Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Application Summaries for Durable Medical Equipment, Prosthetics, Orthotics and Medical Supplies (DMEPOS)

Tuesday, June 11, 2019

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the June 11, 2019 HCPCS Public Meeting for Drugs, Drugs, Biologicals and Radiopharmaceuticals and Radiologic Imaging Agents. 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' 2019-2020 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: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 1

Application # 19.008

TOPIC

Request to establish eleven new Level II HCPCS codes to identify alternative payment models for radiation therapy.

Applicants suggested language:

SXXX1 Episode of care for radiation therapy to the head and neck

SXXX2 Episode of care for radiation therapy to the esophagus

SXXX3 Episode of care for radiation therapy to the thorax

SXXX4 Episode of care for radiation therapy to the mediastinum

SXXX5 Episode of care for radiation therapy to the breast

SXXX6 Episode of care for radiation therapy to the chest wall

SXXX7 Episode of care for radiation therapy to the abdomen

SXXX8 Episode of care for radiation therapy to the pelvis

SXXX9 Episode of care for radiation therapy to the prostate

SXXX10 Episode of care for radiation therapy to the rectum

SXXX11 Episode of care for radiation therapy to the metastasis

BACKGROUND

UnitedHealthcare submitted a request to establish eleven new Level II HCPCS codes to identify an alternative payment models for radiation therapy.

According to applicant, "these codes would be used by providers to bill for and be reimbursed for an entire episode of care for radiation therapy instead of billing for each individual service. These codes will simplify billing and reimbursement of services for a radiation therapy episode of care. As the approaches to radiation therapy and services provided vary by site of service, we

are requesting different codes to reflect the specific site where radiation is delivered. Currently there are no existing codes that adequately address the code of an entire episode of care."

PRELIMINARY HCPCS CODING RECOMMENDATION

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were offered from the applicant at CMS HCPCS Public Meeting in response to our Preliminary recommendations.

FINAL 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.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 2

Application # 19.104

TOPIC

Request to establish a new Level II HCPCS code to identify the Computer Based Training for Cognitive Behavioral Therapy. Trade name: CBT4CBT

BACKGROUND

CBT4CBT LLC requested a new code for the product CBT4CBT (Computer Based Training for Cognitive Behavioral Therapy).

According to the requester, CBT4CBT is web-based software treatment for Substance Use Disorder (SUD)s that teaches a variety of cognitive and behavioral skills that are specific for helping people to reduce substance abuse. CBT4CBT is a self-guided training program that uses narratives, videos, and exercises to teach and reinforce CBT skills. CBT4CBT can be accessed using a computer/laptop/tablet/smartphone with an internet connection. CBT4CBT includes 7 models, each taking about 35 minutes to complete, in a format that reproduces clinician-delivered CBT (introduce the skill, teach the skill, demonstrate the skill, and practice the skill). While CBT4CBT is administered under the general supervision of a licensed clinician, no direct supervision or presence of the clinician is required while the patient is using the CBT4CBT program. CBT4CBT is appropriate for any individual whose alcohol or drug use has been, or is, a problem for them. People using CBT4CBT must be enrolled in a clinical program or working with a qualified clinician who offers CBT4CBT to their clients. According to the requester, the computer-based training modules were developed to "address multiple barriers to the implementation and availability of empirically validated therapies," particularly in rural settings, where "clinicians trained in CBT are scarce." There are no existing code categories into which computer delivery of CBT for treatment of SUDs fits. Current CPT Codes reimburse for clinician time only. H0004 and H0005 only reimburse for a clinician's counseling time and do not reimburse for tools used in counseling sessions or used in the place of counseling.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a Level II HCPCS codes to identify CBT4CBT computer based training has not been approved, because this product is not primarily medical in nature. To the extent there is practitioner involvement in this training with the self-help/training system, CMS refers the applicant to the American Medical Association (AMA) for CPT coding guidance

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendations. The speaker stated that CBT4CBT is primarily medical in nature. The product must be prescribed. The patient can use it at home. It is web based treatment for drug and alcohol abuse.

FINAL DECISION

CMS has given considerable thought to this request to establish a code to identify computer based training for cognitive behavior. CMS has not identified policy or claims processing need on the part of any insurance sector for code to identify self-guided training program on the claim. We understand that self-help web-based software treatment and self-help devices are an important and emerging science. It is our understanding that Food and Drug Administration and American Medical Association are reviewing this technology in detail as they consider product and procedure classification. Please contact me personally at my e-mail: cynthia.hake@cms.hhs.gov, for direct referral within an AMA. CMS would also like to refer you to the insurers in which jurisdiction claims would be filed for coding guidance.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 3

Application # 19.105

TOPIC

Request to establish a new Level II HCPCS code to identify an endotracheal tube holder with foam strap and silicone bite block combination. Trade name: Haider Tube Guard.

BACKGROUND

Haider Sceintific requested a new code to identify the Haider Tube Guard.

According to the applicant, the Haider Tube Guard is an endotracheal tube holder with foam strap and silicone bite block combination. It is used in conjunction with the endotracheal (ET) tube in order to secure the ET tube and prevent it from dislodging or moving more than an acceptable amount. The Haider Tube Guard has a clamshell like body made of silicone and a plastic clamp which is designed to wrap around and attach onto the ET tube. The clamshell rests between the upper and lower teeth or gums. For added security, a Velcro neck strap is attached. The Haider Tube Guard also provides protection for the teeth, lips and tongue. Its soft bite-block feature helps prevent a patient from biting down and compressing the ET tube. It is ideal for patients with allergies to adhesives, those with beards, oily or sensitive skin, elderly patients, patients in trauma or burn cases, or for use during procedures (such as spine surgery) when patient is in the prone position. According to Haider Scientific, there is no product on the market that is comparable to the Haider Tube Guard which functions as an ET tube holder as well as a bite block. All other products only secure the ET tube in place and keep it from dislodging. None of them protects teeth, lips, tongue and gums of the patient. There are currently no codes that allow a hospital to bill for the use of the Tube Guard. Tube Guard is used only during surgical procedures to prevent oral injury to patient and protect unplanned extubation as well as ET tube migration.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a code, to separately identify the Haider Tube guard for use in endotracheal intubation during surgery, is not suitable for coding in HCPCS Level II outside of pass-through codes. A request for separate identification of this product for hospital outpatient use maybe be made to CMS' pass-through application process.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were offered at CMS' HCPCS Public Meeting regarding this application or in response to our published Preliminary recommendation.

FINAL DECISION

This request to establish a code, to separately identify the Haider Tube guard for use in endotracheal intubation during surgery, is not suitable for coding in HCPCS Level II outside of pass-through codes. A request for separate identification of this product for hospital outpatient use maybe be made to CMS' pass-through application process.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 4

Application # 19.106

TOPIC

Request to establish a new Level II HCPCS code to identify a surgical nail splint for the reconstructive surgery of the nail bed. Trade name: INRO Surgical Nail.

BACKGROUND

INRO Medical Designs, Inc. requested a code for INRO Surgical Nail.

According to the applicant, INRO Surgical Nail is a piece of polypropylene plastic shaped to the natural curvature of the nail. After a traumatic injury to the fingernail (with partial or complete loss of the fingernail), INRO Surgical Nail is sutured onto the nail bed. The Surgical Nail allows the new nail to grow under it. The new nail is molded by the Surgical Nail to takes its original shape, size and smoothness of contour. INRO Surgical Nail prevents adhesion of the eponychial fold to the nail bed, provides cosmetic benefit to the new nail, prevents adherence of dressings to an exposed nail bed, reduces the need for analgesic intake following nail bed surgery, and protects the tender nail bed against negative stimuli during treatment phase. No item is similar to INRO Surgical Nail. Only substitute materials with no codes are used for nail avulsion injuries. No codes are used to bill for INRO Surgical Nail.

PRELIMINARY HCPCS CODING RECOMMENDATION

The INRO Surgical Nail is an integral part of a surgical procedure. CMS refers the applicant to the American Medical Association (AMA) for coding guidance for reporting use in conjunction with avulsion surgery.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were offered at CMS' HCPCS Public Meeting regarding this application or in response to our published preliminary coding recommendation.

FINAL DECISION

The INRO Surgical Nail is an integral part of a surgical procedure. CMS refers the applicant to the American Medical Association (AMA) for coding guidance for reporting use in conjunction with avulsion surgery.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 5

Application # 19.107

TOPIC

Request to establish a new Level II HCPCS code to identify a single use device which is fixed to a transrectal ultrasound probe. Trade name: PrecisionPoint Transperineal Access System.

Applicant's suggested language: "PrecisionPoint Transperineal Access System (PPTAS)"

BACKGROUND

Corbin Clinical Resources, LLC requested a code to identify the PrecisionPoint Transperineal Access System (PPTAS).

According to the applicant, the PrecisionPoint Transperineal Access System (PPTAS) provides a guided, systematic, perineal approach to prostate biopsies. The PPTAS eliminates the need for a trans-rectal biopsy, bowel prep, rectal culture, and antibiotics. Its use has been shown to increase cancer detection rate secondary to the ability to access the anterior portion of the prostate. The PPTAS allows the practitioner the ability to manipulate the access needle in synchrony with the ultrasound probe and provides direct access to the prostate gland through the perineum rather than multiple punctures through the contaminated rectal wall as with the traditional trans-rectal approach. The transperineal approach eliminates infection caused by multiple needle sticks through the rectal wall during a trans-rectal prostate biopsy and can be performed under local or general anesthesia. The targeted population are men between the ages of 40-90 who have a need for prostate biopsy to confirm or rule out the diagnosis of prostate cancer. According to the requester, there is a significant therapeutic distinction when compared their product to the use of other, similar items that would otherwise share a code. Patients having a traditional transrectal prostate biopsy are often misclassified due to the diagnostic inaccuracy of the transrectal biopsy method. The transrectal biopsy also has significant biopsy related complications such as sepsis, rectal and urinary bleeding, and urinary retention. Although the Stepper, Grid Stabilizer (SGS) method is an accurate technique, the procedure requires general or spinal anesthesia and delivery typically in a hospital or ambulatory surgery center setting. The existing code categories do not allow for the addition of the PPTAS to the prostate biopsy procedures since the current payment models are limited to a transrectal approach. CPT code 55706 describes a transperineal approach, but it related to the use of stepper/grid system (SGS) requiring general anesthesia of the patient due to positioning requirements (extended lithotomy position) and performance of the procedure in a hospital/ASC setting.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new code to separately identify PrecisionPoint Transperineal Access System (PPTAS) has not been approved. PPTAS is an integral part of a procedure. PPTAS, if used, is included in the procedure, and separate coding could be construed as redundant.

