopedics Inc., submitted a request to establish a new Level II HCPCS code to identify "Tracpatch", a 24/7 remote monitoring and data collection system for use to track a patient's progress post Total Knee Arthroplasty (TKA).

According to the applicant, the TracPatch incorporates a passive and continuous data collection system with advanced learning algorithms and haptic feedback technology which enables healthcare providers to monitor a patient's daily activity including step tracking; range of motion; exercise compliance; sudden events; temperature sensor; reporting of photos of wounds and pain scores. The device operates through an electronic Goniometer and does not use transcutaneous adhesive electrode lead wires to transmit and record patient data. It incorporates BlueTooth connectivity paired with a smartphone.

The TracPatch is a battery operated device, patient worn externally (e.g., on the thigh and lower leg), applied to the skin using adhesive. Healthcare providers view and analyze their patients' data which is conveyed using a portal. It incorporates BlueTooth connectivity paired with a smartphone.

The applicant comments that a new code is warranted because this kind of technology has not existed previously and therefore, no HCPCS codes exist.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified", is available for assignment for insurers if they deem appropriate, to report the TracPatch.

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

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

FINAL DECISION

Existing A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified", is available for assignment for insurers if they deem appropriate, to report the TracPatch.

Wednesday, June 6, 2018

Agenda Item # 6

Application# 18.124

TOPIC

Request to either revise existing Level II HCPCS codes, E0160 and E0161, to include the words “wearable garment”, or to establish a new Level II HCPCS code to identify Sitz Bath Shorts and Briefs; and for Sitz bath garments to be considered Durable Medical Equipment. Trade Name: Sitz Bathwear

Applicant’s suggested language:

Revise existing code E0160 which currently reads “ Sitz type bath or equipment, portable, used with or without commode” to instead read “Sitz type bath, wearable garment, or equipment, portable, used with or without commode” ; and/or

Revise existing code E0161 which currently reads “Sitz type bath or equipment, portable, used with or without commode, with faucet attachment/s” to instead read “Sitz type bath, wearable garment, or equipment, portable, used with or without commode, with faucet attachment/s.”

OR establish: XXXXX- “Sitz bath wearable garment” or “Sitz bath garment”

BACKGROUND

Sitz BathWear, LLC. submitted a request to either revise existing Level II HCPCS codes E0160 and E0161 to include the words "wearable garment", or establish a new code to identify Sitz Bath Shorts and Briefs; and for Sitz bath garments to be considered Durable Medical Equipment. The applicant also included an alternative option for the establishment of a new Level II HCPS code.

According to the applicant, Sitz Bath Shorts and Sitz Bath Briefs are garments made of waterproof polyurethane fabric with elastic and velcro. The garments are designed to hold water, allowing individuals to soak their perineum or private area. They are single-patient use and can withstand repeated use up to six months. The user fills the garment with warm water, and can then add essential oils or Epsom salt as desired. This is used to ease pain and treat inflammation by increasing blood flow to the area. These garments allows an individual to perform a sitz bath without a plastic sitz bowl or access to a sanitary bathtub.

The applicant comments that the Sitz bath garments can be used to aid in a wide range of issues, such as urinary tract infections, hemorrhoids, prostatitis, cramps, and lower pelvic floor issues. The shorts have an elastic gasketing around each leg to prevent water escape, and includes velcro on each leg to allow the individual to adjust and ensure a snug, proper fit. The garments can

either be filled during a shower, or the user can pour warm water from a container. A sitz bath can be taken for up to 15 minutes, three times a day.

The applicant comments that a new code is warranted because the existing codes, E0160 and E0161, refer to a physical bath or piece of equipment, and not a wearable garment such as the Sitz BathWear.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to either revise existing HCPCS codes E0160 and E0161, (which describe portable sitz bath durable medical equipment); to include sitz bath shorts and brief garments; or to establish a new code to identify sitz bath garments, has not been approved. The shorts and briefs are not suitable for the inclusion in the durable medical equipment codes. Existing A4467, "Belt, strap, sleeve, garment, or covering, any type", is available for assignment by insurers if they deem appropriate, to describe the sitz bath garments.

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 and reiterated the original request that E0160 and E0161 be revised to include "wearable garment" or to establish a new Level II code to identify Sitz Bath Shorts and Briefs. The speaker also indicated that these bath garments should be considered DME.

FINAL DECISION

This request to either revise existing HCPCS codes E0160 and E0161, (which describe portable sitz bath durable medical equipment); to include sitz bath shorts and brief garments; or to establish a new code to identify sitz bath garments, has not been approved. Shorts and briefs are not suitable for inclusion in the durable medical equipment codes. Existing code A4467, "Belt, strap, sleeve, garment, or covering, any type", is available for assignment by insurers if they deem appropriate, to describe the sitz bath garments.

Wednesday, June 6, 2018

Agenda Item # 7

Application# 18.105

TOPIC

Request to establish a new Level II HCPCS code to identify a pelvic soft brace, PELV-ICE, Trade Name: PELV-ICE and Mama Strut.