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. The speaker stated that PPTAS is a unique and innovative medical device, which has never been a component of the prostate biopsy procedure. PPTAS does not represent a replacement or substitution, but rather an adjunct for existing procedural supplies. PPTAS should not be considered a device used just for prostate biopsy, but rather a transformation in transperineal surgical access with applications in a multitude of pelvic procedures.

FINAL DECISION

This request to establish a new code to separately identify PrecisionPoint Transperineal Access System (PPTAS), has not been approved. CMS refers the applicant to the American Medical Association (AMA) for consideration of CPT coding performing the service using the transperineal approach using this or other similar devices.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 6

Application # 19.108

TOPIC

Request to establish a new Level II HCPCS code to identify an ostomy smart post-operative starter kit for new patients after surgery. Trade name: Alfred Smart Post-Operative Kit.

Applicant's suggested language: AXXXX Ostomy Smart Post-Operative Kit containing 4 Alfred SmartBags and 1 Alfred SmartWafer, each.

BACKGROUND

11 Health and Technologies Inc. requested a code for an Ostomy Smart Post-Operative kit. According to the applicant, the Alfred Smart Post-Operative Kit is a patient starter kit for new patients after surgery. The Alfred Smart Post-Operative Kit contains a supply of 4 Alfred SmartBags and 1 Alfred SmartWafer for the patient to implement while in the hospital setting prior to hospital discharge. The Alfred SmartBag is the bag component of the Alfred SmartBag system that consists of an integrated thermistor and capacitive sensor sheet, an NFC (Near Field Communication) antenna and a battery. A thermistor and capacitive sensors will be able to continuously determine the patient's estimated output volume. Alfred SmartBag monitors how full the ostomy bag is, based on the continuous wear by patients. The Alfred SmartBag is connected to the Alfred SmartWafer and communicates either directly or, when connectivity through a mobile device is unavailable, through the Alfred SmartHub, to transfer data to the 11 Health Cloud. The Alfred SmartBag is drainable with a maximum volume of 560 ml, and should be replaced every 2 to 3 days. It is indicated for adult use only of 22 years of age and older. The Alfred SmartWafer is comprised of a sheet mounted with an array of sensors, an NFC antenna and battery. The Alfred SmartWafer can continuously monitor the change in temperature around the peristomal region/skin, indicating potential occurrence of leakage or skin complications. The skin temperature data gathered by the Alfred SmartWafer is then sent to the 11 Health Cloud Server. The Alfred SmartWafer is a flat sheet, recommended to be replaced every 3 to 5 days. Indicated for adult use only of 22 years of age and older. The Alfred SmartBag System is intended for use inside and outside of hospitals for any patient with a diversionary urinary or fecal stoma. The Alfred SmartBag System offers a continuous ostomy monitoring system, tracks the estimated volumetric filling of the bag, skin condition around the stoma and the occurrence of leaks, using integrated sensor technology. It works in conjunction with 11 Health's care management platform, providing cumulative output data to the patient and clinical team. The Alfred SmartBag and the Alfred SmartWafer are the only products of their kind on the market today that offers a continuous ostomy monitoring system, tracks the estimated volumetric filling of the bag, skin condition around the stoma and the occurrence of leaks, using integrated sensor technology. There is no current code that accurately describes this unique product and its

functionality. A4221 "Ostomy supply, miscellaneous", is very generic and not specific enough to use for electronic billing and payment and for researching outcomes when analyzing the health data.

PRELIMINARY HCPCS CODING RECOMMENDATION

The Alfred Smart Post-Operative Kit is used for new patients in the hospital setting following the surgery and prior to hospital discharge. As such, if used, it is included in the hospital payment. It is not suitable for coding in HCPCS Level II, and separate reporting may be redundant.

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. The speaker stated the Alfred Care Management for Ostomy Patients has the ability to automate fluid balance volumes, detect leaks before they cause accidents, prevent skin issues, provide real time access to a coach to assist in pre- and post-operative education and psychological support, and real time access to telehealth platform of fully trained wound ostomy and continence nurses.

FINAL DECISION

The Alfred Smart Post-Operative Kit is used for new patients in the hospital setting following the surgery and prior to hospital discharge. As such, if used, it is included in the hospital payment. It is not suitable for coding in HCPCS Level II, and separate reporting may be redundant.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 6

Application # 19.109

TOPIC

Request to establish a new Level II HCPCS code to identify a 30-day supply of ostomy bags and wafers. Trade name: Alfred Smart 30 Day Kit.

Applicant's suggested language: AXXXX “Ostomy Smart 30 Day Kit.”

BACKGROUND

11 Health and Technologies Inc. requested a code for an Ostomy Smart 30 day Kit. The kit contains a 30 day supply of Alfred SmartBags and Alfred SmartWafers; (20 Alfred SmartBags and 5 Alfred SmartWafers). According to the applicant, The Alfred SmartBag is the bag component of the Alfred SmartBag system that consists of an integrated thermistor and capacitive sensor sheet, an NFC (Near Field Communication) antenna and a battery. A thermistor and capacitive sensors continuously determine the patient's estimated output volume. Alfred SmartBag monitors how full the ostomy bag is, based on the continuous wear by patients. The Alfred SmartBag is connected to the Alfred SmartWafer and communicates either directly or, when connectivity through a mobile device is unavailable, through the Alfred SmartHub, to transfer data to the 11 Health Cloud. The Alfred SmartBag is drainable with a maximum volume of 560 ml, and should be replaced every 2 to 3 days. It is indicated for adult use only of 22 years of age and older. The Alfred SmartWafer is comprised of a sheet mounted with an array of sensors, an NFC antenna and battery. The Alfred SmartWafer can continuously monitor the change in temperature around the peristomal region/skin, indicating potential occurrence of leakage or skin complications. The skin temperature data gathered by the The Alfred SmartWafer is then sent to the 11 Health Cloud Server. The Alfred SmartWafer is a flat sheet, recommended to be replaced every 3 to 5 days, indicated for adult use only of 22 years of age and older. The Alfred SmartBag System is intended for use inside and outside of hospitals for any patient with a diversionary urinary or fecal stoma. The Alfred SmartBag System offers a continuous ostomy monitoring system, tracks the estimated volumetric filling of the bag, skin condition around the stoma and the occurrence of leaks, using integrated sensor technology. It works in conjunction with 11 Health's care management platform, providing cumulative output data to the patient and clinical team. The Alfred SmartBag and the Alfred SmartWafer are the only products of their kind on the market today that offer a continuous ostomy monitoring system, tracks the estimated volumetric filling of the bag, skin condition around the stoma and the occurrence of leaks, using integrated sensor technology. There is no current code that accurately describes this unique product and its functionality. A4221 "Ostomy supply, miscellaneous", is very generic and not specific enough to use for electronic billing and payment and for researching outcomes when analyzing the health data.

PRELIMINARY HCPCS CODING RECOMMENDATION

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to this product if covered. For A4420, Pricing=37. For A9279, Pricing=00. For A4409, Pricing=37.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated the Alfred Care Management for Ostomy Patients has the ability to automate fluid balance volumes, detect leaks before they cause accidents, prevent skin issues, provide real time access to a coach to assist in pre- and post-operative education and psychological support, and real time access to telehealth platform of fully trained wound ostomy and continence nurses.

FINAL DECISION

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes describe the products in the kit A4426, "Ostomy pouch, drainable; for use on barrier with locking flange (2 piece system), each" describes the pouch; A4409, "Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, 4 x 4 inches or smaller, each", or A4410, "Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, larger than 4 x 4 inches, each", (depending on size) describes the wafer; and A9279, " Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified", describes the monitoring component, as a general rule, CMS doesn't assign individual products to existing

codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 6

Application # 19.110

TOPIC

Request to establish a new Level II HCPCS code to identify an ostomy supply. Trade name: Alfred SmartBag.

Applicant's suggested language: AXXXX Ostomy smart pouch, drainable, opaque, with sensors, without barrier, each.

BACKGROUND

11 Health and Technologies Inc. requested a code for an Ostomy Supply entitled, Alfred SmartBag.

According to the applicant, The Alfred SmartBag is the bag component of the Alfred SmartBag system that consists of an integrated thermistor and capacitive sensor sheet, an NFC (Near Field Communication) antenna and a battery. A thermistor and capacitive sensors will be able to continuously determine the patient's estimated output volume. Alfred SmartBag monitors how full the ostomy bag is, based on the continuous wear by patients. The Alfred SmartBag is connected to the Alfred SmartWafer and communicates either directly or, when connectivity through a mobile device is unavailable, through the Alfred SmartHub, to transfer data to the 11 Health Cloud. The Alfred SmartBag is drainable with a maximum volume of 560 ml, and should be replaced every 2 to 3 days. Indicated for adult use only of 22 years of age and older. The Alfred SmartBag System is intended for use inside and outside of hospitals for any patient with a diversionary urinary or fecal stoma. The Alfred SmartBag System offers a continuous ostomy monitoring system, tracks the estimated volumetric filling of the bag, skin condition around the stoma and the occurrence of leaks, using integrated sensor technology. It works in conjunction with 11 Health's care management platform, providing cumulative output data to the patient and clinical team. There are no similar products in the United States market place to date. The Alfred SmartBag is the only product of its kind on the market today that offers a continuous ostomy monitoring system, tracks the estimated volumetric filling of the bag, skin condition around the stoma and the occurrence of leaks, using integrated sensor technology. There is no current code that accurately describes this unique product and its functionality. A4221 "Ostomy supply, miscellaneous", is very generic and not specific enough to use for electronic billing and payment and for researching outcomes when analyzing the health data.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4420 "Ostomy pouch, closed; for use on barrier with locking flange (2 piece), each" adequately describes the ostomy pouch component of the ostomy smart pouch and existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the monitoring component of the ostomy smart pouch.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to this product if covered. For A4420, Pricing = 37. For A9279, Pricing = 00

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated the Alfred Care Management for Ostomy Patients has the ability to automate fluid balance volumes, detect leaks before they cause accidents, prevent skin issues, provide real time access to a coach to assist in pre- and post-operative education and psychological support, and real time access to telehealth platform of fully trained wound ostomy and continence nurses.

FINAL DECISION

Existing code A4426 "Ostomy pouch, drainable; for use on barrier with locking flange (2 piece system), each" adequately describes the ostomy pouch component of the ostomy smart pouch and existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type,

includes all accessories, components and electronics, not otherwise classified" adequately describes the monitoring component of the ostomy smart pouch.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 6

Application # 19.111

TOPIC

Request to establish a new Level II HCPCS code to identify a programmed microprocessor which translates data for a continuous monitoring ostomy system. Trade name: Alfred SmartHub.

Applicant's suggested language: AXXXX, Programmed microprocessor translates data for a continuous monitoring ostomy system, each.

BACKGROUND

11 Health and Technologies Inc. requested a code to identify the Alfred SmartHub, a Programmed microprocessor translates data for a continuous monitoring ostomy system.

According to the applicant, the Alfred SmartHub is the central point of communication between the Alfred SmartBag and Alfred SmartWafer and the 11 Health Cloud Service when connectivity through a mobile device is not available or limited. The Alfred SmartBag and Alfred SmartWafer feature integrated sensors to continuously monitor bag filing and drainage, providing cumulative output data to the patient and clinical team. The Alfred SmartBag and Alfred SmartWafer also monitors skin condition around the stoma and the occurrence of leaks. The programmed microprocessor translates data from the Alfred SmartWafer and the Alfred SmartBag into readable information, which is then sent to the 11 Health Cloud service to be downloaded by the user in the Alfred SmartCare mobile application. The Alfred SmartHub is approximately 0.55 inches in height and 3.23 inches in diameter, is rechargeable, and should be replaced after 1 year. The Alfred SmartBag System is intended for use inside and outside of hospitals for any patient with a diversionary urinary or fecal stoma. The Alfred SmartBag System offers a continuous ostomy monitoring system, tracks the estimated volumetric filling of the bag, skin condition around the stoma and the occurrence of leaks, using integrated sensor technology. It works in conjunction with 11 Health's care management platform, providing cumulative output data to the patient and clinical team. The Alfred SmartHub is the only product of its kind on the market today that is programmed to translate data from the Alfred SmartWafer and Alfred SmartBag regarding bag filling, bag drainage, condition of the skin and stoma and contents to the patient, provider and/or caregiver. There is no current code that accurately describes this unique product and its functionality. A4221 "Ostomy supply, miscellaneous", is very generic and not specific enough to use for electronic billing and payment and for researching outcomes when analyzing the health data.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the monitoring feature of the Alfred SmartHub, and is available for assignment by insurers if they deem appropriate.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to this product if covered. For A9279, Pricing = 00

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated the Alfred Care Management for Ostomy Patients has the ability to automate fluid balance volumes, detect leaks before they cause accidents, prevent skin issues, provide real time access to a coach to assist in pre- and post-operative education and psychological support, and real time access to telehealth platform of fully trained wound ostomy and continence nurses.

FINAL DECISION

Existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified", adequately describes the

monitoring feature of the Alfred SmartHub, and is available for assignment by insurers if they deem appropriate.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 6

Application # 19.112

TOPIC

Request to establish a new Level II HCPCS code to identify a sheet mounted with an array of thermistor sensors, an NFC (Near Field Communication) antenna and a battery. Trade name: Alfred SmartWafer.

Applicant's suggested language: AXXXX Skin barrier/wafer, 3.7in by 4.37in, hydrocolloid flat sheet with an array of thermistors, each.

BACKGROUND

11 Health and Technologies Inc. requested a code to identify an Ostomy supply, the Alfred SmartWafer.

According to the applicant, the Alfred SmartWafer is comprised of a sheet mounted with an array of thermistor sensors, a NFC (Near Field Communication) antenna and battery. The sensor array sheet when integrated and fully encased into a conventional hydrocolloid wafer serves as the wafer for the Alfred SmartBag. The Alfred SmartWafer can continuously monitor the change in temperature around the peristomal region/skin, indicating potential occurrence of leakage or skin complications. The skin temperature data gathered by the Alfred SmartWafer is then sent to the 11 Health Cloud Server. The Alfred SmartWafer is approximately 3.74 inch by 4.37 inches, flat sheet. Recommended replacement, every 3 to 5 days. The Alfred SmartBag System (including the Alfred SmartHub, Alfred SmartWafer and Alfred SmartBag) is intended for use inside and outside of hospitals for any patient with a diversionary urinary or fecal stoma. Indicated for adult use only of 22 years of age and older. The Alfred SmartBag System offers a continuous ostomy monitoring system, tracks the estimated volumetric filling of the bag, skin condition around the stoma and the occurrence of leaks, using integrated sensor technology. It works in conjunction with 11 Health's care management platform, providing cumulative output data to the patient and clinical team. The Alfred SmartWafer is the only product of its kind on the market today that continuously monitors the change in temperature around the peristomal region/skin, indication potential occurrence of leakage or skin complications. The skin temperature data gathered by the Alfred SmartWafer is then sent to the 11 Health Cloud Server. There is no current code that accurately describes this unique product and its functionality. A4221 "Ostomy supply, miscellaneous", is very generic and not specific enough to use for electronic billing and payment and for researching outcomes when analyzing the health data.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A4409 "Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, 4 x 4 inches or smaller, each" adequately describes the skin barrier function of this Alfred SmartWafer.

Existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the sensor array monitoring feature of the Alfred SmartWafer.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to this product if covered. For A4409, Pricing = 37. For A9279, Pricing = 00

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated the Alfred Care Management for Ostomy Patients has the ability to automate fluid balance volumes, detect leaks before they cause accidents, prevent skin issues, provide real time access to a coach to assist in pre- and post-operative education and psychological support, and real time access to telehealth platform of fully trained wound ostomy and continence nurses.

FINAL DECISION

Existing code A4409 "Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, 4 x 4 inches or smaller, each" or A4410 "Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, larger than 4 x 4 inches, each", (depending on size) adequately describes the skin barrier function of this Alfred SmartWafer, and are available for assignment by insurers if they deem appropriate.

Existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the sensor array monitoring feature of the Alfred SmartWafer. Effective 01/01/2020

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 7

Application # 19.114

TOPIC

Request to establish a new Level II HCPCS code to identify a cane swing with articulating system and ergonomic handgrip.

BACKGROUND

Applied Mobility Devices, LLC, dba DynaMD, requested a new code to identify a Cane Swing with Articulating System and Ergonomic Handgrip. According to the requester, a Cane Swing with Articulating System, which is a combination of the frame and foot advanced technology designed by Applied Mobility Devices, LLC, to improve patient compliance and performance directed by a medical professional. According to the requester, the Cane Swing with Articulating System, improves patient compliance through the adaptability and adjustability through the swing itself and the articulating system, articulating frame/foot system keeps the foot flatter longer on the ground for maximum traction and safety, the ergonomic design lessens secondary complications and results in safer recovery, larger foot allows for all-terrain use, allowing for more stability, the heel/toe dampening absorbs the nerve damage when striking the ground. Cane Swings are intuitive products designed to function similarly to canes, but with more prominent and stable features. The device is designed for the same patient population as canes and will function with the same demographics. Cane Swings weight capacity to 300 lbs. There are no similar items comparable to the Cane Swings with its features and benefits. According to the requester, the existing code categories are inadequate to describe the product because the existing codes do not contain the additional features that the company has developed, such as an articulating system comprised of frame and foot that maximizes foot flatness for better contact and control, and a foot of the size of an infant's shoe, with a heel and toe-based shock absorbents and heel and toe-based springs to reduce nerve vascular damage in the hand.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing codes E0100 "Cane, includes canes of all materials, adjustable or fixed, with tip" and E0105 "Cane, quad or three prong, includes canes of all materials, adjustable or fixed, with tips", are available for assignment by insures if they deem appropriate to describe the Cane Swing. The applicant submitted insufficient evidence to support a claim of significant therapeutic distinction when the cane swing with articulating system is used, compared with use of other canes currently coded included in code categories E0100 or E0105. Shock absorption and articulation are not new technology. A difference in mechanism of operation by itself does not warrant a separate code. These codes are available for assignment by insurers if they deem appropriate.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to this product if covered. For E0100, Pricing = 32. For E0105, Pricing = 32

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker request a new code for Dynamo cane series product lines. The product features are versatile across a range of mobile assistance requirements. The Dynamo cane swings has an articulating foot system and not a foot tip like conventional canes. The articulating foot system provide better shock absorption and more contact with ground surface, the cane also features a 12 degree bend frame designed to increase strength and stability and an ergonomic handgrip.

FINAL DECISION

Existing codes E0100 "Cane, includes canes of all materials, adjustable or fixed, with tip" and E0105 "Cane, quad or three prong, includes canes of all materials, adjustable or fixed, with tips", are available for assignment by insures if they deem appropriate to describe the Cane Swing. The applicant submitted insufficient evidence to support a claim of significant therapeutic distinction when the cane swing with articulating system is used, compared with use of other canes currently coded included in code categories E0100 or E0105. Shock absorption and articulation are not new technology. A difference in mechanism of operation by itself does not warrant a separate code. These codes are available for assignment by insurers if they deem appropriate.