The applicants suggested language:

The applicants suggested language: Pelvic orthosis, flexible, provides pelvic-sacral support, provides lumbar support, provides pelvic floor/perineal support, provides abdominal support, reduces motion about the sacroliliac joint, hip joint, adjustable flexion, extension, abduction control, produces intracavitary pressure to reduce load on the pelvis, lumbar, abdominals and pelvic floor, includes removable pouches with fel packs for ice/heat therapy on the lumbar, hips, abdominals and perineum, prefabricated, off-the-shelf.

BACKGROUND

PELV-ICE, LLC, submitted a request to establish a new Level II HCPCS code to identify a line of total pelvic supports designed to aid in the recovery of pelvic soft tissue damage and acute or chronic pelvic pain. According to the applicant, PELV-ICE's utility patented devices provide highly adjustable, multi-directional support to all sides of the pelvis, coupled with removable pouches for ice/heat therapy for the perineum, lower back, hips and abdomen. The product is indicated for use in both men and women of all ages with acute or chronic pelvic pain, injuries, pregnancy, postpartum, or pelvic surgeries. The Mama Strut line is targeted specifically towards postpartum care. The applicant also comments that these devices could be used as a preventative device for soft tissue damage prone to injury.

According to the applicant, PELV-ICE products provide total pelvic support with medical grade quality, latex free, anti-microbial abdominal, pelvic-sacral and lumbar support secured by attached compression shorts for maximum stability. There are 3 attached and adjustable pelvic floor/perineum/hernia elastic tension straps that can be adjusted or removed to customize placement and amount of support. There are also removable and adjustable pouches along with gel packs, which can be used for cryotherapy or heat therapy in combination with compression to reduce pain, swelling, and pressure for the lumbar, hips abdomen and perineum.

The applicant comments that a new code is warranted because no existing HCPCS codes adequately describe all aspects of PELV-ICE devices. It is stated that PELV-ICE has invented a new category and advancement in bracing and requires a unique code to reflect this distinction.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify PELV-ICE devices has not been approved. Existing code A4467, "Belt, strap, sleeve, garment, or covering, any type" is available for assignment by insurers to identify the garment, if they deem appropriate. In addition, existing code A9273, "Hot water bottle, ice cap or collar, heat and/or cold wrap, any type", is available for assignment by insurers to identify the fluid-filled pack, if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and indicated that this product fits the definition of DME. The speaker indicated that the product s not just a wrap but a truss abdominal binder that can provide both hot/cold therapy, sanitary belt, feminine pad holder, vulvar floor support and compression. The applicant also proposed different code language.

FINAL DECISION

This request to establish a new Level II HCPCS code to separately identify PELV-ICE devices has not been approved. Existing code A4467, "Belt, strap, sleeve, garment, or covering, any type" is available for assignment by insurers to identify the garment, if they deem appropriate. In addition, existing code A9273, “Hot water bottle, ice cap or collar, heat and/or cold wrap, any type”, is available for assignment by insurers to identify the fluid-filled pack, 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 codes A4467 and A9273 describe the components of the PELV-ICE product, as a general rule, the 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. For Medicare, please contact the Medicare contractor.

Wednesday, June 6, 2018

Agenda Item # 8

Application# 18.093

TOPIC

Request to establish a new Level II HCPCS code to identify a manual lift and transfer device, Trade Name: EZ Lift Vest.

Applicant's suggested language: EXXXX-"Manual lift and Transfer Vest."

BACKGROUND

JP Healthcare Solutions, Inc. submitted a request to establish a new Level II HCPCS code to identify the EZ Lift Vest manufactured by Dunn manufacturing Corporation.

According to the applicant, the EZ Lift Vest is a one-piece unisex cotton garment with a double zipper, eleven hand grip components: 4 on the front, 1 one each side and 5 on the back; and 4 adjustable contour straps, 2 on front, and 2 on back. The product enwraps the individuals' (patients) entire torso, providing complete back support, allowing body weight to be evenly distributed during lifts and transfers. The 11 hand grip components provide balance, control, leverage and proper weight distribution of the patient.

The EZ Lift Vest is used to assist healthcare workers, caregivers and family members with mobility-challenged patients who are at risk for unintentional falls and in needs of assistance during standing, walking and transfer maneuvers.

It provides a safe transfer experience for patient and caregiver allowing the caregiver to have total control of the patient's upper torso minimizing the risk of unintentional falls.

The applicant comments that a new code is warranted because there are no HCPCS codes that effectively describe the EZ Lift Vest.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify EZ Lift Vest, has not been approved. The device is not primarily medical in nature. Existing code E0700, "Safety equipment, device or accessory, any type", 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 that the product is not primarily medical in nature. The speaker indicated that the product was created for the purpose and use as a manual transfer vest for improved safety of the patient as well as providing the benefit of less exertion on the caregiver. The benefits highlighted by the speaker were that the EZ Vest is more than a safety device because it provides both back support and a secure walking aid.