There is also insufficient evidence to substantiate the applicant's claim of reduction in falls attributed to use of the proprietary swing link system.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 7

Application # 19.115

TOPIC

Request to establish a new Level II HCPCS code to identify an Axilla crutch, Sport and Pro Series.

BACKGROUND

Applied Mobility Devices, LLC, dba DynaMD requested a new code to identify an axilla crutch with SwingLink, Sit/stand assist, Articulating System and foot.

According to the applicant, the Sport & Pro Series Swings with SwingLink Articulating system, is a new category of mobility aids with features like the fitted axilla, swing link, sit/stand assist, articulating system, and foot. Sport & Pro Series Swings are a new tool to improve patient compliance and performance directed by a medical professional. According to the requester, the Cane Swing with Articulating System, improves patient compliance through the adaptability and adjustability through the swing itself and the articulating system, articulating frame/foot system keeps the foot flatter longer on the ground for maximum traction and safety, the ergonomic design lessens secondary complications and results in safer recovery, larger foot allows for all-terrain use, allowing for more stability, the heel/toe dampening absorbs the nerve damage when striking the ground, swing link provides predetermined gait control and eliminates forward slip outs and improves all other slip out possibilities. Sport & Pro Series Swings are intuitive products designed to function similarly to crutches, but with more prominent and stable features. The device is designed for the same patient population as crutches and will function with the same demographics. Sport Series Swings weight capacity to 300 lbs. and Pro Series Swings weight capacity to 450 lbs. There are no similar items comparable to the Sport & Pro Series Swings with its features and benefits. According to the requester, the existing code categories are inadequate to describe the product because the existing codes do not contain the additional features that the company has developed, such as axilla designed for armpit fitment, contoured bodily shape, raised pivot point to armpit, maximizing stability and control, SwingLink that adjusts patient's gait based on ailment/mobility limitations, eliminates forward slips because it connects across patient's back, less risk for dropping crutch, increasing safety, sit/stand assist available due to an articulating system which is unique to the sport swings series, addressing patient difficulty of sitting and standing, articulating system comprised of frame and foot that maximizes foot flatness for better contact and control, and a foot designed larger than crutch tip; size of women's size 4 shoe, with a heel and toe-based shock absorbents and heel and toe-based springs to reduce nerve vascular damage in the hand and armpit.

PRELIMINARY HCPCS CODING RECOMMENDATION

The applicant did not submit sufficient evidence to support a claim of significant therapeutic distinction for the Swing Lock articulating system when compared with use of underarm crutches currently included in existing code category E0117 "Crutch, underarm, articulating, spring assisted, each". Shock absorption and articulation are existing technology and the difference in mechanism of operation by itself does not warrant a separate code in accordance with CMS' coding decision criteria. Other features mentioned by the applicant such as axilla design in SwingLink feature and the claim of their benefits also have not been substantiated by clinical evidence. Existing code E0117 is available for assignment by insurers if they deem appropriate to describe the Swing Lock.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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

These codes are available for assignment by insurers if they deem appropriate. While the CMS maintains the Level II HCPCS code set, it does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicare, contact the Medicare contractor. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code E0117 apply to this product if covered.
Pricing = 36

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated that the current code E0117 is generic and does not describe the Dynamo sport and pro series swings. The product features are versatile across a range of mobile assistance requirements with a unique like feature. The Dynamo sport and pro series swings has a articulating foot system and not a foot tip like conventional crutch, the foot system can reduce slips and fall and reduce injuries due to walking impact through supports.

FINAL DECISION

The applicant did not submit sufficient evidence to support a claim of significant therapeutic distinction or reduction in falls attributed to use of proprietary use of SwingLink system, when compared with use of underarm crutches currently included in existing code category E0117 "Crutch, underarm, articulating, spring assisted, each". Shock absorption and articulation are existing technology and the difference in mechanism of operation by itself does not warrant a separate code in accordance with CMS' coding decision criteria. Other features mentioned by the applicant such as axilla design in SwingLink feature and the claim of their benefits also have not been substantiated by clinical evidence. Existing code E0117 is available for assignment by insurers if they deem appropriate to describe the Swing Lock.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 8

Application # 19.116

TOPIC

Request to establish a new Level II HCPCS code to identify an adjustable forearm crutch (with plastic cuff).

BACKGROUND

Applied Mobility Devices, LLC, dba DynaMD requested a new code to identify a forearm crutch system with WaistLink, Articulating and Foot.

According to the applicant, a Versa Swing forearm crutch with WaistLink, Articulating System, and foot features represent a new category of mobility aids. Versa Swings are a new tool to improve patient compliance and performance directed by a medical professional. According to the requester, Versa Swings improve patient compliance through adaptability and adjustability through the swing itself and the articulating system, articulating frame/foot system keeps the foot flatter longer on the ground for maximum traction and safety, the ergonomic design lessens secondary complications and results in safer recovery, the larger foot allows for all-terrain use, allowing for more stability, the heel/toe dampening absorbs the nerve damage when striking the ground, WaistLink provides predetermined gait control and eliminates forward slip outs and improves all other slip out possibilities. Versa Swings are intuitive products designed to function similarly to forearm, cuff crutches, but with more prominent and stable features. The device is designed for the same patient population as forearm cuff crutches and will function with the same demographics. Versa Swings weight capacity to 300 lbs. According to the requester, the existing code categories are inadequate to describe the product because the existing codes do not contain the additional features that the company has developed, such as WaistLink that adjusts patient's gait based on ailment/mobility limitations, eliminates forward slips because it connects across patient's back, less risk for dropping crutch, increasing safety, articulating system comprised of frame and foot that maximizes foot flatness for better contact and control, and a foot designed larger than crutch tip; size of women's size 4 shoe, with a heel and toe-based shock absorbents and heel and toe-based springs to reduce nerve vascular damage in the hand.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code E0110 "Crutches, forearm, includes crutches of various materials, adjustable or fixed, pair, complete with tips and handgrips" or E0111 "Crutch forearm, includes crutches of various materials, adjustable or fixed, each, with tip and handgrips" depending on whether each or pair adequately describes versa swing with waist link articulating system that is the subject of this request. Articulating forearm crutches are included in the array of products in code

functional categories E0110 and E0111. In addition, these codes are all inclusive of bases /feet of the crutches as well as the arms grips. The applicant confirms in the application that versa swings are "designed to function similarly to forearm cuff crutches."

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker believes the current codes do not describe features and functions of Versa Swing. The Versa Swing exceeds current standard crutches coded for E0110 and E0111.

FINAL DECISION

Existing code E0110 "Crutches, forearm, includes crutches of various materials, adjustable or fixed, pair, complete with tips and handgrips" or E0111 "Crutch forearm, includes crutches of various materials, adjustable or fixed, each, with tip and handgrips" depending on whether each or pair adequately describes versa swing with waist link articulating system that is the subject of this request. Articulating forearm crutches are included in the array of products in code functional categories E0110 and E0111. In addition, these codes are all inclusive of bases /feet of the crutches as well as the arms grips. The applicant confirms in the application that versa swings are "designed to function similarly to forearm cuff crutches." There is insufficient evidence to substantiate the applicant's claim of reduction in falls attributed to use of the proprietary swing link system.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 9

Application # 19.117

TOPIC

Request to establish a new Level II HCPCS code identify the Alpha-Stim Cranial Electrotherapy Stimulation (CES) system, Trade Name: Alpha-Stim AID.

Applicant's suggested language: EXXXX "Cranial Electrotherapy Stimulation (CES) starter kit (includes CES device, ear clip electrodes, electrode pads, conductive solution)."

BACKGROUND

Electromedical Products International, Inc. submitted a request to establish a new Level II HCPCS code to identify the Alpha-Stim AID.

According to the applicant, the Alpha-Stim AID device utilizes a microcurrent to deliver proprietary low-level electrical signals, applied transcranially for treatment of anxiety, insomnia and depression. The device consist of an electric pulse generator operated with two 1.5 volt AAA batteries, and patient connect hardware which consist of ear clip electrodes and an electro conductive solution for moistening the electrodes to assure good electrical contract through the skin. The microcurrent is applied by easy to use clips that attach to the ear lobes. Typical physician prescription is for daily 20-60 minute sessions or on as-needed basis. Alpha-Stim may be used as an adjunct or replacement to medication and/or physiotherapy. According to applicant, unlike drugs, Alpha-Stim leaves the mind alert and after treatment, normal activities may be resumed immediately. After the condition is under control, use of the Alpha-Stim 2-3 times a week is usually sufficient to maintain good results.

According to applicant, currently the Alpha-Stim is being billed under E1399, which requires payers to process claims manually, and does not allow payers to identify utilization of Alpha-Stim.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new code EXXXX "Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type."

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Based on guidance contained in Chapter 1, Part 1, Section 30.4 of the Medicare National Coverage Determinations manual, we believe there would be no Medicare payment for this device.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION

Establish new Level II HCPCS code K1002 "Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type." Effective 1/1/2020

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 10

Application # 19.121

TOPIC

Request to establish two new Level II HCPCS codes to identify components of an integrated real-time system continuous glucose monitoring system, Trade Name: Dexcom G6 continuous glucose monitoring system.

Applicant's suggested language: EXXXX "Receiver (monitor) dedicated, for use with continuous glucose monitor."

EXXXX "supply allowance for integrated continuous glucose monitor (CGM), includes all supplies and accessories, 1 unit of service=1 month's supply."

BACKGROUND

Dexcom, Inc. submitted a request to establish two new Level II HCPCS codes to identify components of the Dexcom G6 continuous glucose monitoring system.

According to applicant, the integrated CGM system enables people with diabetes to monitor, track and make treatment decisions in real-time based on their glucose level. The Dexcom G6 communicates with digitally connected devices such as a CGM-enabled insulin pump. The Dexcom G6 system consists of transmitter, receiver, and smartphone application. The CGM transmitter sends encrypted data received from the sensor to the patient's receiver for the patient to adjust their insulin dose or to a connected insulin pump, which will autonomously adjust the patient's insulin dose or alert patient for further action. The smartphone allows the patient to share glucose data with caregiver and physician wirelessly. The patient inserts the CGM sensor under the skin; the sensor generates a biometric signal, which it passes to the CGM transmitter, smartphone, and or a medical device. The transmitter measures and converts the biometric signal into glucose data, encrypted on send and decrypted upon receipt and readable by the patient. The device may be worn under a patient's clothing.

According to applicant, the Dexcom G6 is indicated for the management of diabetes in persons age 2 years and older. It is also intended to replace finger stick blood glucose testing for diabetes treatment decisions and to autonomously communicate with digitally connected devices, including automated insulin dosing (AIDS) systems. The Dexcom G6, has received a differentiated FDA classification as an integrated CGM system.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new code EXXXX "External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing"

Establish new code AXXXX "Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week"

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

For EXXXX, we believe that the item would be paid in accordance with the payment rules that apply to capped rental items if covered. For AXXXX, we believe that the item would be paid in accordance with the payment rules that apply to accessories necessary for the effective use of DME if covered.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated Dexcom G6 continuous glucose monitoring system is recognized as distinct by global diabetes professional community in peer-reviewed journals, and having significant distinctions in both their clinical utility and applicability. iCGM automatically monitors glucose levels every five minutes, while isCGM monitors glucose levels only when scanned by the patient. As a result, iCGM may proactively alerts patients with alarms to dangerously low and high blood sugar levels even while asleep or otherwise unaware, while a CGM is not able to do so.

FINAL DECISION

Existing codes K0553, "Supply allowance for therapeutic continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service", and K0554, "Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system" adequately describe the subject of this application. Effective 01/01/2020

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 10

Application # 19.143

TOPIC

Request to modify an existing Level II HCPCS code A9277 which currently reads, "Transmitter, external, for use with interstitial continuous glucose monitoring system" to instead read, "Transmitter; external, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply."

BACKGROUND

Dexcom requested a modification to existing Level II HCPCS code A9277 to specify a billing unit: 1 unit= 1 day supply, as a means to report multiple durations of use. According to the requester, the Continuous Glucose Monitoring (CGM) system consist of a Sensor, Transmitter, Receiver, and Smartphone Application. The CGM sensor, inserted under the skin, generates a biometric signal, and passes it to CGM Transmitter. The Transmitter measures and converts the biometric signal into encrypted, not human-readable, glucose data, and enables people with diabetes, in real-time, to monitor, track and make treatment decisions based on their glucose level. The CGM Receiver decrypts the glucose data and makes it human-readable. The CGM Receiver contains the hardware and software to provide alerts to the people with diabetes, when attention is needed due to glucose level. The Transmitter is worn outside the body and is physically connected to the Sensor. The Dexcom G6 Continuous Glucose Monitoring (CGM) system and the Dexcom G5Mobile CGM systems are indicated for the management of diabetes in people age 2 years and older. These CGM systems are designed to replace finger stick blood glucose testing for diabetes treatment decisions. The Dexcom G6 is also intended to autonomously communicate with digitally connected devices, including automated Insulin dosing (AID) systems. The Dexcom G4 Platinum CGM system is indicated for detecting trends and tracking patterns in people age 18 years and older. The Dexcom G4 Platinum (Pediatric) CGM system is used in people ages 2 to 17 years. Since code A9277 was established in 2008, the CGM system had changed, especially with regard to the size and duration of transmitters. As Transmitters became smaller in size, the battery lives have shortened. Existing Transmitters have battery life of 90, 180, and 365 days, depending on the manufacturer and model. As all of these products are reported using A9277, the result has been widely differing costs and supply frequencies between models and manufacturers. Confusion over these differences has resulted in denials of supply orders. Using a billing unit of one day could align the billing units for the Transmitters with the billing units for the Sensors. The Sensors are described by HCPCS code A9276 which indicates "one unit= 1 day supply".

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise the descriptor of existing code A9277 has not been approved. The requested change to add a billing unit does not improve the code.

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. While Medicare has adopted code K0554 and K0553 for therapeutic CGM, many commercial plans and the majority of state Medicaid plans still use "A" codes. Our proposed solution would add a simple unit of service to the CGM transmitter code. Accordingly , 90 day transmitters would be billed 4 times annually with 90 units, 180 day transmitters twice annually with 180 units which will standardize billing practices and transmitter prices.

FINAL DECISION

This request to revise the descriptor of existing code A9277 has not been approved. The requested change to add a billing unit does not improve the code. For billing guidance, contact the insurer in whose jurisdiction the claim would be filed.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 11

Application # 19.126

TOPIC

Request to establish a new Level II HCPCS code to identify an insulin Pen Injector with Dose Calculator, Trade Name: InPen.

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

BACKGROUND

Companion Medical submitted a request to establish a new Level II HCPCS code to identify the InPen.

According to the applicant, the InPen is a home-use reusable pen injector for single patient use for insulin. The InPen injector allows the user to dial the desired dose from 0.5 to 30 units in one –half-unit increments. The InPen system is provided in two different model configurations to fit Novolog and Humalog 3 ml U-100 insulin cartridges. The products are identical in function with minor technical differences to account for the cartridge dimensions. The pen injector is compatible with existing Lilly Humalog U-100/Novo Nordisk Novolog 3.0 ml cartridges of insulin and single use detachable and disposable needles. The InPen dose calculator, a component of the InPen app assists with diabetes management. A healthcare provider must provide the patient-specific-target blood glucose, insulin-to-carbohydrate ratio and insulin sensitivity parameters to be programed into the software.

According to the applicant, the InPen system is the only pen injector with connectivity to an app with a dose calculator and diabetes management tools. The InPen system transmits Insulin dose information wirelessly and automatically to a smartphone to ensure a record of reliable, accurate dosing information. The app has dose reminders, a logbook, and a dose calculator to calculate insulin doses while counting active insulin to prevent stacking. The applicant comments that no existing HCPCS code describes a connected insulin pen with integrated diabetes management tools.

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.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated InPen is not a new product; rather it is a new class of product. The convergence of consumer technologies as adjuncts and enablers of medical technologies is here now, not in the future. Existing rules and categories are not wrong; they do not describe the technology that has been described today. This is the first smart pen, but many more connected devices will follow that will not be described by legacy code categories.

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.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 12

Application # 19.127

TOPIC

Request to establish a new Level II HCPCS code to identify a molded thermoplastic barrier for use by persons who self-propel a manual wheelchair to prevent hand contact with the wheels, Trade Name: The Shield.

BACKGROUND

The Shield LLC. Submitted a request to establish a new Level II HCPCS code to identify the Shield.

According to the applicant, the shield is a barrier that covers the contaminated wheels of a wheelchair. It is made of molded thermoplastic polyurethane. The shield prevents the wheelchair users' hands from contacting the wheels and becoming contaminated, thus preventing the cross contamination of the wheelchair user and their environment.

According to the applicant, the shield is indicated for individuals who self-propel their wheelchair. There is currently no other similar product on the market and no existing HCPCS code that identifies this newly patented product.

PRELIMINARY HCPCS CODING RECOMMENDATION

The Shield wheelchair barrier is not primarily medical in nature, and therefore not suitable for inclusion in the 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

We received no comments at CMS' HCPCS Public Meeting regarding this application.

FINAL DECISION

CMS did not identify policy or claims processing need on the part of any insurance sector to establish a code to identify the shield.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 13

Application # 19.128

TOPIC

Request to establish a new Level II HCPCS code to identify tandem t:slim X2 insulin pump.

Applicant's suggested language: EXXXX "External ambulatory insulin infusion pump and therapeutic CGM receiver.

BACKGROUND

Request submitted on behalf of Tandem Diabetes, Inc. to establish a new Level II HCPCS code to identify Tandem t:slim X2 insulin pump.

According to the applicant, the t:slim X2 system is made up of insulin pump and the t-slim 3ml (300 units) cartridge. The t:slim X2 insulin pump delivers insulin in two ways: continuous or basal insulin delivery, and bolus insulin delivery to cover carbohydrates eaten (food bolus) and to lower high blood glucose (correction bolus). The disposable cartridge is filled with Novolog or Humalog insulin and attached to the pump.

According to the applicant, the t-slim X2 insulin pump is indicated for management of diabetes mellitus requiring insulin, for individuals 6 years of age and older. The t:slim X2 pump is intended for subcutaneous delivery of insulin, at set and variable rates. The minimed 630G system is similar in function to this product and can interface with a Medtronic guardian link CGM in order to enable limited algorithmic control of insulin dosing. According to the applicant, existing codes do not differentiate therapeutic CGM devices.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new code EXXXX "External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing"

Establish new code AXXXX "Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week"

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

For EXXXX, we believe that the item would be paid in accordance with the payment rules that apply to capped rental items if covered. For AXXXX, we believe that the item would be paid in accordance with the payment rules that apply to accessories necessary for the effective use of DME if covered.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker supported CMS' recommendation to establish a new "E" code and suggested a modification. The suggestion is "change therapeutic continuous glucose sensing" to "continuous glucose monitoring" in order to ensure consistency in terminology with CMS ruling 1682-R and subsequent coverage determinations for CGM. Since supplies are covered under A4225 for cartridges and A4224 for infusion sets as long as the insulin pump is covered either under existing code E0784 there is no need for a third "A" code.

FINAL DECISION

Establish a new Level II HCPCS code E0787 "External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing",

Establish a new Level II HCPCS code A4226 "Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week".