FINAL DECISION

This request to establish a new Level II HCPCS code to separately identify the EZ Lift Vest, has not been approved. Existing code E0700, "Safety equipment, device or accessory, any type", is available for assignment by insurers if they deem appropriate.

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. For Medicare, contact the Medicare contractor.

Wednesday, June 6, 2018

Agenda Item # 9

Application# 18.108

TOPIC

Request to establish a new Level II HCPCS code to uniquely identify a disposable EKG cable and lead wire system, Trade Name: Kendall DL Disposable Cable & Lead wire system.

Applicant's suggested language: AXXXX-"disposable, single-patient use EKG cable and lead wire set."

BACKGROUND

Cardinal Health 200, LLC, submitted a request to establish a new Level II HCPCS code to identify the Kendall DL Disposable Cable & Lead wire system. According to the applicant, Kendall DL Disposable Cable & Lead wire system is comprised of a variety of 3, 5,6 and 10 lead wire options that connect directly to electrodes and the EKG monitor. EKG is a representation of the heart's electrical activity used to measure the rate and rhythm of heartbeats, and the presence of potential cardiac damage. Reusable EKG lead wires and cables are often cleaned inadequately and may pose a vector for infection transmission. The Kendall DL Disposable Cable & Lead wire system decreases the risk of infection transmission between patients. A push button connection to the electrode provides a locking mechanism for a stronger connection, which has been clinically proven to reduce false "leads off" alarms. It is a single patient use item and is limited to use in hospital inpatient and outpatient facilities. According to the applicant, "enhanced clinical outcomes directly related to the use of Kendall DL Systems have been proven through clinical research. Mounting peer-reviewed clinical evidence supports statistically significant reductions in both false EKG alarm events and infection upon implementation of the Kendall DL and Lead Wire Systems across a growing number of acute care facilities."

The applicant comments that a new code is warranted because "no code/reimbursement category currently exists for single patient use EKG cable and lead wire sets. Current code categories are inadequate in that they do not account for the significant therapeutic distinction … afforded to patients and providers via the use of the single patient use Kendall DL Cable and Lead Wire System."

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new code to identify the Kendall DL Disposable cable and lead wires system for use in EKG procedures, has not been approved. Cable and lead wires are an integral part of the procedure. The Kendall System if used is included in the procedure. Separate reporting could be considered duplicative.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment

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 recommendation.

FINAL DECISION

This request to establish a new code to separately identify Kendall DL Disposable cable and lead wires system for use in EKG procedures, has not been approved. Cable and lead wires are an integral part of a procedure. The Kendall System, if used, is included in the procedure. Separate reporting could be considered duplicative.

Wednesday, June 6, 2018

Agenda Item # 10

Application# 18.110

TOPIC

Request to establish a single new Level II HCPCS code to identify two wound closure devices, Trade names: ZIP Surgical Skin Closure Device and Zip Wound Closure Device.

Applicant's suggested language:

QXXXX-"Zip Surgical Skin Closure Device or Zip XL Wound Closure Device, per cm."

BACKGROUND

ZipLine Medical, Inc. submitted a request to establish a single new Level II HCPCS code to identify The Zip® Surgical Skin Closure Device (SSCD) and Zip ® XL Wound Closure Device (WCD). The products are single use, non-latex devices containing adhesives and polymeric materials engineered for incisions and wound management. The product creates a scaffold around open wounds to stimulate healing. The device can be adjusted to facilitate management of the healing process.

The Zip® Surgical Skin Closure Device and Zip ® XL Wound Closure Devices are indicated for use during and after surgical skin incisions, in chronic wound healing, and delayed closure to approximate skin and hold together skin edges until healing occurs.

The applicant claims therapeutic distinction of the product based on its design and mechanism. The applicant comments that existing code G0168 "wound closure utilizing tissue adhesive(s) only" does not reflect the product features and mechanisms of action of the zip products.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new code to separately identify, Zip surgical skin closure and XL wound closure devices has not been approved. The devices, if used, are included in the procedure.

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 and reiterated the original request to establish a unique HCPCS code for the Wound Closure Device.

The speaker described this product as a chronic wound closure device and indicated that there is nothing else on the market similar to this product. The speaker further requested that the product not be bundled into the current acute CPT codes as a supply.

FINAL DECISION

This request to establish a new code to separately identify Zip surgical skin closure and XL wound closure devices has not been approved. The devices, if used, are included in the procedure. If used in the hospital, the device is included in the DRG. If used in a hospital outpatient or ASC setting it included in the facility fee. If used in a physician's office setting, it would be included in the procedure. Separate reporting could be considered duplicative.

Wednesday, June 6, 2018

Agenda Item # 11

Application# 18.113

TOPIC

Request to establish a new Level II HCPCS code to identify a flat flexible planar radioactive ^{32}Phosphorus polymeric film, Trade Name: RIC Conformal Source Model 100.