Effective 1/1/2020.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 14

Application # 19.129

TOPIC

Request to establish a new Level II HCPCS code to identify a rechargeable electric wearable breast pump that fits in a bra, Trade Name: Willow Wearable Breast Pump.

Applicant's suggested language: E060X "Breast pump, battery-powered, wearable entirely inside bra."

BACKGROUND

Request submitted on behalf of Willow to establish a new code to identify the Willow wearable breast pump.

According to the applicant, the Willow wearable breast pump is a battery-powered, rechargeable electromechanical device. The device operates with other components: flange, flextube, milk bag and a charger. It is a hands-free, mobile device and the entire pump and milk collection system is contained in one form and worn inside the bra.

According to the applicant, the product is an all in one breast pump worn entirely inside the bra and is indicated for use by lactating women to express milk. The device has stimulation and expression phases. It is for multiple use by a single user and designed for one breast. An app displays quantitative data including the milk volume, pumping time, and past pumping sessions. The user aligns her nipple in the breast flange and secures her bra around the wearable breast pump before starting the pumping session. When the pumping session ends, the user removes the pump from the bra, separates the flange from the pump housing and removes the milk bag. There is no existing code that identifies a wearable breast pump entirely in the bra.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code category E0603 "Breast pump, electric (ac and/or dc), any type" adequately describes the Willow Breast Pump and is available for assignment by insurers if they deem appropriate.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner

consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicare, contact the Medicare contractor. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code E0603 apply to this product. Pricing=00.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated the Willow wearable breast pumps located entirely within a bra are technically and clinically different from existing pumps classified under HCPCS code E0603. The technological differences of breast pump and milk collection container wearable entirely within the bra confers substantial clinical and wellness benefits.

FINAL DECISION

Existing code category E0603 "Breast pump, electric (ac and/or dc), any type" adequately describes the Willow Breast Pump and is available for assignment by insurers if they deem appropriate.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 14

Application # 19.136

TOPIC

Request to establish a new Level II HCPCS code to identify disposable milk bags for use with the Willow Wearable Breast Pump.

Applicant's suggested language: AXXXX "Milk collection and storage bag, single-use (per box of 24)."

BACKGROUND

Request submitted on behalf of Willow to establish a new Level II HCPCS code to identify disposable milk bags for use with the Willow wearable breast pump. According to the applicant, the Willow wearable breast pump milk bag is a single-use 4-ounce milk collection and storage bag for use with the Willow wearable breast pump. The milk bag is housed within the breast pump housing and flange during pumping and has a one-way valve that ensures the milk goes into the bag and remains spill proof. The milk bag can be used to store the milk in the refrigerator or freezer. Willow wearable breast pump milk bag is a unique product; there is no other milk collection storage bag with one-way valve that fits entirely inside of the Willow wearable breast pump.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish AXXXX “Disposable collection and storage bag for breast milk, any size, any type, each".

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 agreed with CMS preliminary recommendation.

FINAL DECISION

Establish new Level II HCPCS code K1005 "Disposable collection and storage bag for breast milk, any size, any type, each". Effective 01/01/2020

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 15

Application # 19.130

TOPIC

Request to establish a new Level II HCPCS code to identify a hand-held foam roller manual "traction" or massage device, Trade Name: Tiger Tail.

Applicant's suggested language: EXXXX "Tiger Tail."

BACKGROUND

Polar Fusion LLC dba Tiger Tail USA, submitted a request to establish a new Level II HCPCS code to identify the Tiger Tail hand-held foam roller device for use to apply or self-apply manual "traction" or massage.

According to the applicant, the tiger tail a cushioned but firm massage surface that "grips" with a diameter and circumference for the user to apply an ideal pressure and compression on the skin, fascia and muscle. The Tiger tail traction device features handgrips with flanges to prevent the user to from pinching their skin by getting too close to the center rolling massage surface. The device also contains an interior bearing system that rolls smoothly but not in a free spinning manner. The applied manual traction achieved with the patented design of this device leads to the stimulation and adjustment of the fascia layers, movement of hyaluronic acid, lymph and other fluids between the skin, fascia and muscle, stimulation of muscle and trigger points, and the dissipation of adhesions between the skin, fascia and muscles. The user applies the tiger tail hand-held foam traction device to the belly of the muscle with about 10 pounds of pressure and massages each muscle group for five to ten passes at 10-20 seconds with firm constant strokes per treatment section. The applicant claims there is no current Level II HCPCS code that defines a manual device such as the Tiger tail.

PRELIMINARY HCPCS CODING RECOMMENDATION

The Tiger Tail device is not primarily medical in nature, and as such, 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 recommendation. The speaker stated Tiger Tail fits the definition of a medical device under the Medicare Benefit Policy manual chapter 14 – medical devices section 10 and under The Food and Drug Administration definition of a medical device. There are no current adequate HCPCS codes that the tiger tail device aligns with. Tiger Tail USA is asking that CMS reconsider its original recommendation to grant The Tiger Tail a HCPCS code EXXXX as the product is medical in nature and falls under the FDA definition that CMS recognizes in its medical benefit policy.

FINAL DECISION

CMS did not identify policy and claims processing need to establish unique code to identify the Tiger Tail.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 16

Application # 19.131

TOPIC

Request to establish a new Level II HCPCS code to identify walk-in Portable Hydrotherapy tubs, Trade Name: Portable Hydrotherapy Units.

BACKGROUND

Portable Hydrotherapy Units LLC, submitted a request to establish a new Level II HCPCS code to identify portable walk-in hydrotherapy units.

According to the applicant, hydrotherapy is a natural therapy of heat, water and air that invigorates and massages the body while easing away aches, pains and relaxes sore muscles that can stimulate the release of endorphins. When you soak in a hot water hydrotherapy unit the body temperature begins to rise, causing the blood vessels to dilate, resulting in increased circulation and blood flow.

According to the applicant, the buoyancy of the water reduces body weight by up to 85%. This relieves pressure on the joints and muscles and gives them time to loosen and relax. Hydrotherapy may be used for pain management, improve immunity, respiratory diseases, arthritis, fibromyalgia syndrome, cardiovascular, anorectal disorders, fatigue, endocrine, gastrointestinal, musculoskeletal, urinary and heart diseases. The significant therapeutic distinction of the Hydrotherapy unit is its portability and size that it is made of antibiotic infused acrylic, and provides easy access. There is no existing code to identify a portable hydrotherapy unit.

PRELIMINARY HCPCS CODING RECOMMENDATION

Portable hydrotherapy tubs are not primarily medical in nature and as such, are 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 recommendation. The speaker stated the use of water for soothing pain and treating disease is one of the oldest and safest methods know for treating various medical ailments. Therefore, the advantage of consistent hydrotherapy treatment is documented medically for many body systems and scientific evidence supports the use of Hydrotherapy on various systems of the body.

FINAL DECISION

Establish a new Level II HCPCS code K1003 "Whirlpool tub, walk-in, portable". Effective 01/01/2020

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 17

Application # 19.133, 19.134 & 19.135

TOPIC

Series of three separate applications to establish three new Level II HCPCS codes to identify Surgilube, based on packaging and amount provided per package.

Applicant's suggested language:

1. "Sterile Surgical Lubricant, Per Ounce," to identify sterile surgical Lubricant provided in tubes;

2. "Sterile Surgical Lubricant, per packet," to describe 3g and 5g foilpacs; and

3. "Sterile Surgical Lubricant PER ounce specialty packaging," to describe 31 gm foilpacs and 5 gm metal tubes.

BACKGROUND

HR Pharmaceuticals, Inc. submitted requests to establish a series of three new HCPCS codes to identify Surgilube products, based on package type and amount per package. According to the applicant, the result of a 2018 CODE Verification Review conducted by CMS' Contractor, Noridian, was "temporary" assignment of existing HCPCS codes A4402 "Lubricant, per ounce"; A4332 "Lubricant, individual sterile packet, each"; and A4559 "Coupling gel or paste, for use with ultrasound device, per ounce". The applicant comments that these codes assignments are incorrect. Surgilube is a sterile surgical lubricant, water soluble, BPOC compliant, latex free and carbomer free for lubricating body orifices. The product is clinically beneficial during gynecological procedures, catheter insertion, colonoscopy, enema insertion, endotracheal tube insertion and ultrasound procedures. According to the applicant, Surgilube is the only sterile carbomer free surgical lubricant approved for use with Hologic Thin Prep PAP test and the only carbomer free sterile lubricant on the market. The applicant comments that carbomer "causes Pap test failure". The applicant also comments that "Surgilube is the only sterile lubricant on the market that contains chlorhexidine, a recognized bacteriostatic for added antimicrobial protection." According to the applicant, existing lubricant codes describe medical grade lubricants that contain carbomer, whereas "Surgilube is not a medical lubricant. It is a carbomer-free sterile surgical lubricant. The only one on the market." And the lubricants included in existing code categories (as above), are not comparable to Surgilube" and as such, Surgilube "needs its own codes and reimbursements".

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing codes A4402 "Lubricant, per ounce"; A4332 "Lubricant, individual sterile packet, each"; and A4559 "Coupling gel or paste, for use with ultrasound device, per ounce", adequately describe the lubricants that are the subject of these requests and are available for assignment by insurers if they deem appropriate to describe Surgilube depending on the product characteristics and the amount supplied. The applicant's claim of a therapeutic distinction between pap test results using carbomer vs: non-carbomer lubricant is not substantiated in the information provided by the applicant. And pricing is not a coding criteria.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment when used with physician or institutional procedures. For ostomy, tracheostomy and urological supply use, the payment rules associated with the existing codes apply to this product if covered. For A4402, Pricing = 37. For A4332, Pricing = 37. For A4559, Pricing = 34

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation. The speaker commented that Surgilube's unique formulation claimed is the only sterile carbomer-free lubricant manufactured in the USA; that carbomer-based lubricants adversely impact specimen adequacy and elevate unsatisfactory for evaluation UNSAT rates for Thin Prep Pap testing and as such, separate codes are warranted to distinguish between carbomer-free and carbomer-based lubricants. In addition, the applicant proposed pricing rates designed to decrease "reimbursement

inequities brought on by distributors aggressively marketing their low quality, carbomer-based private label lubricant."

FINAL DECISION

Existing codes A4402 "Lubricant, per ounce"; A4332 "Lubricant, individual sterile packet, each"; and A4559 "Coupling gel or paste, for use with ultrasound device, per ounce", adequately describe the lubricants that are the subject of these requests and are available for assignment by insurers if they deem appropriate to describe Surgilube depending on the product characteristics and the amount supplied. The applicant's claim of a therapeutic distinction between pap test results using carbomer vs: non-carbomer lubricant is not substantiated in the information provided by the applicant. And pricing is not a coding criteria.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 18

Application # 19.137

TOPIC

Request to make newly established code A4563 (effective 1/1/2019), which identifies a rectal control system for vaginal insertion, an "L" code (using the identical language), for the purpose "allowing providers to bill a separately payable L-code for the Eclipse System along with the E/M code that must be used for the second clinician visit."

BACKGROUND

Pelvalon, Inc. submitted a request to make newly established code A4563 (effective 1/1/2019), which identifies a rectal control system for vaginal insertion, an "L" code (using the identical language), for the purpose "allowing providers to bill a separately payable L-code for the Eclipse System along with the E/M code that must be used for the second clinician visit." According to the applicant, the Eclipse system is a prosthetic rectal control system indicated to treat adult women with fecal incontinence. The device is composed of a non-surgical prosthetic placed in the vagina (Eclipse Prosthetic or Insect) and a pressure –regulated pump to inflate and deflate the prosthetic (pump). The eclipse prosthetic is made of stainless-steel spring and support system (base), inflatable balloon, a tube, and a valve. The base positions the balloon and helps maintain the placement of the prosthetic in the vagina. The exterior (patient contact) is silicone. The positioning of the dual-layer balloon relative to the base, the direction of expansion, and the maintenance of air pressure are designed to work in concert with the natural function of the anorectal anatomy. The eclipse prosthetic when inserted controls the rectal space by deflecting the rectovaginal septum.

PRELIMINARY HCPCS CODING RECOMMENDATION

HCPCS code alpha characters do not confer benefit category or reimbursement status on the part of any insurer, and alpha character designations for HCPCS codes are determined by CMS separate and apart from our external code application procedures. However; CMS reviewed the concerns expressed by this applicant, and it is our understanding that the OPPS status indicator for code A4563 has been revised, enabling separate Medicare payment when appropriate. We believe this action resolves the applicants stated concerns.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code A4563 apply to this product if covered. Pricing=38.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation, and requested that CMS instead establish an L –code with an identical descriptor. CMS' decision to establish separate payment for the current HCPCS codes under the Outpatient Prospective Payment System was appreciated, but the policy should go hand in hand with the appropriate payment rate and a HCPCS L code, which would identify the Eclipse System to payers as a complex prosthetic that is separately reimbursed in a physician office or hospital outpatient setting. If CMS retains the A code, it will be a significant barrier for physicians who want to provide this breakthrough treatment to patients.

FINAL DECISION

HCPCS code alpha characters are not dispositive of benefit category or reimbursement status of the product, on the part of any insurer; are not an indicator of relative complexity of the product. Alpha character designations for HCPCS codes are determined by CMS separate and apart from our external code application procedures. However, CMS reviewed the concerns expressed by this applicant, and it is our understanding that the OPPS status indicator for code A4563 has been revised, enabling separate Medicare payment when appropriate. We believe this action resolves the applicants stated concerns.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 19

Application # 19.138

TOPIC

Request to establish a new Level II HCPCS code to identify the "Lumbrella" Lumbar Sacral Orthosis (LSO).

BACKGROUND

Orthotic Solution submitted a request to establish a new Level II HCPCS code to identify the Lumbrella LSO. According to the applicant, the Lumbrella is a pre-fabricated, custom fit; back brace that utilizes innovative design features and micro-adjustable Boa components to deliver support. The Lumbrellas combination of the inner belt, rigid lumber panel and the abdominal panel, act as a true 3 point force system which maintains a neutral lumber alignment. Securing the outer belt produces abdominal compression and tightening the inner belt produces intracavity compression, resulting in axial unloading. According to the applicant, the Lumbrella assists with healing, decreases further injury, controls pain, supports weak muscles and promotes good posture. Use of the Lumbrella clinically benefits individuals with acute or chronic back, pre and post discectomy, fusion and laminectomy, muscle weakness, trauma, osteoporosis, bulging or herniated discs, spinal stenosis, degenerative disc disease and deconditioned or postural back pain. The applicant claims the Lumbrella is the only prefabricated Lumber-Sacral Orthosis in the world that utilizes all 5-motion control principals of motion control. According to applicant, no existing L code accounts for the benefit of the inner belt.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing Level II HCPCS code category L0650 "Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panel(s), posterior extends from sacrococcygeal junction to t-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf " adequately describes the Lumbrella LSO and its functionality.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact

the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with existing code L0650 apply to this product if covered. Pricing=38.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated that existing HCPCS codes do not describe all functional components of Lumbrella. In particular, Lumbrella employs an "inner belt" that offers unique therapeutic benefits due to its static lordodic positioning- 3 point force system and additional level of intracavitary pressure; that there are also distinctions in patent and cost. And suggested that the Lumbrella is more comparable to a custom device and reiterated for a unique code.

FINAL DECISION

Existing Level II HCPCS code category L0650 "Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panel(s), posterior extends from sacrococcygeal junction to t-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf ", addresses intracavitary pressure and adequately describes the Lumbrella LSO and its functionality.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 20

Application # 19.141

TOPIC

Request to 1) revise existing Level II HCPCS code L8032 which currently reads "Nipple prosthesis, reusable, any type, each" to instead read "Areola/Nipple prosthesis, retail/Mass produced, 3 month reusable, each"; and 2) establish a new Level II HCPCS code to identify a nipple prosthesis service.

Applicant's suggested language: L80XX "Areola/Nipple Prosthesis, service/individually produced, 2 year reusable, each."

BACKGROUND

Custom DME, LLC submitted a request to make a distinction, via HCPCS coding, between “retail/mass produced” and “individually produced” nipple prostheses. Specifically this request is to: 1) revise existing Level II HCPCS code L8032 to specify, “retail/mass produced” nipple prostheses and to establish a new Level II HCPCS code to identify the service component of producing “individualized” prostheses. According to the applicant, the individualized prostheses are made with durable biocompatible silicones and colored to match the skin of each patient. It is a prostheses for areola/nipple as part of breast reconstructive surgery. The process includes making rubber impression and photographs of the nipple-Areolar complex prior to a mastectomy. This product is made individually, has better value for patients and insurers, and appear as individual's real areola/nipple. According to the applicant, differentiating a mass-produced retail product from a service-provided individualized product will help CMS and private insurers to know the value of the product and know the frequency of payment. According to applicant, the existing code does not work for service providers, because reimbursement for code L8032 is too low. The applicant also commented that, “conversely, if CMS were to adjust the fee schedule instead of creating a new code, retailers would abuse the code."

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new code LXXXX "nipple prosthesis, custom fabricated, reusable, any material, any type, each."

Revise existing code L8032, which currently reads: "nipple prosthesis, reusable, any type, each", to instead read: "nipple prosthesis, prefabricated, reusable, any type, each".

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

CMS received written comments in reaction to our preliminary recommendation seeking separate coding, apparently, for custom fabrication service.

FINAL DECISION

1) Establish a new Level II HCPCS code L8033 "nipple prosthesis, custom fabricated, reusable, any material, any type, each."

2) Revise existing code L8032, which currently reads: "nipple prosthesis, reusable, any type, each", to instead read: "nipple prosthesis, prefabricated, reusable, any type, each".

The service component is included in the custom code, as with any custom prosthesis.

Effective 1/1/2020

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 21

Application # 19.142

TOPIC

Request to establish a new Level II HCPCS code to identify a remote dosage controller for use by patients in conjunction with a surgically implanted carbon dioxide (CO2) gas-controlled tissue expander. Trade name: AirXpanders AeroForm Dosage Controller.

Applicant's suggested language: LXXXX Remote dosage controller, (external) for use with implantable tissue expander in breast reconstruction following mastectomy.

BACKGROUND

Healthcare Reimbursement Consultation submitted an application on behalf of AirXpanders Inc, to establish a Level II HCPCS code to identify a remote dosage controller (AeroForm Dosage Controller) for use by patients to control a surgically implanted carbon dioxide (CO2) gas-controlled (AeroForm tissue expander.) According to the requester, the AeroForm Tissue Expander System consists of the AeroForm Dosage Controller, AeroForm Tissue Expander, and a Master Key. It is a prescription device intended for temporary subcutaneous or sub-muscular implantation to stretch the skin for breast reconstruction. During post-mastectomy breast reconstruction surgery, the key is inserted into the dosage controller, pairing it to a specific tissue expander. Once paired, the dosage expander cannot be used with any other tissue expander. The AeroForm Dosage Controller is a hand-held battery-operated device that administers programmed doses of CO2 gas from an internal reservoir in the tissue expander resulting in gradual, needle-free enlargement. The AeroForm Dosage Controller is used in conjunction with the AeroForm Tissue Expander to provide needle-free soft tissue expansion in breast reconstruction following mastectomy, for the treatment of underdeveloped breasts, and soft tissue deformities in the breast. The AeroForm Dosage Controller controls the AeroForm Tissue Expander. The AeroForm Tissue Expander System is clinically indicated for women who have had a mastectomy and have chosen 2-stage breast reconstruction. AeroForm gives patients the option to decide when and where to dose, with no needles and less discomfort due to a gradual, low-volume, CO2 gas expansion. Currently, there is no specific HCPCS code for a hand-held battery-operated device used by the patient at home to control an implanted tissue expander. Existing miscellaneous surgical supply code A4649 does not accurately describe the AeroForm Dosage Controller and does not enable claims data tracking.