Applicant's suggested language: "Brachytx, non-stranded, ^{32} Phosphorus"

BACKGROUND

RI Consultants, LLC submitted a request to establish a new Level II HCPCS code to identify the RIC Conformal Source Model 100 Brachytherapy Source**.** Brachytherapy is a form of radiotherapy used in cancer treatment to deliver radiation using an internal source placed on or near tumors. According to the applicant, the RIC Conformal Source is a thin, flexible, polymeric film, containing radioactive beta emitting ^{32} Phosphorus. Each source has a capacity of up to 200 millicuries of ^{32} Phosphorus, is between 0.3mm and 0.7mm thick, and coated with biocompatible silicone.

Due to its structure, it can be conformed to many different surfaces and shapes. The film is applied directly to a tumor or area of recent tumor excavation, and a dose of radiation within the film will release to the tissue in close proximity to the application site. After the correct dosage of radiation has been administered, the film is removed. This direct implementation allows surrounding tissues or organs to be spared from harmful radiation. The film can be prescribed by a doctor for any physical size up to 50 mm by 100 mm. The product is indicated for sole use in hospital outpatient facilities.

The applicant comments that a new code is warranted because existing codes do not describe any brachytherapy sources that use ^{32} Phosphorus.

PRELIMINARY HCPCS CODING RECOMMENDATION

As reported by the applicant, the procedure during which the RIC Conformal source, model 100 Brachytherapy source would be used, is performed exclusively in a hospital outpatient (HOPPS) setting. For coding inquiries and requests for the purpose of reporting HOPPS use to Medicare, CMS redirects the applicant to CMS' Pass-Through coding program. 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

There was no primary speaker for this item. Written comments were submitted by the applicant requesting that CMS modify the HCPCS code set to include "Brachytx, non-stranded,

Phosphorus". The applicant indicated that this product is designed for use in medical brachytherapy applications, including the treatment of cancer by temporary surface irradiation. In addition, the written comments indicate that existing codes do not adequately describe the product to include the radionuclide Phosphorus as the active radionuclide source.

FINAL DECISION

As reported by the applicant, the procedure during which the RIC Conformal source, model 100 Brachytherapy source would be used, is performed exclusively in a hospital outpatient (HOPPS) setting. For coding inquiries and requests for the purpose of reporting HOPPS use to Medicare, CMS redirects the applicant to CMS' Pass-Through coding program. For coding guidance for non-Medicare insurers, contact the insurer in whose jurisdiction a claim would be filed.

Wednesday, June 6, 2018

Agenda Item # 12

Application# 18.121

TOPIC

Request to establish a new Level II HCPCS code to identify a flexible disposable bronchoscope, Trade Name: Ambu® aScope™

Language was not suggested by the applicant.

BACKGROUND

MedDev Consulting, LLC, submitted a request to establish a new Level II HCPCS code to identify a single use, flexible disposable bronchoscope for use in a hospital setting. The applicant comments that the aScope products can be used in intubation, bronchosocopy, lung ventilation, airway management, airway inspection, and in the diagnosis and treatment of conditions of the tracheobronchial tree. It is designed to be used with the aView monitor, endotherapy accessories, and other ancillary equipment.

According to the applicant, re-usable bronchoscopes carry an increased risk of infection and cross-contamination between patients. Disposable, single-use bronchoscopes, such as the Ambu® aScope™, may reduce the occurrence of these instances.

The aScope is available in 3 sizes: Slim 3.8/1.2, Regular 5.0/2.2, and Large 5.8/2.8.

The applicant comments that a new code is warranted because "HCPCS Level II coding specifically for the product or any other disposable or re-usable bronchoscope currently does not exist."

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new code to separately report the AmbuScope bronchoscope has not been approved. Brochoscopes are included in the bronchoscopy procedure. If used during a procedure performed in an ambulance, as the applicant claims, it would be included in the ambulance fee.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION

This request to establish a new code to separately report the AmbuScope bronchoscope has not been approved. Brochoscopes are included in the bronchoscopy procedure. If used during a procedure performed in an ambulance, as the applicant claims, it would be included in the ambulance fee.

Wednesday, June 6, 2018

Agenda Item # 13

Application# 18.076

TOPIC

Request to establish a new Level II HCPCS codes to identify a hydrogel wound dressing containing 4% Lidocaine Hydrochloride, Trade Name: Astero.

Applicant's suggested language: JXXXX, "Hydrogel wound dressing containing 4% Lidocaine. Per 1 metered dose (0.25mL/10 mg Lidocaine Hydrochloride USP)".

BACKGROUND

Genesco Laboratories, LLC., submitted a request to establish a new level II HCPCS code to identify Astero. According to the applicant, Astero is a medicated hydrogel wound dressing containing Lidocaine Hydrochloride 4%, a topical anesthetic.

The applicant comments that, Astero is specifically formulated to create a moist healing environment, which promotes granulation, epithelialization, and autolytic debridement, while providing prolonged anesthesia of the wound thereby lessening the need for systematic pain medications including opiate-based drugs. It is a topically applied prescription product approved for treatment of painful wounds. The onset of action is 3-5 minutes and potential duration of up to 6 hours.

Astero is indicated for stage I-IV pressure ulcers, venous stasis ulcers, ulcerations caused by mixed vascular etiologies, diabetic skin ulcers, first and second degree burns, post-surgical incisions as well as, cuts and abrasions. Astero is supplied as a Metered Dose pump in an airless 30 ml container that delivers 0.25 ml per pump and can be self-administered. Each pump delivers 0.25 mL of Astero (10 mg Lidocaine Hydrochloride USP), enough to cover a 2-inch by 2-inch area of skin. A single application should not exceed 4 pumps, with a maximum of 3 applications (12 pumps) per day. Settings of use include physician's offices, freestanding ambulatory care clinics, patient's home by patient, patient's home by health care provider, nursing home/skilled nursing facilities, and both inpatient and outpatient hospital facilities.

The applicant comments that existing codes do not describe the combination of both of the active ingredients of Astero.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code for separate reporting of Astero has not been approved. Astero is an integral part of a service and payment for that service includes payment for Astero, if it is used.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

If self-administered, it would not be payable under Medicare Part D, because it is a drug.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and requested that CMS reconsider this decision and establish a new J code for Astero because it is not only a surgical dressing but it is also a drug. The speaker commented that Astero is the only product approved for painful wounds serving an unmet medical need. The speaker also commented that use of this product will reduce opioid use.

FINAL DECISION

This request to establish a new Level II HCPCS code to identify Astero has not been approved. For physcians office use, Astero is an integral part of a service and payment for that service includes payment for Astero, if it is used. For home use, existing code A6248 "Hydrogel dressing, wound filler, gel, per fluid ounce", is available for assignment by insurers if they deem appropriate.

Wednesday, June 6, 2018

Agenda Item # 14

Application# 18.106

TOPIC

Request to establish a new Level II HCPCS code to identify an antimicrobial biofilm disruptive wound gel, Trade Name: BlastX.

Applicant's suggested language: AXXXX-"Antimicrobial biofilm wound gel, per fluid milliliter"

BACKGROUND

Next Science, LLC, submitted a request to establish a new Level II HCPCS code to identify BlastX, an antimicrobial biofilm disruptive wound gel. According to the applicant, biofilm acts as a protective barrier for bacteria, delaying the wound healing process. BlastX disrupts and penetrates the healing-inhibiting bacterial biofilm that forms in chronic wounds, while keeping the wound moist to facilitate the healing process. It serves to destroy bacteria, prevent infection, and prevent a new biofilm from forming through its antibacterial properties. Additionally, BlastX promotes formation of blood vessels and a collagen wound bed that enhances healing.

According to the applicant, BlastX wound gel is a indicated for management of wounds such as Stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post-surgical wounds, and first- and second-degree burns, grafted, and donor sites. It is applied topically to a wound site every two to three days, until the wound has healed. BlastX consists of a hydrogel base with active ingredients including sodium citrate and citric acid, and benzalkonium chloride, an antimicrobial. It is currently supplied in ¼ ounce and 1 ounce tubes. In the future, it will instead be supplied in 7.5 ML and 30 ML tubes.

The applicant comments that "although it has been suggested that BlastX should use the current A6248 code (hydrogel dressing, wound filler, gel, per fluid ounce), this code doesn't describe the BlastX antimicrobial biofilm wound gel's unique and new properties. Indeed, the antimicrobial biofilm gel product is not a hydrogel dressing, nor does it simply contain bactericides like others in this category. The hydrogel in the antimicrobial biofilm wound gel serves as a hydrophilic medium for the active ingredients, i.e., the sodium citrate and citric acid and the antimicrobial (benzalkonium chloride), which actively disrupt biofilm and kill bacteria. Thus, the hydrogel doesn't serve to cover the wound like a dressing, but simply offers a moist environment in which the active ingredients can work." The applicant also notes that the FDA issued a special designation of the product as a device with a drug component due to BlastX's combination of features.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify BlastX, has not been approved. Existing code A6248, Hydrogel dressing, wound filler, gel, per fluid ounce adequately describes this product based on composition, 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. Pricing = 35

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and requests reconsideration for a new A code for Antimicrobial biofilm wound gel for the product BlastX. The speaker indicates that the product has a unique composition, that enables it to be able to break down bacteria and that it is inappropriate for BlastX to be reported as a hydrogel wound filler.

FINAL DECISION

This request to establish a new Level II HCPCS code to separately identify BlastX, has not been approved. Existing code A6248, Hydrogel dressing, wound filler, gel, per fluid ounce adequately describes this product based on composition, and is available for assignment by insurers if they deem appropriate.