PRELIMINARY HCPCS CODING RECOMMENDATION

The tissue expander is inserted during a post mastectomy reconstructive surgery in the hospital inpatient setting. The external remote controller for use by the patient with the implanted tissue

expander is provided on an initial issue prior to patient discharge from the hospital and as such, is included in the hospital payment and not suitable for coding in HCPCS Level II. Separate reporting of this external component could be considered redundant.

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. The speaker stated the AeroForm Tissue Expander system provides unique and desirable advantages to a patient and surgeon relative to saline expanders. Access to the device is desired by patients as a two part component system, where the dosage controller is provided to the patient several weeks after surgery, the existing DRG' s do not provide appropriate coverage for this type of system. Expansion of patient access can be achieved with a separate HCPCS code for dosage controller, reflecting its unique position as patient controlled device.

FINAL DECISION

The tissue expander is inserted during a post mastectomy reconstructive surgery in the hospital inpatient setting. The external remote controller for use by the patient with the implanted tissue expander is opened, paired and tested with the specific AirXpander in the operating room during the surgical procedure and as such, is included in the hospital payment and not suitable for coding in HCPCS Level II. Separate reporting of this external component could be considered redundant.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 22

Application # 19.147

TOPIC

Request to establish a new Level II HCPCS code to identify a service/fee for dispensing prescription medications (excluding inhalation drugs and compounding of medications).

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

BACKGROUND

Mitchell resubmitted a request to establish a new Level II HCPCS code for use to separately report a prescription drug(s) dispensing service/fee. According to the applicant, a prescription drug(s) dispensing service/fee is a service/fee reported by pharmacist(s) or other medical provider(s) for dispensing of prescription medications (excluding inhalation drugs and compounding of medication). Aside from the stated exclusions, this service does not relate to any specific product. Because an appropriate code is not available, when the drug is billed, the dispensing fee is being added into the charge from the provider, which inflates the "cost" of the drug or reported with inappropriate codes.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new code to separately 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 or "inflated" drug cost, due to provider-added charges, as reported by the applicant. For coding and billing guidance and information regarding allowable fees, 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 recommendation. The speaker commented that without a separate code to report a dispensing fee, manual calculations will need to be done by the payers to provide correct reimbursement, this result in delay of payment. Providers will receive payment with no way to reconcile what is the drug cost versus dispensing fee. Drugs are charged at a higher amount, resulting in an inflated drug charge.

FINAL DECISION

This request to establish a new code to separately identify a dispensing fee for prescription drugs (excluding inhalation drugs and compounding of medicine), has not been approved. CMS did not identify claims processing need on the part of any insurer. 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. CMS carefully considered this matter and determined that insurers, including Medicaid state agencies, are paying dispensing fees without difficulty, and the addition of a code could create duplicate billing opportunities or "inflated" drug cost, due to provider-added charges, as reported by the applicant. For coding and billing guidance and information regarding allowable fees, contact the insurer in whose jurisdiction a claim would be filed.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 23

Application # 19.145

TOPIC

Repeat request to remove wound dressings from existing all-inclusive code E0446 "Topical Oxygen delivery system, not otherwise specified, includes all supplies and accessories". This request to establish a series of four new Level II HCPCS codes to separately identify composite dressings for use with topical oxygen delivery system for continuous diffusion of oxygen. Trade names: OxySpur and OxySpur Lite Oxygen Diffusion Dressings.

Applicant's suggested language:

Xxxx1 High exudate composite dressing, sterile, pad size 16 sq. in. or less, with integrated oxygen diffusion cannula, with or without adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen system

Xxxx2 High exudate composite dressing, sterile, pad size more than 16 sq. in. but less than 48 sq. in., with integrated oxygen diffusion cannula, with or without adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen system

Xxxx3 Low exudate composite dressing, sterile, pad size 16 sq. in. or less, with integrated oxygen diffusion cannula, with or without adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen system

Xxxx4 Low exudate composite dressing, sterile, pad size more than 16 sq. in. but less than 48 sq. in., with integrated oxygen diffusion cannula, with or without adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen system

BACKGROUND

EO2 Concepts submitted a request to establish a series of four new Level II HCPCS codes to identify OxySpur and OxySpur Lite Oxygen Diffusion Dressings, and to differentiate the dressings based on size and absorbency. According to the applicant, the Oxygen Diffusion Dressings are used with a topical oxygen delivery system for continuous diffusion of oxygen. OxySpur dressings are comprised of a sterile composite pad with integrated oxygen diffusion cannula that evenly distributes the oxygen to the wound bed via an extension set from the oxygen generator to the dressing. OxySpur dressings manage wound exudate levels, protect against wound dehydration and external contamination, and provide offloading of the multiported cannula to prevent tissue breakdown. OxySpur dressings are used to provide continuous diffusion of oxygen for the treatment of oxygen compromised or marginally ischemic wounds

such as diabetic, venous and pressure ulcers, as well as skin grafts, burns, frostbite and infected residual limbs. OxySpur dressings are placed over the wound, secured and connected to the TransCu O2 topical oxygen delivery system for continuous diffusion of oxygen. OxySpur dressings are available in multiple configurations- medium to high absorbency (OxySpur) and low absorbency (OxySpur Lite). There are variety of sizes of dressings available depending on the size, location and configuration of the wound, with or without the hydrocolloid adhesive border. The applicant comments that the dressings should be coded separate from the oxygen generator, because the dressings and the generator are not sold as a comprehensive system. Also, existing composite dressing HCPCS codes A6203-A6205 and specialty Absorptive Dressing HCPCS codes A6251-A6256 do not describe wound dressings with an integrated oxygen cannula and offloading distribution channels.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code E0446 "Topical Oxygen delivery system, not otherwise specified, includes all supplies and accessories", and is intended to be all inclusive. As such, separate reporting of dressings might be considered redundant.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation, stating that the existing code E0446, established January 1, 2011, was intended to describe an earlier version of the E02 technology. The E02 technology has changed substantially in past eight years; this code does not accurately describe the current technology. When E0446 was created, the technology used a cannula with a single outlet requiring the use of other commonly available dressing. This is no longer the standard of care. The current continuous diffusion of oxygen (CDO) generator requires the correct OxySpur Dressing based on diagnosis, wound size and various exudate levels throughout the wound healing process. The applicant reiterated request for new code that is "carrier priced".

FINAL DECISION

Existing code E0446 "Topical Oxygen delivery system, not otherwise specified, includes all supplies and accessories", and is intended to be all-inclusive. As such, separate reporting of dressings might be considered redundant.

The HCPCS Level II codes describe categories of like items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code E0446 describes this product, as a rule, CMS does not classify individual items into code categories on behalf of insurers. Individual insurers have the necessary flexibility to classify specific products into HCPCS Level II code categories and establish their own coding instructions in accordance with their policies and program operating needs.

June 11, 2019

CMS HCPCS Public Meeting

Agenda Item # 23

Application # 19.146

TOPIC

Repeat request to establish another Level II HCPCS code to identify a wearable continuous diffusion of oxygen therapy device, Trade Name: TransCu O2 Oxygen Generator; and to specify within the code that the payment methodology is “rental”.

Applicant’s suggested language: E044X "Topical oxygen delivery system for continuous diffusion of oxygen, rental; includes portable continuous oxygen concentrator, rechargeable batteries, charging system and carrying case";

BACKGROUND

EO2 Concepts submitted a request to establish a new Level II HCPCS code to identify the TransCu O2 Oxygen Generator. According to the applicant, the descriptor of existing code E0446 “Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories,” originally for TransCu Oâ,, “implies the system cost includes all supplies and accessories, when in fact; the EO2 products are not sold as a comprehensive system.” The TransCu Oâ,, oxygen concentrator is available by rental only. TransCu Oâ,, in combination with OxySpur dressings, is a portable and wearable continuous diffusion of oxygen therapy system. TransCu Oâ,, in combination with OxySpur evenly distributes oxygen to the wound bed via an extension set from the device (TransCu Oâ,,) to the dressing (OxySpur). According to the applicant, the device works by extracting oxygen from water vapor in room air; concentrating the oxygen; and then creating a humidified oxygen rich environment of up to 99.9% oxygen for delivery via cannula the dressing at the wound site. Under the supervision of the healthcare professional, it provides an Oxygen-enriched, moist environment conducive to wound healing and is indicated to treat lightly to heavily exuding wounds such as skin ulcerations resulting from diabetes, venous stasis, post-surgical infections, gangrenous lesions, pressure ulcers, infected residual limbs, burns, frostbite. The applicant comments that there are several methodologies for delivery of topical oxygen; including continuous high pressure; intermittent or cycled high pressure; and continuous diffusion; that existing code E0446 “Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories” “lumps various modalities into one term,” “topical oxygen” and does not enable distinction of CDO devices.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code E0446 “Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories”, and is intended to be all-inclusive. As the applicant acknowledges, the TransCu O2 is, in fact, the predicate product for the original establishment of this code.

The HCPCS Level II codes describe categories of like items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code E0446 describes this 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.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation, stating that the existing code E0446, established January 1, 2011, was intended to describe an earlier version of the E02 technology. The E02 technology has changed substantially in past eight years; this code does not accurately describe the current technology. When E0446 was created, the technology used a cannula with a single outlet requiring the use of other commonly available dressing. This is no longer the standard of care. The current continuous diffusion of oxygen (CDO) generator requires the correct OxySpur Dressing based on diagnosis, wound size and various exudate levels throughout the wound healing process. The applicant reiterated request for new code that is "carrier priced".

FINAL DECISION

Existing code E0446 "Topical Oxygen delivery system, not otherwise specified, includes all supplies and accessories", and is intended to be all-inclusive. As such, separate reporting of dressings might be considered redundant.