Wednesday, June 6, 2018

Agenda Item # 15

Application# 18.079

TOPIC

Request to establish a single new Level II HCPCS code to identify 2 collagen matrix products, Trade Names: Geistlich Derma-Gide and MUCOGRAFT.

Applicant's suggested language: Qxxxx-"Derma-Gide and MUCOGRAFT, per square centimeter."

BACKGROUND

Geistlich Pharma North America, submitted a request to establish a single new Level II HCPCS code to identify Derma-Gide and MUCOGRAFT. According to the applicant, Geistlich Derma-Gide and MUCOGRAFT are "identical" products. Both are an animal-sourced, acellular wound matrix that is derived from non-crosslinked, porcine (skin and connective) tissue, which is intended for use in guided tissue regeneration and in the management of wounds. It is a porcine, porous and resorbable 3D collagen matrix.The applicant comments that after the product consists of Types I and III collagen that have been specifically processed to support angiogenesis. Angiogenesis is vital to successful wound healing and in the formation of granulation tissue in the wound bed.

MUCOGRAFT has FDA clearance for the following, dental uses: coverage of implants placed in immediate or delayed extraction sockets; localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants; alveolar ridge reconstruction for prosthetic treatment; and guided tissue regeneration procedures in recession defects for root coverage. MUCOGRAFT is sold in the following membrane sizes: 15x20 mm, 20x30mm and 30x40 mm.

Geistlich Derma-Gide is a new trade name for Geistlich would matrix, and it is intended to be used for the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic venous ulcers, surgical wounds and trauma skin wounds. It is supplied in the following sizes: 15x20 mm (1.5x2 cm); 20x30 mm (2x3 cm); 30x40 mm (3x4 cm).

The applicant comments that a new code is warranted because "Medicare and private payers administer coverage and payment policies for bioengineered skin and soft tissue substitutes used in wound care on a brand-name basis, therefore these wound care matrices must be issued a brand-specific HCPCS code in order to be eligible for claims submission and reimbursement. There is no existing code to describe MUCOGRAFT collagen matrix and Geistlich Derma-Gide."

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a unique Level II HCPCS code to separately identify Derma-Gide, has not been approved. Existing code A6021, Collagen dressing, sterile, size 16 sq. in. or less, is available for assignment by insurers, if they deem appropriate, to identify Derma-Gide. For coding guidance for Mucograft and dental indications, contact the American Dental Association (ADA), and the insurer in whose jurisdiction a claim would be filed.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing = 35.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and requested reconsideration for a new Q code in the skin substitute section for Geistlich Derma-Gide. The speaker provided examples of similar products in the same category. The speaker also described that the product is not a dressing but a dermal substitute that requires suturing and pinning to fixate. The speaker agreed with the CMS comments regarding Mucograft and the referral to the American Dental Association.

FINAL DECISION

Establish new code Q4203 "Derma-gide, per square centimeter" to identify Derma-Gide. For coding guidance for Mucograft and dental indications, contact the American Dental Association (ADA), and the insurer in whose jurisdiction a claim would be filed.

Wednesday, June 6, 2018

Agenda Item # 16

Application# 18.014

TOPIC

Request to establish a new Level II HCPCS code to identify a synthetic, bio-compatible wound matrix, Trade Name: Restrata Wound Matrix

Applicant's suggested language: QXXXX: "Restrata Wound Matrix, per sq. cm"

BACKGROUND

Acera Surgical, Inc., submitted a request to establish a new Level II HCPCS code to identify Restrata Wound Matrix. According to the applicant, Restrata Wound Matrix is a bio-engineered wound matrix made of synthetic biocompatible polymers, which are designated to replicate architecture (e.g., scale porosity, fiber orientation) of native extracellular matrix (ECM). Restrata Wound Matrix adopts advanced material science using nanotechnology, and supports cellular migration needed for effective wound closure. Restrata Wound Matrix has a defined rate of resorption that provides a scaffold for cellular infiltration and vascularization. Working "in the manner of a skin substitute," Restrata permits the ingress of cells and soft tissue formation in the defect space and wound.

Restrata Wound Matrix is intended for use in the management of wounds, including: Partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g., donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds, (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds. It is applied on a wound after the wound bed is prepared with standard methods. The product will fully absorb and does not have to be removed. Restrata is supplied in a variety of sizes up to 10cm x 12.5cm. Restrata may be fenestrated.

The applicant comments that a new code is warranted because Restrata replicates the architecture of native ECM, and because no current HCPCS codes aligns with this product to facilitate proper billing and coding to all payers in the full range of site of care settings.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a unique Level II HCPCS code to separately identify Restrata Wound Matrix, has not been approved. Existing codes A6196, "Alginate or other fiber gelling dressing, wound cover, sterile, pad size 16 sq. in. or less, each dressing", or A6197, "Alginate or other fiber gelling dressing, wound cover, sterile, pad size more than 16 sq. in. but less than or equal to 48 sq. in., each dressing" or A6198, "Alginate or other fiber gelling dressing, wound cover,

sterile, pad size more than 48 sq. in., each dressing", are available for assignment by insurers, if they deem appropriate, to report the product that is the subject of this application.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to this product if covered. For A6196, A6197 Pricing =35, For A6198, Pricing= 46

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and requested that Restrata be given a unique Level II HCPCS Q-code. The speaker provided newly available clinical evidence to support that Restrata fits the definition of a skin substitute as it acts like a biological.

FINAL DECISION

Establish A6460 Synthetic resorbable wound dressing, sterile, pad size 16 sq. in. or less, without adhesive border, each dressing. Effective 1/1/19

Establish A6461 Synthetic resorbable wound dressing, sterile pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing. Effective 1/1/19.

Wednesday, June 6, 2018

Agenda Item # 17

Application# 18.117

TOPIC

Request to establish a new Level II HCPCS code to identify a male comfort model urinal system, Trade Name: Advantage Urinal Systems Comfort Male Model.

Applicant's suggested language: "Urinal system, male, jug-type with integral 2000ml collection bag"

BACKGROUND

Advantage Urinal Systems LLC, submitted a request to establish a new Level II HCPCS code to identify the Advantage Comfort Male Model urinal system. According to the applicant, the Advantage Comfort Male Model system is comprised of a plastic vessel (urinal) with a closed-cell foam surrounding the opening. The urinal connects to a 2,000 mL collection bag via a connector and anti-reflux tubing. The urinal collection system is placed over the penis, allowing urine to enter the plastic vessel and drain into the collection bag. The Advantage Comfort Male Model is not a catheter and is completely external.

The urinal collection system, which is intended for continent and incontinent males living with neuromuscular impairments and/or limited mobility, may be used multiple times before the collection bag is emptied. Because the product is largely self-administered in patients' homes, there is no prescription required. The applicant claims that this urinal collection system, when compared to urinary catheters, is less expensive and reduces the risk of infection.

The applicant comments that a new code is warranted because existing codes, such as A5105, do not cover a complete urinal system with a collection bag.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing codes E0325, "Urinal; male, jug-type, any material", and A4357, "Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each", together describe the product that is the subject of this application. These codes are 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 if covered. For E0325, Pricing = 32, For A4357, Pricing= 37

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and requested a new HCPCS code be assigned for a complete urine capture and collection system. The speaker stated that the total reimbursement of the recommended combined codes is about $17.00 which does not cover the essential features. In addition, the speaker said that E0325 is primarily for continent users while A4357 is primarily used for incontinent users. The speaker also stated that there is a concern that using these 2 codes in combination will cause errors in billing and non-payment.

FINAL DECISION

Existing codes E0325, "Urinal; male, jug-type, any material", and A4357, "Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each", together describe the product that is the subject of this application. These codes are available for assignment by insurers if they deem appropriate.

Wednesday, June 6, 2018

Agenda Item # 18

Application# 18.115

TOPIC

Request to establish 2 new Level II HCPCS codes to identify an incontinence penile garment; one “A” code and one “T” code, using the same language. Trade Name: QuickChange Wrap.

Applicant’s suggested language: “Male Urinary Incontinence Penile Wrap”.

BACKGROUND

UI Medical, LLC submitted a request to establish 2 new Level II HCPCS codes to identify the QuickChange Wrap, an incontinence penile garment intended for chair- and bed-bound adult men with urinary incontinence (UI). The applicant comments, that the QuickChange Wrap is a urine collector with a design that allows for immediate absorption, prevents leaking and incontinence-associated dermatitis, and the elimination of the need to lift or roll patients when changing.

According to the applicant, the QuickChange Wrap has a circular shape. The product is completely wrapped around the penis and not around the waist and legs like adult incontinent briefs. It contains a center hole for various penis sizes with a fold for the penis to be wrapped in at 360 degrees. The applicant comments that the QuickChange Wrap also has a small opening for ventilation.

According to the applicant, the need to treat and care for skin is reduced with usage of this product, due to a lower incidence of leakages. Care-givers can quickly change and replace the QuickChange Wrap ™ without adjusting the position of the patient, thus minimizing occasional disturbances of sleep.

The applicant comments that a new code is warranted because no existing HCPCS code adequately describe the QuickChange Wrap. "Existing "A" codes (A4520, A4454) and existing "T" codes (T4541 – T4544) either have very specific guidelines to the shapes and uses of the products or simply do not fit the description or use of the Penile Wrap."

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Quick Change Wrap incontinence garmenthas not been approved. Existing code T4535, "Disposable liner/shield/guard/pad/undergarment, for incontinence, each", and A4520, "Incontinence garment, any type, (e.g., brief, diaper), each",are 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. Pricing = 00

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision and described this product as a "new category of incontinence products" since there is no need to undress patients but just roll them over. The pricing CMS recommended for assigned code, T4535 would not cover the cost of the wrap.

FINAL DECISION

Establish T4545 Incontinence product, disposable, penile wrap, each. Effective 1/1/19

Wednesday, June 6, 2018

Agenda Item # 19

Application# 18.114

TOPIC

Request to establish a new Level II HCPCS code to identify sterile human milk.

Applicant's suggested language: "BXXXX-Human Milk, ultra high temperature sterilized, per ounce."

BACKGROUND

International Milk Bank (IMB) submitted a request to establish a new Level II HCPCS code to identify Sterile Human Milk, an enteral/parenteral complete or supplemental nutritional product intended to be a human breast milk substitute for preterm, low weight infants. The product functions as a reliable supply of nutritional product for infants whose mothers cannot provide breast milk.

According to the applicant, the product is human milk that undergoes IMB's "Gentle" Ultra High Temperature (UHT) sterilization process. The UHT sterilization process eliminates pathogens such as *Bacteria cereus* spore which is potentially fatal to infants and can survive pasteurization. After the process, Sterile Human Milk provides sterile, nutritionally-preserved sustenance to infants.

The Sterile Human Milk is indicated for use by preterm, low weight infants under physician recommendations. The breast milk is collected from donations given by mothers of newborns. It is screened, tested, processed, and contained aseptically using Tetra PAC's UHT sterilization bottling system. The product can be administered through an enteral feeding tube, pump, or bottle.

The applicant comments that a new code is warranted because "the coding system does not yet recognize human milk as a product and therefore does not provide any codes to bill for that product."

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code T2100, "Human breast milk processing, storage and distribution only", is available for assignment by insurers if they deem appropriate, to describe processing (including sterilization), storage and distribution. The milk itself is considered food that is not especially formulated for a disease/condition (sterilization notwithstanding), in which specific requirements exist. As such, the breast milk itself is not suitable for coding in Level II HCPCS.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

We believe that there would be no Medicare payment for this item.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary coding recommendation. The speaker requested reconsideration of a new unique HCPCS code for a product category of Sterilized Human Breast Milk or for the creation of a new sub-set code for T2101 to differentiate the processing, storage and distribution inputs to recognize the additional cost burden associated with sterilization and maintenance of a stable milk supply to allow billing code differentiation of 2 diverse classes of operating costs.

FINAL DECISION

Existing code T2100, "Human breast milk processing, storage and distribution only", is available for assignment by insurers if they deem appropriate, to describe processing (including sterilization), storage and distribution. The milk itself is considered food that is not especially formulated for a disease/condition (sterilization notwithstanding), for which specific requirements exist. As such, the breast milk itself is not suitable for coding in Level II HCPCS.

Wednesday, June 6, 2018

Agenda Item # 20

Application# 18.122

TOPIC

Request to establish a new Level II HCPCS code to identify a dispensing service or fee for prescription drugs that does not include compounding services and/or is not specific to inhalation drugs.

Applicant's suggested language: "Prescription drug(s) dispensing service/fee"

BACKGROUND

Mitchell International, submitted a request to establish a new Level II HCPCS code to identify a dispensing service or fee for prescription drugs that does not include compounding services and/or is not specific to inhalation drugs. According to the applicant, there are certain states where a mandate exists allowing for a pharmacy dispensing fee to be reported by pharmacists or other medical providers.

The applicant comments that a new code is warranted because existing HCPCS dispensing fee codes "include either compounding of a medication, or are specific to inhalation drugs. Providers currently have no coding option for dispensing of prescription medications that are not inhalation drugs or do not require compounding services."

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a code to identify a dispensing fee for prescriptions drugs (excluding inhalation drugs and compounding of medicine) has not been approved. Pharmacy dispensing fees relate to pricing and payments are not, of themselves medical products. Existing dispensing fee codes for inhalation drugs are included on an exception basis and are associated with statutory requirements in 1842(o) of the SSA. For coding and billing guidance and information regarding allowable fees, contact the insurer(s) in whose jurisdiction a claim would be filed.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and indicated that the 2018 HCPCS code set already has similar dispensing fees and that these fees are also not medical products. In addition, the speaker commented that there are 33 states have a dispensing fee for pharmaceuticals written in statute. The speaker requested that CMS reconsider its recommendation for not assigning a new code for dispensing fees would create confusion for healthcare providers and patients alike and would require manual processing.

FINAL DECISION

This request to establish a code to identify a dispensing fee for prescription drugs (excluding inhalation drugs and compounding of medicine), has not been approved. Pharmacy dispensing fees relate to pricing and payments are not, of themselves medical products. Existing dispensing fee codes for inhalation drugs are included on an exception basis and are associated with statutory requirements in 1842(o) of the SSA. Insurers are paying dispensing fees without difficulty, and the addition of a code could create duplicate billing opportunities. For coding and billing guidance and information regarding allowable fees, contact the insurer in whose jurisdiction a claim would be filed.